



Distributed By:

LeMaitre Vascular, Inc.
63 2nd Avenue
Burlington, MA 01803
(781) 221-2266
Fax: (781) 221-2223

Manufacturer:

Biomateriali S.r.l.
S.S. 7 per Mesagne
72100 Brindisi, Italy
Tel: +39-0831-588025

AlboGraft™ Vascular Graft

Instructions for Use – English
Disposable (Single Use Only)
Sterile

R2078-00 Rev. A 01/10

AlboGraft™ Vascular Graft

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Instructions for Use – English

Description

AlboGraft™ Vascular Grafts are made of synthetic material and designed to replace sections of damaged or mal-functioning arteries. They are made of polyester (polyethylene terephthalate, PET) thread woven into a seamless tube. In response to a range of surgical indications, AlboGraft 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 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. All AlboGraft grafts are crimped in parallel rings so that their tubular shape is maintained without kinking.

A guideline on the outer surface of the graft facilitates implantation.

The AlboGraft Vascular Grafts are impregnated with collagen, reducing permeability to mitigate the problem of hemorrhaging during implantation so that no preclotting is necessary. The process of impregnation using bovine collagen maintains both the original structure of the material, and the structural characteristics of the prosthesis, i.e. flexibility and softness. The collagen is cross-linked to the graft by formaldehyde steaming to ensure a balanced reabsorption rate by the host tissues.

Available Models

AlboGraft Vascular Grafts are available in a wide range of models, types and sizes. The graft can be classified into 2 models according to fabric characteristics, each model being of one or more types (straight "I," bifurcated "II") and sizes (diameter, length). Each graft is identifiable by a code and a lot number. The 3-letter code identifies the fabric and presence of collagen; the 4-digit code identifies the type and sizes of the graft. The lot number serves to retrieve information from the files of the LeMaitre Vascular Quality Assurance Service on the graft's manufacturing and checking data. To facilitate the tracking of the product by the operator all product identification data is given on four self-adhesive labels in each product package, which can be transferred to the patient's clinical record.

Type	Code	Color Code
Double Velour Woven Fabric Impregnated With Collagen	ATC	light blue
Double Velour Knitted Fabric Impregnated With Collagen	AMC	gold

Consult the LeMaitre Vascular catalogue for a detailed listing of models and types available.

Technical Characteristics Of AlboGraft Prostheses

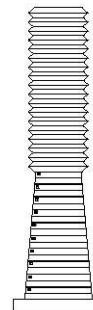
Diameter

The diameter is defined as the value of the nominal internal diameter of the undilated prosthesis. The value is obtained with a conical gauge (anulometer) having a 10° angle from the apex. The prosthesis is gently slipped over the instrument without applying any pressure (see diagram).

D120 = Diameter of the prosthesis under pressure

This value indicates the internal diameter of the prosthesis when exposed to an internal pressure of 120 mmHg; it equals the average natural pressure on the prosthesis when undamped. The diameter is higher than the nominal value as a result of two different concomitant factors:

- distention of the pleated folds;
- radial dilation caused by blood flow pressure (its effect on a knitted prosthesis is more sensible due to the high flexibility and elasticity of the device).



Permeability

Permeability is a chief property of the polyester fabric and depends on the porosity of the material.

This capability is expressed as the amount of water that can pass through 1 cm² of the prosthesis at 120 mmHg over a given unit of time. The table below compares the maximum values (ml x cm² x min⁻¹) of the observed permeability.

Type	Double Velour Knitted Fabric with Collagen	Double Velour Woven Fabric with Collagen
ml cm ⁻² min ⁻¹	0.1	0.1
Force Applied	g. 125	g. 500

Length

This measurement indicates the minimum length of the dilated prosthesis. The prosthesis is dilated by the force of a weight attached to it.

Type	Diameter	Weight (g)
Double Velour Knitted Fabric With Collagen	ALL	500
Double Velour Woven Fabric With Collagen	<24 mm	500
Double Velour Woven Fabric With Collagen	≥24 mm	750

Packaging

AlboGraft Vascular Grafts are supplied sterile within a double container. The internal container is also externally sterile provided that the external container has been neither damaged nor opened. The external container is only internally sterile: it must not be brought into a sterile environment.

Warning: *The collagen-impregnated AlboGraft Vascular Graft double container is wrapped in its own laminated bag. This bag is designed to protect the graft during storage and should be opened only immediately prior to use.*

The external packaging is color coded to identify the fabric characteristics and collagen impregnation of the model contained inside.

Sterility and Resterilization

AlboGraft prostheses are ethylene oxide sterilized by the manufacturer and supplied sterile to the operator. Sterility is guaranteed on the intact package and within the expiration date (use before) printed on the packaging. Collagen-impregnated grafts must never be resterilized.

NEVER CLEAN OR RESTERILIZE CONTAMINATED GRAFTS.

Indications

The AlboGraft Double Velour Knitted and Woven Grafts are indicated for use in the replacement or repair of abdominal and thoracic arteries affected with aneurismal or occlusive disease.

Instruction For Use

Choice and Preparation of the Graft

Choose the graft type and size best suited to the vascular section to be replaced or supplied through a bypass. Carefully examine the double packaging enclosing the selected graft to verify its integrity, the absence of holes, cuts or perforations, and the expiration date. The sterility of the graft is guaranteed only if the container is perfectly intact. Make sure that the period of sterility has not expired, otherwise the sterility of the graft is not guaranteed. Make sure that the information on the labels relative to the model, type, size, and lot number is correct. If it is not, do not use the graft. Pull off the sealing label of the external container and bring the internal container into the sterile environment.

CAUTION: *do not bring the external container into the sterile environment.*

Remove the graft using an aseptic procedure.

Preparation Vascular Grafts

The collagen impregnated vascular grafts can be used as supplied or after immersing it in a sterile saline solution just before implantation, to make them flexible and easy to handle. During the preparation and the operation, care should be taken not to crush or excessively expand the graft. Correct handling helps avoid the risk of damaging the collagen impregnation on the graft walls.

Surgical Technique

Considering how complex a surgical implantation of vascular grafts is and how many factors can influence the patient's condition, it is left to the surgeon to define suture technique and graft type as well as the therapy to adopt before, during and after the operation.

The following precautions should, however, be considered:

- for suturing, cylindrical needles are recommended; although taper cut or other cutting needles are not contraindicated.
- for cutting the graft, especially the woven graft, ophthalmic cautery is recommended to avoid fraying.
- should the surgical technique require the graft to be clamped, atraumatic clamps (preferably with a piece of soft, or lined jaws) should be applied with the minimum force necessary.

Precautions and Warnings

- 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 it 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.
- Ophthalmic cautery is recommended for cutting the woven graft.
- 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.

Conservation and Storage

The grafts must be kept in their original packaging until used. They must be kept in a dustfree and dry environment and at a temperature between 0°C and 30°C.

Notices: Limited Product Warranty; Limitation of Remedies




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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

English	Symbol Legend		Rx only			D	L	D ²⁰⁰
		Distributed By	Caution: Federal USA law restricts this device to sale by or on the order of a physician.	Do Not Use if Package is Opened or Damaged	Water Permeability	Diameter	Length	Diameter of prosthesis under pressure

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