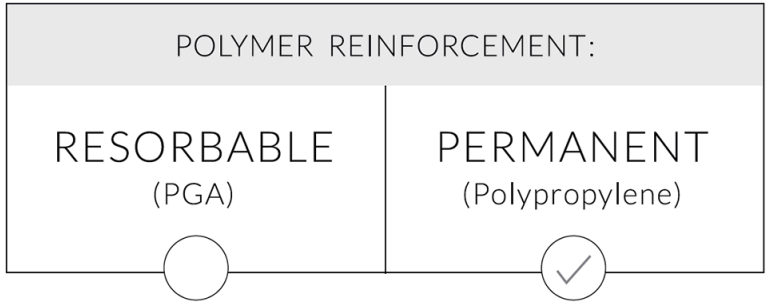
OVITEX® PRS
RESTELLA™



TELA BIO® INC
SURGICAL RECONSTRUCTION COMPANY

OviTex® PRS - Restella™

Permanent Polymer

INSTRUCTIONS FOR USE

DESCRIPTION

OviTex PRS - Restella Permanent ("Restella") is a sterile reconstructive bioscaffold composed of ovine (sheep) derived extracellular matrix (ECM) and monofilament polypropylene. Restella contains fenestrations and holes to facilitate fluid management and cellular repopulation and will incorporate into the recipient tissue with associated cellular and microvascular ingrowth. Restella is provided in arced rectangle, contour, and oval shapes in various sizes to suit surgeon preference and nature of the soft tissue repair in plastic and reconstructive surgery. The device may be trimmed to a desired shape to further accommodate an individual patient's requirements.

INDICATIONS FOR USE

Restella is for implantation to reinforce soft tissue where weakness exists in patients requiring soft tissue repair or reinforcement in plastic and reconstructive surgery. The device is supplied sterile and is intended for one-time use.

CONTRAINDICATIONS

- Do not use Restella in patients with a known sensitivity to materials of ovine (sheep) origin. Use of Restella in this patient population may result in an allergic or immunological reaction.
- Restella is not intended for high load applications (e.g. bridging hernias, etc.)

WARNINGS AND PRECAUTIONS

CAUTION: For Prescription Use Only. Federal law restricts this device to sale by or on order of a physician.

- Single use only. Reuse, resterilization, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device, which may result in device failure and/or patient injury. Open and unused material should be discarded.
- Restella is supplied sterile. Inspect the packaging to ensure it is intact and undamaged prior to use. Do not use the Restella device, and discard prior to use if the packaging is damaged.
- Do not use the product past its expiration date. The expiration date is displayed on the product labeling as the year (4 digits), month (2 digits), and day (2 digits) next to an hourglass symbol.
- Restella has not been tested in breast surgical procedures.
- Place the device in maximum contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.

POTENTIAL COMPLICATIONS

Possible adverse events with the use of a soft tissue reinforcement device or any soft tissue reinforcement surgical procedure may include: additional intervention including surgery, adhesions, allergic reaction, bowel obstruction or perforation, bleeding, bruising, defect recurrence, dysphagia, erosion or extrusion, exposure or protrusion, fever, fistula, GERD, recurrence, infection, irritation or inflammation, pain, seroma or hematoma, swelling, and wound dehiscence.

STERILIZATION

The device has been sterilized with ethylene oxide.

STORAGE

Restella should be stored in a clean, dry location at room temperature (25 °C/77 °F).

MRI SAFETY INFORMATION

Restella is MR Safe.

INSTRUCTIONS

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. Inspect the packaging to ensure it is intact and undamaged.
2. Using aseptic technique, remove the inner pouch from its outer pouch and place the inner pouch in the sterile field.
3. Open the inner pouch carefully and aseptically remove the device using sterile forceps.
4. Place the device into a sterile dish in the sterile field.
5. Rehydrate the device in a sufficient volume of sterile saline or sterile Lactated Ringer's solution for a minimum of 5 minutes.
6. Prepare the site using standard surgical techniques.
7. Using sterile technique, trim and/or shape the device to fit the site, if necessary, providing an allowance for overlap.
8. Using sterile technique, transfer the device to the surgical site.
9. Orient the device considering that the device is more likely to stretch perpendicular to the direction of the slits.
10. Position the device to achieve maximum contact between the device and surrounding tissue. To facilitate cell migration and tissue ingrowth, an overlap of 3-5 cm with healthy well-vascularized tissue is suggested.
11. Suture, staple, or tack into place, avoiding excess tension. Ensure that the device is rehydrated prior to fixing. If suturing, it is recommended to use a 5 mm suture bite.
12. Minimize manipulation of the device during rehydration and implantation.
13. Ensure all layers of the device are secured when suturing, stapling, or tacking.
14. Complete the surgical procedure.
15. Discard any unused portions according to institutional guidelines for medical waste.

ISO 15223-1: 2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements		
5.4.2		Do not reuse
5.2.6		Do not re-sterilize
5.1.4		Use by / Expiration date (YYYY-MM-DD)
5.3.4		Keep dry
5.2.3	STERILE EO	Sterilized using ethylene oxide
5.3.7		Store at room temperature (25 °C/77 °F)
5.4.4		Caution, see instructions for use
5.1.1		Manufacturer
5.1.6	REF	Catalog number
5.1.5	LOT	Lot number
N/A	Rx Only	For Prescription Use Only

Distributed by:

TELA BIO INC
SURGICAL RECONSTRUCTION COMPANY

1 Great Valley Parkway, Suite 24
Malvern, PA 19355 USA
T (844) 835-2246
F (844) 455-8707
www.telabio.com

Aroa Biosurgery Ltd.
2 Kingsford Smith Place
Airport Oaks, Auckland 2022
New Zealand
Tel +6498693035
www.aroabio.com

Endoform® is a registered trademark of Aroa Biosurgery, Ltd.
TELA Bio and OviTex are registered trademarks of TELA Bio, Inc.