1.0 Device Identification and General Information

i) Device trade names: AlboGraft™ Polyester Vascular Graft

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: 08406631AlboGraftR6

v) Device Item Codes, Descriptions, Basic UDI

GTIN-14 (UDI)	Manufacture Item Code	Description
00840663102853	AMC1006	AlboGraft Knitted Collagen Straight Graft 100cmx6mm[LxD]
00840663107797	AMC1007	AlboGraft Polyester Vascular Graft 10cmx7mm[LxD]
00840663102921	AMC1008	AlboGraft Knitted Collagen Straight Graft 100cmx8mm[LxD]
00840663102976	AMC1010	AlboGraft Knitted Collagen Straight Graft 100cmx10mm[LxD]
00840663107742	AMC1206	AlboGraft Polyester Vascular Graft 12cmx6mm[LxD]
00840663103423	AMC1207	AlboGraft Knitted Collagen Bifurcated Graft 12cmx7mm[LxD]
00840663103430	AMC1407	AlboGraft Knitted Collagen Bifurcated Graft 14cmx7mm[LxD]
00840663103447	AMC1408	AlboGraft Knitted Collagen Bifurcated Graft 14cmx8mm[LxD]
00840663102815	AMC1506	AlboGraft Knitted Collagen Straight Graft 1cm5x6mm [L x D]
00840663107759	AMC1507	AlboGraft Polyester Vascular Graft 15cmx7mm[LxD]
00840663102877	AMC1508	AlboGraft Knitted Collagen Straight Graft 15cmx8mm [LxD]
00840663102938	AMC1510	AlboGraft Knitted Collagen Straight Graft 15cmx10mm[LxD]
00840663102983	AMC1512	AlboGraft Knitted Collagen Straight Graft 15cmx12mm[LxD]
00840663103003	AMC1514	AlboGraft Knitted Collagen Straight Graft 15cmx14mm[LxD]
00840663103027	AMC1516	AlboGraft Knitted Collagen Straight Graft 15cmx16mm[LxD]
00840663103041	AMC1518	AlboGraft Knitted Collagen Straight Graft 15cmx18mm[LxD]
00840663103065	AMC1520	AlboGraft Knitted Collagen Straight Graft 15cmx20mm[LxD]
00840663103089	AMC1522	AlboGraft Knitted Collagen Straight Graft 15cmx22mm[LxD]
00840663103102	AMC1524	AlboGraft Knitted Collagen Straight Graft 15cmx24mm[LxD]
00840663103454	AMC1608	AlboGraft Knitted Collagen Bifurcated Graft 16cmx8mm[LxD]
00840663103461	AMC1609	AlboGraft Knitted Collagen Bifurcated Graft 16cmx9mm[LxD]
00840663103478	AMC1809	AlboGraft Knitted Collagen Bifurcated Graft 18cmx9mm[LxD]
00840663103485	AMC1810	AlboGraft Knitted Collagen Bifurcated Graft 18cmx10mm[LxD]
00840663103492	AMC2010	AlboGraft Knitted Collagen Bifurcated Graft 20cmx10mm[LxD]
00840663103508	AMC2011	AlboGraft Knitted Collagen Bifurcated Graft 20cmx11mm[LxD]
00840663103515	AMC2211	AlboGraft Knitted Collagen Bifurcated Graft 22cmx11mm[LxD]
00840663103522	AMC2412	AlboGraft Knitted Collagen Bifurcated Graft 24cmx12mm[LxD]
00840663102822	AMC3006	AlboGraft Knitted Collagen Straight Graft 30cmx6mm[LxD]
00840663107766	AMC3007	AlboGraft Polyester Vascular Graft 30cmx7mm[LxD]
00840663102884	AMC3008	AlboGraft Knitted Collagen Straight Graft 30cmx8mm [LxD]
00840663102945	AMC3010	AlboGraft Knitted Collagen Straight Graft 30cmx10mm[LxD]

00840663102990	AMC3012	AlboGraft Knitted Collagen Straight Graft 30cmx12mm[LxD]
00840663103010	AMC3014	AlboGraft Knitted Collagen Straight Graft 30cmx14mm[LxD]
00840663103034	AMC3016	AlboGraft Knitted Collagen Straight Graft 30cmx16mm[LxD]
00840663103058	AMC3018	AlboGraft Knitted Collagen Straight Graft 30cmx18mm[LxD]
00840663103072	AMC3020	AlboGraft Knitted Collagen Straight Graft 30cmx20mm[LxD]
00840663103096	AMC3022	AlboGraft Knitted Collagen Straight Graft 30cmx22mm[LxD]
00840663103126	AMC3024	AlboGraft Knitted Collagen Straight Graft 30cmx24mm[LxD]
00840663102839	AMC4006	AlboGraft Knitted Collagen Straight Graft 40cmx6mm[LxD]
00840663102860	AMC4007	AlboGraft Knitted Collagen Straight Graft 40cmx7mm [LxD]
00840663102891	AMC4008	AlboGraft Knitted Collagen Straight Graft 40cmx8mm [LxD]
00840663102952	AMC4010	AlboGraft Knitted Collagen Straight Graft 40cmx10mm[LxD]
00840663103119	AMC4012	AlboGraft Knitted Collagen Straight Graft 40cmx12mm[LxD]
00840663110391	AMC4014	AlboGraft® Knitted with Collagen 14mm x 40cm
00840663103546	ASC4006	AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx6mm[LxD]
00840663103553	ASC6006	AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx6mm[LxD]
00840663103560	ASC8006	AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx6mm[LxD]
00840663110407	AMC4016	AlboGraft® Knitted with Collagen 16mm x 40cm
00840663103584	ASC4007	AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx7mm[LxD]
00840663103591	ASC6007	AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx7mm[LxD]
00840663103607	ASC8007	AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx7mm[LxD]
00840663103614	ASC3008	AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx8mm[LxD]
00840663103621	ASC4008	AlboGraft Knitted Collagen Straight Graft with Removable External Support 40cmx8mm[LxD]
00840663103638	ASC6008	AlboGraft Knitted Collagen Straight Graft with Removable External Support 60cmx8mm[LxD]
00840663103645	ASC8008	AlboGraft Knitted Collagen Straight Graft with Removable External Support 80cmx8mm[LxD]
00840663110414	AMC4018	AlboGraft® Knitted with Collagen 18mm x 40cm
00840663110421	AMC4020	AlboGraft® Knitted with Collagen 20mm x 40cm
00840663110438	AMC4022	AlboGraft® Knitted with Collagen 22mm x 40cm
00840663110445	AMC4024	AlboGraft® Knitted with Collagen 24mm x 40cm
00840663102846	AMC6006	AlboGraft Knitted Collagen Straight Graft 60cmx6mm[LxD]
00840663102907	AMC6007	AlboGraft Knitted Collagen Straight Graft 60cmx7mm [LxD]
00840663102914	AMC6008	AlboGraft Knitted Collagen Straight Graft 60cmx8mm [LxD]
00840663102969	AMC6010	AlboGraft Knitted Collagen Straight Graft 60cmx10mm[LxD]
00840663104253	AMC6012	AlboGraft Knitted Collagen Straight Graft 60cmx12mm[LxD]
00840663104260	AMC6014	AlboGraft Knitted Collagen Straight Graft 60cmx14mm[LxD]
00840663104277	AMC6016	AlboGraft Knitted Collagen Straight Graft 60cmx16mm[LxD]
00840663104284	AMC6018	AlboGraft Knitted Collagen Straight Graft 60cmx18mm[LxD]
00840663104291	AMC6020	AlboGraft Knitted Collagen Straight Graft 60cmx20mm[LxD]
00840663104307	AMC6022	AlboGraft Knitted Collagen Straight Graft 60cmx22mm[LxD]
00840663104314	AMC6024	AlboGraft Knitted Collagen Straight Graft 60cmx24mm[LxD]
00840663107773	AMC7006	AlboGraft Polyester Vascular Graft 70cmx6mm[LxD]

