1.0 Device Identification and General Information

i) **Document Number:** MS-0111
ii) **Device trade names:** Pruitt Aortic Occlusion Catheter (PAOC)
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: PAOC: 08406631PAOCK9
vi) Device Item Codes, Descriptions and Basic UDI

GTIN-14 (UDI)	Item Number	Item Description
00840663111350	2100-12M	Pruitt Aortic Occlusion Catheter

vii) Medical device nomenclature description

GMDN Code / Description: 52584 / Intravascular occluding catheter
UMDNS Code / Description: 10-736 / Catheters, Vascular, Occlusion

viii) Class of device

Device Name	MDR Classification	Rule	Directive / Regulation
Pruitt Aortic Occlusion Catheter	III	Rule 7	EU MDR 2017/745

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

Device Name	Date of Initial CE Mark	Date of 510(k)
Pruitt Aortic Occlusion Catheter	December 2000	1987 (K872090)

x) Authorised representative if applicable; name and the SRN

EU Authorized Representative	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 singleidentification number

SGS Belgium NV (1639)
Noorderlaan 87 BE-2030
Antwerpen Belgium

2.0 Intended use of the device

i) Intended Purpose/Use:
- The Pruitt Aortic Occlusion Catheter is intended to obtain rapid control of in-flow blood in the aorta in cases of ruptured aortic aneurysm or in other conditions when dissection of the neck of the aneurysm for different reasons may be especially difficult.

ii) The indication and target populations:

- Indication: The Pruitt Aortic Occlusion Catheter is indicated to occlude the aorta

to achieve control of blood flow during aortic vessel repair, aortic root replacement, and aorta arch repair procedures.
- Target population: Adults of any gender or ethnicity requiring treatment for aortic vessel repair, aortic root replacement, and aorta arch repair.

iii) Contraindications and/or limitations

- The catheter is not to be used as a dilation catheter.
- The catheter is not to be used for the introduction of drugs other than saline.
- The catheter is a temporary device and cannot be implanted.

