1.0 Device Identification and General Information

i) Device trade names: Pruitt F3® and F3-S® Carotid Shunt

ii) Manufacturer's name and address:

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

iii) SRN: US-MF-000016778

iv) Basic UDI-DI: 08406631F3ShuntTP

v) Device Item Codes, Descriptions and Basic UDI

GTIN-14 (UDI)	Item Number	Item Description
00840663101320	2013-10	Pruitt F3 Outlying Carotid Shunt with T-Port 8F
00840663101313	2012-13	Pruitt F3 Outlying Carotid Shunt with T-Port 9F
00840663101221	2012-11	Pruitt F3 Outlying Carotid Shunt without T-Port 9F
00840663101191	2011-10	Pruitt F3 Outlying Carotid Shunt with T-Port 10F
00840663101207	2012-12	Pruitt F3 Inlying Carotid Shunt with T-Port 9F
00840663101313	2012-13	Pruitt F3 Inlying Carotid Shunt with T-Port 9F
00840663101276	2011-12	Pruitt F3 Inlying Carotid Shunt without T-Port 10F
00840663108404	2015-10	Pruitt F3-S Polyurethane Outlying Carotid Shunt with T-Port 8F
00840663108367	2014-10	Pruitt F3-S Polyurethane Outlying Carotid Shunt with T-Port 9F

vi) 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

vii) Class of device

Manufacture Name	MDR Classification	Rule
Pruitt F3 and F3-S Carotid Shunt	III	7

viii) 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)
Pruitt F3-S Carotid Shunt (Latex)	04 January 2016	27 August 2015 (K143454)
Pruitt F3-S Carotid Shut (Polyurethane)		21 January 2016 (K152833)

ix) 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

x) NB's name (the NB that will validate the SSCP) and the NB's singleidentification 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 designed for the purpose of aiding in carotid endarterectomy procedures for the treatment of carotid artery disease.

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

- Indication: The Pruitt F3 Carotid Shunts are indicated 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 and Pruitt F3-S Carotid Shunts are used as temporary conduits to allow for blood flow between the common and internal carotid arteries during carotid endarterectomy procedures. The two devices are similar in design, materials, and intended use when compared to each other. Descriptions of the devices are provided below.

The Pruitt F3 and Pruitt F3-S 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 and F3-S 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 and Pruitt F3-S Carotid Shunts (see Table 4-5 and Table 4-6 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. Both 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 and Pruitt F3-S Carotid Shunts are both available in an inlying or an outlying configuration. Both 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 both the Pruitt F3 Carotid Shunt (see Table 4-5 below) and the Pruitt F3-S Carotid Shunt (see Table 4-6 below) are made of polyurethane. However, the balloons of the Pruitt F3 Carotid Shunt are made of latex, whereas the balloons of the Pruitt F3-S Carotid Shunt are available in either latex or polyurethane. 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 and F3-S 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 and F3-S Carotid Shunts are not indicated for implantation, rather as transient use devices, the lifetime of the device is set at 3 hours.

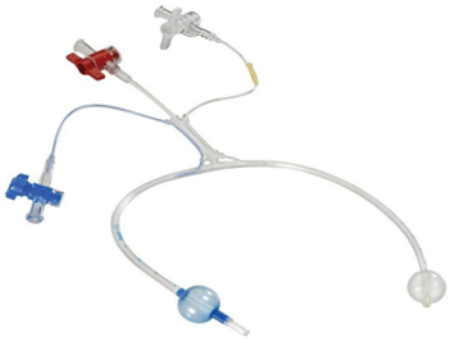	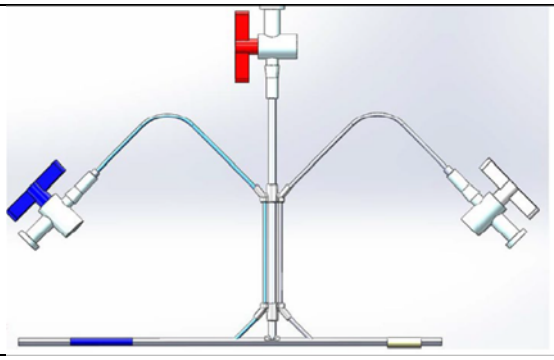
Image of the Pruitt F3 Carotid Shunt	**Image of the Pruitt F3-S Carotid Shunt**

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

iii) 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.

Pruitt F3-S 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.
- 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.

Pruitt F3-S 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. Described procedures are provided for informational purposes only. Each physician must determine the appropriate use of this device for each patient.

- 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 clear balloon into internal carotid artery and blue 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 damaging 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 balloon.
- Make secure connections between the syringe and the hub to avoid introduction of air.
- Dispose of used product in accordance with established hospital protocols for biohazards.
- Do not reinsert the Shunt once it has been removed, it may become occluded from stagnant blood left in the Shunt.

iii) Residual risks and undesirable effects

The observed frequency of residual risks for the device under evaluation compared to the state of the art are provided in the table below. The device-related safety outcomes or outcomes associated with clinical benefit measures reported in the literature included stroke and transient ischemic attack. Of the 2 studies that reported stroke, 1 study met the state of the art benchmark (4%) while the other had higher stroke rates (11.54%) compared to the state of the art, potentially due to the use of selective shunting only in patients that had intraoperative low stump pressure prior to shunting.[1,2] The use of selective shunting based on stump pressure during the procedure could indicate that the perioperative minor stroke may have occurred prior to, but was not associated with, the shunt use. Notably, all stroke patients recovered to preoperative neurological status at time of discharge.[1] Measures of transient ischemic attack met the state of the art benchmark (4%).