00840663104321	AMC7008	AlboGraft Knitted Collagen Straight Graft 70cmx8mm[LxD]
00840663104338	AMC7010	AlboGraft Knitted Collagen Straight Graft 70cmx10mm[LxD]
00840663104345	AMC7512	AlboGraft Knitted Collagen Straight Graft 75cmx12mm[LxD]
00840663104352	AMC7514	AlboGraft Knitted Collagen Straight Graft 75cmx14mm[LxD]
00840663104369	AMC7516	AlboGraft Knitted Collagen Straight Graft 75cmx16mm[LxD]
00840663104376	AMC7518	AlboGraft Knitted Collagen Straight Graft 75cmx18mm[LxD]
00840663104383	AMC7520	AlboGraft Knitted Collagen Straight Graft 75cmx20mm[LxD]
00840663104390	AMC7522	AlboGraft Knitted Collagen Straight Graft 75cmx22mm[LxD]
00840663104406	AMC7524	AlboGraft Knitted Collagen Straight Graft 75cmx24mm[LxD]
00840663107803	AMC8006	AlboGraft Polyester Vascular Graft 80x6
00840663104413	AMC8008	AlboGraft Knitted Collagen Straight Graft 80cmx8mm[LxD]
00840663104420	AMC8010	AlboGraft Knitted Collagen Straight Graft 80cmx10mm[LxD]
00840663103539	ASC3006	AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx6mm[LxD]
00840663103577	ASC3007	AlboGraft Knitted Collagen Straight Graft with Removable External Support 30cmx7mm[LxD]
00840663110384	ATC1206	AlboGraft Woven with Collagen Bifurcated 12mm x 6mm x 50cm
00840663104147	ATC1207	AlboGraft Woven Collagen Bifurcated Graft 12cmx7mm[LxD]
00840663104154	ATC1407	AlboGraft Woven Collagen Bifurcated Graft 14cmx7mm[LxD]
00840663104161	ATC1408	AlboGraft Woven Collagen Bifurcated Graft 14cmx8mm[LxD]
00840663103652	ATC1506	AlboGraft Woven Collagen Straight Graft 15cmx6mm[LxD]
00840663107810	ATC1507	AlboGraft Polyester Vascular Graft 15x7
00840663103690	ATC1508	AlboGraft Woven Collagen Straight Graft 15cmx8mm[LxD]
00840663103737	ATC1510	AlboGraft Woven Collagen Straight Graft 15cmx10mm[LxD]
00840663103775	ATC1512	AlboGraft Woven Collagen Straight Graft 15cmx12mm[LxD]
00840663103805	ATC1514	AlboGraft Woven Collagen Straight Graft 15cmx14mm[LxD]
00840663103829	ATC1516	AlboGraft Woven Collagen Straight Graft 15cmx16mm[LxD]
00840663103843	ATC1518	AlboGraft Woven Collagen Straight Graft 15cmx18mm[LxD]
00840663103867	ATC1520	AlboGraft Woven Collagen Straight Graft 15cmx20mm[LxD]
00840663103881	ATC1522	AlboGraft Woven Collagen Straight Graft 15cmx22mm[LxD]
00840663103911	ATC1524	AlboGraft Woven Collagen Straight Graft 15cmx24mm[LxD]
00840663103942	ATC1526	AlboGraft Woven Collagen Straight Graft 15cmx26mm[LxD]
00840663103973	ATC1528	AlboGraft Woven Collagen Straight Graft 15cmx28mm[LxD]
00840663104000	ATC1530	AlboGraft Woven Collagen Straight Graft 15cmx30mm[LxD]
00840663104031	ATC1532	AlboGraft Woven Collagen Straight Graft 15cmx32mm[LxD]
00840663104062	ATC1534	AlboGraft Woven Collagen Straight Graft 15cmx34mm[LxD]
00840663107384	ATC1536	AlboGraft Woven Collagen Straight Graft 15cmx34mm[LxD]
00840663104093	ATC1538	AlboGraft Woven Collagen Straight Graft 15cmx38mm[LxD]
00840663104178	ATC1608	AlboGraft Woven Collagen Bifurcated Graft 16cmx8mm[LxD]
00840663104185	ATC1609	AlboGraft Woven Collagen Bifurcated Graft 16cmx9mm[LxD]
00840663104192	ATC1809	AlboGraft Woven Collagen Bifurcated Graft 18cmx9mm[LxD]
00840663104208	ATC1810	AlboGraft Woven Collagen Bifurcated Graft 18cmx10mm[LxD]
00840663104215	ATC2010	AlboGraft Woven Collagen Bifurcated Graft 20cmx10mm[LxD]
00840663104222	ATC2011	AlboGraft Woven Collagen Bifurcated Graft 20cmx11mm[LxD]
00840663104239	ATC2211	AlboGraft Woven Collagen Bifurcated Graft 22cmx11mm[LxD]
00840663104246	ATC2412	AlboGraft Woven Collagen Bifurcated Graft 24cmx12mm[LxD]

