TELABIO®

OVITEX®

Reinforced Tissue Matrix

INGUINAL (IHR)

POLYMER REINFORCEMENT

LONG-TERM RESORBABLE

PLGA - Poly(lactic-co-glycolic acid)

Distributed by:

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OviTex® Inguinal

Long-Term Resorbable Polymer

INSTRUCTIONS FOR USE

DESCRIPTION OF THE PRODUCT

OviTex Inguinal Reinforced Tissue Matrix with Long-Term Resorbable Reinforcement (OviTex IHR) is a sterile surgical mesh. Devices are comprised of ovine (sheep) derived extracellular matrix (ECM) and a monofilament poly(lactic-co-glycolic) acid (PLGA) which comprises up to approximately 35 g/m^2 of the final product.

OviTex Inguinal will incorporate into the recipient tissue with associated cellular and microvascular ingrowth. The biologic ECM components provide a scaffold for cell repopulation and to aid during soft tissue repair.

The synthetic component provides additional strength to the implant during the repair process to adequately off-load tissues during healing.

The use of surgical mesh as part of hernia repair has been shown to decrease hernia recurrence rates compared to repairs without the use of surgical mesh.

The device consists of two textured sides which provide surfaces conducive for tissue ingrowth. OviTex Inguinal is not recommended for use with visceral exposure.

OviTex Inguinal is available in various shapes and sizes to suit surgeon preference and the complexity of the soft tissue repair.

OviTex Inguinal may be trimmed to a desired shape to further accommodate an individual patient's requirements.

INDICATIONS FOR USE

OviTex Inguinal is intended for use as a surgical mesh to reinforce and/or repair soft tissue where weakness exists. Indications for use include the repair of inguinal hernias that require the use of reinforcing material to obtain the desired surgical outcome.

CONTRAINDICATIONS

Do not use OviTex Inguinal in patients with a known sensitivity to materials of ovine (sheep) origin. Use of OviTex Inguinal in this patient population may result in an allergic or immunological reaction.

RISK STATEMENTS

WARNINGS

- The device is terminally sterilized using ethylene oxide. Inspect the sterile packaging to ensure it is intact and undamaged prior to use. Do not use OviTex Inguinal, and discard prior to use if the packaging is damaged. Do not re-sterilize.
- 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.
- Discard device if mishandling has caused possible damage or contamination. Open and unused material should be discarded.
- OviTex Inguinal has not been evaluated for use in pediatric populations.

PRECAUTIONS

- The device should not be used in patients with a known sensitivity to poly(lactic-co-glycolic) acid material (PLGA).
- 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.
- Place the device in maximum contact with healthy, well-vascularized tissue to promote cell ingrowth and tissue remodeling.
- Surgical conditions such as contamination or the presence of stomach or bowel contents may impact device performance and/or cause breakdown of the biologic portion of the device.

POTENTIAL COMPLICATIONS

The following adverse events have been reported for surgical repair of hernias (with or without a surgical mesh): pain, infection, dysphagia, hernia recurrence, dehiscence, abscess, adhesion, bowel obstruction, bleeding, fistula, seroma, perforation, mesh migration, and mesh contraction.

MRI SAFETY INFORMATION

OviTex Inguinal is MR Safe.

HOW SUPPLIED

OviTex Inguinal is packaged in a Tyvek/film double pouch configuration.

LATEX INFORMATION

OviTex Inguinal is not made with natural rubber latex.

STORAGE

OviTex Inguinal should be stored at room temperature in a clean and dry area.

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 sterile 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 aseptically.
4. Rehydrate the device in a sufficient volume of sterile saline or sterile Lactated Ringer's solution for a minimum of 5 minutes.
5. Prepare the site using standard surgical techniques.
6. Using aseptic technique, trim the device to fit the site, if necessary, providing an allowance for overlap. 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.

   Note: If the device is too small for the defect, excess tension may be placed on the suture line. This can result in recurrence of the original tissue defect or development of a defect in the adjacent tissue.
7. Using aseptic technique, transfer the device to the surgical site and suture, staple, or tack into place, avoiding excess tension.
8. Complete the surgical procedure.
9. Discard any unused portions according to institutional guidelines for medical waste.

MINIMALLY INVASIVE USE

1. It is recommended to roll the device for minimally invasive use.
2. Using preferred technique, deploy the device through the trocar without using excessive force. If the device does not easily pass down through the trocar, retry with the next available sized trocar.

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
	5.1.3	Date of manufacture
	5.1.4	Use by/Expiration date
	5.1.5	Lot number
	5.1.6	Catalog number
	5.1.8	Importer
	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
	5.2.12	Double sterile barrier system
	5.3.4	Keep dry
	5.4.2	Do not reuse
eifu.aroa.com	5.4.3	Consult electronic instructions for use
	5.4.8	Contains biological material of animal origin
	5.7.7	Medical Device
	-	Number of units
Rx Only	-	Prescription Only. Caution: Federal (USA) law restricts this device to sale by or on the order of a physician