Summary of residual risks for device under evaluation

Residual risk in RMF and IFU	Device under evaluation results	Device under evaluation follow-up	Source	Benchmark & follow-up
Stroke	4% 11.54%	30 days Perioperative	Inčiūra, 2020[29] Lee, 2018[1]	≤9.59% overall ≤3.12% perioperative 0% 24 hours ≤4.6% in hospital

Residual risk in RMF and IFU	Device under evaluation results	Device under evaluation follow-up	Source	Benchmark & follow-up
				≤3.55% 30 days ≤1.3% 1 year ≤6.5% 5 years
Comments: Although Inčiūra,2020 observed results within benchmark range; Lee, 2018 observed an outcome outside the observed range for similar devices from the state of the art literature. However, the 3 patients that exhibited minor stroke had selective shunts due to intraoperative low stump pressure which has been shown to be a significant predictor for ischemic stroke. Further, all 3 patients returned to preoperative neurological status prior to discharge. The acceptance criteria used for the benchmark was established based on a range of outcomes from the clinical literature pertaining to similar devices. When calculating pooled prevalence using a random effects model, the state of the art had a 3.06% risk of stroke (95% CI 1.50% - 5.11%) whereas the subject and equivalent devices combined had a 4.15% risk of stroke (95% CI 1.85% - 7.25%). For pooled prevalence, the subject and equivalent device studies were combined due to low n-size in patients receiving the subject device (n=51). Planned PMCF activities (Section **Error! Reference source not found.**) will continue to gather additional data on the use of the subject devices in order to ensure that the benefits associated with the use of the devices for their intended purpose outweigh the risks.				
Transient Ischemic Attack	4%	30 days	Inčiūra, 2020[29]	≤ 4% 30 days
Comments: The benchmark was met for this outcome.				
Mortality	0% 0%	Perioperative 30 days postop	Lee, 2018[1] Inciurra, 2020[29]	≤5.0% all time points, 0% perioperative, ≤0.40% in hospital, ≤5.0% 30 days
Comments: The benchmark was met for this outcome.				

During 01 January 2016 through 31 December 2021, there were a total of 322 complaints associated with the subject devices and a total of 160,797 devices sold, resulting in an overall cumulative complaint rate of 0.200%. The highest complaint rates were due to leaking at bushing (0.033%), hole in the balloon (0.027%) and balloon would not deflate (0.026%). There were 174 FDA MAUDE reports during this time frame, there was 1 death which could not be attributed to the subject device, 16 injuries, and 157 malfunctions.

During the reporting period of 01 January 2016 to 31 December 2021, 10 CAPAs were opened and all 10 were successfully closed. During the reporting period, 2 field safety corrective actions were opened. One was for the F3 shunt packages containing an inlying shunt rather than the outlying shunt specified on the label and was closed in 2020. The other was opened due to complaints regarding improperly sealed pouches for the F3-S polyurethane shunt and was also closed in 2020. There were 2 recalls, 1 related to the F3

shunt packages containing an inlying shunt rather than the outlying shunt specified on the labels which was closed in 2019. The other recall was due to pouches in a specific lot were not sealed which comprised the sterility, this was also closed in 2019.

Following review of clinical literature and PMS data, it was determined that potential new risks may include hematoma, nerve palsy, and balloon herniation. These potential new risks will be further evaluated through the risk management practice for inclusion in the risk management file or IFU. Based on the clinical benefit and performance data, as well as the safety data, this clinical evaluation supports the safety of the F3 and F3-S carotid shunts when used as intended and provides evidence that the F3 and F3-S carotid shunts are state of the art and conform to the requirement on safety (EU MDR GSPR 1).

Adverse events that were located in the IFU but not found in the literature include:

- Hypertension or hypotension
- Arterial dissection
- Vessel perforation and rupture
- Aneurysms
- Arterial spasm

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

From 01 January 2016 to 31 December 2021, there were a total of 322 complaints associated with both subject devices and a total of 160,797 devices sold, resulting in an overall cumulative complaint rate of 0.200%. There were 265 complaints associated with the Pruitt F3 Carotid Shunt and a total of 147,012 devices sold, resulting in a cumulative complaint rate of 0.180%. There were 21 complaints associated with the Pruitt F3-S Carotid Shunt and a total of 4,113 devices sold, resulting in a cumulative complaint rate of 0.511%. The table below provides the complaint rate for each device for each year.