00840663103669	ATC3006	AlboGraft Woven Collagen Straight Graft 30cmx6mm[LxD]
00840663103706	ATC3008	AlboGraft Woven Collagen Straight Graft 30cmx8mm[LxD]
00840663103744	ATC3010	AlboGraft Woven Collagen Straight Graft 30cmx10mm[LxD]
00840663103782	ATC3012	AlboGraft Woven Collagen Straight Graft 30cmx12mm[LxD]
00840663103812	ATC3014	AlboGraft Woven Collagen Straight Graft 30cmx14mm[LxD]
00840663103836	ATC3016	AlboGraft Woven Collagen Straight Graft 30cmx16mm[LxD]
00840663103850	ATC3018	AlboGraft Woven Collagen Straight Graft 30cmx18mm[LxD]
00840663103874	ATC3020	AlboGraft Woven Collagen Straight Graft 30cmx20mm[LxD]
00840663103898	ATC3022	AlboGraft Woven Collagen Straight Graft 30cmx22mm[LxD]
00840663103928	ATC3024	AlboGraft Woven Collagen Straight Graft 30cmx24mm[LxD]
00840663103959	ATC3026	AlboGraft Woven Collagen Straight Graft 30cmx26mm[LxD]
00840663103980	ATC3028	AlboGraft Woven Collagen Straight Graft 30cmx28mm[LxD]
00840663104017	ATC3030	AlboGraft Woven Collagen Straight Graft 30cmx30mm[LxD]
00840663104048	ATC3032	AlboGraft Woven Collagen Straight Graft 30cmx32mm[LxD]
00840663104079	ATC3034	AlboGraft Woven Collagen Straight Graft 30cmx34mm[LxD]
00840663106677	ATC3036	AlboGraft Woven Collagen Straight Graft 30cmx36
00840663104109	ATC3038	AlboGraft Woven Collagen Straight Graft 30cmx38mm[LxD]
00840663103676	ATC4006	AlboGraft Woven Collagen Straight Graft 40cmx6mm[LxD]
00840663104437	ATC4007	AlboGraft Woven Collagen Straight Graft 40cmx7mm[LxD]
00840663103713	ATC4008	AlboGraft Woven Collagen Straight Graft 40cmx8mm[LxD]
00840663103751	ATC4010	AlboGraft Woven Collagen Straight Graft 40cmx10mm[LxD]
00840663103799	ATC4012	AlboGraft Woven Collagen Straight Graft 40cmx12mm[LxD]
00840663103683	ATC6006	AlboGraft Woven Collagen Straight Graft 60cmx6mm[LxD]
00840663107407	ATC6007	AlboGraft Woven Collagen Straight Graft 60cmx7mm[LxD]
00840663103720	ATC6008	AlboGraft Woven Collagen Straight Graft 60cmx8mm[LxD]
00840663103768	ATC6010	AlboGraft Woven Collagen Straight Graft 60cmx10mm[LxD]
00840663104444	ATC6012	AlboGraft Woven Collagen Straight Graft 60cmx12mm[LxD]
00840663104451	ATC6014	AlboGraft Woven Collagen Straight Graft 60cmx14mm[LxD]
00840663104468	ATC6016	AlboGraft Woven Collagen Straight Graft 60cmx16mm[LxD]
00840663104475	ATC6018	AlboGraft Woven Collagen Straight Graft 60cmx18mm[LxD]
00840663104482	ATC6020	AlboGraft Woven Collagen Straight Graft 60cmx20mm[LxD]
00840663104499	ATC6022	AlboGraft Woven Collagen Straight Graft 60cmx22mm[LxD]
00840663104505	ATC6024	AlboGraft Woven Collagen Straight Graft 60cmx24mm[LxD]
00840663104512	ATC6026	AlboGraft Woven Collagen Straight Graft 60cmx26mm[LxD]
00840663104529	ATC6028	AlboGraft Woven Collagen Straight Graft 60cmx28mm[LxD]
00840663104536	ATC6030	AlboGraft Woven Collagen Straight Graft 60cmx30mm[LxD]
00840663110353	ATC6032	AlboGraft® Woven with Collagen 32mm x 60cm
00840663110360	ATC6034	AlboGraft® Woven with Collagen 34mm x 60cm
00840663110377	ATC6038	AlboGraft® Woven with Collagen 38mm x 60cm
00840663107902	ATO1207	AlboGraft Polyester Vascular Graft 12cmx7mm[LxD]
00840663107919	ATO1407	AlboGraft Polyester Vascular Graft 14cmx7mm[LxD]

vi) Medical device nomenclature description

GMDN Code / Description: 35281 / Synthetic Vascular Graft
UMDNS Code / Description: 13-177 / Prostheses, Blood Vessel, Artificial
EMDN Code / Description: P07010201 / Vascular prosthesis, dacron

vii) Class of device

Manufacture Name	MDR Classification	Rule
AlboGraft Polyester Vascular Graft	III Implantable	18

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

Device Name	Date of Initial CE Mark	Date of 510(k)
AlboGraft™ Polyester Vascular Graft	15 April 2011	14 January 2010 (K093231) 19 January 2011 (K103080)

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) Intended purpose: The AlboGraft Vascular Grafts are designed for the purpose of systemic vascular repair including replacement or bypass procedures in aneurysmal and occlusive disease of the arteries including the thoracic aorta and for femoral popliteal reconstruction in the treatment of abdominal aortic aneurysm, thoracic aortic aneurysm, and peripheral artery disease.

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

- Indication:
  - The AlboGraft Knitted and Woven Vascular Grafts are indicated for use in the replacement or repair of arteries affected with aneurismal or occlusive disease, such as Abdominal Aortic Aneurysm, Thoracic Aortic Aneurysm, and Occlusive Peripheral Artery Disease (e.g., TASC C or D type lesions)

involving the iliac arteries.
- The AlboGraft Vascular Graft (ASC models only) are indicated in extra-anatomic reconstructions and reconstructions requiring enhanced resistance to kinking and compression, such as femoro-popliteal bypass.

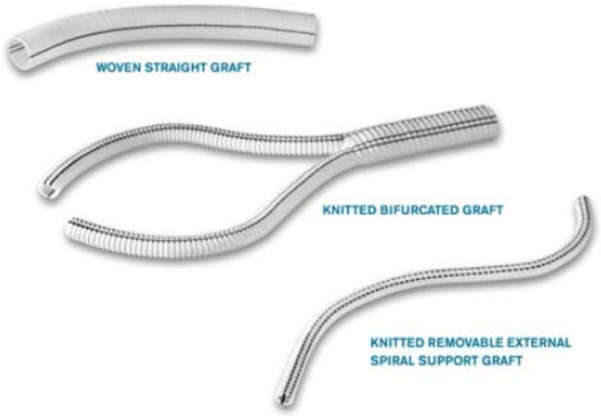
- Target Population: Patients of any gender, age or ethnicity in need of systemic vascular repair including replacement or bypass procedures in aneurysmal & occlusive disease of the arteries including the thoracic aorta and for axillo-femoral/bi-femoral bypass & femoral popliteal reconstruction.

iii) Contraindications and/or limitations
- AlboGraft Vascular Grafts are contraindicated for use in coronary arteries.
- AlboGraft Vascular Grafts are contraindicated in patients with known or suspected hypersensitivity to bovine collagen.

3.0 Device Description

i) Description of the device

The AlboGraft Polyester Vascular Grafts are made of synthetic material and designed to replace sections of damaged or malfunctioning arteries. They are made of polyester (polyethylene terephthalate, PET) thread woven into a seamless tube. In response to a range of surgical indications, AlboGraft Polyester Vascular Grafts are offered in two designs: double velour knitted fabric and double velour woven fabric. The knitted grafts are designed with a run-proof structure to reduce the risk of fraying or wearing down on their ends. The velour grafts have low profile loops on their endoluminal surface to avoid any lumen reduction, and high-profile loops on their outer surface to promote graft anchoring into the surrounding tissues. Each design is further offered in the different shapes: straight, bifurcated, axillo-bifemoral, and side arm configurations. All AlboGraft grafts are crimped in parallel rings so that their tubular shape is maintained without kinking. AlboGraft Polyester Vascular Grafts are available with removable external spiral reinforcement (ASC models) made of a radiopaque biocompatible polypropylene thread, allowing for easy identification of the prosthesis with x-ray. The external spiral reinforcement is removable, facilitating the creation of anastomoses to the vessel. AlboGraft Polyester Vascular Grafts are available in a wide range of models, types and sizes. The graft can be classified into models according to fabric characteristics (knitted or woven), each model being of one or more types (straight or bifurcated) and sizes (various diameter and length). The AlboGraft grafts are implantable devices intended for long term use. They are ethylene oxide sterilized, provided sterile in Tyvek packaging, and intended for single use only.

