1.0 Device Identification and General Information

i) Document number: MS-0071

ii) Device trade names: Flexcel™ Carotid Shunt

iii) Manufacturer's name and address:

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

iv) SRN: US-MF-000016778

v) Basic UDI-DI: 08406631FlexcelLB

vi) Device Item Codes, Descriptions, Basic UDI, GMDN Code and MDR Classification

Catalog Number	Description	GTIN
2020-01M	Flexcel Carotid Shunt Single Pack (8F, 10F, 12F, 14F)	00840663111060
2020-05M	Flexcel Carotid Shunt 5 Pack (8F, 10F, 12F, 14F)	00840663111077
2020-11M	Flexcel Carotid Shunt Single Pack (8F)	00840663111084
2020-15M	Flexcel Carotid Shunt 5 Pack (8F)	00840663111091
2020-21M	Flexcel Carotid Shunt Single Pack (10F)	00840663111107
2020-25M	Flexcel Carotid Shunt 5 Pack (10F)	00840663111114
2020-31M	Flexcel Carotid Shunt Single Pack (12F)	00840663111121
2020-35M	Flexcel Carotid Shunt 5 Pack (12F)	00840663111138
2020-41M	Flexcel Carotid Shunt Single Pack (14F)	00840663111145
2020-45M	Flexcel Carotid Shunt 5 Pack (14F)	00840663111152

vii) Medical device nomenclature description

GMDN Code/Description: 47113/ Carotid artery shunt
UMDNS Code/Description: 17-797/ Shunts, Carotid Artery
EMDN Code/Description: C019006/ Carotid Artery Shunts

viii) Class of device

Manufacture Name	MDR Classification	Rule
Flexcel Carotid Shunt	III	7

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

Device Name	Date of Initial CE Mark	Date of 510(k)
Flexcel Carotid Shunt	25 October 2005	29 August 2007 (K071367)

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 single identification number

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

2.0 Intended use of the device

i) The Flexcel Carotid Shunt is intended to act as a temporary conduit to allow for blood flow between the common and internal carotid arteries during endarterectomy procedures.
Indication(s) and target population(s)

- Indication: The Flexcel Carotid Shunt is indicated to facilitate carotid endarterectomy procedures for the treatment of carotid artery disease.
- Target Population: The Flexcel Carotid Shunt is to be used only for adults undergoing carotid endarterectomies

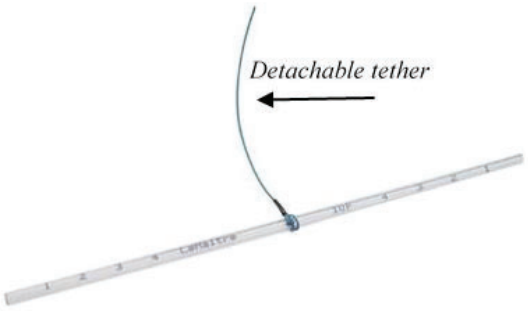
ii) Contraindications and/or limitations

- The shunt is a temporary device that should not be implanted.
- Do not use a carotid bypass shunt if the arteries demonstrate atherosclerosis that would prevent safe insertion and placement of the shunt.

3.0 Device Description

i) Description of the device

The LeMaitre Flexcel Carotid Shunt (Flexcel) is designed to serve as an artificial passage connecting two blood vessels, allowing blood flow from one vessel to another. This is accomplished by using a clear, flexible, conduit that is held in place by a stabilization technique on both ends of the conduit. The shunt is sterilized by ethylene oxide gas, and is guaranteed to be sterile unless packaging is compromised. The Flexcel is a single lumen blood conduit for use in the carotid artery. The shunt is equipped with depth markings running the length of the device and features atraumatic tips. In addition, the shunt has a removable tether to facilitate the removal of the shunt after the procedure.

	Flexcel Carotid Shunt

ii) A reference to previous generations or variants: The product is a mature product currently on the market for a well-established intended use. It has been developed by incremental changes and is based on the LeMaitre® Vascular, Inc. Straight Carotid Shunt (510(k) # K033159) and the Pruitt F3 Carotid Shunt (510(k) # K051067) predecessor devices. 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, although minor changes have been made to the device to provide incremental benefits to the user/patients. These include improved flexibility, increased flow, pre-attached tether around the center to facilitate removal of an inlying device, center marking, extensive depth markings, and atraumatic tips. Additionally, during introduction of the initial Flexcel™ Carotid Shunt design to market, user feedback was gained as to the flexibility and length of the shunt. In an effort to provide the optimum shunt based on surgeon preference, a redesign effort was undertaken to provide a slightly stiffer and longer (14.5 cm) shunt. This new shunt replaced the previous version.

iii) Description of any accessories which are intended to be used in combination with the device: No accessories are supplied with this device.

