**FRITS: FRED™/FRED™ Jr/ FRED™ X Intracranial aneurysm Treatment Study**

**Protocol FRITS**

Protocol No. 18-01

Version 1.0 – 9 July 2018

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|  | **MicroVention Europe**  2 avenue Edouard BELIN  92500 RUEIL MALMAISON  France |

Interim Statistical report

Version 0.5

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| Author: | STATITEC  Dienabou SYLLA |

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| --- | --- | --- | --- |
| **Fonction** | **Nom** | **Date** | **Signature** |
| Clinical Research Manager  MICROVENTION Europe | Hermien ATASSI |  |  |
| Coordinating Principal Investigator | Prof. Dr. med Arndt Dörfler |  |  |
| Statistician reviewer  CRO – STATITEC | Karine ANDRE |  |  |
| Statistician  CRO – STATITEC | Dienabou SYLLA |  |  |

TABLE OF CONTENTS

[1. Introduction 11](#_Toc163236736)

[2. Disposition of patients in the interim analysis 11](#_Toc163236737)

[2.1. Data sets analysed 11](#_Toc163236738)

[2.1.1. At procedure 16](#_Toc163236739)

[2.1.2. 6 months 18](#_Toc163236740)

[2.1.3. 12 months 22](#_Toc163236741)

[2.2. Study premature end 26](#_Toc163236742)

[3. Treatment at 12 months visit 28](#_Toc163236743)

[4. Efficacy results 31](#_Toc163236744)

[4.1. Type of imaging at 6 months and 12 months 31](#_Toc163236745)

[4.1.1. 6 months 31](#_Toc163236746)

[4.1.2. 12 months 32](#_Toc163236747)

[4.2. Anatomical results at procedure 6 months and 12 months 33](#_Toc163236748)

[4.2.1. At procedure 33](#_Toc163236749)

[4.2.2. 6 months 37](#_Toc163236750)

[4.2.3. 12 months 43](#_Toc163236751)

[4.2.4. Evolution of aneurysm occlusion between 6 months and 12 months 53](#_Toc163236752)

[5. Primary Efficacy endpoint 57](#_Toc163236753)

[5.1. 6 months 57](#_Toc163236754)

[5.2. 12 months 57](#_Toc163236755)

[6. Safety results 60](#_Toc163236756)

[6.1. Morbidity Rate at 12 months 60](#_Toc163236757)

[6.2. Mortality rate at 12 months 62](#_Toc163236758)

[6.3. Complications 62](#_Toc163236759)

[6.3.1. All complications until 12 months for all patients 62](#_Toc163236760)

[6.3.2. Complications until 12 months for ITT population 65](#_Toc163236761)

[6.3.3. Post-procedural complications between 6 months and 12 months for ITT population 67](#_Toc163236762)

[7. APPENDIX 75](#_Toc163236763)

[7.1. APPENDIX 1 Treatment at 12 months visit in FAS population 75](#_Toc163236764)

[7.1.1. In FAS population 75](#_Toc163236765)

[7.1.2. In PP population 77](#_Toc163236766)

[7.2. APPENDIX 2 – RESULTS IN THE PP POPULATION FOR EFFICACY ANALYSIS 79](#_Toc163236767)

[7.2.1. Type of imaging at 6 months and 12 months 79](#_Toc163236768)

[7.2.1.1. 6 months 79](#_Toc163236769)

[7.2.1.2. 12 months 80](#_Toc163236770)

[7.2.2. Anatomical results procedure, at 6 and 12 months 81](#_Toc163236771)

[7.2.2.1. At procedure 81](#_Toc163236772)

[7.2.2.2. 6 months 84](#_Toc163236773)

[7.2.2.3. 12 months 90](#_Toc163236774)

[7.2.2.4. Evolution of aneurysm occlusion between 6 months and 12 months 99](#_Toc163236775)

[7.2.3. Primary Efficacy endpoint 103](#_Toc163236776)

[7.3. APPENDIX 3 – RESULTS IN THE FAS AND PP POPULATIONS FOR SAFETY ANALYSIS 104](#_Toc163236777)

[7.3.1. Morbidity Rate at 12 months in FAS population 104](#_Toc163236778)

[7.3.2. Morbidity Rate at 12 months in PP population 106](#_Toc163236779)

[7.3.3. Complications 108](#_Toc163236780)

[7.3.3.1. All complications until 12 months for FAS population from 139 patients 108](#_Toc163236781)

[7.3.3.2. Complications until 12 months for FAS population 111](#_Toc163236782)

[7.3.3.3. Complications until 12 months for PP population 113](#_Toc163236783)

[7.3.3.4. Post-procedural complications between 6 months and 12 months for FAS population 116](#_Toc163236784)

[7.3.3.5. Post-procedural complications between 6 months and 12 months for PP population 124](#_Toc163236785)

[7.4. APPENDIX 4 – LISTING OF ALL COMPLICATIONS UNTIL 12 MONTHS 129](#_Toc163236786)

[7.4.1. All patients 129](#_Toc163236787)

[7.4.2. All patients – FAS population from 139 patients 143](#_Toc163236788)

[7.4.3. ITT population from 143 patients 153](#_Toc163236789)

[7.4.4. FAS population from 130 patients 164](#_Toc163236790)

[7.4.5. PP population from 124 patients 174](#_Toc163236791)

LIST OF TABLES

[**Table 1 : Data sets analysed [Included patients (N=156 patients)]** 11](#_Toc163237059)

[**Table 2 : Listing of patients with no FRED implanted [N= 2 patients]**  14](#_Toc163237060)

[**Table 3 : Listing of retreated patients at 12-month [N= 3 patients])** 14](#_Toc163237061)

[**Table 4 : Listing of patients not assessed by Core lab at 12-month (CORELAB) [N= 2 patients])** 14](#_Toc163237062)

[**Table 5 : Listing of analyzed patients into Intent-To-Treat (ITT) at procedure [Included patients (N=156 patients)]** 16](#_Toc163237063)

[**Table 6 : Listing of analyzed patients in Full Analysis Set (FAS) at procedure [Included patients (N=139 patients)]** 17](#_Toc163237064)

[**Table 7 : Listing of analyzed patients into Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit [Included patients (N=136 patients)]** 18](#_Toc163237065)

[**Table 8 : Listing of analyzed patients into Full Analysis Set (FAS) for safety analysis at 6-month follow-up visit [Included patients (N=122 patients)]** 19](#_Toc163237066)

[**Table 9 : Listing of analyzed patients into Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit [Included patients (N=129 patients)]** 20](#_Toc163237067)

[**Table 10 : Listing of analyzed patients into Per-Protocol (PP) for efficacy analysis at 6-month follow-up visit [Included patients (N=117 patients)]** 21](#_Toc163237068)

[**Table 11 : Listing of analyzed patients into Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit [Included patients (N=143 patients)]** 22](#_Toc163237069)

[**Table 12 : Listing of analyzed patients into Full Analysis Set (FAS) for safety analysis at 12-month follow-up visit [Included patients (N=130 patients)]** 23](#_Toc163237070)

[**Table 13 : Listing of analyzed patients into Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit [Included patients (N=136 patients)]** 24](#_Toc163237071)

[**Table 14 : Listing of analyzed patients into Per-Protocol (PP) for efficacy analysis and safety analysis at 12-month follow-up visit [Included patients (N=124 patients)]** 25](#_Toc163237072)

[**Table 15 : Study premature end [ITT - N=1 patients]** 26](#_Toc163237073)

[**Table 16 : Listing of patients with premature study end study [ITT - N=1 patient]** 27](#_Toc163237074)

[**Table 17 : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N=143 patients]** 28](#_Toc163237075)

[**Table 18 : Listing of patients without antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 1 patient]** 29](#_Toc163237076)

[**Table 19 : Listing of patients with other antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 3 patients]** 29](#_Toc163237077)

[**Table 20 :Antiplatelet functional test at 12 months visit (INVESTIGATORS) [ITT - N=143 patients]** 29](#_Toc163237078)

[**Table 21 : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [ITT - N=129 patients]** 31](#_Toc163237079)

[**Table 22 : TIME OF IMAGING AT 6-MONTHS FOLLOW-UP (CORELAB) [ITT - N=129 patients]** 31](#_Toc163237080)

[**Table 23 : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [ITT - N=136 patients]** 32](#_Toc163237081)

[**Table 24 : TIME OF IMAGING AT 12-MONTHS FOLLOW-UP (CORELAB) [ITT - N=136 patients]** 32](#_Toc163237082)

[**Table 25 : Aneurysm filling at procedure (CORELAB) [ITT - N=154 patients]** 33](#_Toc163237083)

[**Table 26 : Aneurysm filling for patients without FRED implanted (CORELAB) [ITT - N=2 patients]** 33](#_Toc163237084)

[**Table 27 : Stasis status at procedure (CORELAB) [ITT - N=154 patients]** 33](#_Toc163237085)

[**Table 28 : OKM scale at procedure (CORELAB) [ITT - N=154 patients]** 34](#_Toc163237086)

[**Table 29 : OKM grade at procedure (CORELAB) [ITT - N=154 patients]** 34](#_Toc163237087)

[**Table 30 : Permeability of the Parent Artery at the procedure (CORELAB) [ITT - N=154 patients]** 35](#_Toc163237088)

[**Table 31 : Flow diverter cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]** 35](#_Toc163237089)

[**Table 32 : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]** 35](#_Toc163237090)

[**Table 33 : Aneurysm complete occlusion rate (Raymond score) at 6 months (CORELAB) [ITT - N=129 patients]** 37](#_Toc163237091)

[**Table 34 : Aneurysm complete occlusion rate (OKM score) at 6 months (CORELAB) [ITT - N=129 patients]** 37](#_Toc163237092)

[**Table 35 : Adequate occlusion rate (Raymond score) at 6 months (CORELAB) [ITT - N=129 patients]** 37](#_Toc163237093)

[**Table 36 : Adequate occlusion rate (OKM score) at 6 months (CORELAB) [ITT - N=129 patients]** 37](#_Toc163237094)

[**Table 37 : Occlusion degree (Raymond-Roy score) at 6 months (CORELAB) [ITT - N=129 patients]** 38](#_Toc163237095)

[**Table 38 : Aneurysm filling at 6 months (CORELAB) [ITT - N=129 patients]** 38](#_Toc163237096)

[**Table 39 : Stasis phase at 6 months (CORELAB) [ITT - N=129 patients]** 40](#_Toc163237097)

[**Table 40 : OKM scale at 6 months (CORELAB) [ITT - N=129 patients]** 40](#_Toc163237098)

[**Table 41 : OKM grade at 6 months (CORELAB) [ITT - N=129 patients]** 40](#_Toc163237099)

[**Table 42 : Aneurysm sac size change at 6 months (CORELAB) [ITT - N=129 patients]** 40](#_Toc163237100)

[**Table 43 : Stent Stability at 6 months (CORELAB) [ITT - N=129 patients]** 41](#_Toc163237101)

[**Table 44 : Stent covering the neck at 6 months (CORELAB) [ITT - N=129 patients]** 41](#_Toc163237102)

[**Table 45 : Parent artery permeability at 6 months (CORELAB) [ITT - N=129 patients]** 41](#_Toc163237103)

[**Table 46 : Retreatment rate at 6 months (CORELAB) [ITT - N=129 patients]** 42](#_Toc163237104)

[**Table 47 : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]** 43](#_Toc163237105)

[**Table 48 : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]** 43](#_Toc163237106)

[**Table 49 : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]** 43](#_Toc163237107)

[**Table 50 : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]** 44](#_Toc163237108)

[**Table 51 : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [ITT - N=136 patients]** 44](#_Toc163237109)

[**Table 52 : Aneurysm filling at 12 months (CORELAB) [ITT - N=136 patients]** 45](#_Toc163237110)

[**Table 53 : Aneurysm Occlusion stability at 12 months (CORELAB) [ITT - N=136 patients]** 46](#_Toc163237111)

[**Table 54 : Stasis phase at 12 months (CORELAB) [ITT - N=136 patients]** 48](#_Toc163237112)

[**Table 55 : OKM scale at 12 months (CORELAB) [ITT - N=136 patients]** 48](#_Toc163237113)

[**Table 56 : OKM grade at 12 months (CORELAB) [ITT - N=136 patients** 49](#_Toc163237114)

[**Table 57 : Aneurysm sac size change at 12 months (CORELAB) [ITT - N=136 patients]** 49](#_Toc163237115)

[**Table 58 : Stent Stability at 12 months (CORELAB) [ITT - N=136 patients]** 49](#_Toc163237116)

[**Table 59 : Stent covering the neck at 12 months (CORELAB) [ITT - N=136 patients]** 50](#_Toc163237117)

[**Table 60 : Parent artery permeability at 12 months (CORELAB) [ITT - N=136 patients]** 50](#_Toc163237118)

[**Table 61 : Retreatment rate at 12 months (INVESTIGATORS) [ITT - N=143 patients]** 51](#_Toc163237119)

[**Table 62 : Change of aneurysm occlusion stability at 12 months compared with 6 months (CORELAB) [ITT - N=116 patients]** 53](#_Toc163237120)

[**Table 63 : Change of aneurysm occlusion degree (Raymond-Roy score) at 12 months compared with 6 months (CORELAB) [ITT - N=116 patients]** 53](#_Toc163237121)

[**Table 64 : Rate of complete aneurysm occlusion at 6 months** without associated stenosis of the parent artery **(CORELAB) [ITT - N=129 patients]** 57](#_Toc163237122)

[**Table 65 : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [ITT - N=136 patients]** 57](#_Toc163237123)

[**Table 66 : Parent artery permeability at 12 months (CORELAB) [ITT - N=136 patients]** 58](#_Toc163237124)

[**Table 67 : Rate of complete aneurysm occlusion at 12 months** without associated stenosis of the parent artery **(CORELAB) [ITT - N=136 patients]** 59](#_Toc163237125)

[**Table 68 : Morbidity rate at the 12-month visit (INVESTIGATORS) [ITT - N=143 patients]** 60](#_Toc163237126)

[**Table 69 : mRS score at the 12-month visit (INVESTIGATORS) [ITT - N=143 patients]** 60](#_Toc163237127)

[**Table 70 : mRS change between baseline and 12-month visit (INVESTIGATORS) [ITT - N=143 patients]** 61](#_Toc163237128)

[**Table 71 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 156 patients [All patients - N=156 patients]** 62](#_Toc163237129)

[**Table 72 : Description of all complications until 12-month follow-up (CEC) from 156 patients [All patients- N=49 patients - 70 complications]** 62](#_Toc163237130)

[**Table 73 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 143 patients [ITT at 12-month - N=143 patients]** 65](#_Toc163237131)

[**Table 74 : Description of all complications until 12-month follow-up (CEC) from 143 patients [ITT - N=42 patients - 59 complications]** 65](#_Toc163237132)

[**Table 75 : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=143 patients]** 67](#_Toc163237133)

[**Table 76 : Description of post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=11 patients - 11 complications]** 68](#_Toc163237134)

[**Table 77 : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N= 9 patients - 9 complications]**  72](#_Toc163237135)

[**Table 78 : Listing of all post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=11 patients - 11complications]** 73](#_Toc163237136)

[**Table 79 : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=2 patients - 2 complications]** 74](#_Toc163237137)

[**Table 80 : Number and type of antiplatelet medications at 12-month visit [FAS - N=130 patients]** 75](#_Toc163237138)

[**Table 81 : Listing of patient without antiplatelet medications at 12-month visit [FAS - N= 1 patient]** 76](#_Toc163237139)

[**Table 82 : Listing of patient without antiplatelet medications at 12-month visit [FAS - N= 3 patients]** 76](#_Toc163237140)

[**Table 83 :** **Antiplatelet functional test at 12 months visit [FAS - N=130 patients]** 76](#_Toc163237141)

[**Table 84 : Number and type of antiplatelet medications at 12-month visit [PP - N=124 patients]** 77](#_Toc163237142)

[**Table 85 : Listing of patient without antiplatelet medications at 12-month visit [PP - N= 1 patient]** 78](#_Toc163237143)

[**Table 86 : Listing of patient without antiplatelet medications at 12-month visit [PP - N= 3 patients]** 78](#_Toc163237144)

[**Table 87 :** **Antiplatelet functional test at 12 months visit [PP - N=124 patients]** 78](#_Toc163237145)

[**Table 88 : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [PP - N=117 patients]** 79](#_Toc163237146)

[**Table 89 : TIME OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [PP - N=117 patients]** 79](#_Toc163237147)

[**Table 90 : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [PP - N=124 patients]** 80](#_Toc163237148)

[**Table 91 : TIME OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [PP - N=124 patients]** 80](#_Toc163237149)

[**Table 92 : Aneurysm filling at procedure (CORELAB) [PP - N=138 patients]** 81](#_Toc163237150)

[**Table 93 : Stasis status at procedure (CORELAB) [PP - N=138 patients]** 81](#_Toc163237151)

[**Table 94 : OKM scale at procedure (CORELAB) [PP - N=138 patients]** 82](#_Toc163237152)

