**Table : Disposition [ITT - N=156 patients]**

|  | | **Total N=156** |
| --- | --- | --- |
|  |  |  |
| **Intent-To-Treat (ITT) at procedure** | N | 156 |
|  | Missing data | 0 |
|  | Yes | 156 (100.0%) |
|  |  |  |
| **Full Analysis Set (FAS)at procedure** | N | 156 |
|  | Missing data | 0 |
|  | No | 17 (10.9%) |
|  | Yes | 139 (89.1%) |
|  |  |  |
| **Per Protocol(PP) at procedure visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 18 (11.5%) |
|  | Yes | 138 (88.5%) |
|  |  |  |
| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 20 (12.8%) |
|  | Yes | 136 (87.2%) |
|  |  |  |
| **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 27 (17.3%) |
|  | Yes | 129 (82.7%) |
|  |  |  |
| **Full Analysis Set (FAS) at 6-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 34 (21.8%) |
|  | Yes | 122 (78.2%) |
|  |  |  |
| **Per Protocol(PP) at 6-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 39 (25.0%) |
|  | Yes | 117 (75.0%) |
|  |  |  |
| **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 13 (8.3%) |
|  | Yes | 143 (91.7%) |
|  |  |  |
| **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 20 (12.8%) |
|  | Yes | 136 (87.2%) |
|  |  |  |
| **Full Analysis Set (FAS) at 12-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 26 (16.7%) |
|  | Yes | 130 (83.3%) |
|  |  |  |
| **Per Protocol(PP) at 12-month follow-up visit** | N | 156 |
|  | Missing data | 0 |
|  | No | 32 (20.5%) |
|  | Yes | 124 (79.5%) |

**Table : Listing of patients with no FRED implanted [N= 2 patients]**

| **Subject Identifier for the Study** | **FRED used type** | **Subgroup device** | **PROC FRED1: Distal access catheter** | **PROC FRED1: Flow diverter implanted** | **PROC FRED1 not implanted: Reason** |
| --- | --- | --- | --- | --- | --- |
| 07-001 | FRED | FRED / FRED Jr | No | No | Tortuous anatomy of the parent artery |
| 07-006 | FRED | FRED / FRED Jr | No | No | Technical issues |
| N = 2 | | | | | |

**Table : Listing of retreated patients at 12-month [ITT - N= 3 patients]**

| **Subject Identifier for the Study** | **FRED used type** | **Subgroup device** | **PROCEDURE DATE** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **1Y Retreatment: Date** | **Retreatment delay since the procedure (in months)** | **Retreatment delay** | **1Y: Coils implanted** | **1Y: Other intrasaccular device** | **1Y: Specify other intrasaccular device** | **1Y: Flow diverter** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | FRED | FRED / FRED Jr | 19/05/2020 | 22/05/2020 | 09/10/2020 | 02/02/2021 | 02/02/2021 | 8.51 | Between 6 months and 12 months FU visit | . | . |  | checked |
| 05-004 | FRED X | FRED X | 30/04/2021 | 03/05/2021 | 02/08/2021 | 07/06/2022 | 02/09/2021 | 4.11 | Between 6 months and 12 months FU visit | . | . |  | checked |
| 07-036 | FRED | FRED / FRED Jr | 21/10/2021 | 24/10/2021 | 05/04/2022 | 09/05/2023 | 13/05/2022 | 6.70 | Between 6 months and 12 months FU visit | checked | checked | ONYX EMBOLISATION | . |
| N = 3 | | | | | | | | | | | | | |

| **1Y: Specify flow diverter** | **1Y: retreatment specify other FD** | **1Y: retreatment FRED reference** | **1Y: retreatment FRED batch number** | **1Y : Permeability of the parent artery at the end of the 1Yedure** |
| --- | --- | --- | --- | --- |
| FRED |  | FRED3507 | 20040251Y | Stenosis < 50 % |
| Other | SURPASS EVOLVE |  |  | No stenosis |
| . |  |  |  | No stenosis |
| N = 3 | | | | |

**Table : end of study [ITT - N=156 patients]**

|  | | **Total N=1** |
| --- | --- | --- |
|  |  |  |
| **Did the patient stop the study prematurely?** | N | 1 |
|  | Missing data | 0 |
|  | Yes | 1 (100.0%) |
|  |  |  |
| **Reason** | N | 1 |
|  | Missing data | 0 |
|  | Patient decision | 1 (100.0%) |

**Table : Listing of prematurely stop study [ITT - N=156 patients]**

| **Subject Identifier for the Study** | **FRED used type** | **Subgroup device** | **Age calculated** | **PROCEDURE DATE** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Duration of prematurely stop since procedure (in months)** | **End of study date** | **Duration of prematurely stop since procedure (in months)** | **Duration of prematurely stop** | **Did the patient stop the study prematurely?** | **Reason** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 06-001 | FRED | FRED / FRED Jr | 36 | 18/09/2019 | 21/09/2019 | 17/02/2020 | . | 11.63 | 06/09/2020 | 11.63 | Between 6 months and 12 months FU visit | Yes | Patient decision |
| N = 1 | | | | | | | | | | | | | |

**Results from Check\_Log macro**

| **Log file name** | **Date of execution** | **Detected issue** |
| --- | --- | --- |
| FRITS\_1\_1\_Patient Characteristics | 29SEP23:16:58:33 | No problem |
| FRITS\_1\_2\_Aneurysm Baseline characteristics | 02OCT23:14:56:46 | No problem |
| FRITS\_3\_Morbidity rate | 09OCT23:16:33:36 | No problem |
| FRITS\_3\_3\_AE | 13OCT23:11:17:33 | No problem |
| FRITS\_3\_3\_1\_Per procedure complications | 31JAN24:11:14:23 | No problem |
| FRITS\_3\_3\_2\_Post procedure complications until discharge | 31JAN24:15:11:33 | No problem |
| FRITS\_2\_1\_Type of imaging at 6-month and 12-month | 07FEB24:17:33:49 | No problem |
| FRITS\_2\_2\_Aneurysm complete occlusion rate at 12 months | 13FEB24:10:06:07 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_3\_1\_Morbidity rate | 14FEB24:15:23:14 | No problem |
| FRITS\_3\_2\_Mortality rate | 14FEB24:16:01:03 | NOTE: The data set WORK.DSDEATH has 0 observations and 36 variables. |
| FRITS\_2\_2\_3\_Anatomical results at procedure | 20FEB24:17:29:21 | No problem |
| FRITS\_3\_3\_6\_Occurrence per patient of all complications until the 12-month follow-up from ITT | 23FEB24:15:11:43 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_3\_3\_4\_Post procedure complications between 6-month and 12-month follow-up visit | 23FEB24:15:32:46 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_2\_2\_2\_Aneurysm complete occlusion rate at 12 months | 05MAR24:16:59:10 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_2\_3\_2\_Primary Efficacy endpoint rate at 6 months | 05MAR24:18:36:37 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_2\_3\_Primary Efficacy endpoint rate at 12 months | 05MAR24:18:39:22 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_4\_Treatment at 12-month | 06MAR24:12:14:20 | No problem |
| FRITS\_2\_1\_1\_Type of imaging at 6-month | 06MAR24:15:51:51 | WARNING: The SAS/STAT product with which NPAR1WAY is associated will be expiring soon, and is currently in warning mode to indicate this upcoming expi |
| FRITS\_2\_2\_1\_Aneurysm complete occlusion rate at 6 months | 06MAR24:15:56:35 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_3\_3\_5\_Occurrence per patient of all complications until the 12-month follow-up | 06MAR24:16:02:40 | WARNING: The Freq output formerly named BinomialProp is now named Binomial. Please use the new output name in the future; the old syntax might not wor |
| FRITS\_2\_1\_2\_Type of imaging at 12-month | 06MAR24:16:43:24 | No problem |
| FRITS\_2\_4\_Evolution of aneurysm occlusion | 06MAR24:17:34:41 | No problem |
| FRITS\_MEF\_POP | 19MAR24:10:32:44 | No problem |
| FRITS\_1\_0\_disposition | 19MAR24:11:12:39 | No problem |

**FRITS**

**EFFICACY**

**Table : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=84** | **FRED X N=52** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 6 months** | N | 77 |  | 77 |
|  | Missing data | 7 | 1 | 8 |
|  | Angiography (DSA) | 20 (26.0%) | 16 (31.4%) | 36 (28.1%) |
|  | Magnetic resonance angiography (MRA) | 52 (67.5%) | 31 (60.8%) | 83 (64.8%) |
|  | Angio-scanner (CTA) | 5 (6.5%) | 4 (7.8%) | 9 (7.0%) |
|  | Between group test |  |  | 0.730 (Fisher) |

**FRITS**

**EFFICACY**

**Table : TIME OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=77** | **FRED X N=51** | **Total N=128** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 6 months** | N | 77 | 51 | 128 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 6.24 (3.62) | 4.95 (1.95) | 5.72 (3.12) |
|  | Median | 6.01 | 5.68 | 5.94 |
|  | Q1 - Q3 | 5.42 - 6.21 | 3.25 - 6.04 | 3.55 - 6.16 |
|  | Min - Max | 1.44 - 27.36 | 1.71 - 11.56 | 1.44 - 27.36 |
|  | Between group test |  |  | 0.005 (Wilcoxon) |

**FRITS**

**EFFICACY**

**Table : Listing of missing data of imaging at 6-month (CORELAB) [ITT - N= 7 patients]**

| **Subject Identifier for the Study** | **Subgroup device** | **6M : Date of imaging (c)** | **Type of imaging at 6 months** | **6M : Imaging modality - Angiography** |
| --- | --- | --- | --- | --- |
| 05-001 | FRED / FRED Jr | 16/10/2019 | . | K |
| 06-001 | FRED / FRED Jr |  | . | . |
| 07-003 | FRED / FRED Jr |  | . | . |
| 07-004 | FRED / FRED Jr |  | . | . |
| 07-021 | FRED / FRED Jr |  | . | . |
| 07-024 | FRED / FRED Jr |  | . | . |
| 07-025 | FRED / FRED Jr |  | . | . |
| 07-038 | FRED X |  | . | . |
| N = 8 | | | | |

| **6M : Imaging modality - Magnetic Resonance Angiography** | **6M : Imaging modality - Angio-scanner** | **Time of imaging at 6 months** | **6M : Retreatment** |
| --- | --- | --- | --- |
| K | K | 3.41544 | No |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| N = 8 | | | |

**FRITS**

**EFFICACY**

**Table : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 6 months** | N | 69 |  | 69 |
|  | Missing data | 1 |  | 1 |
|  | Angiography (DSA) | 16 (23.2%) | 14 (29.8%) | 30 (25.9%) |
|  | Magnetic resonance angiography (MRA) | 48 (69.6%) | 29 (61.7%) | 77 (66.4%) |
|  | Angio-scanner (CTA) | 5 (7.2%) | 4 (8.5%) | 9 (7.8%) |
|  | Between group test |  |  | 0.714 (Fisher) |

**FRITS**

**EFFICACY**

**Table : TIME OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=69** | **FRED X N=47** | **Total N=116** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 6 months** | N | 69 | 47 | 116 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 6.43 (3.75) | 4.84 (1.89) | 5.79 (3.22) |
|  | Median | 6.04 | 5.06 | 5.98 |
|  | Q1 - Q3 | 5.85 - 6.37 | 3.22 - 6.04 | 3.60 - 6.17 |
|  | Min - Max | 1.44 - 27.36 | 1.71 - 11.56 | 1.44 - 27.36 |
|  | Between group test |  |  | <0.001 (Wilcoxon) |

**FRITS**

**EFFICACY**

**Table : Listing of missing data of imaging at 6-month (CORELAB) [PP - N= 2 patients]**

| **Subject Identifier for the Study** | **Subgroup device** | **6M : Date of imaging (c)** | **Type of imaging at 6 months** | **6M : Imaging modality - Angiography** |
| --- | --- | --- | --- | --- |
| 05-001 | FRED / FRED Jr | 16/10/2019 | . | K |
| N = 1 | | | | |

| **6M : Imaging modality - Magnetic Resonance Angiography** | **6M : Imaging modality - Angio-scanner** | **Time of imaging at 6 months** | **6M : Retreatment** |
| --- | --- | --- | --- |
| K | K | 3.41544 | No |
| N = 1 | | | |

**FRITS**

**EFFICACY**

**Table : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [FAS - N=122 patients]**

|  | | **FRED / FRED Jr N=74** | **FRED X N=48** | **Total N=122** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 6 months** | N | 69 |  | 69 |
|  | Missing data | 5 | 1 | 6 |
|  | Angiography (DSA) | 16 (23.2%) | 14 (29.8%) | 30 (25.9%) |
|  | Magnetic resonance angiography (MRA) | 48 (69.6%) | 29 (61.7%) | 77 (66.4%) |
|  | Angio-scanner (CTA) | 5 (7.2%) | 4 (8.5%) | 9 (7.8%) |
|  | Between group test |  |  | 0.714 (Fisher) |

**FRITS**

**EFFICACY**

**Table : TIME OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [FAS - N=122 patients]**

|  | | **FRED / FRED Jr N=69** | **FRED X N=47** | **Total N=116** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 6 months** | N | 69 | 47 | 116 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 6.43 (3.75) | 4.84 (1.89) | 5.79 (3.22) |
|  | Median | 6.04 | 5.06 | 5.98 |
|  | Q1 - Q3 | 5.85 - 6.37 | 3.22 - 6.04 | 3.60 - 6.17 |
|  | Min - Max | 1.44 - 27.36 | 1.71 - 11.56 | 1.44 - 27.36 |
|  | Between group test |  |  | <0.001 (Wilcoxon) |

**FRITS**

**EFFICACY**

**Table : Listing of missing data of imaging at 6-month (CORELAB) [FAS - N= 2 patients]**

| **Subject Identifier for the Study** | **Subgroup device** | **6M : Date of imaging (c)** | **Type of imaging at 6 months** | **6M : Imaging modality - Angiography** |
| --- | --- | --- | --- | --- |
| 05-001 | FRED / FRED Jr | 16/10/2019 | . | K |
| 06-001 | FRED / FRED Jr |  | . | . |
| 07-003 | FRED / FRED Jr |  | . | . |
| 07-024 | FRED / FRED Jr |  | . | . |
| 07-025 | FRED / FRED Jr |  | . | . |
| 07-038 | FRED X |  | . | . |
| N = 6 | | | | |

| **6M : Imaging modality - Magnetic Resonance Angiography** | **6M : Imaging modality - Angio-scanner** | **Time of imaging at 6 months** | **6M : Retreatment** |
| --- | --- | --- | --- |
| K | K | 3.41544 | No |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| . | . | . | . |
| N = 6 | | | |

**FRITS**

**EFFICACY**

**Table : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 12 months** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Angiography (DSA) | 68 (78.2%) | 36 (73.5%) | 104 (76.5%) |
|  | Magnetic resonance angiography (MRA) | 18 (20.7%) | 12 (24.5%) | 30 (22.1%) |
|  | Angio-scanner (CTA) | 1 (1.1%) | 1 (2.0%) | 2 (1.5%) |
|  | Between group test |  |  | 0.776 (Fisher) |

**FRITS**

**EFFICACY**

**Table : TIME OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 12 months** | N | 87 | 49 | 136 |
|  | DM | 0 | 0 | 0 |
|  | Moyenne (e.t.) | 12.43 (1.72) | 13.35 (3.77) | 12.76 (2.67) |
|  | Médiane | 12.12 | 12.35 | 12.18 |
|  | Q1 - Q3 | 11.72 - 13.23 | 11.92 - 13.60 | 11.84 - 13.46 |
|  | Min - Max | 5.98 - 17.87 | 2.76 - 27.36 | 2.76 - 27.36 |
|  | Test inter-groupes |  |  | 0.121 (Wilcoxon) |

**FRITS**

**EFFICACY**

**Table : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 12 months** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Angiography (DSA) | 63 (79.7%) | 32 (71.1%) | 95 (76.6%) |
|  | Magnetic resonance angiography (MRA) | 15 (19.0%) | 12 (26.7%) | 27 (21.8%) |
|  | Angio-scanner (CTA) | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | Between group test |  |  | 0.451 (Fisher) |

**FRITS**

**EFFICACY**

**Table : TIME OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 12 months** | N | 79 | 45 | 124 |
|  | DM | 0 | 0 | 0 |
|  | Moyenne (e.t.) | 12.56 (1.60) | 13.36 (3.91) | 12.85 (2.69) |
|  | Médiane | 12.12 | 12.35 | 12.18 |
|  | Q1 - Q3 | 11.76 - 13.30 | 11.92 - 13.60 | 11.84 - 13.46 |
|  | Min - Max | 8.34 - 17.87 | 2.76 - 27.36 | 2.76 - 27.36 |
|  | Test inter-groupes |  |  | 0.198 (Wilcoxon) |

**FRITS**

**EFFICACY**

**Table : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 12 months** | N | 82 |  | 82 |
|  | Missing data | 0 | 2 | 2 |
|  | Angiography (DSA) | 65 (79.3%) | 33 (71.7%) | 98 (76.6%) |
|  | Magnetic resonance angiography (MRA) | 16 (19.5%) | 12 (26.1%) | 28 (21.9%) |
|  | Angio-scanner (CTA) | 1 (1.2%) | 1 (2.2%) | 2 (1.6%) |
|  | Between group test |  |  | 0.510 (Fisher) |

**FRITS**

**EFFICACY**

**Table : TIME OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 12 months** | N | 82 | 46 | 128 |
|  | DM | 0 | 2 | 2 |
|  | Moyenne (e.t.) | 12.58 (1.74) | 13.36 (3.87) | 12.86 (2.71) |
|  | Médiane | 12.09 | 12.40 | 12.18 |
|  | Q1 - Q3 | 11.72 - 13.30 | 11.92 - 13.60 | 11.79 - 13.46 |
|  | Min - Max | 8.34 - 18.56 | 2.76 - 27.36 | 2.76 - 27.36 |
|  | Test inter-groupes |  |  | 0.155 (Wilcoxon) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rate(Aneurysm complete occlusion rate at 6 months(Raymond score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 27 20.93 34.62 62.79 | 51 39.53 65.38 59.30 | 78 60.47 |
| **FRED X** | 16 12.40 31.37 37.21 | 35 27.13 68.63 40.70 | 51 39.53 |
| **Total** | 43 33.33 | 86 66.67 | 129 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1459 | 0.7025 |
| **Test du rapport de vraisemblance** | 1 | 0.1465 | 0.7019 |
| **Khi-2 continuité ajustée** | 1 | 0.0365 | 0.8485 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1448 | 0.7036 |
| **Coefficient Phi** |  | 0.0336 |  |
| **Coefficient de contingence** |  | 0.0336 |  |
| **V de Cramer** |  | 0.0336 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 27 |
| **Pr <= F unilatérale à gauche** | 0.7155 |
| **Pr >= F unilatérale à droite** | 0.4261 |
|  |  |
| **Probabilité de la table (P)** | 0.1415 |
| **Pr <= P bilatéral** | 0.8487 |

|  |
| --- |
| ***Taille de l'échantillon = 129*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 6 months(Raymond score)** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | No | 27 (34.6%) | 16 (31.4%) | 43 (33.3%) |
|  | Yes | 51 (65.4%) | 35 (68.6%) | 86 (66.7%) |
|  | 95% CI | 54.8% - 75.9% | 55.9% - 81.4% | 58.5% - 74.8% |
|  | Between group test |  |  | 0.702 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rateb(Aneurysm complete occlusion rate at 6 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 9 20.93 32.14 69.23 | 19 44.19 67.86 63.33 | 28 65.12 |
| **FRED X** | 4 9.30 26.67 30.77 | 11 25.58 73.33 36.67 | 15 34.88 |
| **Total** | 13 30.23 | 30 69.77 | 43 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1389 | 0.7094 |
| **Test du rapport de vraisemblance** | 1 | 0.1405 | 0.7078 |
| **Khi-2 continuité ajustée** | 1 | 0.0006 | 0.9806 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1356 | 0.7127 |
| **Coefficient Phi** |  | 0.0568 |  |
| **Coefficient de contingence** |  | 0.0567 |  |
| **V de Cramer** |  | 0.0568 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 9 |
| **Pr <= F unilatérale à gauche** | 0.7616 |
| **Pr >= F unilatérale à droite** | 0.4961 |
|  |  |
| **Probabilité de la table (P)** | 0.2578 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 43*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 6 months(OKM score)** | N | 28 |  | 28 |
|  | Missing data | 50 | 36 | 86 |
|  | No | 9 (32.1%) | 4 (26.7%) | 13 (30.2%) |
|  | Yes | 19 (67.9%) | 11 (73.3%) | 30 (69.8%) |
|  | 95% CI | 50.6% - 85.2% | 51.0% - 95.7% | 56% - 83.5% |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rate(Adequate occlusion rate at 6 months(Raymond score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 22 17.05 28.21 64.71 | 56 43.41 71.79 58.95 | 78 60.47 |
| **FRED X** | 12 9.30 23.53 35.29 | 39 30.23 76.47 41.05 | 51 39.53 |
| **Total** | 34 26.36 | 95 73.64 | 129 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.3473 | 0.5556 |
| **Test du rapport de vraisemblance** | 1 | 0.3505 | 0.5538 |
| **Khi-2 continuité ajustée** | 1 | 0.1482 | 0.7003 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.3446 | 0.5572 |
| **Coefficient Phi** |  | 0.0519 |  |
| **Coefficient de contingence** |  | 0.0518 |  |
| **V de Cramer** |  | 0.0519 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 22 |
| **Pr <= F unilatérale à gauche** | 0.7854 |
| **Pr >= F unilatérale à droite** | 0.3525 |
|  |  |
| **Probabilité de la table (P)** | 0.1379 |
| **Pr <= P bilatéral** | 0.6834 |

|  |
| --- |
| ***Taille de l'échantillon = 129*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 6 months(Raymond score)** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | No | 22 (28.2%) | 12 (23.5%) | 34 (26.4%) |
|  | Yes | 56 (71.8%) | 39 (76.5%) | 95 (73.6%) |
|  | 95% CI | 61.8% - 81.8% | 64.8% - 88.1% | 66% - 81.2% |
|  | Between group test |  |  | 0.556 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rateb(Adequate occlusion rate at 6 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 8 18.60 28.57 66.67 | 20 46.51 71.43 64.52 | 28 65.12 |
| **FRED X** | 4 9.30 26.67 33.33 | 11 25.58 73.33 35.48 | 15 34.88 |
| **Total** | 12 27.91 | 31 72.09 | 43 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0176 | 0.8944 |
| **Test du rapport de vraisemblance** | 1 | 0.0177 | 0.8942 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0172 | 0.8956 |
| **Coefficient Phi** |  | 0.0202 |  |
| **Coefficient de contingence** |  | 0.0202 |  |
| **V de Cramer** |  | 0.0202 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 8 |
| **Pr <= F unilatérale à gauche** | 0.6823 |
| **Pr >= F unilatérale à droite** | 0.5943 |
|  |  |
| **Probabilité de la table (P)** | 0.2766 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 43*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 6 months(OKM score)** | N | 28 |  | 28 |
|  | Missing data | 50 | 36 | 86 |
|  | No | 8 (28.6%) | 4 (26.7%) | 12 (27.9%) |
|  | Yes | 20 (71.4%) | 11 (73.3%) | 31 (72.1%) |
|  | 95% CI | 54.7% - 88.2% | 51.0% - 95.7% | 58.7% - 85.5% |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Occlusion degree (Raymond-Roy score) at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm occlusion degree** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | Obliteration | 51 (65.4%) | 35 (68.6%) | 86 (66.7%) |
|  | Residual neck | 5 (6.4%) | 4 (7.8%) | 9 (7.0%) |
|  | Residual aneurysm | 17 (21.8%) | 9 (17.6%) | 26 (20.2%) |
|  | Cannot be assessed from the imaging | 5 (6.4%) | 3 (5.9%) | 8 (6.2%) |
|  | Between group test |  |  | 0.948 (Fisher) |
|  |  |  |  |  |
| **6M : Aneurysm occlusion degree specification** | N | 7 |  | 7 |
|  | Missing data | 71 | 44 | 115 |
|  | Class IIIa | 0 | 5 (71.4%) | 5 (35.7%) |
|  | Class IIIb | 7 (100.0%) | 2 (28.6%) | 9 (64.3%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm filling** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 4 (5.1%) | 2 (3.9%) | 6 (4.7%) |
|  | B: subtotal filling (5-95%) | 5 (6.4%) | 6 (11.8%) | 11 (8.5%) |
|  | C: entry remnant (<5%) | 1 (1.3%) |  | 1 (0.8%) |
|  | D: no filling (0%) | 19 (24.4%) | 11 (21.6%) | 30 (23.3%) |
|  | Cannot be assessed from the imaging | 49 (62.8%) | 30 (58.8%) | 79 (61.2%) |
|  | Not applicable | 0 | 2 (3.9%) | 2 (1.6%) |
|  | Between group test |  |  | 0.463 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm Occlusion stability at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm Occlusion stability** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | Better | 42 (53.8%) | 30 (58.8%) | 72 (55.8%) |
|  | Same | 10 (12.8%) | 6 (11.8%) | 16 (12.4%) |
|  | Cannot be assessed from the imaging | 26 (33.3%) | 15 (29.4%) | 41 (31.8%) |
|  | Between group test |  |  | 0.855 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stasis phase at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Stasis phase** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 1 (1.3%) | 1 (2.0%) | 2 (1.6%) |
|  | 2: moderate stasis (clearance before venous phase) | 4 (5.1%) |  | 4 (3.1%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 5 (6.4%) | 4 (7.8%) | 9 (7.0%) |
|  | Cannot be assessed from the imaging | 39 (50.0%) | 18 (35.3%) | 57 (44.2%) |
|  | Not applicable | 29 (37.2%) | 28 (54.9%) | 57 (44.2%) |
|  | Between group test |  |  | 0.135 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm sac size change at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm sac size change** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | Stable | 26 (33.3%) | 16 (31.4%) | 42 (32.6%) |
|  | Decreased sac size | 15 (19.2%) | 13 (25.5%) | 28 (21.7%) |
|  | Cannot be assessed from the imaging | 37 (47.4%) | 22 (43.1%) | 59 (45.7%) |
|  | Between group test |  |  | 0.698 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stent Stability at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Stent Stability** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | Yes | 46 (59.0%) | 33 (64.7%) | 79 (61.2%) |
|  | Cannot be assessed from the imaging | 32 (41.0%) | 18 (35.3%) | 50 (38.8%) |
|  | Between group test |  |  | 0.514 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stent covering the neck at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Stent covering the neck** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | No | 1 (1.3%) |  | 1 (0.8%) |
|  | Yes | 47 (60.3%) | 32 (62.7%) | 79 (61.2%) |
|  | Cannot be assessed from the imaging | 30 (38.5%) | 19 (37.3%) | 49 (38.0%) |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Parent artery permeability at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Parent Artery permeability** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 16 (20.5%) | 12 (23.5%) | 28 (21.7%) |
|  | Stenosis < 50% | 7 (9.0%) | 6 (11.8%) | 13 (10.1%) |
|  | On MRA or CTA images, no stenosis or Stenosis < 50% | 51 (65.4%) | 26 (51.0%) | 77 (59.7%) |
|  | Stenosis >= 50 % | 0 | 1 (2.0%) | 1 (0.8%) |
|  | Complete occlusion | 1 (1.3%) | 1 (2.0%) | 2 (1.6%) |
|  | On MRA or CTA images, Stenosis >= 50 % or complete occlusion | 2 (2.6%) | 2 (3.9%) | 4 (3.1%) |
|  | Cannot be assessed from the imaging | 1 (1.3%) | 3 (5.9%) | 4 (3.1%) |
|  | Between group test |  |  | 0.447 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Retreatment** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (100.0%) | 51 (100.0%) | 129 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rate(Aneurysm complete occlusion rate at 6 months(Raymond score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 25 21.37 35.71 62.50 | 45 38.46 64.29 58.44 | 70 59.83 |
| **FRED X** | 15 12.82 31.91 37.50 | 32 27.35 68.09 41.56 | 47 40.17 |
| **Total** | 40 34.19 | 77 65.81 | 117 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1804 | 0.6710 |
| **Test du rapport de vraisemblance** | 1 | 0.1811 | 0.6704 |
| **Khi-2 continuité ajustée** | 1 | 0.0511 | 0.8212 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1789 | 0.6723 |
| **Coefficient Phi** |  | 0.0393 |  |
| **Coefficient de contingence** |  | 0.0392 |  |
| **V de Cramer** |  | 0.0393 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 25 |
| **Pr <= F unilatérale à gauche** | 0.7325 |
| **Pr >= F unilatérale à droite** | 0.4123 |
|  |  |
| **Probabilité de la table (P)** | 0.1448 |
| **Pr <= P bilatéral** | 0.6961 |

