



Instructions For Use



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Device Tracking Labels

Please complete and return Atrium's Patient Registration/Implant Tracking Report provided. The enclosed Device Tracking Labels should be attached to the patient/hospital records.

Description

The iVena Vascular Patch is constructed from expanded polytetrafluoroethylene. All iVena Vascular Patches are supplied sterile and non-pyrogenic unless the package is opened or damaged. This is a single use device.

Indications For Use

The iVena Vascular Patch is indicated for use in the repair and closure of the vascular system.

Contraindications

The iVena Vascular Patch is not indicated for:

- Reconstruction of hernias and tissue deficiencies.
- Reconstruction and repair of passive biological membranes such as dura mater, pericardium, or peritoneum.

Use of this prosthesis in nonvascular applications can cause potentially serious complications, such as suture pull out, failure of closure or repair, or undesired healing to surrounding tissues.

Warnings

1. The iVena Vascular Patch is not elastic. Care must be taken to cut the patches sufficiently large enough to eliminate anastomotic stresses.
2. Do not resterilize the iVena Vascular Patch using radiation.

Precautions

1. Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
2. Do not prewet the iVena Vascular Patch by exposure to organic solvents such as alcohol or force aqueous solutions through the material as the hydrophobic properties of the material may be effected, which may result in excessive serum leakage and/or perigraft seroma formation.
3. Do not subject the patch to excessive manipulation or pressure, which would force fluid or blood through the patch wall.
4. Do not use absorbable sutures.
5. Do not use less than a 1mm suture bite in peripheral vascular applications.
6. Do not suture two patches together to make a larger patch.
7. Do not contaminate or damage the patch.
8. Do not patch in areas that may be subject to repeated punctures.
9. Do not expose the patch to either an open flame or to a laser without first providing adequate ventilation since highly toxic decomposition products will be produced at temperatures above 752°F (400°C).

Adverse Reactions

Possible complications with the use of any vascular patch include, but are not limited to: infection, thrombus formation, anastomotic blood leakage, peripatch seroma formation, pseudoaneurysm formation, and hematomas.

Sizing:

Proper sizing of patches is critical for closure or repair. The iVena Vascular Patch is provided in a variety of sizes to minimize cutting of the patch. Cutting the patch too small increases the tension on the suture line which may result in elongated suture holes, thus causing increased suture line bleeding. Never suture two patches together to form a larger

patch. This is not an accepted design criteria of the iVena Vascular Patch and may result in an inadequate repair or closure.

Suturing

Use only a non-cutting tapered needle with a non-absorbable monofilament suture approximately the same size as the needle. Follow the curve of the needle to minimize suture hole elongation and bleeding from suture holes. Application of a topical hemostatic agent will aid in controlling any bleeding that may occur. The manufacturer's instructions for these products should be followed.

When placing a suture, avoid excessive tension on the suture line and incorporate sufficient material in the stitch. Use a minimum 1mm suture bite for peripheral vascular applications.

Resterilization

Should the original sterile package be inadvertently opened or damaged prior to use, iVena vascular patches may be resterilized using either validated steam or ETO sterilization methods, up to a maximum of one (1) time. Suitable lot number traceability must accompany the product through all phases of handling, repackaging, and sterilization. Do not resterilize or reuse any vascular patch that has been in contact or contaminated by blood or other substances. Avoid placing heavy or sharp objects on or in direct contact with the patch material during any part of handling, repackaging, and/or sterilization process. iVena Vascular Patches should never be exposed to temperatures greater than 482°F (250°C). Sterility and fitness of resterilized product will be the sole responsibility of the hospital. Sterilization recommendations provide no assurance for the sterility of the resterilized product and serve only as a guide. Do not resterilize this patch using radiation sterilization techniques.

Steam Sterilization

If an iVena Vascular Patch must be resterilized, place it in a separate container suitable for use with steam sterilization. No part of the original package should be in direct contact with the patch during steam sterilization. For gravity displacement and/or prevacuum (flash) steam sterilizers, autoclave at or above the minimum temperature requirements of 270°F (132°C) for 4 minutes at 30 PSI (2 Kg/cm²).

Ethylene Oxide (ETO) Gas Sterilization

Place the iVena Vascular Patch in a container or package suitable for use with ETO sterilization. Selection of a specific, validated, ETO sterilization cycle and aeration requirements are the responsibility of the hospital. After ETO sterilization, it is essential that the iVena Vascular Patch be adequately aerated prior to use either by an ambient shelf method or mechanical aeration.

SYMBOLS USED ON PRODUCT LABELS

REF CODE NUMBER **LOT** LOT NUMBER **DIM** DIMENSIONS

STERIL **EO** STERILE. STERILIZED BY ETHYLENE OXIDE.

! SEE PACKAGE INSERT **⊘** SINGLE USE ONLY

Rx ONLY Prescription Only **⌚** EXPIRATION DATE

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