Overall device complaint rates per year

Year	# Complaints	# Devices sold	Complaint rate[a]
F3-S			
2016	0	374	0.000%
2017	1	887	0.113%
2018	10	942	1.062%
2019	9	1,235	0.729%
2020	4	861	0.465%
2021 (annualized)	6	1,136	0.528%
F3-S Total	**30**	**5,435**	**0.552%**
F3			
2016	37	24,150	0.153%
2017	44	25,295	0.174%
2018	64	26,682	0.240%
2019	55	29,149	0.189%
2020	45	24,083	0.187%

2021 (annualized)	47	26,003	0.181%
F3 Total	**292**	**155,362**	**0.188%**
F3 and F3-S			
2016	37	24,524	0.151%
2017	45	26,182	0.172%
2018	74	27,624	0.268%
2019	64	30,384	0.211%
2020	49	24,944	0.196%
2021 (annualized)	53	27,139	0.195%
F3 and F3-S Total	**322**	**160,797**	**0.200%**

The complaints per type/category are summarized in the table below.

Device complaints per category

Complaint type	# of complaints	Complaint rate[a]
F3-S & F3 Total		
Leaking at bushing	59	0.037%
Hole in the balloon	47	0.029%
Balloon would not deflate	46	0.029%
Packaging issue	32	0.020%
Safety balloon leakage	30	0.019%
Off center balloon	14	0.009%
Balloon failure during procedure	13	0.008%
Balloon would not inflate	13	0.008%
Safety balloon activation	12	0.007%
Balloon degradation	10	0.006%
Leaking from inflation-main arm joint	9	0.006%
Safety balloon issue	9	0.006%
Ink flaked	7	0.004%
Balloon failure	4	0.002%
Blood flow issue	4	0.002%
Hair in the package	4	0.002%
Hole in the syringe	4	0.002%
Leaking balloon	2	0.001%
Ink came off	1	0.0001%
Irrigation issue	1	0.0001%
Kinked lumen	1	0.0001%
F3-S		
Leaking at bushing	12	0.221%
Off center balloon	7	0.129%
Balloon would not deflate	4	0.074%

Complaint type	# of complaints	Complaint rate[a]
F3-S & F3 Total		
Balloon would not inflate	2	0.037%
Packaging issue	2	0.037%
Irrigation issue	1	0.018%
Hole in the balloon	1	0.018%
Leaking from inflation- main arm joint	1	0.018%
F3		
Leaking at bushing	47	0.030%
Hole in the balloon	46	0.030%
Balloon would not deflate	42	0.027%
Safety balloon leakage	30	0.019%
Packaging issue	30	0.019%
Balloon failure during procedure	13	0.008%
Safety balloon activation	12	0.008%
Balloon would not inflate	11	0.007%
Balloon degradation	10	0.006%
Safety balloon issue	9	0.006%
Leaking from inflation- main arm joint	8	0.005%
Ink flaked	7	0.005%
Off center balloon	7	0.005%
Balloon failure	5	0.003%
Blood flow issue	4	0.003%
Hole in the syringe	4	0.003%
Hair in the package	4	0.003%
Leaking balloon	2	0.001%
Ink came off	1	0.001%
Kinked lumen	1	0.001%
a. Complaint rate = (number of complaints /overall number of sales) *100%		

The top complaint categories for the Pruitt F3 Carotid Shunt were hole in the balloon (n = 54), leak at the bushing (n = 35), and packaging issue (n = 30). Twenty-eight of the complaints in the top complaint categories were reportable. There were 72 additional reportable complaints in the following complaint categories: balloon would not deflate, safety balloon leakage, safety balloon issue, balloon degradation, balloon would not inflate, ink flaked, leaking from inflation-main arm joint, off-center balloon, balloon failure during procedure, safety balloon activation, kinked lumen, and user error: artery was not occluded. Thus, a total of 100 complaints were reportable, resulting in a reportable complaint rate of 0.068%.

It was not specified if customer complaints were related to the latex or polyurethane models of the Pruitt F3-S Carotid Shunt. The top complaint categories for this subject device were leaking at bushing (n = 8), off center balloon (n = 5), balloon would not deflate (n = 3), and packaging issue (n = 2). Furthermore, 17 of the complaints in the top complaint categories were reportable, and there was 1 additional reportable complaint for “hole in the balloon” for a total

of 18 reportable complaints. The reportable complaint rate was 0.438%. Although the complaint and reportable complaint rates were higher for the Pruitt F3-S Carotid Shunt than for the Pruitt F3 Carotid Shunt, the underlying causes of these complaints have been addressed by CAPAs as described below.

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 2015 to 30 June 2020. It also includes information related to CAPA 2014-009, which was not opened during the relevant time frame but was referenced in the customer complaints from 01 January 2015 to 30 June 2020. Additionally, CAPA 2016-018 was included even though it was not associated with customer complaints or with the risk management process. As of 28 August 2020, there is only 1 open CAPA (CAPA 2019-027). This CAPA was initiated due to complaints for leaks at the bushing and at the safety balloon, and corrective actions have been identified.