|  |
| --- |
| ***Taille de l'échantillon = 117*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 6 months(Raymond score)** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | No | 25 (35.7%) | 15 (31.9%) | 40 (34.2%) |
|  | Yes | 45 (64.3%) | 32 (68.1%) | 77 (65.8%) |
|  | 95% CI | 53.1% - 75.5% | 54.8% - 81.4% | 57.2% - 74.4% |
|  | Between group test |  |  | 0.671 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rateb(Aneurysm complete occlusion rate at 6 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 8 21.62 34.78 72.73 | 15 40.54 65.22 57.69 | 23 62.16 |
| **FRED X** | 3 8.11 21.43 27.27 | 11 29.73 78.57 42.31 | 14 37.84 |
| **Total** | 11 29.73 | 26 70.27 | 37 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.7429 | 0.3887 |
| **Test du rapport de vraisemblance** | 1 | 0.7648 | 0.3818 |
| **Khi-2 continuité ajustée** | 1 | 0.2412 | 0.6234 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.7228 | 0.3952 |
| **Coefficient Phi** |  | 0.1417 |  |
| **Coefficient de contingence** |  | 0.1403 |  |
| **V de Cramer** |  | 0.1417 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 8 |
| **Pr <= F unilatérale à gauche** | 0.8927 |
| **Pr >= F unilatérale à droite** | 0.3160 |
|  |  |
| **Probabilité de la table (P)** | 0.2087 |
| **Pr <= P bilatéral** | 0.4766 |

|  |
| --- |
| ***Taille de l'échantillon = 37*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 6 months(OKM score)** | N | 23 |  | 23 |
|  | Missing data | 47 | 33 | 80 |
|  | No | 8 (34.8%) | 3 (21.4%) | 11 (29.7%) |
|  | Yes | 15 (65.2%) | 11 (78.6%) | 26 (70.3%) |
|  | 95% CI | 45.8% - 84.7% | 57.1% - 100.0% | 55.5% - 85% |
|  | Between group test |  |  | 0.477 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rate(Adequate occlusion rate at 6 months(Raymond score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 21 17.95 30.00 65.63 | 49 41.88 70.00 57.65 | 70 59.83 |
| **FRED X** | 11 9.40 23.40 34.38 | 36 30.77 76.60 42.35 | 47 40.17 |
| **Total** | 32 27.35 | 85 72.65 | 117 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6157 | 0.4327 |
| **Test du rapport de vraisemblance** | 1 | 0.6231 | 0.4299 |
| **Khi-2 continuité ajustée** | 1 | 0.3285 | 0.5666 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6104 | 0.4346 |
| **Coefficient Phi** |  | 0.0725 |  |
| **Coefficient de contingence** |  | 0.0723 |  |
| **V de Cramer** |  | 0.0725 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 21 |
| **Pr <= F unilatérale à gauche** | 0.8404 |
| **Pr >= F unilatérale à droite** | 0.2850 |
|  |  |
| **Probabilité de la table (P)** | 0.1253 |
| **Pr <= P bilatéral** | 0.5273 |

|  |
| --- |
| ***Taille de l'échantillon = 117*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 6 months(Raymond score)** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | No | 21 (30.0%) | 11 (23.4%) | 32 (27.4%) |
|  | Yes | 49 (70.0%) | 36 (76.6%) | 85 (72.6%) |
|  | 95% CI | 59.3% - 80.7% | 64.5% - 88.7% | 64.6% - 80.7% |
|  | Between group test |  |  | 0.433 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rateb(Adequate occlusion rate at 6 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 8 21.62 34.78 72.73 | 15 40.54 65.22 57.69 | 23 62.16 |
| **FRED X** | 3 8.11 21.43 27.27 | 11 29.73 78.57 42.31 | 14 37.84 |
| **Total** | 11 29.73 | 26 70.27 | 37 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.7429 | 0.3887 |
| **Test du rapport de vraisemblance** | 1 | 0.7648 | 0.3818 |
| **Khi-2 continuité ajustée** | 1 | 0.2412 | 0.6234 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.7228 | 0.3952 |
| **Coefficient Phi** |  | 0.1417 |  |
| **Coefficient de contingence** |  | 0.1403 |  |
| **V de Cramer** |  | 0.1417 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 8 |
| **Pr <= F unilatérale à gauche** | 0.8927 |
| **Pr >= F unilatérale à droite** | 0.3160 |
|  |  |
| **Probabilité de la table (P)** | 0.2087 |
| **Pr <= P bilatéral** | 0.4766 |

|  |
| --- |
| ***Taille de l'échantillon = 37*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 6 months(OKM score)** | N | 23 |  | 23 |
|  | Missing data | 47 | 33 | 80 |
|  | No | 8 (34.8%) | 3 (21.4%) | 11 (29.7%) |
|  | Yes | 15 (65.2%) | 11 (78.6%) | 26 (70.3%) |
|  | 95% CI | 45.8% - 84.7% | 57.1% - 100.0% | 55.5% - 85% |
|  | Between group test |  |  | 0.477 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Occlusion degree (Raymond-Roy score) at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm occlusion degree** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | Obliteration | 45 (64.3%) | 32 (68.1%) | 77 (65.8%) |
|  | Residual neck | 4 (5.7%) | 4 (8.5%) | 8 (6.8%) |
|  | Residual aneurysm | 17 (24.3%) | 8 (17.0%) | 25 (21.4%) |
|  | Cannot be assessed from the imaging | 4 (5.7%) | 3 (6.4%) | 7 (6.0%) |
|  | Between group test |  |  | 0.762 (Fisher) |
|  |  |  |  |  |
| **6M : Aneurysm occlusion degree specification** | N | 7 |  | 7 |
|  | Missing data | 63 | 40 | 103 |
|  | Class IIIa | 0 | 5 (71.4%) | 5 (35.7%) |
|  | Class IIIb | 7 (100.0%) | 2 (28.6%) | 9 (64.3%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm filling** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 4 (5.7%) | 2 (4.3%) | 6 (5.1%) |
|  | B: subtotal filling (5-95%) | 5 (7.1%) | 5 (10.6%) | 10 (8.5%) |
|  | D: no filling (0%) | 15 (21.4%) | 11 (23.4%) | 26 (22.2%) |
|  | Cannot be assessed from the imaging | 46 (65.7%) | 27 (57.4%) | 73 (62.4%) |
|  | Not applicable | 0 | 2 (4.3%) | 2 (1.7%) |
|  | Between group test |  |  | 0.466 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm Occlusion stability at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm Occlusion stability** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | Better | 36 (51.4%) | 28 (59.6%) | 64 (54.7%) |
|  | Same | 9 (12.9%) | 6 (12.8%) | 15 (12.8%) |
|  | Cannot be assessed from the imaging | 25 (35.7%) | 13 (27.7%) | 38 (32.5%) |
|  | Between group test |  |  | 0.637 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stasis phase at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Stasis phase** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 1 (1.4%) | 1 (2.1%) | 2 (1.7%) |
|  | 2: moderate stasis (clearance before venous phase) | 3 (4.3%) |  | 3 (2.6%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 5 (7.1%) | 3 (6.4%) | 8 (6.8%) |
|  | Cannot be assessed from the imaging | 36 (51.4%) | 17 (36.2%) | 53 (45.3%) |
|  | Not applicable | 25 (35.7%) | 26 (55.3%) | 51 (43.6%) |
|  | Between group test |  |  | 0.170 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm sac size change at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm sac size change** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | Stable | 22 (31.4%) | 15 (31.9%) | 37 (31.6%) |
|  | Decreased sac size | 14 (20.0%) | 12 (25.5%) | 26 (22.2%) |
|  | Cannot be assessed from the imaging | 34 (48.6%) | 20 (42.6%) | 54 (46.2%) |
|  | Between group test |  |  | 0.737 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stent Stability at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Stent Stability** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | Yes | 41 (58.6%) | 32 (68.1%) | 73 (62.4%) |
|  | Cannot be assessed from the imaging | 29 (41.4%) | 15 (31.9%) | 44 (37.6%) |
|  | Between group test |  |  | 0.298 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stent covering the neck at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Stent covering the neck** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | No | 1 (1.4%) |  | 1 (0.9%) |
|  | Yes | 41 (58.6%) | 31 (66.0%) | 72 (61.5%) |
|  | Cannot be assessed from the imaging | 28 (40.0%) | 16 (34.0%) | 44 (37.6%) |
|  | Between group test |  |  | 0.737 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Parent artery permeability at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Parent Artery permeability** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 13 (18.6%) | 11 (23.4%) | 24 (20.5%) |
|  | Stenosis < 50% | 6 (8.6%) | 6 (12.8%) | 12 (10.3%) |
|  | On MRA or CTA images, no stenosis or Stenosis < 50% | 48 (68.6%) | 23 (48.9%) | 71 (60.7%) |
|  | Stenosis >= 50 % | 0 | 1 (2.1%) | 1 (0.9%) |
|  | Complete occlusion | 1 (1.4%) | 1 (2.1%) | 2 (1.7%) |
|  | On MRA or CTA images, Stenosis >= 50 % or complete occlusion | 2 (2.9%) | 2 (4.3%) | 4 (3.4%) |
|  | Cannot be assessed from the imaging | 0 | 3 (6.4%) | 3 (2.6%) |
|  | Between group test |  |  | 0.130 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Retreatment** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | No | 70 (100.0%) | 47 (100.0%) | 117 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rate(Aneurysm complete occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 12 8.82 13.79 63.16 | 75 55.15 86.21 64.10 | 87 63.97 |
| **FRED X** | 7 5.15 14.29 36.84 | 42 30.88 85.71 35.90 | 49 36.03 |
| **Total** | 19 13.97 | 117 86.03 | 136 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0063 | 0.9366 |
| **Test du rapport de vraisemblance** | 1 | 0.0063 | 0.9367 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0063 | 0.9368 |
| **Coefficient Phi** |  | -0.0068 |  |
| **Coefficient de contingence** |  | 0.0068 |  |
| **V de Cramer** |  | -0.0068 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 12 |
| **Pr <= F unilatérale à gauche** | 0.5636 |
| **Pr >= F unilatérale à droite** | 0.6375 |
|  |  |
| **Probabilité de la table (P)** | 0.2011 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 136*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 12 (13.8%) | 7 (14.3%) | 19 (14.0%) |
|  | Yes | 75 (86.2%) | 42 (85.7%) | 117 (86.0%) |
|  | 95% CI | 79.0% - 93.5% | 75.9% - 95.5% | 80.2% - 91.9% |
|  | Between group test |  |  | 0.937 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rateb(Aneurysm complete occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.14 9.72 53.85 | 65 57.02 90.28 64.36 | 72 63.16 |
| **FRED X** | 6 5.26 14.29 46.15 | 36 31.58 85.71 35.64 | 42 36.84 |
| **Total** | 13 11.40 | 101 88.60 | 114 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.5468 | 0.4596 |
| **Test du rapport de vraisemblance** | 1 | 0.5336 | 0.4651 |
| **Khi-2 continuité ajustée** | 1 | 0.1884 | 0.6643 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.5420 | 0.4616 |
| **Coefficient Phi** |  | -0.0693 |  |
| **Coefficient de contingence** |  | 0.0691 |  |
| **V de Cramer** |  | -0.0693 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.3266 |
| **Pr >= F unilatérale à droite** | 0.8517 |
|  |  |
| **Probabilité de la table (P)** | 0.1783 |
| **Pr <= P bilatéral** | 0.5452 |

|  |
| --- |
| ***Taille de l'échantillon = 114*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months(OKM score)** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | No | 7 (9.7%) | 6 (14.3%) | 13 (11.4%) |
|  | Yes | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |
|  | 95% CI | 83.4% - 97.1% | 75.1% - 96.3% | 82.8% - 94.4% |
|  | Between group test |  |  | 0.545 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rate(Adequate occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 9 6.62 10.34 75.00 | 78 57.35 89.66 62.90 | 87 63.97 |
| **FRED X** | 3 2.21 6.12 25.00 | 46 33.82 93.88 37.10 | 49 36.03 |
| **Total** | 12 8.82 | 124 91.18 | 136 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6946 | 0.4046 |
| **Test du rapport de vraisemblance** | 1 | 0.7314 | 0.3924 |
| **Khi-2 continuité ajustée** | 1 | 0.2689 | 0.6040 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6895 | 0.4063 |
| **Coefficient Phi** |  | 0.0715 |  |
| **Coefficient de contingence** |  | 0.0713 |  |
| **V de Cramer** |  | 0.0715 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 9 |
| **Pr <= F unilatérale à gauche** | 0.8767 |
| **Pr >= F unilatérale à droite** | 0.3096 |
|  |  |
| **Probabilité de la table (P)** | 0.1863 |
| **Pr <= P bilatéral** | 0.5362 |

|  |
| --- |
| ***Taille de l'échantillon = 136*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 9 (10.3%) | 3 (6.1%) | 12 (8.8%) |
|  | Yes | 78 (89.7%) | 46 (93.9%) | 124 (91.2%) |
|  | 95% CI | 83.3% - 96.1% | 87.2% - 100.0% | 86.4% - 95.9% |
|  | Between group test |  |  | 0.536 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rateb(Adequate occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.14 9.72 63.64 | 65 57.02 90.28 63.11 | 72 63.16 |
| **FRED X** | 4 3.51 9.52 36.36 | 38 33.33 90.48 36.89 | 42 36.84 |
| **Total** | 11 9.65 | 103 90.35 | 114 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0012 | 0.9724 |
| **Test du rapport de vraisemblance** | 1 | 0.0012 | 0.9724 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0012 | 0.9725 |
| **Coefficient Phi** |  | 0.0032 |  |
| **Coefficient de contingence** |  | 0.0032 |  |
| **V de Cramer** |  | 0.0032 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.6329 |
| **Pr >= F unilatérale à droite** | 0.6234 |
|  |  |
| **Probabilité de la table (P)** | 0.2562 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 114*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months(OKM score)** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | No | 7 (9.7%) | 4 (9.5%) | 11 (9.6%) |
|  | Yes | 65 (90.3%) | 38 (90.5%) | 103 (90.4%) |
|  | 95% CI | 83.4% - 97.1% | 81.6% - 99.4% | 84.9% - 95.8% |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Obliteration | 75 (86.2%) | 42 (85.7%) | 117 (86.0%) |
|  | Residual neck | 3 (3.4%) | 4 (8.2%) | 7 (5.1%) |
|  | Residual aneurysm | 9 (10.3%) | 3 (6.1%) | 12 (8.8%) |
|  | Between group test |  |  | 0.393 (Fisher) |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree specification** | N | 3 |  | 3 |
|  | Missing data | 84 | 48 | 132 |
|  | Class IIIa | 0 | 1 (100.0%) | 1 (25.0%) |
|  | Class IIIb | 3 (100.0%) |  | 3 (75.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm filling** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 3 (3.4%) | 2 (4.1%) | 5 (3.7%) |
|  | B: subtotal filling (5-95%) | 5 (5.7%) | 2 (4.1%) | 7 (5.1%) |
|  | C: entry remnant (<5%) | 0 | 2 (4.1%) | 2 (1.5%) |
|  | D: no filling (0%) | 65 (74.7%) | 36 (73.5%) | 101 (74.3%) |
|  | Cannot be assessed from the imaging | 13 (14.9%) | 7 (14.3%) | 20 (14.7%) |
|  | Not applicable | 1 (1.1%) |  | 1 (0.7%) |
|  | Between group test |  |  | 0.600 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm Occlusion stability at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm Occlusion stability** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Better | 41 (47.1%) | 19 (38.8%) | 60 (44.1%) |
|  | Same | 31 (35.6%) | 20 (40.8%) | 51 (37.5%) |
|  | Cannot be assessed from the imaging | 15 (17.2%) | 10 (20.4%) | 25 (18.4%) |
|  | Between group test |  |  | 0.640 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stasis phase at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stasis phase** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 1 (1.1%) | 1 (2.0%) | 2 (1.5%) |
|  | 2: moderate stasis (clearance before venous phase) | 2 (2.3%) | 2 (4.1%) | 4 (2.9%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 4 (4.6%) | 3 (6.1%) | 7 (5.1%) |
|  | Cannot be assessed from the imaging | 12 (13.8%) | 8 (16.3%) | 20 (14.7%) |
|  | Not applicable | 68 (78.2%) | 35 (71.4%) | 103 (75.7%) |
|  | Between group test |  |  | 0.831 (Fisher) |

**FRITS**

**EFFICACY**

**Table : OKM scale at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 12 months** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | A1 | 1 (1.4%) | 1 (2.4%) | 2 (1.8%) |
|  | A2 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | A3 | 1 (1.4%) |  | 1 (0.9%) |
|  | B2 | 2 (2.8%) |  | 2 (1.8%) |
|  | B3 | 3 (4.2%) | 2 (4.8%) | 5 (4.4%) |
|  | C2 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | C3 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | D1 | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |

**FRITS**

**EFFICACY**

**Table : OKM grade at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 12 months** | N | 72 |  | 72 |
|  | Missing data | 15 | 7 | 22 |
|  | OKM A | 2 (2.8%) | 2 (4.8%) | 4 (3.5%) |
|  | OKM B | 5 (6.9%) | 2 (4.8%) | 7 (6.1%) |
|  | OKM C | 0 | 2 (4.8%) | 2 (1.8%) |
|  | OKM D | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm sac size change at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm sac size change** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Increased sac size | 1 (1.1%) |  | 1 (0.7%) |
|  | Stable | 26 (29.9%) | 18 (36.7%) | 44 (32.4%) |
|  | Decreased sac size | 17 (19.5%) | 7 (14.3%) | 24 (17.6%) |
|  | Cannot be assessed from the imaging | 43 (49.4%) | 24 (49.0%) | 67 (49.3%) |
|  | Between group test |  |  | 0.758 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent Stability at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent Stability** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 1 (1.1%) | 3 (6.1%) | 4 (2.9%) |
|  | Yes | 79 (90.8%) | 46 (93.9%) | 125 (91.9%) |
|  | Cannot be assessed from the imaging | 7 (8.0%) |  | 7 (5.1%) |
|  | Between group test |  |  | 0.035 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent covering the neck at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent covering the neck** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 4 (4.6%) | 1 (2.0%) | 5 (3.7%) |
|  | Yes | 77 (88.5%) | 48 (98.0%) | 125 (91.9%) |
|  | Cannot be assessed from the imaging | 6 (6.9%) |  | 6 (4.4%) |
|  | Between group test |  |  | 0.145 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Parent artery permeability at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Parent Artery permeability** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 56 (64.4%) | 29 (59.2%) | 85 (62.5%) |
|  | Stenosis < 50% | 13 (14.9%) | 7 (14.3%) | 20 (14.7%) |
|  | On MRA or CTA images, no stenosis or Stenosis < 50% | 13 (14.9%) | 11 (22.4%) | 24 (17.6%) |
|  | Stenosis >= 50 % | 2 (2.3%) | 2 (4.1%) | 4 (2.9%) |
|  | Complete occlusion | 1 (1.1%) |  | 1 (0.7%) |
|  | On MRA or CTA images, Stenosis >= 50 % or complete occlusion | 1 (1.1%) |  | 1 (0.7%) |
|  | Cannot be assessed from the imaging | 1 (1.1%) |  | 1 (0.7%) |
|  | Between group test |  |  | 0.895 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Retreatment** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No | 87 (100.0%) | 49 (100.0%) | 136 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (INVESTIGATORS) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y: Retreatment** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 88 (96.7%) | 51 (98.1%) | 139 (97.2%) |
|  | Yes | 3 (3.3%) | 1 (1.9%) | 4 (2.8%) |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Listing of patient with missing data for Retreatment at 12 months (INVESTIGATORS) [ITT - N=136 patients]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| 05-004 | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| 07-002 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 07-036 | Yes | Yes | Yes | Yes | No | Yes | No | Yes |
| N = 4 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Iteration Number** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | 59 | Female | FRED / FRED Jr | FRED | 19/05/2020 | 1 | 1 |
| Yes | Yes | Yes | 65 | Female | FRED X | FRED X | 30/04/2021 | 1 | 1 |
| No | No | No | 86 | Female | FRED / FRED Jr | FRED | 21/11/2019 | 1 | 1 |
| Yes | Yes | Yes | 48 | Female | FRED / FRED Jr | FRED | 21/10/2021 | 1 | 1 |
| N = 4 | | | | | | | | | |

| **1Y: visit performed** | **1Y: reason for not performed** | **1Y Date** | **1Y Date - Partial date** | **1Y: mRS** | **1Y: Antiplatelet changes** | **1Y: AE** | **1Y: Imaging done** | **1Y Imaging: Date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes |  | 02/02/2021 | 02/02/2021 | 0 - No symptoms at all | No | No | Yes | 02/02/2021 |
| Yes |  | 07/06/2022 | 07/06/2022 | 0 - No symptoms at all | Yes | No | Yes | 07/06/2022 |
| Yes |  | 10/11/2020 | 10/11/2020 | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | Yes | No | Yes | 10/11/2020 |
| Yes |  | 09/05/2023 | 09/05/2023 | 0 - No symptoms at all | No | Yes | Yes | 09/05/2023 |
| N = 4 | | | | | | | | |

| **1Y Imaging: Date - Partial date** | **1Y: Imaging type** | **1Y: Stent placement** | **1Y: Aneurysm occlusion degree** | **1Y: Aneurysm occlusion degree OKM scale** | **Y1\_StasisPhase\_OKM\_LD** | **1Y: Aneurysm occlusion change** | **1Y: Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 02/02/2021 | Angiography (DSA) | Correct | Class I: Obliteration | Grade C: Entry remnant | 1 | Same | Stable |
| 07/06/2022 | Angiography (DSA) | Correct | Class I: Obliteration | Grade B: Subtotal filling | Non applicable | Same | Stable |
| 10/11/2020 | Magnetic resonance angiography (MRA) | Cannot be assessed from the imaging | Class II: Residual neck | Not applicable | Non applicable | Worse | Stable |
| 09/05/2023 | Angiography (DSA) | Correct | Class I: Obliteration | Grade D: No filling | Non applicable | Same | Stable |
| N = 4 | | | | | | | |

| **1Y: Parent artery permeability** | **1Y: Retreatment** | **1Y Retreatment: Date** | **1Y Retreatment: Date - Partial date** | **1Y: Coils implanted** | **1Y: Number of coils** | **1Y: Other intrasaccular device** | **1Y: Specify other intrasaccular device** | **1Y: Standard stent** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Stenosis < 50 % | Yes | 02/02/2021 | 02/02/2021 | . | . | . |  | . |
| No stenosis | Yes | 02/09/2021 | 02/09/2021 | . | . | . |  | . |
| No stenosis | Yes | 16/03/2021 | 16/03/2021 | checked | 1 | . |  | checked |
| No stenosis | Yes | 13/05/2022 | 13/05/2022 | checked | D | checked | ONYX EMBOLISATION | . |
| N = 4 | | | | | | | | |