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

4.0 Risks and Warnings

i) 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

- Potential Complications (as noted in the IFU)

Adverse Event	Rate	Timepoint	Source from CER
Stroke	0% 2.4%	Perioperative <30 days	Cyrek, 2020 PMCF report 210413
Transient Ischemic attack	0% to 5.9%	Perioperative to 30 days	Cyrek, 2020 Bellosta, 2006 Yang, 2014 Kong, 2017 Piazza, 2018* Leopardi, 2019* Kumar, 2021* Squizzato, 2022* Zhang, 2022*
Neurological complication	3.7% 0%	Postoperative 30 days	Cyrek, 2020 PMCF report 210413
Embolization of blood clots, arteriosclerotic plaque or air	-	-	No reported occurrence
Infection	0% to 0.7%	Perioperative to 12.3 months	Cyrek, 2020 Chang, 2000 Bellosta, 2006 Chongruksut, 2014* Yüksel, 2014* Kumar, 2021* Squizzato, 2021* Chuatrakoon, 2022* Ribieras, 2022*
Intimal disruption (intimal flaps)	1.9	Intraoperative	Cyrek, 2020
Vessel perforation and rupture	-	-	No reported occurrence
Hemorrhage	0.3% to 1.3%	Perioperative	Chongruksut, 2014* Chuatrakoon, 2022* Squizzato, 2022*
Arterial thrombosis	-	-	No reported occurrence
Arterial spasm	-	-	No reported occurrence
Vessel occlusion	0%	Postoperative	Cyrek, 2020

**SOTA*

Risks from SOTA were included to ensure all data is considered. The risks associated with the subject device will be present in similar devices even if no complaints have been filed on the subject device. Thus, risks and adverse events associated with the similar devices as listed in the SOTA are included above.

ii) Warnings and precautions

- Warnings
  i. Do not reuse. Do not re-sterilize. The shunt is for single use only.
  ii. Assure that the shunt is properly stabilized in the artery or slippage may occur.
  iii. Do not force a shunt that is too large into an artery. This may result in vessel disruption or damage.
- Precautions
  i. 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.
  ii. Only qualified physicians thoroughly familiar with cardiovascular surgical procedures involving the carotid artery should use the shunt.

iii. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

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

From 01 January 2017 to 31 July 2022, there were a total of 5 complaints associated with the subject device and a total of 89,858 devices sold, resulting in an overall cumulative complaint rate of 0.006%. The table below provides the complaint rate for each year.

For the 5 total complaints, the complaint codes were "boxes damaged during shipping" (n=2; 0.002%) "tip out of tolerance" (n=2; 0.002%), Threads separated (n=1; 0.001%) The complaint rate over the 6-year period for the EU was 0.006% and for the rest of the world 0.005%. Three complaints (1 tip out of tolerance and 2 sharp edges) resulted in an Engineering Change Order (ECO-3225) to add visual aids to manufacturing instructions and updated tipping die settings at slightly hotter temperature. In 2016, 1 center reported 10 complaints for "ends of shunts too traumatic" (complaint type: tips out of tolerance). After further evaluation, the root cause was likely a manufacturing error and has been addressed.

Overall device complaint rates per year

Year	# Complaints	# Devices sold	Complaint rate
2017	1	14,585	0.007%
2018	1	15,880	0.006%
2019	0	16,958	0.000%
2020	0	12,981	0.000%
2021	0	17,476	0.000%
2022*	3	11,978	0.025%
Total World-Wide Complaints	**5**	**89,858**	**0.006%**

**up to July 31st*

Complaints by Region and Year

Complaints by Region / Year/ World-Wide	2017	2018	2019	2020	2021	2022*	Total
Total Sales	14,585	15,880	16,958	12,981	17,476	11,978	89,858
Total Complaints	1	1	0	0	0	3	5
Total Complaint Rate	0.007%	0.006%	0%	0%	0%	0.025%	0.006%
Europe	**2017**	**2018**	**2019**	**2020**	**2021**	**2022***	**Total**
Complaints	1	0	0	0	0	3	4
Sales	11,520	12,650	12,743	10,136	13,226	7,858	68,133
Rate (complaints/sales)	0.009%	0%	0%	0%	0%	0.038%	0.006%

