1.0 Device Identification and General Information

i) Document Number: MS-0074

ii) Device trade names: Pruitt F3® Carotid Shunt

iii) Manufacturer's name and address:

Legal manufacturer name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue, Burlington, MA. 01803, USA

iv) SRN: US-MF-000016778

v) Basic UDI-DI: 08406631F3ShuntTP

vi) Device Item Codes, Descriptions and Basic UDI

GTIN-14 (UDI)	Item Number	Item Description
00840663101191	2011-10	Pruitt F3 Outlying Carotid Shunt with T-Port 10F
00840663101276	2011-12	Pruitt F3 Inlying Carotid Shunt without T-Port 10F
00840663101221	2012-11	Pruitt F3 Outlying Carotid Shunt without T-Port 9F
00840663101207	2012-12	Pruitt F3 Inlying Carotid Shunt with T-Port 9F
00840663101313	2012-13	Pruitt F3 Outlying Carotid Shunt with T-Port 9F
00840663101313	2012-13	Pruitt F3 Inlying Carotid Shunt with T-Port 9F
00840663101320	2013-10	Pruitt F3 Outlying Carotid Shunt with T-Port 8F
00840663110698	2011-10M	Pruitt F3 Outlying Carotid Shunt with T-Port 10F
00840663110704	2011-12M	Pruitt F3 Inlying Carotid Shunt without T-Port 10F
00840663110711	2012-11M	Pruitt F3 Outlying Carotid Shunt without T-Port 9F
00840663110728	2012-12M	Pruitt F3 Inlying Carotid Shunt with T-Port 9F
00840663110735	2012-13M	Pruitt F3 Outlying Carotid Shunt with T-Port 9F
00840663110742	2012-13M	Pruitt F3 Inlying Carotid Shunt with T-Port 9F
00840663110759	2013-10M	Pruitt F3 Outlying Carotid Shunt with T-Port 8F

vii) Medical device nomenclature description

GMDN Code / Description: 47113 / Carotid artery shunt
UMDNS Code / Description: 17-797 / Shunts, Carotid Artery
EMDN Code / Description: 47113 / Carotid artery shunt

viii) Class of device

Manufacture Name	MDR Classification	Rule
Pruitt F3 Carotid Shunt	III	7

ix) Year when the first certificate (CE) was issued covering the device

Device Name	Date of Initial CE Mark	Date of 510(k)
Pruitt F3 Carotid Shunt	14 May 2010	27 May 2005 (K051067)

x) Authorised representative if applicable; name and the SRN

EU Authorized Representative	Tobias Malcharczik LeMaitre Vascular GmbH Otto-Volger-Str. 5 a/b 65843, Sulzbach/Ts Germany
SRN:	DE-AR-000013539

xi) NB's name (the NB that will validate the SSCP) and the NB's single identification number

BSI Group The Netherlands B.V.
Identification Number: 2797
Say Building, John M. Keynesplein 9, 1066 EP
Amsterdam, Netherlands

2.0 Intended use of the device

i) Intended Purpose: The Pruitt F3 Carotid Shunts are intended to act as a temporary conduit to allow for blood flow between the common and internal carotid arteries during endarterectomy procedures.

ii) Indication(s) and target population(s)

- Indication: The Pruitt F3 Carotid Shunts are indicated to facilitate carotid endarterectomy procedure for the treatment of carotid artery disease.
- Target population: Product is designed for patients of any gender, age or ethnicity undergoing carotid endarterectomies.

iii) Contraindications and/or limitations

- The shunt is a temporary device that should not be implanted.
- The Shunt is not indicated for use in embolectomy, thrombectomy, or vessel dilation.

3.0 Device Description

i) Description of the device

The Pruitt F3 Carotid Shunts are used as temporary conduits to allow for blood flow between the common and internal carotid arteries during carotid endarterectomy procedures.

The Pruitt F3 Carotid Shunts are provided sterile and are intended for single-use only. They should not be re-used, re-sterilized, reprocessed and/or repackaged. The devices are not implantable and are intended for short-term use (>60 minutes – 30 days). The Pruitt F3 Carotid Shunts are indicated for use as a carotid shunt during endarterectomies. These procedures are expected to take approximately 1-2 hours to complete. The shunts are removed as part of the procedure and discarded. They do not incorporate medicinal substances, tissues, or blood products.