| **1Y: Specify standard stent** | **1Y: Flow diverter** | **1Y: Specify flow diverter** | **1Y: retreatment specify other FD** | **1Y: retreatment FRED reference** | **1Y: retreatment FRED batch number** | **1Y : Permeability of the parent artery at the end of the 1Yedure** |
| --- | --- | --- | --- | --- | --- | --- |
|  | checked | FRED |  | FRED3507 | 20040251Y | Stenosis < 50 % |
|  | checked | Other | SURPASS EVOLVE |  |  | No stenosis |
| SILK STENT | . | . |  |  |  | No stenosis |
|  | . | . |  |  |  | No stenosis |
| N = 4 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rate(Aneurysm complete occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 12 9.68 15.19 63.16 | 67 54.03 84.81 63.81 | 79 63.71 |
| **FRED X** | 7 5.65 15.56 36.84 | 38 30.65 84.44 36.19 | 45 36.29 |
| **Total** | 19 15.32 | 105 84.68 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0030 | 0.9566 |
| **Test du rapport de vraisemblance** | 1 | 0.0029 | 0.9567 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0029 | 0.9568 |
| **Coefficient Phi** |  | -0.0049 |  |
| **Coefficient de contingence** |  | 0.0049 |  |
| **V de Cramer** |  | -0.0049 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 12 |
| **Pr <= F unilatérale à gauche** | 0.5745 |
| **Pr >= F unilatérale à droite** | 0.6285 |
|  |  |
| **Probabilité de la table (P)** | 0.2030 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 12 (15.2%) | 7 (15.6%) | 19 (15.3%) |
|  | Yes | 67 (84.8%) | 38 (84.4%) | 105 (84.7%) |
|  | 95% CI | 76.9% - 92.7% | 73.9% - 95.0% | 78.3% - 91% |
|  | Between group test |  |  | 0.957 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par ACO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **ACO\_rateb(Aneurysm complete occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.80 10.77 53.85 | 58 56.31 89.23 64.44 | 65 63.11 |
| **FRED X** | 6 5.83 15.79 46.15 | 32 31.07 84.21 35.56 | 38 36.89 |
| **Total** | 13 12.62 | 90 87.38 | 103 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par ACO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.5480 | 0.4591 |
| **Test du rapport de vraisemblance** | 1 | 0.5352 | 0.4644 |
| **Khi-2 continuité ajustée** | 1 | 0.1873 | 0.6651 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.5427 | 0.4613 |
| **Coefficient Phi** |  | -0.0729 |  |
| **Coefficient de contingence** |  | 0.0727 |  |
| **V de Cramer** |  | -0.0729 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.3272 |
| **Pr >= F unilatérale à droite** | 0.8524 |
|  |  |
| **Probabilité de la table (P)** | 0.1796 |
| **Pr <= P bilatéral** | 0.5429 |

|  |
| --- |
| ***Taille de l'échantillon = 103*** |

**FRITS**

**EFFICACY**

**Table : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months(OKM score)** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | No | 7 (10.8%) | 6 (15.8%) | 13 (12.6%) |
|  | Yes | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |
|  | 95% CI | 81.7% - 96.8% | 72.6% - 95.8% | 81% - 93.8% |
|  | Between group test |  |  | 0.543 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rate** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rate(Adequate occlusion rate at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 9 7.26 11.39 75.00 | 70 56.45 88.61 62.50 | 79 63.71 |
| **FRED X** | 3 2.42 6.67 25.00 | 42 33.87 93.33 37.50 | 45 36.29 |
| **Total** | 12 9.68 | 112 90.32 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rate*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.7325 | 0.3921 |
| **Test du rapport de vraisemblance** | 1 | 0.7712 | 0.3798 |
| **Khi-2 continuité ajustée** | 1 | 0.2916 | 0.5892 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.7266 | 0.3940 |
| **Coefficient Phi** |  | 0.0769 |  |
| **Coefficient de contingence** |  | 0.0766 |  |
| **V de Cramer** |  | 0.0769 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 9 |
| **Pr <= F unilatérale à gauche** | 0.8817 |
| **Pr >= F unilatérale à droite** | 0.3017 |
|  |  |
| **Probabilité de la table (P)** | 0.1834 |
| **Pr <= P bilatéral** | 0.5335 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 9 (11.4%) | 3 (6.7%) | 12 (9.7%) |
|  | Yes | 70 (88.6%) | 42 (93.3%) | 112 (90.3%) |
|  | 95% CI | 81.6% - 95.6% | 86.0% - 100.0% | 85.1% - 95.5% |
|  | Between group test |  |  | 0.534 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par AAO\_rateb** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **AAO\_rateb(Adequate occlusion rate at 12 months(OKM score))** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 7 6.80 10.77 63.64 | 58 56.31 89.23 63.04 | 65 63.11 |
| **FRED X** | 4 3.88 10.53 36.36 | 34 33.01 89.47 36.96 | 38 36.89 |
| **Total** | 11 10.68 | 92 89.32 | 103 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par AAO\_rateb*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0015 | 0.9693 |
| **Test du rapport de vraisemblance** | 1 | 0.0015 | 0.9692 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0015 | 0.9694 |
| **Coefficient Phi** |  | 0.0038 |  |
| **Coefficient de contingence** |  | 0.0038 |  |
| **V de Cramer** |  | 0.0038 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 7 |
| **Pr <= F unilatérale à gauche** | 0.6353 |
| **Pr >= F unilatérale à droite** | 0.6224 |
|  |  |
| **Probabilité de la table (P)** | 0.2577 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 103*** |

**FRITS**

**EFFICACY**

**Table : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months(OKM score)** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | No | 7 (10.8%) | 4 (10.5%) | 11 (10.7%) |
|  | Yes | 58 (89.2%) | 34 (89.5%) | 92 (89.3%) |
|  | 95% CI | 81.7% - 96.8% | 79.7% - 99.2% | 83.4% - 95.3% |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Obliteration | 67 (84.8%) | 38 (84.4%) | 105 (84.7%) |
|  | Residual neck | 3 (3.8%) | 4 (8.9%) | 7 (5.6%) |
|  | Residual aneurysm | 9 (11.4%) | 3 (6.7%) | 12 (9.7%) |
|  | Between group test |  |  | 0.390 (Fisher) |
|  |  |  |  |  |
| **1Y : Aneurysm occlusion degree specification** | N | 3 |  | 3 |
|  | Missing data | 76 | 44 | 120 |
|  | Class IIIa | 0 | 1 (100.0%) | 1 (25.0%) |
|  | Class IIIb | 3 (100.0%) |  | 3 (75.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm filling** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 3 (3.8%) | 2 (4.4%) | 5 (4.0%) |
|  | B: subtotal filling (5-95%) | 5 (6.3%) | 2 (4.4%) | 7 (5.6%) |
|  | C: entry remnant (<5%) | 0 | 2 (4.4%) | 2 (1.6%) |
|  | D: no filling (0%) | 58 (73.4%) | 32 (71.1%) | 90 (72.6%) |
|  | Cannot be assessed from the imaging | 12 (15.2%) | 7 (15.6%) | 19 (15.3%) |
|  | Not applicable | 1 (1.3%) |  | 1 (0.8%) |
|  | Between group test |  |  | 0.609 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Aneurysm Occlusion stability at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm Occlusion stability** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Better | 37 (46.8%) | 15 (33.3%) | 52 (41.9%) |
|  | Same | 27 (34.2%) | 20 (44.4%) | 47 (37.9%) |
|  | Cannot be assessed from the imaging | 15 (19.0%) | 10 (22.2%) | 25 (20.2%) |
|  | Between group test |  |  | 0.334 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Stasis phase at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stasis phase** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | 2: moderate stasis (clearance before venous phase) | 2 (2.5%) | 2 (4.4%) | 4 (3.2%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 4 (5.1%) | 3 (6.7%) | 7 (5.6%) |
|  | Cannot be assessed from the imaging | 11 (13.9%) | 8 (17.8%) | 19 (15.3%) |
|  | Not applicable | 61 (77.2%) | 31 (68.9%) | 92 (74.2%) |
|  | Between group test |  |  | 0.806 (Fisher) |

**FRITS**

**EFFICACY**

**Table : OKM scale at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 12 months** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | A1 | 1 (1.5%) | 1 (2.6%) | 2 (1.9%) |
|  | A2 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | A3 | 1 (1.5%) |  | 1 (1.0%) |
|  | B2 | 2 (3.1%) |  | 2 (1.9%) |
|  | B3 | 3 (4.6%) | 2 (5.3%) | 5 (4.9%) |
|  | C2 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | C3 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | D1 | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |

**FRITS**

**EFFICACY**

**Table : OKM grade at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 12 months** | N | 65 |  | 65 |
|  | Missing data | 14 | 7 | 21 |
|  | OKM A | 2 (3.1%) | 2 (5.3%) | 4 (3.9%) |
|  | OKM B | 5 (7.7%) | 2 (5.3%) | 7 (6.8%) |
|  | OKM C | 0 | 2 (5.3%) | 2 (1.9%) |
|  | OKM D | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm sac size change at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm sac size change** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | Increased sac size | 1 (1.3%) |  | 1 (0.8%) |
|  | Stable | 23 (29.1%) | 18 (40.0%) | 41 (33.1%) |
|  | Decreased sac size | 16 (20.3%) | 5 (11.1%) | 21 (16.9%) |
|  | Cannot be assessed from the imaging | 39 (49.4%) | 22 (48.9%) | 61 (49.2%) |
|  | Between group test |  |  | 0.408 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent Stability at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent Stability** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | Yes | 73 (92.4%) | 44 (97.8%) | 117 (94.4%) |
|  | Cannot be assessed from the imaging | 5 (6.3%) |  | 5 (4.0%) |
|  | Between group test |  |  | 0.267 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Stent covering the neck at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Stent covering the neck** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 4 (5.1%) | 1 (2.2%) | 5 (4.0%) |
|  | Yes | 70 (88.6%) | 44 (97.8%) | 114 (91.9%) |
|  | Cannot be assessed from the imaging | 5 (6.3%) |  | 5 (4.0%) |
|  | Between group test |  |  | 0.220 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Parent artery permeability at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Parent Artery permeability** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 52 (65.8%) | 27 (60.0%) | 79 (63.7%) |
|  | Stenosis < 50% | 13 (16.5%) | 5 (11.1%) | 18 (14.5%) |
|  | On MRA or CTA images, no stenosis or Stenosis < 50% | 10 (12.7%) | 11 (24.4%) | 21 (16.9%) |
|  | Stenosis >= 50 % | 1 (1.3%) | 2 (4.4%) | 3 (2.4%) |
|  | Complete occlusion | 1 (1.3%) |  | 1 (0.8%) |
|  | On MRA or CTA images, Stenosis >= 50 % or complete occlusion | 1 (1.3%) |  | 1 (0.8%) |
|  | Cannot be assessed from the imaging | 1 (1.3%) |  | 1 (0.8%) |
|  | Between group test |  |  | 0.405 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Retreatment** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (100.0%) | 45 (100.0%) | 124 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Retreatment rate at 12 months (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y: Retreatment** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (98.7%) | 45 (100.0%) | 123 (99.2%) |
|  | Yes | 1 (1.3%) |  | 1 (0.8%) |
|  | Between group test |  |  | 1.000 (Fisher) |

**FRITS**

**EFFICACY**

**Table : Listing of patient with missing data for Retreatment at 12 months (INVESTIGATORS) [PP - N=124 patients]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-002 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 1 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Iteration Number** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No | No | No | 86 | Female | FRED / FRED Jr | FRED | 21/11/2019 | 1 | 1 |
| N = 1 | | | | | | | | | |

| **1Y: visit performed** | **1Y: reason for not performed** | **1Y Date** | **1Y Date - Partial date** | **1Y: mRS** | **1Y: Antiplatelet changes** | **1Y: AE** | **1Y: Imaging done** | **1Y Imaging: Date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes |  | 10/11/2020 | 10/11/2020 | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | Yes | No | Yes | 10/11/2020 |
| N = 1 | | | | | | | | |

| **1Y Imaging: Date - Partial date** | **1Y: Imaging type** | **1Y: Stent placement** | **1Y: Aneurysm occlusion degree** | **1Y: Aneurysm occlusion degree OKM scale** | **Y1\_StasisPhase\_OKM\_LD** | **1Y: Aneurysm occlusion change** | **1Y: Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 10/11/2020 | Magnetic resonance angiography (MRA) | Cannot be assessed from the imaging | Class II: Residual neck | Not applicable | Non applicable | Worse | Stable |
| N = 1 | | | | | | | |

| **1Y: Parent artery permeability** | **1Y: Retreatment** | **1Y Retreatment: Date** | **1Y Retreatment: Date - Partial date** | **1Y: Coils implanted** | **1Y: Number of coils** | **1Y: Other intrasaccular device** | **1Y: Specify other intrasaccular device** | **1Y: Standard stent** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| No stenosis | Yes | 16/03/2021 | 16/03/2021 | checked | 1 | . |  | checked |
| N = 1 | | | | | | | | |

| **1Y: Specify standard stent** | **1Y: Flow diverter** | **1Y: Specify flow diverter** | **1Y: retreatment specify other FD** | **1Y: retreatment FRED reference** | **1Y: retreatment FRED batch number** | **1Y : Permeability of the parent artery at the end of the 1Yedure** |
| --- | --- | --- | --- | --- | --- | --- |
| SILK STENT | . | . |  |  |  | No stenosis |
| N = 1 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Aneurysm filling** | N | 99 |  | 99 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 58 (58.6%) | 40 (72.7%) | 98 (63.6%) |
|  | B: subtotal filling (5-95%) | 17 (17.2%) | 9 (16.4%) | 26 (16.9%) |
|  | C: entry remnant (<5%) | 6 (6.1%) | 1 (1.8%) | 7 (4.5%) |
|  | D: no filling (0%) | 18 (18.2%) | 5 (9.1%) | 23 (14.9%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling for patients without FRED implanted (CORELAB) [ITT - N=2 patients]**

|  | | **FRED / FRED Jr N=2** | **Total N=2** |
| --- | --- | --- | --- |
|  |  |  |  |
| **Procedure : Aneurysm filling** | N | 2 | 2 |
|  | Missing data | 0 | 0 |
|  | B: subtotal filling (5-95%) | 1 (50.0%) | 1 (50.0%) |
|  | D: no filling (0%) | 1 (50.0%) | 1 (50.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling for patients without FRED implanted (CORELAB) [ITT - N=2 patients]**

| **Subject Identifier for the Study** | **Age calculated** | **Gender** | **FRED used type** | **Subgroup device** | **Procedure : Aneurysm filling** | **Stasis status** | **OKM scale** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 07-001 | 61 | Female | FRED | FRED / FRED Jr | B: subtotal filling (5-95%) | 3: significant stasis (persistent contrast at venous phase) | B3 |
| 07-006 | 40 | Male | FRED | FRED / FRED Jr | D: no filling (0%) | Not applicable | D1 |
| N = 2 | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Stasis status at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Stasis status** | N | 99 |  | 99 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 30 (30.3%) | 12 (21.8%) | 42 (27.3%) |
|  | 2: moderate stasis (clearance before venous phase) | 17 (17.2%) | 11 (20.0%) | 28 (18.2%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 33 (33.3%) | 27 (49.1%) | 60 (39.0%) |
|  | Not applicable | 19 (19.2%) | 5 (9.1%) | 24 (15.6%) |

**FRITS**

**EFFICACY**

**Table : OKM scale at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale** | N | 98 |  | 98 |
|  | Missing data | 1 |  | 1 |
|  | A1 | 25 (25.5%) | 10 (18.2%) | 35 (22.9%) |
|  | A2 | 13 (13.3%) | 10 (18.2%) | 23 (15.0%) |
|  | A3 | 20 (20.4%) | 20 (36.4%) | 40 (26.1%) |
|  | B1 | 2 (2.0%) | 1 (1.8%) | 3 (2.0%) |
|  | B2 | 4 (4.1%) | 1 (1.8%) | 5 (3.3%) |
|  | B3 | 11 (11.2%) | 7 (12.7%) | 18 (11.8%) |
|  | C1 | 3 (3.1%) | 1 (1.8%) | 4 (2.6%) |
|  | C3 | 2 (2.0%) |  | 2 (1.3%) |
|  | D1 | 18 (18.4%) | 5 (9.1%) | 23 (15.0%) |

**FRITS**

**EFFICACY**

**Table : OKM grade at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade** | N | 98 |  | 98 |
|  | Missing data | 1 |  | 1 |
|  | OKM A | 58 (59.2%) | 40 (72.7%) | 98 (64.1%) |
|  | OKM B | 17 (17.3%) | 9 (16.4%) | 26 (17.0%) |
|  | OKM C | 5 (5.1%) | 1 (1.8%) | 6 (3.9%) |
|  | OKM D | 18 (18.4%) | 5 (9.1%) | 23 (15.0%) |

**FRITS**

**EFFICACY**

**Table : Permeability of the Parent Artery at the procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Permeability of the Parent Artery at the end of the procedure** | N | 99 |  | 99 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 97 (98.0%) | 52 (94.5%) | 149 (96.8%) |
|  | Stenosis < 50 % | 2 (2.0%) | 3 (5.5%) | 5 (3.2%) |

**FRITS**

**EFFICACY**

**Table : Flow diverter cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 1)** | N | 99 |  | 99 |
|  | Missing data | 0 |  | 0 |
|  | Yes | 99 (100.0%) | 55 (100.0%) | 154 (100.0%) |

**FRITS**

**EFFICACY**

**Table : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Did the internal stent (flow-diverter part) cover the aneurysm neck ? (Nr 1)** | N | 99 |  | 99 |
|  | Missing data | 0 |  | 0 |
|  | No | 0 | 1 (1.8%) | 1 (0.6%) |
|  | Yes | 99 (100.0%) | 54 (98.2%) | 153 (99.4%) |

**FRITS**

**EFFICACY**

**Table : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 08-013 | Yes | No | No | Yes | Yes | No | No | No |
| N = 1 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Study name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | No | 57 | Female | FRED X | FRED X | 15/09/2021 | 1 | FRITS |
| N = 1 | | | | | | | | | |

| **Pre-procedure : Date of imaging (c)** | **Pre-procedure : Date of imaging** | **Pre-procedure : Aneurysm type** | **Pre-procedure : Height** | **Pre-procedure : Width** |
| --- | --- | --- | --- | --- |
| 15/09/2021 | 15/09/2021 | Saccular | 4 | 4 |
| N = 1 | | | | |

| **Pre-procedure : Neck** | **Pre-procedure : Dome-to-Neck ratio** | **Pre-procedure : Distal diameter** | **Pre-procedure : Proximal diameter** |
| --- | --- | --- | --- |
| 2 | < 2 | 2.5 | 3 |
| N = 1 | | | |

| **Pre-procedure : Aneurysm location** | **Pre-procedure : Specification segment** | **Pre-procedure : Specification** | **Pre-procedure : Laterality:** |
| --- | --- | --- | --- |
| Supraclinoid internal carotid artery | OPHTALMIC |  | Right |
| N = 1 | | | |

| **Pre-procedure : Corelab validation** | **Pre-procedure : If no, explain** | **Pre-procedure : Validation date by the CoreLab (c)** | **Pre-procedure : Validation date by the CoreLab** |
| --- | --- | --- | --- |
| Yes |  | 14/09/2022 | 14/09/2022 |
| N = 1 | | | |

| **Pre-procedure : Validation Comments** | **Procedure : Number of flow diverter implanted** | **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 1)** | **Procedure : Did the internal stent (flow-diverter part) cover the aneurysm neck ? (Nr 1)** | **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 2)** | **Procedure : Did the internal stent (flow-diverter part) cover the aneurysm neck ? (Nr 2)** |
| --- | --- | --- | --- | --- | --- |
|  | 1 | Yes | No | . | . |
| N = 1 | | | | | |

| **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 3)** | **Procedure : Did the internal stent (flow-diverter part) cover the aneurysm neck ? (Nr 3)** | **Procedure : Aneurysm filling** | **Stasis status** | **Procedure : Permeability of the Parent Artery at the end of the procedure** |
| --- | --- | --- | --- | --- |
| . | . | A: total filling (>95%) | 2: moderate stasis (clearance before venous phase) | Stenosis < 50 % |
| N = 1 | | | | |

| **Procedure : Corelab validation** | **Procedure : If no, explain** | **Procedure : Validation date by the CoreLab (c)** | **Procedure : Validation date by the CoreLab** | **Procedure : Validation Comments** | **6M : Date of imaging (c)** |
| --- | --- | --- | --- | --- | --- |
| Yes |  | 14/09/2022 | 14/09/2022 |  | 29/12/2021 |
| N = 1 | | | | | |

| **6M : Date of imaging** | **6M : Imaging modality - Angiography** | **6M : Imaging modality - Magnetic Resonance Angiography** | **6M : Imaging modality - Angio-scanner** | **6M : Stent Stability** | **6M : Migration** |
| --- | --- | --- | --- | --- | --- |
| 29/12/2021 | checked | checked | . | Cannot be assessed from the imaging | . |
| N = 1 | | | | | |

| **6M : Migration specification** | **6M : Shortage** | **6M : Shortage specification** | **6M : Stent covering the neck** | **6M : Parent Artery permeability** | **6M : Aneurysm occlusion degree** | **6M : Aneurysm occlusion degree specification** |
| --- | --- | --- | --- | --- | --- | --- |
| . | . | . | Cannot be assessed from the imaging | On MRA or CTA images, no stenosis or Stenosis < 50% | Obliteration | . |
| N = 1 | | | | | | |

| **6M : Aneurysm filling** | **6M : Stasis phase** | **6M : Aneurysm Occlusion stability** | **6M : Aneurysm sac size change** | **6M : Retreatment** | **6M : Date of the retreatment (c)** | **6M : Date of the retreatment** | **6M : Imaging assessment done** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Cannot be assessed from the imaging | Cannot be assessed from the imaging | Better | Stable | No |  | . | . |
| N = 1 | | | | | | | |

| **6M : Corelab validation** | **6M : If no, explain** | **6M : Validation date by the CoreLab (c)** | **6M : Validation date by the CoreLab** | **6M : Validation Comments** | **1Y : Date of imaging (c)** | **1Y : Date of imaging** | **1Y : Imaging modality - Angiography** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes |  | 08/01/2024 | 08/01/2024 |  | 13/09/2022 | 13/09/2022 | checked |
| N = 1 | | | | | | | |

| **1Y : Imaging modality - Magnetic Resonance Angiography** | **1Y : Imaging modality - Angio-scanner** | **1Y : Stent Stability** | **1Y : Migration** | **1Y : Migration specification** | **1Y : Shortage** | **1Y : Shortage specification** |
| --- | --- | --- | --- | --- | --- | --- |
| checked | . | No | checked | Proximal | checked | Proximal |
| N = 1 | | | | | | |

| **1Y : Stent covering the neck** | **1Y : Parent Artery permeability** | **1Y : Aneurysm occlusion degree** | **1Y : Aneurysm occlusion degree specification** | **1Y : Aneurysm filling** | **1Y : Stasis phase** | **1Y : Aneurysm Occlusion stability** | **1Y : Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Stenosis < 50% | Obliteration | . | D: no filling (0%) | Not applicable | Better | Decreased sac size |
| N = 1 | | | | | | | |

| **1Y : Retreatment** | **1Y : Date of the retreatment (c)** | **1Y : Date of the retreatment** | **1Y : Imaging assessment done** | **1Y : Corelab validation** | **1Y : If no, explain** | **1Y : Validation date by the CoreLab (c)** | **1Y : Validation date by the CoreLab** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No |  | . | . | Yes |  | 08/01/2024 | 08/01/2024 |
| N = 1 | | | | | | | |

| **1Y : Validation Comments** | **2Y : Date of imaging (c)** | **2Y : Date of imaging** | **2Y : Imaging modality - Angiography** | **2Y : Imaging modality - Magnetic Resonance Angiography** | **2Y : Imaging modality - Angio-scanner** | **2Y : Stent Stability** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | . | . | . | . | . |
| N = 1 | | | | | | |

| **2Y : Migration** | **2Y : Migration specification** | **2Y : Shortage** | **2Y : Shortage specification** | **2Y : Stent covering the neck** | **2Y : Parent Artery permeability** | **2Y : Aneurysm occlusion degree** | **2Y : Aneurysm occlusion degree specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . |
| N = 1 | | | | | | | |

| **2Y : Aneurysm filling** | **2Y : Stasis phase** | **2Y : Aneurysm Occlusion stability** | **2Y : Aneurysm sac size change** | **2Y : Retreatment** | **2Y : Date of the retreatment (c)** | **2Y : Date of the retreatment** | **2Y : Imaging assessment done** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . |  | . | . |
| N = 1 | | | | | | | |

| **2Y : Corelab validation** | **2Y : If no, explain** | **2Y : Validation date by the CoreLab (c)** | **2Y : Validation date by the CoreLab** | **2Y : Validation Comments** | **3Y : Date of imaging (c)** | **3Y : Date of imaging** | **3Y : Imaging modality - Angiography** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . |  |  | . |  |  | . | . |
| N = 1 | | | | | | | |

| **3Y : Imaging modality - Magnetic Resonance Angiography** | **3Y : Imaging modality - Angio-scanner** | **3Y : Stent Stability** | **3Y : Migration** | **3Y : Migration specification** | **3Y : Shortage** | **3Y : Shortage specification** |
| --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . |
| N = 1 | | | | | | |

| **3Y : Stent covering the neck** | **3Y : Parent Artery permeability** | **3Y : Aneurysm occlusion degree** | **3Y : Aneurysm occlusion degree specification** | **3Y : Aneurysm filling** | **3Y : Stasis phase** | **3Y : Aneurysm Occlusion stability** | **3Y : Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . |
| N = 1 | | | | | | | |

| **3Y : Retreatment** | **3Y : Date of the retreatment (c)** | **3Y : Date of the retreatment** | **3Y : Imaging assessment done** | **3Y : Corelab validation** | **3Y : If no, explain** | **3Y : Validation date by the CoreLab (c)** | **3Y : Validation date by the CoreLab** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . |  | . | . | . |  |  | . |
| N = 1 | | | | | | | |

| **3Y : Validation Comments** | **4Y : Date of imaging (c)** | **4Y : Date of imaging** | **4Y : Imaging modality - Angiography** | **4Y : Imaging modality - Magnetic Resonance Angiography** | **4Y : Imaging modality - Angio-scanner** | **4Y : Stent Stability** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | . | . | . | . | . |
| N = 1 | | | | | | |

| **4Y : Migration** | **4Y : Migration specification** | **4Y : Shortage** | **4Y : Shortage specification** | **4Y : Stent covering the neck** | **4Y : Parent Artery permeability** | **4Y : Aneurysm occlusion degree** | **4Y : Aneurysm occlusion degree specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . |
| N = 1 | | | | | | | |

| **4Y : Aneurysm filling** | **4Y : Stasis phase** | **4Y : Aneurysm Occlusion stability** | **4Y : Aneurysm sac size change** | **4Y : Retreatment** | **4Y : Date of the retreatment (c)** | **4Y : Date of the retreatment** | **4Y : Imaging assessment done** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . |  | . | . |
| N = 1 | | | | | | | |

| **4Y : Corelab validation** | **4Y : If no, explain** | **4Y : Validation date by the CoreLab (c)** | **4Y : Validation date by the CoreLab** | **4Y : Validation Comments** | **5Y : Date of imaging (c)** | **5Y : Date of imaging** | **5Y : Imaging modality - Angiography** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . |  |  | . |  |  | . | . |
| N = 1 | | | | | | | |

| **5Y : Imaging modality - Magnetic Resonance Angiography** | **5Y : Imaging modality - Angio-scanner** | **5Y : Stent Stability** | **5Y : Migration** | **5Y : Migration specification** | **5Y : Shortage** | **5Y : Shortage specification** |
| --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . |
| N = 1 | | | | | | |

| **5Y : Stent covering the neck** | **5Y : Parent Artery permeability** | **5Y : Aneurysm occlusion degree** | **5Y : Aneurysm occlusion degree specification** | **5Y : Aneurysm filling** | **5Y : Stasis phase** | **5Y : Aneurysm Occlusion stability** | **5Y : Aneurysm sac size change** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . |
| N = 1 | | | | | | | |

| **5Y : Retreatment** | **5Y : Date of the retreatment (c)** | **5Y : Date of the retreatment** | **5Y : Imaging assessment done** | **5Y : Corelab validation** | **5Y : If no, explain** | **5Y : Validation date by the CoreLab (c)** | **5Y : Validation date by the CoreLab** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| . |  | . | . | . |  |  | . |
| N = 1 | | | | | | | |

| **5Y : Validation Comments** | **OKM scale** | **OKM grade** |
| --- | --- | --- |
|  | A2 | OKM A |
| N = 1 | | |