Table 4-1: CAPA summary

CAPA #	Description	Corrective or Preventive Action(s)	Open (Dated)	Closed (Date)
2014-009	During final product inspection, an increased trend for common balloons not deflating within the specified acceptance criteria (15 s) was observed.	- The length of the common balloon was reduced for better concentricity.	25 February 2014	18 October 2016
2016-001	Three separate non-conforming material reports have been opened for a small tear in the shunt foil pouch. If the shunt is dropped, a small tear could occur in the foil pouch which eliminates the sterile barrier.	- Retraining the operators on transporting the shunts to and from the sterilizer. - Redesign the sterilization tray to have taller walls. - Redesign the foil pouch to better fit the shunt, to eliminate the need for double folding and to thicken the material.	11 January 2016	13 August 2017
2016-006	During the removal of shunts from the trays by the users, balloons could be caught and damaged by the snap features of the tray. The tight snap features make the user pull the device out of the tray with excessive force which contributes to the damage. Multiple complaints have been received that could potentially be related to this issue.	- Removal of two locking features on the tray to eliminate the damage to the balloon. We conducted formal ship testing to ensure that removal of the locking features does not cause the shunt to fall out of the tray. Ship testing was successful,	28 January 2016	24 July 2018

CAPA #	Description	Corrective or Preventive Action(s)	Open (Dated)	Closed (Date)
		so the tray design change was implemented.		
2016-018	Preventive action to prevent tear in the shunt foil pouch due to accidental dropping and folding of the pouch (which could eliminate the sterile barrier) by improving the foil pouch design. The vendor recommended not folding over the Tyvek when packaging the product.	- CAPA 2016-001 was implemented to address the issue of tearing of the foil pouch due to dropping. As the dropping of the shunt was solved in CAPA 2016-001, the Tyvek material will not be thickened as was proposed in CAPA 2016-001. - The foil pouch is being redesigned to eliminate folding. This was originally part of CAPA 2016-001 but was later found to be a preventive rather than a corrective action.	02 June 2016	31 December 2019
2016-025	Increase in complaints indicating that the shunt balloon would not deflate.	- New design with additional deflation holes and a different angle of the holes. The new design has been validated.	16 August 2016	23 January 2020
2018-035	Packages contain an inlying shunt rather than the outlying shunt specified on the labels.	- A recall was initiated and all affected customers were contacted. 68/77 distributed devices were retrieved. - 15 inspection documents were updated to include a check of the product configuration against the label.	19 July 2018	19 December 2019
2018-037	Upward trend in complaints for the F3-S polyurethane shunts that the balloon is not concentric when inflated. The complaint rate exceeds the frequency that is specified in the FMEA. A non-concentric balloon could lead to the balloon not deflating properly or not occluding the artery properly.	- Operators were retrained on the use of corn starch prior to gluing the balloon to the extrusion. Product containment was not required as a Health Hazard Analysis determined that no quarantine or field corrective action was required.	23 August 2018	21 February 2020

CAPA #	Description	Corrective or Preventive Action(s)	Open (Dated)	Closed (Date)
2018-043	Complaints regarding improperly sealed pouches for the F3-S polyurethane shunt.	- A recall was initiated. - All F3 and Inahara shunts in LeMaitre facilities worldwide were inspected for inadequate or missing seals. All seals were found to be acceptable. - Awareness training for packaging and quality inspection teams. - Evaluation of personnel needs in manufacturing and inspection.	28 September 2018	17 June 2019
2018-055	Pinholes have been observed in a small number of the foil pouches. 28 visual defects were found in 5570 pouches upon inspection. Pouches that were rejected from visual inspection were leak tested, and 2 failed the test.	- Inspect the pouches for pinholes and assess the results (completed). - Based on the Leak Testing Summary and Health Hazard Analysis, there is no need for additional corrective action as controls are in place to reduce potential risk, including the following: a) pouch and box redesign so there is no longer a need to fold the pouch (per CAPA 2016-018), b) the work order includes a 100% visual inspection for damaged foil pouches, and c) the IFU contains a precaution to inspect the product and package prior to use.	17 December 2018	31 December 2019
2019-027	Complaints for leaks at the bushing and at the safety balloon.	- Leaks at the safety balloons addressed by adding a layer of Conathane over the ends of the balloons. - Manufacturing instructions were updated to include photos of good and bad adhesive joints. - Training of assemblers on the issues related to this CAPA.	03 May 2019	Open

Recalls and Field Safety Corrective Actions (FSCAs)

There were 2 FSCAs / recalls that have been initiated for the subject devices or equivalent device from 01 January 2015 to 30 June 2020. One recall was related to the Pruitt F3 Carotid Shunt and the other was related to the Pruitt F3-S Carotid Shunt. The table below provides a summary of each FSCA / recall. The corrective actions that were taken are summarized in table below. Both 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
3 October 2018	Complaints regarding improperly sealed pouches for the F3-S polyurethane shunt.	CAPA 2018-043	7 April 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 06 August 2020)

Study Details	Results (Performance / Safety Outcomes	Study Conclusions
Lee, 2018		
Subject/ Eq. Device: Pruitt F3® Polyurethane Carotid shunt with outlying Tport (LeMaitre Vascular, Inc.) (n=26) **Comparisons:** No shunting (n=56) **Design/ Objectives:** Retrospective comparative study **Indications**: CEA: severe stenosis (symptomatic patients with 60-79% stenosis, asymptomatic patients with 80-99%	**Performance:** Observed intraoperative changes in EEG were reversed after shunting was performed. **Safety, Mortality:** No postoperative 30- day adjusted mortality (operative mortality defined as death within 30 days from operation or death during the admission period for operation).	Perioperative stroke rate was 4.3% for CEA under general anesthesia based on dual intraoperative monitoring with SP and EEG, without any 30-day adjusted mortality or adverse cardiac event. Severe stenosis or occlusion of contralateral internal carotid artery is related to shunting ($P<0.010$).

