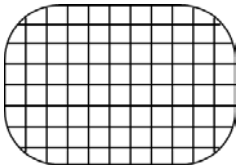
OviTex™ 1S Reinforced BioScaffold

Permanent Polymer

INSTRUCTIONS FOR USE

DESCRIPTION

OviTex™ 1S Reinforced BioScaffold with Permanent Polymer (OviTex 1S) is a sterile bioscaffold composed of ovine (sheep) derived extracellular matrix (ECM) and monofilament polypropylene colored with ([phathalocyaninato(2-)] copper). The device consists of two sides: a textured and smooth side. The textured side of the device, indicated with blue polypropylene, provides a surface conducive for tissue ingrowth. The smooth side of the device, containing clear polypropylene, provides a surface designed to minimize tissue attachment. OviTex 1S will incorporate into the recipient tissue with associated cellular and microvascular ingrowth.



Textured side

Smooth side

OviTex 1S is provided in various shapes and sizes to suit surgeon preference and the complexity of the soft tissue repair. The device may be trimmed to a desired shape to further accommodate an individual patient's requirements.

INDICATIONS FOR USE

OviTex 1S 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 hernias and/or abdominal wall defects that require the use of reinforcing or bridging material to obtain the desired surgical outcome.

CONTRAINDICATIONS

Do not use OviTex 1S in patients with a known sensitivity to materials of ovine (sheep) origin. Use of OviTex 1S in this patient population may result in an allergic or immunological reaction.

WARNINGS

- Device is supplied sterile. Inspect the packaging to ensure it is intact and undamaged prior to use.
- 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.

PRECAUTIONS

- 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.

ADVERSE EVENTS

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

MRI SAFETY INFORMATION

OviTex 1S has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of OviTex 1S in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

HOW SUPPLIED

OviTex 1S is packaged in a Tyvek/film double pouch configuration.

STORAGE

OviTex 1S should be stored in a clean, dry location at room temperature (25 °C/77 °F).

CAUTION

Federal law restricts this device to sale by or on the order of a physician.

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 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 cut 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.
8. Using aseptic technique, transfer the device to the surgical site and suture, staple, or tack into place, avoiding excess tension.
   Note: In circumstances where OviTex 1S may contact the viscera, it is recommended to place the smooth side of the product in contact with the viscera.
9. Complete the surgical procedure.
10. Discard any unused portions according to institutional guidelines for medical waste.

Symbols Glossary

All 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


Caution, see instructions for use. Ref.: 5.4.4


Do not reuse. Ref.: 5.4.2

Sterilized using ethylene oxide. Ref.: 5.2.3


Do not resterilize. Ref.: 5.2.6

Upper limit of temperature (25°C). Ref.: 5.3.6


Keep dry. Ref.: 5.3.4

Rx only Prescription use only


Manufacturer. Ref.: 5.1.1

Catalog number. Ref.: 5.1.6

Lot number. Ref.: 5.1.5


Use by/Expiration date. Ref.: 5.1.4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