**FRITS**

**EFFICACY**

**Table : The flow diverter cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 2)** | N | 4 |  | 4 |
|  | Missing data | 95 | 55 | 150 |
|  | Yes | 4 (100.0%) |  | 4 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Aneurysm filling at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Aneurysm filling** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | A: total filling (>95%) | 55 (63.2%) | 37 (72.5%) | 92 (66.7%) |
|  | B: subtotal filling (5-95%) | 16 (18.4%) | 9 (17.6%) | 25 (18.1%) |
|  | C: entry remnant (<5%) | 5 (5.7%) | 1 (2.0%) | 6 (4.3%) |
|  | D: no filling (0%) | 11 (12.6%) | 4 (7.8%) | 15 (10.9%) |

**FRITS**

**EFFICACY**

**Table : Stasis status at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Stasis status** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | 1: no stasis (arterial phase clearance, before capillary phase) | 29 (33.3%) | 12 (23.5%) | 41 (29.7%) |
|  | 2: moderate stasis (clearance before venous phase) | 16 (18.4%) | 9 (17.6%) | 25 (18.1%) |
|  | 3: significant stasis (persistent contrast at venous phase) | 31 (35.6%) | 26 (51.0%) | 57 (41.3%) |
|  | Not applicable | 11 (12.6%) | 4 (7.8%) | 15 (10.9%) |

**FRITS**

**EFFICACY**

**Table : OKM scale at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | A1 | 25 (28.7%) | 10 (19.6%) | 35 (25.4%) |
|  | A2 | 12 (13.8%) | 8 (15.7%) | 20 (14.5%) |
|  | A3 | 18 (20.7%) | 19 (37.3%) | 37 (26.8%) |
|  | B1 | 1 (1.1%) | 1 (2.0%) | 2 (1.4%) |
|  | B2 | 4 (4.6%) | 1 (2.0%) | 5 (3.6%) |
|  | B3 | 11 (12.6%) | 7 (13.7%) | 18 (13.0%) |
|  | C1 | 3 (3.4%) | 1 (2.0%) | 4 (2.9%) |
|  | C3 | 2 (2.3%) |  | 2 (1.4%) |
|  | D1 | 11 (12.6%) | 4 (7.8%) | 15 (10.9%) |

**FRITS**

**EFFICACY**

**Table : OKM grade at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | OKM A | 55 (63.2%) | 37 (72.5%) | 92 (66.7%) |
|  | OKM B | 16 (18.4%) | 9 (17.6%) | 25 (18.1%) |
|  | OKM C | 5 (5.7%) | 1 (2.0%) | 6 (4.3%) |
|  | OKM D | 11 (12.6%) | 4 (7.8%) | 15 (10.9%) |

**FRITS**

**EFFICACY**

**Table : Permeability of the Parent Artery at the procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Permeability of the Parent Artery at the end of the procedure** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | No stenosis | 86 (98.9%) | 50 (98.0%) | 136 (98.6%) |
|  | Stenosis < 50 % | 1 (1.1%) | 1 (2.0%) | 2 (1.4%) |

**FRITS**

**EFFICACY**

**Table : Flow diverter cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 1)** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Yes | 87 (100.0%) | 51 (100.0%) | 138 (100.0%) |

**FRITS**

**EFFICACY**

**Table : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Did the internal stent (flow-diverter part) cover the aneurysm neck ? (Nr 1)** | N | 87 |  | 87 |
|  | Missing data | 0 |  | 0 |
|  | Yes | 87 (100.0%) | 51 (100.0%) | 138 (100.0%) |

**FRITS**

**EFFICACY**

**Table : The flow diverter cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=51** | **Total N=138** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Procedure : Did the flow diverter cover the aneurysm neck?(Nr 2)** | N | 2 |  | 2 |
|  | Missing data | 85 | 51 | 136 |
|  | Yes | 2 (100.0%) |  | 2 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 6 months (CORELAB) [ITT - N=129 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par CJP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **CJP(Rate of complete aneurysm occlusion at 6 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **Echec** | **Success** | **Total** |
| **FRED / FRED Jr** | 30 23.26 38.46 62.50 | 48 37.21 61.54 59.26 | 78 60.47 |
| **FRED X** | 18 13.95 35.29 37.50 | 33 25.58 64.71 40.74 | 51 39.53 |
| **Total** | 48 37.21 | 81 62.79 | 129 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par CJP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1324 | 0.7159 |
| **Test du rapport de vraisemblance** | 1 | 0.1328 | 0.7156 |
| **Khi-2 continuité ajustée** | 1 | 0.0315 | 0.8590 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1314 | 0.7170 |
| **Coefficient Phi** |  | 0.0320 |  |
| **Coefficient de contingence** |  | 0.0320 |  |
| **V de Cramer** |  | 0.0320 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 30 |
| **Pr <= F unilatérale à gauche** | 0.7079 |
| **Pr >= F unilatérale à droite** | 0.4309 |
|  |  |
| **Probabilité de la table (P)** | 0.1388 |
| **Pr <= P bilatéral** | 0.8524 |

|  |
| --- |
| ***Taille de l'échantillon = 129*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Rate of complete aneurysm occlusion at 6 months** | N | 78 |  | 78 |
|  | Missing data | 0 |  | 0 |
|  | Echec | 30 (38.5%) | 18 (35.3%) | 48 (37.2%) |
|  | Success | 48 (61.5%) | 33 (64.7%) | 81 (62.8%) |
|  | 95% CI | 50.7% - 72.3% | 51.6% - 77.8% | 54.4% - 71.1% |
|  | Between group test |  |  | 0.716 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 6 months (CORELAB) [PP - N=117 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par CJP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **CJP(Rate of complete aneurysm occlusion at 6 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **Echec** | **Success** | **Total** |
| **FRED / FRED Jr** | 28 23.93 40.00 62.22 | 42 35.90 60.00 58.33 | 70 59.83 |
| **FRED X** | 17 14.53 36.17 37.78 | 30 25.64 63.83 41.67 | 47 40.17 |
| **Total** | 45 38.46 | 72 61.54 | 117 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par CJP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1743 | 0.6764 |
| **Test du rapport de vraisemblance** | 1 | 0.1747 | 0.6759 |
| **Khi-2 continuité ajustée** | 1 | 0.0500 | 0.8230 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1728 | 0.6777 |
| **Coefficient Phi** |  | 0.0386 |  |
| **Coefficient de contingence** |  | 0.0386 |  |
| **V de Cramer** |  | 0.0386 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 28 |
| **Pr <= F unilatérale à gauche** | 0.7287 |
| **Pr >= F unilatérale à droite** | 0.4127 |
|  |  |
| **Probabilité de la table (P)** | 0.1414 |
| **Pr <= P bilatéral** | 0.7027 |

|  |
| --- |
| ***Taille de l'échantillon = 117*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Rate of complete aneurysm occlusion at 6 months** | N | 70 |  | 70 |
|  | Missing data | 0 |  | 0 |
|  | Echec | 28 (40.0%) | 17 (36.2%) | 45 (38.5%) |
|  | Success | 42 (60.0%) | 30 (63.8%) | 72 (61.5%) |
|  | 95% CI | 48.5% - 71.5% | 50.1% - 77.6% | 52.7% - 70.4% |
|  | Between group test |  |  | 0.676 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 12 months (CORELAB) [ITT - N=137 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 12 months (CORELAB) [ITT - N=137 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par CJP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **CJP(Rate of complete aneurysm occlusion at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **Echec** | **Success** | **Total** |
| **FRED / FRED Jr** | 17 12.41 19.32 65.38 | 71 51.82 80.68 63.96 | 88 64.23 |
| **FRED X** | 9 6.57 18.37 34.62 | 40 29.20 81.63 36.04 | 49 35.77 |
| **Total** | 26 18.98 | 111 81.02 | 137 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par CJP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0185 | 0.8918 |
| **Test du rapport de vraisemblance** | 1 | 0.0186 | 0.8916 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0184 | 0.8922 |
| **Coefficient Phi** |  | 0.0116 |  |
| **Coefficient de contingence** |  | 0.0116 |  |
| **V de Cramer** |  | 0.0116 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 17 |
| **Pr <= F unilatérale à gauche** | 0.6370 |
| **Pr >= F unilatérale à droite** | 0.5416 |
|  |  |
| **Probabilité de la table (P)** | 0.1787 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 137*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 12 months (CORELAB) [ITT - N=137 patients]**

|  | | **FRED / FRED Jr N=88** | **FRED X N=49** | **Total N=137** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Rate of complete aneurysm occlusion at 12 months** | N | 88 |  | 88 |
|  | Missing data | 0 |  | 0 |
|  | Echec | 17 (19.3%) | 9 (18.4%) | 26 (19.0%) |
|  | Success | 71 (80.7%) | 40 (81.6%) | 111 (81.0%) |
|  | 95% CI | 72.4% - 88.9% | 70.8% - 92.5% | 74.5% - 87.6% |
|  | Between group test |  |  | 0.892 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 12 months (CORELAB) [PP - N=125 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 12 months (CORELAB) [PP - N=125 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par CJP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **CJP(Rate of complete aneurysm occlusion at 12 months)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **Echec** | **Success** | **Total** |
| **FRED / FRED Jr** | 16 12.80 20.00 64.00 | 64 51.20 80.00 64.00 | 80 64.00 |
| **FRED X** | 9 7.20 20.00 36.00 | 36 28.80 80.00 36.00 | 45 36.00 |
| **Total** | 25 20.00 | 100 80.00 | 125 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par CJP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0000 | 1.0000 |
| **Test du rapport de vraisemblance** | 1 | 0.0000 | 1.0000 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0000 | 1.0000 |
| **Coefficient Phi** |  | 0.0000 |  |
| **Coefficient de contingence** |  | 0.0000 |  |
| **V de Cramer** |  | 0.0000 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 16 |
| **Pr <= F unilatérale à gauche** | 0.5869 |
| **Pr >= F unilatérale à droite** | 0.5968 |
|  |  |
| **Probabilité de la table (P)** | 0.1837 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 125*** |

**FRITS**

**EFFICACY**

**Table : Rate of complete aneurysm occlusion at 12 months (CORELAB) [PP - N=125 patients]**

|  | | **FRED / FRED Jr N=80** | **FRED X N=45** | **Total N=125** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Rate of complete aneurysm occlusion at 12 months** | N | 80 |  | 80 |
|  | Missing data | 0 |  | 0 |
|  | Echec | 16 (20.0%) | 9 (20.0%) | 25 (20.0%) |
|  | Success | 64 (80.0%) | 36 (80.0%) | 100 (80.0%) |
|  | 95% CI | 71.2% - 88.8% | 68.3% - 91.7% | 73% - 87% |
|  | Between group test |  |  | 1.000 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm occlusion at 6 months (CORELAB) [ITT - N=152 patients]**

|  | | **FRED / FRED Jr N=98** | **FRED X N=54** | **Total N=152** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm Occlusion stability** | N | 84 |  | 84 |
|  | Missing data | 14 | 1 | 15 |
|  | Better | 42 (50.0%) | 29 (54.7%) | 71 (51.8%) |
|  | Same | 9 (10.7%) | 6 (11.3%) | 15 (10.9%) |
|  | Cannot be assessed from the imaging | 33 (39.3%) | 18 (34.0%) | 51 (37.2%) |
|  | Between group test |  |  | 0.820 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm occlusion at 12 months (CORELAB) [ITT - N=152 patients]**

|  | | **FRED / FRED Jr N=98** | **FRED X N=54** | **Total N=152** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm Occlusion stability** | N | 88 |  | 88 |
|  | Missing data | 10 | 5 | 15 |
|  | Better | 42 (47.7%) | 19 (38.8%) | 61 (44.5%) |
|  | Same | 31 (35.2%) | 20 (40.8%) | 51 (37.2%) |
|  | Cannot be assessed from the imaging | 15 (17.0%) | 10 (20.4%) | 25 (18.2%) |
|  | Between group test |  |  | 0.599 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Evolution of aneurysm occlusion between 6 months and 12 months (CORELAB) [ITT - N=152 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**Subgroup device=FRED / FRED Jr**

| **CL6MAOS** | **CL1YAOS** | **Fréquence** | **Fréquence cumulée** |
| --- | --- | --- | --- |
| **.** | **.** | 4 | 4 |
| **.** | **Better** | 2 | 6 |
| **ND** | **Better** | 5 | 11 |
| **ND** | **Same** | 3 | 14 |
| **Better** | **.** | 2 | 16 |
| **Better** | **ND** | 2 | 18 |
| **Better** | **Better** | 11 | 29 |
| **Better** | **Same** | 16 | 45 |
| **Better** | **Cannot be assessed from the imaging** | 11 | 56 |
| **Same** | **.** | 1 | 57 |
| **Same** | **Better** | 2 | 59 |
| **Same** | **Same** | 5 | 64 |
| **Same** | **Cannot be assessed from the imaging** | 1 | 65 |
| **Cannot be assessed from the imaging** | **.** | 1 | 66 |
| **Cannot be assessed from the imaging** | **Better** | 22 | 88 |
| **Cannot be assessed from the imaging** | **Same** | 7 | 95 |
| **Cannot be assessed from the imaging** | **Cannot be assessed from the imaging** | 3 | 98 |

**FRITS**

**EFFICACY**

**Table : Evolution of aneurysm occlusion between 6 months and 12 months (CORELAB) [ITT - N=152 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**Subgroup device=FRED X**

| **CL6MAOS** | **CL1YAOS** | **Fréquence** | **Fréquence cumulée** |
| --- | --- | --- | --- |
| **.** | **.** | 1 | 1 |
| **Better** | **.** | 2 | 3 |
| **Better** | **Better** | 7 | 10 |
| **Better** | **Same** | 14 | 24 |
| **Better** | **Cannot be assessed from the imaging** | 6 | 30 |
| **Same** | **.** | 1 | 31 |
| **Same** | **Better** | 1 | 32 |
| **Same** | **Same** | 2 | 34 |
| **Same** | **Cannot be assessed from the imaging** | 2 | 36 |
| **Cannot be assessed from the imaging** | **ND** | 1 | 37 |
| **Cannot be assessed from the imaging** | **Better** | 11 | 48 |
| **Cannot be assessed from the imaging** | **Same** | 4 | 52 |
| **Cannot be assessed from the imaging** | **Cannot be assessed from the imaging** | 2 | 54 |

**FRITS**

**EFFICACY**

**Table : Aneurysm occlusion at 6 months (CORELAB) [PP - N=136 patients]**

|  | | **FRED / FRED Jr N=86** | **FRED X N=50** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **6M : Aneurysm Occlusion stability** | N | 74 |  | 74 |
|  | Missing data | 12 | 1 | 13 |
|  | Better | 36 (48.6%) | 27 (55.1%) | 63 (51.2%) |
|  | Same | 8 (10.8%) | 6 (12.2%) | 14 (11.4%) |
|  | Cannot be assessed from the imaging | 30 (40.5%) | 16 (32.7%) | 46 (37.4%) |
|  | Between group test |  |  | 0.676 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Aneurysm occlusion at 12 months (CORELAB) [PP - N=136 patients]**

|  | | **FRED / FRED Jr N=86** | **FRED X N=50** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **1Y : Aneurysm Occlusion stability** | N | 80 |  | 80 |
|  | Missing data | 6 | 5 | 11 |
|  | Better | 38 (47.5%) | 15 (33.3%) | 53 (42.4%) |
|  | Same | 27 (33.8%) | 20 (44.4%) | 47 (37.6%) |
|  | Cannot be assessed from the imaging | 15 (18.8%) | 10 (22.2%) | 25 (20.0%) |
|  | Between group test |  |  | 0.299 (Chi-2) |

**FRITS**

**EFFICACY**

**Table : Evolution of aneurysm occlusion between 6 months and 12 months (CORELAB) [PP - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**Subgroup device=FRED / FRED Jr**

| **CL6MAOS** | **CL1YAOS** | **Fréquence** | **Fréquence cumulée** |
| --- | --- | --- | --- |
| **.** | **.** | 4 | 4 |
| **.** | **Better** | 2 | 6 |
| **ND** | **Better** | 5 | 11 |
| **ND** | **Same** | 1 | 12 |
| **Better** | **ND** | 1 | 13 |
| **Better** | **Better** | 8 | 21 |
| **Better** | **Same** | 16 | 37 |
| **Better** | **Cannot be assessed from the imaging** | 11 | 48 |
| **Same** | **Better** | 2 | 50 |
| **Same** | **Same** | 5 | 55 |
| **Same** | **Cannot be assessed from the imaging** | 1 | 56 |
| **Cannot be assessed from the imaging** | **.** | 1 | 57 |
| **Cannot be assessed from the imaging** | **Better** | 21 | 78 |
| **Cannot be assessed from the imaging** | **Same** | 5 | 83 |
| **Cannot be assessed from the imaging** | **Cannot be assessed from the imaging** | 3 | 86 |

**FRITS**

**EFFICACY**

**Table : Evolution of aneurysm occlusion between 6 months and 12 months (CORELAB) [PP - N=136 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**Subgroup device=FRED X**

| **CL6MAOS** | **CL1YAOS** | **Fréquence** | **Fréquence cumulée** |
| --- | --- | --- | --- |
| **.** | **.** | 1 | 1 |
| **Better** | **.** | 2 | 3 |
| **Better** | **Better** | 5 | 8 |
| **Better** | **Same** | 14 | 22 |
| **Better** | **Cannot be assessed from the imaging** | 6 | 28 |
| **Same** | **.** | 1 | 29 |
| **Same** | **Better** | 1 | 30 |
| **Same** | **Same** | 2 | 32 |
| **Same** | **Cannot be assessed from the imaging** | 2 | 34 |
| **Cannot be assessed from the imaging** | **ND** | 1 | 35 |
| **Cannot be assessed from the imaging** | **Better** | 9 | 44 |
| **Cannot be assessed from the imaging** | **Same** | 4 | 48 |
| **Cannot be assessed from the imaging** | **Cannot be assessed from the imaging** | 2 | 50 |

**FRITS**

**Complications**

**Table : Per-procedural complications [ITT - N=156 patients]**

|  | | **FRED / FRED Jr N=101** | **FRED X N=55** | **Total N=156** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **At least one Per-procedural complications** | N | 101 | 55 | 156 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 95 (94.1%) | 46 (83.6%) | 141 (90.4%) |
|  | Yes | 6 (5.9%) | 9 (16.4%) | 15 (9.6%) |

**FRITS**

**Complications**

**Table : Summary of Per-procedural complications [ITT - N=16 complications]**

|  | | **FRED / FRED Jr N=6** | **FRED X N=10** | **Total N=16** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 1 (16.7%) | 1 (10.0%) | 2 (12.5%) |
|  | Thromboembolic complications | 2 (33.3%) | 4 (40.0%) | 6 (37.5%) |
|  | Puncture site complications | 1 (16.7%) | 2 (20.0%) | 3 (18.8%) |
|  | Other complications | 2 (33.3%) | 3 (30.0%) | 5 (31.3%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 4 (66.7%) | 5 (50.0%) | 9 (56.3%) |
|  | Patient symptomatic | 2 (33.3%) | 5 (50.0%) | 7 (43.8%) |
|  |  |  |  |  |
| **AE severity** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 3 (50.0%) | 5 (50.0%) | 8 (50.0%) |
|  | Moderate | 2 (33.3%) | 4 (40.0%) | 6 (37.5%) |
|  | Severe | 1 (16.7%) | 1 (10.0%) | 2 (12.5%) |
|  |  |  |  |  |
| **Causal relationship** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (16.7%) | 1 (10.0%) | 2 (12.5%) |
|  | Procedure related AE | 2 (33.3%) | 5 (50.0%) | 7 (43.8%) |
|  | Device and procedure related AE | 3 (50.0%) | 4 (40.0%) | 7 (43.8%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 1 | 5 |
|  | Missing data | 2 | 9 | 11 |
|  | checked | 4 (100.0%) | 1 (100.0%) | 5 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 1 | 5 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (25.0%) | 0 | 1 (20.0%) |
|  | Concurrent treatment | 1 (25.0%) | 0 | 1 (20.0%) |
|  | Other | 2 (50.0%) | 1 (100.0%) | 3 (60.0%) |
|  |  |  |  |  |
| **Serious AE** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 5 (83.3%) | 9 (90.0%) | 14 (87.5%) |
|  | Yes | 1 (16.7%) | 1 (10.0%) | 2 (12.5%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 1 | 1 | 2 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 1 (100.0%) | 0 | 1 (50.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (50.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 6 (100.0%) | 7 (70.0%) | 13 (81.3%) |
|  | Not resolved / ongoing | 0 | 3 (30.0%) | 3 (18.8%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 0.00 (0.00) | 0.40 (0.70) | 0.25 (0.58) |
|  | Median | 0.00 | 0.00 | 0.00 |
|  | Q1 - Q3 | 0.00 - 0.00 | 0.00 - 1.00 | 0.00 - 0.00 |
|  | Min - Max | 0.00 - 0.00 | 0.00 - 2.00 | 0.00 - 2.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 6 | 10 | 16 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 0.00 (0.00) | 0.01 (0.02) | 0.01 (0.02) |
|  | Median | 0.00 | 0.00 | 0.00 |
|  | Q1 - Q3 | 0.00 - 0.00 | 0.00 - 0.03 | 0.00 - 0.00 |
|  | Min - Max | 0.00 - 0.00 | 0.00 - 0.07 | 0.00 - 0.07 |

**FRITS**

**Complications**

**Table : Listing of other Per-procedural complications [ITT - N=5 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** |
| --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation |
| N = 5 | | | | | | |

| **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0 |
| Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0 |
| Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0 |
| Patient symptomatic | Mild | Device and procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0 |
| Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0 |
| N = 5 | | | | | | | | |