The Pruitt F3 Carotid Shunts (see Table below) are multi-lumen devices with balloons at both the distal (internal carotid) and proximal (common carotid) ends of the shunt. The balloons, when inflated independently, act as a stabilization mechanism to maintain the position of the shunt when

it is placed within the common and internal carotid arteries. The inflation lumen is used to inflate and deflate the balloons, while the major lumen serves as the conduit between the common and internal carotid arteries. The shunts have features to aid the user during shunt insertion and balloon inflation. The inflation path of the proximal (common carotid) balloon is color coded, where sterile saline is injected from the blue stopcock, through the blue lumen and into the blue common carotid balloon. Likewise, to inflate the distal (internal carotid) balloon, sterile saline is injected from the white stopcock, through the white lumen and into the white internal carotid balloon. Depth markings on the shunt body are for reference during insertion.

The Pruitt F3 Carotid Shunts are available in an inlying or an outlying configuration. The shunts are available with or without a T-port with a red stopcock, which is connected to the major lumen and provides an access point to blood flow during the procedure.

The shunt body, inflation arms, and T-port arm in the Pruitt F3 Carotid Shunt (see image below) are made of polyurethane, while the balloons of the Pruitt F3 Carotid Shunt are made of latex.. Additionally, the Pruitt F3 Carotid Shunt includes an external safety balloon located on the inflation arm leading to the distal (internal carotid) balloon. This balloon acts as a mechanism to relieve pressure on the internal carotid balloon in the event it inflates above optimal size and pressure, thus reducing the possibility of balloon over inflation and resultant vessel damage. The sleeve of the external safety balloon is yellow to increase its visibility.

The Pruitt F3 Carotid Shunts are indicated for use as a carotid shunt during endarterectomies. These procedures are expected to take approximately 1-2 hours to complete. The shunts are removed as part of the procedure and discarded. As the Pruitt F3 Carotid Shunts are not indicated for implantation, rather as transient use devices, the lifetime of the device is set at 3 hours.

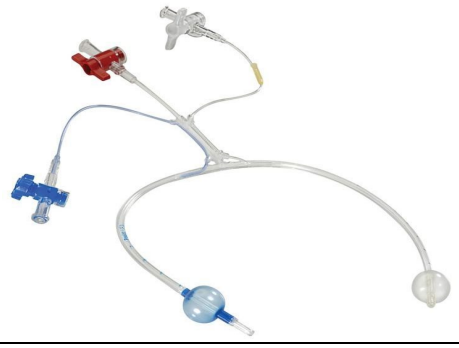

Image of the Pruitt F3 Carotid Shunt

ii) Previous generations: The devices are mature products currently on the market for a well-established intended use. They have been developed by incremental changes. The Pruitt F3® Carotid Shunt is based on the Pruitt-Inahara® Carotid Shunt predecessor device. There are no novel design features, indications, or target populations for the Pruitt F3® Carotid Shunt compared to the Pruitt-Inahara® Carotid Shunt. However, the following claims were made regarding the Pruitt F3® Carotid Shunt compared to the predecessor device which may impact safety and performance:

- Increased flexibility

- Improved kink resistance
- Increased flow rate

Additionally, minor changes have been made to the predecessor device to provide incremental benefits to the user/patients which were based on customer feedback. These include:

- Color-coding to clarify the inflation path leading to the common balloon
- A yellow safety sleeve to draw attention to and ensure proper use of the safety balloon
- Stopcock separators to prevent the stopcocks from tangling
- Depth markings to indicate insertion length in the carotid artery

iii) Description of any accessories which are intended to be used in combination with the device: The Pruitt F3 Carotid Shunts are provided with 3 cc syringes that are used for inflating and deflating the balloons.

iv) Description of any other devices and products which are intended to be used in combination with the device: No other devices or products are intended to be used in combination with this device.

