1.0 Device Identification and General Information

i) Device trade names: Artegraft Collagen Vascular Graft

ii) Document Number/Version: RCD 131-01-001 Rev. B

iii) Manufacturer's name and address:

Legal manufacturer name:	LeMaitre Vascular Inc.
Address:	206 N Center Drive, North Brunswick, NJ, 08902 USA

iv) SRN: US-MF-000034551

v) Basic UDI-DI: 0316837ArtegraftDW

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

Catalog Number	Description	GTIN
AG540M	Artegraft Collagen Vascular Graft 4mm, 40cm	00316837000008
AG630M	Artegraft Collagen Vascular Graft 5mm, 30cm	00316837000015
AG636M	Artegraft Collagen Vascular Graft 5mm, 35cm	00316837000022
AG640M	Artegraft Collagen Vascular Graft 5mm, 40cm	00316837000039
AG645M	Artegraft Collagen Vascular Graft 5mm, 45cm	00316837000046
AG715M	Artegraft Collagen Vascular Graft 6mm, 15cm	00316837000053
AG730M	Artegraft Collagen Vascular Graft 6mm, 30cm	00316837000060
AG735M	Artegraft Collagen Vascular Graft 6mm, 35cm	00316837000077
AG740M	Artegraft Collagen Vascular Graft 6mm, 40cm	00316837000084
AG745M	Artegraft Collagen Vascular Graft 6mm, 45cm	00316837000091
AG750M	Artegraft Collagen Vascular Graft 6mm, 50cm	00316837000107
AG830M	Artegraft Collagen Vascular Graft 7mm, 30cm	00316837000114
AG840M	Artegraft Collagen Vascular Graft 7mm, 40cm	00316837000121
AG845M	Artegraft Collagen Vascular Graft 7mm, 45cm	00316837000138
AG1015M	Artegraft Collagen Vascular Graft 8mm, 15cm	00316837000145
AG1030M	Artegraft Collagen Vascular Graft 8mm, 30cm	00316837000152

a. Medical device nomenclature description / text
P07010101 VASCULAR PATCHES, PERICARDIUM

b. Class of device

Manufacture Name	GMDN Code	MDR Classification	Rule
Artegraft Collagen Vascular Graft	52745	III	18

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

Device Name	Date of Initial CE Mark	Date/No. of PMA
Artegraft Collagen Vascular Graft	NA	01 Aug 1979 / N16837

viii) Authorized 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

ix) 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 Artegraft is intended to serve as a substitute conduit for blood where bypass or replacement of occluded or diseased arterial segments is required or to establish a conduit for hemodialysis.

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

- Indication: The Artegraft is indicated for the following:
  - Hemodialysis
    - Arteriovenous (AV) fistula salvage and repair
    - Primary AV Graft
    - AV Graft Replacement
  - Lower extremity bypass
  - Arterial trauma
- Target Population: Adults of any gender or ethnicity that need an arterial bypass or arteriovenous shunt or surgery requiring an arterial graft.

iii) Contraindications and/or limitations

- The Artegraft should not be used in venous or low-pressure systems.
- The Artegraft is also contraindicated in patients with known or suspected hypersensitivity to bovine collagen and bovine pericardium.

3.0 Device Description

i) Description of the device

The Artegraft is composed of a section of specially selected bovine carotid artery that has been subjected to enzymatic digestion.

The Artegraft Collagen Vascular Graft is of bovine origin and the surgical staff must prepare the graft for implantation. The sterile graft is preserved in a tube filled with USP purified water and ethyl alcohol. The Artegraft is composed of a section of specially selected bovine carotid artery that has been subjected to enzymatic digestion with ficin and tanned with dialdehyde starch. The Artegraft is intended for use distal to the aorta as a segmental arterial replacement, as an arterial bypass, as an arteriovenous shunt where more conventional methods have proven inadequate, or as an arterial patch graft. The function and action of the Artegraft is simply to serve as a substitute conduit for blood where bypass or replacement of occluded or diseased arterial segments is required or to establish a conduit for hemodialysis.

The collagen graft is composed of specially selected and harvested bovine carotid arteries which have been subjected to enzymatic digestion with ficin enzyme solution and tanned with dialdehyde starch solution to cross link the collagen matrix in order to maximize strength and performance. Artegraft is of biological origin and the surgical staff must prepare the graft for implantation. Instructions for implant are defined in the IFU. The sterile graft is preserved in a tube filled with USP purified water and ethyl alcohol. The Artegraft is packaged in a specially designed tube containing a sterilizing solution prepared with 1% propylene oxide in 40% aqueous U.S.P. ethyl alcohol. Each tube is enclosed in a set-up box for protection during shipment and storage.

