**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

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

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

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

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

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

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

**FRITS**

**Complications**

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

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

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

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

**FRITS**

**Complications**

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

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

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

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

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

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

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

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

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

**FRITS**

**Complications**

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

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

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

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

**FRITS**

**Complications**

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

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

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

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