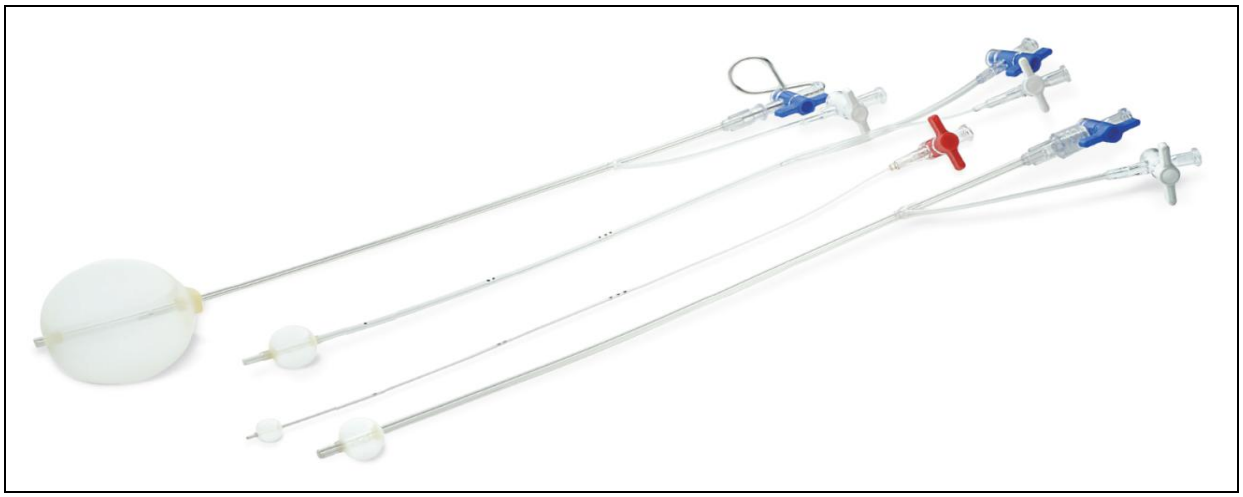
3.0 Device Description

i) Description of the device

The Pruitt Aortic Occlusion Catheters are 12 French (4.0 mm), dual lumen catheters with a large, latex balloon (maximum liquid inflation capacity 50 mL) specifically designed and sized for use in the outlined general procedures. The first lumen (inflation lumen indicated by the white stopcock) is used for balloon inflation, while the second lumen (irrigation lumen indicated by the blue stopcock) allows access to the vessel distal to the occlusion. Other features include 2 stopcocks with a luer-lock fitting at the proximal end of the irrigation lumen to facilitate control of such procedures, a balloon wall thickness designed to reduce the possibility of puncture by calcium deposits, and a stopcock to maintain balloon inflation level throughout the procedure.

A stainless steel stylet is inserted in the irrigation lumen of the catheter and serves as a stiffening medium to aid the physician during the introduction of the catheter into the patient's aorta.

The device is considered an orphan device in the European market and the premarket clinical data is relatively limited. (See Memo "Pruitt Aortic Occlusion Catheter and Orphan Device Status in the EU, Memo 2024-0057" for justification of this status.)



ii) **Reference to the previous generation(s) or variants if such exist, and a description of the differences:** The Pruitt Aortic Occlusion Catheter is a mature product currently on the market for

a well-established intended use. It is based on the Fogarty Occlusion Catheter and has been in clinical use for more than 20 years. Minor changes have been made to the materials used in the subject device, which has a Pebax with Barium Sulfate catheter compared to a PVC catheter used in the competitor device. There are no novel design features, indications, claims, or target populations for the subject device compared to the competitor device that impact safety and performance. It was originally manufactured by Ideas for Medicine (St. Petersburg, FL). LeMaitre Vascular acquired it from Ideas for Medicine in 2001, and a product transfer of all manufacturing processes to LeMaitre Vascular's Burlington, MA, facility was conducted in 2006. Product designs were not changed in the transfer.

iii) **Description of any accessories which are intended to be used in combination with the device:**
- A Formed Stylet made of stainless steel is included with the Pruitt Aortic Occlusion Catheter. It serves as a stiffening medium to aid the physician during the introduction of the catheter into the patient's aorta.
- A 30 ml syringe to be used for inflating and deflating the balloon.

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 Warnings and Precautions

Warnings:

1. Do not reuse. The catheter is for single use only.
2. Air or gas should not be used to inflate the balloon during patient use.
3. Do not inflate the balloon to any greater volume than is necessary to obstruct the blood flow. DO NOT EXCEED the recommended maximum balloon inflation capacity (maximum liquid inflation capacity 50 mL).
4. Exercise caution when encountering extremely diseased vessels. Arterial rupture or balloon failure due to sharp calcified plaque, may occur.
5. Deflate the balloon prior to inserting or withdrawing the catheter. Avoid using excessive force to push or pull catheter against resistance.
6. The possibility of balloon rupture or failure must be taken into account when considering the risk involved in a balloon catheterization procedure.
7. All agents to be infused should be used according to the manufacturer's Instructions for Use.
8. If the catheter is occluding blood flow to the kidneys, it should not be left in longer than 30-45 minutes.

Precautions:

1. Inspect the product and package prior to use and do not use the catheter if there is any evidence that the package or the catheter has been damaged.
2. Avoid extended or excessive exposure to fluorescent light, heat, sunlight, or chemical fumes to reduce balloon degradation. Excessive handling during insertion, or plaque and other deposits within the blood vessel may damage the balloon and can increase the possibility of balloon rupture.
3. Ensure proper connections between all syringes and hubs to avoid the introduction of air.
4. Do not grasp the balloon with instruments at any time to avoid damage to the latex.
5. Aspirate the irrigation lumen of the catheter during insertion until there is free back flow of blood from the catheter to reduce the chance of air embolism.

iii) Residual risks and undesirable effects

– Residual risk evaluation is conducted as part of our FMEAs and risk management procedure. We have concluded that the benefits outweigh any residual risks and that the risk has been reduced as far as possible

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

From 01 January 2018 to 31 January 2024, there were a total of 12 complaints and 6 adverse events (reportable complaints and / or complaints that required CAPA initiation) associated with the subject devices and a total of 4,755 devices sold, resulting in an overall cumulative complaint rate of 0.252% and overall adverse event rate of 0.189%. The table below provides the complaint rate for each subject device each year.

