OVITEX®

REINFORCED TISSUE MATRIX

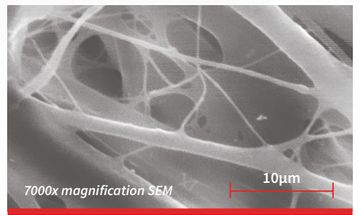
REINFORCED BIOLOGIC
FOR HERNIA REPAIR
AND ABDOMINAL WALL
RECONSTRUCTION

TELABIO®
SCIENCE. VALUE. INNOVATION.

OviTex® Reinforced Tissue Matrix

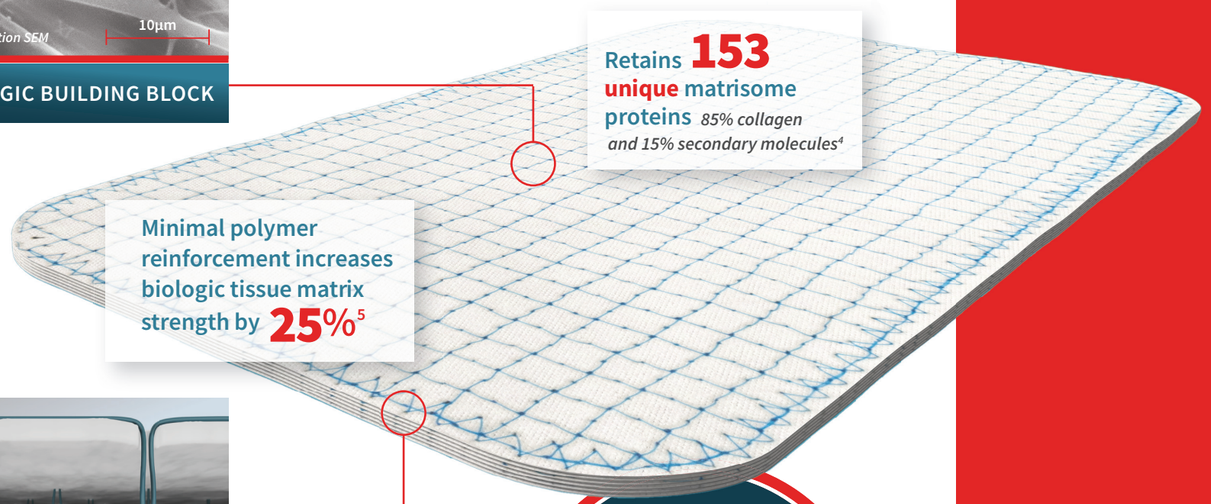
OviTex Reinforced Tissue Matrix (RTM) is a next generation soft tissue repair platform that utilizes layers of ovine (sheep) rumen interwoven with just enough polymer suture for added strength. This combination results in a very low polymer load (areal density) that is less than lightweight mesh. By having a low polymer load, OviTex effectively reduces the amount of plastic placed in the body.[1]*

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.



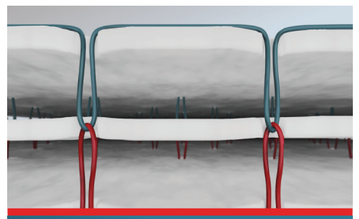
~95 BIOLOGIC BUILDING BLOCK

- Retains open-pore collagenous microarchitecture facilitating cellular infiltration[2]
- Facilitates angiogenesis[2]*
- Low elastin content[3]



Retains **153** **unique** matrisome proteins *85% collagen and 15% secondary molecules*[4]

Minimal polymer reinforcement increases biologic tissue matrix strength by **25%**[5]



~5% SUTURE REINFORCEMENT

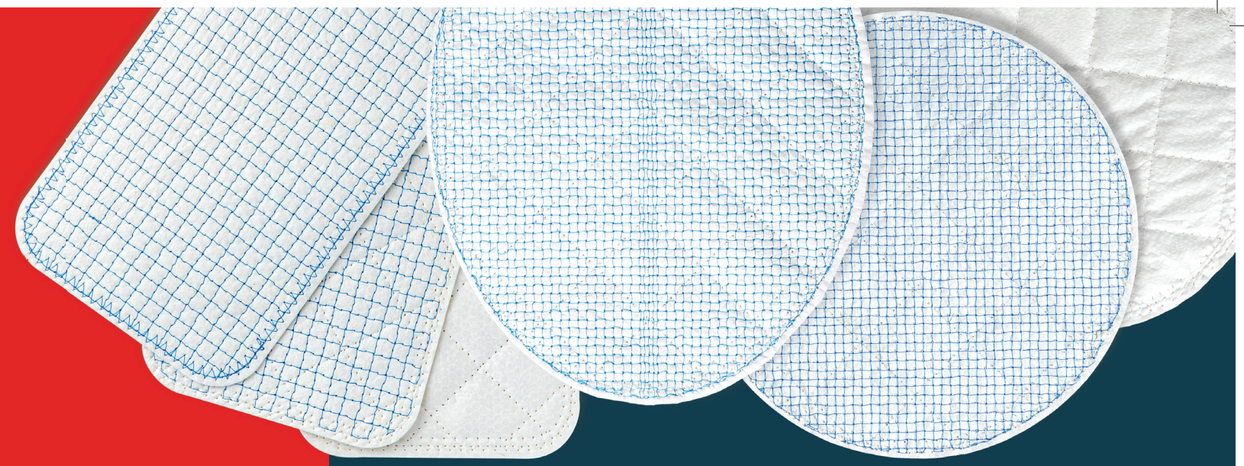
Red polymer shown for illustrative purposes only.