stenosis); selective shunting: EEG changes (i.e., slowing, flattening, or asymmetry) regardless of SP (4/26), SP<35 mmHg (19/26), or SP<35 mmHg with EEG changes (3/26) **Interventions**: Conventional CEA under general anesthesia (GA) with bovine pericardial patch closure and selective shunting using the Pruitt F3® shunt if the SP<35 mmHg regardless of EEG or if intraoperative EEG showed any changes different from preoperative one regardless of SP.	**Safety, Complications:** No adverse cardiac events, even among patients with ischemic heart diseases. Postoperative morbidities (2/70): bleeding with hematoma requiring reoperation and hypoglossal nerve injury; perioperative stroke rate: 3/70 (4.3%) minor postoperative stroke though all 3 were in the shunt group, reaching preoperative neurologic status at discharge.	
Inčiūra, 2020		
Subject Device: Pruitt F3 Carotid Shunt (LeMaitre Vascular) (n=24; selective) **Comparisons:** No shunt (n=106) Pruitt F3 shunt (n=25) **Design/ Objectives:** Retrospective nonrandomized **Indications**: Temporary conduit during carotid endarterectomy **Interventions**: Carotid artery stenosis assessed by carotid colour Doppler-assisted duplex ultrasound and confirmed by angiography.	**Performance/Safety:** Reduced risk of stroke: perioperative to 30 days postoperation ≥90.41% at up to 5 years. Transient Ischemic Attack: ≤ 4% (30 days postoperative)	The main objective of the study was to investigate nearinfrared spectroscopy as a predictor of cerebral ischaemia. Secondary outcomes found no differences in shunted versus non shunted groups Intraoperative outcomes were measured, and 30 day outcomes of TIA, stroke, MI, and death were measured

Conclusions

During 01 January 2016 through 31 December 2021, there were a total of 322 complaints associated with the subject devices and a total of 160,797 devices sold, resulting in an overall cumulative complaint rate of 0.200%. The highest complaint rates were due to leaking at bushing (0.033%), hole in the balloon (0.027%) and balloon would not deflate (0.026%).

There were 174 FDA MAUDE reports during this time frame, there was 1 death which could not be attributed to the subject device, 16 injuries, and 157 malfunctions. During the reporting period of 01 January 2016 to 31 December 2021, 10 CAPAs were opened and all

10 were successfully closed. During the reporting period, 2 field safety corrective actions were opened. One was for the F3 shunt packages containing an inlying shunt rather than the outlying shunt specified on the label and was closed in 2020. The other was opened due to complaints regarding improperly sealed pouches for the F3-S polyurethane shunt and was also closed in 2020.
There were 2 recalls, 1 related to the F3 shunt packages containing an inlying shunt rather than the outlying shunt specified on the labels which was closed in 2019. The other recall was due to pouches in a specific lot were not sealed which comprised the sterility, this was also closed in 2019. Following review of clinical literature and PMS data, it was determined that potential new risks may include hematoma, nerve palsy, and balloon herniation. These potential new risks will be further evaluated through the risk management practice for inclusion in the risk management file or IFU.
Based on the clinical benefit and performance data, as well as the safety data, this clinical evaluation supports the safety of the F3 and F3-S carotid shunts when used as intended and provides evidence that the F3 and F3-S carotid shunts are state of the art and conform to the requirement on safety (EU MDR GSPR 1).
The outcomes relating to the safety and performance of the subject device are consistent with those expected for this type of device when used as intended.

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

Clinical performance

The Pruitt F3® and Pruitt F3®-S Polyurethane Carotid Shunts are used as temporary conduits to allow for blood flow between the common and internal carotid arteries during carotid endarterectomy procedures. The clinical literature pertaining to F3 and F3-S carotid shunts included 2 articles and 51 patients.

The devices under evaluation, met acceptance criteria for operation time, restenosis, and technical success. A single study found that clamp time was significantly higher in the equivalent device compared to a two-way shunt; however, the authors did not advise against the use of the three-way shunt. Rate of survival and reduced risk of stroke met all acceptance criteria set forth by the state of the art with the exception of one study which found freedom from stroke to be 88.46% which may be attributed to the use of selective shunting due to low stump pressure. Besides the stroke rate in this study, the rate of adverse events including transient ischemic attack, stroke, embolization, and infection all met the state of the art acceptance criteria. Postoperative neurological complications acceptance criteria was not met however intrastudy differences were not significant and methodological details make comparison difficult. Lastly, the equivalent device had higher rates of intimal flap that were not significantly greater than a two-way shunt. The literature also identified potential adverse events that will be reviewed via LeMaitre's risk management process including nerve palsy, hematoma, and balloon herniation. Together, the data support a greater clinical benefit, reduced risk of stroke and survival, of procedures involving F3 and F3-S shunt outweigh the potential risks.

Outcome measures

A summary of the clinical evaluation outcome parameters for evaluation of the safety, performance, and clinical benefits of the subject devices is provided in the table below.