4.0 Risks and Warnings

i. Warnings

Pruitt F3 Carotid Shunt

- Do not reuse. Do not resterilize. For single use only.
- Do not use air or gas to inflate the balloons. Inflate the balloons with sterile saline.
- Do not inflate the internal carotid balloon to any greater volume than is necessary to obstruct blood flow for the internal carotid artery. DO NOT EXCEED the recommended maximum balloon liquid capacity (common carotid balloon: 1.5 mL, internal carotid balloon: 0.25 mL).
- Exercise caution when encountering extremely diseased vessels. Arterial rupture or balloon failure due to sharp calcified plaque may occur. The possibility of balloon rupture must be taken into account when considering the risks involved in the endarterectomy procedure.
- Deflate the balloons prior to Shunt removal. Avoid using excessive force to push or pull the Shunt against resistance.

ii. Precautions

Pruitt F3 Carotid Shunt

- Inspect the product and package prior to use and do not use if there is any evidence that the package or the Shunt has been damaged.
- The Shunt should be used only by qualified physicians thoroughly familiar with cardiovascular surgical procedures involving the carotid artery.
- Pretest the Shunt according to the pretest procedure prior to patient use to ensure the lumen is free of obstructions and the balloons are functional.
- Aspirate the balloons prior to inflation.
- Place internal carotid balloon into internal carotid artery and common carotid

balloon in common carotid artery.
- If the Shunt is not properly maintained in position through balloon stabilization, it may migrate within the internal carotid artery, potentially scuffing the intima.
- Avoid extended or excessive exposure to fluorescent light, heat, sunlight, or chemical fumes to reduce balloon degradation. Excessive handling during insertion, and/or plaque and other deposits within the blood vessel, may damage the balloon and increase the possibility of balloon rupture.
- Do not grasp the balloon with instruments at any time to avoid damage to the latex.
- Make secure connections between the syringe and the hub to avoid introduction of air.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations.

iii) Residual risks and undesirable effects

Summary of residual risks for the device under evaluation

Adverse event	Rate	timepoint	Source from CER
Aneurysms	0-9%	0-30 days	DUE
Arterial dissection	-	-	Not reported
Arterial spasm	-	-	Not reported
Arterial thrombosis	-	-	Not reported
Embolization of blood clots, arteriosclerotic plaque, or air	-	-	Not reported
Hemorrhage	≤0.3%	NR	PMS complaints
Hypertension or hypotension	-	-	Not reported
Infection	0-7%	6 months	SOTA
Intimal disruption	-	-	Not reported
Neurologic complications	-	-	Not reported
Stroke	0-9%	Postoperative – 7 months	Antuševas, 2023; Grillo 2022; Inčiūra, 2020; DUE
Transient ischemic attack	4%	NR	Inčiūra, 2020; DUE
Vessel perforation and rupture	-	-	Not reported

iv) Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN) if applicable

Overall device sales, complaints and complaint rates (complaints/units sold) per year

Device	Model	2018	2019	2020	2021	2022	2023	Total
Pruitt F3 Outlying Carotid Shunt	2013-10	5,960	6,302	5,708	6,505	7,222	5,463	37,160
	2012-10	16,990	18,596	15,120	15,768	17,127	12,411	96,012
	2012-11	614	651	445	440	400	342	2,892
	2011-10	613	762	602	838	897	495	4,207
Pruitt F3 Inlying Carotid Shunt	2012-12	2,079	2,204	1,832	1,900	2,146	1,458	11,619
	2012-13	249	208	157	158	142	127	1,041
	2011-12	131	246	129	286	337	119	1,248
Total		**27,569**	**30,199**	**24,854**	**27,030**	**29,291**	**21,217**	**154,179**

**through September*

The complaints per year are summarized in the table below:

Device	Model	2018		2019		2020		2021		2022		2023 (Jan-Sep)		Total	
		No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate	No.	Rate
Pruitt F3 Outlying Carotid Shunt	2013-10	10	0.168 %	20	0.317 %	20	0.350 %	5	0.077 %	11	0.152 %	15	0.275 %	68	0.183 %
	2012-10	47	0.277 %	28	0.151 %	28	0.185 %	40	0.254 %	22	0.128 %	39	0.314 %	212	0.221 %
	2012-11	0	0.000 %	2	0.307 %	2	0.449 %	0	0.000 %	4	1.000 %	1	0.292 %	8	0.277 %
	2011-10	0	0.000 %	2	0.262 %	2	0.332 %	1	0.119 %	0	0.000 %	2	0.404 %	5	0.119 %
Pruitt F3 Inlying Carotid Shunt	2012-12	3	0.144 %	3	0.136 %	3	0.164 %	0	0.000 %	3	0.140 %	0	0.000 %	10	0.086 %
	2012-13	1	0.402 %	0	0.000 %	0	0.000 %	0	0.000 %	0	0.000 %	0	0.000 %	1	0.096 %
	2011-12	0	0.000 %	0	0.000 %	0	0.000 %	0	0.000 %	0	0.000 %	0	0.000 %	0	0.000 %
Unknown		0	3	-	0	-	0	-	1	-	2	-	2	-	8
Total		**74**	**0.268 %**	**64**	**0.212 %**	**64**	**0.258 %**	**53**	**0.196 %**	**45**	**0.154 %**	**63**	**0.297 %**	**348**	**0.202 %**

During 01 January 2018 to 30 September 2023, there were 312 complaints associated with the subject devices and a total of 154,179 devices sold, resulting in an overall cumulative complaint

rate of 0.202%. The highest complaint rates were due to leaking at stopcock (0.046%), balloon would not deflate (0.029%) and hole in the balloon (0.023%). There were 213 FDA MAUDE reports during this period; there was 1 death that could not be attributed to the subject device, 17 injuries, and 195 malfunctions.

During the reporting period of 01 January 2018 to 30 September 2023, 3 CAPAs were opened for the Pruitt F3. All CAPAs were successfully closed. There was 1 recall, related to the F3 shunt packages containing an inlying shunt rather than the outlying shunt specified on the labels which was closed in 2020. There were no complaints related to the syringe accessory.

Corrective and Preventative Actions:

The table below lists the CAPAs relevant to the safety and performance of the subject devices that were opened from 01 January 2018 to 30 September 2023, there are 3 CAPAs. CAPA 2022-003 was initiated due to the high rate of complaints associated with a vendor-supplied syringe. Corrective actions have been identified and are being addressed.

Table 4-1: CAPA summary

CAPA #	Device	Reason for initiation	Status
2018-035	F3	Shunt packaged with inlying vs outlying.	Closed on 19 December 2019
2019-027	F3	Shunt leakage.	Closed on 17 August 2021
2022-003	F3	There have been 4 syringe related complaints in the past 6 months.	Closed on 14 March 2022

Recalls and Field Safety Corrective Actions (FSCAs)

There was 1 FSCA / recall that was initiated for the subject devices or equivalent device from 01 January 2018 to 30 September 2023. The table below provides a summary of each FSCA / recall. The corrective actions that were taken are summarized in table below. These recalls have been closed.

Table 4-2: Field safety corrective action / recall summary

Date Initiated	Description	Corrective Action	Status (Date Closed)
20 July 2018	F3 Shunt packages contain an inlying shunt rather than the outlying shunt specified on the labels.	CAPA 2018-035	3 January 2020

5.0 Summary of clinical evaluation and post-market clinical follow-up (PMCF)

i) **Summary of clinical data related to equivalent device, if applicable:** N/A

ii) **Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable (data prior May 2010)**

The data available prior to CE-marking was conducted on the equivalent predecessor device, the Pruitt-Inahara Carotid Shunt.

iii) **Summary of clinical data from other sources, if applicable**

Summary of Included Literature (01 January 2018 to 30 September 2023)

CER Revision / Timeframe	Included Articles
CER-0013, Rev. 15 01 February 2022 to 27 October 2023	Antuševas, 2023[53] Grillo, 2022[54]
CER-0013, Rev. 12 01 January 2020 to 02 February 2022	Inčiūra, 2020[51]
CER-0013, Rev. 09 01 January 2018 to 06 August 2020	No new articles identified
CER-0013, Rev. 08 Up to 26 November 2018	Lee, 2018[55]

iv) **An overall summary of the clinical performance and safety**

Performance

Verification and validation testing demonstrated that the Pruitt F3 Carotid Shunt meets specifications and applicable industry and regulatory standards. It also passed all biocompatibility testing, including cytotoxicity, hemolysis, sensitization, intracutaneous toxicity, and systemic toxicity, per ISO 10993-1.

