AZIYO®
BIOLOGICS

# VasCure™

FOR

## Vascular Repair

## Instructions for Use

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### Indications for Use
VasCure™ for Vascular Repair is indicated for use as a patch material for repair and reconstruction of peripheral vasculature including the carotid, renal, iliac, femoral, and tibial blood vessels. VasCure for Vascular Repair may be used for patch closure of vessels, as a pledget, or for suture line buttressing when repairing peripheral vessels.

**Caution: Federal (U.S.) law restricts this device to sale by or on the order of a physician.**

**Contents**: One (1) sterile, non-pyrogenic VasCure for Vascular Repair

### Product Description
VasCure for Vascular Repair acts as a decellularized scaffold for use as a vascular patch to repair the peripheral vessels. The extracellular matrix (ECM) scaffold is a biomaterial derived from porcine small intestinal submucosa (SIS). The SIS is developed from a select layer of tissue that is recovered from porcine small intestine. The decellularized ECM scaffold allows the patient's own cells to migrate and attach within the ECM to naturally repair the tissue defect. VasCure for Vascular Repair is MR (Magnetic Resonance) Safe in that it poses no known hazards in MR environments.

### How Supplied
VasCure for Vascular Repair is supplied **STERILE**. Provided that the integrity of the sterile pouch is not compromised in any way, it serves as an effective sterile barrier until the "Use By" (expiration) date printed on the pouch.

### Contraindications
VasCure for Vascular Repair is derived from a porcine source and should not be used in patients with a known sensitivity to porcine material.

### Warnings and Precautions
- For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization will compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.
- Discard all open or unused portions of VasCure.
- Device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- The device must be used prior to the expiration date.
- Discard device if mishandling has caused possible damage or contamination.
- Always handle the device using aseptic technique.
- Ensure that the device is hydrated prior to suturing. Without proper hydration, VasCure may tear and not retain sutures. Additionally, excessive hydration may result in delamination. If delamination is observed, do not use VasCure.
- Device is not recommended to be used with glue containing glutaraldehyde.
- Device must be sutured to viable native tissue and must not be sutured to homografts, synthetic or chemically cross-linked materials.
- Device is not recommended to be used with platelet gel.
- Device is not recommended to be used with resorbable suture material.
- Once hydrated, VasCure should either be used or discarded. VasCure should not be rehydrated.
- If surgical intervention such as vessel cannulation is required after implantation of VasCure, caution should be exercised not to damage the implanted VasCure.

### Potential Complications
The following complications are possible. If any of these conditions occur, the VasCure should be removed.

- Acute or chronic inflammation (Initial application of the VasCure may be associated with transient, mild, localized inflammation.)
- Allergic reaction
- Aneurysm
- Bleeding
- Calcification
- Embolization of VasCure
- Fever
- Hematoma
- Infection
- Migration of VasCure
- Patch dehiscence / rupture (deterioration)
- Pseudoaneurysm
- Reformation of defect
- Stenosis
- Thromboembolism
- Thrombosis formation
- Vessel occlusion
- Undesired tissue remodeling (e.g., poor tissue integration, excessive scar tissue formation, or rapid degradation of VasCure)

### Storage
This device should be stored in a clean, dry location at 10°C-30°C.

### Sterilization
This device has been sterilized with ethylene oxide gas.

### Required Materials
- A sterile dish (kidney dish or other bowl)
- Sterile forceps
- Hydration fluid: At least 50mL of room temperature sterile water, sterile saline or sterile lactated Ringer's solution

### Suggested Instructions for Using VasCure for Vascular Repair
These recommendations are designed to serve only as a general guideline. They are not intended to supersede institutional protocols or professional clinical judgment concerning patient care.

1. Using aseptic technique, remove the inner pouch from the outer pouch, and place the inner pouch containing VasCure into the sterile field.
2. Open the inner pouch carefully, and aseptically remove VasCure with sterile forceps.
3. Hydrate VasCure by placing it in a bowl of sterile saline or other sterile isotonic solution for approximately 1-2 minutes prior to use. Use at least 50mL of the sterile solution for hydration. It is recommended that VasCure not be excessively handled or manipulated prior to use.
4. Prepare the tissue deficiency/defect or treatment area using standard methods.
5. If required, VasCure can be cut to the appropriate size, using aseptic technique, in order to adequately cover the tissue deficiency/defect or treatment area. If delamination is observed, do not implant VasCure.
6. Place the edge of VasCure in contact with viable tissue. To ensure adequate remodeling, it is important that VasCure is sewn to viable tissue.
7. Suture VasCure to the area of treatment or tissue deficiency/defect. A non-absorbable monofilament suture is preferred.
8. Complete the standard surgical procedure.
9. Discard any unused portions of VasCure.

### Return Goods Policy
For information on product returns and return authorization, contact Aziyo Biologics by calling +1 470-514-4080. All products returned to Aziyo Biologics must be accompanied by a Return Goods Authorization Number.

### Medical Device Reporting
Any potential adverse incident involving Aziyo Biologics products should be reported immediately by calling +1 470-514-4080.

### Symbols and Their Explanations

| | |
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| | Use By |
| | Consult Instructions for Use |
| REF | Catalog Number |
| LOT | Lot Number |
| 10° 30° | Store at 10° C - 30° C |
| STERILE EO | Sterilized using Ethylene Oxide |
| | Do Not Reuse |
| | Manufacturer |
| MR | MR Safe |
| 2 | Do Not Resterilize |
| | Do Not Use if the Package is Damaged or Open |
| | Non-pyrogenic |
| | Contents |