**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

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

**FRITS**

**Complications**

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

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

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

**FRITS**

**Complications**

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

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

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

**FRITS**

**Complications**

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

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

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

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