Image	Device name
	LeMaitre AlboGraft™ Polyester Vascular Graft Configurations (straight, bifurcated, external supported)

ii) Reference to previous generations: 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 Hemashield Microvel Double Velour Knitted and Woven Vascular Graft. The AlboGraft was previously manufactured by Biomateriali S. r. l., a subsidiary of LeMaitre Vascular, Inc. in Brindisi, Italy. LeMaitre Vascular has transferred the manufacturing from Italy to Burlington MA.

iii) There are no novel design features, indications, claims, or target populations for the subject device compared to the competitor devices that impact safety and performance, although minor changes have been made to the device to provide incremental benefits to the user/patients. A primary difference is the option of grafts with and without collagen impregnation for the AlboGraft Polyester Vascular Grafts.

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

v) 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:

Adverse Event	Rate	Source from CER
Stroke	6%	Hsu, #37
Paraplegia	0%	Post market study 2009
Paraparesis	1%	Biomateriali, 2008
Myocardial Infarction	1%	Biomateriali, 2008
Renal Dysfunction	2.8%	Lamelas, #38
Ischemia	5%	Almasri, #1
Embolism	-	No reported occurence
Thrombosis	1.3%	Kim, #35
Bleeding	2%	Biomateriali 2009
Graft Infection	-	No reported occurrence
Wound Infection	1%	Biomaterilai, 2008
Aneurysm	-	No reported occurrence
Pneumonia	-	No reported occurrence
Amputation	1.6%	Biomateriali, 2010
Death	<6.6%	Tamura, #40
Graft Dilation	-	No reported occurrence
Graft disintegration	-	No reported occurrence
Graft stenosis	-	No reported occurrence
Pseudoaneurysm	-	No reported occurrence
Intraluminal graft thrombus	-	No reported occurrence
Perigraft air	-	No reported occurrence
Respiratory failure	5%	Hsu, #37
Arterial fibrillation	27.7%	Lamelas, #38
Chylothorax	4.7%	Rajbanshi, #39
Temporary psychotic syndrome	8%	Hsu, #37
Hemiparesis	3.9%	Biomateriali, 2009
Visceral ischemia	3.9%	Biomateriali, 2009
Gluteal necrosis	1%	Biomaterilai, 2008
Ileus	2.9%	Biomaterilai, 2008
Acute kidney failure	1.3%	Biomaterilai, 2009
Compartment syndrome	1.3%	Biomaterilai, 2009
Paravalvular leak	1.3%	Biomaterilai, 2008
Descending aorta dissection	1.4%	Biomaterilai, 2009
Deep vein thrombosis	1.4%	Biomaterilai, 2009
Sternum instability	1.4	Biomaterilai, 2009
Bypass occlusions	1.6%	Biomaterilai, 2010
Wound hematoma	1.5%	Biomaterilai, 2010
Groin Seroma	1.5%	Biomaterilai, 2010
Urinary tract infection	1.5%	Biomaterilai, 2010
Angina abdominalis	1.6%	Biomaterilai, 2010

ii) Warnings and precautions

- Do not use a prosthesis if the container and/or seal has been opened or damaged, or if the period of sterility has expired.
- The collagen-impregnated graft must never be resterilized.
- Grafts contaminated with blood during the preceding procedures must not be re-used or resterilized.
- The vascular grafts must be handled so as to avoid contact with extraneous particles which, if they adhere to the graft wall, may generate emboli or undesirable interactions with the blood.
- Furthermore, surgical gloves used to handle grafts should not contain powders, preservatives or lubricants.
- Avoid overstretching the graft; gently expand the graft to smooth the folds.
- Avoid damaging the graft when handling, use atraumatic clamps and appropriate instruments (e.g. vascular clamps). Avoid using these instruments with undue force, otherwise the collagen coating or fabric will be damaged.
- Atraumatic needles are recommended.
- Low temperature ophthalmic cautery (≤ 704° C/1300° F) is recommended for cutting woven grafts to avoid fraying.
- AlboGraft Removable Spiral Reinforcement Prosthesis (ASC Models)*: Avoid clamping the graft on its reinforced area.
- AlboGraft Removable Spiral Reinforcement Prosthesis (ASC Models)*: Gently remove the support spiral, otherwise the collagen film will be damaged.
- Care should be taken to ligate and/or cauterize lymphatics in the groin to minimize the occurrence of seroma formation and lymphatic collection subsequent to aorto-femoral or femoropopliteal reconstruction.
- These prostheses should not be implanted in patients who exhibit sensitivity to polyester or materials of bovine origin.

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

- There were 36 vigilance reports between 01 January 2012 and 01 March 2022. During this reporting period there have been 12 CAPAs. The section below provides a summary of each CAPA.

CAPA Number	Reason CAPA initiated	Status	Date closed
CAPA 2012-016	Leaking Graft	Closed	13-Nov-13
CAPA 2013-023	Leaking Graft	Closed	09-Sep-14
CAPA 2014-004	Leaking Graft/Off label use	Closed	04-Jun-14
CAPA 2017-013	AlboGraft dilatation	Closed	28-Sep-17
CAPA 2017-036	Overall system improvements for labeling	Closed	20-Jan-20
CAPA 2017-038	Leaking Graft	Closed	13-Jan-20
ECO-3772 (correction)	Packaging issue	Closed	21-Dec-17

CAPA 2018-032	AlboGraft Twisting and Warping MIs	Closed	21-Aug-19
CAPA 2019-014	ISO 22442 standards conformance	Closed	31-Dec-21
CAPA 2019-055	AlboGraft labels not matching on all of the packaging.	Closed	23-Mar-21
CAPA 2021-004	ISO 22442 Compliance	Closed	22-Feb-22
CAPA 2022-001	Removal of no-CE devices after derogation has expired	Closed	28-Apr-2022

- FSCA: There were 6 recall notifications sent out by LeMaitre for the AlboGraft product family during the reporting period of 01 January 2012 and 01 March 2022.

Date Initiated	Recall # /FSCA number	Region	Products Involved	Description
18 October 2012	MHRA reference number: MDA/2012/072	UK	All lots	In April 2012 the MHRA issued MDA/2012/018 informing users of the Prohibition Notice preventing the manufacturer from selling the AlboGraft in the UK. The MIHRA has since carried out a detailed audit of the graft manufacturing facility. We were provided with evidence of a number of ongoing changes that the manufacturer was making to the processes to improve control of manufacturing. As a consequence the MHRA has now lifted the Prohibition Notice and permitted sales of the AlboGraft in the UK.
17 June 2013	FDA reference number: Z-17(54 through70)-2013	US	Model Numbers: AMC1608 AMC1408 AMC2010 AMC1809 AMC1810 AMC1506 AMC4007 AMC4008 AMC6006 AMC6007 AMC6008 ATC1526 ATC1530 ATC3016 ATC3018 ATC3024 ATC3026	LeMaitre Vascular has received reports that AlboGraft Polyester Vascular Grafts did show blood blushing/extravasation from the surface of the grafts after implantation. LeMaitre Vascular does not currently have sufficient information to finally determine the root causes of these events. LeMaitre Vascular is therefore issuing this Field Safety Notice to withdraw the affected product from the field while investigating the final root cause of this issue.