Overall device complaint rates per year

Complaints by Region / Year	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	0	2	7	0	2	1	0	12
Sales	1,273	1,339	943	489	358	331	22	4,755
Rate (complaints/sales	0		0.742%	0.000%	0.559%	0.302%	0.000%	0.252%
Europe	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	0	0	3	0	0	0	0	3
Sales	816	858	536	194	41	0	0	2,445
Rate (complaints/sales	0	0	0.560%	0.000%	0.000%	0.000%	0.000%	0.123%
Americas	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	0	0	0	0	0	0	0	0
Sales	46	72	62	59	52	53	5	344
Rate (complaints/sales		0.000%	0.000%	0.000%	0.000%	0.000%	0.000%	0.000%
APAC	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	0	2	4	0	2	1	0	9
Sales	411	409	345	236	265	278	17	1,944
Rate (complaints/sales	0	0.489%	1.159%	0.000%	0.755%	0.360%	0.000%	0.463%

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

Device complaints per category

Complaint Category	**2018**	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**	**Complaint Rate**
Balloon degradation	0	0	3	0	1	0	0	4	0.084%
Balloon failure	0	0	1	0	1	0	0	2	0.042%
Balloon rupture	0	1	0	0	0	0	0	1	0.021%
Damage syringe	0	0	1	0	0	0	0	1	0.021%
Leakage at the joint	0	1	0	0	0	0	0	1	0.021%
Leaking at stopcock joint	0	0	1	0	0	0	0	1	0.021%
Off centered balloon	0	0	0	0	0	1	0	1	0.021%
User error	0	0	1	0	0	0	0	1	0.021%

The top complaint categories for the Pruitt Aortic Occlusion Catheter were balloon degradation (n = 6) and balloon failure (n = 2). There were 6 additional reportable complaints for this device, including 1 for balloon degradation, 1 for balloon rupture, 2 for balloon failure, and 2 for leakage at the joint. The root cause of the balloon rupture complaint was determined to be that the balloon was punctured by a sharp object that it contacted during the procedure, damaging the balloon. The root cause of 1 balloon failure and 2 leakage at the joint complaints was determined to be operator error, where not enough glue was applied during the assembly process. The remaining devices were not returned for evaluation, so the root cause could not be determined. One balloon failure complaint without device return reported patient blood loss, but no other MDRs reported patient problems. There were no complaints related to the Formed Stylet accessory.

i) Corrective and Preventative Actions:

The table below lists the CAPAs relevant to the safety and performance of the subject device that were opened between 01 January 2018 to 31 January 2024.

CAPA summary

CAPA Number	Reason CAPA initiated	Corrective action taken	Status	Date initiated	Date closed
CAPA 2019-027	Complaints related to liquid leakage on the stopcock to sidearm and luer to body tube joint. The root cause of the issue was determined to an operator error- not enough glue was applied during bonding.	Awareness memo dated 02-May-2019 and training	Closed	3-May-19	17-Aug-21

***ii)* Recalls and Field Safety Corrective Actions (FSCAs)**

There were 0 recalls initiated for the Pruitt Aortic Occlusion Catheter, between 01 January 2018 to 31 January 2024.

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

i) **Summary of clinical data related to equivalent device, if applicable:** No equivalency is used in the assessment of these devices.

ii) Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable (prior 1999): NA

The CE-marking was initially received by the previous owner. The devices have been developed by incremental changes. All data used to determine safety and performance has been generated on the updated products.

