LeMaitre®

Artegraft® Collagen Vascular Graft

Artegraft® Collagen Vascular Graft
English - Instructions for use

Artegraft® Collagen Vascular Graft

(Model Numbers AG540, AG630, AG636, AG640, AG645, AG715, AG730, AG735, AG740, AG745, AG750, AG830, AG840, AG845, AG1015, AG1030)
English - Instructions for Use

STERILE LC **Rx only**

Artegraft is a medical device of biological origin, that has been subjected to enzymatic digestion and tanning. The sterile graft is preserved in a tube filled with USP purified water and ethyl alcohol. The surgical staff must prepare the graft for implantation as instructed below.
Not Made with Natural Rubber Latex
Non-Antigenic

Preparation for Implant



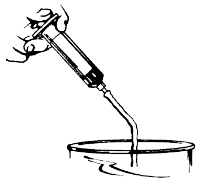
1. Fill basin with a minimum of 500 ml of 0.9% sodium chloride solution (sterile saline).
2. Remove graft from the container using sterile technique by grasping the support rod with fine-tipped forceps while container is held in semi-upright position.
3. Withdraw rod without touching top or outside rim & drain away excess alcohol from graft.
4. Immerse graft in basin during surgical preparation.
5. Flush alcohol from lumen before implanting. It is recommended to irrigate 7 to 8 times with ~30 ml of solution using bulb or piston syringe (with slip tip).



6. In a second basin, prepare a suggested ratio of 120 ml sterile saline solution with 2500 units of heparin for final rinse. See PRECAUTIONS. Using the same syringe or bulb, it is recommended to irrigate a minimum of one time with ~30 ml of solution using bulb or piston syringe (with slip tip).
7. Artegraft is manometry pressure tested and quality inspected. Before implanting, occlude one end of graft and pressure test with bulb or syringe filled with saline.

Device Description

The Artegraft is composed of a section of specially selected bovine carotid artery 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.



Intended Use

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.

Indications For Use

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 use of the Artegraft for femoropopliteal bypass should be reserved for those patients where the autologous saphenous vein is absent or inadequate. It is also not recommended for reconstruction across the knee joint. However, in the absence of other viable alternatives, the surgeon may well find the benefit to risk ratio warrants its use as an attempted limb salvage procedure.

Contraindications

1. The Artegraft should not be used in venous or low pressure systems.

Warnings

1. After the Artegraft has been removed from the container in the manner prescribed to preserve its sterility, it should be gently and thoroughly washed and rinsed to minimize carryover of preserving fluid. For aseptic removal and wash procedures, please see INSTRUCTIONS FOR USE Section.
2. Silk is not recommended for anastomosis. This suture occasionally was found to give rise to thick suture-line pannus in the dog.
3. The prosthesis 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.
4. A minimum of ten 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.
5. Thrombosis of the graft has been reported from inadvertent external compression. Patients and those administering dialysis should be cautioned against compression of the graft for prolonged periods.
6. Aneurysmal degeneration or disruption of the graft or anastomosis may occur in the presence of an ongoing infection.

Precautions

1. Once the package seal is broken, the graft should be used immediately. Any left-over material should be discarded.
2. The graft should not be used after the expiration date imprinted on the label.
3. In the event of early occlusion, re-exploration of the graft and removal of the thrombus with a LeMaitre catheter or other means often results in effective

restoration of long-term patency. This procedure is somewhat easier to perform in the case of the Artegraft than with other prostheses.

4. 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.
5. During implantation, meticulous technique is essential to avoid twisting and to achieve accurate approximation at the suture lines.
6. Clinical evidence suggests that subfascial, rather than subcutaneous, implantation in the lower extremity is the more satisfactory procedure.

For precautions regarding true aneurysms, please see POTENTIAL COMPLICATIONS Section.

Potential Device-Related Complications:

- Amputation
- Aneurysm
- Aneurysmal degeneration
- Bleeding
- Central venous stenosis
- Delamination
- Graft Dilatation
- Hematoma
- Infection
- Inflammation
- Mortality
- Nonmaturation
- Pseudoaneurysm
- Pseudointima formation
- Pseudodiaphragm formation
- Reintervention
- Renal failure
- Seroma
- Steal syndrome
- Stenosis
- Thrombosis formation
- Wound dehiscence

Potential Procedure-related Complications:

- Anastomotic pseudoaneurysm
- Arrhythmia
- Congestive Heart Failure
- Graft replacement
- Lymph Fistula
- Major Adverse Cardiovascular Event
- Myocardial Infarction
- Occlusion
- Pneumonia
- Pulmonary embolism
- Respiratory Failure
- Sepsis or Systemic Inflammatory Signs
- Skin rash
- Stroke
- Transient low grade fever
- Wound complication

Instructions for Use

Since the Artegraft is intended as a conduit for arterial blood, no specific rules can be laid down as to the number and size of Artegrafts to be used in any given case, since individual requirements will vary widely.