Date Initiated	Recall # /FSCA number	Region	Products Involved	Description
28 June 2013	Lot Recall BfArM reference number: 03398-13	Wordwide	Model Number: AMC1608	LeMaitre Vascular has received reports that AlboGraft Polyester Vascular Grafts did show blood blushing/extravasation from the surface of the grafts after implantation. LeMaitre Vascular does not currently have sufficient information to finally determine the root causes of these events. LeMaitre Vascular is therefore issuing this Field Safety Notice to withdraw the affected product from the field while investigating the final root cause of this issue.
15 February 2022	Urgent field safety notice BfArM Reference: 04068/22	Spain market	Model Numbers: AMC1407 AMC1408 AMC1516 AMC1518 AMC1520 AMC1522 AMC1608 AMC1809 AMC2010 AMC2211 AMC3006 AMC3008 AMC3010 AMC3014 AMC3016 AMC3018 AMC3020 AMC3022 AMC4006 AMC4007 AMC4008 AMC6006 AMC6007 AMC6008 AMC6010 ASC4006 ASC4008 ASC6006 ASC6008 ASC8006 ASC8008 ATC1207	LeMaitre is withdrawing and exchanging AlboGraft devices without a CE mark due to a change in regulatory status. BACKGROUND: In 2020, AEMPS granted LeMaitre permission (derogation) to supply AlboGraft devices on the Spain market, without a CE mark. This derogation was requested because our previous notified body had stopped providing CE marking services and our new notified body had not completed their on-boarding review of the technical documentation. We are grateful to AEMPS for allowing us to serve our customers while we worked to gain approval from our new notified body. AEMPS has received a copy of this letter. LeMaitre has now received the CE mark approval from our new notified body for AlboGraft and we now have adequate capacity to serve all of our European customers with CE marked product. Although there is no safety risk with any of the derogated devices, we are required to withdraw any remaining devices as a condition of the derogation
18 February 2022	Urgent field safety notice	Dutch market	AMC1407 AMC1608	LeMaitre is withdrawing and exchanging certain AlboGraft devices

Date Initiated	Recall # /FSCA number	Region	Products Involved	Description
	BfArM Reference: 03253A/22		AMC1809 AMC2211 AMC3016 AMC3018 AMC3020 AMC6006 ASC4006 ASC4008 ASC8006 ASC8008 ATC1526 ATC1528 ATC1530 ATC3006 ATC3008 ATC3028 ATC3030 ATC3032 ATC4006	due to a change in regulatory status. BACKGROUND: In 2020, Ministerie van Volksgezondheid, Welzijn en Sport granted LeMaitre permission (derogation) to supply AlboGraft devices on the Dutch market, without a CE mark. This derogation was requested because our previous notified body had stopped providing CE marking services and our new notified body had not completed their on-boarding review of the technical documentation. We are grateful to Ministerie van Volksgezondheid, Welzijn en Sport for allowing us to serve our customers while we worked to gain approval from our new notified body. They have received a copy of this letter. LeMaitre has now received the CE mark approval from our new notified body for AlboGraft and we now have adequate capacity to serve all of our European customers with CE marked product. Although there is no safety risk with any of the derogated devices, we are required to withdraw any remaining devices as a condition of the derogation.
01 March 2022	MHRA reference number: 2022/003/003/601/002	UK	AMC1008 AMC1206 AMC1207 AMC1407 AMC1508 AMC1514 AMC1516 AMC1518 AMC1520 AMC1522 AMC1524 AMC1608 AMC1609 AMC1809 AMC2010 AMC2011 AMC2211 AMC2412 AMC3006 AMC3008 AMC3010	LeMaitre is withdrawing and exchanging AlboGraft devices without a CE mark due to a change in regulatory status. BACKGROUND: In 2020, MHRA granted LeMaitre permission (derogation) to supply AlboGraft devices on the UK market, without a CE mark. This derogation was requested because our previous notified body had stopped providing CE marking services and our new notified body had not completed their on-boarding review of the technical documentation. We are grateful to MHRA for allowing us to serve our customers while we worked to gain approval from our new notified body. MHRA has received a copy of this letter. LeMaitre has now received the CE mark approval from our new notified body for AlboGraft and we

Date Initiated	Recall # /FSCA number	Region	Products Involved	Description
			AMC3012 AMC3014 AMC3016 AMC3018 AMC3020 AMC3022 AMC3024 AMC4006 AMC4007 AMC4008 AMC6006 AMC6007 AMC6008 AMC1520 ASC3008 ASC4006 ASC4008 ASC6006 ASC6007 ASC6008 ASC8006 ASC8007 ASC8008 ATC1407 ATC1518 ATC1522 ATC1608 ATC3012 ATC3014 ATC3016 ATC3020	now have adequate capacity to serve all of our European customers with CE marked product. Although there is no safety risk with any of the derogated devices, we are required to withdraw any remaining devices as a condition of the derogation.

The failure modes resulting in the serious incidents during the surveillance period were previously identified in D1682-00 FAILURE MODES AND EFFECTS ANALYSIS AlboGraft Vascular Graft Product FMEA. The actual occurrences of the serious incidents (injury and malfunction) exceeded the acceptable occurrence rankings for the corresponding device problems, primarily due to the 8 reports due to leaking. CAPA 2017-038 was assigned accordingly.

Complaints involving temporary removal of product from the market due to changes in regulatory status or design changes (UK, Spain, and the Netherlands) or in response to CAPAs initiated following complaints involving blood blushing/extravasation (graft leaking) for specific lots in Germany and the US. Leakage complaints and the results of CAPA 2017-038 are further detailed in section 5.c. CER-002 AlboGraft Polyester Vascular Graft Clinical Evaluation Report indicates that patient benefits of the AlboGraft graft outweigh the potential risks associated with the product family when used as intended. Further information about benefit-risk analysis is available in Section 7.0.

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 used in the assessment of these devices.

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

There were no manufacturer sponsored pre-market investigations conducted with the device. The AlboGraft Polyester Vascular Patch was previously manufactured by Biomateriali S.r.l., a subsidiary of LeMaitre Vascular Inc., in Brindisi, Italy. The device was first approved for CE mark under LeMaitre Vascular Inc. in 2010. The Post-Market Clinical Follow-up studies performed for the subject device are listed below:

- Biomateriali Albograft™- A Retrospective Clinical Data Review (2008)
- Biomateriali Albograft™ Thoracic Aortic Application A Retrospective Clinical Data Review (2009)
- Biomateriali AlboGraft™ - A Retrospective Clinical Data Review (2010)

The findings of these studies are summarized below.

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 Hemashield Microvel Double Velour Knitted and Woven Vascular Graft. The AlboGraft was previously manufactured by Biomateriali S. r. l., a subsidiary of LeMaitre Vascular, Inc. in Brindisi, Itay. LeMaitre Vascular has transferred the manufacturing from Italy to Burlington, MA.