[**Table 95 : OKM scale at procedure (CORELAB) [PP - N=138 patients]** 82](#_Toc163237153)

[**Table 96 : Flow diverter cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]** 82](#_Toc163237154)

[**Table 97 : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]** 83](#_Toc163237155)

[**Table 98 : Aneurysm complete occlusion rate (Raymond score) at 6 months (CORELAB) [PP - N=117 patients]** 84](#_Toc163237156)

[**Table 99 : Aneurysm complete occlusion rate (OKM score) at 6 months (CORELAB) [PP - N=117 patients]** 84](#_Toc163237157)

[**Table 100 : Adequate occlusion rate (Raymond score) at 6 months (CORELAB) [PP - N=117 patients]** 84](#_Toc163237158)

[**Table 101 : Adequate occlusion rate OKM score) at 6 months (CORELAB) [PP - N=117 patients]** 84](#_Toc163237159)

[**Table 102 : Occlusion degree (Raymond-Roy score) at 6 months (CORELAB) [PP - N=117 patients]** 85](#_Toc163237160)

[**Table 103 : Aneurysm filling at 6 months (CORELAB) [PP - N=117 patients]** 86](#_Toc163237161)

[**Table 104 : Aneurysm Occlusion stability at 6 months (CORELAB) [PP - N=117 patients]** 86](#_Toc163237162)

[**Table 105 : Stasis phase at 6 months (CORELAB) [PP - N=117 patients]** 87](#_Toc163237163)

[**Table 106 : OKM scale at 6 months (CORELAB) [PP - N=117 patients]** 87](#_Toc163237164)

[**Table 107 : OKM grade at 6 months (CORELAB) [PP - N=117 patients]** 87](#_Toc163237165)

[**Table 108 : Aneurysm sac size change at 6 months (CORELAB) [PP - N=117 patients]** 87](#_Toc163237166)

[**Table 109 : Stent Stability at 6 months (CORELAB) [PP - N=117 patients]** 88](#_Toc163237167)

[**Table 110 : Stent covering the neck at 6 months (CORELAB) [PP - N=117 patients]** 89](#_Toc163237168)

[**Table 111 : Parent artery permeability at 6 months (CORELAB) [PP - N=117 patients]** 89](#_Toc163237169)

[**Table 112 : Retreatment rate at 6 months (CORELAB) [PP - N=117 patients]** 89](#_Toc163237170)

[**Table 113 : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]** 90](#_Toc163237171)

[**Table 114 : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]** 90](#_Toc163237172)

[**Table 115 : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]** 90](#_Toc163237173)

[**Table 116 : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]** 91](#_Toc163237174)

[**Table 117 : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [PP - N=124 patients** 91](#_Toc163237175)

[**Table 118 : Aneurysm filling at 12 months (CORELAB) [PP - N=124 patients]** 93](#_Toc163237176)

[**Table 119 : Aneurysm Occlusion stability at 12 months (CORELAB) [PP - N=124 patients]** 94](#_Toc163237177)

[**Table 120 : Stasis phase at 12 months (CORELAB) [PP - N=124 patients]** 94](#_Toc163237178)

[**Table 121 : OKM scale at 12 months (CORELAB) [PP - N=124 patients]** 95](#_Toc163237179)

[**Table 122 : OKM grade at 12 months (CORELAB) [PP - N=124 patients]** 95](#_Toc163237180)

[**Table 123 : Aneurysm sac size change at 12 months (CORELAB) [PP - N=124 patients]** 95](#_Toc163237181)

[**Table 124 : Stent Stability at 12 months (CORELAB) [PP - N=124 patients]** 96](#_Toc163237182)

[**Table 125 : Stent covering the neck at 12 months (CORELAB) [PP - N=124 patients]** 96](#_Toc163237183)

[**Table 126 : Parent artery permeability at 12 months (CORELAB) [PP - N=124 patients]** 97](#_Toc163237184)

[**Table 127 : Retreatment rate at 12 months (INVESTIGATORS) [PP - N=129 patients]** 98](#_Toc163237185)

[**Table 128 : Change of aneurysm occlusion stability at 12 months compared with 6 months (CORELAB) [PP - N=108 patients]** 99](#_Toc163237186)

[**Table 129 : Change of aneurysm occlusion degree (Raymond-Roy score) at 12 months compared with 6 months (CORELAB) [PP - N=108 patients]** 100](#_Toc163237187)

[**Table 130 : Rate of complete aneurysm occlusion at 6 months without associated stenosis of the parent artery (CORELAB) [PP - N=117 patients]** 103](#_Toc163237188)

[**Table 131 : Rate of complete aneurysm occlusion at 12 months without associated stenosis of the parent artery (CORELAB) [PP - N=124 patients]** 103](#_Toc163237189)

[**Table 132 : Morbidity rate at the 12-month visit (INVESTIGATORS) [FAS - N=130 patients]** 104](#_Toc163237190)

[**Table 133 : mRS score at the 12-month visit (INVESTIGATORS) [FAS - N=130 patients]** 104](#_Toc163237191)

[**Table 134 : mRS change between baseline and 12-month visit (INVESTIGATORS) [FAS - N=130 patients]** 105](#_Toc163237192)

[**Table 135 : Morbidity rate at the 12-month visit (INVESTIGATORS) [PP - N=124 patients]** 106](#_Toc163237193)

[**Table 136 : mRS score at the 12-month visit (INVESTIGATORS) [FAS - N=130 patients]** 106](#_Toc163237194)

[**Table 137 : mRS change between baseline and 12-month visit (INVESTIGATORS) [PP - N=124 patients]** 106](#_Toc163237195)

[**Table 138 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 139 patients [All patients - N=139 patients]** 108](#_Toc163237196)

[**Table 139 : Description of all complications until 12-month follow-up (CEC) from 139 patients [All patients - N=43 patients - 60 complications]** 108](#_Toc163237197)

[**Table 140 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 130 patients [FAS - N=130 patients]** 111](#_Toc163237198)

[**Table 141 : Description of all complications until 12-month follow-up (CEC) from 130 patients [FAS - N=38 patients - 55 complications]** 111](#_Toc163237199)

[**Table 142 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 124 patients [PP - N=124 patients]** 113](#_Toc163237200)

[**Table 143 : Description of all complications until 12-month follow-up (CEC) from 124 patients [PP - N=37 patients – 53 complications]** 113](#_Toc163237201)

[**Table 144 : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=130 patients]** 116](#_Toc163237202)

[**Table 145 : Description of post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=10 patients - 10 complications]** 117](#_Toc163237203)

[**Table 146 : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=8 patients - 8 complications]** 121](#_Toc163237204)

[**Table 147 : Listing of all post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=10 patients - 10 complications]** 122](#_Toc163237205)

[**Table 148 : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=2 patients - 2 complications]** 123](#_Toc163237206)

[**Table 149 : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=124 patients]** 124](#_Toc163237207)

[**Table 150 : Description of post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=10 patients - 10 complications]** 125](#_Toc163237208)

[**Table 151 : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=8 patients - 8 complications]** 127](#_Toc163237209)

[**Table 152 : Listing of all post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=10 patients - 10 complications]** 127](#_Toc163237210)

[**Table 153 : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) from 124 patients [PP - N=2 patients - 2 complications]** 128](#_Toc163237211)

[**Table 154 : Listing of other complications until 12-month (CEC) from 156 patients [All patients - N=36 patients - 45 complications]** 129](#_Toc163237212)

[**Table 155 : Listing of all complications until 12-month (CEC) from 156 patients [All patients- N=49 patients - 70 complications]**  132](#_Toc163237213)

[**Table 156 : Listing of all Thromboembolic complications until 12-month (CEC) from 156 patients [All patients - N=17 patients - 19 complications]** 140](#_Toc163237214)

[**Table 157 : Listing of other complications until 12-month (CEC) from 139 patients [All patients - N=31 patients - 39 complications]** 143](#_Toc163237215)

[**Table 158 : Listing of all complications until 12-month (CEC) from 139 patients [All patients- N=43 patients - 60 complications]** 146](#_Toc163237216)

[**Table 159 : Listing of all Thromboembolic complications until 12-month (CEC) from 139 patients [All patients - N=14 patients - 16 complications]** 151](#_Toc163237217)

[**Table 160 : Listing of other complications until 12-month (CEC) from 143 patients [ITT - N=32 patients - 40 complications]** 153](#_Toc163237218)

[**Table 161 : Listing of all complications until 12-month (CEC) from the 143 patients [ITT - N=42 patients - 59 complications]** 157](#_Toc163237219)

[**Table 162 : Listing of all Thromboembolic complications until 12-month (CEC) from the 143 patients [ITT - N=16 patients - 16 complications]** 162](#_Toc163237220)

[**Table 163 : Listing of other complications until 12-month (CEC) from 130 patients [FAS - N=29 patients - 37 complications]** 164](#_Toc163237221)

[**Table 164 : Listing of all complications until 12-month (CEC) from 130 patients [FAS - N=38 patients - 55 complications]** 167](#_Toc163237222)

[**Table 165 : Listing of all Thromboembolic complications until 12-month (CEC) from the 143 patients [FAS - N=13 patients - 15 complications]** 172](#_Toc163237223)

[**Table 166 : Listing of other complications until 12-month (CEC) from 124 patients [PP - N=28 patients - 36 complications]** 174](#_Toc163237224)

[**Table 167 : Listing of all complications until 12-month (CEC) from 124 patients [PP - N=37 patients - 53 complications]** 176](#_Toc163237225)

[**Table 168 : Listing of all Thromboembolic complications until 12-month (CEC) from the 124 patients [PP - N=12 patients - 14 complications]** 180](#_Toc163237226)

LIST OF FIGURES

[Figure 1: **CONSORT flow diagram for ITT analysis** 13](#_Toc163237227)

[Figure 2: **CONSORT flow diagram for FAS / PP analysis** 13](#_Toc163237228)

# ****Introduction****

This interim analysis was performed with all patients until the 12-month follow-up visit.

This report presents results of all descriptive and comparative analyses on all patients until the 12-month follow-up, as planned in the Statistical Analysis Plan V 1.0 of\_20230313 of the study.

# ****Disposition of patients in the interim analysis****

## Data sets analysed

For this interim analysis at 12 months follow-up, 130 patients had data available at the time of database freeze for the efficacy analysis, and 143 patients had data available for the safety analysis. The patients included in each of the analysis populations are detailed in the table,the CONSORT flow diagrams and listings below.

**Table 1 : Data sets analysed [Included patients (N=156 patients)]**

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

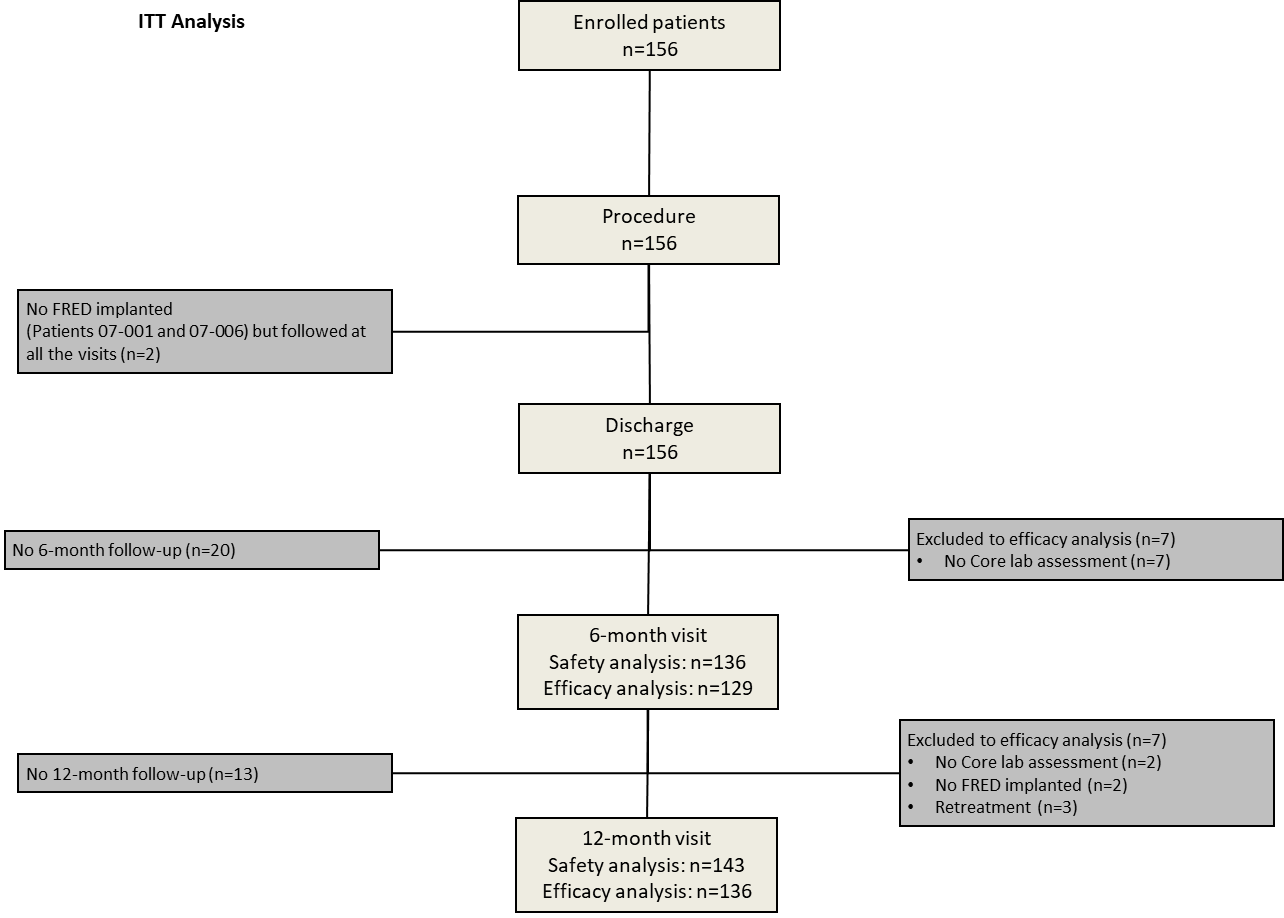
****

Figure 1: **CONSORT flow diagram for ITT analysis**

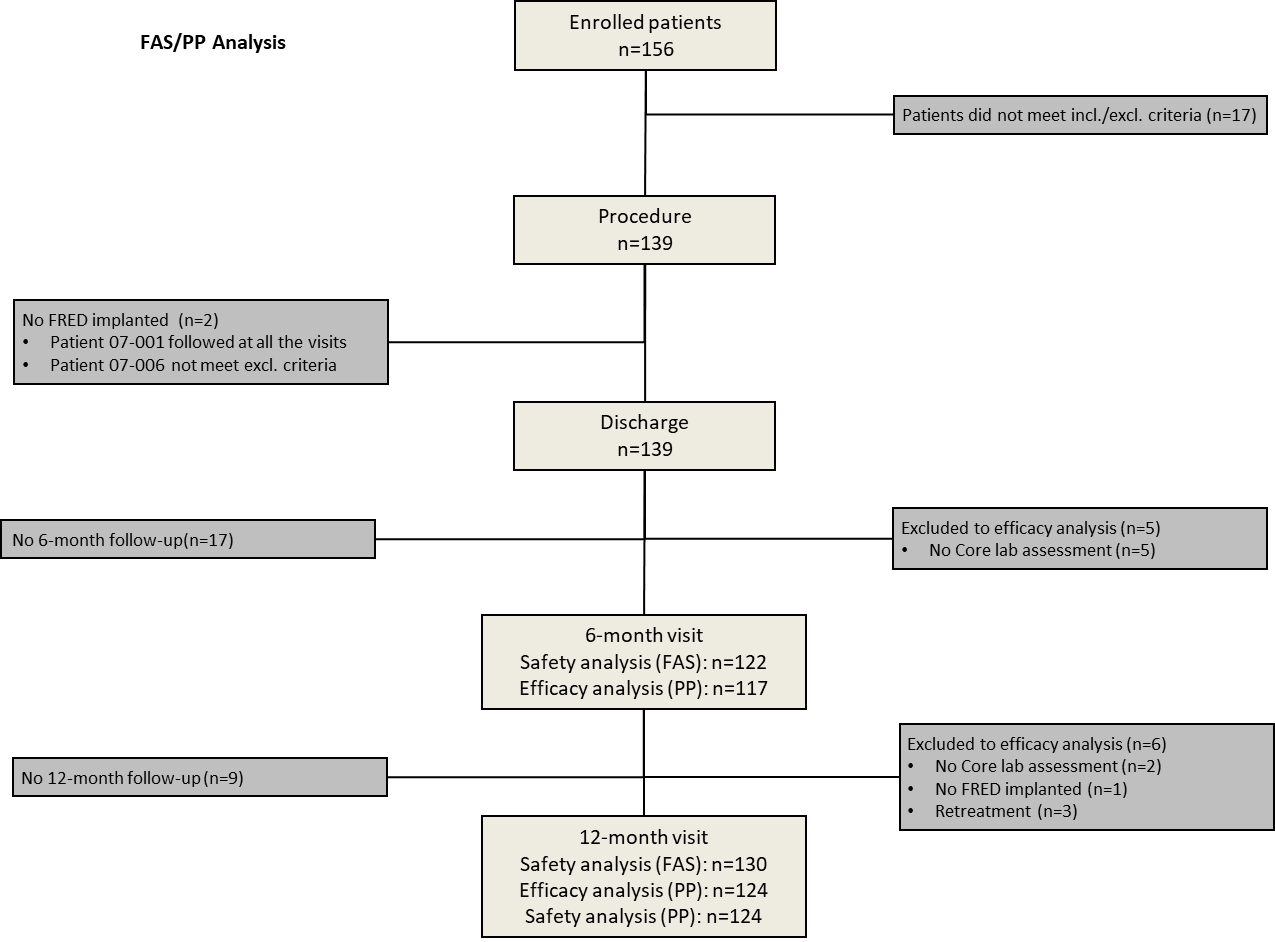


Figure 2: **CONSORT flow diagram for FAS / PP analysis**

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

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| Subject Identifier for the Study | Subgroup device | Distal access catheter | Flow diverter implanted | Reason not implanted |
| 07-001 | FRED / FRED Jr | No | No | Tortuous anatomy of the parent artery |
| 07-006 | FRED / FRED Jr | No | No | Technical issues |