Image of the device

ArteGraft Collagen Vascular Graft	

The length and inner diameter of each Artegraft are specified on the packaging labels. The inner diameter of the Artegraft is approximate, rounded to the nearest mm, due to the nature of the biologic source material. The availability of graft diameters and lengths is dependent upon the animal source. Product codes and sizes are referenced in the chart below. Outer diameters vary, but typically 1mm larger.

ii) A reference to previous generation(s) or variants if such exist, and a description of the differences:

In 1970, the original US FDA approval for the Artegraft® Collagen Vascular Graft™ was obtained by sponsor Johnson & Johnson. In 1993, Artegraft, Inc. purchased the rights and assets of Artegraft® Collagen Vascular Graft™ including all regulatory approvals and assets from Johnson & Johnson. LeMaitre Vascular, Inc. purchased the rights and assets in 2021.

The Artegraft® Collagen Vascular Graft™ has been in continuous commercial distribution, both in the USA and in periodic international distribution since its initial US FDA NDA/PMA approval in 1970. The process of obtaining the harvested carotid arteries, subjecting these arteries to tissue stripping, various chemical processes, ligation, pressure testing, sizing and other activities through terminal sterilization, has remained virtually unchanged since the original NDA approval by the FDA in 1970 (NDA 16-837). The only changes to the packaged graft have been the change from a glass outer package to a PET plastic outer primary package and the addition of additional suppliers for the bovine arteries. These changes were approved by the US FDA via individual PMA Supplements, on file. In addition to FDA approvals, the suppliers of these new materials were subjected to the standard QS Artegraft, Inc. supplier certification process.

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 conclude that the benefits outweigh any residual risks and that the risk has been reduced as far as possible.

Potential device-related complications:

Adverse Event	Rate	Source from CER	Follow up
Aneurysm	0%-33%	Harlander-Locke, 2014; DUE Kester, 1979; SOTA	Mean follow-up 8.0 ± 7.5 months
Bleeding	1-3%	Abdoli, 2018; DUE	30 days
Central venous stenosis	0.19 ± 0.13%	Marcus, 2019; DUE	34 ± 13 months
Hematoma	0-7.8%	Abdoli, 2018; Naazie, 2022; Kester, 1979; DUE	4-30 days
Infection	0-15%	Naazie, 2022; Abdoli, 2018; Katzman, 1976; Kennealey, 2011; Marcus, 2019; Pineda, 2017; Arhuidese, 2017; Harlander-Locke, 2014; DUE	30 days to 3.5 years
Nonmaturation	0.06 ± 0.02%	Marcus, 2019; DUE	34 ± 13 months
Pseudoaneurysm	0-4%	Marcus, 2019, Arhuidese, 2017, Harlander-Locke, 2014, Kennealey, 2011, Hurt, 1983; DUE	3.5 years
Seroma	0-3%	Abdoli, 2018; DUE	30 days
Steal syndrome	0.03-25% (n=1/4)	Marcus, 2019; Arhuidese, 2017; Harlander-Locke, 2019; DUE	8 months-3.5 years
Stenosis	2%	Naazie, 2022; DUE	Median 280 days
Thrombosis formation	15.7%	Naazie, 2022; DUE	Median FU of 80 days

Potential procedure-related complications (sourced from the SOTA)

Adverse Event	Rate %	Source from CER	Follow up period
Amputation			
Aneurysmal Degeneration	1.67%	Lindsey, 2018	30 days
Congestive Heart Failure	2.2%	Nguyen, 2018	30 days
Mortality	0-10%	SOTA	Intraoperative to 1 year
Occlusion	0-24%	SOTA	In-hospital to 1 year
Reintervention			

Sepsis or Systemic Inflammatory Signs	0-18.18%	Kester, 1979	Not reported
Wound Complication	6.9%	Borghese, 2020	Not reported

ii) Warnings and precautions

Warnings

- Do NOT re-sterilise the Artegraft. Use the graft immediately after opening the package and discard any unused portions.
- The graft should not be used after the expiration date imprinted on the label.
- After the Artegraft has been removed from the container in the manner prescribed to maintain its sterility, it should be gently and thoroughly washed and rinsed to minimize carryover of preserving fluid.
- Silk is not recommended for anastomosis.
- The graft is not to be used unless the capacity of the run-off vessel is adequate, as shown by pre-operative arteriography. Artegraft selection must be of comparable cross-sectional diameter to the host artery, particularly at the distal end, in order to avoid early thrombosis.
- A minimum of twelve (12) days should be allowed after implantation before puncturing the graft with needles for hemodialysis. If edema appears around or distal to the graft, this should be allowed to resolve before cannulation.
- Avoid external compression of the graft.