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

Summary of Included Literature (01 January 2018 to 31 January 2024)

The clinical literature evaluation identified 1 retrospective review, 2 case series, and 1 observational study with clinical data applicable to the subject devices. The case report does not meet current inclusion criteria and was therefore excluded from further analysis. Four articles with at least 80 patients reported use of the Pruitt Aortic Occlusion Catheter, it should be noted an equivalent device is no longer used in the clinical evaluation of the subject devices.

Study Details	Results (Performance / Safety Outcomes	Study Conclusions
Pruitt Aortic Occlusion Catheter - Emrecan, et al., 2006[6]		
Design Retrospective case series **Objectives** To describe the operative and postoperative results of aortic arch replacement under whole-body perfusion and moderate-degree hypothermia **Methods** Retrospective review of patients operated on under whole-body perfusion from Mar 2003 to Nov 2005 in Turkey **Tests of Significance** Mann-Whitney U test performed using SPSS, given statistical significance at P<0.05 **Sample Sizes** Total sample size: 12 **Demographics** 2 Women, 10 men; age (years; mean ±SD, range) 53.5 ±7.3, 42-65 **Follow-up** ICU (days; mean ±SD, range) stay: 3.7 ±2.7, 2-12; postoperative hospital stay (days; mean ±SD, range): 8.2 ±3.2, 6-18 **Indications** Chronic type A aortic dissection, acute type A aortic dissection, ascending and arch aorta aneurysm **Interventions** Total arch replacement, where the proximal part of the descending aorta was occluded using a subject occlusion catheter when the aorta was transected. The procedure was conducted under whole-body perfusion and moderate-degree hypothermia by an alternate device.	**Performance** ICU stay (days; mean ±SD, range): 3.7 ±2.7, 2-12 days; postoperative hospital stay (days; mean ±SD, range): 8.2 ±3.2, 6-18; hemorrhage, postoperative (mL, mean ±SD): 1200±690.2; red blood cells transfused (450-mL bag, mean ±SD): 3.4±2.2; serum creatinine (mg/dL, mean ±SD): 0.9±0.2 before, 1.1±0.3 after, p=0.098; alanine aminotransferase (U/L, mean ±SD): 27.0±6.5 before, 33.7±6.6 after, p=0.032; blood urea nitrogen (mg/dL, mean ±SD): 27±5 before, 32.2±7.4 after, p=0.087 **Safety, Mortality** In-hospital mortality: 8% (1/12), due to respiratory complications **Safety, Complications** No neurologic deficit	**Conclusions** May provide adequate cerebral and visceral protection from complications of ischemia **Benefits** More time for the surgeon **Limitations** Those inherent to study design
Pruitt Aortic Occlusion Catheter - Touati, et al., 2003[7]		
Design Case series **Objectives** To propose a strategy to avoid limitations and complications of hypothermic circulatory arrest with normothermic replacement of the aortic arch **Methods** Review of patients that underwent aortic arch replacement in France	**Performance** Cardiac function was excellent in all; other performance outcomes not stratified by technique **Safety, mortality** Operative and postoperative mortality: 0% (0/5) **Safety, complications**	**Conclusions** Can preserve autoregulation of cerebral blood flow and maintains body perfusion without high vascular resistance **Benefits** Should provide the same advantages but eliminate the