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



|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Subject Identifier for the Study** | **FRED used type** | **Subgroup device** | **PROCEDURE DATE** | **DISCHARGE** | **FU 6 MONTHS** | **FU 1 YEAR** | **1Y Retreatment: Date** | **Retreatment delay since the procedure (in months)** | **Retreatment delay** | **1Y: Coils implanted** | **1Y: Other intrasaccular device** | **1Y: Specify other intrasaccular device** | **1Y: Flow diverter** | **1Y: Specify flow diverter** | **1Y: retreatment specify other FD** | **1Y: retreatment FRED reference** | **1Y: retreatment FRED batch number** |
| 01-021 | FRED | FRED / FRED Jr | 19/05/2020 | 22/05/2020 | 09/10/2020 | 02/02/2021 | 02/02/2021 | 8.51 | Between 6 months and 12 months FU visit | . | . |  | checked | FRED |  | FRED3507 | 20040251Y |
| 05-004 | FRED X | FRED X | 30/04/2021 | 03/05/2021 | 02/08/2021 | 07/06/2022 | 02/09/2021 | 4.11 | Between 6 months and 12 months FU visit | . | . |  | checked | Other | SURPASS EVOLVE |  |  |
| 07-036 | FRED | FRED / FRED Jr | 21/10/2021 | 24/10/2021 | 05/04/2022 | 09/05/2023 | 13/05/2022 | 6.70 | Between 6 months and 12 months FU visit | checked | checked | ONYX EMBOLISATION | . | . |  |  |  |

**Table 4 : Listing of patients not assessed by Core lab at 12-month (CORELAB) [N= 2 patients])**

|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Subject Identifier for the Study | Intent-To-Treat (ITT) at 12-month follow-up visit | Full Analysis Set (FAS) at 12-month follow-up visit | Per Protocol(PP) at 12-month follow-up visit | Subgroup device | 1Y : Date of imaging (c) | 1Y : Imaging modality - Angiography | 1Y : Imaging modality - Magnetic Resonance Angiography | 1Y : Imaging modality - Angio-scanner | 1Y : Retreatment |
| 05-009 | Yes | Yes | Yes | FRED X |  | . | . | . | . |
| 08-019 | Yes | Yes | Yes | FRED X |  | . | . | . | . |

### At procedure

**Table 5 : Listing of analyzed patients into Intent-To-Treat (ITT) at procedure [Included patients (N=156 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-012 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-031 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-043 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 02-002 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-003 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-007 |
| 05-008 |
| 05-009 |
| 06-001 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-001 |
| 07-002 |
| 07-003 |
| 07-004 |
| 07-005 |
| 07-006 |
| 07-007 |
| 07-009 |
| 07-011 |
| 07-012 |
| 07-014 |
| 07-015 |
| 07-017 |
| 07-019 |
| 07-021 |
| 07-022 |
| 07-023 |
| 07-024 |
| 07-025 |
| 07-026 |
| 07-027 |
| 07-028 |
| 07-029 |
| 07-030 |
| 07-031 |
| 07-033 |
| 07-034 |
| 07-035 |
| 07-036 |
| 07-037 |
| 07-038 |
| 07-039 |
| 07-040 |
| 07-041 |
| 07-042 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-005 |
| 08-006 |
| 08-007 |
| 08-008 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-013 |
| 08-014 |
| 08-015 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 08-027 |
| 09-001 |

**Table 6 : Listing of analyzed patients in Full Analysis Set (FAS) at procedure [Included patients (N=139 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-012 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-043 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-008 |
| 05-009 |
| 06-001 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-001 |
| 07-002 |
| 07-003 |
| 07-005 |
| 07-009 |
| 07-011 |
| 07-019 |
| 07-022 |
| 07-024 |
| 07-025 |
| 07-026 |
| 07-027 |
| 07-028 |
| 07-029 |
| 07-030 |
| 07-031 |
| 07-034 |
| 07-035 |
| 07-036 |
| 07-037 |
| 07-038 |
| 07-039 |
| 07-040 |
| 07-041 |
| 07-042 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-006 |
| 08-007 |
| 08-008 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-014 |
| 08-015 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 09-001 |

### 6 months

**Table 7 : Listing of analyzed patients into Intent-To-Treat (ITT) for safety analysis at 6-month follow-up visit [Included patients (N=136 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-012 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-031 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-043 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 02-002 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-003 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-007 |
| 05-008 |
| 05-009 |
| 06-001 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-003 |
| 07-004 |
| 07-007 |
| 07-011 |
| 07-012 |
| 07-014 |
| 07-015 |
| 07-021 |
| 07-022 |
| 07-024 |
| 07-025 |
| 07-033 |
| 07-036 |
| 07-037 |
| 07-038 |
| 07-039 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-005 |
| 08-006 |
| 08-007 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-013 |
| 08-014 |
| 08-015 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 08-027 |
| 09-001 |

**Table 8 : Listing of analyzed patients into Full Analysis Set (FAS) for safety analysis at 6-month follow-up visit [Included patients (N=122 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-012 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-033 |
| 01-034 |
| 01-037 |
| 01-039 |
| 01-040 |
| 01-042 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-019 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-005 |
| 06-001 |
| 06-002 |
| 06-003 |
| 06-004 |
| 07-003 |
| 07-011 |
| 07-022 |
| 07-024 |
| 07-025 |
| 07-036 |
| 07-039 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-006 |
| 08-007 |
| 08-009 |
| 01-035 |
| 01-036 |
| 01-038 |
| 01-041 |
| 01-043 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-020 |
| 04-021 |
| 05-004 |
| 05-006 |
| 05-008 |
| 05-009 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-037 |
| 07-038 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-014 |
| 08-015 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 09-001 |

**Table 9 : Listing of analyzed patients into Intent-To-Treat (ITT) for efficacy analysis at 6-month follow-up visit [Included patients (N=129 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-012 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-031 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-043 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 02-002 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-003 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-007 |
| 05-008 |
| 05-009 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-007 |
| 07-011 |
| 07-012 |
| 07-014 |
| 07-015 |
| 07-022 |
| 07-033 |
| 07-036 |
| 07-037 |
| 07-039 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-005 |
| 08-006 |
| 08-007 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-013 |
| 08-014 |
| 08-015 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 08-027 |
| 09-001 |

**Table 10 : Listing of analyzed patients into Per-Protocol (PP) for efficacy analysis at 6-month follow-up visit [Included patients (N=117 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-012 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-043 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-008 |
| 05-009 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-011 |
| 07-022 |
| 07-036 |
| 07-037 |
| 07-039 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-006 |
| 08-007 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-014 |
| 08-015 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 09-001 |

### 12 months

**Table 11 : Listing of analyzed patients into Intent-To-Treat (ITT) for safety analysis at 12-month follow-up visit [Included patients (N=143 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-031 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 02-002 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-003 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-007 |
| 05-008 |
| 05-009 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-001 |
| 07-002 |
| 07-003 |
| 07-004 |
| 07-006 |
| 07-009 |
| 07-012 |
| 07-017 |
| 07-019 |
| 07-021 |
| 07-022 |
| 07-023 |
| 07-024 |
| 07-025 |
| 07-026 |
| 07-027 |
| 07-028 |
| 07-029 |
| 07-030 |
| 07-031 |
| 07-036 |
| 07-037 |
| 07-038 |
| 07-039 |
| 07-041 |
| 07-042 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-005 |
| 08-006 |
| 08-007 |
| 08-008 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-013 |
| 08-014 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 08-027 |
| 09-001 |

**Table 12 : Listing of analyzed patients into Full Analysis Set (FAS) for safety analysis at 12-month follow-up visit [Included patients (N=130 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-021 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-004 |
| 05-005 |
| 05-006 |
| 05-008 |
| 05-009 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-001 |
| 07-002 |
| 07-003 |
| 07-009 |
| 07-019 |
| 07-022 |
| 07-024 |
| 07-025 |
| 07-026 |
| 07-027 |
| 07-028 |
| 07-029 |
| 07-030 |
| 07-031 |
| 07-036 |
| 07-037 |
| 07-038 |
| 07-039 |
| 07-041 |
| 07-042 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-006 |
| 08-007 |
| 08-008 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-014 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-019 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 09-001 |

**Table 13 : Listing of analyzed patients into Intent-To-Treat (ITT) for efficacy analysis at 12-month follow-up visit [Included patients (N=136 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-031 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 02-002 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-003 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-005 |
| 05-006 |
| 05-007 |
| 05-008 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-002 |
| 07-003 |
| 07-004 |
| 07-009 |
| 07-012 |
| 07-017 |
| 07-019 |
| 07-021 |
| 07-022 |
| 07-023 |
| 07-024 |
| 07-025 |
| 07-026 |
| 07-027 |
| 07-028 |
| 07-029 |
| 07-030 |
| 07-031 |
| 07-037 |
| 07-038 |
| 07-039 |
| 07-041 |
| 07-042 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-005 |
| 08-006 |
| 08-007 |
| 08-008 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-013 |
| 08-014 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 08-027 |
| 09-001 |

**Table 14 : Listing of analyzed patients into Per-Protocol (PP) for efficacy analysis and safety analysis at 12-month follow-up visit [Included patients (N=124 patients)]**

| **Subject Identifier for the Study** |
| --- |
| 01-001 |
| 01-002 |
| 01-003 |
| 01-004 |
| 01-005 |
| 01-006 |
| 01-007 |
| 01-008 |
| 01-009 |
| 01-010 |
| 01-011 |
| 01-013 |
| 01-014 |
| 01-015 |
| 01-016 |
| 01-017 |
| 01-018 |
| 01-019 |
| 01-020 |
| 01-022 |
| 01-023 |
| 01-024 |
| 01-025 |
| 01-026 |
| 01-027 |
| 01-028 |
| 01-029 |
| 01-033 |
| 01-034 |
| 01-035 |
| 01-036 |
| 01-037 |
| 01-038 |
| 01-039 |
| 01-040 |
| 01-041 |
| 01-042 |
| 01-044 |
| 01-045 |
| 01-046 |
| 01-047 |
| 01-048 |
| 01-049 |
| 02-001 |
| 03-001 |
| 03-002 |
| 03-003 |
| 03-004 |
| 04-001 |
| 04-002 |
| 04-004 |
| 04-005 |
| 04-006 |
| 04-007 |
| 04-008 |
| 04-009 |
| 04-010 |
| 04-011 |
| 04-012 |
| 04-013 |
| 04-014 |
| 04-015 |
| 04-016 |
| 04-017 |
| 04-018 |
| 04-019 |
| 04-020 |
| 04-021 |
| 05-001 |
| 05-002 |
| 05-003 |
| 05-005 |
| 05-006 |
| 05-008 |
| 06-002 |
| 06-003 |
| 06-004 |
| 06-005 |
| 06-006 |
| 06-007 |
| 06-008 |
| 06-009 |
| 06-010 |
| 07-002 |
| 07-003 |
| 07-009 |
| 07-019 |
| 07-022 |
| 07-024 |
| 07-025 |
| 07-026 |
| 07-027 |
| 07-028 |
| 07-029 |
| 07-030 |
| 07-031 |
| 07-037 |
| 07-038 |
| 07-039 |
| 07-041 |
| 07-042 |
| 08-001 |
| 08-002 |
| 08-003 |
| 08-004 |
| 08-006 |
| 08-007 |
| 08-008 |
| 08-009 |
| 08-010 |
| 08-011 |
| 08-012 |
| 08-014 |
| 08-016 |
| 08-017 |
| 08-018 |
| 08-020 |
| 08-021 |
| 08-022 |
| 08-023 |
| 08-024 |
| 08-025 |
| 08-026 |
| 09-001 |

## Study premature end

**Table 15 : Study premature end [ITT - N=1 patients]**



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

The 1 patientwith study premature end are listed below:

**Table 16 : Listing of patients with premature study end study [ITT - N=1 patient]**



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

# ****Treatment at 12 months visit****

The analyses were performed on the ITT population, on the FAS population and on PP population and on investigator data. Results for the FAS population and PP population are presented in Appendix 1.

**Table 17 : Number and type of antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N=143 patients]**

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

**Table 18 : Listing of patients without antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 1 patient]**

| **Subject Identifier for the Study** | **Age calculated** | **Subgroup device** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type of antiplatelet therapy** | **Treatment name** | **Daily dose** | **Unit** | **Start date** | **Ongoing** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | 62 | FRED / FRED Jr | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet | ASA (Aspirin) | 100 | MG | 30/10/2019 | No | 01/04/2020 |
| 04-005 | 62 | FRED / FRED Jr | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet | Clopidogrel (Plavix) | 75 | MG | 30/10/2019 | No | 04/02/2020 |

**Table 19 : Listing of patients with other antiplatelet medications at 12-month visit (INVESTIGATORS) [ITT - N= 3 patients]**

| **Subject Identifier for the Study** | **Age calculated** | **Subgroup device** | **Antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **FU 6 MONTHS** | **FU 1 YEAR** | **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | 73 | FRED / FRED Jr | Dual antiplatelet therapy | ASA (Aspirin) + Other | . | 18/12/2020 | 11/06/2021 | Other | ELIQUIS | 10 | MG | 02/07/2020 |
| 07-041 | 76 | FRED X | Triple antiplatelet therapy | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | . | 27/02/2023 | Other | EDOXABAN | 60 | MG | 20/01/2022 |
| 08-008 | 68 | FRED / FRED Jr | Triple antiplatelet therapy | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | . | 08/11/2021 | Other | TIROFIBAN | 15 | ML/HR | 06/02/2021 |

**Table 20 :Antiplatelet functional test at 12 months visit (INVESTIGATORS) [ITT - N=143 patients]**

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

# ****Efficacy results****

In this section, the analyses were performed on the ITT population and the PP population and on CORE LAB data. Results for the PP population are presented in Appendix 2.

