**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 |