1.0 Device Identification and General Information

i) Device trade names: Flexcel™ 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: 08406631FlexcelLB

v) 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

vi) 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

vii) Class of device

Manufacture Name	MDR Classification	Rule
Flexcel 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)
Flexcel Carotid Shunt	25 October 2005	29 August 2007 (K071367)

ix) 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

x) 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: Patients of any gender, age or ethnicity in need of carotid artery repair surgery. There is limited data for the use of this device on pregnant women and children. It is at the surgeon's discretion on whether to use it on this population.

ii) Contraindications and/or limitations

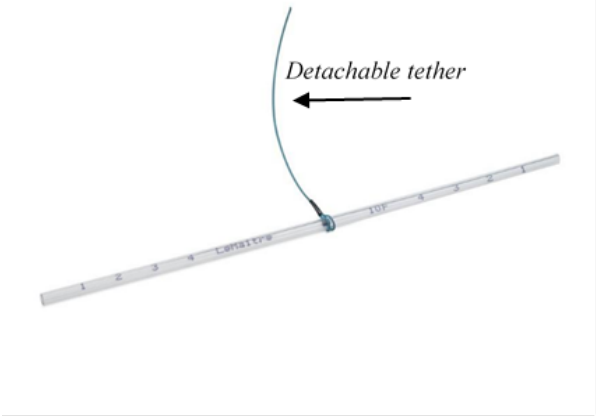
- The shunt is a temporary device that should not be implanted.
- Do not use a carotid bypass shunt if the arteries demonstrate atherosclerosis that would prevent safe insertion and placement of the shunt.

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.Image	Device name

	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, 2021Squizzato, 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

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 16 total complaints, the complaint codes were "tips out of tolerance" (n=12; 75%), "sharp edges" (n=2; 12.5%), and "barcode did not correspond to GS1" (n=2; 12.5%). The complaint rate over the 6-year period for the EU was 0.021% and for the Americas 0.004% (Table 6-13). 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%**

**through 31 Aug 2021*

Complaints by Region and Year

Complaints by Region / Year	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**Total**
Total Sales	14,585	15,889	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%
Canada	**2017**	**2018**	**2019**	**2020**	**2021**	**2022**	**Total**
Complaints	0	0	0	0	0	0	0
Sales	105	115	190	150	205	185	955
Rate (complaints/sales)	0%	0%	0%	0%	0%	0%	0%

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%

Device complaints per category

Complaint type	# of complaints	Complaint rate
Boxes damaged during shipping	2	0.002%
Tip out of tolerance	2	0.002%
Threads separated	1	0.001%

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 to 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**

- There were no manufacturer sponsored pre-market investigations conducted with the device. The Flexcel Carotid Shunt was submitted based on the following:

  Wilkinson, 1997 discusses a study measuring hemodynamic properties, embolization, and neurological outcomes in a larger sample population is needed to reach a definitive conclusion with regards to shunt type. The authors recommend the use of a shunt with tapered design (like Javid) for flow properties but with holding mechanism like a balloon (like Pruitt) to reduce intimal damage.

  Ballotta, 2003 discusses shunting with eversion CEA was feasible, but the authors concluded that study lacked proper statistical power to make a conclusive statement with regards to perioperative death, restenosis, and stroke.

  Chang, 2000 discusses carotid shunt insertion not associated with increased stroke/death rates and can be used effectively during eversion CEA.

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 Flexcel shunt was associated with reduced risk of stroke and increased survival, comparable to rates observed for similar devices and/or no shunting as determined by intra-study comparisons.

Based on this clinical evaluation, which includes both non-clinical and clinical data, 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

The following alternative devices and treatments were examined in the CER:

- No shunt CEA; 27 studies
- Unspecified shunt; 11 studies
- Pruitt-Inahara® (LeMaitre Vascular Inc.); 10 studies
- Pruitt F3® (LeMaitre Vascular Inc.); 2 studies
- Vascushunt (Edwards); 1 study
- Aesculap shunt (Braun); 1 study
- Carotid artery stenting; 1 study

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 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 10993-1:2018
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 10993-4:2017

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 10993-10:2023
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 10993-17:2009
Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2019
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2019
Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	ISO 11737-1:2018/A1:2021
Tests of sterility performed in the definition, validation and maintenance of a sterilization process	ISO 11737-2:2020
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 14971:2019
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements	EN ISO 15223-1:2021

9.0 Revision History

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
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	15 Feb 2022	Removed patient section, updated the purpose and indications, updated model numbers/GTINS	☐ Yes Validation language: English ☐ No

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