## Type of imaging at 6 months and 12 months

### 6 months

**Table 21 : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 6 months** | N | 78 | 51 | 78 |
|  | Missing data | 0 |  | 0 |
|  | Angiography (DSA) | 21 (26.9%) | 16 (31.4%) | 37 (28.7%) |
|  | Magnetic resonance angiography (MRA) | 52 (66.7%) | 31 (60.8%) | 83 (64.3%) |
|  | Angio-scanner (CTA) | 5 (6.4%) | 4 (7.8%) | 9 (7.0%) |
|  | Between group test |  |  | 0.766 (Fisher) |

**Table 22 : TIME OF IMAGING AT 6-MONTHS FOLLOW-UP (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 6 months** | N | 78 | 51 | 129 |
|  | Missing data | 0 |  | 0 |
|  | Mean (s.d.) | 6.20 (3.61) | 4.95 (1.95) | 5.71 (3.11) |
|  | Median | 5.99 | 5.68 | 5.94 |
|  | Q1 - Q3 | 5.29 - 6.21 | 3.25 - 6.04 | 3.51 - 6.14 |
|  | Min - Max | 1.44 - 27.36 | 1.71 - 11.56 | 1.44 - 27.36 |
|  | Between group test |  |  | **0.006 (Wilcoxon)** |

### 12 months

**Table 23 : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [ITT - N=136 patients]**

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

**Table 24 : TIME OF IMAGING AT 12-MONTHS FOLLOW-UP (CORELAB) [ITT - N=136 patients]**

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

## Anatomical results at procedure 6 months and 12 months

### At procedure

**Table 25 : Aneurysm filling at procedure (CORELAB) [ITT - N=154 patients]**

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

**Table 26 : Aneurysm filling for patients without FRED implanted (CORELAB) [ITT - N=2 patients]**

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

**Table 27 : Stasis status at procedure (CORELAB) [ITT - N=154 patients]**

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



**Table 28 : OKM scale at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale** | N | 98 | 55 | 153 |
|  | Missing data | 1 |  | 1 |
|  | A1 | 25 (25.5%) | 10 (18.2%) | 35 (22.9%) |
|  | A2 | 13 (13.3%) | 10 (18.2%) | 23 (15.0%) |
|  | A3 | 20 (20.4%) | 20 (36.4%) | 40 (26.1%) |
|  | B1 | 2 (2.0%) | 1 (1.8%) | 3 (2.0%) |
|  | B2 | 4 (4.1%) | 1 (1.8%) | 5 (3.3%) |
|  | B3 | 11 (11.2%) | 7 (12.7%) | 18 (11.8%) |
|  | C1 | 3 (3.1%) | 1 (1.8%) | 4 (2.6%) |
|  | C3 | 2 (2.0%) |  | 2 (1.3%) |
|  | D | 18 (18.4%) | 5 (9.1%) | 23 (15.0%) |

**Table 29 : OKM grade at procedure (CORELAB) [ITT - N=154 patients]**

|  | | **FRED / FRED Jr N=99** | **FRED X N=55** | **Total N=154** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade** | N | 98 | 55 | 153 |
|  | Missing data | 1 |  | 1 |
|  | OKM A | 58 (59.2%) | 40 (72.7%) | 98 (64.1%) |
|  | OKM B | 17 (17.3%) | 9 (16.4%) | 26 (17.0%) |
|  | OKM C | 5 (5.1%) | 1 (1.8%) | 6 (3.9%) |
|  | OKM D | 18 (18.4%) | 5 (9.1%) | 23 (15.0%) |

**Table 30 : Permeability of the Parent Artery at the procedure (CORELAB) [ITT - N=154 patients]**

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

**Table 31 : Flow diverter cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]**



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

**Table 32 : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [ITT - N=154 patients]**



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

### 6 months

**Table 33 : Aneurysm complete occlusion rate (Raymond score) at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 34 : Aneurysm complete occlusion rate (OKM score) at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 6 months (OKM score)** | N | 29 | 16 | 45 |
|  | Not applicable and / or not assessed | 49 | 35 | 84 |
|  | No | 10 (34.5%) | 5 (31.3%) | 15 (33.3%) |
|  | Yes | 19 (65.5%) | 11 (68.8%) | 30 (66.7%) |
|  | 95% CI | 48.2% - 82.8% | 46.0% - 91.5% | 52.9% - 80.4% |
|  | Between group test |  |  | 0.826 (Chi-2) |

**Table 35 : Adequate occlusion rate (Raymond score) at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 36 : Adequate occlusion rate (OKM score) at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 6 months (OKM score)** | N | 29 | 16 | 45 |
|  | Missing data | 49 | 35 | 84 |
|  | No | 9 (31.0%) | 5 (31.3%) | 14 (31.1%) |
|  | Yes | 20 (69.0%) | 11 (68.8%) | 31 (68.9%) |
|  | 95% CI | 52.1% - 85.8% | 46.0% - 91.5% | 55.4% - 82.4% |
|  | Between group test |  |  | 1.000 (Fisher) |

**Table 37 : Occlusion degree (Raymond-Roy score) at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm occlusion degree** | N | 78 | 51 | 129 |
|  | Missing data | 0 | 0 | 0 |
|  | Obliteration | 51 (65.4%) | 35 (68.6%) | 86 (66.7%) |
|  | Residual neck | 5 (6.4%) | 4 (7.8%) | 9 (7.0%) |
|  | Residual aneurysm | 17 (21.8%) | 9 (17.6%) | 26 (20.2%) |
|  | Cannot be assessed from the imaging | 5 (6.4%) | 3 (5.9%) | 8 (6.2%) |
|  | Between group test |  |  | 0.948 (Fisher) |
|  |  |  |  |  |
| **Residual aneurysm occlusion degree specification** | N | 7 | 7 | 14 |
|  | Missing data | 77 | 45 | 122 |
|  | Class IIIa | 0 | 5 (71.4%) | 5 (35.7%) |
|  | Class IIIb | 7 (100.0%) | 2 (28.6%) | 9 (64.3%) |

**Table 38 : Aneurysm filling at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 39 : Stasis phase at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 40 : OKM scale at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 6 months** | N | 29 | 16 | 45 |
|  | Not applicable and / or not assessed | 49 | 35 | 84 |
|  | A1 | 1 (3.4%) | 1 (6.3%) | 2 (4.4%) |
|  | A3 | 3 (10.3%) |  | 3 (6.7%) |
|  | B2 | 3 (10.3%) |  | 3 (6.7%) |
|  | B3 | 2 (6.9%) | 4 (25.0%) | 6 (13.3%) |
|  | C2 | 1 (3.4%) |  | 1 (2.2%) |
|  | D | 19 (65.5%) | 11 (68.8%) | 30 (66.7%) |

**Table 41 : OKM grade at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 6 months** | N | 29 | 16 | 45 |
|  | Not applicable and / or not assessed | 49 | 35 | 84 |
|  | OKM A | 4 (13.8%) | 1 (6.3%) | 5 (11.1%) |
|  | OKM B | 5 (17.2%) | 4 (25.0%) | 9 (20.0%) |
|  | OKM C | 1 (3.4%) |  | 1 (2.2%) |
|  | OKM D | 19 (65.5%) | 11 (68.8%) | 30 (66.7%) |

**Table 42 : Aneurysm sac size change at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 43 : Stent Stability at 6 months (CORELAB) [ITT - N=129 patients]**

|  | | **FRED / FRED Jr N=78** | **FRED X N=51** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Stent Stability** | N | 78 | 51 | 129 |
|  | Missing data | 0 | 01 | 0 |
|  | Yes | 46 (59.0%) | 33 (64.7%) | 79 (61.2%) |
|  | Cannot be assessed from the imaging | 32 (41.0%) | 18 (35.3%) | 50 (38.8%) |
|  | Between group test |  |  | 0.514 (Chi-2) |

**Table 44 : Stent covering the neck at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 45 : Parent artery permeability at 6 months (CORELAB) [ITT - N=129 patients]**

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

**Table 46 : Retreatment rate at 6 months (CORELAB) [ITT - N=129 patients]**

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

### 12 months

Aneurysm complete occlusion rate by Raymond score at 12 months was 86.2% FRED / FRED Jr group and 85.7% in FRED X group.

There was no statistical difference between the 2 groups (p=0.937).

**Table 47 : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**



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

**Table 48 : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months (OKM score)** | N | 72 | 42 | 114 |
|  | Not applicable and / or not assessed | 15 | 7 | 22 |
|  | No | 7 (9.7%) | 6 (14.3%) | 13 (11.4%) |
|  | Yes | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |
|  | 95% CI | 83.4% - 97.1% | 75.1% - 96.3% | 82.8% - 94.4% |
|  | Between group test |  |  | 0.545 (Fisher) |

**Table 49 : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [ITT - N=136 patients]**



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

**Table 50 : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months (OKM score)** | N | 72 | 42 | 114 |
|  | Not applicable and / or not assessed | 15 | 7 | 22 |
|  | No | 7 (9.7%) | 4 (9.5%) | 11 (9.6%) |
|  | Yes | 65 (90.3%) | 38 (90.5%) | 103 (90.4%) |
|  | 95% CI | 83.4% - 97.1% | 81.6% - 99.4% | 84.9% - 95.8% |
|  | Between group test |  |  | 1.000 (Fisher) |

**Table 51 : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [ITT - N=136 patients]**

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



**Table 52 : Aneurysm filling at 12 months (CORELAB) [ITT - N=136 patients]**

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







**Table 53 : Aneurysm Occlusion stability at 12 months (CORELAB) [ITT - N=136 patients]**



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

**Table 54 : Stasis phase at 12 months (CORELAB) [ITT - N=136 patients]**

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



**Table 55 : OKM scale at 12 months (CORELAB) [ITT - N=136 patients]**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 12 months** | N | 72 | 42 | 114 |
|  | Not applicable and / or not assessed | 15 | 7 | 22 |
|  | A1 | 1 (1.4%) | 1 (2.4%) | 2 (1.8%) |
|  | A2 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | A3 | 1 (1.4%) |  | 1 (0.9%) |
|  | B2 | 2 (2.8%) |  | 2 (1.8%) |
|  | B3 | 3 (4.2%) | 2 (4.8%) | 5 (4.4%) |
|  | C2 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | C3 | 0 | 1 (2.4%) | 1 (0.9%) |
|  | D | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |

**Table 56 : OKM grade at 12 months (CORELAB) [ITT - N=136 patients**

|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 12 months** | N | 72 | 42 | 114 |
|  | Not applicable and / or not assessed | 15 | 7 | 22 |
|  | OKM A | 2 (2.8%) | 2 (4.8%) | 4 (3.5%) |
|  | OKM B | 5 (6.9%) | 2 (4.8%) | 7 (6.1%) |
|  | OKM C | 0 | 2 (4.8%) | 2 (1.8%) |
|  | OKM D | 65 (90.3%) | 36 (85.7%) | 101 (88.6%) |

**Table 57 : Aneurysm sac size change at 12 months (CORELAB) [ITT - N=136 patients]**

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

**Table 58 : Stent Stability at 12 months (CORELAB) [ITT - N=136 patients]**



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

**Table 59 : Stent covering the neck at 12 months (CORELAB) [ITT - N=136 patients]**

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

**Table 60 : Parent artery permeability at 12 months (CORELAB) [ITT - N=136 patients]**

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



**Table 61 : Retreatment rate at 12 months (INVESTIGATORS) [ITT - N=143 patients]**

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

### Evolution of aneurysm occlusion between 6 months and 12 months

Patients with data available at 6 and 12 months were analyzed in this section. 116 patients were followed up at 6 and 12 months.

**Table 62 : Change of aneurysm occlusion stability at 12 months compared with 6 months (CORELAB) [ITT - N=116 patients]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Aneurysm Occlusion stability at 6 months** | **Aneurysm Occlusion stability at 12 months** | | | | **Total number of patients (N=116 patients)** |
| **Better** | **Same** | **Worse** | **Cannot be assessed from the imaging** |
| **Better** | **17/116 (14.7%)** | **30/116 (25.9%)** | **0 /116 (0.0%)** | **17/116 (14.7%)** | **64/116 (55.2%)** |
| FRED/ FRED Jr | 10/70 (14.3%) | 16/70 (22.9%) | 0 /70 (0.0%) | 11/70 (15.7%) | 37/70 (52.9%) |
| FRED X | 7/46 (15.2%) | 14/46 (30.4%) | 0/46 (0.0%) | 6/46 (13.0%) | 27/46 (58.7%) |
| **Same** | **3/116 (2.6%)** | **7/116 (6.0%)** | **0 /116 (0.0%)** | **3/116 (2.6%)** | **13/116 (11.2%)** |
| FRED/ FRED Jr | 2/70 (2.9%) | 5/70 (7.1%) | 0 /70 (0.0%) | 1/70 (1.4%) | 8/70 (11.4%) |
| FRED X | 1/46 (2.2%) | 2/46 (4.3%) | 0/46 (0.0%) | 2/46 (4.3%) | 5/46 (10.9%) |
| **Worse** | **0 /116 (0.0%)** | **0 /116 (0.0%)** | **0 /116 (0.0%)** | **0 /116 (0.0%)** | **0 /116 (0.0%)** |
| FRED/ FRED Jr | 0 /70 (0.0%) | 0 /70 (0.0%) | 0 /70 (0.0%) | 0 /70 (0.0%) | 0 /70 (0.0%) |
| FRED X | 0/46 (0.0%) | 0/46 (0.0%) | 0/46 (0.0%) | 0/46 (0.0%) | 0/46 (0.0%) |
| **Cannot be assessed from the imaging** | **30/116 (25.9%)** | **5/116 (4.3%)** | **0 /116 (0.0%)** | **4/116 (3.4%)** | **39/116 (33.6%)** |
| FRED/ FRED Jr | 20/70 (28.6%) | 3/70 (4.3%) | 0 /70 (0.0%) | 2/70 (2.9%) | 25/70 (35.7%) |
| FRED X | 10/46 (21.7%) | 2/46 (4.3%) | 0/46 (0.0%) | 2/46 (4.3%) | 14/46 (4.4%) |

**Table 63 : Change of aneurysm occlusion degree (Raymond-Roy score) at 12 months compared with 6 months (CORELAB) [ITT - N=116 patients]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Aneurysm Occlusion stability at 6 months** | **Aneurysm Occlusion stability at 12 months** | | | | **Total number of patients (N=116 patients)** |
| **Obliteration** | **Residual neck** | **Residual aneurysm** | **Cannot be assessed from the imaging** |
| **Obliteration** | **75/116 (64.7%)** | **2/116 (1.7%)** | **2/116 (1.7%)** | **0/116 (0.0%)** | **79/116 (68.1%)** |
| FRED/ FRED Jr | 43/70 (61.4%) | 2/70 (2.9%) | 2/70 (2.9%) | 0/70 (0.0%) | 47/70 (67.1%) |
| FRED X | 32/46 (69.6%) | 0/46 (0.0%) | 0/46 (0.0%) | 0/46 (0.0%) | 32/46 (69.6%) |
| **Residual neck** | **4/116 (3.4%)** | **3/116 (2.9%)** | **1/116 (0.9%)** | **0/116 (0.0%)** | **8/116 (6.9%)** |
| FRED/ FRED Jr | 4/70 (5.7%) | 0/70 (0.0%) | 0/70 (0.0%) | 0/70 (0.0%) | 4/70 (5.7%) |
| FRED X | 0/46 (0.0%) | 3/46 (6.5%) | 1/46 (2.2%) | 0/46 (0.0%) | 4/46 (8.7%) |
| **Residual aneurysm** | **12/116 (10.3%)** | **2/116 (1.7%)** | **8/116 (6.9%)** | **0/116 (0.0%)** | **22/116 (19.0%)** |
| FRED/ FRED Jr | 7/70 (10.0%) | 1/70 (1.4%) | 7/70 (10.0%) | 0/70 (0.0%) | 15/70 (21.4%) |
| FRED X | 5/46 (10.9%) | 1/46 (2.2%) | 1/46 (2.2%) | 0/46 (0.0%) | 7/46 (15.2%) |
| **Cannot be assessed from the imaging** | **6/116 (5.2%)** | **0/116 (0.0%)** | **1/116 (0.9%)** | **0/116 (0.0%)** | **7/166 (6.0%)** |
| FRED/ FRED Jr | 4/70 (5.7%) | 0/70 (0.0%) | 0/70 (0.0%) | 0/70 (0.0%) | 4/70 (5.7%) |
| FRED X | 2/46 (4.3%) | 0/46 (0.0%) | 1/46 (2.2%) | 0/46 (0.0%) | 3/46 (6.5%) |















# ****Primary Efficacy endpoint****

The primary efficacy endpoint is rate of complete aneurysm occlusion at 12 months without associated stenosis of the parent artery (> 50%).

Derivate variable was designed as

**Success** if Aneurysm occlusion degree (Modified Raymond-Roy Classification) = Obliteration and Parent Artery permeability is checked No stenosis, or Stenosis <50%, or On MRA or CTA images, no stenosis or Stenosis < 50%

The proportion of success was estimated with a 2 sided exact 95% confidence interval (CI).

## 6 months

**Table 64 : Rate of complete aneurysm occlusion at 6 months** without associated stenosis of the parent artery **(CORELAB) [ITT - N=129 patients]**

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

## 12 months

**Table 65 : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [ITT - N=136 patients]**



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

**Table 66 : Parent artery permeability at 12 months (CORELAB) [ITT - N=136 patients]**



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

**Table 67 : Rate of complete aneurysm occlusion at 12 months** without associated stenosis of the parent artery **(CORELAB) [ITT - N=136 patients]**



|  | | **FRED / FRED Jr N=87** | **FRED X N=49** | **Total N=136** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Rate of complete aneurysm occlusion at 12 months without associated stenosis of the parent artery** | N | 87 | 49 | 136 |
|  | Missing data | 0 |  | 0 |
|  | Echec | 17 (19.5%) | 9 (18.4%) | 26 (19.1%) |
|  | Success | 70 (80.5%) | 40 (81.6%) | 110 (80.9%) |
|  | 95% CI | 72.1% - 88.8% | 70.8% - 92.5% | 74.3% - 87.5% |
|  | Between group test |  |  | 0.867 (Chi-2) |

# ****Safety results****

In this section, the analyses were performed on the ITT population, the FAS population and PP population and on investigator data and CEC data. Results for the FAS and PP populations are presented in Appendix 3 and 4.

## Morbidity Rate at 12 months

Morbidity rate is defined as mRS between 3 and 5 at the 12-month visit.