Biomaterali conducted the following three studies:

1. A Retrospective Clinical Data Review (2008), which concluded that "overall, aortic reconstruction with the Albograft performed favourably compared with existing literature. Albograft has comparable short and long term patency, and also exhibits similar mortality and morbity rates in the follow-up period, when compared with existing literature. We did not observe any adverse events which were directly related to the Albograft Polyester prosthesis. The overall handling in terms of suturing, conformability to the anastomosis, and suture hole bleeding compares well with polyester grafts of other brands previously used (C.R.BARD Dialine II; Boston Scientific Hemashield). One of the major reasons we originally switched to the Albograft was a competitive price offer by the current distributor."

2. Thoracic Aortic Application A Retrospective Clinical Data Review (2009), which concluded "Overall, aortic reconstruction with the Albograft performed favourably compared with existing literature. Albograft has comparable short and long term patency and also exhibits similar mortality and morbidly rates in the follow-up period when compared with existing literature. We did not observe any adverse events which were directly related to the AlboGraft Polyester prosthesis."

3. A Retrospective Clinical Data Review (2010), which concluded that "Overall, the

peripheral intraoperative reconstructions and outcomes with the AlboGraft described in this report performed well when compared with existing literature. The AlboGraft had comparable immediate (30 day) and long term (24 month) patency and also exhibits similar mortality and morbidity rates in the follow-up period up to max. 36 month when compared with existing literature. We did not observe any adverse events which were directly related to the AlboGraft Polyester prosthesis."

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

The table below provides direct comparisons between the performance outcomes reported for the subject device (from clinical literature on equivalent device and clinical investigations with the subject device) and the acceptance criteria for those outcomes established by the state of the art assessment. Many articles did not report the performance outcomes as described in the state of the art, including secondary patency, and are not included in the table. In addition, limb salvage is a potential benefit associated with the subject device that was not reported by any of the articles in the state of the art assessment and acceptance criteria could not be established for this outcome. Van Det et al. reported that the limb salvage rate at 10-years was 96.5%.[1] The acceptance criteria was met for primary patency and survival for most studies. For van Det et al. the acceptance criteria was not met for all time points. However, the 10-year follow up for this study exceeded the follow-up range upon which the acceptance criteria for this outcome was established.

Table 6-17: Comparison of performance outcomes to acceptance criteria

Outcome	Rate / value observed in literature	Source(s)	Acceptance Criteria	Criteria Met
Primary patency	70%, 52%, & 28% (2-, 5-, & 10-years)	van Det, 2009[1]	≥ 49%	No[b]
	90% & 94.8% (hospital discharge & follow up)	PMCF Clinical investigation (2008)		Yes
	82% (follow up)	PMCF Clinical Investigation (2009)		Yes
	88.9% & 95.1% (1- & 2-years)	PMCF Clinical Investigation (2010)		Yes
Secondary patency	No reports from clinical literature or clinical investigations		≥ 76%	Not applicable
Survival	94±3%, 84±5%, & 59±11% (estimated 1-, 5-, and 10-year)	Hsu, 2014[2]	≥ 39.3%	Yes
	97.7% (operative)[a]	Rajbanshi, 2019[3]		Yes
	93.4% (operative)[a]	Tamura, 2011[4]		Yes
	98.1% (30-day)[a]	Lamelas, 2018[5]		Yes

	94.8%, 98%, & 94.8% (in hospital, 30-days, and 1-year)[a]	PMCF Clinical investigation (2008)		Yes
	99%, 94.8%, & 94.5% (in-hospital, 30-days, 1-year)[a]	PMCF Clinical Investigation (2009)		Yes
	93.9%, 95.5%, 96.8% (in-hospital, 30-days, 1-year)[a]	PMCF Clinical Investigation (2010)		Yes

a) Authors did not report survival. The value was computed using mortality rate: 100% - mortality rate (%)
b) Acceptance criteria was not met for all time points. The 10-year follow up for this study exceeded the follow-up range upon which the acceptance criteria for this outcome was established.

The table below provides direct comparisons between the safety outcomes (restenosis, bleeding, stroke, transient ischemic attack, myocardial infarction, infection, occlusion, thrombosis, and mortality) for the subject device (from clinical literature, reported complaints, and clinical investigations) and the acceptance criteria for those outcomes established by the state of the art assessment. The complete reporting of complaints for 01 January 2010 to 01 December 2020 are provided in Section 6.6.1. Some outcomes (e.g. bleeding, graft dilation, graft disintegration, etc.) reported in the clinical literature pertaining to the equivalent device were not reported in the state of the art literature. Therefore, since acceptance criteria for these outcomes could not be established, they were not included in the table below. For the most part, graft-related outcomes occurred at low rates (i.e. individual case reports). In addition, outcomes such as bleeding reported in the clinical literature for the equivalent device were shown to be modulated in part by procedural characteristics (see Lamelas et al.). Procedural bleeding reported in PMCF clinical investigations occurred at rates of 0%, 1%, & 10.6%. However, no procedural complications were directly attributed to the graft implanted. The acceptance criteria for mortality was met for all studies. One study from the clinical literature (Hsu et al.) failed to meet the acceptance criteria for stroke. However, patients in this study were treated via the combination of a Hemashield tube graft with reinforced "sandwich" technique for aortic dissection and the complicated technical aspects of this procedure may have contributed to a greater risk of postoperative complications.

Comparison of safety outcomes to acceptance criteria

Safety Outcome	Rate / value observed in literature	Source(s)	Acceptance Criteria	Criteria Met
Stroke	6% (5/63)	Hsu, 2014[2]	≤ 2.2%	No
	1.0% (1/103)	Lamelas, 2018[5]		Yes
	None reported from clinical investigations and complaint data			Not applicable

Ischemia	No reports from clinical literature, clinical investigations (2008 & 2010), and complaint data		≤ 9%	Not applicable
	14.3% intraoperative	PMCF Clinical Investigation (2009)		No
Thrombosis	No reports from clinical literature, clinical investigations, and complaint data		≤ 6.6%	Not applicable
Wound complications	No reports from clinical literature, clinical investigations, and complaint data		≤ 4.44%	Not applicable
Myocardial infarction	No reports from clinical literature, clinical investigations, or complaint data		≤ 9.13%	Not applicable
Mortality	6% (operative)	Hsu, 2014[2]	≤ 67%	Yes
	2.3% (operative)	Rajbanshi, 2019[3]		Yes
	6.6% (operative)	Tamura, 2011[4]		Yes
	1.9% (30-day)	Lamelas, 2018[5]		Yes
	5.2%, 2%, & 5.2% (in hospital, 30-day, & 1-year)	PMCF Clinical investigation (2008)		Yes
	1%, 5.2%, & 5.5% (in hospital, 30-day, & 1-year)	PMCF Clinical Investigation (2009)		Yes
	6.1%, 4.5%, & 3.2% (in hospital, 30-day, & 1-year)	PMCF Clinical Investigation (2010)		Yes
	None reported	Complaint data 2010-2020		Yes

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

Per EU MDR GSPR 1 and 6 a complete summary of performance and clinical benefit outcomes for the device under evaluation in comparison to the state of the art acceptance criteria is presented in Table 7-1 in section 7 of the CER. At up to 2-years follow-up, primary patency (49.0-87.9%), secondary patency (55.0-93.0%), survival (76.0-93.0%) limb salvage (98.4%), and reintervention rates (reported as reoperation for bleeding; 2.9%) for the subject devices were comparable to similar treatments and within the acceptable limits reported in the state of the art literature evaluation for the treatment of aneurysmal and occlusive disease. Following the treatment of occlusive disease of the iliac arteries in PMCF study C, the survival rate at 30 days (93.9%), but not at 1 year (96.7%), exceeded the acceptance criterion. The acceptance criteria for other measures, primary patency and limb salvage, were met in the same study.