Study Details	Results (Performance / Safety Outcomes	Study Conclusions
Tests of Significance None **Sample Sizes** Total sample size: 6 (occlusion catheter: 5, clamp: 1) **Demographics** All techniques: gender not reported; age (years; mean ±SD, range) 57.6 ±11, 40-72 **Follow-up** Not reported **Indications** Not reported **Interventions** Complete replacement of the aortic arch, where the descending thoracic aorta was occluded using either a subject occlusion catheter or a clamp. The procedure was performed with cerebral and myocardial normothermic perfusion using two alternate devices.	Neurological deficit: 0% (0/5); no coagulopathy, hepatic, or renal impairment observed	adverse effects of hypothermia and circulatory arrest **Limitations** Those inherent to observational and low sample size designs; vantage point (i.e., retrospective or prospective) not reported; years of care not reported; outcomes partially not stratified by technique
Pruitt Aortic Occlusion Catheter - Touati, et al., 2007[47]		
Design Case series **Objectives** To propose a strategy to avoid limitations and complications of hypothermic circulatory arrest with normothermic replacement of the aortic arch **Methods** Review of patients that underwent aortic arch replacement in France **Tests of Significance** None **Sample Sizes** Total sample size: 29 (use of occlusion catheter not disclosed) **Demographics** All techniques: gender not reported; age (years; mean ±SD, range) 59.6 ±11, 40-82 **Follow-up** All techniques (months; mean ±SD, range): 21.6 ±9, 4-70 **Indications** Aneurysm of the aortic arch and acute or chronic aortic dissection **Interventions** Complete replacement of the aortic arch, where the descending thoracic aorta was occluded using either a subject occlusion catheter or a clamp. The procedure was performed under cerebral, body, and myocardial normothermic perfusion using alternate devices.	**Performance** Not stratified by technique **Safety, mortality** Not stratified by technique **Safety, complications** No coagulopathy, hepatic or renal impairment observed; no cardiac or neurological events or disorders of orientation, attention or memory observed; false lumen of the dissection only partially occluded in one patient	**Conclusions** May ensure a more physiological autoregulation of cerebral blood flow and maintains body perfusion without high vascular resistance **Benefits** Should provide the same advantages but eliminate the adverse effects of hypothermia and circulatory arrest **Limitations** Those inherent to study design; vantage point (i.e., retrospective or prospective) not reported; sample size/power analysis not reported; complications largely not stratified by technique
Pruitt Aortic Occlusion Catheter - Hohri, et al., 2020[11]		

Study Details	Results (Performance / Safety Outcomes	Study Conclusions
Design: Observational study **Objective**: To evaluate the prevalence of spinal cord injury in total arch replacement with frozen elephant trunk for acute type A aortic dissection using a spinal cord protection technique. **Sample Sizes:** 33 patients **Demographics**: Age (mean±SD): 67.8±13.2 years Sex: 57.6% male Risk factors: 63.6% hypertension, 12.1% preoperative cardiac pulmonary arrest, 9.1% diabetes mellitus, 6.1% creatinine > 2 mg/dL, 3.0% history of cerebrovascular event **Follow-up:** Computed tomography and evaluation of aortic diameter at 1-2 weeks, 12 weeks, and 36 weeks postoperative; mean±SD follow-up, 33.9±21.0 months **Indications:** Acute type A aortic dissection **Interventions:** Total arch replacement with frozen elephant trunk	**Safety Outcomes:** Operative time – 361.3±62.7 min 30-day mortality – 2 deaths (6.1%) due to preoperative severe cerebral malperfusion and cardiac pulmonary arrest 3-year survival rate – 93.9±4.1% Major complications – 6 cases (18.2%) of cerebrovascular events in patients who were in critical preoperative condition; no cases of spinal cord injury, paraplegia, or paraparesis Malperfusion rate – 18.2% cerebral, 3.0% lower limb, 0% cardiac, 0% intestinal, 0% renal Reintervention rate – 1 case (3.0%) of reoperation for downstream aorta dilation; 3-year freedom from reintervention, 95.0±4.9% **Performance Outcomes:** NRP	**Conclusions:** The surgical strategy, which includes insertion of the aortic occlusion balloon into the frozen elephant trunk during the distal anastomosis to preserve spinal cord perfusion through the intercostal arteries, protects from spinal cord ischemia and achieves excellent aortic remodeling.