**Table 68 : Morbidity rate at the 12-month visit (INVESTIGATORS) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** | **Total N=143** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Morbidity at the 12-month visit** | N | 91 | 52 | 143 |
|  | Missing data | 0 | 0 | 0 |
|  | mRS < 3 | 91 (100.0%) | 52 (100.0%) | 143 (100.0%) |

**Table 69 : mRS score at the 12-month visit (INVESTIGATORS) [ITT - N=143 patients]**

|  | | **FRED / FRED Jr N=91** | **FRED X N=52** |  | **Total N=143** |
| --- | --- | --- | --- | --- | --- |
|  |  |  |  |  |  |
| **mRS score** | N | 91 | 52 |  | 143 |
|  | Missing data | 0 | 0 |  | 0 |
|  | 0 - No symptoms at all | 76 (83.5%) | 43 (82.7%) |  | 119 (83.2%) |
|  | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | 12 (13.2%) | 8 (15.4%) |  | 20 (14.0%) |
|  | 2 - Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance | 3 (3.3%) | 1 (1.9%) |  | 4 (2.8%) |
|  | Between group test |  |  |  | 0.926 (Fisher) |

For the **mRS** score change, patients analyzed at 12 months were considered (N=143 patients)..

**Table 70 : mRS change between baseline and 12-month visit (INVESTIGATORS) [ITT - N=143 patients]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Baseline mRS** | **12 Months mRS** | | | **Total number of patients (N=143 patients)** |
| **mRS 0** | **mRS 1** | **mRS 2** |
| **mRS 0** | **97/143 (67.8%)** | **4/143 (2.8%)** | **2/143 (1.4%)** | **103/143 (72.0%)** |
| FRED/ FRED Jr | 60/91 (65.9%) | 2/91 (2.2%) | 1/91 (1.1%) | 63/91 (69.2%) |
| FRED X | 37/52 (71.1%) | 2/52 (3.8%) | 1/52 (1.9%) | 40/52 (76.9%) |
| **mRS 1** | **22/143 (15.4%)** | **13/143 (9.1%)** | **1/143 (0.7%)** | **36/143 (25.2%)** |
| FRED/ FRED Jr | 16/91 (17.6%) | 8/91 (8.8%) | 1/91 (1.1%) | 25/91 (27.5%) |
| FRED X | 6/52 (11.5%) | 5/52 (9.6%) | 0/52 (0.0%) | 11/52 (21.1%) |
| **mRS 2** | **0/143 (0.0%)** | **3/143 (2.1%)** | **1/143 (0.7%)** | **4/143 (2.8%)** |
| FRED/ FRED Jr | 0/91 (0.0%) | 2/91 (2.2%) | 1/91 (1.1%) | 3/91 (3.3%) |
| FRED X | 0/52 (0.0%) | 1/52 (1.9%) | 0/52 (0.0%) | 1/52 (1.9%) |

## Mortality rate at 12 months

The rate of all-cause mortality at 12 months is 0%.

## Complications

All complications have been adjudicated by an independent Clinical Event Committee (CEC).

Post-procedural (or post-operative) complications are defined as adverse events (AEs) occurring after the patient wakes up until discharge, from discharge to the 6-month visit and between the 6-month visit and 12-month visit.

This section provides the post-procedural complications between the 6-month visit and 12-month visit.

### All complications until 12 months for all patients

**Table 71 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 156 patients [All patients - N=156 patients]**

|  | | **FRED / FRED Jr N=101** | **FRED X N=55** | **Total N=156** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 101 | 55 | 156 |
|  | 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) |

**Table 72 : Description of all complications until 12-month follow-up (CEC) from 156 patients [All patients- N=49 patients - 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 |

***Listing of all complications until 12-month* from 156 patients *is in Appendix 4.***

### Complications until 12 months for ITT population

**Table 73 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 143 patients [ITT at 12-month - N=143 patients]**

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

**Table 74 : Description of all complications until 12-month follow-up (CEC) from 143 patients [ITT - N=42 patients - 59 complications]**

|  | | **FRED / FRED Jr N=31** | **FRED X N=28** | **Total N=59** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 31 | 28 | 59 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 0 | 1 (3.6%) | 1 (1.7%) |
|  | Thromboembolic complications | 9 (29.0%) | 7 (25.0%) | 16 (27.1%) |
|  | Puncture site complications | 0 | 2 (7.1%) | 2 (3.4%) |
|  | Other complications | 22 (71.0%) | 18 (64.3%) | 40 (67.8%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 31 | 28 | 59 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 9 (29.0%) | 6 (21.4%) | 15 (25.4%) |
|  | Patient symptomatic | 22 (71.0%) | 22 (78.6%) | 44 (74.6%) |
|  |  |  |  |  |
| **AE severity** | N | 31 | 28 | 59 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 18 (58.1%) | 11 (39.3%) | 29 (49.2%) |
|  | Moderate | 6 (19.4%) | 14 (50.0%) | 20 (33.9%) |
|  | Severe | 7 (22.6%) | 3 (10.7%) | 10 (16.9%) |
|  |  |  |  |  |
| **Causal relationship** | N | 31 | 28 | 59 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 6 (19.4%) | 5 (17.9%) | 11 (18.6%) |
|  | Procedure related AE | 7 (22.6%) | 11 (39.3%) | 18 (30.5%) |
|  | Device and procedure related AE | 7 (22.6%) | 9 (32.1%) | 16 (27.1%) |
|  | Oher | 11 (35.5%) | 3 (10.7%) | 14 (23.7%) |
|  |  |  |  |  |
| **Other relationship** | N | 19 | 5 | 24 |
|  | Missing data | 12 | 23 | 35 |
|  | 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 | 7 (36.8%) | 1 (20.0%) | 8 (33.3%) |
|  | Other | 8 (42.1%) | 2 (40.0%) | 10 (41.7%) |
|  |  |  |  |  |
| **Serious AE** | N | 31 | 28 | 59 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 22 (71.0%) | 23 (82.1%) | 45 (76.3%) |
|  | Yes | 9 (29.0%) | 5 (17.9%) | 14 (23.7%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 9 | 5 | 14 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 7 (77.8%) | 2 (40.0%) | 9 (64.3%) |
|  | Permanent damage / Disability | 2 (22.2%) | 3 (60.0%) | 5 (35.7%) |
|  |  |  |  |  |
| **Event outcome** | N | 31 | 28 | 59 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 24 (77.4%) | 19 (67.9%) | 43 (72.9%) |
|  | Not resolved / ongoing | 7 (22.6%) | 8 (28.6%) | 15 (25.4%) |
|  | Unknown | 0 | 1 (3.6%) | 1 (1.7%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 30 | 28 | 58 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 88.47 (113.18) | 50.82 (110.84) | 70.29 (112.68) |
|  | Median | 23.50 | 2.00 | 4.00 |
|  | Q1 - Q3 | 1.00 - 173.00 | 0.50 - 29.00 | 1.00 - 104.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 30 | 28 | 58 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 2.90 (3.72) | 1.67 (3.64) | 2.31 (3.70) |
|  | Median | 0.77 | 0.06 | 0.13 |
|  | Q1 - Q3 | 0.04 - 5.68 | 0.02 - 0.95 | 0.04 - 3.42 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

***Listing of all complications until 12-month* from 143 patients *is in Appendix 4.***

### Post-procedural complications between 6 months and 12 months for ITT population

**Table 75 : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=143 patients]**

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

**Table 76 : Description of post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=11 patients - 11 complications]**

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



**Table 77 : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N= 9 patients - 9 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | No | Resolved without sequelae | 6.34 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | Yes | Not resolved / ongoing | 13.40 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | No | Not resolved / ongoing | 13.60 |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | No | Resolved without sequelae | 3.44 |
|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | Yes | Resolved without sequelae | 5.68 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | Yes | Not resolved / ongoing | 12.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | No | Resolved without sequelae | 3.42 |

**Table 78 : Listing of all post-procedural complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=11 patients - 11complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Other relationship** | **Serious** | **Event outcome** | **Other relationship** | **Serious** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | checked | No | Not resolved / ongoing | checked | No | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | checked | No | Resolved without sequelae | checked | No | 6.34 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | . | Yes | Not resolved / ongoing | . | Yes | 10.14 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | checked | Yes | Not resolved / ongoing | checked | Yes | 13.40 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | checked | No | Resolved without sequelae | checked | No | 3.98 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | . | No | Resolved without sequelae | . | No | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | . | No | Not resolved / ongoing | . | No | 13.60 |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | . | No | Resolved without sequelae | . | No | 3.44 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | . | Yes | Resolved without sequelae | . | Yes | 5.68 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | . | Yes | Not resolved / ongoing | . | Yes | 12.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | . | No | Resolved without sequelae | . | No | 3.42 |

**Table 79 : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) from 143 patients [ITT - N=2 patients - 2 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |

# APPENDIX

## APPENDIX 1 Treatment at 12 months visit in FAS population

### In FAS population

**Table 80 : Number and type of antiplatelet medications at 12-month visit [FAS - N=130 patients]**

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

**Table 81 : Listing of patient without antiplatelet medications at 12-month visit [FAS - N= 1 patient]**

| **Subject Identifier for the Study** | **Age calculated** | **Subgroup device** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type of antiplatelet therapy** | **Treatment name** | **Daily dose** | **Unit** | **Start date** | **Ongoing** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | 62 | FRED / FRED Jr | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet | ASA (Aspirin) | 100 | MG | 30/10/2019 | No | 01/04/2020 |
| 04-005 | 62 | FRED / FRED Jr | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet | Clopidogrel (Plavix) | 75 | MG | 30/10/2019 | No | 04/02/2020 |

**Table 82 : Listing of patient without antiplatelet medications at 12-month visit [FAS - N= 3 patients]**

| **Subject Identifier for the Study** | **Age calculated** | **Subgroup device** | **Antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **FU 6 MONTHS** | **FU 1 YEAR** | **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | 73 | FRED / FRED Jr | Dual antiplatelet therapy | ASA (Aspirin) + Other | . | 18/12/2020 | 11/06/2021 | Other | ELIQUIS | 10 | MG | 02/07/2020 |
| 07-041 | 76 | FRED X | Triple antiplatelet therapy | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | . | 27/02/2023 | Other | EDOXABAN | 60 | MG | 20/01/2022 |
| 08-008 | 68 | FRED / FRED Jr | Triple antiplatelet therapy | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | . | 08/11/2021 | Other | TIROFIBAN | 15 | ML/HR | 06/02/2021 |

**Table 83 :** **Antiplatelet functional test at 12 months visit [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 82 | 48 | 130 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (7.3%) | 3 (6.3%) | 9 (6.9%) |
|  | Yes | 76 (92.7%) | 45 (93.8%) | 121 (93.1%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 76 | 45 | 121 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 71 (93.4%) | 42 (93.3%) | 113 (93.4%) |
|  | Aspirin resistance | 1 (1.3%) |  | 1 (0.8%) |
|  | Plavix resistance | 4 (5.3%) | 3 (6.7%) | 7 (5.8%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 5 | 3 | 8 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 5 (100.0%) | 3 (100.0%) | 8 (100.0%) |

### In PP population

**Table 84 : Number and type of antiplatelet medications at 12-month visit [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet therapy** | N | 79 | 45 | 124 |
|  | Missing data | 0 |  | 0 |
|  | No treatment | 1 (1.3%) |  | 1 (0.8%) |
|  | Single antiplatelet therapy | 54 (68.4%) | 28 (62.2%) | 82 (66.1%) |
|  | Dual antiplatelet therapy | 23 (29.1%) | 14 (31.1%) | 37 (29.8%) |
|  | Triple antiplatelet therapy | 1 (1.3%) | 3 (6.7%) | 4 (3.2%) |
|  | Between group test |  |  | 0.346 (Fisher) |
|  |  |  |  |  |
| **Single antiplatelet therapy** | N | 54 | 28 | 82 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) | 53 (98.1%) | 28 (100.0%) | 81 (98.8%) |
|  | Ticlagrelor (Brilique) | 1 (1.9%) |  | 1 (1.2%) |
|  |  |  |  |  |
| **Dual antiplatelet therapy** | N | 23 | 14 | 37 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) | 20 (87.0%) | 12 (85.7%) | 32 (86.5%) |
|  | ASA (Aspirin) + Prasugrel (Efient) | 1 (4.3%) | 2 (14.3%) | 3 (8.1%) |
|  | ASA (Aspirin) + Ticlagrelor (Brilique) | 1 (4.3%) |  | 1 (2.7%) |
|  | ASA (Aspirin) + Other | 1 (4.3%) |  | 1 (2.7%) |
|  |  |  |  |  |
| **Triple antiplatelet therapy** | N | 1 | 3 | 4 |
|  | Missing data | 0 |  | 0 |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Other | 1 (100.0%) | 1 (33.3%) | 2 (50.0%) |
|  | ASA (Aspirin) + Clopidogrel (Plavix) + Prasugrel (Efient) | 0 | 1 (33.3%) | 1 (25.0%) |
|  | ASA (Aspirin) + Prasugrel (Efient) + Ticlagrelor (Brilique) | 0 | 1 (33.3%) | 1 (25.0%) |

**Table 85 : Listing of patient without antiplatelet medications at 12-month visit [PP - N= 1 patient]**

| **Subject Identifier for the Study** | **Age calculated** | **Subgroup device** | **FU 6 MONTHS** | **FU 1 YEAR** | **Antiplatelet therapy number** | **Type of antiplatelet therapy** | **Treatment name** | **Daily dose** | **Unit** | **Start date** | **Ongoing** | **End date** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04-005 | 62 | FRED / FRED Jr | 04/05/2020 | 09/11/2020 | 1 | Antiplatelet | ASA (Aspirin) | 100 | MG | 30/10/2019 | No | 01/04/2020 |
| 04-005 | 62 | FRED / FRED Jr | 04/05/2020 | 09/11/2020 | 2 | Antiplatelet | Clopidogrel (Plavix) | 75 | MG | 30/10/2019 | No | 04/02/2020 |

**Table 86 : Listing of patient without antiplatelet medications at 12-month visit [PP - N= 3 patients]**

| **Subject Identifier for the Study** | **Age calculated** | **Subgroup device** | **Antiplatelet therapy** | **Dual antiplatelet therapy** | **Triple antiplatelet therapy** | **FU 6 MONTHS** | **FU 1 YEAR** | **Treatment name** | **Other treatment specification** | **Daily dose** | **Unit** | **Start date (c)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 07-024 | 73 | FRED / FRED Jr | Dual antiplatelet therapy | ASA (Aspirin) + Other | . | 18/12/2020 | 11/06/2021 | Other | ELIQUIS | 10 | MG | 02/07/2020 |
| 07-041 | 76 | FRED X | Triple antiplatelet therapy | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | . | 27/02/2023 | Other | EDOXABAN | 60 | MG | 20/01/2022 |
| 08-008 | 68 | FRED / FRED Jr | Triple antiplatelet therapy | . | ASA (Aspirin) + Clopidogrel (Plavix) + Other | . | 08/11/2021 | Other | TIROFIBAN | 15 | ML/HR | 06/02/2021 |

**Table 87 :** **Antiplatelet functional test at 12 months visit [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Antiplatelet functional test performed** | N | 79 | 45 | 124 |
|  | Missing data | 0 |  | 0 |
|  | No | 6 (7.6%) | 2 (4.4%) | 8 (6.5%) |
|  | Yes | 73 (92.4%) | 43 (95.6%) | 116 (93.5%) |
|  | Between group test |  |  | 0.710 (Fisher) |
|  |  |  |  |  |
| **Antiplatelet functional test results** | N | 73 | 43 | 116 |
|  | Missing data | 0 |  | 0 |
|  | No resistance | 68 (93.2%) | 40 (93.0%) | 108 (93.1%) |
|  | Aspirin resistance | 1 (1.4%) |  | 1 (0.9%) |
|  | Plavix resistance | 4 (5.5%) | 3 (7.0%) | 7 (6.0%) |
|  | Between group test |  |  | 1.000 (Fisher) |
|  |  |  |  |  |
| **Action undertaken** | N | 5 | 3 | 8 |
|  | Missing data | 0 |  | 0 |
|  | Change in antiplatelet therapy | 5 (100.0%) | 3 (100.0%) | 8 (100.0%) |

## APPENDIX 2 – RESULTS IN THE PP POPULATION FOR EFFICACY ANALYSIS

### Type of imaging at 6 months and 12 months

#### 6 months

**Table 88 : TYPE OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of imaging at 6 months** | N | 70 | 47 | 70 |
|  | Missing data | 0 |  | 0 |
|  | Angiography (DSA) | 17 (24.3%) | 14 (29.8%) | 31 (26.5%) |
|  | Magnetic resonance angiography (MRA) | 48 (68.6%) | 29 (61.7%) | 77 (65.8%) |
|  | Angio-scanner (CTA) | 5 (7.1%) | 4 (8.5%) | 9 (7.7%) |
|  | Between group test |  |  | 0.716 (Fisher) |