Outcome parameters for benefits, performance, and safety:

Outcome parameter	Evaluates	Description of outcome parameter	Benchmarks/acceptance criteria
Reduced risk of stroke	Clinical benefit	Incidence of freedom from stroke.	≥90.41%
Survival	Clinical benefit	Incidence of postoperative survival.	≥95.00%
Restenosis	Device performance	Assessment of the degree to which blood vessels are blocked or obstructed by ≥50%.	≤25.8%
Operation Time	Device performance	Total CEA operation time	≤112.5 min
Clamp Time	Device performance	Time of clamping during operation	≤22 min
Mortality	Safety	Incidence of postoperative transient ischemic attack	≤5.00%
Stroke	Safety	Incidence of postoperative neurological complication	≤9.59%
Transient Ischemic Attack	Safety	Incidence of postoperative transient ischemic complications	≤4.00%
Neurological Complications	Safety	Incidence of postoperative neurological complications	≤2.7%
Prolonged embolization episodes	Safety	Prolonged embolization (>1 sec) episodes during shunt insertion and shunt removal	During shunt insertion: ≤40%. During shunt removal: ≤70%
Infection	Safety	Incidence of postoperative infection	0%
Intimal Flap	Safety	Incidence of postoperative intimal flap	≤2.1%

Summary of undesirable side-effects

The device-related safety outcomes or outcomes associated with clinical benefit measures reported in the literature and identified in the IFU included stroke, transient ischemic attack, postoperative neurological deficits, embolization, hemorrhage, infection, thrombosis, and intimal disruption. The risks and undesirable side effects of the device under evaluation were within the range observed in the state of the art literature or

intrastudy comparisons demonstrated the rates were similar to the alternative treatment. Additional risks identified in the literature including hematoma, nerve palsy, and balloon herniation will be evaluated through the risk management practice for potential inclusion in the risk management file or IFU.

Based on this clinical evaluation, there is sufficient data to demonstrate conformity to the applicable requirements and confirm that the subject devices are safe and perform as intended and claimed, and are state of the art devices as temporary conduits to allow for blood flow between the common and internal carotid arteries during carotid endarterectomy. Review of the post-market data and the risk management documentation confirms that the risks are appropriately identified and consistent with the state of the art, and that the risks associated with the use of the devices are acceptable when weighed against the benefits.

Clinical benefits

Clinical benefit benchmarks reported in the literature for similar devices and alternative treatments are provided in the table below. These benchmarks are based on results from clinical studies on similar devices, meta-analyses, review articles, and also includes findings from 13 articles identified in the device under evaluation literature search (Section 4.84.7).27-29

Freedom from Stroke

Many studies reported the rate of stroke, as opposed to freedom of stroke, and is indicated as such in the table below. A portion of studies found no difference in freedom from stroke comparing CEA without shunt use to shunt use.5,9,13,27-29 Kordzadeh, 20204, found patients with no shunt during CEA had greater freedom from ischemic stroke ($p<0.001$) than those with shunt use and this was true at different carotid stump pressures of 25 ($p<0.01$), 30 ($p=0.02$), and 40mmHg ($p<0.01$) but there were no differences at 50mmHg. Dakour-Aridi, 20208 found significant differences on in-hospital stroke rates between no shunt use, selective shunting, and routing shunting under both general anesthesia ($p<0.01$) and local/regional anesthesia ($p<0.001$). Lastly, Chongruksut, 201410 found that freedom from stroke was dependent on the follow-up time, type of stroke, and type of analyses as no differences were found perioperatively on any stroke (best case, $p=0.07$; worst case, $p=0.56$), within 30 days of surgery on any stroke ($p=0.51$), worst case and best case analysis of ipsilateral stroke perioperative ($p=0.071$; $p=0.56$) and worst case within 30 days ($p=0.76$). Chongruksut, 201410 did find greater freedom from any stroke in the shunt patients 24 hours post-surgery ($p=0.024$) and using best case analyses to measure ipsilateral stroke within 30 days of surgery ($p=0.042$). In the study by Hayes et al., stroke was reported in a total of 3.10% (17/548) of patients who were treated with the Pruitt-Inahara.33 However, in 12 of these patients, stroke was not directly attributable to shunting, and thus the rate of shunt-related stroke was 0.912% (5/548). In 2 of these patients, stroke was due to sustained embolization. In the remaining 3 patients, stroke was postoperative and with unidentified cause, and the patients awoke with no neurologic deficit. Lastly, Squizzato 2021 showed a post-operative stroke rate at 30 days of 2.3% which was due to 5 ischemic strokes and 1 hemorrhagic stroke.30

-No shunt (8 studies):
94.69% - 100% follow-up perioperative to five years
96.11% - 97.87% perioperative
94.69% 24 hours postoperative
99.0% - 99.3% in-hospital
95.51% - 99.64% 30 days
96.8% - 100% 3 months
98.8% - 99.5% 1 year
95.9% - 97.7% 5 years
-Shunt (10 12 studies):
90.41%-100% follow-up perioperative to five years
96.88% - 98.61% perioperative
100% 24 hours
95.4.% - 98.2% in hospital
96.45% - 98.34% 30 days
98.7% - 99.0% 1 year
93.5% - 97.4% 5 years