Precautions

- In the event of early occlusion, re-exploration of the graft and removal of the thrombus with an embolectomy or thrombectomy catheter can be effective for restoration of long-term patency.
- Patients subjected to heparin anticoagulant rinse and flush should be confirmed to be heparin-induced thrombocytopenia (HIT) free, and of heparin associated allergic reactions. Some surgeons recommend systemic heparinization of the patient after completion of the preparatory dissection, with or without subsequent neutralization with protamine sulfate. Others rely on the periodic injection of diluted heparin into the arterial tree during the period of vascular clamping and anastomosis. Post-operative heparinization is usually not employed.
- During implantation ensure the graft does not twist as it is tunneled to its distal location.
- Patients should be monitored for the presence of fever and transient low grade fever to prevent disruption of anastomosis
- Patients should be monitored for high output congestive heart failure in patients with heart disease.

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

- The table below lists 2 CAPAs relevant to the safety and performance of the subject device that was opened from 01 January 2019 to 01 August 2024.

CAPA summary

Reference Number	CAPA Description Summary	Corrective Action	Status (Date Closed)
CAPA-00055	Inadequate instructions for use	IFU updated to include the amount of saline to use during flush.	Closed (01 May 2021)
CAPA-00039	Packaging error	Demo graft was used in error. The hospital was notified to destroy all "DEMO" labeled grafts.	Closed (6 October 2017)

There were 0 FSCAs / recalls that have been initiated or reported for the subject device from 01 January 2019 to 01 August 2024.

Complaints by region and year

Complaints by Region / Year	2019	2020	2021	2022	2023	2024*	Total
Total Sales	14,310	7,962	14,259	14,253	15,389	6,367	72,550
Total Complaints	11	5	14	10	19	17	76
Total Complaint Rate	0.077%	0.063%	0.098%	0.070%	0.123%	0.267%	0.105%
Americas	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	11	5	14	10	18	17	75
Sales	14,310	7,962	14,258	14,254	15,370	6,359	72,513
Rate (complaints/sales)	0.077%	0.063%	0.098%	0.070%	0.117%	0.267%	0.103%
Asia	**2019**	**2020**	**2021**	**2022**	**2023**	**2024***	**Total**
Complaints	No sales	No sales	0	0	1	0	1
Sales	0	0	1	9	19	8	37
Rate (complaints/sales)	No sales	No sales	0	0	5.263%	0.000%	2.703%

** Up to August*

Device complaints by category, and rates per year

Complaint Category	2019	2020	2021	2022	2023	2024*	Total	Rate
Leaking graft	0	0	3	4	3	3	13	0.018%
Packaging error	4	2	2	2	1	1	12	0.017%
Graft diameter	3	2	1	1	3	1	11	0.015%
Infection	1	0	3	1	2	3	10	0.014%
Inflammation	0	0	0	0	3	3	6	0.008%
Labeling error	2	0	1	0	0	2	5	0.007%
Aneurysm	0	0	0	0	3	2	5	0.007%
Delamination	0	0	1	0	2	0	3	0.004%
Contamination (hair)	0	0	2	0	0	0	2	0.003%
Graft thrombosis/occlusion	0	0	0	1	1	0	2	0.003%

Complaint Category	2019	2020	2021	2022	2023	2024*	Total	Rate
Inadequate instructions in IFU	0	1	1	0	0	0	2	0.003%
Graft too thick	1	0	0	0	0	0	1	0.001%
Foreign particles in the graft	0	0	0	1	0	0	1	0.001%
Ruptured graft	0	0	0	0	0	1	1	0.001%
Seroma	0	0	0	0	0	1	1	0.001%
Shipping damage	0	0	0	0	1	0	1	0.001%

**up to August*

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

i) Summary of clinical data related to equivalent device, if applicable:

- An equivalent device was not used for this clinical evaluation.

ii) Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

One clinical study has been performed and completed for the Artegraft Collagen Vascular Graft. The study is summarized in the paper, "A prospective, randomized comparison of bovine carotid artery and expanded polytetrafluoroethylene for permanent hemodialysis vascular access" by Kennealey et al. Results are described within Section 4.7 and in Table 10-21 and Table 10-22 of the CER.

Summary of data

Study ref.	Objective	Devices / Interventions (sample size)	Relevant performance outcomes measured	Relevant safety outcomes measured	Brief conclusions
Kennealey, 2011[21]	Compare the standard cuffed ePTFE with the Artegraft.	Artegraft (model not specified; n= 26) Comparator: cuffed ePTFE (Venaflow, Bard Peripheral Vascular; n= 27)	☐ Technical success ☒ Primary patency ☒ Primary assisted patency ☒ Secondary patency ☒ Other: Interventions	☐ Pseudointima formation ☐ Pseudodiaphragm formation ☐ Disruption of anastomoses, in the presence of infection and transient low grade fever ☒ Thrombosis ☒ Infection ☐ Aneurysm ☐ Bleeding ☐ Hematoma ☒ Steal syndrome ☐ High output congestive heart failure in patients with heart disease	The Artegraft is an excellent option for patients on hemodialysis that are not suitable for native arteriovenous fistulas, as these grafts required fewer interventions than the ePTFE grafts to maintain patency.