**FRITS**

**Complications**

**Table : Listing of all Per-procedural complications [ITT - N=16 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. |
| 06-001 | FRED / FRED Jr | FRED | Technical issues | ACCESS DEVICE RELATED VASOSPAM | VASOSPASM DISTAL CERVICAL ICA DURING PROCEDURE |
| 06-008 | FRED X | FRED X | Puncture site complications |  | SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN |
| 06-009 | FRED X | FRED X | Puncture site complications |  | PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING |
| 07-011 | FRED / FRED Jr | FRED | Puncture site complications |  | GROIN HEMATOMA |
| 07-014 | FRED / FRED Jr | FRED | Thromboembolic complications |  | VESSEL M3 OCCLUSION LEFT + SMALL BLEEDING VESTIBLE ON CT SCAN LEFT FRONTAL |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT | FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 16 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| K01 Arterial Spasm | Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Procedure related AE | Possible | Probable | . | No |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Procedure related AE | Possible | Probable | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Procedure related AE | Probable | Certain | . | No |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No |
| K01 Arterial Spasm | Patient asymptomatic | Moderate | Device and procedure related AE | Not related | Certain | . | No |
| K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Device and procedure related AE | Not related | Certain | . | No |
| K10 Other | Patient symptomatic | Mild | Device and procedure related AE | Not related | Certain | checked | No |
| K05 Access site pseudoaneurysm | Patient symptomatic | Mild | Device and procedure related AE | Not related | Certain | checked | No |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Procedure related AE | Possible | Certain | checked | No |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device and procedure related AE | Not related | Probable | . | No |
| A29 Visual impairment | Patient symptomatic | Severe | Procedure related AE | Certain | Certain | . | No |
| B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No |
| N01 Other | Patient asymptomatic | Mild | Procedure related AE | Certain | Certain | . | No |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Procedure related AE | Possible | Certain | . | Yes |
| N = 16 | | | | | | | |

| **Event outcome** | **Event onset delay (in months)** |
| --- | --- |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.065681 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Not resolved / ongoing | 0.032841 |
| Resolved without sequelae | 0.000000 |
| Not resolved / ongoing | 0.000000 |
| Not resolved / ongoing | 0.032841 |
| N = 16 | |

**FRITS**

**Complications**

**Table : Per-procedural complications [FAS - N=139 patients]**

|  | | **FRED / FRED Jr N=88** | **FRED X N=51** | **Total N=139** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **At least one Per-procedural complications** | N | 88 | 51 | 139 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 83 (94.3%) | 42 (82.4%) | 125 (89.9%) |
|  | Yes | 5 (5.7%) | 9 (17.6%) | 14 (10.1%) |

**FRITS**

**Complications**

**Table : Summary of Per-procedural complications [FAS - N=15 complications]**

|  | | **FRED / FRED Jr N=5** | **FRED X N=10** | **Total N=15** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 1 (20.0%) | 1 (10.0%) | 2 (13.3%) |
|  | Thromboembolic complications | 1 (20.0%) | 4 (40.0%) | 5 (33.3%) |
|  | Puncture site complications | 1 (20.0%) | 2 (20.0%) | 3 (20.0%) |
|  | Other complications | 2 (40.0%) | 3 (30.0%) | 5 (33.3%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 3 (60.0%) | 5 (50.0%) | 8 (53.3%) |
|  | Patient symptomatic | 2 (40.0%) | 5 (50.0%) | 7 (46.7%) |
|  |  |  |  |  |
| **AE severity** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 3 (60.0%) | 5 (50.0%) | 8 (53.3%) |
|  | Moderate | 2 (40.0%) | 4 (40.0%) | 6 (40.0%) |
|  | Severe | 0 | 1 (10.0%) | 1 (6.7%) |
|  |  |  |  |  |
| **Causal relationship** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (20.0%) | 1 (10.0%) | 2 (13.3%) |
|  | Procedure related AE | 1 (20.0%) | 5 (50.0%) | 6 (40.0%) |
|  | Device and procedure related AE | 3 (60.0%) | 4 (40.0%) | 7 (46.7%) |
|  |  |  |  |  |
| **Other relationship** | N | 3 | 1 | 4 |
|  | Missing data | 2 | 9 | 11 |
|  | checked | 3 (100.0%) | 1 (100.0%) | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (33.3%) | 0 | 1 (25.0%) |
|  | Concurrent treatment | 1 (33.3%) | 0 | 1 (25.0%) |
|  | Other | 1 (33.3%) | 1 (100.0%) | 2 (50.0%) |
|  |  |  |  |  |
| **Serious** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 4 (80.0%) | 9 (90.0%) | 13 (86.7%) |
|  | Yes | 1 (20.0%) | 1 (10.0%) | 2 (13.3%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 1 | 1 | 2 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 1 (100.0%) | 0 | 1 (50.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (50.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 5 (100.0%) | 7 (70.0%) | 12 (80.0%) |
|  | Not resolved / ongoing | 0 | 3 (30.0%) | 3 (20.0%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 0.00 (0.00) | 0.40 (0.70) | 0.27 (0.59) |
|  | Median | 0.00 | 0.00 | 0.00 |
|  | Q1 - Q3 | 0.00 - 0.00 | 0.00 - 1.00 | 0.00 - 0.00 |
|  | Min - Max | 0.00 - 0.00 | 0.00 - 2.00 | 0.00 - 2.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 5 | 10 | 15 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 0.00 (0.00) | 0.01 (0.02) | 0.01 (0.02) |
|  | Median | 0.00 | 0.00 | 0.00 |
|  | Q1 - Q3 | 0.00 - 0.00 | 0.00 - 0.03 | 0.00 - 0.00 |
|  | Min - Max | 0.00 - 0.00 | 0.00 - 0.07 | 0.00 - 0.07 |

**FRITS**

**Complications**

**Table : Listing of other Per-procedural complications [FAS - N=5 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** |
| --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation |
| N = 5 | | | | | | |

| **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0 |
| Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0 |
| Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0 |
| Patient symptomatic | Mild | Device and procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0 |
| Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0 |
| N = 5 | | | | | | | | |

**FRITS**

**Complications**

**Table : Listing of all Per-procedural complications [FAS - N=15 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. |
| 06-001 | FRED / FRED Jr | FRED | Technical issues | ACCESS DEVICE RELATED VASOSPAM | VASOSPASM DISTAL CERVICAL ICA DURING PROCEDURE |
| 06-008 | FRED X | FRED X | Puncture site complications |  | SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN |
| 06-009 | FRED X | FRED X | Puncture site complications |  | PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING |
| 07-011 | FRED / FRED Jr | FRED | Puncture site complications |  | GROIN HEMATOMA |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT | FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 15 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| K01 Arterial Spasm | Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Procedure related AE | Possible | Probable | . | No |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Procedure related AE | Possible | Probable | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Procedure related AE | Probable | Certain | . | No |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No |
| K01 Arterial Spasm | Patient asymptomatic | Moderate | Device and procedure related AE | Not related | Certain | . | No |
| K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Device and procedure related AE | Not related | Certain | . | No |
| K10 Other | Patient symptomatic | Mild | Device and procedure related AE | Not related | Certain | checked | No |
| K05 Access site pseudoaneurysm | Patient symptomatic | Mild | Device and procedure related AE | Not related | Certain | checked | No |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device and procedure related AE | Not related | Probable | . | No |
| A29 Visual impairment | Patient symptomatic | Severe | Procedure related AE | Certain | Certain | . | No |
| B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Device and procedure related AE | Not related | Certain | . | No |
| N01 Other | Patient asymptomatic | Mild | Procedure related AE | Certain | Certain | . | No |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Procedure related AE | Possible | Certain | . | Yes |
| N = 15 | | | | | | | |

| **Event outcome** | **Event onset delay (in months)** |
| --- | --- |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.065681 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Resolved without sequelae | 0.000000 |
| Not resolved / ongoing | 0.032841 |
| Resolved without sequelae | 0.000000 |
| Not resolved / ongoing | 0.000000 |
| Not resolved / ongoing | 0.032841 |
| N = 15 | |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of post-procedural complications)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 84 58.74 92.31 63.64 | 7 4.90 7.69 63.64 | 91 63.64 |
| **FRED X** | 48 33.57 92.31 36.36 | 4 2.80 7.69 36.36 | 52 36.36 |
| **Total** | 132 92.31 | 11 7.69 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0000 | 1.0000 |
| **Test du rapport de vraisemblance** | 1 | 0.0000 | 1.0000 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0000 | 1.0000 |
| **Coefficient Phi** |  | 0.0000 |  |
| **Coefficient de contingence** |  | 0.0000 |  |
| **V de Cramer** |  | 0.0000 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 84 |
| **Pr <= F unilatérale à gauche** | 0.6358 |
| **Pr >= F unilatérale à droite** | 0.6179 |
|  |  |
| **Probabilité de la table (P)** | 0.2538 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPOTH** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPOTH(Occurrence of Other complication)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 86 60.14 94.51 64.18 | 5 3.50 5.49 55.56 | 91 63.64 |
| **FRED X** | 48 33.57 92.31 35.82 | 4 2.80 7.69 44.44 | 52 36.36 |
| **Total** | 134 93.71 | 9 6.29 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPOTH*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2710 | 0.6026 |
| **Test du rapport de vraisemblance** | 1 | 0.2644 | 0.6071 |
| **Khi-2 continuité ajustée** | 1 | 0.0265 | 0.8708 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2691 | 0.6039 |
| **Coefficient Phi** |  | 0.0435 |  |
| **Coefficient de contingence** |  | 0.0435 |  |
| **V de Cramer** |  | 0.0435 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 86 |
| **Pr <= F unilatérale à gauche** | 0.8116 |
| **Pr >= F unilatérale à droite** | 0.4246 |
|  |  |
| **Probabilité de la table (P)** | 0.2362 |
| **Pr <= P bilatéral** | 0.7236 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPSER** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPSER(Occurrence of serious adverse events)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 88 61.54 96.70 63.31 | 3 2.10 3.30 75.00 | 91 63.64 |
| **FRED X** | 51 35.66 98.08 36.69 | 1 0.70 1.92 25.00 | 52 36.36 |
| **Total** | 139 97.20 | 4 2.80 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPSER*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2296 | 0.6318 |
| **Test du rapport de vraisemblance** | 1 | 0.2428 | 0.6222 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2280 | 0.6330 |
| **Coefficient Phi** |  | -0.0401 |  |
| **Coefficient de contingence** |  | 0.0400 |  |
| **V de Cramer** |  | -0.0401 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 88 |
| **Pr <= F unilatérale à gauche** | 0.5383 |
| **Pr >= F unilatérale à droite** | 0.8400 |
|  |  |
| **Probabilité de la table (P)** | 0.3782 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPDEV** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPDEV(Occurrence of device-related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 90 62.94 98.90 63.83 | 1 0.70 1.10 50.00 | 91 63.64 |
| **FRED X** | 51 35.66 98.08 36.17 | 1 0.70 1.92 50.00 | 52 36.36 |
| **Total** | 141 98.60 | 2 1.40 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPDEV*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1630 | 0.6864 |
| **Test du rapport de vraisemblance** | 1 | 0.1569 | 0.6921 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1619 | 0.6875 |
| **Coefficient Phi** |  | 0.0338 |  |
| **Coefficient de contingence** |  | 0.0337 |  |
| **V de Cramer** |  | 0.0338 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 90 |
| **Pr <= F unilatérale à gauche** | 0.8694 |
| **Pr >= F unilatérale à droite** | 0.5967 |
|  |  |
| **Probabilité de la table (P)** | 0.4661 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPPRO** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPPRO(Occurrence of procedure related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 91 63.64 100.00 64.08 | 0 0.00 0.00 0.00 | 91 63.64 |
| **FRED X** | 51 35.66 98.08 35.92 | 1 0.70 1.92 100.00 | 52 36.36 |
| **Total** | 142 99.30 | 1 0.70 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPPRO*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.7623 | 0.1843 |
| **Test du rapport de vraisemblance** | 1 | 2.0355 | 0.1537 |
| **Khi-2 continuité ajustée** | 1 | 0.0809 | 0.7761 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7500 | 0.1859 |
| **Coefficient Phi** |  | 0.1110 |  |
| **Coefficient de contingence** |  | 0.1103 |  |
| **V de Cramer** |  | 0.1110 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 91 |
| **Pr <= F unilatérale à gauche** | 1.0000 |
| **Pr >= F unilatérale à droite** | 0.3636 |
|  |  |
| **Probabilité de la table (P)** | 0.3636 |
| **Pr <= P bilatéral** | 0.3636 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of post-procedural complications** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 84 (92.3%) | 48 (92.3%) | 132 (92.3%) |
|  | Yes | 7 (7.7%) | 4 (7.7%) | 11 (7.7%) |
|  | 95% CI | 2.2% - 13.2% | 0.4% - 14.9% | 3.3% - 12.1% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of Thromboembolic complication** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 89 (97.8%) | 52 (100.0%) | 141 (98.6%) |
|  | Yes | 2 (2.2%) |  | 2 (1.4%) |
|  |  |  |  |  |
| **Occurrence of Delayed intracranial hematoma** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 91 (100.0%) | 52 (100.0%) | 143 (100.0%) |
|  |  |  |  |  |
| **Occurrence of Other complication** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 86 (94.5%) | 48 (92.3%) | 134 (93.7%) |
|  | Yes | 5 (5.5%) | 4 (7.7%) | 9 (6.3%) |
|  | 95% CI | 0.8% - 10.2% | 0.4% - 14.9% | 2.3% - 10.3% |
|  | Between group test |  |  | 0.724 (Fisher) |
|  |  |  |  |  |
| **Occurrence of serious adverse events** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 88 (96.7%) | 51 (98.1%) | 139 (97.2%) |
|  | Yes | 3 (3.3%) | 1 (1.9%) | 4 (2.8%) |
|  | 95% CI | 0.0% - 7.0% | 0.0% - 5.7% | 0.1% - 5.5% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device-related AEs only** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 90 (98.9%) | 51 (98.1%) | 141 (98.6%) |
|  | Yes | 1 (1.1%) | 1 (1.9%) | 2 (1.4%) |
|  | 95% CI | 0.0% - 3.2% | 0.0% - 5.7% | 0% - 3.3% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of procedure related AEs only** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 91 (100.0%) | 51 (98.1%) | 142 (99.3%) |
|  | Yes | 0 | 1 (1.9%) | 1 (0.7%) |
|  | Between group test |  |  | 0.364 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device and procedure related AEs** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 89 (97.8%) | 52 (100.0%) | 141 (98.6%) |
|  | Yes | 2 (2.2%) |  | 2 (1.4%) |

**FRITS**

**Complications**

**Table : Summary of post-procedural complications between 6-month and 12-month (CEC) [ITT - N=11 complications]**

|  | | **FRED / FRED Jr N=7** | **FRED X N=4** | **Total N=11** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Thromboembolic complications | 2 (28.6%) | 0 | 2 (18.2%) |
|  | Other complications | 5 (71.4%) | 4 (100.0%) | 9 (81.8%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 2 (28.6%) | 1 (25.0%) | 3 (27.3%) |
|  | Patient symptomatic | 5 (71.4%) | 3 (75.0%) | 8 (72.7%) |
|  |  |  |  |  |
| **AE severity** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 4 (57.1%) | 2 (50.0%) | 6 (54.5%) |
|  | Moderate | 2 (28.6%) | 1 (25.0%) | 3 (27.3%) |
|  | Severe | 1 (14.3%) | 1 (25.0%) | 2 (18.2%) |
|  |  |  |  |  |
| **Causal relationship** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (14.3%) | 1 (25.0%) | 2 (18.2%) |
|  | Procedure related AE | 0 | 1 (25.0%) | 1 (9.1%) |
|  | Device and procedure related AE | 2 (28.6%) | 0 | 2 (18.2%) |
|  | Oher | 4 (57.1%) | 2 (50.0%) | 6 (54.5%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 3 | 4 | 7 |
|  | checked | 4 (100.0%) | 0 | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Concurrent condition | 1 (25.0%) |  | 1 (25.0%) |
|  | Other | 3 (75.0%) |  | 3 (75.0%) |
|  |  |  |  |  |
| **Serious AE** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 4 (57.1%) | 3 (75.0%) | 7 (63.6%) |
|  | Yes | 3 (42.9%) | 1 (25.0%) | 4 (36.4%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 3 (100.0%) | 0 | 3 (75.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (25.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 4 (57.1%) | 2 (50.0%) | 6 (54.5%) |
|  | Not resolved / ongoing | 3 (42.9%) | 2 (50.0%) | 5 (45.5%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 227.14 (109.99) | 283.75 (138.26) | 247.73 (117.51) |
|  | Median | 193.00 | 308.50 | 250.00 |
|  | Q1 - Q3 | 121.00 - 309.00 | 177.00 - 390.50 | 121.00 - 367.00 |
|  | Min - Max | 105.00 - 408.00 | 104.00 - 414.00 | 104.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 7 | 4 | 11 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 7.46 (3.61) | 9.33 (4.54) | 8.14 (3.86) |
|  | Median | 6.34 | 10.14 | 8.22 |
|  | Q1 - Q3 | 3.98 - 10.14 | 5.82 - 12.83 | 3.98 - 12.06 |
|  | Min - Max | 3.44 - 13.40 | 3.42 - 13.60 | 3.42 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 9 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 9 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 13.40 |
| 8.22 |
| 13.60 |
| 3.44 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 9 |

**FRITS**

**Complications**

**Table : Listing of all post-procedural complications between 6-month and 12-month (CEC) [ITT - N=11 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 11 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 11 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 10.14 |
| 13.40 |
| 3.98 |
| 8.22 |
| 13.60 |
| 3.44 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 11 |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) [ITT - N=11 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| N = 2 | | | | | | | |

| **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| N = 2 | | | | | | | |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of post-procedural complications)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 76 58.46 92.68 63.33 | 6 4.62 7.32 60.00 | 82 63.08 |
| **FRED X** | 44 33.85 91.67 36.67 | 4 3.08 8.33 40.00 | 48 36.92 |
| **Total** | 120 92.31 | 10 7.69 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0440 | 0.8338 |
| **Test du rapport de vraisemblance** | 1 | 0.0436 | 0.8346 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0437 | 0.8344 |
| **Coefficient Phi** |  | 0.0184 |  |
| **Coefficient de contingence** |  | 0.0184 |  |
| **V de Cramer** |  | 0.0184 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 76 |
| **Pr <= F unilatérale à gauche** | 0.7143 |
| **Pr >= F unilatérale à droite** | 0.5414 |
|  |  |
| **Probabilité de la table (P)** | 0.2558 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPOTH** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPOTH(Occurrence of Other complication)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 78 60.00 95.12 63.93 | 4 3.08 4.88 50.00 | 82 63.08 |
| **FRED X** | 44 33.85 91.67 36.07 | 4 3.08 8.33 50.00 | 48 36.92 |
| **Total** | 122 93.85 | 8 6.15 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPOTH*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6259 | 0.4289 |
| **Test du rapport de vraisemblance** | 1 | 0.6055 | 0.4365 |
| **Khi-2 continuité ajustée** | 1 | 0.1706 | 0.6796 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6211 | 0.4306 |
| **Coefficient Phi** |  | 0.0694 |  |
| **Coefficient de contingence** |  | 0.0692 |  |
| **V de Cramer** |  | 0.0694 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 78 |
| **Pr <= F unilatérale à gauche** | 0.8776 |
| **Pr >= F unilatérale à droite** | 0.3319 |
|  |  |
| **Probabilité de la table (P)** | 0.2095 |
| **Pr <= P bilatéral** | 0.4662 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPSER** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPSER(Occurrence of serious adverse events)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 79 60.77 96.34 62.70 | 3 2.31 3.66 75.00 | 82 63.08 |
| **FRED X** | 47 36.15 97.92 37.30 | 1 0.77 2.08 25.00 | 48 36.92 |
| **Total** | 126 96.92 | 4 3.08 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPSER*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2519 | 0.6157 |
| **Test du rapport de vraisemblance** | 1 | 0.2666 | 0.6056 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2500 | 0.6171 |
| **Coefficient Phi** |  | -0.0440 |  |
| **Coefficient de contingence** |  | 0.0440 |  |
| **V de Cramer** |  | -0.0440 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 79 |
| **Pr <= F unilatérale à gauche** | 0.5282 |
| **Pr >= F unilatérale à droite** | 0.8460 |
|  |  |
| **Probabilité de la table (P)** | 0.3742 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPDEV** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPDEV(Occurrence of device-related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 81 62.31 98.78 63.28 | 1 0.77 1.22 50.00 | 82 63.08 |
| **FRED X** | 47 36.15 97.92 36.72 | 1 0.77 2.08 50.00 | 48 36.92 |
| **Total** | 128 98.46 | 2 1.54 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPDEV*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1491 | 0.6994 |
| **Test du rapport de vraisemblance** | 1 | 0.1440 | 0.7043 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1480 | 0.7005 |
| **Coefficient Phi** |  | 0.0339 |  |
| **Coefficient de contingence** |  | 0.0339 |  |
| **V de Cramer** |  | 0.0339 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 81 |
| **Pr <= F unilatérale à gauche** | 0.8655 |
| **Pr >= F unilatérale à droite** | 0.6039 |
|  |  |
| **Probabilité de la table (P)** | 0.4694 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPPRO** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPPRO(Occurrence of procedure related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 82 63.08 100.00 63.57 | 0 0.00 0.00 0.00 | 82 63.08 |
| **FRED X** | 47 36.15 97.92 36.43 | 1 0.77 2.08 100.00 | 48 36.92 |
| **Total** | 129 99.23 | 1 0.77 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPPRO*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.7216 | 0.1895 |
| **Test du rapport de vraisemblance** | 1 | 2.0059 | 0.1567 |
| **Khi-2 continuité ajustée** | 1 | 0.0740 | 0.7856 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7083 | 0.1912 |
| **Coefficient Phi** |  | 0.1151 |  |
| **Coefficient de contingence** |  | 0.1143 |  |
| **V de Cramer** |  | 0.1151 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 82 |
| **Pr <= F unilatérale à gauche** | 1.0000 |
| **Pr >= F unilatérale à droite** | 0.3692 |
|  |  |
| **Probabilité de la table (P)** | 0.3692 |
| **Pr <= P bilatéral** | 0.3692 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of post-procedural complications** | N | 82 | 48 | 130 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 76 (92.7%) | 44 (91.7%) | 120 (92.3%) |
|  | Yes | 6 (7.3%) | 4 (8.3%) | 10 (7.7%) |
|  | 95% CI | 1.7% - 13.0% | 0.5% - 16.2% | 3.1% - 12.3% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of Thromboembolic complication** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 80 (97.6%) | 48 (100.0%) | 128 (98.5%) |
|  | Yes | 2 (2.4%) |  | 2 (1.5%) |
|  |  |  |  |  |
| **Occurrence of Delayed intracranial hematoma** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 82 (100.0%) | 48 (100.0%) | 130 (100.0%) |
|  |  |  |  |  |
| **Occurrence of Other complication** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (95.1%) | 44 (91.7%) | 122 (93.8%) |
|  | Yes | 4 (4.9%) | 4 (8.3%) | 8 (6.2%) |
|  | 95% CI | 0.2% - 9.5% | 0.5% - 16.2% | 2% - 10.3% |
|  | Between group test |  |  | 0.466 (Fisher) |
|  |  |  |  |  |
| **Occurrence of serious adverse events** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (96.3%) | 47 (97.9%) | 126 (96.9%) |
|  | Yes | 3 (3.7%) | 1 (2.1%) | 4 (3.1%) |
|  | 95% CI | 0.0% - 7.7% | 0.0% - 6.1% | 0.1% - 6% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device-related AEs only** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 81 (98.8%) | 47 (97.9%) | 128 (98.5%) |
|  | Yes | 1 (1.2%) | 1 (2.1%) | 2 (1.5%) |
|  | 95% CI | 0.0% - 3.6% | 0.0% - 6.1% | 0% - 3.7% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of procedure related AEs only** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 82 (100.0%) | 47 (97.9%) | 129 (99.2%) |
|  | Yes | 0 | 1 (2.1%) | 1 (0.8%) |
|  | Between group test |  |  | 0.369 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device and procedure related AEs** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 81 (98.8%) | 48 (100.0%) | 129 (99.2%) |
|  | Yes | 1 (1.2%) |  | 1 (0.8%) |

**FRITS**

**Complications**

**Table : Summary of post-procedural complications between 6-month and 12-month (CEC) [FAS - N=10 complications]**

|  | | **FRED / FRED Jr N=6** | **FRED X N=4** | **Total N=10** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Thromboembolic complications | 2 (33.3%) | 0 | 2 (20.0%) |
|  | Other complications | 4 (66.7%) | 4 (100.0%) | 8 (80.0%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Patient symptomatic | 4 (66.7%) | 3 (75.0%) | 7 (70.0%) |
|  |  |  |  |  |
| **AE severity** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Moderate | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Severe | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  |  |  |  |  |
| **Causal relationship** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  | Procedure related AE | 0 | 1 (25.0%) | 1 (10.0%) |
|  | Device and procedure related AE | 1 (16.7%) | 0 | 1 (10.0%) |
|  | Oher | 4 (66.7%) | 2 (50.0%) | 6 (60.0%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 2 | 4 | 6 |
|  | checked | 4 (100.0%) | 0 | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Concurrent condition | 1 (25.0%) |  | 1 (25.0%) |
|  | Other | 3 (75.0%) |  | 3 (75.0%) |
|  |  |  |  |  |
| **Serious** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 3 (50.0%) | 3 (75.0%) | 6 (60.0%) |
|  | Yes | 3 (50.0%) | 1 (25.0%) | 4 (40.0%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 3 (100.0%) | 0 | 3 (75.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (25.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Not resolved / ongoing | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 247.50 (105.06) | 283.75 (138.26) | 262.00 (113.38) |
|  | Median | 237.00 | 308.50 | 265.50 |
|  | Q1 - Q3 | 173.00 - 309.00 | 177.00 - 390.50 | 173.00 - 367.00 |
|  | Min - Max | 121.00 - 408.00 | 104.00 - 414.00 | 104.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 8.13 (3.45) | 9.33 (4.54) | 8.61 (3.72) |
|  | Median | 7.78 | 10.14 | 8.72 |
|  | Q1 - Q3 | 5.68 - 10.14 | 5.82 - 12.83 | 5.68 - 12.06 |
|  | Min - Max | 3.98 - 13.40 | 3.42 - 13.60 | 3.42 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other post-procedural complications between 6-month and 12-month (CEC) [FAS - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 8 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 8 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 13.40 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 8 |