Survival

The majority of studies reported mortality, therefore survival was calculated and is noted in the table below. Of the six studies that only compared no shunt to shunt use, there were no significant differences in survival (Andrasi, 201511(p=n.s.); Kordzadeh, 20204 (p>0.05); Bennett, 201512(p=0.10); Yüksel, 201426(p=0.486); Chongruksut, 201410(p=0.22); Inčiūra, 202029(p=1.00). In those with no shunt, routine, and selective shunt groups; there was no difference comparing no shunt survival to routine shunt (p=0.49) nor was there a difference comparing selective versus routine shunt survival (p=0.45; Wiske, 201813). There were no differences between these three groups when the CEA was performed under general anesthesia (p=0.67) or under local/regional anesthesia (p=0.39).8 Lastly, a single study9 compared those who received a Javid shunt compared to a Pruitt-Inahara shunt and although the reasons for death and mortality percentage were given, there were no statistical comparisons between the two groups.

-No shunt (6 studies):
97.9% - 100% follow-up perioperative to 30 days postoperative
100% perioperative
99.80% - 99.83% in hospital
97.9% - 99.5% 30 days
-Shunt (9 12 studies):
95.0% - 100% follow-up perioperative to 30 days postoperative
98.72% - 100% perioperative
99.60% - 99.78% in hospital
95.00% - 100% 30 days

Stroke-related death

Three studies measured stroke-related death comparing no shunt to shunt use10,27 and comparing no shunt, selective shunting, and routine shunting.8,10 Chongruksut, 201410 found worst-case outcome there was no difference in stroke related death within 30 days of surgery (p=0.32) however best-case outcome showed lower stroke-related deaths in shunt groups compared to no shunt groups (p=0.045). Dakour-Aridi, 20208 also found significant difference in stroke-related death in both the general anesthesia groups (p<0.001) and the local/regional anesthesia groups (p<0.001). Comparing conventional to eversion CEA, and therefore shunt to no shunt use, respectively, Kumar, 202127 also found no differences in stroke-related death.

-No shunt (3 studies):
0%-1.20% follow-up in hospital to 30 days postoperative
0.70% - 0.91% in hospital
0% - 1.20% 30 days
-Shunt (3 studies):
0% - 4.9% follow-up in hospital to 30 days postoperative
1.1% - 4.9% in hospital
0% - 0.31% 30 days

Incidence of combined postoperative stroke/transient ischemic attack

Of the two studies that investigated the incidence of postoperative stroke along with transient ischemic attack, one found significant differences on in-hospital incidences between the no shunt, selective shunting, and routine shunting with both general anesthesia (p<0.01) and local/regional anesthesia (p<0.001).8 Conversely, Bennett, 201512, found no differences on 30-day incidences in all patients (p=0.64) or in those with preoperative severe stenosis (p=0.08).

-No shunt (2 studies):
1.1% - 4.9% follow-up in hospital to 30 days
1.1% - 1.7% in hospital
3.4% - 4.9% 30 days
-Shunt (2 studies):
1.8% - 9.8% follow-up in hospital to 30 days
1.8% - 5.9% in hospital
3.7% - 9.8% 30 days

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

The manufacturer conducts ongoing PMS of the subject device according to the following procedures (Post Market Surveillance Plan F3 Carotid Shunt, SOP28-002, Rev. A):

- 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 Q3 of 2020, 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	- 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
			shunt placement, and obscuring of the arterial 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]

Treatment Alternative/ Device or Device Type	Description	Advantages/ Benefits	Disadvantages/ Limitations/ Risks	Safety and Performance Outcomes
				- No significant differences in incidence of postoperative 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 14971:2012
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

References:

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6. 19 Eidt JF, Kahn MB, Barone GW, Cook JM, Barnes RW. Malfunction of a double-balloon carotid shunt as a result of herniation of the proximal balloon. *J Vasc Surg.* 1990;12(1):62-64.
7. 20 Chung BH, Heo SH, Park YJ, Kim YW, Woo SY, Kim DI. Comparative Analysis Using Propensity Score Matching Analysis: Primary Closure versus Patch Angioplasty During Carotid Endarterectomy. *Annals of Vascular Surgery.* 2020;62:166-172.
8. 6 Yuksel V, Canbaz S, Ege T, Sunar H. Is it necessary to use an intraluminal shunt in symptomatic patients with contralateral carotid artery stenosis? *Acta Chir Belg.* 2014;114(3):179-182.

9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
001	28 March 2022	Initial release	☐ Yes Validation language: ☐ 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)
002	Please see last page	Added patient section, made edits throughout per BSI feedback	☐ Yes Validation language:No ☐

10.0 Patient Information

A summary of the safety and clinical performance of the device, intended for patients, is given below.

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. Your healthcare provider has a more extensive summary of safety and clinical performance.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare provider in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an implant card or the instructions for use to provide information on the safe use of the device.