**Table 89 : TIME OF IMAGING AT 6-MONTH FOLLOW-UP (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Time of imaging at 6 months** | N | 70 | 47 | 117 |
|  | Missing data | 0 |  | 0 |
|  | Mean (s.d.) | 6.39 (3.74) | 4.84 (1.89) | 5.77 (3.21) |
|  | Median | 6.03 | 5.06 | 5.98 |
|  | Q1 - Q3 | 5.68 - 6.37 | 3.22 - 6.04 | 3.58 - 6.17 |
|  | Min - Max | 1.44 - 27.36 | 1.71 - 11.56 | 1.44 - 27.36 |
|  | Between group test |  |  | **0.001 (Wilcoxon)** |

#### 12 months

**Table 90 : TYPE OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [PP - N=124 patients]**

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

**Table 91 : TIME OF IMAGING AT 12-MONTH FOLLOW-UP (CORELAB) [PP - N=124 patients]**

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

### Anatomical results procedure, at 6 and 12 months

#### At procedure

**Table 92 : Aneurysm filling at procedure (CORELAB) [PP - N=138 patients]**

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

**Table 93 : Stasis status at procedure (CORELAB) [PP - N=138 patients]**



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

**Table 94 : OKM scale at procedure (CORELAB) [PP - N=138 patients]**

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

**Table 95 : OKM scale at procedure (CORELAB) [PP - N=138 patients]**

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

**Table 96 : Flow diverter cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]**



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

**Table 97 : The internal stent (flow-diverter part) cover the aneurysm neck at procedure (CORELAB) [PP - N=138 patients]**



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

#### 6 months

**Table 98 : Aneurysm complete occlusion rate (Raymond score) at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 99 : Aneurysm complete occlusion rate (OKM score) at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 6 months (OKM score)** | N | 24 | 15 | 39 |
|  | Not applicable and / or not assessed | 46 | 32 | 78 |
|  | No | 9 (37.5%) | 4 (26.7%) | 13 (33.3%) |
|  | Yes | 15 (62.5%) | 11 (73.3%) | 26 (66.7%) |
|  | 95% CI | 43.1% - 81.9% | 51.0% - 95.7% | 51.9% - 81.5% |
|  | Between group test |  |  | 0.485 (Chi-2) |

**Table 100 : Adequate occlusion rate (Raymond score) at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 101 : Adequate occlusion rate OKM score) at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 6 months (OKM score)** | N | 24 | 15 | 39 |
|  | Not applicable and / or not assessed | 46 | 32 | 78 |
|  | No | 9 (37.5%) | 4 (26.7%) | 13 (33.3%) |
|  | Yes | 15 (62.5%) | 11 (73.3%) | 26 (66.7%) |
|  | 95% CI | 43.1% - 81.9% | 51.0% - 95.7% | 51.9% - 81.5% |
|  | Between group test |  |  | 0.485 (Chi-2) |

**Table 102 : Occlusion degree (Raymond-Roy score) at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm occlusion degree** | N | 70 | 47 | 117 |
|  | Missing data | 0 | 0 | 0 |
|  | Obliteration | 45 (64.3%) | 32 (68.1%) | 77 (65.8%) |
|  | Residual neck | 4 (5.7%) | 4 (8.5%) | 8 (6.8%) |
|  | Residual aneurysm | 17 (24.3%) | 8 (17.0%) | 25 (21.4%) |
|  | Cannot be assessed from the imaging | 4 (5.7%) | 3 (6.4%) | 7 (6.0%) |
|  | Between group test |  |  | 0.762 (Fisher) |
|  |  |  |  |  |
| **Residual aneurysm occlusion degree specification** | N | 7 | 7 | 14 |
|  | Missing data | 67 | 41 | 108 |
|  | Class IIIa | 0 | 5 (71.4%) | 5 (35.7%) |
|  | Class IIIb | 7 (100.0%) | 2 (28.6%) | 9 (64.3%) |

**Table 103 : Aneurysm filling at 6 months (CORELAB) [PP - N=117 patients]**

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



**Table 104 : Aneurysm Occlusion stability at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 105 : Stasis phase at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 106 : OKM scale at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 6 months** | N | 24 | 15 | 39 |
|  | Not applicable and / or not assessed | 46 | 32 | 78 |
|  | A1 | 1 (4.2%) | 1 (6.7%) | 2 (5.1%) |
|  | A3 | 3 (12.5%) |  | 3 (7.7%) |
|  | B2 | 3 (12.5%) |  | 3 (7.7%) |
|  | B3 | 2 (8.3%) | 3 (20.0%) | 5 (12.8%) |
|  | D | 15 (62.5%) | 11 (73.3%) | 26 (66.7%) |

**Table 107 : OKM grade at 6 months (CORELAB) [PP - N=117 patients]**

|  | | **FRED / FRED Jr N=70** | **FRED X N=47** | **Total N=117** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 6 months** | N | 24 | 15 | 39 |
|  | Not applicable and / or not assessed | 46 | 32 | 78 |
|  | OKM A | 4 (16.7%) | 1 (6.7%) | 5 (12.8%) |
|  | OKM B | 5 (20.8%) | 3 (20.0%) | 8 (20.5%) |
|  | OKM D | 15 (62.5%) | 11 (73.3%) | 26 (66.7%) |

**Table 108 : Aneurysm sac size change at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 109 : Stent Stability at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 110 : Stent covering the neck at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 111 : Parent artery permeability at 6 months (CORELAB) [PP - N=117 patients]**

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

**Table 112 : Retreatment rate at 6 months (CORELAB) [PP - N=117 patients]**

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

#### 12 months

**Table 113 : Aneurysm complete occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**



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

**Table 114 : Aneurysm complete occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Aneurysm complete occlusion rate at 12 months (OKM score)** | N | 65 | 38 | 103 |
|  | Not applicable and / or not assessed | 14 | 7 | 21 |
|  | No | 7 (10.8%) | 6 (15.8%) | 13 (12.6%) |
|  | Yes | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |
|  | 95% CI | 81.7% - 96.8% | 72.6% - 95.8% | 81% - 93.8% |
|  | Between group test |  |  | 0.543 (Fisher) |

**Table 115 : Adequate occlusion rate (Raymond score) at 12 months (CORELAB) [PP - N=124 patients]**

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

**Table 116 : Adequate occlusion rate (OKM score) at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Adequate occlusion rate at 12 months (OKM score)** | N | 65 | 38 | 103 |
|  | Not applicable and / or not assessed | 14 | 7 | 21 |
|  | No | 7 (10.8%) | 4 (10.5%) | 11 (10.7%) |
|  | Yes | 58 (89.2%) | 34 (89.5%) | 92 (89.3%) |
|  | 95% CI | 81.7% - 96.8% | 79.7% - 99.2% | 83.4% - 95.3% |
|  | Between group test |  |  | 1.000 (Fisher) |

**Table 117 : Occlusion degree (Raymond-Roy score) at 12 months (CORELAB) [PP - N=124 patients**

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

**Table 118 : Aneurysm filling at 12 months (CORELAB) [PP - N=124 patients]**

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







**Table 119 : Aneurysm Occlusion stability at 12 months (CORELAB) [PP - N=124 patients]**

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

**Table 120 : Stasis phase at 12 months (CORELAB) [PP - N=124 patients]**

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

**Table 121 : OKM scale at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM scale at 12 months** | N | 65 | 38 | 103 |
|  | Not applicable and / or not assessed | 14 | 7 | 21 |
|  | A1 | 1 (1.5%) | 1 (2.6%) | 2 (1.9%) |
|  | A2 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | A3 | 1 (1.5%) |  | 1 (1.0%) |
|  | B2 | 2 (3.1%) |  | 2 (1.9%) |
|  | B3 | 3 (4.6%) | 2 (5.3%) | 5 (4.9%) |
|  | C2 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | C3 | 0 | 1 (2.6%) | 1 (1.0%) |
|  | D | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |

**Table 122 : OKM grade at 12 months (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **OKM grade at 12 months** | N | 65 | 38 | 103 |
|  | Not applicable and / or not assessed | 14 | 7 | 21 |
|  | OKM A | 2 (3.1%) | 2 (5.3%) | 4 (3.9%) |
|  | OKM B | 5 (7.7%) | 2 (5.3%) | 7 (6.8%) |
|  | OKM C | 0 | 2 (5.3%) | 2 (1.9%) |
|  | OKM D | 58 (89.2%) | 32 (84.2%) | 90 (87.4%) |

**Table 123 : Aneurysm sac size change at 12 months (CORELAB) [PP - N=124 patients]**

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

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

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

**Table 125 : Stent covering the neck at 12 months (CORELAB) [PP - N=124 patients]**



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

**Table 126 : Parent artery permeability at 12 months (CORELAB) [PP - N=124 patients]**

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



**Table 127 : Retreatment rate at 12 months (INVESTIGATORS) [PP - N=129 patients]**

|  | | **FRED / FRED Jr N=81** | **FRED X N=48** | **Total N=129** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Retreatment** | N | 81 | 48 | 129 |
|  | Missing data | 0 |  | 0 |
|  | No | 78 (96.3%) | 47 (97.9%) | 125 (96.9%) |
|  | Yes | 3 (3.7%) | 1 (2.1%) | 4 (3.1%) |
|  | Between group test |  |  | 1.000 (Fisher) |

#### Evolution of aneurysm occlusion between 6 months and 12 months

Patients with data available at 6 and 12 months were analyzed in this section. 108 patients were followed up at 6 and 12 months for PP population.

**Table 128 : Change of aneurysm occlusion stability at 12 months compared with 6 months (CORELAB) [PP - N=108 patients]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Aneurysm Occlusion stability at 6 months** | **Aneurysm Occlusion stability at 12 months** | | | | **Total number of patients (N=108 patients)** |
| **Better** | **Same** | **Worse** | **Cannot be assessed from the imaging** |
| **Better** | **12/108 (11.1%)** | **30/108 (27.8%)** | **0/108 (0.0%)** | **17/108 (15,7%)** | **59/108 (54.6%)** |
| FRED/ FRED Jr | 7/66 (10.6%) | 16/66 (24.2%) | 0/66 (0.0%) | 11/66 (16.7%) | 34/66 (51.5%) |
| FRED X | 5/42 (11.9%) | 14/42 (33.3%) | 0/42 (0.0%) | 6/42 (14.3%) | 25/42 (59.5%) |
| **Same** | **3/108 (2.8%)** | **7/108 (6.5%)** | **0/108 (0.0%)** | **3/108 (2.8%)** | **13/108 (12.0%)** |
| FRED/ FRED Jr | 2/66 (3.0%) | 5/66 (7.6%) | 0/66 (0.0%) | 1/66 (1.5%) | 8/66 (12.1%) |
| FRED X | 1/42 (2.4%) | 2/42 (4.8%) | 0/42 (0.0%) | 2/42 (4.8%) | 5/42 (11.9%) |
| **Worse** | **0/108 (0.0%)** | **0/108 (0.0%)** | **0/108 (0.0%)** | **0/108 (0.0%)** | **0/108 (0.0%)** |
| FRED/ FRED Jr | 0/66 (0.0%) | 0/66 (0.0%) | 0/66 (0.0%) | 0/66 (0.0%) | 0/66 (0.0%) |
| FRED X | 0/42 (0.0%) | 0/42 (0.0%) | 0/42 (0.0%) | 0/42 (0.0%) | 0/42 (0.0%) |
| **Cannot be assessed from the imaging** | **27/108 (25.0%)** | **5/108 (4.6%)** | **0/108 (0.0%)** | **4/108 (3.7%)** | **36/108 (33.3%)** |
| FRED/ FRED Jr | 19/66 (28.8%) | 3/66 (4.6%) | 0/66 (0.0%) | 2/66 (3.0%) | 24/66 (36.4%) |
| FRED X | 8/42 (19.0%) | 2/42 (4.8%) | 0/42 (0.0%) | 2/42 (4.8%) | 12/42 (28.6%) |

**Table 129 : Change of aneurysm occlusion degree (Raymond-Roy score) at 12 months compared with 6 months (CORELAB) [PP - N=108 patients]**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Aneurysm Occlusion stability at 6 months** | **Aneurysm Occlusion stability at 12 months** | | | | **Total number of patients (N=108 patients)** |
| **Obliteration** | **Residual neck** | **Residual aneurysm** | **Cannot be assessed from the imaging** |
| **Obliteration** | **69/108 (63.9%)** | **2/108 (1.2%)** | **2/108 (1.2%)** | **0/108 (0.0%)** | **73/108 (67.6%)** |
| FRED/ FRED Jr | 40/66 (60.6%) | 2/66 (3.0%) | 2/66 (3.0%) | 0/66 (0.0%) | 44/66 (66.7%) |
| FRED X | 29/42 (69.0%) | 0/42 (0.0%) | 0/42 (0.0%) | 0/42 (0.0%) | 29/42 (69.0%) |
| **Residual neck** | **4/108 (3.7%)** | **3/108 (2.8%)** | **1/108 (0.9%)** | **0/108 (0.0%)** | **8/108 (7.4%)** |
| FRED/ FRED Jr | 4/66 (6.1%) | 0/66 (0.0%) | 0/66 (0.0%) | 0/66 (0.0%) | 4/66 (6.1%) |
| FRED X | 0/42 (0.0%) | 3/42 (7.1%) | 1/42 (2.4%) | 0/42 (0.0%) | 4/42 (9.5%) |
| **Residual aneurysm** | **11/108 (10.2%)** | **2/108 (1.2%)** | **8/108 (7.4%)** | **0/108 (0.0%)** | **21/108 (19.4%)** |
| FRED/ FRED Jr | 7/66 (10.6%) | 1/66 (1.5%) | 7/66 (10.6%) | 0/66 (0.0%) | 15/66 (22.7%) |
| FRED X | 4/42 (9.5%) | 1/42 (2.4%) | 1/42 (2.4%) | 0/42 (0.0%) | 6/42 (14.3%) |
| **Cannot be assessed from the imaging** | **5/108 (4.6%)** | **0/108 (0.0%)** | **1/108 (0.9%)** | **0/108 (0.0%)** | **6/108 (5.6%)** |
| FRED/ FRED Jr | 3/66 (4.5%) | 0/66 (0.0%) | 0/66 (0.0%) | 0/66 (0.0%) | 3/66 (4.5%) |
| FRED X | 2/42 (4.8%) | 0/42 (0.0%) | 1/42 (2.4%) | 0/42 (0.0%) | 3/42 (7.1%) |















### Primary Efficacy endpoint

**Table 130 : Rate of complete aneurysm occlusion at 6 months without associated stenosis of the parent artery (CORELAB) [PP - N=117 patients]**

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

**Table 131 : Rate of complete aneurysm occlusion at 12 months without associated stenosis of the parent artery (CORELAB) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Rate of complete aneurysm occlusion at 12 months without associated stenosis of the parent artery** | N | 79 | 45 | 124 |
|  | Missing data | 0 |  | 0 |
|  | Echec | 16 (20.3%) | 9 (20.0%) | 25 (20.2%) |
|  | Success | 63 (79.7%) | 36 (80.0%) | 99 (79.8%) |
|  | 95% CI | 70.9% - 88.6% | 68.3% - 91.7% | 72.8% - 86.9% |
|  | Between group test |  |  | 0.973 (Chi-2) |

## APPENDIX 3 – RESULTS IN THE FAS AND PP POPULATIONS FOR SAFETY ANALYSIS

### Morbidity Rate at 12 months in FAS population

**Table 132 : Morbidity rate at the 12-month visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Morbidity at the 12-month visit** | N | 82 | 48 | 130 |
|  | Missing data | 0 | 0 | 0 |
|  | mRS < 3 | 82 (100.0%) | 48 (100.0%) | 130 (100.0%) |

**Table 133 : mRS score at the 12-month visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=82** | **FRED X N=48** | **Total N=130** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **mRS score** | N | 82 | 48 | 130 |
|  | Missing data | 0 | 0 | 0 |
|  | 0 - No symptoms at all | 68 (82.9%) | 40 (83.3%) | 108 (83.1%) |
|  | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | 11 (13.4%) | 7 (14.6%) | 18 (13.8%) |
|  | 2 - Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance | 3 (3.7%) | 1 (2.1%) | 4 (3.1%) |
|  | Between group test |  |  | 1.000 (Fisher) |

For the **mRS** score change, patients analyzed at 12 months were considered (N=130 patients).