The usability study demonstrated 100% (33/33) of users were "satisfied" or "very satisfied" with the successful application of the Pruitt F3 Carotid Shunt. The general consensus was that the Pruitt F3 devices are safe and easy to use and resulted in favorable results. This survey study performed shows that the device is safe, effective, performs as intended, and is well-liked by end users.

Clinical benefits and performance outcomes reported in the clinical literature for the device under evaluation, relative to benchmarks from the state of the art, are provided in the table below.

All studies demonstrated 100% technical success (i.e., successful placement of the Pruitt F3 Carotid Shunt without complications or technical defects) and met the acceptance criteria. No studies reported on reversal of intraoperative EEG changes following shunt placement.

Two studies with a total of 26 patients treated with the Pruitt F3 Carotid Shunt demonstrated 100% survival rates and met the acceptance criteria. One study did not meet the acceptance criteria; however, this population included patients both with and without the Pruitt F3 Carotid Shunt and did not specify how many shunted patients survived.[53]

One out of three studies met the acceptance criteria for freedom from stroke, and two did not. In one study, the population included patients both with and without the Pruitt F3 Carotid Shunt without specifying how many of each were in the total population, but it did report equal numbers of patients who suffered postoperative stroke with (n=6) and without (n=6) shunting.[53] Another study reported a 96% rate of freedom from transient ischemic attack and minor stroke, but this represented a single patient who underwent stroke from a population that was selectively shunted due to low stump pressure.[51] Low stump pressure Is a significant predictor for ischemic stroke, so it is likely that this single case is due to preoperative factors and not attributed to the subject device.

Summary of device performance and clinical benefits for the Pruitt F3 Carotid Shunt

Outcome	Pruitt F3 Carotid Shunt	Benchmarks	Comments
Technical success	100% (1/1)[54]	≥98.4%	All studies met the acceptance criteria and demonstrated 100% technical success (i.e., successful placement of the Pruitt F3 Carotid Shunt without complications or technical defects).
	100% (25/25)[51]		
EEG changes	Not reported	≥95.8%	There were no available data on EEG changes after placement of the Pruitt F3 Carotid Shunt.
Survival	95.5% (128/134*) early survival[53]	≥98.8% perioperative ≥99.7% in-hospital ≥99.4% at 2 weeks ≥99.0% at 30 days	Two studies with a total of 26 patients treated with the Pruitt F3 Carotid Shunt demonstrated 100% survival rates. One study did not meet the acceptance criteria; however, this population included patients both with and without the Pruitt F3 Carotid Shunt and did not specify how many shunted patients survived.[53]
	100% (1/1) survival at 7 months[54]		
	100% (25/25) survival at 30 days[51]		
Freedom from stroke	91% (122/134*) early freedom from stroke[53]	≥98.4% perioperative ≥97.9% in-hospital ≥99.3% at 2 weeks ≥97.4% at 30 days	Two out of three studies did not meet the acceptance criteria. In one study, the population included patients both with and without the Pruitt F3 Carotid Shunt without specifying how many of each were in the total population, but it did report equal numbers of patients who suffered postoperative stroke with (n=6) and without (n=6) shunting.[53] Another study reported a 96% rate of freedom from transient ischemic attack and minor stroke, but this represented a single patient who underwent stroke from a population that was selectively shunted due to low stump pressure.[51] Low stump pressure Is a significant predictor for ischemic stroke, so it is likely that this single case is due to preoperative factors and not attributed to the subject device.
	100% (1/1) freedom from stroke at 7 months[54]		
	96% (24/25) freedom from stroke at 30 days[51]		

Safety

Verification and validation testing demonstrated that the Pruitt F3 Carotid Shunt meets specifications and applicable industry and regulatory standards. It also passed all biocompatibility testing, including cytotoxicity, hemolysis, sensitization, intracutaneous toxicity, and systemic toxicity, per ISO 10993-1.