NRP = no renal perfusion
RP = renal perfusion

iv) Conclusions

The device under evaluation is intended to control blood flow in the aorta. These types of devices provide indirect clinical benefits including protection of the kidneys, liver, and spinal cord when aortic arch replacement or repair for aortic dissection or aneurysm. While there were statistically significant results favoring the ABO procedure for AKI, RIFLE Grade II/III, and acute hepatic injury, there were no statistically significant results favoring conventional aortic arch replacements, indicating the ABO procedure reduces risks relative to the conventional procedure. Since treatment is necessary for conditions as severe as aortic aneurysm or dissection to prevent death, a reduction in risk improves the benefit risk ratio relative to the state of the art.

The procedural performance benchmark was met, indicating the benefit is consistent with the state of the art. All safety benchmarks except the benchmark for CVAs were met indicating the risk is consistent with the state of the art. CVAs are a procedure-related adverse event and aortic balloons are not directly involved in the cerebral perfusion circuit. Therefore, the benefit risk ratio as it relates to risks for the device is consistent with the state of the art.

The data for the device under evaluation is considered sufficient in quality because it is level 4 data or better, the minimum level permissible for Class III legacy devices according to MDCG 2020-6, Appendix

III. Regarding quantity, the number of patients in each study is shown in the table below. This was a sufficient quantity to demonstrate performance. Regarding the applicability to the EU population, the locations of the studies are also listed in the table below. Just over half of the patients were in the EU or a bordering country..

v) An overall summary of the clinical performance and safety

Performance

The PAOC is intended to occlude the abdominal aorta to achieve control of blood flow during aortic vessel repair, aortic root replacement, and aorta arch repair procedures. Since balloon function is critical to procedural success in these types of procedures, the performance and clinical benefit outcome evaluated to demonstrate conformity to GSPR 1 was:

- Procedural success

Based on the information summarized below, this clinical evaluation supports the performance and benefits of the Pruitt Aortic Occlusion Catheter when used as intended and provides evidence that the Pruitt Aortic Occlusion Catheter is state of the art and conforms to the requirement on performance (GSPR 1).

A comparison of this outcome for the device under evaluation relative to benchmarks from the state of the art are provided in the table below. The device has no direct benefit in that it is not the treatment for any condition. Its benefits are indirect, come from the procedure in which it is used, and can be assumed based on performance. (If the device is performing as intended, it is assumed the patient received the benefit.)

Summary of device performance and clinical benefits for device under evaluation

Outcome	Device under evaluation	Benchmark	Comments
Procedural Success	Pooled Prevalence: 98.8% (95% CI 96.1% to 100%)	Pooled prevalence benchmark: 99.8% (95% CI 99.2% to 100%)	CIs overlap. Benchmark met

Safety

Based on the information summarized below, this clinical evaluation supports the safety of the Pruitt Aortic Occlusion Catheters when used as intended and provides evidence that the Pruitt Aortic Occlusion Catheter is state of the art and conforms to the requirement on safety (MDR GSPR 1).

The observed frequency of adverse events observed in the literature for the device under evaluation compared to the state of the art are provided in the table below. This list is from the literature and does not match the list above. The relations to the list above are discussed below the table.

With the exception of cerebrovascular accidents (stroke), the rates of all adverse events that could be compared to the state of the art either met the benchmark or were otherwise comparable to the state of the art. CVAs are a procedure-related adverse event and aortic balloons are not directly involved in the

cerebral perfusion circuit. In some cases where pooled prevalences could be calculated, the 95% CI for the DUE extended beyond (was greater than) the 95% CI for the SOTA. However, statistically powering for safety is impractical.

There were 12 complaints with 4755 devices sold for a complaint rate of 0.252%. There were not any significant complaint trends or vigilance issues.

