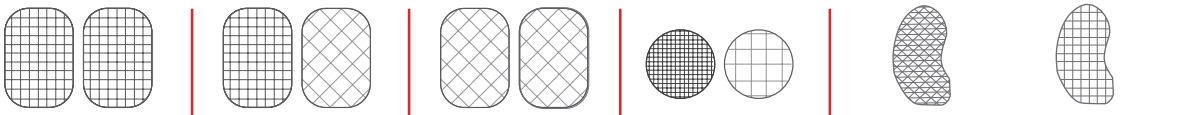
REFERENCE GUIDE

OVITEX®

Reinforced Tissue Matrix

OviTex Reinforced Tissue Matrix (RTM) is a next generation soft tissue repair platform that utilizes layers of ovine (sheep) rumen interwoven with just enough polymer suture for added strength. All OviTex RTM devices are designed to leverage a patient's natural healing response, facilitate tissue remodeling, optimize strength, and minimize the foreign body footprint of synthetic polymer.

OVITEX PORTFOLIO OVERVIEW



	OviTex Core	OviTex 1S	OviTex 2S	OviTex Low Profile (LPR)	OviTex Inguinal (IHR)	
LAYERS OF TISSUE MATRIX	4	6	8	4	3†	4
TEXTURED SIDE PATTERN	6 mm Grid	6 mm Grid	N/A	3 mm Grid	4 mm Triaxial Grid	6 mm Rectangular Grid
SMOOTH SIDE PATTERN	N/A	25 mm Grid	25 mm Grid	25 mm Grid	N/A	N/A
SUTURE TYPE	Permanent OR Short Term resorbable	Permanent OR Short Term resorbable	Permanent OR Short Term resorbable	Permanent OR Short Term resorbable	Permanent	Permanent
SHAPES	Square / Rectangle	Square / Rectangle	Square / Rectangle	Circle / Ellipse	Anatomical	Anatomical
INTRA-ABDOMINAL PLACEMENT	✗	✓***	✓***	✓***	✗	✗
USE IN MIS PROCEDURES	✓	✓	✓	✓	✓	✓
USE WITH FIXATION	✓	✓	✓	✓	✓	✓
TRIMMABLE	✓	✓	✓	✓	✓	✓

†Not available in UK
*Permanent Reinforcement: All suture is 5-0 Polypropylene (PP) – blue and clear
**Short Term Resorbable: All suture is 6-0 multifilament Polyglycolic Acid (PGA) - clear only"
***Smooth side only against the viscera

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TIPS AND BEST PRACTICES

Hydration

Rehydrate the device in a sufficient volume of sterile saline or sterile Lactated Ringer's solution for ~5 minutes. It is also recommended to remove any excess fluid absorbed by the product during the hydration process, especially in laparoscopic/ robotic procedures to allow the device to be as thin as possible for trocar insertion.

Trimming

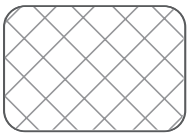
The polymer weave in OviTex products was developed specifically to allow for trimming. The lockstitch embroidery pattern minimizes unraveling when cut.

Fixation

When suturing OviTex products, it is recommended to use a CT-1 or smaller needle. Tackers have been used in laparoscopic procedures with OviTex. The following products have been tested by surgeons during our design validation process: Covidien ProTack™, Covidien AbsorbaTack™, and Bard SorbaFix™[1]. Tacking devices with a depth of 5mm or more are suitable for OviTex fixation. It is also recommended to use a few stay sutures in addition to the tacks for thorough fixation.

TROCAR COMPATIBILITY

For ease of insertion, it is recommended that OviTex products 1S, 2S and Low Profile be rolled along the shortest dimension with the smooth side facing out.



Use preferred rolling technique for passing OviTex through trocar assembly.

PRODUCT SIZE	TROCAR SIZE*				
	CORE	1S	2S	Low Profile	Inguinal
4 x 8 cm	5 mm	8 mm	8 mm	---	---
6 x 10 cm	5 mm	8 mm	10 mm	---	---
10 x 12 cm	8 mm	10 mm	10 mm	---	---
10 x 20 cm	8 mm	10 mm	10 mm	---	---
16 x 20 cm	10 mm	12 mm	15 mm	---	---
18 x 22 cm	10 mm	15 mm	15 mm	---	---
20 x 20 cm	10 mm	15 mm	15 mm	---	---
9 cm (Circle)	---	---	---	8 mm	---
12 cm (Circle)	---	---	---	10 mm	---
15 cm (Circle)	---	---	---	10 mm	---
12 x 18 cm (Ellipse)	---	---	---	10 mm	---
15x20 cm (Ellipse)	---	---	---	10 mm	---
15x25 cm (Ellipse)	---	---	---	10 mm	---
10x17 cm 3-layer (Anatomical)	---	---	---	---	8 mm
10x17 cm 4-layer (Anatomical)	---	---	---	---	8 mm

*Trocar size recommendations were developed using a 3.0 mm grasper.

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1. PD-VAL-0002-R

Indications and Important Safety Information: OviTex Reinforced Tissue Matrix 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. OviTex Inguinal (IHR) 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.

Caution: Federal (US) law restricts this device to sale by or on order of a physician. Do not use OviTex in patients known to be sensitive to materials of ovine (sheep) origin. Use of OviTex in this patient population may result in an allergic or immunological reaction. 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. For additional important safety information, please see the OviTex Instructions for Use. Healthcare professionals must use their own clinical judgment in evaluating appropriate treatment options for a particular patient. Treatment of a specific patient should be based on individual needs and the medical care deemed necessary by the patient's treating physician and institutional protocols. Always refer to the package insert, product label, and/or instructions for use before using any TELA Bio product. Products may not be available in all markets because product availability is subject to the regulatory and/or medical practices in individual markets. Please contact your TELA Bio representative if you have questions about TELA Bio products. TELA Bio, the TELA Bio logo, and OviTex are each registered trademarks of TELA Bio, Inc.

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