**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 |