However, accepted vascular surgical techniques should always be employed, including the use of non-crushing clamps to control the host artery and very gentle handling of the ends of the graft itself.

Removing the Graft from the container

1. To remove the Artegraft aseptically from its container, the container should be held in a semi-upright position.
2. After carefully removing the cap without contaminating the rim of the container, the supporting rod and the graft itself should be lifted from the container with long fine-tipped thumb forceps.
3. As soon as the graft itself becomes accessible, it should be grasped and removed from the container with the support rod and drain away excess alcohol from graft, care being taken not to touch the outside rim of the container.

Rinsing the Graft

1. Immerse the graft in a large basin with a minimum of 500 ml of sterile 0.9% sodium chloride solution (sterile saline).
2. Irrigate the graft's lumen at least seven times with ~30ml of solution using a bulb or piston syringe (with slip tip).
3. A final irrigation and immersion should be performed. In a second basin, prepare a suggested ratio of 120ml sterile saline solution with 2500 units of heparin, unless HIT is diagnosed (see PRECAUTIONS).
4. Before implanting, occlude one end of the graft and pressure test with a bulb or syringe filled with saline.

The graft is now considered ready for insertion into a patient.

Implantation

1. Accepted vascular surgical techniques should always be employed. Precise anastomosis without tension, bulging or twisting is mandatory.
2. The use of fine non-cutting rather than cutting-type needles helps avoid troublesome punctate bleeding at the anastomotic sites, particularly in the smaller diameter grafts.
3. If troublesome bleeding does occur, it may readily be controlled by simply applying a small piece of excess Artegraft as a patch to the bleeding area in a reverse manner so that the adventitia of the patch is in direct contact with adventitia.
4. In order to avoid possible snarling of the suture in the rather shaggy adventitia of the graft, it has been found convenient to start the stitch in the host artery rather than starting it in the graft. In so doing, care should be exercised to avoid the possibility of displacing an atheromatous plaque.
5. The graft lot number and its length and diameter should be recorded on the patient's chart, as well as the actual length of the graft implanted into the patient.

How Supplied

The Artegraft is packaged in a specially designed tube containing a sterilizing solution prepared with 0.3 (wt) % 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.

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.

The approximate desired length and inner diameter of each graft should be specified when ordering; the nearest available sizes will be supplied upon confirmation.

NOTE: Outer diameters vary, but typically 1mm larger

Artegraft comes in the following sizes:

Model	Inner Diameter (mm)	Minimum Length (cm)		Model	Inner Diameter (mm)	Minimum Length (cm)
AG540	4 mm	40 cm		AG740	6 mm	40 cm
AG630	5 mm	30 cm		AG745	6 mm	45 cm
AG636	5 mm	35 cm		AG750	6 mm	50 cm
AG640	5 mm	40 cm		AG830	7 mm	30 cm
AG645	5 mm	45 cm		AG840	7 mm	40 cm
AG715	6 mm	15 cm		AG845	7 mm	45 cm
AG730	6 mm	30 cm		AG1015	8 mm	15 cm
AG735	6 mm	35 cm		AG1030	8 mm	30 cm

Storage

The graft must be kept in its original packaging until used. It must be kept in a dust free and dry environment at room temperature (16° C to 25° C).

Incident Reporting

If serious medical incidents should arise during use of this medical device, users should notify both LeMaitre Vascular and the Competent Authority of the country where the user is located.

Safe Handling and Disposal

This product contains no sharps, heavy metals or radioisotopes, and is not infectious or pathogenic. There are no special requirements for disposal. Please consult local regulations to verify proper disposal.

Dispose of storage solution according to local and federal regulations. Solution should not be disposed using septic systems. If there are no disposal restrictions, solution may be diluted and disposed in a sanitary sewer system.

Packaging and shipping of explanted Artegraft:

Return of the shipment to LeMaitre Vascular depends on 3 crucial questions:

1. Is the explant obtained from a patient with a known or presumed pathogenic condition at the time of the explant?
2. Is the explant obtained from a patient that has a known treatment history that involves therapeutic radionuclides within the last 6 months?
3. Has the clinician obtained consent from the patient for the sample to be returned to the manufacturer for research purposes?

If the response to question 1 or 2 is affirmative, LeMaitre Vascular does not provide adequate guidance for shipment. THESE EXPLANTS SHOULD NOT BE RETURNED TO LEMAITRE VASCULAR UNDER ANY CIRCUMSTANCES. In these cases, the explant should be disposed according to local regulations.