Summary of residual risks for device under evaluation

Adverse event in literature	**Device under evaluation (literature, investigations, PMCF, registries)**	**Benchmark**	**Comment**
Renal impairment (also support of performance / benefit)	Pooled prevalence: 1.2% (95% CI 0% to 6.2%)	Pooled prevalence benchmark for AKI: 24.6% (95% CI 18.1% to 31.7%)	The results for the DUE were better than the benchmark.
Hepatic impairment (also support of performance / benefit)	Pooled Prevalence: : 1.2% (95% CI 0% to 6.2%)	Pooled prevalence benchmark for hepatic injury / dysfunction: 7.7% (95% CI 2.2% to 15.9%)	The results for the DUE are well within the 95% CI of the SOTA, thus meeting the benchmark.
Paraplegia (also support of performance / benefit)	Pooled prevalence: 2.2% (95% CI 0% to 5.7%)	Pooled prevalence paraplegia benchmark: 1.6% (95% CI 0.9% to 2.5%)	The pooled result for the DUE is within the 95% CI for the SOTA, thus meeting the benchmark. Although the 95% CI for the DUE extends beyond (greater than) the CI for the SOTA, it should be considered that the analysis was biased against the DUE, this is only supplementary performance, not the main performance outcome, and that statistically powering for safety can be impractical.
Mortality	Pooled prevalence: 6.5% (95% CI 2.25 to 12.6%)	Pooled prevalence benchmark: 3.3% (95% CI 0 to 8.6%)	The pooled result for the DUE is within the 95% CI for the SOTA, thus meeting the benchmark. Although the 95% CI for the DUE extends beyond (is greater than) the 95% CI for the SOTA, it should be considered that statistically powering for safety can be impractical. Not listed in the residual risk and side effects list. Will be added to the risk management.

Adverse event in literature	Device under evaluation (literature, investigations, PMCF, registries)	Benchmark	Comment
Cerebrovascular accidents	18.2% (6/33)	The highest rate reported in the SOTA is 4.1% as reported by Liang 2021	Above the benchmark. This is a procedure-related adverse event. Aortic balloons are not involved in the cerebral perfusion circuit. Not listed in the residual risk and side effects list. Will be added to the risk management.
Postoperative cardiac pulmonary arrest	6.1% (2/33)	No comparable result reported in SOTA	Not listed in the residual risk and side effects list. Will be added to the risk management.
Respiratory complications	6.1% (2/33)	No comparable result reported in SOTA	
Aortic event	9.1% (3/33)	No comparable result reported in SOTA	
Dilated down stream (reoperation for)	3.1% (1/33)	No comparable result reported in SOTA	

In the SOTA literature, the adverse events not listed in the list of primary residual clinical risks from the IFU and risk management were hepatic injury / dysfunction, mortality, and stroke or other neurological dysfunction such as delirium / transient mental dysfunction, temporary neurologic deficiency, and permanent neurologic deficiency. (All kidney function results were grouped under the renal insufficiency item in the IFU list and spinal cord ischemia was grouped under the paraplegia item.) Hepatic injury / dysfunction (hepatic impairment), mortality, and stroke were also reported in the DUE and are discussed below.

When the DUE adverse event list is compared to list of primary residual clinical risks from the IFU and risk management, only infection, hemorrhage, paraplegia, and renal insufficiency were reported in the DUE literature. Hemorrhage is associated with both the condition treated and the procedure, while renal insufficiency and paraplegia are associated with the procedure. Additional adverse events that occurred at rates greater than 0% were:

- Mortality which was also reported in the SOTA and is also associated with the condition and procedure
- Cerebrovascular accidents, which was also reported in the SOTA (as stroke)
- Postoperative cardiac pulmonary arrest (comparable result not reported in SOTA)
- Respiratory complications (comparable result not reported in SOTA)
- Aortic event (comparable result not reported in SOTA)
- Reoperation for dilated down stream (comparable result not reported in SOTA)

These have been reviewed and will be added to the risk management documentation to ensure the benefits continue to outweigh the risks.