The usability study demonstrated 100% (33/33) of users were "satisfied" or "very satisfied" with the successful application of the Pruitt F3 Carotid Shunt. The general consensus was that the Pruitt F3 devices are safe and easy to use and resulted in favorable results. This survey study performed shows that the device is safe, effective, performs as intended, and is well-liked by end users.

Safety outcomes and adverse events reported in the clinical literature for the device under evaluation, relative to benchmarks from the state of the art, are provided in the table below.

Two studies with a total of 26 patients treated with the Pruitt F3 Carotid Shunt demonstrated 0% mortality rates. One study did not meet the acceptance criteria; however, this population included patients both with and without the Pruitt F3 Carotid Shunt and did not specify how many deaths were in shunted patients.

No studies reported wound complications associated with the Pruitt F3 Carotid Shunt. All studies met the acceptance criteria for complications including hemorrhage and SSI.

Two studies did not meet the acceptance criteria for stroke rate. In one study, the population included patients both with and without the Pruitt F3 Carotid Shunt without specifying how many of each were in the total population, but it did report equal numbers of patients who suffered postoperative stroke with (n=6) and without (n=6) shunting. Another study reported a rate of transient ischemic attack above the acceptance criteria, but this percentage represents a single patient from a population that was selectively shunted due to low stump pressure, which is a significant predictor for ischemic stroke. Therefore, the high incidence of stroke is likely due to preoperative factors and not attributed to the subject device.

Two studies reported no cardiovascular complications in patients with the Pruitt F3 Carotid Shunt and met the acceptance criteria. The third study reported high rates of cardiovascular complications in a population that included patients both with and without the Pruitt F3 Carotid Shunt.

The overall complaint rate demonstrated through the PMS data was low (0.202%) for the period from 01 January 2018 to 30 September 2023. The observed frequency of residual risks for the devices under evaluation compared to the state-of-the-art clinical literature are provided in the table below.

Summary of residual risks for the device under evaluation

Residual risk	Pruitt F3 Carotid Shunt (clinical literature)	Pruitt F3 Carotid Shunt (complaints / vigilance)	Benchmark	Comment
Mortality	4.5% (6/134*) early mortality[53] 0% (0/1) mortality at 7 months[54] 0% (0/25) mortality at 30 days[51]	1 MDR for patient death (0.0006% complaint rate), but confirmed unrelated to the use of the device	≤1.2% perioperative ≤0.3% in-hospital ≤0.6% at 2 weeks ≤1.0% at 30 days	Two studies demonstrated 0% mortality rates, and the PMS data indicated a 0.0006% mortality rate based on units sold. One study did not meet the acceptance criteria; however, this population included patients both with and without the Pruitt F3 Carotid Shunt and did not specify how many deaths were in shunted patients.[53]
Wound complications	None reported	2 MDRs for blood loss and 2 MDRs for hemorrhage / bleeding (0.003% complaint rate)	≤0.3% with hemorrhage / severe bleeding ≤0.6% with SSI	No studies reported wound complications associated with the Pruitt F3 Carotid Shunt. All studies met the acceptance criteria for complications including hemorrhage and SSI. There was a total of 4 MDRs indicating bleeding complications and none indicating infection or other wound complications.
Restenosis	None reported	0 MDRs	≤0.3%	No cases of restenosis were reported in the clinical literature or the PMS data.
Thrombosis	None reported	0 MDRs	≤0.2%	No cases of thrombosis were reported in the clinical literature or the PMS data.
Embolism	None reported	0 MDRs	≤0.3%	No cases of embolism were reported in the clinical literature or the PMS data.
Stroke	9% (12/134*) early stroke[53] 0% (0/1) stroke at 7 months[54]	2 MDRs for hemorrhagic stroke and 1 MDR for ischemic stroke	≤1.6% perioperative ≤2.1% in-hospital	The PMS data inidcated a low rate of stroke which met the acceptance criteria. However, two clinical studies did not meet the acceptance criteria. In one study, the population included patients both with and without the Pruitt F3 Carotid Shunt without specifying how many of each were