Non-clinical testing data (Section 6.3 in the CER) provided by the manufacturer showed no signs of systemic toxicity following bilateral implantation of the AlboGraft Polyester Vascular Graft into the carotid artery of sheep for 6 weeks. In addition, the device under evaluation was tolerated as well as and displayed similar collagen reabsorption to the predicate control graft (Hemashield).

The overall ranges of rates for performance, clinical benefit, and safety outcomes reported in the state of the art clinical literature review are used to establish acceptance criteria, with the lower bound of the ranges used as the minimally acceptable rates for performance objectives, and higher bounds of the ranges as the highest acceptable occurrence rates for the safety objectives. After review of the available data pertaining to the state of the art, it was determined that separate acceptance criteria for occlusive and aneurysmal disease was suitable. However, the variety of anatomical areas, insufficiency of data for all individual anatomical areas, and low variability in reported outcomes across anatomical regions contributed to the decision to combine outcomes across regions in order to establish acceptance criteria. A summary of the overall indicative ranges, as well as the weighted averages across studies, for the safety and performance outcomes selected as specific and measurable outcomes used to establish acceptance criteria in patients following open surgical repair of aneurysm or peripheral occlusive vascular diseases. Weighted averages were used to establish the acceptance criteria to account for variability in observed rates and/or sample sizes across studies. Overall, acceptance criteria were determined from data on at least 239,189 patients/procedures from 32 articles from the current state of the art clinical literature evaluation discussing open surgical repair. Comparative analysis between performance and safety outcomes associated with the device under evaluation and the acceptance criteria from state of the art is presented in Section 7 of the CER. Based on the 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 clinical follow-up**

The manufacturer conducts ongoing post-market surveillance (PMS) of the subject device according to the following procedure, SOP28-001. 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 was conducted to capture all relevant and up to date published information regarding the Albograft device. The second step will involve completion of multi-center study in Europe. Contract negotiations were completed in Q2 of 2022, with the study start ongoing.

The purpose of the study is to conduct a retrospective analysis on the performance and safety of the AlboGraft Vascular Graft on patients undergoing surgical treatment for aneurysmal or occlusive disease with a maximal follow up of one year.

It is anticipated this study will be extended into an on-going registry to confirm the safety and effectiveness throughout the expected lifetime of the device through the proactive and continuous collection of data.

6.0 Possible diagnostic or therapeutic alternatives:

-- *Peripheral Vascular Repair*: Invasive treatments are not recommended for asymptomatic peripheral arterial disease. In many cases, intermittent claudication caused by peripheral arterial disease can be managed with medical treatment (e.g., smoking cessation interventions, statin therapy, antiplatelet therapy) or exercise therapy. However, SVS recommends invasive (endovascular or surgical) treatment for patients with "significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks."[6] Invasive treatment should be individualized to the patient. For instance, endovascular procedures are recommended over open surgery for focal occlusive disease of the superficial femoral artery, whereas surgical bypass is recommended as an initial revascularization strategy for patients with diffuse femoro-popliteal disease or extensive calcification of the superficial femoral artery (depending on patient anatomy).[7] ESC/ESVS suggest endovascular therapy as the first choice of treatment for femoro-popliteal lesions <25 cm and surgical bypass (especially when using the great saphenous vein) for occlusion/stenosis >25 cm in length.

Bypass may be achieved using autologous vein, biological graft such as human umbilical vein, synthetic grafts (typically ePTFE [also referred to as PTFE] or Dacron), or biosynthetic grafts (e.g., LeMaitre Omniflow II, which is constructed of polyester mesh and ovine collagen). Heparin-bonded synthetic grafts, designed to reduce risk of thrombosis, have also been introduced to the market. The consensus by professional societies, including the European Society of Cardiology and European Society for Vascular Surgery, is that autologous vein should be used for bypass whenever possible, but the use of a prosthetic graft should be considered in the absence of suitable vein.[6,7] The clinical practice guidelines do not contraindicate

the use of synthetic grafts in the coronary arteries, and prosthetic grafts are required for coronary artery bypass grafting when the availability of suitable autologous conduits is limited[8]. However, the nonsystematic review by Desai et al. (2011) concluded that existing synthetic grafts do not meet the equivalent function and durability of the internal mammary artery or long saphenous vein in coronary artery bypass grafting[8]. Therefore, a contraindication of the use of grafts like AlboGraft in the coronary arteries is appropriate.

-- *Abdominal aortic aneurysm repair*: Endovascular repair for AAAs became available in 1991. While endovascular interventions are increasing in use, open repair remains the standard procedure for AAA repair. Given that there are no proven medical therapies available to slow the expansion of AAAs, surgical interventions are typically required when the growth exceeds a certain threshold (≥5.5 cm for men and ≥5.0cm for women) or there is a rupture. When rapid AAA growth is observed (≥1 cm/year) or there is an increase in symptoms, more urgent referral to a vascular surgeon is recommended.[6] Open surgical repair involves a large incision, along the abdomen in the case of AAA, removal of the damaged vessel at the site of the aneurysm and implantation of a graft to replace that segment. Polyethylene terephthalate, also known by its brand name Dacron, is the most frequently used material in open surgical repair of AAA for the last 60 years. Dacron grafts are available with different kinds of impregnation (i.e. gelatin, albumin, etc) to decrease the porosity of the graft. Expanded polytetrafluoroethylene (PTFE) is an alternative synthetic graft material. Endovascular aneurysm repair is a minimally invasive option involving a smaller incision in the groin and the insertion of stent grafts via catheter, via either percutaneous or surgical access, in the artery that is then threaded up to the location of the aneurysm. The placement of the stent graft then acts to support the aneurysm. Unlike grafts used in open repair, a stent graft is meant to seal the sac from the inside of the aneurysm, while the aneurysm wall is left untouched. Most of the stent graft devices require a degree of oversizing of the graft relative to the vessel (≈10-25%) to ensure adequate sealing and fixation. Percutaneous endovascular stent placement is associated with fewer access-related complications, such as groin infection and lymphocele.

7.0 Suggested profile and training for users

The AlboGraft Vascular Graft is an implant intended for use by experienced vascular surgeons trained in the procedures for which they are intended.