**FRITS**

**Complications**

**Table : Listing of all post-procedural complications between 6-month and 12-month (CEC) [FAS - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 10 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 10 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 10.14 |
| 13.40 |
| 3.98 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 10 |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) [FAS - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| N = 2 | | | | | | | |

| **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| N = 2 | | | | | | | |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of post-procedural complications)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 73 58.87 92.41 64.04 | 6 4.84 7.59 60.00 | 79 63.71 |
| **FRED X** | 41 33.06 91.11 35.96 | 4 3.23 8.89 40.00 | 45 36.29 |
| **Total** | 114 91.94 | 10 8.06 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.0647 | 0.7992 |
| **Test du rapport de vraisemblance** | 1 | 0.0640 | 0.8004 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.0642 | 0.7999 |
| **Coefficient Phi** |  | 0.0228 |  |
| **Coefficient de contingence** |  | 0.0228 |  |
| **V de Cramer** |  | 0.0228 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 73 |
| **Pr <= F unilatérale à gauche** | 0.7297 |
| **Pr >= F unilatérale à droite** | 0.5241 |
|  |  |
| **Probabilité de la table (P)** | 0.2538 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPOTH** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPOTH(Occurrence of Other complication)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 75 60.48 94.94 64.66 | 4 3.23 5.06 50.00 | 79 63.71 |
| **FRED X** | 41 33.06 91.11 35.34 | 4 3.23 8.89 50.00 | 45 36.29 |
| **Total** | 116 93.55 | 8 6.45 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPOTH*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.6952 | 0.4044 |
| **Test du rapport de vraisemblance** | 1 | 0.6703 | 0.4130 |
| **Khi-2 continuité ajustée** | 1 | 0.2058 | 0.6501 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.6896 | 0.4063 |
| **Coefficient Phi** |  | 0.0749 |  |
| **Coefficient de contingence** |  | 0.0747 |  |
| **V de Cramer** |  | 0.0749 |  |
| **WARNING: 25% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 75 |
| **Pr <= F unilatérale à gauche** | 0.8860 |
| **Pr >= F unilatérale à droite** | 0.3174 |
|  |  |
| **Probabilité de la table (P)** | 0.2033 |
| **Pr <= P bilatéral** | 0.4595 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPSER** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPSER(Occurrence of serious adverse events)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 76 61.29 96.20 63.33 | 3 2.42 3.80 75.00 | 79 63.71 |
| **FRED X** | 44 35.48 97.78 36.67 | 1 0.81 2.22 25.00 | 45 36.29 |
| **Total** | 120 96.77 | 4 3.23 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPSER*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.2279 | 0.6331 |
| **Test du rapport de vraisemblance** | 1 | 0.2409 | 0.6236 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.2260 | 0.6345 |
| **Coefficient Phi** |  | -0.0429 |  |
| **Coefficient de contingence** |  | 0.0428 |  |
| **V de Cramer** |  | -0.0429 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 76 |
| **Pr <= F unilatérale à gauche** | 0.5395 |
| **Pr >= F unilatérale à droite** | 0.8398 |
|  |  |
| **Probabilité de la table (P)** | 0.3793 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPDEV** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPDEV(Occurrence of device-related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 78 62.90 98.73 63.93 | 1 0.81 1.27 50.00 | 79 63.71 |
| **FRED X** | 44 35.48 97.78 36.07 | 1 0.81 2.22 50.00 | 45 36.29 |
| **Total** | 122 98.39 | 2 1.61 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPDEV*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 0.1653 | 0.6844 |
| **Test du rapport de vraisemblance** | 1 | 0.1590 | 0.6901 |
| **Khi-2 continuité ajustée** | 1 | 0.0000 | 1.0000 |
| **Khi-2 de Mantel-Haenszel** | 1 | 0.1639 | 0.6856 |
| **Coefficient Phi** |  | 0.0365 |  |
| **Coefficient de contingence** |  | 0.0365 |  |
| **V de Cramer** |  | 0.0365 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 78 |
| **Pr <= F unilatérale à gauche** | 0.8702 |
| **Pr >= F unilatérale à droite** | 0.5960 |
|  |  |
| **Probabilité de la table (P)** | 0.4662 |
| **Pr <= P bilatéral** | 1.0000 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMPPRO** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMPPRO(Occurrence of procedure related AEs only)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 79 63.71 100.00 64.23 | 0 0.00 0.00 0.00 | 79 63.71 |
| **FRED X** | 44 35.48 97.78 35.77 | 1 0.81 2.22 100.00 | 45 36.29 |
| **Total** | 123 99.19 | 1 0.81 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMPPRO*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.7698 | 0.1834 |
| **Test du rapport de vraisemblance** | 1 | 2.0415 | 0.1531 |
| **Khi-2 continuité ajustée** | 1 | 0.0820 | 0.7747 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7556 | 0.1852 |
| **Coefficient Phi** |  | 0.1195 |  |
| **Coefficient de contingence** |  | 0.1186 |  |
| **V de Cramer** |  | 0.1195 |  |
| **WARNING: 50% des cellules ont un effectif théorique inférieur à 5. Le test du Khi-2 peut ne pas convenir.** | | | |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 79 |
| **Pr <= F unilatérale à gauche** | 1.0000 |
| **Pr >= F unilatérale à droite** | 0.3629 |
|  |  |
| **Probabilité de la table (P)** | 0.3629 |
| **Pr <= P bilatéral** | 0.3629 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Post-procedural complications between 6-month and 12-month (CEC) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of post-procedural complications** | N | 79 | 45 | 124 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 73 (92.4%) | 41 (91.1%) | 114 (91.9%) |
|  | Yes | 6 (7.6%) | 4 (8.9%) | 10 (8.1%) |
|  | 95% CI | 1.8% - 13.4% | 0.6% - 17.2% | 3.3% - 12.9% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of Thromboembolic complication** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 77 (97.5%) | 45 (100.0%) | 122 (98.4%) |
|  | Yes | 2 (2.5%) |  | 2 (1.6%) |
|  |  |  |  |  |
| **Occurrence of Delayed intracranial hematoma** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (100.0%) | 45 (100.0%) | 124 (100.0%) |
|  |  |  |  |  |
| **Occurrence of Other complication** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 75 (94.9%) | 41 (91.1%) | 116 (93.5%) |
|  | Yes | 4 (5.1%) | 4 (8.9%) | 8 (6.5%) |
|  | 95% CI | 0.2% - 9.9% | 0.6% - 17.2% | 2.1% - 10.8% |
|  | Between group test |  |  | 0.460 (Fisher) |
|  |  |  |  |  |
| **Occurrence of serious adverse events** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 76 (96.2%) | 44 (97.8%) | 120 (96.8%) |
|  | Yes | 3 (3.8%) | 1 (2.2%) | 4 (3.2%) |
|  | 95% CI | 0.0% - 8.0% | 0.0% - 6.5% | 0.1% - 6.3% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device-related AEs only** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (98.7%) | 44 (97.8%) | 122 (98.4%) |
|  | Yes | 1 (1.3%) | 1 (2.2%) | 2 (1.6%) |
|  | 95% CI | 0.0% - 3.7% | 0.0% - 6.5% | 0% - 3.8% |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Occurrence of procedure related AEs only** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 79 (100.0%) | 44 (97.8%) | 123 (99.2%) |
|  | Yes | 0 | 1 (2.2%) | 1 (0.8%) |
|  | Between group test |  |  | 0.363 (Fisher) |
|  |  |  |  |  |
| **Occurrence of device and procedure related AEs** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (98.7%) | 45 (100.0%) | 123 (99.2%) |
|  | Yes | 1 (1.3%) |  | 1 (0.8%) |

**FRITS**

**Complications**

**Table : Summary of post-procedural complications between 6-month and 12-month (CEC) [PP - N=10 complications]**

|  | | **FRED / FRED Jr N=6** | **FRED X N=4** | **Total N=10** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Thromboembolic complications | 2 (33.3%) | 0 | 2 (20.0%) |
|  | Other complications | 4 (66.7%) | 4 (100.0%) | 8 (80.0%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Patient symptomatic | 4 (66.7%) | 3 (75.0%) | 7 (70.0%) |
|  |  |  |  |  |
| **AE severity** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Moderate | 2 (33.3%) | 1 (25.0%) | 3 (30.0%) |
|  | Severe | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  |  |  |  |  |
| **Causal relationship** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 1 (16.7%) | 1 (25.0%) | 2 (20.0%) |
|  | Procedure related AE | 0 | 1 (25.0%) | 1 (10.0%) |
|  | Device and procedure related AE | 1 (16.7%) | 0 | 1 (10.0%) |
|  | Oher | 4 (66.7%) | 2 (50.0%) | 6 (60.0%) |
|  |  |  |  |  |
| **Other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 2 | 4 | 6 |
|  | checked | 4 (100.0%) | 0 | 4 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 4 | 0 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Concurrent condition | 1 (25.0%) |  | 1 (25.0%) |
|  | Other | 3 (75.0%) |  | 3 (75.0%) |
|  |  |  |  |  |
| **Serious** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 3 (50.0%) | 3 (75.0%) | 6 (60.0%) |
|  | Yes | 3 (50.0%) | 1 (25.0%) | 4 (40.0%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 3 | 1 | 4 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 3 (100.0%) | 0 | 3 (75.0%) |
|  | Permanent damage / Disability | 0 | 1 (100.0%) | 1 (25.0%) |
|  |  |  |  |  |
| **Event outcome** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  | Not resolved / ongoing | 3 (50.0%) | 2 (50.0%) | 5 (50.0%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 247.50 (105.06) | 283.75 (138.26) | 262.00 (113.38) |
|  | Median | 237.00 | 308.50 | 265.50 |
|  | Q1 - Q3 | 173.00 - 309.00 | 177.00 - 390.50 | 173.00 - 367.00 |
|  | Min - Max | 121.00 - 408.00 | 104.00 - 414.00 | 104.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 6 | 4 | 10 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 8.13 (3.45) | 9.33 (4.54) | 8.61 (3.72) |
|  | Median | 7.78 | 10.14 | 8.72 |
|  | Q1 - Q3 | 5.68 - 10.14 | 5.82 - 12.83 | 5.68 - 12.06 |
|  | Min - Max | 3.98 - 13.40 | 3.42 - 13.60 | 3.42 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other post-procedural complications between 6-month and 12-month (CEC) [PP - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 8 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 8 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 13.40 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 8 |

**FRITS**

**Complications**

**Table : Listing of all post-procedural complications between 6-month and 12-month (CEC) [PP - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| N = 10 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |
| N = 10 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 9.22 |
| 6.34 |
| 10.14 |
| 13.40 |
| 3.98 |
| 8.22 |
| 13.60 |
| 5.68 |
| 12.06 |
| 3.42 |
| N = 10 |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) [PP - N=10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic |
| N = 2 | | | | | | | |

| **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| N = 2 | | | | | | | |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 156 patients [ITT at procedure - N=156 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 156 patients [ITT at procedure - N=156 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of all complications until 12-month)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 73 46.79 72.28 68.22 | 28 17.95 27.72 57.14 | 101 64.74 |
| **FRED X** | 34 21.79 61.82 31.78 | 21 13.46 38.18 42.86 | 55 35.26 |
| **Total** | 107 68.59 | 49 31.41 | 156 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.8081 | 0.1787 |
| **Test du rapport de vraisemblance** | 1 | 1.7833 | 0.1817 |
| **Khi-2 continuité ajustée** | 1 | 1.3552 | 0.2444 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.7965 | 0.1801 |
| **Coefficient Phi** |  | 0.1077 |  |
| **Coefficient de contingence** |  | 0.1070 |  |
| **V de Cramer** |  | 0.1077 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 73 |
| **Pr <= F unilatérale à gauche** | 0.9356 |
| **Pr >= F unilatérale à droite** | 0.1226 |
|  |  |
| **Probabilité de la table (P)** | 0.0581 |
| **Pr <= P bilatéral** | 0.2079 |

|  |
| --- |
| ***Taille de l'échantillon = 156*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 156 patients [ITT at procedure - N=156 patients]**

|  | | **FRED / FRED Jr N=101** | **FRED X N=55** | **Total N=156** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 101 |  | 101 |
|  | Missing data | 0 |  | 0 |
|  | No | 73 (72.3%) | 34 (61.8%) | 107 (68.6%) |
|  | Yes | 28 (27.7%) | 21 (38.2%) | 49 (31.4%) |
|  | 95% CI | 19.0% - 36.5% | 25.3% - 51.0% | 24.1% - 38.7% |
|  | Between group test |  |  | 0.179 (Chi-2) |

**FRITS**

**Complications**

**Table : Summary of all complications until 12-month follow-up (CEC) from 156 patients [ITT at procedure - N=70 complications]**

|  | | **FRED / FRED Jr N=39** | **FRED X N=31** | **Total N=70** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 39 | 31 | 70 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 1 (2.6%) | 1 (3.2%) | 2 (2.9%) |
|  | Thromboembolic complications | 11 (28.2%) | 8 (25.8%) | 19 (27.1%) |
|  | Puncture site complications | 1 (2.6%) | 2 (6.5%) | 3 (4.3%) |
|  | Delayed IC hematoma | 1 (2.6%) | 0 | 1 (1.4%) |
|  | Other complications | 25 (64.1%) | 20 (64.5%) | 45 (64.3%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 39 | 31 | 70 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 11 (28.2%) | 6 (19.4%) | 17 (24.3%) |
|  | Patient symptomatic | 28 (71.8%) | 25 (80.6%) | 53 (75.7%) |
|  |  |  |  |  |
| **AE severity** | N | 39 | 31 | 70 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 19 (48.7%) | 13 (41.9%) | 32 (45.7%) |
|  | Moderate | 11 (28.2%) | 14 (45.2%) | 25 (35.7%) |
|  | Severe | 9 (23.1%) | 4 (12.9%) | 13 (18.6%) |
|  |  |  |  |  |
| **Causal relationship** | N | 39 | 31 | 70 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 6 (15.4%) | 6 (19.4%) | 12 (17.1%) |
|  | Procedure related AE | 12 (30.8%) | 12 (38.7%) | 24 (34.3%) |
|  | Device and procedure related AE | 9 (23.1%) | 9 (29.0%) | 18 (25.7%) |
|  | Oher | 12 (30.8%) | 4 (12.9%) | 16 (22.9%) |
|  |  |  |  |  |
| **Other relationship** | N | 23 | 5 | 28 |
|  | Missing data | 16 | 26 | 42 |
|  | checked | 23 (100.0%) | 5 (100.0%) | 28 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 23 | 5 | 28 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (4.3%) | 0 | 1 (3.6%) |
|  | Concurrent condition | 4 (17.4%) | 2 (40.0%) | 6 (21.4%) |
|  | Concurrent treatment | 7 (30.4%) | 1 (20.0%) | 8 (28.6%) |
|  | Other | 11 (47.8%) | 2 (40.0%) | 13 (46.4%) |
|  |  |  |  |  |
| **Serious AE** | N | 39 | 31 | 70 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 27 (69.2%) | 24 (77.4%) | 51 (72.9%) |
|  | Yes | 12 (30.8%) | 7 (22.6%) | 19 (27.1%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 12 | 7 | 19 |
|  | Missing data | 0 | 0 | 0 |
|  | Life-threatening illness or injury | 1 (8.3%) | 0 | 1 (5.3%) |
|  | Hospitalization (initial or prolonged) | 9 (75.0%) | 4 (57.1%) | 13 (68.4%) |
|  | Permanent damage / Disability | 2 (16.7%) | 3 (42.9%) | 5 (26.3%) |
|  |  |  |  |  |
| **Event outcome** | N | 39 | 31 | 70 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 31 (79.5%) | 21 (67.7%) | 52 (74.3%) |
|  | Not resolved / ongoing | 8 (20.5%) | 9 (29.0%) | 17 (24.3%) |
|  | Unknown | 0 | 1 (3.2%) | 1 (1.4%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 38 | 31 | 69 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 76.11 (106.90) | 53.94 (111.57) | 66.14 (108.78) |
|  | Median | 14.00 | 2.00 | 4.00 |
|  | Q1 - Q3 | 1.00 - 121.00 | 1.00 - 48.00 | 1.00 - 92.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 38 | 31 | 69 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 2.50 (3.51) | 1.77 (3.67) | 2.17 (3.57) |
|  | Median | 0.46 | 0.06 | 0.14 |
|  | Q1 - Q3 | 0.04 - 3.98 | 0.04 - 1.58 | 0.04 - 3.02 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other complications until 12-month (CEC) from 156 patients [ITT at procedure - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE |
| 07-014 | FRED / FRED Jr | FRED | Other complications | FEVER |
| 07-014 | FRED / FRED Jr | FRED | Other complications | GASTROINTESTINAL BLEEDING |
| 07-014 | FRED / FRED Jr | FRED | Other complications | TRACHEOBRONCHITIS |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| N = 45 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| ANAMNESTIC PTSD, MILD SYMPTOMS PRIOR TO ENDOVASCULAR TREATMENT, WORSENING OF SYMPTOMS OVER THE TIME OBSERVED, ACTUAL A WALKING AID REQUIRED. SYMPTOMS NOT OBVIOUSLY RELATED TO ENDOVASCULAR TREATMENT | A30 Other | Patient symptomatic | Severe | Oher | Not related |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| (FEVER) PYREXIA | G04 Fever (Non-infectious) | Patient symptomatic | Moderate | Oher | Not related |
| GASTROINTESTINAL BLEEDING | D03 GI Bleed | Patient symptomatic | Moderate | Procedure related AE | Not related |
| TRACHEOBRONCHITIS | E11 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| N = 45 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Probable | . | No | Resolved without sequelae | 3.02 |
| Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Not resolved / ongoing | . |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Possible | . | No | Resolved without sequelae | 3.44 |
| Not probable | checked | No | Resolved without sequelae | 0.10 |
| Possible | checked | Yes | Resolved without sequelae | 6.20 |
| Probable | . | Yes | Resolved without sequelae | 0.78 |
| Certain | checked | No | Resolved without sequelae | 0.10 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Certain | . | No | Resolved without sequelae | 0.14 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| N = 45 | | | | |

**FRITS**

**Complications**

**Table : Listing of all complications until 12-month (CEC) from 156 patients [ITT at procedure - N=70 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-003 | FRED / FRED Jr | FRED Jr | Thromboembolic complications |  |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-001 | FRED / FRED Jr | FRED | Technical issues | ACCESS DEVICE RELATED VASOSPAM |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-008 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-011 | FRED / FRED Jr | FRED | Puncture site complications |  |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE |
| 07-014 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 07-014 | FRED / FRED Jr | FRED | Other complications | FEVER |
| 07-014 | FRED / FRED Jr | FRED | Delayed IC hematoma |  |
| 07-014 | FRED / FRED Jr | FRED | Other complications | GASTROINTESTINAL BLEEDING |
| 07-014 | FRED / FRED Jr | FRED | Other complications | TRACHEOBRONCHITIS |
| 07-015 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND |
| N = 70 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable |
| FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| ANAMNESTIC PTSD, MILD SYMPTOMS PRIOR TO ENDOVASCULAR TREATMENT, WORSENING OF SYMPTOMS OVER THE TIME OBSERVED, ACTUAL A WALKING AID REQUIRED. SYMPTOMS NOT OBVIOUSLY RELATED TO ENDOVASCULAR TREATMENT | A30 Other | Patient symptomatic | Severe | Oher | Not related |
| ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible |
| LEFT HEMIPARESIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain |
| RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| NEW NEGLECT AND TRANSIENT LIGHT HEMIPARESIS WITH INFARCTION IN THE PARENT VESSEL OF THE FD. ASS/CLOPI TEST WERE POSITIVE. DSA SHOWED NO OCCLUSION, SLIGHT VASOSPASM. | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable |
| SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| VASOSPASM DISTAL CERVICAL ICA DURING PROCEDURE | K01 Arterial Spasm | Patient asymptomatic | Moderate | Procedure related AE | Not related |
| PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related |
| PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| GROIN HEMATOMA | K05 Access site pseudoaneurysm | Patient symptomatic | Mild | Procedure related AE | Not related |
| HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| VESSEL M3 OCCLUSION LEFT + SMALL BLEEDING VESTIBLE ON CT SCAN LEFT FRONTAL | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device and procedure related AE | Possible |
| (FEVER) PYREXIA | G04 Fever (Non-infectious) | Patient symptomatic | Moderate | Oher | Not related |
| INTRACRANIAL BLEEDING FRONTAL LEFT,FOLLOWED BY VASOSPASM AND MEDIAINFARCTION LEFT | A06 ICH | Patient symptomatic | Severe | Device and procedure related AE | Possible |
| GASTROINTESTINAL BLEEDING | D03 GI Bleed | Patient symptomatic | Moderate | Procedure related AE | Not related |
| TRACHEOBRONCHITIS | E11 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| GAIT ABNORMALITY (GANGATAXIE) | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain |
| SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| N = 70 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Possible | . | No | Resolved without sequelae | 3.02 |
| Probable | . | No | Resolved without sequelae | 3.02 |
| Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| Probable | . | No | Resolved without sequelae | 0.06 |
| Not related | . | Yes | Resolved without sequelae | 8.02 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Not resolved / ongoing | . |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not probable | . | No | Not resolved / ongoing | 6.10 |
| Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Probable | checked | No | Resolved without sequelae | 0.06 |
| Not related | . | Yes | Resolved without sequelae | 0.32 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Probable | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.26 |
| Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 3.98 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 4.56 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 3.44 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not probable | checked | No | Resolved without sequelae | 0.10 |
| Certain | . | Yes | Not resolved / ongoing | 0.60 |
| Possible | checked | Yes | Resolved without sequelae | 6.20 |
| Probable | . | Yes | Resolved without sequelae | 0.78 |
| Possible | . | No | Resolved without sequelae | 0.14 |
| Certain | checked | No | Resolved without sequelae | 0.10 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Certain | . | No | Resolved without sequelae | 0.14 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Not related | checked | Yes | Resolved without sequelae | 2.88 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 0.04 |
| Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| Certain | . | No | Not resolved / ongoing | 0.00 |
| Certain | . | Yes | Not resolved / ongoing | 0.04 |
| N = 70 | | | | |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications until 12-month (CEC) from 156 patients [ITT at procedure - N=70 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  | LEFT HEMIPARESIS |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. |
| 04-003 | FRED / FRED Jr | FRED Jr | Thromboembolic complications |  | NEW NEGLECT AND TRANSIENT LIGHT HEMIPARESIS WITH INFARCTION IN THE PARENT VESSEL OF THE FD. ASS/CLOPI TEST WERE POSITIVE. DSA SHOWED NO OCCLUSION, SLIGHT VASOSPASM. |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. |
| 07-014 | FRED / FRED Jr | FRED | Thromboembolic complications |  | VESSEL M3 OCCLUSION LEFT + SMALL BLEEDING VESTIBLE ON CT SCAN LEFT FRONTAL |
| 07-015 | FRED / FRED Jr | FRED | Thromboembolic complications |  | GAIT ABNORMALITY (GANGATAXIE) |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 19 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable | Not related | . | Yes | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | . | Yes | Resolved without sequelae |
| A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device and procedure related AE | Possible | Certain | checked | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing |
| N = 19 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 3.02 |
| 0.06 |
| 8.02 |
| 6.10 |
| 10.14 |
| 0.06 |
| 0.32 |
| 0.04 |
| 0.00 |
| 0.00 |
| 0.26 |
| 0.32 |
| 3.98 |
| 4.56 |
| 0.00 |
| 0.14 |
| 2.88 |
| 0.04 |
| 0.04 |
| N = 19 |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 139 patients [FAS at procedure - N=139 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 139 patients [FAS at procedure - N=139 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of all complications until 12-month)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 66 47.48 75.00 68.75 | 22 15.83 25.00 51.16 | 88 63.31 |
| **FRED X** | 30 21.58 58.82 31.25 | 21 15.11 41.18 48.84 | 51 36.69 |
| **Total** | 96 69.06 | 43 30.94 | 139 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 3.9545 | 0.0467 |
| **Test du rapport de vraisemblance** | 1 | 3.8903 | 0.0486 |
| **Khi-2 continuité ajustée** | 1 | 3.2336 | 0.0721 |
| **Khi-2 de Mantel-Haenszel** | 1 | 3.9261 | 0.0475 |
| **Coefficient Phi** |  | 0.1687 |  |
| **Coefficient de contingence** |  | 0.1663 |  |
| **V de Cramer** |  | 0.1687 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 66 |
| **Pr <= F unilatérale à gauche** | 0.9848 |
| **Pr >= F unilatérale à droite** | 0.0368 |
|  |  |
| **Probabilité de la table (P)** | 0.0216 |
| **Pr <= P bilatéral** | 0.0576 |

|  |
| --- |
| ***Taille de l'échantillon = 139*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 139 patients [FAS at procedure - N=139 patients]**

|  | | **FRED / FRED Jr N=88** | **FRED X N=51** | **Total N=139** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 88 |  | 88 |
|  | Missing data | 0 |  | 0 |
|  | No | 66 (75.0%) | 30 (58.8%) | 96 (69.1%) |
|  | Yes | 22 (25.0%) | 21 (41.2%) | 43 (30.9%) |
|  | 95% CI | 16.0% - 34.0% | 27.7% - 54.7% | 23.3% - 38.6% |
|  | Between group test |  |  | 0.047 (Chi-2) |