Residual risk	Pruitt F3 Carotid Shunt (clinical literature)	Pruitt F3 Carotid Shunt (complaints / vigilance)	Benchmark	Comment
	4% (1/25) transient ischemic attack at 30 days[51]	(0.002% complaint rate)	≤0.7% at 2 weeks ≤2.6% at 30 days	in the total population, but it did report equal numbers of patients who suffered postoperative stroke with (n=6) and without (n=6) shunting.[53] Another study reported a rate of transient ischemic attack above the acceptance criteria, but this percentage represents a single patient from a population that was selectively shunted due to low stump pressure, which is a significant predictor for ischemic stroke.[51] Therefore, the high incidence of stroke is likely due to preoperative factors and not attributed to the subject device.
Cardiovascular complications	1.5% (2/134*) early myocardial infarction[53] 6% (8/134*) early cardiogenic shock[53] 17.9% (24/134*) early arrhythmia[53]	1 MDR for ischemia (0.0006% complaint rate)	≤1.7% perioperative ≤0.5% in-hospital ≤0.3% 2 weeks ≤1.9% at 30 days	Two studies reported no cardiovascular complications in patients with the Pruitt F3 Carotid Shunt and met the acceptance criteria. The third study reported high rates of cardiovascular complications in a population that included patients both with and without the Pruitt F3 Carotid Shunt.[53]
	0% (0/1) cardiovascular complications at 7 months[54]			
	0% (0/25) myocardial infarction at 30 days[51]			

v) **Ongoing or planned post-market clinical follow-up**

The manufacturer conducts ongoing PMS of the subject device according to internal procedures (SOP28-002, SOP14-001, and SOP14-002), the PMS Plan (MS-0064, Rev. D), and the PMCF Plan (PMCF012, Rev. D) Ongoing PMCF activities include an annual systematic literature review, an end-user survey, and a retrospective patient registry to collect long-term performance and safety data for the devices under evaluation.

- SOP08-005, Field Corrective Action
- SOP14-001, Corrective and Preventative Action
- SOP14-002, Complaint Handling
- SOP14-008, Analysis of Data Procedure (Trend reporting)
- SOP24-002, Failure Modes and Effects Analysis
- SOP24-003, Risk Management
- SOP28-001, Market Surveillance
- SOP28-002, Post Market Surveillance Plan
- SOP30-045, Clinical Evaluation
- SOP35-012, Summary of Safety and Clinical Performance
- SOP35-013, Post Market Clinical Follow-up

Additionally, a PMCF study (F3-18-001) is planned to begin in Q1 of 2025, as per PMCF plan #PMCF012. This study will be a retrospective analysis of patient data to assess the performance and safety profile of the subject devices during carotid endarterectomy procedures. The goals of the study are to confirm the expected performance of these devices, to identify previously unknown side-effects and monitor the identified side-effects and contraindications, to identify and analyze emergent risks on the basis of factual evidence, and to ensure the continued acceptability of the benefit/risk ratio. The final study endpoints will be determined by a panel of clinical and area experts to ensure the appropriate data is captured to confirm the manufacturer's claims.

6.0 Possible diagnostic or therapeutic alternatives:

Treatment Alternative/ Device or Device Type	Description	Advantages/ Benefits	Disadvantages/ Limitations/ Risks	Safety and Performance Outcomes
No shunting	A shunt is not used as a temporary conduit between the common and internal carotid arteries during carotid endarterectomy.	No risks associated with shunt use	Risk of hemodynamic brain injury	- Shorter operative time for no shunting versus shunting with the equivalent device.[6]
Selective shunting	A shunt is used as a temporary conduit between the common and internal carotid arteries during carotid endarterectomy in selected patients with an inadequate blood supply to the brain.	Avoidance of temporary hemodynamic neurological deficits due to clamping of the carotid arteries, while avoiding risks of shunt use in patients that do not require shunt placement	Risk of not inserting a shunt in patients that could benefit from shunt use; risks associated with shunt use such as: embolism of atheromatous debris or air through the shunt, mechanical injury to the distal internal carotid artery during shunt placement, and obscuring of the arterial	- Shorter length of hospital stay for selective shunting vs routine shunting.[5] - Higher rate of in-hospital stroke, in-hospital stroke/ transient ischemic attack, and in-hospital stroke/ death for selective shunting vs no shunting or routine shunting.[7]

