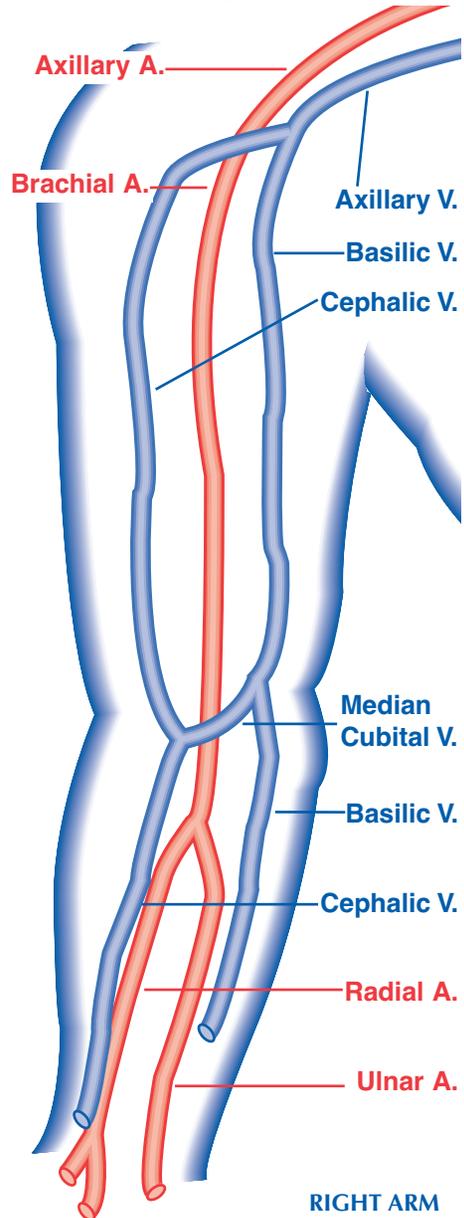


Artegraft Collagen Vascular Graft



Patient ID _____

Surgeon _____

Date _____

Product Code _____

Lot Number _____

DOSAGE AND ADMINISTRATION Cont'd

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 inserted into the patient. 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. Precise anastomosis without tension, bulging or twisting is mandatory.

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.

If troublesome bleeding does occur, it may readily be controlled by simply applying a small bit of Artegraft as a patch to the bleeding area in a reverse manner so that the adventitia is in direct contact with adventitia.

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.



Contents Sterile. Sterile LC: Device Sterilized Using Liquid Chemical Sterilant, compliant to EN/ISO 14160



Do Not Resterilize



Do Not Reuse

Rx only

HOW SUPPLIED

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.

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

Product Code	Description	
	Inner Diameter	Minimum Length
AG 535	4 mm	35 cm
AG 540	4 mm	40 cm
AG 616	5 mm	15 cm
AG 630	5 mm	30 cm
AG 636	5 mm	35 cm
AG 640	5 mm	40 cm
AG 645	5 mm	45 cm
AG 715	6 mm	15 cm
AG 730	6 mm	30 cm
AG 735	6 mm	35 cm
AG 740	6 mm	40 cm
AG 745	6 mm	45 cm
AG 750	6 mm	50 cm
AG 830	7mm	30 cm
AG 840	7 mm	40 cm
AG 845	7 mm	45 cm
AG 1015	8 mm	15 cm
AG 1030	8 mm	30 cm

Artegraft, Inc.

North Brunswick, NJ, U.S.A. 08902
800-631-5264 • 732-422-8333

Artegraft® is a registered trademark and Collagen Vascular Graft, Bovine Graft, Bovine Carotid Artery Graft, Arterial Conduit in a Bottle and BCA Graft are trademarks of Artegraft, Inc.

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LS 012 Rev. Q www.bovinegraft.com

Artegraft®

Collagen Vascular Graft™ Bovine Carotid Artery Graft™ (BCA) Arterial Conduit in a Bottle™

Artegraft is of biological 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.

Not Made with Natural Rubber Latex

Non - Antigenic

Preparation for Implant



1. Fill basin with 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. Irrigate 7 to 8 times with bulb or piston syringe.



6. Final rinse of graft and lumen in a suggested ratio of 120ml sterile saline solution with 2500 units of heparin. See PRECAUTIONS

7. Artegraft is manometry pressure tested and quality inspected. Before implanting, occlude one end of graft and pressure test with syringe filled with saline solution.