**FRITS**

**Complications**

**Table : Summary of all complications until 12-month follow-up (CEC) from 139 patients [FAS at procedure - N=60 complications]**

|  | | **FRED / FRED Jr N=29** | **FRED X N=31** | **Total N=60** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 29 | 31 | 60 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 1 (3.4%) | 1 (3.2%) | 2 (3.3%) |
|  | Thromboembolic complications | 8 (27.6%) | 8 (25.8%) | 16 (26.7%) |
|  | Puncture site complications | 1 (3.4%) | 2 (6.5%) | 3 (5.0%) |
|  | Other complications | 19 (65.5%) | 20 (64.5%) | 39 (65.0%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 29 | 31 | 60 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 10 (34.5%) | 6 (19.4%) | 16 (26.7%) |
|  | Patient symptomatic | 19 (65.5%) | 25 (80.6%) | 44 (73.3%) |
|  |  |  |  |  |
| **AE severity** | N | 29 | 31 | 60 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 17 (58.6%) | 13 (41.9%) | 30 (50.0%) |
|  | Moderate | 7 (24.1%) | 14 (45.2%) | 21 (35.0%) |
|  | Severe | 5 (17.2%) | 4 (12.9%) | 9 (15.0%) |
|  |  |  |  |  |
| **Causal relationship** | N | 29 | 31 | 60 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 5 (17.2%) | 6 (19.4%) | 11 (18.3%) |
|  | Procedure related AE | 8 (27.6%) | 12 (38.7%) | 20 (33.3%) |
|  | Device and procedure related AE | 6 (20.7%) | 9 (29.0%) | 15 (25.0%) |
|  | Oher | 10 (34.5%) | 4 (12.9%) | 14 (23.3%) |
|  |  |  |  |  |
| **Other relationship** | N | 19 | 5 | 24 |
|  | Missing data | 10 | 26 | 36 |
|  | checked | 19 (100.0%) | 5 (100.0%) | 24 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 19 | 5 | 24 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (5.3%) | 0 | 1 (4.2%) |
|  | Concurrent condition | 3 (15.8%) | 2 (40.0%) | 5 (20.8%) |
|  | Concurrent treatment | 6 (31.6%) | 1 (20.0%) | 7 (29.2%) |
|  | Other | 9 (47.4%) | 2 (40.0%) | 11 (45.8%) |
|  |  |  |  |  |
| **Serious AE** | N | 29 | 31 | 60 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 22 (75.9%) | 24 (77.4%) | 46 (76.7%) |
|  | Yes | 7 (24.1%) | 7 (22.6%) | 14 (23.3%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 7 | 7 | 14 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 6 (85.7%) | 4 (57.1%) | 10 (71.4%) |
|  | Permanent damage / Disability | 1 (14.3%) | 3 (42.9%) | 4 (28.6%) |
|  |  |  |  |  |
| **Event outcome** | N | 29 | 31 | 60 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 23 (79.3%) | 21 (67.7%) | 44 (73.3%) |
|  | Not resolved / ongoing | 6 (20.7%) | 9 (29.0%) | 15 (25.0%) |
|  | Unknown | 0 | 1 (3.2%) | 1 (1.7%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 28 | 31 | 59 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 84.07 (116.13) | 53.94 (111.57) | 68.24 (113.78) |
|  | Median | 13.00 | 2.00 | 3.00 |
|  | Q1 - Q3 | 0.50 - 147.00 | 1.00 - 48.00 | 1.00 - 92.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 28 | 31 | 59 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 2.76 (3.81) | 1.77 (3.67) | 2.24 (3.74) |
|  | Median | 0.42 | 0.06 | 0.10 |
|  | Q1 - Q3 | 0.02 - 4.83 | 0.04 - 1.58 | 0.04 - 3.02 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other complications until 12-month (CEC) from 139 patients [FAS - N=60 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) | VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA | INGUINAL HAEMATOMA |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT | SCINTILLATING SCOTOMA LEFT EYE |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE |
| N = 39 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No |
| N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No |
| K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No |
| A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No |
| A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes |
| K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No |
| A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No |
| A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No |
| D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No |
| K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No |
| K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes |
| G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No |
| E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No |
| K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No |
| K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes |
| K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No |
| K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not probable | . | Yes |
| K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes |
| B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No |
| A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No |
| K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No |
| N = 39 | | | | | | | |

| **Event outcome** | **Event onset delay (in months)** |
| --- | --- |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 2.76 |
| Resolved without sequelae | 3.02 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 9.22 |
| Not resolved / ongoing | . |
| Resolved without sequelae | 6.34 |
| Not resolved / ongoing | 8.80 |
| Resolved without sequelae | 0.00 |
| Not resolved / ongoing | 13.40 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 8.22 |
| Not resolved / ongoing | 13.60 |
| Resolved without sequelae | 0.86 |
| Resolved without sequelae | 0.68 |
| Resolved without sequelae | 0.14 |
| Resolved without sequelae | 0.10 |
| Resolved without sequelae | 0.00 |
| Unknown | 0.10 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.16 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 5.68 |
| Resolved without sequelae | 0.26 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 0.04 |
| Resolved without sequelae | 0.22 |
| Not resolved / ongoing | 12.06 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 1.58 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.06 |
| Resolved without sequelae | 3.42 |
| Not resolved / ongoing | 1.70 |
| N = 39 | |

**FRITS**

**Complications**

**Table : Listing of all complications until 12-month (CEC) from 139 patients [FAS - N=60 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-001 | FRED / FRED Jr | FRED | Technical issues | ACCESS DEVICE RELATED VASOSPAM |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-008 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-011 | FRED / FRED Jr | FRED | Puncture site complications |  |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND |
| N = 60 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable |
| FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible |
| LEFT HEMIPARESIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain |
| RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable |
| SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| VASOSPASM DISTAL CERVICAL ICA DURING PROCEDURE | K01 Arterial Spasm | Patient asymptomatic | Moderate | Procedure related AE | Not related |
| PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related |
| PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| GROIN HEMATOMA | K05 Access site pseudoaneurysm | Patient symptomatic | Mild | Procedure related AE | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain |
| SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| N = 60 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Possible | . | No | Resolved without sequelae | 3.02 |
| Probable | . | No | Resolved without sequelae | 3.02 |
| Probable | . | No | Resolved without sequelae | 0.06 |
| Not related | . | Yes | Resolved without sequelae | 8.02 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Not resolved / ongoing | . |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not probable | . | No | Not resolved / ongoing | 6.10 |
| Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Probable | checked | No | Resolved without sequelae | 0.06 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Probable | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.26 |
| Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 3.98 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 4.56 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Certain | . | No | Resolved without sequelae | 0.14 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Not related | checked | Yes | Resolved without sequelae | 2.88 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 0.04 |
| Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| Certain | . | No | Not resolved / ongoing | 0.00 |
| Certain | . | Yes | Not resolved / ongoing | 0.04 |
| N = 60 | | | | |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications until 12-month (CEC) from 139 patients [FAS - N=70 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  | LEFT HEMIPARESIS |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 16 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable | Not related | . | Yes | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae |
| A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing |
| N = 16 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 3.02 |
| 0.06 |
| 8.02 |
| 6.10 |
| 10.14 |
| 0.06 |
| 0.04 |
| 0.00 |
| 0.00 |
| 0.26 |
| 0.32 |
| 3.98 |
| 4.56 |
| 2.88 |
| 0.04 |
| 0.04 |
| N = 16 |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 143 patients [ITT at 12-month - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 143 patients [ITT at 12-month - N=143 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of all complications until 12-month)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 67 46.85 73.63 66.34 | 24 16.78 26.37 57.14 | 91 63.64 |
| **FRED X** | 34 23.78 65.38 33.66 | 18 12.59 34.62 42.86 | 52 36.36 |
| **Total** | 101 70.63 | 42 29.37 | 143 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 1.0836 | 0.2979 |
| **Test du rapport de vraisemblance** | 1 | 1.0705 | 0.3008 |
| **Khi-2 continuité ajustée** | 1 | 0.7227 | 0.3953 |
| **Khi-2 de Mantel-Haenszel** | 1 | 1.0760 | 0.2996 |
| **Coefficient Phi** |  | 0.0870 |  |
| **Coefficient de contingence** |  | 0.0867 |  |
| **V de Cramer** |  | 0.0870 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 67 |
| **Pr <= F unilatérale à gauche** | 0.8905 |
| **Pr >= F unilatérale à droite** | 0.1971 |
|  |  |
| **Probabilité de la table (P)** | 0.0876 |
| **Pr <= P bilatéral** | 0.3419 |

|  |
| --- |
| ***Taille de l'échantillon = 143*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 143 patients [ITT at 12-month - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 67 (73.6%) | 34 (65.4%) | 101 (70.6%) |
|  | Yes | 24 (26.4%) | 18 (34.6%) | 42 (29.4%) |
|  | 95% CI | 17.3% - 35.4% | 21.7% - 47.5% | 21.9% - 36.8% |
|  | Between group test |  |  | 0.298 (Chi-2) |

**FRITS**

**Complications**

**Table : Summary of all complications until 12-month follow-up (CEC) from 143 patients [ITT at 12-month - N=58 complications]**

|  | | **FRED / FRED Jr N=30** | **FRED X N=28** | **Total N=58** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 0 | 1 (3.6%) | 1 (1.7%) |
|  | Thromboembolic complications | 9 (30.0%) | 7 (25.0%) | 16 (27.6%) |
|  | Puncture site complications | 0 | 2 (7.1%) | 2 (3.4%) |
|  | Other complications | 21 (70.0%) | 18 (64.3%) | 39 (67.2%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 9 (30.0%) | 6 (21.4%) | 15 (25.9%) |
|  | Patient symptomatic | 21 (70.0%) | 22 (78.6%) | 43 (74.1%) |
|  |  |  |  |  |
| **AE severity** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 17 (56.7%) | 11 (39.3%) | 28 (48.3%) |
|  | Moderate | 6 (20.0%) | 14 (50.0%) | 20 (34.5%) |
|  | Severe | 7 (23.3%) | 3 (10.7%) | 10 (17.2%) |
|  |  |  |  |  |
| **Causal relationship** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 6 (20.0%) | 5 (17.9%) | 11 (19.0%) |
|  | Procedure related AE | 7 (23.3%) | 11 (39.3%) | 18 (31.0%) |
|  | Device and procedure related AE | 7 (23.3%) | 9 (32.1%) | 16 (27.6%) |
|  | Oher | 10 (33.3%) | 3 (10.7%) | 13 (22.4%) |
|  |  |  |  |  |
| **Other relationship** | N | 18 | 5 | 23 |
|  | Missing data | 12 | 23 | 35 |
|  | checked | 18 (100.0%) | 5 (100.0%) | 23 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 18 | 5 | 23 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (5.6%) | 0 | 1 (4.3%) |
|  | Concurrent condition | 3 (16.7%) | 2 (40.0%) | 5 (21.7%) |
|  | Concurrent treatment | 7 (38.9%) | 1 (20.0%) | 8 (34.8%) |
|  | Other | 7 (38.9%) | 2 (40.0%) | 9 (39.1%) |
|  |  |  |  |  |
| **Serious AE** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 21 (70.0%) | 23 (82.1%) | 44 (75.9%) |
|  | Yes | 9 (30.0%) | 5 (17.9%) | 14 (24.1%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 9 | 5 | 14 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 7 (77.8%) | 2 (40.0%) | 9 (64.3%) |
|  | Permanent damage / Disability | 2 (22.2%) | 3 (60.0%) | 5 (35.7%) |
|  |  |  |  |  |
| **Event outcome** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 24 (80.0%) | 19 (67.9%) | 43 (74.1%) |
|  | Not resolved / ongoing | 6 (20.0%) | 8 (28.6%) | 14 (24.1%) |
|  | Unknown | 0 | 1 (3.6%) | 1 (1.7%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 88.47 (113.18) | 50.82 (110.84) | 70.29 (112.68) |
|  | Median | 23.50 | 2.00 | 4.00 |
|  | Q1 - Q3 | 1.00 - 173.00 | 0.50 - 29.00 | 1.00 - 104.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 30 | 28 | 58 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 2.90 (3.72) | 1.67 (3.64) | 2.31 (3.70) |
|  | Median | 0.77 | 0.06 | 0.13 |
|  | Q1 - Q3 | 0.04 - 5.68 | 0.02 - 0.95 | 0.04 - 3.42 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other complications until 12-month (CEC) from 143 patients [ITT at 12-month - N= complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| N = 39 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| ANAMNESTIC PTSD, MILD SYMPTOMS PRIOR TO ENDOVASCULAR TREATMENT, WORSENING OF SYMPTOMS OVER THE TIME OBSERVED, ACTUAL A WALKING AID REQUIRED. SYMPTOMS NOT OBVIOUSLY RELATED TO ENDOVASCULAR TREATMENT | A30 Other | Patient symptomatic | Severe | Oher | Not related |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| N = 39 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Probable | . | No | Resolved without sequelae | 3.02 |
| Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Possible | . | No | Resolved without sequelae | 3.44 |
| Certain | checked | No | Resolved without sequelae | 0.10 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| N = 39 | | | | |

**FRITS**

**Complications**

**Table : Listing of all complications until 12-month (CEC) from 143 patients [ITT at 12-month - N=58 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-003 | FRED / FRED Jr | FRED Jr | Thromboembolic complications |  |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-008 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND |
| N = 58 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable |
| FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| ANAMNESTIC PTSD, MILD SYMPTOMS PRIOR TO ENDOVASCULAR TREATMENT, WORSENING OF SYMPTOMS OVER THE TIME OBSERVED, ACTUAL A WALKING AID REQUIRED. SYMPTOMS NOT OBVIOUSLY RELATED TO ENDOVASCULAR TREATMENT | A30 Other | Patient symptomatic | Severe | Oher | Not related |
| ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain |
| RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| NEW NEGLECT AND TRANSIENT LIGHT HEMIPARESIS WITH INFARCTION IN THE PARENT VESSEL OF THE FD. ASS/CLOPI TEST WERE POSITIVE. DSA SHOWED NO OCCLUSION, SLIGHT VASOSPASM. | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable |
| SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related |
| PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| N = 58 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Possible | . | No | Resolved without sequelae | 3.02 |
| Probable | . | No | Resolved without sequelae | 3.02 |
| Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| Probable | . | No | Resolved without sequelae | 0.06 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not probable | . | No | Not resolved / ongoing | 6.10 |
| Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Probable | checked | No | Resolved without sequelae | 0.06 |
| Not related | . | Yes | Resolved without sequelae | 0.32 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Probable | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.26 |
| Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 3.98 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 4.56 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Possible | . | No | Resolved without sequelae | 3.44 |
| Certain | checked | No | Resolved without sequelae | 0.10 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Not related | checked | Yes | Resolved without sequelae | 2.88 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| Certain | . | No | Not resolved / ongoing | 0.00 |
| Certain | . | Yes | Not resolved / ongoing | 0.04 |
| N = 58 | | | | |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications until 12-month (CEC) from 143 patients [ITT at 12-month - N=58 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. |
| 04-003 | FRED / FRED Jr | FRED Jr | Thromboembolic complications |  | NEW NEGLECT AND TRANSIENT LIGHT HEMIPARESIS WITH INFARCTION IN THE PARENT VESSEL OF THE FD. ASS/CLOPI TEST WERE POSITIVE. DSA SHOWED NO OCCLUSION, SLIGHT VASOSPASM. |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 16 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | . | Yes | Resolved without sequelae |
| A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing |
| N = 16 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 3.02 |
| 0.06 |
| 6.10 |
| 10.14 |
| 0.06 |
| 0.32 |
| 0.04 |
| 0.00 |
| 0.00 |
| 0.26 |
| 0.32 |
| 3.98 |
| 4.56 |
| 2.88 |
| 0.04 |
| 0.04 |
| N = 16 |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 130 patients [FAS at 12-month - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 130 patients [FAS at 12-month - N=130 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of all complications until 12-month)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 62 47.69 75.61 67.39 | 20 15.38 24.39 52.63 | 82 63.08 |
| **FRED X** | 30 23.08 62.50 32.61 | 18 13.85 37.50 47.37 | 48 36.92 |
| **Total** | 92 70.77 | 38 29.23 | 130 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 2.5155 | 0.1127 |
| **Test du rapport de vraisemblance** | 1 | 2.4752 | 0.1157 |
| **Khi-2 continuité ajustée** | 1 | 1.9216 | 0.1657 |
| **Khi-2 de Mantel-Haenszel** | 1 | 2.4961 | 0.1141 |
| **Coefficient Phi** |  | 0.1391 |  |
| **Coefficient de contingence** |  | 0.1378 |  |
| **V de Cramer** |  | 0.1391 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 62 |
| **Pr <= F unilatérale à gauche** | 0.9621 |
| **Pr >= F unilatérale à droite** | 0.0836 |
|  |  |
| **Probabilité de la table (P)** | 0.0457 |
| **Pr <= P bilatéral** | 0.1614 |

|  |
| --- |
| ***Taille de l'échantillon = 130*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 130 patients [FAS at 12-month - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 62 (75.6%) | 30 (62.5%) | 92 (70.8%) |
|  | Yes | 20 (24.4%) | 18 (37.5%) | 38 (29.2%) |
|  | 95% CI | 15.1% - 33.7% | 23.8% - 51.2% | 21.4% - 37% |
|  | Between group test |  |  | 0.113 (Chi-2) |

**FRITS**

**Complications**

**Table : Summary of all complications until 12-month follow-up (CEC) from 130 patients [FAS at 12-month - N=54 complications]**

|  | | **FRED / FRED Jr N=26** | **FRED X N=28** | **Total N=54** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 0 | 1 (3.6%) | 1 (1.9%) |
|  | Thromboembolic complications | 8 (30.8%) | 7 (25.0%) | 15 (27.8%) |
|  | Puncture site complications | 0 | 2 (7.1%) | 2 (3.7%) |
|  | Other complications | 18 (69.2%) | 18 (64.3%) | 36 (66.7%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 9 (34.6%) | 6 (21.4%) | 15 (27.8%) |
|  | Patient symptomatic | 17 (65.4%) | 22 (78.6%) | 39 (72.2%) |
|  |  |  |  |  |
| **AE severity** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 15 (57.7%) | 11 (39.3%) | 26 (48.1%) |
|  | Moderate | 6 (23.1%) | 14 (50.0%) | 20 (37.0%) |
|  | Severe | 5 (19.2%) | 3 (10.7%) | 8 (14.8%) |
|  |  |  |  |  |
| **Causal relationship** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 5 (19.2%) | 5 (17.9%) | 10 (18.5%) |
|  | Procedure related AE | 6 (23.1%) | 11 (39.3%) | 17 (31.5%) |
|  | Device and procedure related AE | 6 (23.1%) | 9 (32.1%) | 15 (27.8%) |
|  | Oher | 9 (34.6%) | 3 (10.7%) | 12 (22.2%) |
|  |  |  |  |  |
| **Other relationship** | N | 17 | 5 | 22 |
|  | Missing data | 9 | 23 | 32 |
|  | checked | 17 (100.0%) | 5 (100.0%) | 22 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 17 | 5 | 22 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (5.9%) | 0 | 1 (4.5%) |
|  | Concurrent condition | 3 (17.6%) | 2 (40.0%) | 5 (22.7%) |
|  | Concurrent treatment | 6 (35.3%) | 1 (20.0%) | 7 (31.8%) |
|  | Other | 7 (41.2%) | 2 (40.0%) | 9 (40.9%) |
|  |  |  |  |  |
| **Serious AE** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 19 (73.1%) | 23 (82.1%) | 42 (77.8%) |
|  | Yes | 7 (26.9%) | 5 (17.9%) | 12 (22.2%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 7 | 5 | 12 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 6 (85.7%) | 2 (40.0%) | 8 (66.7%) |
|  | Permanent damage / Disability | 1 (14.3%) | 3 (60.0%) | 4 (33.3%) |
|  |  |  |  |  |
| **Event outcome** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 21 (80.8%) | 19 (67.9%) | 40 (74.1%) |
|  | Not resolved / ongoing | 5 (19.2%) | 8 (28.6%) | 13 (24.1%) |
|  | Unknown | 0 | 1 (3.6%) | 1 (1.9%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 90.54 (118.13) | 50.82 (110.84) | 69.94 (115.08) |
|  | Median | 23.50 | 2.00 | 3.00 |
|  | Q1 - Q3 | 1.00 - 173.00 | 0.50 - 29.00 | 1.00 - 92.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 26 | 28 | 54 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 2.97 (3.88) | 1.67 (3.64) | 2.30 (3.78) |
|  | Median | 0.77 | 0.06 | 0.10 |
|  | Q1 - Q3 | 0.04 - 5.68 | 0.02 - 0.95 | 0.04 - 3.02 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other complications until 12-month (CEC) from 130 patients [FAS at 12-month - N=54 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) | VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE |
| N = 36 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No |
| N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No |
| K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No |
| A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes |
| K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No |
| A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No |
| A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No |
| D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No |
| A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No |
| K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes |
| G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No |
| E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No |
| K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No |
| K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes |
| K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No |
| K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes |
| B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No |
| A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No |
| K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No |
| N = 36 | | | | | | | |

| **Event outcome** | **Event onset delay (in months)** |
| --- | --- |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 2.76 |
| Resolved without sequelae | 3.02 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 9.22 |
| Resolved without sequelae | 6.34 |
| Not resolved / ongoing | 8.80 |
| Resolved without sequelae | 0.00 |
| Not resolved / ongoing | 13.40 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 8.22 |
| Not resolved / ongoing | 13.60 |
| Resolved without sequelae | 0.86 |
| Resolved without sequelae | 0.68 |
| Resolved without sequelae | 0.10 |
| Resolved without sequelae | 0.00 |
| Unknown | 0.10 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.16 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 5.68 |
| Resolved without sequelae | 0.26 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.22 |
| Not resolved / ongoing | 12.06 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 1.58 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.06 |
| Resolved without sequelae | 3.42 |
| Not resolved / ongoing | 1.70 |
| N = 36 | |

**FRITS**

**Complications**

**Table : Listing of all complications until 12-month (CEC) from 130 patients [FAS at 12-month - N=54 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-008 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND |
| N = 54 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable |
| FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain |
| RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable |
| SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related |
| PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| N = 54 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Possible | . | No | Resolved without sequelae | 3.02 |
| Probable | . | No | Resolved without sequelae | 3.02 |
| Probable | . | No | Resolved without sequelae | 0.06 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not probable | . | No | Not resolved / ongoing | 6.10 |
| Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Probable | checked | No | Resolved without sequelae | 0.06 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Probable | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.26 |
| Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 3.98 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 4.56 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Not related | checked | Yes | Resolved without sequelae | 2.88 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| Certain | . | No | Not resolved / ongoing | 0.00 |
| Certain | . | Yes | Not resolved / ongoing | 0.04 |
| N = 54 | | | | |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications until 12-month (CEC) from 130 patients [FAS at 12-month - N=58 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 15 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae |
| A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing |
| N = 15 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 3.02 |
| 0.06 |
| 6.10 |
| 10.14 |
| 0.06 |
| 0.04 |
| 0.00 |
| 0.00 |
| 0.26 |
| 0.32 |
| 3.98 |
| 4.56 |
| 2.88 |
| 0.04 |
| 0.04 |
| N = 15 |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 124 patients [PP at 12-month - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 124 patients [PP at 12-month - N=124 patients]**

|  |
| --- |
| ***La procédure FREQ*** |

| **Table de fgroup par COMP** | | | |
| --- | --- | --- | --- |
| **fgroup(Subgroup device)** | **COMP(Occurrence of all complications until 12-month)** | | |
| **Fréquence Pourcentage Pct de ligne Pct de col.** | **No** | **Yes** | **Total** |
| **FRED / FRED Jr** | 60 48.39 75.95 68.97 | 19 15.32 24.05 51.35 | 79 63.71 |
| **FRED X** | 27 21.77 60.00 31.03 | 18 14.52 40.00 48.65 | 45 36.29 |
| **Total** | 87 70.16 | 37 29.84 | 124 100.00 |

|  |
| --- |
| ***Statistiques pour la table de fgroup par COMP*** |

| **Statistique** | **DDL** | **Valeur** | **Prob** |
| --- | --- | --- | --- |
| **Khi-2** | 1 | 3.4836 | 0.0620 |
| **Test du rapport de vraisemblance** | 1 | 3.4201 | 0.0644 |
| **Khi-2 continuité ajustée** | 1 | 2.7634 | 0.0964 |
| **Khi-2 de Mantel-Haenszel** | 1 | 3.4555 | 0.0630 |
| **Coefficient Phi** |  | 0.1676 |  |
| **Coefficient de contingence** |  | 0.1653 |  |
| **V de Cramer** |  | 0.1676 |  |

| **Test exact de Fisher** | |
| --- | --- |
| **Cellule (1,1) Fréquence (F)** | 60 |
| **Pr <= F unilatérale à gauche** | 0.9801 |
| **Pr >= F unilatérale à droite** | 0.0491 |
|  |  |
| **Probabilité de la table (P)** | 0.0292 |
| **Pr <= P bilatéral** | 0.0695 |

|  |
| --- |
| ***Taille de l'échantillon = 124*** |

**FRITS**

**Complications**

**Table : Occurrence per patient of all complications until 12-month follow-up (CEC) from 124 patients [PP at 12-month - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 60 (75.9%) | 27 (60.0%) | 87 (70.2%) |
|  | Yes | 19 (24.1%) | 18 (40.0%) | 37 (29.8%) |
|  | 95% CI | 14.6% - 33.5% | 25.7% - 54.3% | 21.8% - 37.9% |
|  | Between group test |  |  | 0.062 (Chi-2) |

