AZIYO®
BIOLOGICS

VasCure™

FOR

Vascular Repair

Instructions for Use

Manufacturer:
Aziyo Biologics, Inc.
1100 Old Ellis Road, Suite 1200
Roswell, GA 30076 USA
Phone: +1 470-514-4080
Fax: +1 678-680-5486
www.aziyo.com

Indications for Use

DVXUH IRUDVFXODUHSDLUVLQGLFDWHGIRUXVHDVDSDWFKPDWHULDOWRUHSDLU UHFRQVWUXFWRUHSODFHSLSKYDOXODUODWHUDOWRDQGRUDQWHULRUDDQG WLEEDORRGHVVHOVDVXUHIRUDVFXODUHSDLUPDEHXVHGEHWZHHQORZEH YHVVHOVDVGHHGJHRWIRUVXWXUHOHVLQZKHUHSHUILLSKHUDOVHOV

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

Contents

QHZWHULOHQRQSURJHQLFDVXUHIRUDVFXODUHSDLU

Product Description

DVXUHIRU DVFXODUHSDLU is 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 URLH HLHULRIHVHULH SRF LVR FRPSURPLVH L VHUHVV HIIHFLHVHULEUULHU H V H 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

-
- VasCure.
-
-
-
-
- VasCure may tear and not retain sutures. Additionally, excessive hydration may result in delamination. If delamination is observed, do not use VasCure.
-
-
-
-
- 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

KH IROORZLQJ FRPSOLFDWLRQV DUH SRVVLEOH DQG RI WKHVH FRQGLWLRQV RFFXU should be removed.

- Acute or chronic inflammation (Initial application of the VasCure may be associated with transient, mild, localized inflammation.)
-
- neurysm
-
- Calcification
- VasCure
- Fever
- Hematoma
- Infection
- Migration of VasCure
- / rupture (deteriorati
-
- Reformation of defect
- Stenosis
- Thromboembolism
- formation
- Vessel occlusion
- Undesired tissue remodeling (e.g., poor tissue integration, excessive scar tissue formation, or rapid degradation of VasCure)

Storage

KLVGHYLFHVKRXOGEHVWRUHGLQDFOHDQGUORFDWLRQDW

Sterilization

KLVGHYLFHKDVEHHQVWHULOLHGZLWKHWKOHQHRLGHJDV

Required Materials

-
-
- 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

. Using aseptic techni ue, 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.
. Discard any unused portions of VasCure.

Return Goods Policy

RULQIRUPDWLRQRQSURGXFWUHWXUQGUHWXUQDXWKRUL+1 470-514-4080. All products returned to Aziyo Biologics must be accompanied by a Return Goods Authorization Number.

Medical Device Reporting

Q SRWHQWLDO DGYHUVH LQFLGHQW products should be reported immediately by calling +1 470-514-4080.

Symbols and Their Explanations

	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
2 STERILIZE	RRHVHULLH
	RRVHLHHENHLVPHRUSH
	RSURHLF
	RHV

Aziyo® is a registered trademark of Aziyo Biologics, Inc.
© 2018 Aziyo Biologics, Inc. All rights reserved.