1. **Device name and general information**
    - **a. Device trade name**
        - i. Pruitt F3® Carotid Shunt (Shunts)
        - ii. Pruitt F3®-S Polyurethane Carotid Shunt (Shunts)
    - **b. Producer; name and address**
        - i. LeMaitre Vascular, Inc. 32 Third Avenue, Burlington, MA 01803
    - **c. Basic UDI-DI**
        - i. 08406631F3ShuntTP
    - **d. Year when the device was first CE-marked**
        - i. The Shunts have been marketed in the United States (US) since 27 May 2005 (K051067) and 27 August 2017 (K152833),
2. **Intended use of the device**
    - **a. Intended purpose**

      Shunts are for use in major arteries to allow for blood flow between the common and internal major arteries.
    - **b. Indications and intended patient groups**
        - i. The intended patient population is patients undergoing major artery procedures. The products are designed for all sexes and ages
    - **c. Do not use for:**
        - i. The shunt is a temporary device and should not be implanted.
        - ii. The shunt is not for use in removal of blood clots, or vessel dilation.
3. **Device description**
    - **a. Device description and material/substances in contact with patient tissues**
    - **b.** The Shunts are multi-lumen devices made of polyurethane (e.g., shunt body, inflation arms, and T-port arms) with plastic stopcocks. Shunts are also designed with latex or polyurethane balloons at both internal and common ends of the shunt **Information about medicinal substances in the device, if any**
        - i. N/A, the device does not incorporate medicinal substances, animal or human tissues, or blood products.
    - **c. Description of how the device is achieving its intended mode of action**
    - **d.** Per regulations, the Shunts achieve its therapeutic effect through non-medicinal means. It achieves this goal as a conduit device mode of action.**Description of accessories, if any**

4. The Shunts come with a syringe used for inflating and deflating the internal major artery or common artery balloons. This accessory is in scope for this clinical assessment. **Risks and warnings**

Contact your healthcare provider if you believe that you are experiencing side effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare provider if needed.

- **How potential risks have been controlled or managed**
  - Residual risk assessment is conducted as part of our risk management procedure. We have concluded that the benefits outweigh any residual risks. Remaining risks have been reduced as far as possible.
- **Remaining risks and unwanted effects**
  - - The data in this clinical assessment is considered sufficient to determine if unwanted side effects exist for the subject device. We conclude that the device conforms to the requirement of the side effects per regulations.
  - - The device-related safety outcome or outcomes related to clinical benefit measures reported in the literature and identified in the IFU included stroke, temporary stroke, limited use of part of body, blood flow, release of blood from broken vessel, infection, blood clot blockage, and intimal disruption. The risks and unwanted side effects of the device were within the range observed in the state of the art literature or study comparisons. Additional risks identified in the literature including bad bruise, nerve disorder, and balloon herniation will be checked through the risk management for potential inclusion in the risk management file or IFU.
- **Warnings and precautions**
  - 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 surgical procedures involving the major 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.
  - If the Shunt is not properly maintained in position through balloon balancing, it may migrate within the internal carotid artery, potentially scuffing the inner artery.
  - 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 chance 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 it according to accepted medical practice, and applicable local, state, and federal laws and regulations.

5. Summary of clinical assessment and post-market clinical follow-up

a. Clinical background of the device

The Shunts are used as temporary tubes to allow for blood flow between the common and internal carotid arteries during major artery procedures.

They are multi-lumen devices made of polyurethane (e.g., shunt body, inflation arms, and T-port arms) with plastic stopcocks. Devices are also designed with latex or polyurethane balloons at both the internal carotid and common carotid ends of the shunt. The balloons act as a stabilizer to maintain the position of the shunt when placed within the common and internal carotid arteries to provide fixation for the device without the need for clamping. Both shunts have features to aid the user during shunt insertion and balloon inflation. The inflation path of the proximal balloon is color coded. Sterile saline is injected from the blue stopcock, through the blue lumen and into the blue common carotid balloon.
The Shunt also features an external safety balloon located on the inflation arm leading to the distal balloon that acts as a mechanism to relieve pressure on the internal carotid balloon in the event it inflates above optimal size and pressure. The external safety balloon feature reduces the chance of balloon over-inflation and resultant vessel damage. The sleeve of the external safety balloon is yellow to increase its clarity. The devices are provided with syringes that are used for inflating and deflating the balloons when attached to the stopcocks. Syringes are essential accessories and the only accessories to be used with the device. The devices are designed with atraumatic tips to minimize vessel trauma upon insertion. The devices do not incorporate medicinal substances, animal or human tissues, or blood products. The shunts are intended for single-use only. They should not be re-used, re-sterilized, reprocessed, and/or repackaged. Devices are sterilized by ethylene oxide gas and provided sterile. The sterility of the package is assured as long as it is unopened and undamaged. The devices are not implantable and are intended for short term use (>60 minutes but < 30 days).

b. The clinical evidence for the CE-marking

c. The device was first approved for CE mark under LeMaitre Vascular Inc. in 2010. Studies were conducted to ensure the devices were safe and effective. See the IFU for further details. **Safety**
There are ongoing clinical trials on this device that will be used to confirm the safety and performance throughout the expected lifetime of the device through the proactive and continuous collection of data.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare provider who can take into account your situation.

7. Suggested training for users

This device is intended to be used by surgeons. Considering how complex this surgery is, it is left to the surgeon to select the proper device type as well as the therapy to adopt before, during and after the operation.