**Table 134 : mRS change between baseline and 12-month visit (INVESTIGATORS) [FAS - N=130 patients]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Baseline mRS** | **12 Months mRS** | | | **Total number of patients (N=130 patients)** |
| **mRS 0** | **mRS 1** | **mRS 2** |
| **mRS 0** | **88/130 (67.7%)** | **3/130 (2.3%)** | **2/130 (1.5%)** | **93/130 (71.5%)** |
| FRED/ FRED Jr | 53/82 (64.6%) | 1/82 (1.2%) | 1/82 (1.2%) | 55/82 (67.1%) |
| FRED X | 35/48 (72.9%) | 2/48 (4.2%) | 1/48 (2.1%) | 38/48 (79.2%) |
| **mRS 1** | **20/130 (15.4%)** | **12/130 (9.2%)** | **1/130 (0.8%)** | **33/130 (25.4%)** |
| FRED/ FRED Jr | 15/82 (18.3%) | 8/82 (9.8%) | 1/82 (1.2%) | 24/82 (29.3%) |
| FRED X | 5/48 (10.4%) | 4/48 (8.3%) | 0/48 (0.0%) | 9/48 (18.7%) |
| **mRS 2** | **0/130 (0.0%)** | **3/130 (2.3%)** | **1/130 (0.8%)** | **4/130 (3.1%)** |
| FRED/ FRED Jr | 0/82 (0.0%) | 2/82 (2.4%) | 1/82 (1.2%) | 3/82 (3.7%) |
| FRED X | 0/48 (0.0%) | 1/48 (2.1%) | 0/48 (0.0%) | 1/48 (2.1%) |

### Morbidity Rate at 12 months in PP population

**Table 135 : Morbidity rate at the 12-month visit (INVESTIGATORS) [PP - N=124 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Morbidity at the 12-month visit** | N | 79 | 45 | 124 |
|  | Missing data | 0 | 0 | 0 |
|  | mRS < 3 | 79 (100.0%) | 45 (100.0%) | 124 (100.0%) |

**Table 136 : mRS score at the 12-month visit (INVESTIGATORS) [FAS - N=130 patients]**

|  | | **FRED / FRED Jr N=79** | **FRED X N=45** | **Total N=124** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **mRS score** | N | 79 | 45 | 124 |
|  | Missing data | 0 | 0 | 0 |
|  | 0 - No symptoms at all | 65 (82.3%) | 37 (82.2%) | 102 (82.3%) |
|  | 1 - No significant disability despite symptoms; able to carry out all usual duties and activities | 11 (13.9%) | 7 (15.6%) | 18 (14.5%) |
|  | 2 - Slight disability; unable to carry out all previous activities, but able to look after own affairs without assistance | 3 (3.8%) | 1 (2.2%) | 4 (3.2%) |
|  | Between group test |  |  | 1.000 (Fisher) |

For the **mRS** score change, patients analyzed at 12 months were considered (N=124 patients)..

**Table 137 : mRS change between baseline and 12-month visit (INVESTIGATORS) [PP - N=124 patients]**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Baseline mRS** | **12 Months mRS** | | | **Total number of patients (N=124 patients)** |
| **mRS 0** | **mRS 1** | **mRS 2** |
| **mRS 0** | **84/124 (67.7%)** | **3/124 (2.4%)** | **2/124 (1.6%)** | **89/124 (71.8%)** |
| FRED/ FRED Jr | 51/79 (64.6%) | 1/79 (1.3%) | 1/79 (1.3%) | 53/79 (67.1%) |
| FRED X | 33/45 (73.3%) | 2/45 (4.4%) | 1/45 (2.2%) | 36/45 (80.0%) |
| **mRS 1** | **18/124 (14.5%)** | **12/124 (9.7%)** | **1/124 (0.8%)** | **31/124 (25.0%)** |
| FRED/ FRED Jr | 14/79 (17.7%) | 8/79 (10.1%) | 1/79 (1.3%) | 23/79 (29.1%) |
| FRED X | 4/45 (8.9%) | 4/45 (8.9%) | 0/45 (0.0%) | 8/45 (17.8%) |
| **mRS 2** | **0/124 (0.0%)** | **3/124 (2.4%)** | **1/124 (0.8%)** | **4/124 (3.2%)** |
| FRED/ FRED Jr | 0/79 (0.0%) | 2/79 (2.5%) | 1/79 (1.3%) | 3/79 (3.8%) |
| FRED X | 0/45 (0.0%) | 1/45 (2.2%) | 0/45 (0.0%) | 1/45 (2.2%) |

### Complications

#### All complications until 12 months for FAS population from 139 patients

**Table 138 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 139 patients [All patients - N=139 patients]**

|  | | **FRED / FRED Jr N=88** | **FRED X N=51** | **Total N=139** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Occurrence of all complications until 12-month** | N | 88 | 51 | 139 |
|  | 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) |

**Table 139 : Description of all complications until 12-month follow-up (CEC) from 139 patients [All patients - N=43 patients - 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 |

***Listing of all complications until 12-month* from 139 patients *is in Appendix 4.***

#### Complications until 12 months for FAS population

**Table 140 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 130 patients [FAS - N=130 patients]**

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

**Table 141 : Description of all complications until 12-month follow-up (CEC) from 130 patients [FAS - N=38 patients - 55 complications]**

|  | | **FRED / FRED Jr N=27** | **FRED X N=28** | **Total N=55** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 27 | 28 | 55 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 0 | 1 (3.6%) | 1 (1.8%) |
|  | Thromboembolic complications | 8 (29.6%) | 7 (25.0%) | 15 (27.3%) |
|  | Puncture site complications | 0 | 2 (7.1%) | 2 (3.6%) |
|  | Other complications | 19 (70.4%) | 18 (64.3%) | 37 (67.3%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 27 | 28 | 55 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 9 (33.3%) | 6 (21.4%) | 15 (27.3%) |
|  | Patient symptomatic | 18 (66.7%) | 22 (78.6%) | 40 (72.7%) |
|  |  |  |  |  |
| **AE severity** | N | 27 | 28 | 55 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 16 (59.3%) | 11 (39.3%) | 27 (49.1%) |
|  | Moderate | 6 (22.2%) | 14 (50.0%) | 20 (36.4%) |
|  | Severe | 5 (18.5%) | 3 (10.7%) | 8 (14.5%) |
|  |  |  |  |  |
| **Causal relationship** | N | 27 | 28 | 55 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 5 (18.5%) | 5 (17.9%) | 10 (18.2%) |
|  | Procedure related AE | 6 (22.2%) | 11 (39.3%) | 17 (30.9%) |
|  | Device and procedure related AE | 6 (22.2%) | 9 (32.1%) | 15 (27.3%) |
|  | Oher | 10 (37.0%) | 3 (10.7%) | 13 (23.6%) |
|  |  |  |  |  |
| **Other relationship** | N | 18 | 5 | 23 |
|  | Missing data | 9 | 23 | 32 |
|  | checked | 18 (100.0%) | 5 (100.0%) | 23 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 18 | 5 | 23 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (5.6%) | 0 | 1 (4.3%) |
|  | Concurrent condition | 3 (16.7%) | 2 (40.0%) | 5 (21.7%) |
|  | Concurrent treatment | 6 (33.3%) | 1 (20.0%) | 7 (30.4%) |
|  | Other | 8 (44.4%) | 2 (40.0%) | 10 (43.5%) |
|  |  |  |  |  |
| **Serious AE** | N | 27 | 28 | 55 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 20 (74.1%) | 23 (82.1%) | 43 (78.2%) |
|  | Yes | 7 (25.9%) | 5 (17.9%) | 12 (21.8%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 7 | 5 | 12 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 6 (85.7%) | 2 (40.0%) | 8 (66.7%) |
|  | Permanent damage / Disability | 1 (14.3%) | 3 (60.0%) | 4 (33.3%) |
|  |  |  |  |  |
| **Event outcome** | N | 27 | 28 | 55 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 21 (77.8%) | 19 (67.9%) | 40 (72.7%) |
|  | Not resolved / ongoing | 6 (22.2%) | 8 (28.6%) | 14 (25.5%) |
|  | Unknown | 0 | 1 (3.6%) | 1 (1.8%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 26 | 28 | 54 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 90.54 (118.13) | 50.82 (110.84) | 69.94 (115.08) |
|  | Median | 23.50 | 2.00 | 3.00 |
|  | Q1 - Q3 | 1.00 - 173.00 | 0.50 - 29.00 | 1.00 - 92.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 26 | 28 | 54 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 2.97 (3.88) | 1.67 (3.64) | 2.30 (3.78) |
|  | Median | 0.77 | 0.06 | 0.10 |
|  | Q1 - Q3 | 0.04 - 5.68 | 0.02 - 0.95 | 0.04 - 3.02 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

***Listing of complications until 12-month* from 130 patients *is in Appendix 4.***

#### Complications until 12 months for PP population

**Table 142 : Occurrence per patient of all complications until 12-month follow-up (CEC) from 124 patients [PP - N=124 patients]**

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

**Table 143 : Description of all complications until 12-month follow-up (CEC) from 124 patients [PP - N=37 patients – 53 complications]**

|  | | **FRED / FRED Jr N=25** | **FRED X N=28** | **Total N=53** |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
| **Type of complication** | N | 25 | 28 | 53 |
|  | Missing data | 0 | 0 | 0 |
|  | Technical issues | 0 | 1 (3.6%) | 1 (1.9%) |
|  | Thromboembolic complications | 7 (28.0%) | 7 (25.0%) | 14 (26.4%) |
|  | Puncture site complications | 0 | 2 (7.1%) | 2 (3.8%) |
|  | Other complications | 18 (72.0%) | 18 (64.3%) | 36 (67.9%) |
|  |  |  |  |  |
| **AE clinical impact** | N | 25 | 28 | 53 |
|  | Missing data | 0 | 0 | 0 |
|  | Patient asymptomatic | 7 (28.0%) | 6 (21.4%) | 13 (24.5%) |
|  | Patient symptomatic | 18 (72.0%) | 22 (78.6%) | 40 (75.5%) |
|  |  |  |  |  |
| **AE severity** | N | 25 | 28 | 53 |
|  | Missing data | 0 | 0 | 0 |
|  | Mild | 14 (56.0%) | 11 (39.3%) | 25 (47.2%) |
|  | Moderate | 6 (24.0%) | 14 (50.0%) | 20 (37.7%) |
|  | Severe | 5 (20.0%) | 3 (10.7%) | 8 (15.1%) |
|  |  |  |  |  |
| **Causal relationship** | N | 25 | 28 | 53 |
|  | Missing data | 0 | 0 | 0 |
|  | Device related AE | 5 (20.0%) | 5 (17.9%) | 10 (18.9%) |
|  | Procedure related AE | 6 (24.0%) | 11 (39.3%) | 17 (32.1%) |
|  | Device and procedure related AE | 4 (16.0%) | 9 (32.1%) | 13 (24.5%) |
|  | Oher | 10 (40.0%) | 3 (10.7%) | 13 (24.5%) |
|  |  |  |  |  |
| **Other relationship** | N | 18 | 5 | 23 |
|  | Missing data | 7 | 23 | 30 |
|  | checked | 18 (100.0%) | 5 (100.0%) | 23 (100.0%) |
|  |  |  |  |  |
| **Specification for other relationship** | N | 18 | 5 | 23 |
|  | Missing data | 0 | 0 | 0 |
|  | Study disease condition | 1 (5.6%) | 0 | 1 (4.3%) |
|  | Concurrent condition | 3 (16.7%) | 2 (40.0%) | 5 (21.7%) |
|  | Concurrent treatment | 6 (33.3%) | 1 (20.0%) | 7 (30.4%) |
|  | Other | 8 (44.4%) | 2 (40.0%) | 10 (43.5%) |
|  |  |  |  |  |
| **Serious AE** | N | 25 | 28 | 53 |
|  | Missing data | 0 | 0 | 0 |
|  | No | 18 (72.0%) | 23 (82.1%) | 41 (77.4%) |
|  | Yes | 7 (28.0%) | 5 (17.9%) | 12 (22.6%) |
|  |  |  |  |  |
| **Seriousness grade** | N | 7 | 5 | 12 |
|  | Missing data | 0 | 0 | 0 |
|  | Hospitalization (initial or prolonged) | 6 (85.7%) | 2 (40.0%) | 8 (66.7%) |
|  | Permanent damage / Disability | 1 (14.3%) | 3 (60.0%) | 4 (33.3%) |
|  |  |  |  |  |
| **Event outcome** | N | 25 | 28 | 53 |
|  | Missing data | 0 | 0 | 0 |
|  | Resolved without sequelae | 19 (76.0%) | 19 (67.9%) | 38 (71.7%) |
|  | Not resolved / ongoing | 6 (24.0%) | 8 (28.6%) | 14 (26.4%) |
|  | Unknown | 0 | 1 (3.6%) | 1 (1.9%) |
|  |  |  |  |  |
| **Event onset delay (in days)** | N | 24 | 28 | 52 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 90.42 (123.16) | 50.82 (110.84) | 69.10 (117.23) |
|  | Median | 13.00 | 2.00 | 2.50 |
|  | Q1 - Q3 | 1.00 - 179.50 | 0.50 - 29.00 | 1.00 - 96.00 |
|  | Min - Max | 0.00 - 408.00 | 0.00 - 414.00 | 0.00 - 414.00 |
|  |  |  |  |  |
| **Event onset delay (in months)** | N | 24 | 28 | 52 |
|  | Missing data | 1 | 0 | 1 |
|  | Mean (s.d.) | 2.97 (4.04) | 1.67 (3.64) | 2.27 (3.85) |
|  | Median | 0.42 | 0.06 | 0.08 |
|  | Q1 - Q3 | 0.04 - 5.89 | 0.02 - 0.95 | 0.04 - 3.15 |
|  | Min - Max | 0.00 - 13.40 | 0.00 - 13.60 | 0.00 - 13.60 |

***Listing of complications until 12-month* from 124 patients *is in Appendix 4.***

#### Post-procedural complications between 6 months and 12 months for FAS population

**Table 144 : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=130 patients]**

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

**Table 145 : Description of post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=10 patients - 10 complications]**

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



**Table 146 : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=8 patients - 8 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |  | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |  | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |  | 6.34 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |  | 13.40 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |  | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |  | 13.60 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |  | 5.68 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |  | 12.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |  | 3.42 |

**Table 147 : Listing of all post-procedural complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=10 patients - 10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |

**Table 148 : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) from 130 patients [FAS - N=2 patients - 2 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |

#### Post-procedural complications between 6 months and 12 months for PP population

**Table 149 : Occurrence per patient of post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=124 patients]**

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

**Table 150 : Description of post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=10 patients - 10 complications]**

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

**Table 151 : Listing of other post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=8 patients - 8 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** |  | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing |  | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae |  | 6.34 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing |  | 13.40 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae |  | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing |  | 13.60 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae |  | 5.68 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing |  | 12.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae |  | 3.42 |

**Table 152 : Listing of all post-procedural complications between 6-month and 12-month (CEC) from 124 patients [PP - N=10 patients - 10 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |  |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |  |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |  |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |  |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |  |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |  |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |  |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |  |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |  |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |  |

**Table 153 : Listing of all Thromboembolic complications between 6-month and 12-month (CEC) from 124 patients [PP - N=2 patients - 2 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |

## APPENDIX 4 – LISTING OF ALL COMPLICATIONS UNTIL 12 MONTHS

### All patients

**Table 154 : Listing of other complications until 12-month (CEC) from 156 patients [All patients - N=36 patients - 45 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER | 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 | Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae | 3.44 |
| 07-014 | FRED / FRED Jr | FRED | Other complications | FEVER | (FEVER) PYREXIA | G04 Fever (Non-infectious) | Patient symptomatic | Moderate | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.10 |
| 07-014 | FRED / FRED Jr | FRED | Other complications | GASTROINTESTINAL BLEEDING | GASTROINTESTINAL BLEEDING | D03 GI Bleed | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | Yes | Resolved without sequelae | 6.20 |
| 07-014 | FRED / FRED Jr | FRED | Other complications | TRACHEOBRONCHITIS | TRACHEOBRONCHITIS | E11 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Probable | . | Yes | Resolved without sequelae | 0.78 |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI | HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.10 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA | INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.14 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT | SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |

**Table 155 : Listing of all complications until 12-month (CEC) from 156 patients [All patients- N=49 patients - 70 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER | 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 | Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  | LEFT HEMIPARESIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable | Not related | . | Yes | Resolved without sequelae | 8.02 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | . | Yes | Resolved without sequelae | 0.32 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-001 | FRED / FRED Jr | FRED | Technical issues | ACCESS DEVICE RELATED VASOSPAM | VASOSPASM DISTAL CERVICAL ICA DURING PROCEDURE | K01 Arterial Spasm | Patient asymptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 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 | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-011 | FRED / FRED Jr | FRED | Puncture site complications |  | GROIN HEMATOMA | K05 Access site pseudoaneurysm | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae | 3.44 |
| 07-014 | FRED / FRED Jr | FRED | Thromboembolic complications |  | 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 | Certain | checked | No | Resolved without sequelae | 0.00 |
| 07-014 | FRED / FRED Jr | FRED | Other complications | FEVER | (FEVER) PYREXIA | G04 Fever (Non-infectious) | Patient symptomatic | Moderate | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.10 |
| 07-014 | FRED / FRED Jr | FRED | Delayed IC hematoma |  | INTRACRANIAL BLEEDING FRONTAL LEFT,FOLLOWED BY VASOSPASM AND MEDIAINFARCTION LEFT | A06 ICH | Patient symptomatic | Severe | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.60 |
| 07-014 | FRED / FRED Jr | FRED | Other complications | GASTROINTESTINAL BLEEDING | GASTROINTESTINAL BLEEDING | D03 GI Bleed | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | Yes | Resolved without sequelae | 6.20 |
| 07-014 | FRED / FRED Jr | FRED | Other complications | TRACHEOBRONCHITIS | TRACHEOBRONCHITIS | E11 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Probable | . | Yes | Resolved without sequelae | 0.78 |
| 07-015 | FRED / FRED Jr | FRED | Thromboembolic complications |  | GAIT ABNORMALITY (GANGATAXIE) | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | . | No | Resolved without sequelae | 0.14 |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI | HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.10 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA | INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.14 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT | SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |
| 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 | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.00 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