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

The manufacturer conducts ongoing PMS of the subject device according to the following procedures (SOP28-002, Rev. H):

- 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

PMCF activities are planned for the subject devices as described in the PMCF plan (PMCF041). In brief, there is an ongoing end-user survey that commenced in Q2 of 2023 and is anticipated to be completed in Q4 of 2024. A prospective clinical study is planned to start protocol drafting in Q3 of 2025 to confirm the expected performance of these devices, identify previously unknown side-effects, monitor the identified side-effects and contraindications, identify and analyze emergent risks on the basis of factual evidence, ensure the continued acceptability of the benefit / risk ratio, and identify possible systematic misuse or off-label use of the device. The primary endpoints that will be investigated include transfusion volumes, duration of hospital and ICU stays, safety outcomes (i.e., mortality, neurological impact, and complications within the first year postoperative), and misuse or off-label use of the devices. To address the gap in clinical data relevant to the LeMaitre Aortic Occlusion Catheter, the PMCF end user survey will be usedto guide the endpoints in the prospective study and determine any gaps in data.

6.0 Possible diagnostic or therapeutic alternatives:

Reference	Objectives	Methods	Conclusions
Clinical Practice Guidelines			
European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Abdominal Aorto-iliac Artery Aneurysms[12] https://www.ejves.com/article/S1078-5884(23)00889-4/fulltext	To update and expand on the previously published guidelines for the care of patients with aneurysms of the abdominal aorta and iliac artery, with the aim of assisting physicians in selecting the best management strategy.	The guideline is based on scientific evidence completed with expert opinion on the matter. By evaluating the best available evidence, recommendations for the evaluation and treatment have been formulated. The recommendations are graded according to a modified European	- Haemodynamically unstable patients with a ruptured abdominal aortic aneurysm undergoing open or endovascular repair may be considered for aortic balloon occlusion under fluoroscopy guidance to obtain proximal control (downgraded [from prior version of

Reference	Objectives	Methods	Conclusions
		Society of Cardiology grading system, where the strength (class) of each recommendation is graded from I to III and the letters A to C mark the level of evidence.	guidelines] to Class IIb) - For patients with a ruptured complex abdominal aortic aneurysm (or who are deemed urgent for any other reason), open surgical or endovascular repair. . . . Should be considered based on patient status, anatomy, and patient preferences (rephrased and upgraded to Class IIa [from prior version of guidelines]) - Recommendation 2: Centres or networks of collaborating centres treating patients with abdominal aortic aneurysms should be able to provide both endovascular and open aortic surgery.
The Society for Vascular Surgery (SVS) Practice Guidelines on the Care of Patients with an Abdominal Aortic Aneurysm[13] doi.org/10.1016/j.jvs.2017.10.044	To provide guidelines for the management and postoperative surveillance of patients with an AAA.	Randomised trials have initial high rating. Observational studies have initial low rating. Rating is then modified based on risk of bias, consistency of results across studies, directness of the populations and interventions of the studies to the question at hand, precision of the estimates of effect, and size of the observed effect.	- Proximal control of the aorta is crucial at the beginning of the AAA repair. Indications for aortic balloon occlusion include circulatory collapse, hemodynamic instability, and anatomic limitations that prevent expeditious repair.

7.0 Suggested profile and training for users:

Intended users include vascular surgeons. LeMaitre Vascular, Inc. assumes that any surgeon performing the above operations has received adequate training and is thoroughly familiar with the pertinent scientific literature.

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
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
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
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 15223-1:2021
Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes	ISO 13485:2016
Medical devices — Part 1: Application of usability engineering to medical devices	IEC 62366-1: 2015
Biological evaluation of medical devices – Part 1: Evaluation and testing	ISO 10993-1: 2018
Biological evaluation of medical devices – Part 7: Ethylene oxide sterilization residuals	ISO 10993-7: 2008/Amd 1:2019
Biological evaluation of medical devices — Part 18: Chemical characterization of medical device materials within a risk management process	ISO 10993-18: 2020
Sterilization of health care products – Ethylene oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	ISO 11135: 2014/Amd 1:2018
Medical devices — Information to be supplied by the manufacturer	ISO 20417: 2021

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9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
A	11/04/2024	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)