OVITEX® PRS

REINFORCED TISSUE MATRIX

POLYMER REINFORCEMENT
LONG-TERM RESORBABLE Poly(lactic-co-glycolic Acid)

STRETCH
BI-DIRECTIONAL

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AROA™ AROA ECM™

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SCIENCE. VALUE. INNOVATION.

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OviTex® PRS

Long-Term Resorbable Polymer

EN

INSTRUCTIONS FOR USE

DESCRIPTION OF THE PRODUCT

OviTex® PRS (Long-Term Resorbable) ("OviTex PRS") is a sterile reinforced tissue matrix composed of ovine (sheep) derived extracellular matrix (ECM) and a long-term resorbable polymer, Poly(lactic-co-glycolic Acid) (PLGA). OviTex PRS is permeable to facilitate fluid management and cellular repopulation and will incorporate into the recipient tissue with associated cellular and microvascular ingrowth. The device contains bi-directional fenestrations to allow for conformability at the surgical site. The long-term resorbable PLGA polymer imparts additional structure to the ECM and maintains device integrity through the initial phases of healing. OviTex PRS is provided in 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

OviTex PRS (Long-Term Resorbable) 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 OviTex PRS in patients with a known sensitivity to materials of ovine (sheep) origin. Use of OviTex PRS in this patient population may result in an allergic or immunological reaction.
- OviTex PRS 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.
- OviTex PRS is supplied sterile. Inspect the packaging to ensure it is intact and undamaged prior to use. Do not use the OviTex PRS 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.
- OviTex PRS 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.
- Do not pre-stretch the device before implantation. If stretched beyond the point of elasticity, the device will not return to its original shape upon implantation.
- OviTex PRS has not been evaluated for use in pediatric patient populations.

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

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

MRI SAFETY INFORMATION

OviTex PRS 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, peel open the outer pouch and transfer the sterile inner pouch to the sterile field.
3. Open the inner pouch carefully and aseptically remove the device.
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 surgical site using standard surgical technique.
7. Using sterile technique, trim and/or shape the device to fit the site, if necessary, providing an allowance for 3-5cm of overlap.
8. Using sterile technique, transfer the device to the surgical site.
9. 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.
10. Suture into place, avoiding excess tension. Ensure that the device is rehydrated prior to fixing. When suturing, it is recommended to use a 5 mm suture bite depth.
11. Minimize manipulation of the device during rehydration and implantation.
12. Ensure all layers of the device are secured when suturing.
13. Complete the surgical procedure.
14. Discard any unused portions according to institutional guidelines for medical waste.

SYMBOLS GLOSSARY

Symbols contained in ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements are indicated below.		
	5.1.1	Manufacturer
	5.1.4	Use by date/Expiration date
	5.1.5	Lot number
	5.1.6	Catalog number
	5.2.3	Sterilized using ethylene oxide
	5.2.6	Do not resterilize
	5.2.8	Do not use if packaging is damaged and consult instructions for use
	5.3.4	Keep dry
	5.4.2	Do not reuse
	5.4.3	Consult instructions for use
Rx Only	N/A	Prescription use only. Federal (USA) law restricts this device to sale by or on the order of a physician.