DESCRIPTION

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.

ACTIONS

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

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.
2. Once the package seal is broken, the graft should be used immediately. Any left-over material should be discarded.
3. The graft should not be used after the expiration date imprinted on the label.

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 carry-over of preserving fluid. For aseptic removal and wash procedures, please see DOSAGE AND ADMINISTRATION 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.

PRECAUTIONS

1. In the event of early occlusion, re-exploration of the graft and removal of the thrombus with a Fogarty 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.

2. 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.

3. During implantation, meticulous technique is essential to avoid twisting and to achieve accurate approximation at the suture lines.

4. 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 ADVERSE REACTIONS Section.

ADVERSE REACTIONS

Pseudointima formation and less frequently pseudodiaphragm formation may occur. Disruption of anastomoses, especially in the presence of infection, has been observed and, in a few cases, transient low grade fever, the etiology, of which has not been obvious, has been experienced. In humans, immunologically-mediated rejection of the Artegraft has not been demonstrated.

True aneurysms have been reported. In view of this, patients with implanted Artegrafts should be observed so that appropriate action can be taken if an aneurysm should occur. This adverse reaction should also be considered when treating conditions in which extended periods of implantation are expected.

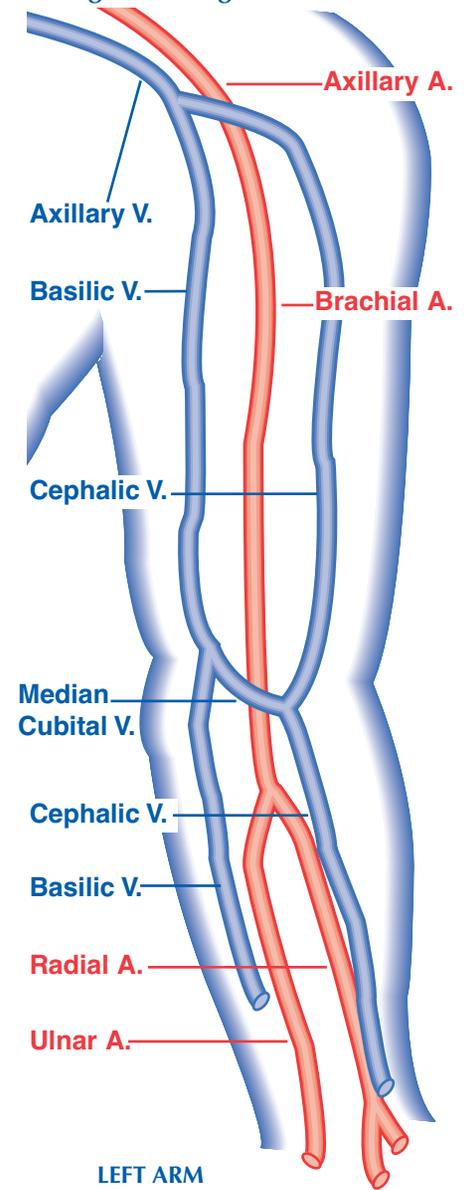
The complications encountered when the Artegraft is used as an A-V shunt for dialysis include thrombosis, infection, aneurysm, and bleeding and/or hematoma. The true incidence of these will vary depending upon the frequency with which the graft is needle-punctured, the length of time the graft has been implanted and, very importantly, the condition of the patient, since the graft is recommended for use when more conventional measures prove inadequate. Less frequent complications include "steal syndrome" and, in patients with heart disease, a significant incidence of high output congestive heart failure secondary to an arteriovenous shunt.

DOSAGE AND ADMINISTRATION

To remove the Artegraft aseptically from its container, the container should be held in a semi-upright position. 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. As soon as the graft itself becomes accessible, it should be grasped and removed from the container with the support rod, care being taken not to touch the outside rim of the container.

The surgeon should immerse the graft in a large basin of sterile 0.9% sodium chloride solution and, using a syringe, irrigate the graft's lumen at least seven or eight times with sterile 0.9% sodium chloride solution. A final irrigation and immersion should be performed in a suggested ratio of 120ml sterile saline solution with 2500 units of heparin, unless HIT is diagnosed (see PRECAUTIONS). The graft is now considered ready for insertion into a patient.

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