Study ref.	Objective	Devices / Interventions (sample size)	Relevant performance outcomes measured	Relevant safety outcomes measured	Brief conclusions
				☒ Other: Pseudoaneurysm	

All published literature has been reviewed in the writing of the clinical evaluation report. The more recent publications are used in preference to older studies to ensure our knowledge base keeps up with the state-of-the-art.

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

Studies included in the literature evaluation by indication

Indications	Total Studies	Total Grafts	References
Hemodialysis	12	781	Abdoli, 2018[33] (n=63); Arhuidese, 2017[8] (n=52 grafts); Aziz, 2023 (n=74); Cui, 2016[10] (n=44); GnanaDev, 2023[32] (n=16); Harlander-Locke, 2014[34] (n=17); Hurt, 1983[13] (n=62); Katzman, 1976[35] (n=100); Kennealey, 2011[14] (n=26); Marcus, 2019[15] (n=142); Naazie, 2022[37] (n=51); Pineda, 2017[38] (n=134 grafts in 126 patients)
Lower extremity bypass	1	124	Lindsey, 2018[36] (n=124 grafts in 120 patients)
Arterial trauma	1	12	Reilly, 2019[18] (n=12)
Total	14	917	---

iv) An overall summary of the clinical performance and safety

Hemodialysis:

A summary of performance and clinical benefit outcomes for the device under evaluation in comparison to the state of the art acceptance criteria for hemodialysis, both at 36 months of follow-up, is presented in the table below.

The technical success rate of the DUE (Artegraft – 89.3%) met the acceptance criteria (≥ 84%) established by the SotA analysis. In the table below, performance analysis was conducted at the 36-month time point, which is the closest timepoint to the device lifetime for hemodialysis indication (40 months) with comparative data available for each patency endpoint. When comparing each patency outcome at this 36-month endpoint – in most cases via Kaplan-Meier curves -- benchmarks were met in all cases.

The lifetime of the device under evaluation (Artegraft) is 40 months when used for hemodialysis. Therefore, the available clinical data provides evidence supporting the characteristics and performance of the device are not adversely affected to such a degree that the health or safety of the patient is compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use (EU MDR GSPR 6).

Based on the information summarized for the 36-month timepoint, in table below, this clinical evaluation supports the performance and benefits of Artegraft when used as intended. Therefore, the available clinical data provide evidence that Artegraft is state of the art and conforms to the requirement on performance (MDR GSPR 1).

Summary of device performance and clinical benefits for device under evaluation

Outcome	Device under evaluation	SOTA Benchmark	Follow-up (months)	Conclusion
Technical Success	89.3%	≥84%	Not applicable	Acceptance criteria met
Primary Patency	19.3	≥2	36	Acceptance criteria met
Primary Assisted Patency	36	≥6	36	Acceptance criteria met
Secondary Patency	64.1	≥8	36	Acceptance criteria met

Lower extremity bypass

Performance data

A summary of performance and clinical benefit outcomes for the device under evaluation in comparison to the state of the art acceptance criteria for lower extremity bypass, at the 60 month timepoint, is presented in **Error! Reference source not found.** table below.

For lower extremity bypass, patency and limb salvage benchmarks were compared to SotA data at the device lifetime of 5 years for this indication. At this timepoint (60 months), benchmarks were met in all cases with the exceptions of primary-assisted patency for which no data were available. Generally, ranges for the DUE are within the ranges for the SOTA or exceed the ranges for the SOTA throughout the time-

course presented in those figures. No data for technical success was available for lower extremity bypass applications.

The lifetime of the device under evaluation is 5 years when used in the treatment of lower extremity bypass. Therefore, the available clinical data provides evidence supporting the characteristics and performance of the device are not adversely affected to such a degree that the health or safety of the patient is compromised during the lifetime of the device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use (EU MDR GSPR 6).

Summary of device performance and clinical benefits for device under evaluation, lower extremity bypass

Outcome	Device under evaluation	SOTA Benchmark	Follow-up (months)	Conclusion
Primary Patency	67.5	≥34.1	60	Yes
Secondary Patency	67.5	≥35.5	60	Yes
Limb Salvage	80	≥56.5	60	Yes
Primary Assisted Patency	Not available	≥45	60	No data available
Technical success	Not available	Not available	---	No data available

Clinical benefit data

Limb salvage was measured in a single study at 1 (83.6%) and 5 years (86.2%) after the use of Artegraft. These rates were lower than the pooled average limb salvage rates following the use of vascular prostheses with alternative materials at 1 year (90.56%); however, limb salvage was higher compared to state-of-the-art literature at similar time points (1 year: 74%; 5 years: 86.2%).

