Xenograft Implant (XI-S+®)

INSTRUCTIONS FOR HANDLING AND USE

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

DESCRIPTION

Colorado Therapeutics® Xenograft Implant is a sterile implant consisting of porcine pericardium. It is glutaraldehyde cross-linked, sterilized by ethylene oxide (EO) and packaged dry with no rehydration required. The Colorado Therapeutics proprietary process produces a uniquely thin and dry xenograft implant that provides the suitable strength and biocompatibility for a soft tissue repair implant.

STORAGE

The Xenograft Implant should be stored at room temperature. Store unopened implants at 2°C-40°C (35.6°F-104°F) and away from direct heat sources. Avoid prolonged exposure to elevated temperatures. The expiration date for the Xenograft Implant is recorded on the device envelope and the outer Tyvek pouch label. The dispensing service and or end user must maintain the tissue under appropriate storage conditions. Do not use the tissue past the date of expiration indicated on the device packaging. Each implant has been sterilized by EO and should not be resterilized.

INDICATIONS FOR USE

The Colorado Therapeutics Xenograft Implant (XI-S+®) is intended to be used for implantation to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes.

CONTRAINDICATIONS

- Known hypersensitivity to Collagen
- Known hypersensitivity to Porcine

WARNINGS/ PRECAUTIONS

- Do not use to bridge discrete hernia defect.
- After use, unused product and packaging may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice.
- Use of this device in a contaminated or infected field has not been tested.
- The Xenograft Implant is for single-patient use only and is to be implanted surgically. If the outer Tyvek pouch has been perforated or torn in shipment or storage, then the enclosed Xenograft Implant should not be used.
- Use in pregnancy has not been established.
- Use of the Xenograft Implant in patients undergoing radiotherapy has not been established.
- Proper surgical procedures and techniques must be followed. As with any surgery, infections and other complications not related to the implant itself may result. It is important that the highest level of aseptic care be used when handling and preparing the Xenograft Implant. If infection is diagnosed, frequent monitoring of the surgical site and appropriate use of antibiotics is advised.

PREPARING THE XENOGRAFT IMPLANT FOR SURGICAL USE

Do not use the Xenograft Implant if either the outer or inner pouch is punctured, torn or not intact, or if the device is visibly damaged or compromised.

Optional Materials - SURGEON'S DISCRETION

- One sterile basin per Xenograft Implant.
- A solution of at least 100ml sterile normal saline or sterile lactated Ringer's solution.
- Sterile non-toothed forceps.

Preparing the Xenograft Implant

- Each packaging envelope contains one (1) Xenograft Implant and Instructions for Use.
- Open the outer envelope and remove Tyvek pouch.
- Using aseptic technique, remove the Xenograft Implant inner pouch from its outer pouch, and place the inner pouch in the sterile field.
- Retain the outer pouch until the peel-off labels have been placed on the patient records and data card.
- Carefully open the inner pouch and aseptically remove the Xenograft Implant.
- No rinsing or rehydration of the Xenograft Implant is required prior to use.
- The Xenograft Implant may be aseptically trimmed to the required dimensions.

IMPLANTATION AND SUTURING

- When handling the Xenograft Implant use sterile, powder-free gloves or non-toothed forceps to remove the tissue from the pouch or basin.
- The Xenograft Implant may be cut to fill the tissue space and shaped to whatever contour is required.
- The Xenograft Implant should be anchored or sutured into place. Being a strong material, it will take and hold anchors and sutures firmly, and will remain in-situ while it is incorporated into the surrounding tissue.
- Adequate overlap is recommended to ensure sufficient margins for incorporation.
- The Xenograft Implant has been packaged with the tissue orientation as rough side up, smooth side down.

SYMBOL IDENTIFICATION KEY

Rx only	CAUTION: Federal (U.S.A.) Law restricts this device to sale by or on the order of a physician.
	Do not reuse
	Caution
STERILE EO	Sterilized by Ethylene Oxide
	Non-pyrogenic
	Do not resterilize
	Do not use if packaging is opened or damaged
	Temperature Limitations
REF	Catalog number
LOT	Lot number / Batch code
	Use by date
	Manufacturer

Colorado Therapeutics®
www.co-therapeutics.com

Colorado Therapeutics LLC
486 South Pierce Avenue Suite A
Louisville, CO 80027 USA
Phone: 1 (877) 290-0045 [toll free]
1 (303) 469-9459
E-mail: info@co-therapeutics.com