8.0 Reference to any harmonized standards and CS applied

Standard Title	Standard Reference: Revision Year
Sterilization of medical devices. Requirements for medical devices to be designated "STERILE". Part 2: Requirements for aseptically processed medical devices	EN 556-2:2015
Information supplied by the manufacturer of medical devices	EN 1041:2008
Cardiovascular implants and extracorporeal systems – Vascular prostheses -- Tubular vascular grafts and vascular patches	ISO 7198:2016
Biological evaluation of medical devices – Part 1: Evaluation and testing	ISO 10993-1:2009
Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	ISO 10993-3:2009
Biological evaluation of medical devices – Part 4: Selection of tests for interactions with blood	EN ISO 10993-4:2006
Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	ISO 10993-5:2009
Biological evaluation of medical devices – Part 6: Tests for local effects after implantation	EN ISO 10993-6:2007
Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity	ISO 10993-10:2010
Biological evaluation of medical devices – Part 11: Tests for systemic toxicity	ISO 10993-11:2018
Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances	EN ISO 10993-17:2008
Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems	ISO 11607-1:2006
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes	ISO 11607-2:2006
Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products	ISO 11737-1:2006
Tests of sterility performed in the definition, validation and maintenance of a sterilization process	ISO 11737-2:2009
Aseptic processing of health care products – Part 1: General requirements	ISO 13408-1:2008
Medical devices – Quality management systems – Requirements for regulatory purposes	EN ISO 13485:2016
Sterilization of health care products – Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives – Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	ISO 14160:2011
Cleanrooms and associated controlled environments – Part 1: Classification of air cleanliness	ISO 14644-1:2015
Medical devices – Application of risk management to medical devices	EN ISO 14971:2012
Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied —Part 1: General requirements	EN ISO 15223-1:2016
Medical devices utilizing animal tissues and their derivatives – Part 1: Application of risk management	ISO 22442-1:2015
Medical devices utilizing animal tissues and their derivatives – Part 2: Controls on sourcing, collection and handling	ISO 22442-2:2015
Medical devices utilizing animal tissues and their derivatives – Part 3: Validation of the elimination and/or inactivation of viruses and TSE agents	ISO 22442-3:2007

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9.0 Revision History

SSCP revision number	Date Released	Change description	Revision validated by the Notified Body
001/A	24 March 2022	Initial release	☒ Yes ☐ Validation language: English (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)
002/B	09 December 2022	Added section 10 patient info, and made updates per BSI feedback	☒ Yes Validation language:English ☐ No

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. AlboGraft Polyester Vascular Graft (Graft)
    - **b. Producer; name and address**
        - i. LeMaitre Vascular, Inc. 32 Third Avenue, Burlington, MA 01803
    - **c. Basic UDI-DI**
        - i. 08406631AlboGraftR6
    - **d. Year when the device was first CE-marked**
        - i. 2011
2. **Intended use of the device**
    - **a. Intended purpose**
        - i. The Grafts are intended to be used as a replacement of diseased vessels.
        - ii. The Grafts are used in blood vessel and reconstructions requiring enhanced resistance to kinking and compression exerted by tendon and muscles. The Graft is usually used to repair and replace vessels in the legs and lower abdomen
    - **b. Indications and intended patient groups**
        - i. The Graft comes in knitted and woven grafts are indicated for use in the replacement or repair of abdominal and thoracic arteries affected with aneurismal or narrowing or blockages of an artery. The product is designed for patients with variable ages, weights, diagnoses and health statuses.
    - **c. Do not use for:**
        - i. The Grafts should not be used in coronary arteries and in patients with known or suspected negative reaction to any form of protein derived from cows.
3. **Device description**
    - **a. Device description and material/substances in contact with patient tissues**
        - i. The Grafts are made of synthetic material designed to replace sections of damaged or arteries. They are made of polyester PET thread woven into a seamless tube. The following materials are what make up the graft, polyester cow collagen and a preserving agent. All materials have passed testing to ensure they are safe to use
    - **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 affect 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.

Patient Related Adverse Event	Severity	Occurrence	RPN
Stroke	8	2	16
Complete/partial paralysis in legs or lower abdomen	8	2	16
Partial paralysis of both legs	8	2	16
Heart attack	8	2	16
Kidney stops working	8	2	16
Blood flow limited	8	2	16
Blood clot that blocks blood flow	8	2	16
Blood clotting in vein	8	1	8
The process of losing blood from the body	8	2	16
Growth of germs in or around the wound	8	2	16
Bulge in the wall of an artery	8	2	16
Lung inflammation with tiny fluid filled air sacs	8	1	8
Loss or removal of a body part	8	1	8
Death	10	1	10
Injured blood vessel wall that leads to leaking	8	2	16
The formation of a blood clot inside the artery and vein	8	1	8
A serious condition that makes it difficult to breathe on your own	8	1	8
An irregular and often very rapid heart rhythm that can lead to blood clots in the heart	8	1	8
Fluid leaking into space between lung and chest wall	8	2	16
Temporarily not in ones right mind	8	1	8
Total or partial paralysis of one	8	1	8

side of the body			
Poor blood supply to nervous system	8	1	8
Numbness running down buttocks to back of legs	8	1	8
Intestines not able to move food through digestive system	8	1	8
Severe and sudden kidney failure	8	1	8
Swelling or bleeding occurs within a compartment usually in legs, feet, arms or hands	8	1	8
Leaking caused by space left between heart and valves	8	1	8
Tear in inner layer of your aorta, the main artery that delivers blood you're your heart to your body	8	1	8
Blood clot develops in veins deep in your body	8	1	8
Excessive movement due to disruption of the wires connecting the surgically divided sternum	6	1	6
Patient will need a two-part surgery combining open microsurgery and endovascular coiling. The reason for this surgery is to coil the entire diseased part of the blood vessel and then bypass the blood flow to the specific location in the brain	8	2	16
A bad bruise	6	1	6
A collection of fluid that builds up under the surface of your skin	6	1	6
An infection in any part of your urinary system	8	1	8
Local pain in the stomach area	8	1	8

Device Related Adverse Event	Severity	Occurrence	RPN
Graft is stretched or enlarged beyond normal	8	2	16
Graft losing cohesion or strength	8	2	16
Graft is narrowing	8	1	8
Graft is infected	8	1	8
Air in or around the graft	8	1	8

- **How potential risks have been controlled or managed**
  - Analysis have concluded that the benefits outweigh any residual risks and that the risk has been reduced as far as possible
- **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 maybe 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, a 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 Graft is categorized as Class II device in US and Class III device in EU. The Grafts are made of synthetic material and designed to replace sections of damaged or malfunctioning arteries. They are made of polyester thread woven into a seamless tube. In response to a range of surgical indications, the Grafts are offered in two designs: double velour knitted fabric and double velour woven fabric. The knitted grafts are designed with a run-proof structure to reduce the risk of fraying or wearing down at their ends. The velour grafts have low profile loops on their endoluminal surface to avoid any lumen reduction, and high profile loops on their outer surface to promote graft anchoring into the surrounding tissues. The AlboGraft will also be available with or without collagen coating. All of the grafts are crimped in parallel rings so that their tubular shape is maintained without kinking.

The Grafts are available with removable external spiral reinforcement made of a thread, allowing for easy identification with x-ray. The external spiral reinforcement is removable, helping the joingin of the vessel to the graft.

The Grafts are made with collagen to reduce leakage so that no pre-clotting is necessary. The process of using bovine collagen maintains both the original structure of the material, and the structural characteristics of the graft, i.e. flexibility and softness.

b. The clinical evidence for the CE-marking

The device was first approved for CE mark under LeMaitre Vascular Inc. in 2011. Studies were conducted to ensure the grafts were safe and effective. See the IFU for further details.

c. 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.