Safety data

Hematoma rates following use of Artegraft (0.83%) met the pooled average acceptance criteria established by the state-of-the-art clinical literature (≤4.93% (≤30 days); 0% (>1 year); ≤3.45% (follow-up not reported%).

Arterial trauma

Performance data

Benchmarks were met in all cases, with the exception of primary-assisted patency for which no data were available. The DUE-SotA comparison was conducted at the 19-month timepoint for arterial trauma due this being the only follow-up time for which there was data.

The lifetime of the device under evaluation is 32 months when used in the treatment of arterial trauma. The available clinical data was taken at 19 months, about 60% of the device lifetime. Considering that PMS data supports a low rate of reported adverse events for a 5-year reporting interval. The available 19-month data may provide evidence supporting the characteristics and performance of the device are not adversely affected to such a degree that the health or safety of the patient is compromised during the lifetime of the

device, as indicated by the manufacturer, when the device is subjected to the stresses which can occur during normal conditions of use (EU MDR GSPR 6).

Note that for arterial trauma applications, Artegraft was studied in a head-to-head comparison to a similar device and statistical differences were calculated by the study authors. In the benchmark analysis for arterial trauma, the benchmark was considered met if the study demonstrated that no difference was observed between Artegraft and the similar devices, as indicated by a p-value above 0.05 in the study.

A summary of arterial trauma performance and clinical benefit outcomes for the device under evaluation in comparison to the state of the art acceptance criteria is presented in the table below.

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

Summary of device performance and clinical benefits for device under evaluation

Outcome	Device under evaluation	SOTA Benchmark	Follow-up	Conclusion
Primary patency	78%	≥85% or statistically comparable	Mean follow up 19 ± 13 months	Acceptance criteria met
Secondary patency	78%	≥100% or statistically comparable	Mean follow up 19 ± 13 months	Acceptance criteria met
Limb salvage	82%	≥94.7% or statistically comparable	Mean follow up 19 ± 13 months	Acceptance criteria met
Primary Assisted Patency	Not available	≥45	60	No data available

Conclusions

Hemodialysis

Analysis of Condition

The Artegraft® Collagen Vascular Graft is intended to establish a conduit for hemodialysis. Hemodialysis vascular access is imperative in patients with acute renal failure or end stage renal disease requiring renal replacement therapy.

Conclusions

Based on this clinical evaluation, which includes non-clinical and clinical data, there is sufficient data to demonstrate conformity to the applicable requirements and confirm the that the Artegraft® Collagen Vascular Graft is safe and performs as intended and claimed by LeMaitre Vascular, Inc. This is evident by all but a single one of the performance and safety endpoints for which clinical literature data were available meeting the acceptance criteria established in the SotA. The one endpoint (steal syndrome) that did not meet the benchmark showed some similarity to the SotA data, as evident by an overlap in the SotA and DUE ranges for the data (4 – 6% and 4 – 9%, respetively). The safety of this device for hemodialysis is further supported by PMS data that showed showed a 0.105% complaint rate over 5 years.

Artegraft® Collagen Vascular Graft is a state-of-the-art for establishing a conduit for hemodialysis. Review of the post-market data, information materials, and the risk management documentation provided by

LeMaitre Vascular, Inc 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.

Lower Extremity Bypass

Analysis of Condition
The Artegraft® Collagen Vascular Graft is intended to serve as a substitute conduit for blood where bypass of occluded or diseased arterial segments is required. Occluded or diseased arteries cause restricted blood flow. If untreated, these conditions can lead to permanent adverse events (i.e., amputation) or death.

Conclusions
Based on this clinical evaluation, which includes non-clinical and clinical data, there is sufficient data to demonstrate conformity to the applicable requirements and confirm the that the Artegraft® Collagen Vascular Graft is safe and performs as intended and claimed by LeMaitre Vascular, Inc. This is evident by all three of the performance endpoints and 1 performance endpoint for which there was data available in the literature meeting the acceptance criteria established in the SotA.Despite there being minimal availability of data for safety endpoints for this indication, the safety of this device for lower extremity bypass is support by PMS data that showed showed a 0.105% complaint rate over 5 years.

The Artegraft® Collagen Vascular Graft is a state-of-the-art when serving as as a substitute conduit for blood where bypass of occluded or diseased arterial segments is required . Review of the post-market data, information materials, and the risk management documentation provided by LeMaitre Vascular, Inc 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.

Arterial Trauma

Analysis of Condition
The Artegraft® Collagen Vascular Graft is intended to serve as a substitute conduit for blood where replacement of damaged arterial segments is required. Damaged arteries cause restricted blood flow. If untreated, these conditions can lead to permanent adverse events (i.e., amputation) or death.