ROW	2017	2018	2019	2020	2021	2022*	Total
Complaints	0	1	0	0	0	0	1
Sales	3,065	3,230	4,215	2,845	4,250	4,120	21,725
Rate (complaints/sales)	0%	0.031%	0%	0%	0%	0%	0.005%

**up to July 31st*

Device complaints per category

Complaint Category	2017	2018	2019	2020	2021	2022*	Total	Complaint Rate
Tip out of tolerance	1	1	0	0	0	0	2	0.002%
Shipping Damage	0	0	0	0	0	2	2	0.002%
Threads Separated	0	0	0	0	0	1	1	0.001%
Total	1	1	0	0	0	3	5	0.005%

**up to July 31st*

Corrective and Preventative Actions: There are no CAPAs relevant to the safety and performance of the subject device that were opened between 01 January 2017 and 31 July 2022.

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

i) **Summary of performance data from the equivalent device, if applicable**

- NA

ii) **Summary of performance data from conducted studies of the device prior to CE-marking: NA**

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

- Cyrek, 2020 discusses the routine intraoperative flow measurement in the setting of carotid revascularization is a safe and reliable diagnostic method for intraoperative quality control. Technical errors and hemodynamic flow irregularities can be detected and remedied immediately. This method can also be helpful in a teaching setting to examine surgical technique and results performed by trainees.

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

The subject device is intended to act as a temporary conduit to allow for blood flow between the common and internal carotid arteries during endarterectomy procedures. Survival and reduced risk of neurologic outcomes are commonly reported as clinical benefit outcomes following carotid endarterectomy procedures, with or without shunt use. Both outcomes are likely to be impacted by other variables, including underlying patient morbidity, other procedural variables like anaesthesia use, etc. In addition, shunt use is often used selectively at the discretion

of the surgeon, and often based on clinical measures suggestive of an increased likelihood of ischemic complications (e.g., degree of contralateral stenosis, EEG changes). Therefore, the clinical benefits associated with the use of the Flexcel Carotid Shunt include reduced risk of stroke, no decrease in neurological function, and increased survival compared to rates observed in similar devices and no shunting. In addition to the clinical benefits of the subject device, the successful use of the device as intended is the primary performance measure, along with clamping duration. Other performance outcomes, e.g., patency and operating time, are often reported in clinical studies pertaining to carotid endarterectomy but are not directly associated with the subject device performing as intended. These outcomes are summarized in the report but were not considered in the benefit-risk analysis and therefore acceptance criteria for these outcomes are not established.

Performance data
Technical success, as defined a successful use of the device without device-related complications, was reported in the clinical literature at 100% (107/107) and 100% (251/251) in the PMCF study. These results are within the acceptance criteria as set forth by the state-of-the-art literature (≥98.5%).

Clinical data
Survival was reported at 100% (251/251 and 107/107) in the PMCF study and a retrospective cohort study, respectively. These results were comparable to the acceptable limits as determined by the state of the art (≥98.7%). The retrospective cohort study also reported on freedom from stroke and postoperative neurological function. Both outcomes were reported to be 100% (107/107), which was greater than the acceptance criteria determined through the state-of-the-art analysis, ≥96.9% and ≥96.6%, for freedom from stroke and postoperative neurological function, respectively.

Safety data
The device-related safety outcomes or outcomes associated with the carotid endarterectomy procedure included mortality (0%) and stroke (0-2.4%) up to 2 years, occlusion (0-3.5%) up to 1 year, as well as TIA (0-0.4%), neurological complications (0-3.7%), intimal flaps (1.9%), infection (0%), and hematoma (0.4-3.7%) up to 30 days. Of the reported outcomes, long-term (≥12 months) occlusion (3.5%) was not within the acceptance criteria. However, this outcome is highly dependent upon the patient comorbidities and less dependent upon the shunt.

Based on this clinical evaluation, there is sufficient data to demonstrate conformity to the applicable requirements and confirm that the subject device is safe and performs as intended and claimed by LeMaitre Vascular, Inc. and is state of the art

device for use as in the replacement or repair of arteries affected with aneurismal or occlusive disease, such as abdominal aortic aneurysm, thoracic aortic aneurysm, and peripheral vascular disease. Review of the post-market data, information materials, 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 device are acceptable when weighed against the benefits.