For explants that do not have pathogenic or radiologic hazards, please use the following:

Pre-explantation:

1. If possible, perform a CT or Ultrasound scan of the device to document patency.
2. LeMaitre Vascular can accept clinical information that is patient-anonymized. LeMaitre Vascular requests information including:
   a) The original diagnosis which resulted in use of the implant.
   b) The patient's medical history relevant to the implant, including the hospital or clinic at which the device was implanted.
   c) The patient's implant experience prior to implant removal.
   d) The hospital or clinic at which the explantation was performed, and date of retrieval.

Explantation:

1. Explanted Artegrafts should be directly transferred to a sealable container filled with a solution of alkaline buffered 2% glutaraldehyde or 4% formaldehyde prior to shipment.
2. Cleaning of explanted grafts should be minimal if necessary. Proteolytic digestion should not be used in any circumstances.
3. Artegraft explants should not be decontaminated under any circumstances. DO NOT autoclave the sample or use ethylene oxide gas to decontaminate.

Packaging:

1. Explants should be sealed and packed in a manner that minimizes potential for breakage, contamination of the environment or exposure to those handling such packages during transit. Material that is absorbent and is cushioning should be selected for isolating the sealable container inside the secondary packaging. Primary and secondary packaging must then be packaged inside an outer package.
2. Explants in sealed primary containers should be labeled with an ISO 7000-0659 Biohazard symbol. The same symbol should be attached to the secondary packaging and to the outer packaging. Outer packaging should also be labelled with Name, Address and Telephone Number of Sender, and the statement, "Upon discovery of damage or leakage, the package should be isolated and sender notified".
3. Packages prepared in the above manner may be shipped to:

LeMaitre Vascular
Attn: Complaint Lab
63 Second Avenue
Burlington, MA 01803, USA

Limited Product Warranty; Limitation of Remedies

LeMaitre Vascular, Inc., warrants that reasonable care has been used in the manufacture of this device and that this device is suitable for the indication(s) expressly specified in these instructions for use. Except as explicitly provided herein, LEMAITRE VASCULAR (AS USED IN THIS SECTION, SUCH TERM INCLUDES LEMAITRE VASCULAR, INC., ITS AFFILIATES, AND THEIR RESPECTIVE EMPLOYEES, OFFICERS, DIRECTORS, MANAGERS, AND AGENTS) MAKES NO EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THIS DEVICE, WHETHER ARISING BY OPERATION OF LAW OR OTHERWISE (INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE) AND HEREBY DISCLAIMS THE SAME. This limited warranty does not apply to the extent of any abuse or misuse of, or failure to properly store, this device by the purchaser or any third party. The sole remedy for a breach of this limited warranty shall be replacement of, or refund of the purchase price for, this device (at LeMaitre Vascular's sole option) following the purchaser's return of the device to LeMaitre Vascular. This warranty shall terminate on the expiration date for this device.

IN NO EVENT SHALL LEMAITRE VASCULAR BE LIABLE FOR ANY DIRECT, INDIRECT, CONSEQUENTIAL, SPECIAL, PUNITIVE, OR EXEMPLARY DAMAGES. IN NO EVENT WILL THE AGGREGATE LIABILITY OF LEMAITRE VASCULAR WITH RESPECT TO THIS DEVICE, HOWEVER ARISING, UNDER ANY THEORY OF LIABILITY, WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EXCEED ONE THOUSAND DOLLARS (US$1,000), REGARDLESS OF WHETHER LEMAITRE VASCULAR HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH LOSS, AND NOTWITHSTANDING THE FAILURE OF THE ESSENTIAL PURPOSE OF ANY REMEDY. THESE LIMITATIONS APPLY TO ANY THIRD-PARTY CLAIMS.

A revision or issue date for these instructions is included on the back page of these Instructions for Use for the user's information. If twenty-four (24) months has elapsed between this date and product use, the user should contact LeMaitre Vascular to see if additional product information is available.

Symbol Legend

Distributed By:	#	⌀ ID	⊢ cm ⊣	STERILE LC	Rx only
Distributed By	Quantity	Inner Diameter	Usable Length	Contents Sterile. Sterile LC: Device Sterilized Using Liquid Chemical Sterilant, compliant to EN/ISO 14160	Caution: U.S. Federal and other law restricts this device to sale by or on the order of a physician

		MR	D^{120} (mm):	0.2mL/cm²/min	STORED IN PROPYLENE OXIDE
Straight Prosthesis	Flammable	MR Safe	Diameter of prosthesis under pressure	Water Permeability	Stored in Propylene Oxide

Distributed By:

LeMaitre Vascular, Inc.
Customer Service:
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