Conclusions
Based on this clinical evaluation, which includes non-clinical and clinical data, there is sufficient data to demonstrate conformity to the applicable requirements and confirm the that the Artegraft® Collagen Vascular Graft is safe and performs as intended and claimed by LeMaitre Vascular, Inc. This is evident by all three of the performance endpoints and 1 performance endpoint for which there was data available in the literature meeting the acceptance criteria established in the SotA.Despite there being minimal availability of data for safety endpoints for this indication, the safety of this device for lower extremity bypass is support by PMS data that showed showed a 0.105% complaint rate over 5 years.
Artegraft® Collagen Vascular Graft is a state-of-the-art serving as a substitute conduit for blood where replacement of damaged arterial segments is required. Review of the post-market data, information materials, and the risk management documentation provided by LeMaitre Vascular, Inc 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.

Post-market surveillance data

Adverse events and risks were also identified from complaints and a search of the MAUDE database for MDRs. The complete reporting of complaints for 01 January 2019 to 01 August 2024 is provided above. The overall complaint rate for the device under evaluation was 0.254% for 72,550 devices sold (data annualized for 2024). The top complaint categories were leaking graft (n=13, 0.018% complaint rate), packaging errors (n=12, 0.017% complaint rate), graft diameter issues (n=11, 0.015% complaint rate), and infections (n=10, 0.014% complaint rate). There were no complaint trends noted by region or year. There were 2 CAPAs were initiated for the device under evaluation between 01 January 2019 and 01 August 2024. The CAPAs pertained to updates to package and IFU information. One of the 4 CAPAs have been closed, and 3 out of 4 are in process. There were 0 recalls during the reporting period and also no MDV reports.

There were 36 events involving Artegraft in the FDA MAUDE database, which were related to injury in 14 cases or malfunction in the remaining 22 cases. No deaths related to Artegraft were reported in the FDA MAUDE database. Upon review of clinical literature and PMS data, no new risks were identified. However, patency related reintervention was noted as an outcome to be considered as a potentially device-related risk. Furthermore, there are no special design features that pose special safety concerns or training of the end-user required other than the instructions for use. No further action is needed to address any inconsistencies between the documents

Ongoing or planned post-market clinical follow-up.

Ongoing post-market surveillance (PMS) of the subject device according to the following procedure, SOP-090. Post-market clinical Follow-up (PMCF) activities are planned for the subject device. A multi-stepped approach will be used to substantiate the performance claims of the device and ensure that the risk/benefit remains positive. First, a thorough literature review will be conducted to capture all relevant and up to date published information regarding the Artegraft device. At this current time, no PMCF studies have been initiated. The Manufacturer plans to commence a prospective PMCF study and an End User Survey study in Q2 of 2027. The Manufacturer plans to start a Registry in Q1 of 2030 to collect lifetime data on the device.

6.0 Possible diagnostic or therapeutic alternatives:

- Vascular prosthesis with alternative materials
- Catheter for short-term vascular access
- Endovascular therapy
- Arteriovenous fistula for long-term vascular access

These have the same or similar intended purpose as the Artegraft but, as described in the table below, have different technological characteristics than the Artegraft.

Overview of treatment options

Treatment Options	Description	Advantages	Disadvantages
Vascular prosthesis with alternative materials	Synthetic grafts composed of Dacron, PTFE, or autologous vein graft.	Biological graft: Theoretically, biological grafts would mimic the compliance of native tissue and be more resistant to	Biological graft: Long-term durability is a concern. May be prone to

		intimal hyperplasia and wall degeneration than synthetic grafts.[22] Dacron graft: Well-established vascular graft material.[22,23] ePTFE: ePTFE/PTFE grafts have been widely used for hemodialysis since the 1970s.[22] Do not require preclotting, unlike Dacron grafts.[22] Good long-term durability.[24]	aneurysm and rupture.[24] Relatively high cost.[24] Dacron graft: Rates of infection and integration are reportedly worse than ePTFE grafts in vascular access applications.[22,23] ePTFE: Neointimal hyperplasia and distal arteriosclerosis are risks.[22]
Catheter for short-term vascular access	Tunneled cuffed central venous catheters for arteriovenous access	Recommended for long-term AV access when creation of fistulas or grafts is impossible or in patients with limited life expectancy[24]	Higher risk of infection and hospitalization and lower survival compared to permanent access types such as arteriovenous fistula and arteriovenous grafts.[8]
Endovascular therapy	Includes balloon angioplasty, stents and stent-grafts, plaque debulking,thrombolysis, remote superficial femoral artery endarterectomy (RSFAE) and percutaneous thrombectomy	Less invasive than open surgical procedures; recommended as first choice of therapy for focal occlusive disease of the superficial femoral artery and femoropopliteal lesions<25 cm.[23]	May not be effective for diffuse arterial disease or in cases of extensive calcification.[25,26]
Arteriovenous fistula for long-term vascular access	Considered first-line for permanent vascular access for hemodialysis.	Potential for fewer infectious complications and higher patency rates.[27]	Patient with inadequate arterial and/or venous anatomy are not surgical candidates which is frequent in end-stage renal disease.[27]