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

- The manufacturer conducts ongoing PMS of the subject device according to the following procedures (Post Market Surveillance Plan Flexcel® 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

A PMCF plan (PMCF006, Rev. B) to assess the performance and safety profile of the Flexcel™ Carotid Shunt to ensure that claims are substantiated, the device is safe, and the risk/benefit ratio remains positive when the device is used as intended includes a literature review (Q3 of 2022), a PMCF study (Q4 of 2025), and an end-user survey (Q4 of 2025). This comprehensive approach allows for a critical evaluation of the subject device by surveying broad, relevant information sources with minimization of bias. The planned PMCF study aims to 1) confirm the safety of the medical device (e.g., reported rates of mortality, infection, loss of limb, surgical complications and other adverse effects), 2) identify previously unknown side-effects (related to the procedures or to the medical devices), 3) monitor the identified side-effects and contraindications, 4) identify and analyze emergent risks, 5) ensure the continued acceptability of the benefit-risk ratio, and 6) identify possible systematic misuse or off-label use of the device. Technical success and patency rates will be used as device performance outcomes for the carotid shunts, but final study endpoints will be determined by a panel of clinical and area experts to ensure capture of the appropriate data to confirm claims for the device. Study sample size, timing, and endpoints will be determined as part of the Clinical Investigation Plan. A contract research organization will be included to ensure the study is conducted in a non-biased manner and perform statistical analyses to ensure the quality of all outcomes. Data will be analyzed for potential unforeseen side effects, and new performance or adverse events will result in a follow-up study to confirm newly discovered data. The separate end user survey will be conducted to also identify unknown side-effects, analyze emergent risks, ensure continued acceptability of the benefit-risk ratio, and identify possible systematic mis- or off-label use of the device.

6.0 Possible diagnostic or therapeutic alternatives

Treatment Alternative/ Device or Device Type	Description	Advantages/ Benefits	Disadvantages/ Limitations/ Risks	Safety and Performance Outcomes
No shunting	A shunt is not used as a temporary conduit between the common and internal carotid arteries during carotid endarterectomy.	No risks associated with shunt use	Risk of hemodynamic brain injury	- Shorter operative time for no shunting versus shunting with the equivalent device.[6]
Selective shunting	A shunt is used as a temporary conduit between the common and internal carotid arteries during carotid endarterectomy in selected patients with an inadequate blood supply to the brain.	Avoidance of temporary hemodynamic neurological deficits due to clamping of the carotid arteries, while avoiding risks of shunt use in patients that do not require shunt placement	Risk of not inserting a shunt in patients that could benefit from shunt use; risks associated with shunt use such as: embolism of atheromatous debris or air through the shunt, mechanical injury to the distal internal carotid artery during shunt placement, and obscuring of the arterial anatomy at the distal zone of carotid endarterectomy[12]	- Shorter length of hospital stays 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]

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]

Printed on: 16 Oct 2023, 11:24:40 am; Printed by: AWENZEL

Treatment Alternative/ Device or Device Type	Description	Advantages/ Benefits	Disadvantages/ Limitations/ Risks	Safety and Performance Outcomes
				- No significant differences in clamp time or length of hospital stay between shunting (including shunting with the equivalent device) and no shunting.[1,5,6] - No significant differences in incidence of postoperative 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:

Only qualified physicians thoroughly familiar with the cardiovascular surgical procedures involving the carotid artery should use the shunt

8.0 Reference to any harmonized standards and CS applied

Standard Reference: Revision Year	Standard Title
ASTM F1980-21	Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Devices
EN ISO 10993-1:2020	Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-7:2008	Biological evaluation of medical devices — Part 7: Ethylene oxide sterilization residuals
EN ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
EN ISO 10993-11:2018	Biological evaluation of medical devices — Part 11: Tests for systemic toxicity

EN ISO 10993-17:2009	Biological evaluation of medical devices – Part 17: Establishment of allowable limits for leachable substances
EN ISO 10993-18:2020	Biological evaluation of medical devices - Part 18: Chemical characterization of medical device materials within a risk management process
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2020	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018/A1:2021	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice
EN ISO 14644-1:2015	Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration
EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
EN ISO 15223-1:2021	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
IEC 62366-1:2015	Amd1:2020 Medical devices - Part 1: Application of usability engineering to medical devices
ISO 10555-1:2013 Amd1:2017	Intravascular catheters — Sterile and single-use catheters — Part 1: General requirements — Amendment 1
BS EN 556-1:2001	Sterilization of medical devices. Requirements for medical devices to be designated "STERILE" - Part 1. Requirements for terminally sterilized medical devices

9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody/BSI
A	21 March 2022	Initial release	☒ Yes Validation language: English ☐ No (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)

B	05 May 2023	Updated per NB feedback: Removed patient section, updated the purpose and indications, updated model numbers/GTINS, risks, literature	☒ Yes Validation language: English ☐ No
C	19 July 2023	Updated patient population, standards, clinical benefit	☒ Yes Validation language: English ☐ No

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