**FRITS**

**Complications**

**Table : Summary of all complications until 12-month follow-up (CEC) from 124 patients [PP at 12-month - N=52 complications]**

|  | | **FRED / FRED Jr N=24** | **FRED X N=28** | **Total N=52** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 0 | 1 (3.6%) | 1 (1.9%) |
|  | Thromboembolic complications | 7 (29.2%) | 7 (25.0%) | 14 (26.9%) |
|  | Puncture site complications | 0 | 2 (7.1%) | 2 (3.8%) |
|  | Other complications | 17 (70.8%) | 18 (64.3%) | 35 (67.3%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 7 (29.2%) | 6 (21.4%) | 13 (25.0%) |
|  | Patient symptomatic | 17 (70.8%) | 22 (78.6%) | 39 (75.0%) |
|  |  |  |  |  |
| **AE severity** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 13 (54.2%) | 11 (39.3%) | 24 (46.2%) |
|  | Moderate | 6 (25.0%) | 14 (50.0%) | 20 (38.5%) |
|  | Severe | 5 (20.8%) | 3 (10.7%) | 8 (15.4%) |
|  |  |  |  |  |
| **Causal relationship** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 5 (20.8%) | 5 (17.9%) | 10 (19.2%) |
|  | Procedure related AE | 6 (25.0%) | 11 (39.3%) | 17 (32.7%) |
|  | Device and procedure related AE | 4 (16.7%) | 9 (32.1%) | 13 (25.0%) |
|  | Oher | 9 (37.5%) | 3 (10.7%) | 12 (23.1%) |
|  |  |  |  |  |
| **Other relationship** | N | 17 | 5 | 22 |
|  | Missing data | 7 | 23 | 30 |
|  | checked | 17 (100.0%) | 5 (100.0%) | 22 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 17 | 5 | 22 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (5.9%) | 0 | 1 (4.5%) |
|  | Concurrent condition | 3 (17.6%) | 2 (40.0%) | 5 (22.7%) |
|  | Concurrent treatment | 6 (35.3%) | 1 (20.0%) | 7 (31.8%) |
|  | Other | 7 (41.2%) | 2 (40.0%) | 9 (40.9%) |
|  |  |  |  |  |
| **Serious AE** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 17 (70.8%) | 23 (82.1%) | 40 (76.9%) |
|  | Yes | 7 (29.2%) | 5 (17.9%) | 12 (23.1%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 7 | 5 | 12 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 6 (85.7%) | 2 (40.0%) | 8 (66.7%) |
|  | Permanent damage / Disability | 1 (14.3%) | 3 (60.0%) | 4 (33.3%) |
|  |  |  |  |  |
| **Event outcome** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 19 (79.2%) | 19 (67.9%) | 38 (73.1%) |
|  | Not resolved / ongoing | 5 (20.8%) | 8 (28.6%) | 13 (25.0%) |
|  | Unknown | 0 | 1 (3.6%) | 1 (1.9%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 90.42 (123.16) | 50.82 (110.84) | 69.10 (117.23) |
|  | Median | 13.00 | 2.00 | 2.50 |
|  | Q1 - Q3 | 1.00 - 179.50 | 0.50 - 29.00 | 1.00 - 96.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 24 | 28 | 52 |
|  | Missing data | 0 | 0 | 0 |
|  | Mean (s.d.) | 2.97 (4.04) | 1.67 (3.64) | 2.27 (3.85) |
|  | Median | 0.42 | 0.06 | 0.08 |
|  | Q1 - Q3 | 0.04 - 5.89 | 0.02 - 0.95 | 0.04 - 3.15 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

**FRITS**

**Complications**

**Table : Listing of other complications until 12-month (CEC) from 124 patients [PP at 12-month - N=52 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) | VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION | SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY | MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION | SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE |
| N = 35 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No |
| K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No |
| A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No |
| K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No |
| A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No |
| A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes |
| K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No |
| A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No |
| N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No |
| A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No |
| A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No |
| D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No |
| A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No |
| K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes |
| G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No |
| E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No |
| K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No |
| K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes |
| K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No |
| K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes |
| B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No |
| A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No |
| K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No |
| H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No |
| A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No |
| N = 35 | | | | | | | |

| **Event outcome** | **Event onset delay (in months)** |
| --- | --- |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 2.76 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 9.22 |
| Resolved without sequelae | 6.34 |
| Not resolved / ongoing | 8.80 |
| Resolved without sequelae | 0.00 |
| Not resolved / ongoing | 13.40 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 8.22 |
| Not resolved / ongoing | 13.60 |
| Resolved without sequelae | 0.86 |
| Resolved without sequelae | 0.68 |
| Resolved without sequelae | 0.10 |
| Resolved without sequelae | 0.00 |
| Unknown | 0.10 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.16 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 5.68 |
| Resolved without sequelae | 0.26 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.22 |
| Not resolved / ongoing | 12.06 |
| Resolved without sequelae | 0.00 |
| Resolved without sequelae | 0.04 |
| Not resolved / ongoing | 1.58 |
| Resolved without sequelae | 0.04 |
| Resolved without sequelae | 0.06 |
| Resolved without sequelae | 3.42 |
| Not resolved / ongoing | 1.70 |
| N = 35 | |

**FRITS**

**Complications**

**Table : Listing of all complications until 12-month (CEC) from 124 patients [PP at 12-month - N=52 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** |
| --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM |
| 01-017 | FRED / FRED Jr | FRED | Other complications | VISUAL IMPAIRMENT OF UNKNOWN ETIOLOGY (COLOUR PERCEPTION DISTURBANCE) |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  |
| 04-021 | FRED X | FRED X | Other complications | PARTIAL IN STENT THROMBOSIS. THROMBUS APPOSITION |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION |
| 06-008 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Puncture site complications |  |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE |
| 07-041 | FRED X | FRED X | Other complications | TIA |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION |
| 08-009 | FRED / FRED Jr | FRED | Other complications | MULTIPLE STROKES IN MCA/ NON COMPLIANT WITH ANTIPLATELET THERAPY |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA |
| 08-022 | FRED X | FRED X | Other complications | ND |
| 08-023 | FRED X | FRED X | Other complications | ARTERIAL DISSECTION |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE |
| 09-001 | FRED X | FRED X | Technical issues | DEPLOYMENT |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND |
| N = 52 | | | | |

| **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** |
| --- | --- | --- | --- | --- | --- |
| VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related |
| VISUAL IMPAIRMENT OF BOTH EYES AND EAR NOISES IN BOTH SIDES | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related |
| ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible |
| BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related |
| SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related |
| HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related |
| WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible |
| UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain |
| RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain |
| THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain |
| SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible |
| RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable |
| TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related |
| PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable |
| SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain |
| IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| SLIGHT IN-STENT THROMBOSIS DURING THE PROCEDURE AFTER STENT DEPLOYMENT. | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device related AE | Certain |
| PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible |
| DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable |
| COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related |
| SHEATH INDRODUCTIONINTO A. CIRCUMFLEXA ILII ON THE RIGHT SIDE WITH ACTIVE BLEEDING. OCCLUSION WITH GLUE ( MAGIC GLUE), HB CONTROL AND CONTROL SONOGRAPHY. UNEVENTFUL, ONLY SAME PAIN | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related |
| PUNCTURE FAILURE GROIN RICHT SIDE, CONTRAST APPLICATION OUTSIDE VESSEL.AFTER SUCCESFUL INSURTION OF 7 F SHEAT - CONTROLANGIO IN TOW PLANE AND AT THE END OF PROCEDURE IN ONE PLANE. NO CONTRAST EXTRVASCULARE, NO BLEEDING | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related |
| STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related |
| GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related |
| VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related |
| PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related |
| WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related |
| EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related |
| THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain |
| RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related |
| MULTIPLE STROKES ARTERIA CEREBRI MEDIA AND POSTERIOR LEFT | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related |
| HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related |
| FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related |
| RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related |
| SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain |
| HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related |
| LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible |
| SLIGHT DISSECTION IN DISTAL CERVICAL ICA DUE TO NEURON MAX 6F SHEATH | B01 Dissection / Vascular injury / Pseudoaneurysm formation | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related |
| DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related |
| HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related |
| HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible |
| FOREWARD FOLDING OF ONE OF THE PROXIMAL FLAIRES ENDS WITHIN THE MICROCATHETER RESULTING IN INSUFFICIENT EXPANSION | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain |
| NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible |
| N = 52 | | | | | |

| **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 2.76 |
| Probable | . | No | Resolved without sequelae | 0.06 |
| Certain | checked | No | Resolved without sequelae | 0.04 |
| Not probable | checked | No | Not resolved / ongoing | 9.22 |
| Not related | checked | No | Resolved without sequelae | 6.34 |
| Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| Not probable | . | No | Not resolved / ongoing | 6.10 |
| Possible | . | Yes | Not resolved / ongoing | 10.14 |
| Not related | checked | No | Resolved without sequelae | 0.00 |
| Probable | checked | No | Resolved without sequelae | 0.06 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| Probable | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.00 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | Yes | Resolved without sequelae | 0.26 |
| Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| Not probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 3.98 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | No | Resolved without sequelae | 4.56 |
| Not related | . | No | Resolved without sequelae | 8.22 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Certain | checked | No | Resolved without sequelae | 0.00 |
| Not related | . | No | Not resolved / ongoing | 13.60 |
| Not related | checked | No | Resolved without sequelae | 0.86 |
| Not related | checked | No | Resolved without sequelae | 0.68 |
| Possible | . | No | Resolved without sequelae | 0.10 |
| Probable | . | No | Resolved without sequelae | 0.00 |
| Not related | checked | Yes | Unknown | 0.10 |
| Not probable | checked | No | Resolved without sequelae | 0.04 |
| Not related | checked | No | Resolved without sequelae | 0.04 |
| Possible | checked | No | Resolved without sequelae | 0.16 |
| Not related | checked | Yes | Resolved without sequelae | 2.88 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Not related | . | Yes | Resolved without sequelae | 5.68 |
| Certain | . | No | Resolved without sequelae | 0.26 |
| Probable | checked | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.22 |
| Not related | . | Yes | Not resolved / ongoing | 12.06 |
| Certain | . | No | Resolved without sequelae | 0.00 |
| Possible | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Not resolved / ongoing | 1.58 |
| Probable | . | No | Resolved without sequelae | 0.04 |
| Certain | . | No | Resolved without sequelae | 0.06 |
| Certain | . | No | Resolved without sequelae | 3.42 |
| Not probable | . | No | Not resolved / ongoing | 1.70 |
| Certain | . | No | Not resolved / ongoing | 0.00 |
| Certain | . | Yes | Not resolved / ongoing | 0.04 |
| N = 52 | | | | |

**FRITS**

**Complications**

**Table : Listing of all Thromboembolic complications until 12-month (CEC) from 124 patients [PP at 12-month - N=58 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** |
| --- | --- | --- | --- | --- | --- |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS |
| 04-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | SLIGHT DIZZYNESS AND NON-REPRODUCEABLE IMPAIRMENT, CONDITION KNOWN TO PATIENT, AS IT IS OCCURING FREQUENTLY, NO DWI LESION IN POSTERIOR CIRCULATION. |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS |
| N = 14 | | | | | |

| **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing |
| A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae |
| A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae |
| B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae |
| A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae |
| A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae |
| A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing |
| A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing |
| N = 14 | | | | | | | | |

| **Event onset delay (in months)** |
| --- |
| 0.06 |
| 6.10 |
| 10.14 |
| 0.06 |
| 0.04 |
| 0.00 |
| 0.00 |
| 0.26 |
| 0.32 |
| 3.98 |
| 4.56 |
| 2.88 |
| 0.04 |
| 0.04 |
| N = 14 |

**FRITS**

**EFFICACY**

**Table : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.1%) |  | 1 (0.7%) |
|  | Single antiplatelet therapy | 59 (64.8%) | 33 (63.5%) | 92 (64.3%) |
|  | Dual antiplatelet therapy | 29 (31.9%) | 16 (30.8%) | 45 (31.5%) |
|  | Triple antiplatelet therapy | 2 (2.2%) | 3 (5.8%) | 5 (3.5%) |
|  | Between group test |  |  | 0.713 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 59 |  | 59 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 58 (98.3%) | 33 (100.0%) | 91 (98.9%) |
|  | Ticlagrelor (Brilique) | 1 (1.7%) |  | 1 (1.1%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 29 |  | 29 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 23 (79.3%) | 14 (87.5%) | 37 (82.2%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 3 (10.3%) | 2 (12.5%) | 5 (11.1%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 2 (6.9%) |  | 2 (4.4%) |
|  | ASA (Aspirin) + Other | 1 (3.4%) |  | 1 (2.2%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 2 |  | 2 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (50.0%) | 1 (33.3%) | 2 (40.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 1 (50.0%) | 1 (33.3%) | 2 (40.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (20.0%) |

**FRITS**

**EFFICACY**

**Table : Listing of patient without antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| N = 2 | | | | | | | |

| **Full Analysis Set (FAS) at 6-month follow-up visit** | **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| N = 2 | | | | | | | |

| **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** | **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| N = 2 | | | | | | | | |

| **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** | **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | 12 | No treatment | . | . | . |
| . | . | . | . | 12 | No treatment | . | . | . |
| N = 2 | | | | | | | | |

| **Study name** | **Visit num** | **Visit name** | **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet |
| N = 2 | | | | | | | | |

| **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASA (Aspirin) |  | 100 | MG | 30/10/2019 | 30/10/2019 | No | 01/04/2020 | 01/04/2020 |
| Clopidogrel (Plavix) |  | 75 | MG | 30/10/2019 | 30/10/2019 | No | 04/02/2020 | 04/02/2020 |
| N = 2 | | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Listing of patient with other antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 07-041 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 08-008 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 3 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | No | 73 | Female | FRED / FRED Jr | FRED | 22/06/2020 | 1 | 1 |
| No | No | No | 76 | Female | FRED X | FRED X | 12/01/2022 | 1 | 1 |
| No | No | No | 68 | Male | FRED / FRED Jr | FRED | 10/11/2020 | 1 | 1 |
| N = 3 | | | | | | | | | |

| **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** | **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| N = 3 | | | | | | | | |

| **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **Study name** | **Visit num** | **Visit name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 12 | Dual antiplatelet therapy | . | ASA (Aspirin) + Other | . | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| N = 3 | | | | | | | | |

| **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** | **Treatment name** | **Other treatment specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No | 25/06/2020 | 18/12/2020 | 11/06/2021 | 3 | Antiplatelet | Other | ELIQUIS |
| No | 22/01/2022 | . | 27/02/2023 | 3 | Antiplatelet | Other | EDOXABAN |
| Yes | 16/11/2020 | . | 08/11/2021 | 4 | Antiplatelet | Other | TIROFIBAN |
| N = 3 | | | | | | | |

| **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | MG | 02/07/2020 | 02/07/2020 | Yes |  | . |
| 60 | MG | 20/01/2022 | 20/01/2022 | Yes |  | . |
| 15 | ML/HR | 06/02/2021 | 06/02/2021 | No | 07/02/2021 | 07/02/2021 |
| N = 3 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Antiplatelet functional test at 12 months visit (INVESTIGATORS) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 91 |  | 91 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (6.6%) | 4 (7.7%) | 10 (7.0%) |
|  | Yes | 85 (93.4%) | 48 (92.3%) | 133 (93.0%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 85 |  | 85 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 76 (89.4%) | 45 (93.8%) | 121 (91.0%) |
|  | Aspirin resistance | 1 (1.2%) |  | 1 (0.8%) |
|  | Plavix resistance | 8 (9.4%) | 3 (6.3%) | 11 (8.3%) |
|  | Between group test |  |  | 0.837 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 9 |  | 9 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 9 (100.0%) | 3 (100.0%) | 12 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.2%) |  | 1 (0.8%) |
|  | Single antiplatelet therapy | 55 (67.1%) | 29 (60.4%) | 84 (64.6%) |
|  | Dual antiplatelet therapy | 25 (30.5%) | 16 (33.3%) | 41 (31.5%) |
|  | Triple antiplatelet therapy | 1 (1.2%) | 3 (6.3%) | 4 (3.1%) |
|  | Between group test |  |  | 0.352 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 55 |  | 55 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 54 (98.2%) | 29 (100.0%) | 83 (98.8%) |
|  | Ticlagrelor (Brilique) | 1 (1.8%) |  | 1 (1.2%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 25 |  | 25 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 22 (88.0%) | 14 (87.5%) | 36 (87.8%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 1 (4.0%) | 2 (12.5%) | 3 (7.3%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 1 (4.0%) |  | 1 (2.4%) |
|  | ASA (Aspirin) + Other | 1 (4.0%) |  | 1 (2.4%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 1 |  | 1 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (100.0%) | 1 (33.3%) | 2 (50.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 0 | 1 (33.3%) | 1 (25.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (25.0%) |

**FRITS**

**EFFICACY**

**Table : Listing of patient without antiplatelet medications at 12-month visit (INVESTIGATORS) [FAS - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| N = 2 | | | | | | | |

| **Full Analysis Set (FAS) at 6-month follow-up visit** | **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| N = 2 | | | | | | | |

| **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** | **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| N = 2 | | | | | | | | |

| **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** | **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | 12 | No treatment | . | . | . |
| . | . | . | . | 12 | No treatment | . | . | . |
| N = 2 | | | | | | | | |

| **Study name** | **Visit num** | **Visit name** | **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet |
| N = 2 | | | | | | | | |

| **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASA (Aspirin) |  | 100 | MG | 30/10/2019 | 30/10/2019 | No | 01/04/2020 | 01/04/2020 |
| Clopidogrel (Plavix) |  | 75 | MG | 30/10/2019 | 30/10/2019 | No | 04/02/2020 | 04/02/2020 |
| N = 2 | | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Listing of patient with other antiplatelet medications at 12-month visit [FAS - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 07-041 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 08-008 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 3 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | No | 73 | Female | FRED / FRED Jr | FRED | 22/06/2020 | 1 | 1 |
| No | No | No | 76 | Female | FRED X | FRED X | 12/01/2022 | 1 | 1 |
| No | No | No | 68 | Male | FRED / FRED Jr | FRED | 10/11/2020 | 1 | 1 |
| N = 3 | | | | | | | | | |

| **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** | **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| N = 3 | | | | | | | | |

| **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **Study name** | **Visit num** | **Visit name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 12 | Dual antiplatelet therapy | . | ASA (Aspirin) + Other | . | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| N = 3 | | | | | | | | |

| **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** | **Treatment name** | **Other treatment specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No | 25/06/2020 | 18/12/2020 | 11/06/2021 | 3 | Antiplatelet | Other | ELIQUIS |
| No | 22/01/2022 | . | 27/02/2023 | 3 | Antiplatelet | Other | EDOXABAN |
| Yes | 16/11/2020 | . | 08/11/2021 | 4 | Antiplatelet | Other | TIROFIBAN |
| N = 3 | | | | | | | |

| **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | MG | 02/07/2020 | 02/07/2020 | Yes |  | . |
| 60 | MG | 20/01/2022 | 20/01/2022 | Yes |  | . |
| 15 | ML/HR | 06/02/2021 | 06/02/2021 | No | 07/02/2021 | 07/02/2021 |
| N = 3 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Antiplatelet functional test at 12 months visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 82 |  | 82 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (7.3%) | 3 (6.3%) | 9 (6.9%) |
|  | Yes | 76 (92.7%) | 45 (93.8%) | 121 (93.1%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 76 |  | 76 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 71 (93.4%) | 42 (93.3%) | 113 (93.4%) |
|  | Aspirin resistance | 1 (1.3%) |  | 1 (0.8%) |
|  | Plavix resistance | 4 (5.3%) | 3 (6.7%) | 7 (5.8%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 5 |  | 5 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 5 (100.0%) | 3 (100.0%) | 8 (100.0%) |

**FRITS**

**EFFICACY**

**Table : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.3%) |  | 1 (0.8%) |
|  | Single antiplatelet therapy | 54 (68.4%) | 28 (62.2%) | 82 (66.1%) |
|  | Dual antiplatelet therapy | 23 (29.1%) | 14 (31.1%) | 37 (29.8%) |
|  | Triple antiplatelet therapy | 1 (1.3%) | 3 (6.7%) | 4 (3.2%) |
|  | Between group test |  |  | 0.346 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 54 |  | 54 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 53 (98.1%) | 28 (100.0%) | 81 (98.8%) |
|  | Ticlagrelor (Brilique) | 1 (1.9%) |  | 1 (1.2%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 23 |  | 23 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 20 (87.0%) | 12 (85.7%) | 32 (86.5%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 1 (4.3%) | 2 (14.3%) | 3 (8.1%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 1 (4.3%) |  | 1 (2.7%) |
|  | ASA (Aspirin) + Other | 1 (4.3%) |  | 1 (2.7%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 1 |  | 1 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (100.0%) | 1 (33.3%) | 2 (50.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 0 | 1 (33.3%) | 1 (25.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (25.0%) |

**FRITS**

**EFFICACY**

**Table : Listing of patient without antiplatelet medications at 12-month visit (INVESTIGATORS) [PP - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 04-005 | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| N = 2 | | | | | | | |

| **Full Analysis Set (FAS) at 6-month follow-up visit** | **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| Yes | Yes | Yes | Yes | 62 | Female | FRED / FRED Jr | FRED |
| N = 2 | | | | | | | |

| **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** | **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| 04/11/2019 | 1 | 0 | . | . | . | . | . | . |
| N = 2 | | | | | | | | |

| **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** | **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | 12 | No treatment | . | . | . |
| . | . | . | . | 12 | No treatment | . | . | . |
| N = 2 | | | | | | | | |

| **Study name** | **Visit num** | **Visit name** | **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet |
| FRITS | 4 | FU 1 YEAR | No | 07/11/2019 | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet |
| N = 2 | | | | | | | | |

| **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| ASA (Aspirin) |  | 100 | MG | 30/10/2019 | 30/10/2019 | No | 01/04/2020 | 01/04/2020 |
| Clopidogrel (Plavix) |  | 75 | MG | 30/10/2019 | 30/10/2019 | No | 04/02/2020 | 04/02/2020 |
| N = 2 | | | | | | | | |

**FRITS**

**EFFICACY**

**Table : Listing of patient with other antiplatelet medications at 12-month visit [PP - N= 1 patient]**

| **Subject Identifier for the Study** | **Intent-To-Treat (ITT) at procedure** | **Full Analysis Set (FAS)at procedure** | **Per Protocol(PP) at procedure visit** | **Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit** | **Full Analysis Set (FAS) at 12-month follow-up visit** | **Per Protocol(PP) at 12-month follow-up visit** | **Full Analysis Set (FAS) at 6-month follow-up visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | Yes |
| 07-041 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| 08-008 | Yes | Yes | Yes | Yes | Yes | Yes | Yes | No |
| N = 3 | | | | | | | | |

| **Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit** | **Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit** | **Per Protocol(PP) at 6-month follow-up visit** | **Age calculated** | **Gender** | **Subgroup device** | **FRED used type** | **PROCEDURE DATE** | **all** | **Antiplatelet therapy at the 12-month visit** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | No | 73 | Female | FRED / FRED Jr | FRED | 22/06/2020 | 1 | 1 |
| No | No | No | 76 | Female | FRED X | FRED X | 12/01/2022 | 1 | 1 |
| No | No | No | 68 | Male | FRED / FRED Jr | FRED | 10/11/2020 | 1 | 1 |
| N = 3 | | | | | | | | | |

| **ASA (Aspirin)** | **Clopidogrel (Plavix)** | **Ticlopidine (Ticlid)** | **Prasugrel (Efient)** | **Ticlagrelor (Brilique)** | **Warfarin (Coumadin)** | **Acenocoumarol (Mini-Sintrom)** | **Acenocoumarol (Sintrom)** | **Fluindione (Previscan)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| . | . | . | . | . | . | . | . | . |
| N = 3 | | | | | | | | |

| **Other** | **i** | **Antiplatelet therapy** | **Single antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **Study name** | **Visit num** | **Visit name** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1 | 12 | Dual antiplatelet therapy | . | ASA (Aspirin) + Other | . | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| 1 | 12 | Triple antiplatelet therapy | . | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | FRITS | 4 | FU 1 YEAR |
| N = 3 | | | | | | | | |

| **Premedication/Concomitant therapy** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type** | **Treatment name** | **Other treatment specification** |
| --- | --- | --- | --- | --- | --- | --- | --- |
| No | 25/06/2020 | 18/12/2020 | 11/06/2021 | 3 | Antiplatelet | Other | ELIQUIS |
| No | 22/01/2022 | . | 27/02/2023 | 3 | Antiplatelet | Other | EDOXABAN |
| Yes | 16/11/2020 | . | 08/11/2021 | 4 | Antiplatelet | Other | TIROFIBAN |
| N = 3 | | | | | | | |

| **Daily dose** | **Unit** | **Start date (c)** | **Start date** | **Ongoing** | **End date (c)** | **End date** |
| --- | --- | --- | --- | --- | --- | --- |
| 10 | MG | 02/07/2020 | 02/07/2020 | Yes |  | . |
| 60 | MG | 20/01/2022 | 20/01/2022 | Yes |  | . |
| 15 | ML/HR | 06/02/2021 | 06/02/2021 | No | 07/02/2021 | 07/02/2021 |
| N = 3 | | | | | | |

**FRITS**

**EFFICACY**

**Table : Antiplatelet functional test at 12 months visit (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 79 |  | 79 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (7.6%) | 2 (4.4%) | 8 (6.5%) |
|  | Yes | 73 (92.4%) | 43 (95.6%) | 116 (93.5%) |
|  | Between group test |  |  | 0.710 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 73 |  | 73 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 68 (93.2%) | 40 (93.0%) | 108 (93.1%) |
|  | Aspirin resistance | 1 (1.4%) |  | 1 (0.9%) |
|  | Plavix resistance | 4 (5.5%) | 3 (7.0%) | 7 (6.0%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 5 |  | 5 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 5 (100.0%) | 3 (100.0%) | 8 (100.0%) |