References made from the Artegraft CER Rev. 03

7.0 Suggested profile and training for users:

Artegraft 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 10993-10:2021
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
Packaged-Products for Parcel Delivery System Shipment 70 Kg (150 lb) Or Less	ISTA-3A:2018
Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	ISO 11737-1:2018
Tests of sterility performed in the definition, validation and maintenance of a sterilization process	ISO 11737-2:2019
Sterilization of health care products: Sterilization of health care products: Microbiological methods: Part 3: Bacterial endotoxin testing	ISO 11737-3:2023
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 14160:2020
non-active surgical implants: General requirements	ISO 14630:2012
Cardiovascular implants and extracorporeal systems: Vascular prostheses: Tubular vascular grafts and vascular patches	ISO 7198:2016
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
Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management	ISO 22442-1:2020
Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling	ISO 22442-2:2020
Medical Devices. Information To Be Supplied by The Manufacturer (British Standard)	EN ISO 20417: 2021
Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	EN ISO 15223-1:2021
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
Summary of safety and clinical performance A guide for manufacturers and notified bodies - August 2019	MDCG-2019-9
Clinical Evaluation – Equivalence: A guide for manufacturers and notified bodies.	MDCG 2020-5
Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC: A guide for manufacturers and notified bodies.	MDCG 2020-6 Regulation (EU) 2017/745
Summary of safety and performance Template	MDCG 2022-9
Regulation (EU) 2017/745 of the European Parliament and the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC	MDR 2017/745
Clinical investigation of medical devices for human subjects — Good clinical practice	ISO 14155:2020

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9.0 Revision Table:

SSCP revision number	Date issued	Change description	Revision validated by the NotifiedBody
New	28-12-2023	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)
A	28-05-2024	Updated per notified body feedback	☒ 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	12-11-2024	Periodic update	☐ Yes Validation language: English ☒ **No, the safety and performance profile of the device has not changed. Therefore, NB submission not required.**

10. 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 professional 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 general information**
    - **a. Device trade name**
        - i. Artegraft Collagen Vascular Graft (Graft)
    - **b. Producer; name and address**
        - i. LeMaitre Vascular, Inc., North Brunswick, NJ, 08902 USA
    - **c. Basic UDI-DI**
        - i. 0316837ArtegraftDW
    - **d. Year when the device was first CE-marked**
        - i. NA
2. **Intended use of the device**
    - **a. Intended purpose**
        - i. The Graft is intended to serve as a substitute channel for blood where replacement of blocked or diseased arteries is required or to establish a blood channel for getting dialysis.
    - **b. Indications and intended patient groups**
        - i. The Graft is used for procedures that require the repair of damaged arteries, and patients needing a better blood channel for dialysis
        - ii. The product is designed for adult patients with variable weights, diagnoses, and health statuses.
    - **c. Do not use for:**
        - i. The Grafts should not be used in patients with known or suspected negative reactions to any form of protein derived from cows.
3. **Device description**
    - **a. Device description and material/substances in contact with patient tissues**
        - i. The Graft is composed of a section of specially selected blood vessels taken from cows that have been subjected to enzymatic digestion. The sterile graft is preserved in a tube filled with USP-purified water and ethyl alcohol.
    - **b. Information about medicinal substances in the device if any**
        - i. n/a
    - **c. Description of how the device is achieving its intended mode of action.**
        - i. Per regulations, the Graft achieves its effect through non-medicinal means. It achieves this goal as a physical barrier device as its mode of action.
    - **d. Description of accessories, if any**
        - i. n/a
4. **Risks and warnings**

Contact your healthcare professional 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 professional if needed.

The table below presents all the risks that are possible to occur during the use of this device or the procedure.