Treatment Alternative/ Device or Device Type	Description	Advantages/ Benefits	Disadvantages/ Limitations/ Risks	Safety and Performance Outcomes
			anatomy at the distal zone of carotid endarterectomy[12]	

Routine shunting	A shunt is used as a temporary conduit between the common and internal carotid arteries during carotid endarterectomy as a matter of routine. Shunting can be performed with either a two-way or a three-way shunt.	Avoidance of temporary hemodynamic neurological deficits due to clamping of the carotid arteries	Risks associated with shunt use such as: embolism of atheromatous debris or air through the shunt, mechanical injury to the distal internal carotid artery during shunt placement, and obscuring of the arterial anatomy at the distal zone of carotid endarterectomy[12]	- *Two-way (similar) shunts vs three-way (equivalent) shunts:*
				  - Shorter clamp times for the two-way shunt.[4] Higher MCAV during shunting and higher rate of restoration of MCAV to preoperative levels, but increased incidence of prolonged embolization episodes after shunt removal for the two-way shunt.[8]
				  - No significant differences in the following outcomes: ease of insertion, postoperative thrombotic complications, postoperative intimal flaps, decrease in regional oxygen saturation, prolonged embolization episodes after shunt insertion, stroke, or mortality.[4,8]
				- No significant differences in clamp time or length of hospital stay between shunting (including shunting with the equivalent device) and no shunting.[1,5,6]
				- No significant differences in incidence of postoperative

Treatment Alternative/ Device or Device Type	Description	Advantages/ Benefits	Disadvantages/ Limitations/ Risks	Safety and Performance Outcomes
				stroke/ transient ischemic attack, mortality, and other adverse events between shunting (including shunting with the equivalent device) and no shunting; no significant differences in rate of new stroke, mortality, or other adverse events between no shunting, selective shunting, and routine shunting.[3-5,6-8] - Higher rate of in-hospital stroke/ death for routine vs no shunting.[7] - No clear difference in outcomes, such as 30-day morbidity and mortality, between routine and selective shunting.[6,8]

7.0 Suggested profile and training for users:

The Pruitt F3 Carotid Shunt is a surgical tool intended for use by experienced vascular surgeons trained in the procedures for which they are intended.

8.0 Reference to any harmonized standards and CS applied

Standard Title	Standard Reference: Revision Year
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 2: Requirements for aseptically processed medical devices	EN 556-2:2015
Information supplied by the manufacturer of medical devices	EN 1041:2008
Cardiovascular implants and extracorporeal systems – Vascular prostheses -- Tubular vascular grafts and vascular patches	ISO 7198:2016
Biological evaluation of medical devices – Part 1: Evaluation and testing	ISO 10993-1:2009
Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3:2009
Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2006
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	EN ISO 10993-6:2007
Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	ISO 10993-10:2010

Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	ISO 10993-11:2018
Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2008
Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2006
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2006
Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	ISO 11737-1:2006
Tests of sterility performed in the definition, validation and maintenance of a sterilization process	ISO 11737-2:2009
Aseptic processing of health care products – Part 1: General requirements	ISO 13408-1:2008
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Sterilization of health care products – Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives – Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	ISO 14160:2011
Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	ISO 14644-1:2015
Medical devices – Application of risk management to medical devices	EN ISO 14971:2019
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements	EN ISO 15223-1:2016
Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management	ISO 22442-1:2015
Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling	ISO 22442-2:2015
Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and TSE agents	ISO 22442-3:2007

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9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
A	28 March 2022	Initial release	☐ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

B	29 April 2023	Added patient section, made edits throughout per BSI feedback, updated to align with CER	☐ Yes Validation language: English ☐ No
C	09 February 2024	Annual update	☐ Yes Validation language: English ☐ No