**Table 156 : Listing of all Thromboembolic complications until 12-month (CEC) from 156 patients [All patients - N=17 patients - 19 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  | LEFT HEMIPARESIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable | Not related | . | Yes | Resolved without sequelae | 8.02 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | . | Yes | Resolved without sequelae | 0.32 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 07-014 | FRED / FRED Jr | FRED | Thromboembolic complications |  | 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 | Certain | checked | No | Resolved without sequelae | 0.00 |
| 07-015 | FRED / FRED Jr | FRED | Thromboembolic complications |  | GAIT ABNORMALITY (GANGATAXIE) | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | . | No | Resolved without sequelae | 0.14 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

### All patients – FAS population from 139 patients

**Table 157 : Listing of other complications until 12-month (CEC) from 139 patients [All patients - N=31 patients - 39 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA | INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.14 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT | SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |

**Table 158 : Listing of all complications until 12-month (CEC) from 139 patients [All patients- N=43 patients - 60 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  | LEFT HEMIPARESIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable | Not related | . | Yes | Resolved without sequelae | 8.02 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-001 | FRED / FRED Jr | FRED | Technical issues | ACCESS DEVICE RELATED VASOSPAM | VASOSPASM DISTAL CERVICAL ICA DURING PROCEDURE | K01 Arterial Spasm | Patient asymptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 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 | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-011 | FRED / FRED Jr | FRED | Puncture site complications |  | GROIN HEMATOMA | K05 Access site pseudoaneurysm | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-035 | FRED X | FRED X | Other complications | PUNCTURE SITE HEMATOMA | INGUINAL HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.14 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 08-015 | FRED X | FRED X | Other complications | VISUAL IMPAIRMENT | SCINTILLATING SCOTOMA LEFT EYE | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not probable | . | Yes | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |
| 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 | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.00 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

**Table 159 : Listing of all Thromboembolic complications until 12-month (CEC) from 139 patients [All patients - N=14 patients - 16 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 01-043 | FRED X | FRED X | Thromboembolic complications |  | LEFT HEMIPARESIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Probable | Not related | . | Yes | Resolved without sequelae | 8.02 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

### ITT population from 143 patients

**Table 160 : Listing of other complications until 12-month (CEC) from 143 patients [ITT - N=32 patients - 40 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER | 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 | Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae | 3.44 |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI | HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.10 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |

**Table 161 : Listing of all complications until 12-month (CEC) from the 143 patients [ITT - N=42 patients - 59 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 01-031 | FRED / FRED Jr | FRED Jr | Other complications | POST TRAUMATIC STRESS DISORDER | 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 | Not probable | . | Yes | Not resolved / ongoing | 5.98 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | . | Yes | Resolved without sequelae | 0.32 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 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 | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-012 | FRED / FRED Jr | FRED | Other complications | HYPERTENSIVE CRISIS, HEADACHE | HEADACHE AND HYPERTENSION | A17 Headache | Patient symptomatic | Mild | Device and procedure related AE | Certain | Possible | . | No | Resolved without sequelae | 3.44 |
| 07-017 | FRED / FRED Jr | FRED | Other complications | HAEMORRHAGIA UTI | HAEMORRHAGIC URINARY TRACT INFECTION | L01 Hematuria | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.10 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |
| 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 | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.00 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

**Table 162 : Listing of all Thromboembolic complications until 12-month (CEC) from the 143 patients [ITT - N=16 patients - 16 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | . | Yes | Resolved without sequelae | 0.32 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

### FAS population from 130 patients

**Table 163 : Listing of other complications until 12-month (CEC) from 130 patients [FAS - N=29 patients - 37 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |

**Table 164 : Listing of all complications until 12-month (CEC) from 130 patients [FAS - N=38 patients - 55 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-021 | FRED / FRED Jr | FRED | Other complications | FORTHSHORTENING OF FD | FORTHSHORTENING OF THE PROXIMAL FD | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Probable | . | No | Resolved without sequelae | 3.02 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 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 | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |
| 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 | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.00 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

**Table 165 : Listing of all Thromboembolic complications until 12-month (CEC) from the 143 patients [FAS - N=13 patients - 15 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-021 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINOR STROKE | A04 Ischemic Stroke | Patient asymptomatic | Mild | Device and procedure related AE | Probable | Possible | . | No | Resolved without sequelae | 3.02 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |

### PP population from 124 patients

**Table 166 : Listing of other complications until 12-month (CEC) from 124 patients [PP - N=28 patients - 36 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |

**Table 167 : Listing of all complications until 12-month (CEC) from 124 patients [PP - N=37 patients - 53 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-016 | FRED / FRED Jr | FRED | Other complications | VASOSPASM | VASOSPASM AT TIP OF GUIDING CATHETER | K01 Arterial Spasm | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | A29 Visual impairment | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 2.76 |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | BLEEDING AT PUNCTURE SITE | K04 Access site pain/bleeding/bruising | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.04 |
| 03-002 | FRED / FRED Jr | FRED | Other complications | SENSORY DISTURBANCES (TINGLING) | SENSORY DISTURBANCES (TINGLING SENSATIONS, PAIN) AT SHOULDER-NECK-AREA, LEFT SIDED, INTERMITTEND | A27 Tingling fingers/feet (extremities) | Patient asymptomatic | Mild | Oher | Not related | Not probable | checked | No | Not resolved / ongoing | 9.22 |
| 03-003 | FRED / FRED Jr | FRED | Other complications | PARTIAL CRANIAL NERVE TINGLING | SENSORY DISTURBANCES (TINGLING SENSATIONS) AT V2 (NERVUS MAXILLARIS) LEFT | A30 Other | Patient symptomatic | Mild | Oher | Not probable | Not related | checked | No | Not resolved / ongoing | . |
| 03-003 | FRED / FRED Jr | FRED | Other complications | 6 MFU | HEAMATOMA AT RIGHT GROIN | K06 Access site hematoma | Patient asymptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 6.34 |
| 03-004 | FRED / FRED Jr | FRED | Other complications | WORSENING OF PRE-EXSISTING CONDITION | WORSENING OF APHASIA | A10 Aphasia/Loss of Speech/Word-finding difficulty/Dysarthria | Patient symptomatic | Severe | Device related AE | Possible | Not related | checked | Yes | Not resolved / ongoing | 8.80 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 04-002 | FRED / FRED Jr | FRED | Other complications | CLOT BUT NOT EMBOLISM | THROMBUS (CLOT) | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Mild | Device related AE | Certain | Not related | checked | No | Resolved without sequelae | 0.00 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-007 | FRED / FRED Jr | FRED | Other complications | ORBITAL PAIN UNKNOWN ETIOLOGY | RETRO0RBITAL PAIN | A30 Other | Patient symptomatic | Severe | Oher | Not probable | Not related | checked | Yes | Not resolved / ongoing | 13.40 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-008 | FRED / FRED Jr | FRED | Other complications | ACCESS SITE COMPLICATION | GROIN HEMATOMA | K06 Access site hematoma | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 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 | Patient asymptomatic | Moderate | Device related AE | Certain | Not probable | . | No | Resolved without sequelae | 0.00 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-004 | FRED / FRED Jr | FRED | Other complications | DIZZINESS AND DOUBLE VISION | DIZZINESS AND DOUBLE VISION | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 06-006 | FRED X | FRED X | Other complications | VIRAL INFECTION | COVID 19 POSITIV | N01 Other | Patient symptomatic | Mild | Oher | Not related | Not related | . | No | Resolved without sequelae | 8.22 |
| 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 | K04 Access site pain/bleeding/bruising | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 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 | K10 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | checked | No | Resolved without sequelae | 0.00 |
| 06-009 | FRED X | FRED X | Other complications | MOOD DISORDER | DEPRESSION | A30 Other | Patient symptomatic | Moderate | Oher | Not related | Not related | . | No | Not resolved / ongoing | 13.60 |
| 07-003 | FRED / FRED Jr | FRED | Other complications | TRAUMA CAUSING HEADACHE | STRONG HEADACHE AFTER SMALL ACCIDENT (HEADER) | A30 Other | Patient symptomatic | Mild | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.86 |
| 07-026 | FRED / FRED Jr | FRED | Other complications | GASTRITIS | GASTRITIS | D04 Heartburn | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.68 |
| 07-038 | FRED X | FRED X | Other complications | VISUAL DISTURBANCES AND HEADACHE | VISUAL DISTURBANCES AND HEADACHE | A30 Other | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.10 |
| 07-041 | FRED X | FRED X | Other complications | TIA | POSTINTERVENTIONAL PARESIS OF RIGHT HAND AND APHASIA | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | . | No | Resolved without sequelae | 0.00 |
| 07-041 | FRED X | FRED X | Other complications | PULMONARY EMBOLISM | PULMONARY EMBOLISM | K09 Pulmonary Embolism | Patient symptomatic | Moderate | Oher | Not related | Not related | checked | Yes | Unknown | 0.10 |
| 08-001 | FRED / FRED Jr | FRED | Other complications | WATERING EYES | WATERING EYES | G08 Other | Patient symptomatic | Mild | Oher | Not related | Not probable | checked | No | Resolved without sequelae | 0.04 |
| 08-003 | FRED / FRED Jr | FRED | Other complications | TRAUMATIC GASTRIC TUBING | EPISTAXIS AND ANEMIA | E09 Epistaxis | Patient symptomatic | Severe | Oher | Not related | Not related | checked | No | Resolved without sequelae | 0.04 |
| 08-007 | FRED / FRED Jr | FRED | Other complications | THROMBOPHLEBITIS | THROMBOPHLEBITIS VENA SAPHENA MAGNA LEFT | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Possible | checked | No | Resolved without sequelae | 0.16 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-009 | FRED / FRED Jr | FRED | Other complications | PUNCTURE SITE COMPLICATION | RIGHT RADIAL ARTERY THROMBOSIS | K07 Access site occlusion | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 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 | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Oher | Not related | Not related | . | Yes | Resolved without sequelae | 5.68 |
| 08-010 | FRED X | FRED X | Other complications | HEMATOMA LEFT BACK OF THE HAND | HEMATOMA LEFT BACK OF THE HAND | K10 Other | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.26 |
| 08-011 | FRED X | FRED X | Other complications | FLASHING LIGHTS IN THE EYES | FLASHING LIGHTS | A30 Other | Patient symptomatic | Mild | Procedure related AE | Not related | Probable | checked | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Other complications | PUNCTURE SITE COMPLICATION | RETROPERITONEAL HEMATOMA RIGHT | K06 Access site hematoma | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.04 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 08-020 | FRED X | FRED X | Other complications | GROIN HEMATOMA | HAEMATOMA | K06 Access site hematoma | Patient symptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.22 |
| 08-022 | FRED X | FRED X | Other complications | ND | LOSS OF VISUS | A29 Visual impairment | Patient symptomatic | Severe | Device related AE | Possible | Not related | . | Yes | Not resolved / ongoing | 12.06 |
| 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 | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.00 |
| 08-023 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 08-023 | FRED X | FRED X | Other complications | ANEURYSM THROMBOSIS= AGGRAVATION OF CRANIAL NERVE IRRITATION | PROLIFERATION OF SIXTH NERVE PALSY RIGHT | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Not resolved / ongoing | 1.58 |
| 08-025 | FRED X | FRED X | Other complications | MASS EFFECT FROM ANEURYSM MAYBE THROMBOSED | DIPLOPIA | A13 Cranial Nerve Damage | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.04 |
| 08-025 | FRED X | FRED X | Other complications | ANEURYSM SPURIUM | ANEURYSMA SPURIUM RIGHT INGUINAL | K05 Access site pseudoaneurysm | Patient symptomatic | Moderate | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 0.06 |
| 08-025 | FRED X | FRED X | Other complications | HAIRLOSS CIRCUMSCRIBED | HAIRLOSS | H01 Alopecia | Patient asymptomatic | Mild | Procedure related AE | Not related | Certain | . | No | Resolved without sequelae | 3.42 |
| 08-026 | FRED X | FRED X | Other complications | HEADACHE | HEADACHE | A17 Headache | Patient symptomatic | Moderate | Device related AE | Possible | Not probable | . | No | Not resolved / ongoing | 1.70 |
| 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 | N01 Other | Patient asymptomatic | Mild | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.00 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |
| N = 53 | | | | |  |  |  |  | N = 53 |  |  |  |  |  | N = 53 |

**Table 168 : Listing of all Thromboembolic complications until 12-month (CEC) from the 124 patients [PP - N=12 patients - 14 complications]**

| **Subject Identifier for the Study** | **Subgroup device** | **FRED used type** | **Specification for type event** | **Specification for other complication** | **Event description** | **AE code** | **Clinical impact** | **Severity** | **Causal relationship** | **Device relation ship** | **Index procedure relationship** | **Other relationship** | **Serious** | **Event outcome** | **Event onset delay (in months)** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 01-035 | FRED X | FRED X | Thromboembolic complications |  | ASYMPTOMATIC DWI LESION IN F MRT | A01 Thromboembolic Event - No Perfusion Deficit | Patient asymptomatic | Mild | Device and procedure related AE | Possible | Probable | . | No | Resolved without sequelae | 0.06 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | UNWITNESSED OCCLUSION OF PARENT ARTERY | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient asymptomatic | Severe | Device related AE | Certain | Not probable | . | No | Not resolved / ongoing | 6.10 |
| 04-001 | FRED / FRED Jr | FRED | Thromboembolic complications |  | RECURRENT AMAUROSIS | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Moderate | Device and procedure related AE | Certain | Possible | . | Yes | Not resolved / ongoing | 10.14 |
| 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. | A04 Ischemic Stroke | Patient symptomatic | Mild | Device and procedure related AE | Possible | Probable | checked | No | Resolved without sequelae | 0.06 |
| 04-006 | FRED / FRED Jr | FRED | Thromboembolic complications |  | MINIMAL FACIAL POLSY ON THE LEFT 1 DAY AFTER INTERVENTION. | A14 Facial Palsy | Patient symptomatic | Mild | Device and procedure related AE | Possible | Possible | . | No | Resolved without sequelae | 0.04 |
| 04-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | TRANSIT WEAKNESS LEFT ARM | A04 Ischemic Stroke | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Probable | checked | Yes | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | PARTIAL STENT THROMBOSIS 20 MIN AFTER DEPLOYMENT | B04 Thrombosis - Parent or branch artery | Patient asymptomatic | Moderate | Device and procedure related AE | Probable | Certain | . | No | Resolved without sequelae | 0.00 |
| 04-014 | FRED X | FRED X | Thromboembolic complications |  | SUBTOTAL OCCLUSION OF FRED X | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Mild | Device and procedure related AE | Certain | Certain | checked | Yes | Resolved without sequelae | 0.26 |
| 04-020 | FRED X | FRED X | Thromboembolic complications |  | IN-STENT THROMBOSIS LEADING TO INFARCTIONS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not probable | . | Yes | Not resolved / ongoing | 0.32 |
| 06-002 | FRED / FRED Jr | FRED | Thromboembolic complications |  | PATIENT INFORMED ABOUT TEMPORARY SCOTOMA FOR ABOUT 10 MIN ON 10-APRIL-2020. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Possible | Not related | checked | No | Resolved without sequelae | 3.98 |
| 06-006 | FRED X | FRED X | Thromboembolic complications |  | AMAUROSIS FUGAX LEFT EYE FOR ABOUT 10 MIN. | A03 Transient Ischemic Attack (TIA) | Patient symptomatic | Mild | Device related AE | Probable | Not related | checked | No | Resolved without sequelae | 4.56 |
| 08-008 | FRED / FRED Jr | FRED | Thromboembolic complications |  | STENT THROMBOSIS | A04 Ischemic Stroke | Patient symptomatic | Severe | Device related AE | Certain | Not related | checked | Yes | Resolved without sequelae | 2.88 |
| 08-012 | FRED X | FRED X | Thromboembolic complications |  | SCOTOMA | A29 Visual impairment | Patient symptomatic | Severe | Device and procedure related AE | Certain | Certain | . | No | Not resolved / ongoing | 0.04 |
| 09-001 | FRED X | FRED X | Thromboembolic complications | ND | NEW NEUROLOGICAL DEFICIT WITH DYSARTHRIA AND RIGHT SIDED WEAKNESS | A02 Thromboembolic Event - Perfusion Deficit Observed | Patient symptomatic | Moderate | Device and procedure related AE | Possible | Certain | . | Yes | Not resolved / ongoing | 0.04 |