Potential device-related complications:

Adverse events	Chance of Occurrence
Aneurysm	0 - 7%
Bleeding	9.09%
Central venous stenosis	0.19%
Hematoma	0%
Infection	.06 - 5.6%
Nonmaturation	.06%
Pseudoaneurysm	.06 – 2.9%
Seroma	0%
Steal syndrome	.08 – 6.7%
Stenosis	.19%
Thrombosis formation	.21%
A bulge or ballooning in a blood vessel	0%
The patch needs time to mature and for the vein to enlarge to a size where it can be needled for dialysis. When this is not achieved it is a risk.	0.06 ± 0.02%
Narrowing at the central vein	0.19 ± 0.13%
A mass or lump caused by a buildup of clear fluid in a tissue or organ	0-3%
Blood clots	15.7%
Infection	0-15%
Bruises or black and blue marks	0-7.8%
Blood flow diversion away from its normal target	0.03-25% (1/4)

Potential procedure-related complications:

Adverse events	Chance of occurrence
A form of false aneurysm, whose wall does not consist of all normal layers of arterial wall	3.3%
Amputation	≤ 19.4%
Aneurysmal degeneration	NR
Congestive heart failure	NR
Mortality	NR
Occlusion	.03%
Reintervention	24-61%

Sepsis or systemic inflammatory signs	NR
Wound complications	NR
Aging results in changes in collagen and elastin, which lead to weakening of the aortic wall and aneurysmal dilation.	1.67%
The hearts capacity to pump blood cannot keep up with the body's need	2.2%
The patch material degrades	20.9%
A blood clot that blocks a blood vessel	0-4.55%
An abnormal connection or communication between lymphatic vessels, resulting in the leakage of lymphatic fluid	1.9%
Death	0-10%
Heart attack	0-10%
Chance of vessels closing up or being blocked	0-24%
Wound Complication	6.9%

- **How potential risks have been controlled or managed**
  Risk analysis is conducted on an ongoing basis. The potential risks are detected through literature reviews and direct feedback from physicians and hospital staff. These are continuously monitored in order to ensure the benefits outweigh any residual risks.
- **Remaining risks and undesirable effects**
  - Please refer to the device IFU or your healthcare provider.
- **Warnings and precautions**
  1. Your new device is a foreign body and therefore needs close monitoring and careful observation. It may take 6-8 weeks for full recovery.
  2. After placement, the implant area may be swollen and tender for up to a week.
  3. Observe for any new redness or tenderness.
  4. Observe for any opening in the incisions.
  5. Observe for numbness, tingling, or pain in the leg.
     NOTE if you experience any of the above (2-5) please contact your provider.
  6. Do not puncture or manipulate the graft.
  7. You may shower according to your provider's instructions.
  8. Swelling in the extremity is expected because of increased blood flow. Move according to your provider's instructions, if the graft was implanted in your leg. Keep your leg elevated above your heart.
  9. It is preferable to have the graft covered for the first week to protect skin and incisions. (Follow your provider's instructions).
  10. Keep bandages or compression bandages on as per your provider's instructions.
  11. If your staples have been removed, you will probably have Steri-Strips (small pieces of tape) across your incision. Wear loose clothing that does not rub against your incision.
  12. You may shower or get the incision wet, once your provider says you can. DO NOT soak, scrub, or have the shower beat directly on them. If you have Steri-Strips, they will curl up and fall off on their own after a week.

13. DO NOT soak in the bathtub, hot tub, or swimming pool. Ask your provider when you can start doing these activities again.
14. Your provider will tell you how often to change your dressing (bandage) and when you may stop using one. Keep your wound dry. If your incision goes to your groin, keep a dry gauze pad over it to keep it dry.
15. Clean your incision with soap and water every day once your provider says you can. Look carefully for any changes. Gently pat it dry.
16. DO NOT put any lotion, cream, or herbal remedy on your wound without asking your provider first if that is ok.
17. Bypass surgery does not cure the cause of the blockage in your arteries. Your arteries may become narrow again.
18. Eat a heart-healthy diet, exercise, stop smoking (if you smoke), and reduce stress. Doing these things will help lower your chances of developing a blocked artery again.
19. Your provider may give you medicine to help lower your cholesterol.
20. If you are taking prescriptions for high blood pressure or diabetes, take them as prescribed.
21. Your provider may ask you to take aspirin or a medicine called clopidogrel (Plavix) when you go home. These medicines keep your blood from forming clots in your arteries. DO NOT stop taking them without talking to your provider first.

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

a. Clinical background of the device

The collagen graft is composed of specially selected and harvested cow neck arteries which have been subjected to chemical processing to improve performance. The Graft is of biological origin and the surgical staff must prepare the graft for implantation. Instructions for implant are defined in the IFU. The sterile graft is preserved in a tube filled with USP purified water and a type of alcohol. The Graft is packaged in a specially designed tube containing a sterilizing solution. Each tube is enclosed in a set-up box for protection during shipment and storage.

The clinical evidence for the CE-marking

The device was never CE-marked or sold in the EU market. This current submission is to CE mark the device for the first time under EU MDR. The device has been approved in the US since 1970. Studies were conducted and confirmed the grafts were safe and effective. See the IFU for further details.

b. Safety

There are ongoing clinical trials on this graft 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 alternatives

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

7. Suggested training for users

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