- Lock-stitch embroidery minimizes unraveling when cut[5]
- Device construct: 95% Extracellular Matrix (ECM) / 5% Polymer (minimizes permanent foreign body footprint)[5]
- Available in permanent (5-0 Polypropylene (PP) – blue and clear) or resorbable (6-0 Polyglycolic Acid (PGA) – clear only) suture reinforcement

The layered, permeable construct of OviTex provides a biologic building block that facilitates angiogenesis, cell migration, and proliferation.[2]*

Available in 4, 6, or 8 layers

**Animal test results may not always accurately predict the clinical performance or response in humans.*



Benefits of **OviTex RTM**

Strong & More Natural Construct

Strong construct provides support across the fascia while also providing a matrix that encourages rapid granulation leading to tissue remodeling. The high tensile strength with low elastin content minimizes stretching (matching compliance of the abdominal wall) and makes OviTex effective for placement under tension.[5]

Just Enough Reinforcement Material

The low amount of interwoven polymer holds the biologic layers together while providing strength, structure and improved handling. The polymer also provides additional reinforcement during the early healing phase.[5]

Rapid Integration And Remodeling

Pores allow for fluid transfer (permeability); the embroidered construction creates hundreds of pores to the already highly porous ECM, allowing for fluid transfer through the device. High rates of permeability and fluid transfer complement the use of negative pressure wound therapy.

Assists In Complex Environments

OviTex retains its integrity and has shown resilience in cases of complex surgical repairs.[4] The use of OviTex RTM assists in delivering an effective and durable fascial repair.[6, 7]

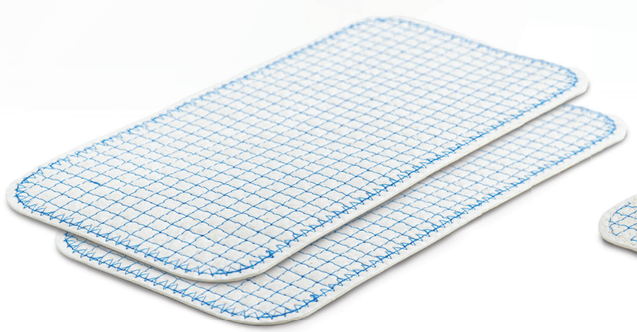
Ovitex Reinforced Tissue Matrix
A More Natural Hernia Repair™

Our comprehensive portfolio of solutions offers four configurations of OviTex specifically designed for hernia repair and abdominal wall reconstruction applications. Each device has its own unique features to ensure you have the right solution at the right time.

Indications for Use

OviTex 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 outcomes.



OviTex Core

4-layer device
No smooth sides
Thickness: ~0.9 mm

OviTex Core is designed to reinforce primary hernia repairs where the device will not come into contact with bowel.

Areas of use example(s):

- Retrorectus repair
- Onlay repair

OviTex 1S

6-layer device
1 smooth side
Thickness: ~1.1 mm

OviTex 1S incorporates a smooth side that is designed to minimize tissue attachment and to reinforce primary hernia repairs where the device may come into contact with bowel (e.g. intraperitoneal).

Areas of use example(s):

- Most hernia repairs

OviTex 2S

8-layer device
2 smooth sides
Thickness: ~1.6 mm

OviTex 2S incorporates eight layers of tissue for added strength. The two smooth sides make it suitable for intraperitoneal placement.

Areas of use example(s):

- Sugarbaker repair
- Bridging repair
- Large loss of tissue repair

OviTex LPR*

4-layer device
1 smooth side
Thickness: ~0.9 mm

OviTex LPR is designed specifically for use in laparoscopic and robotic hernia repair procedures. The design also incorporates a smooth side making it suitable for intraperitoneal placement.

Areas of use example(s):

- Most robotic and laparoscopic repairs

**~87% extracellular matrix / ~13% suture reinforcement*
Only available with permanent polymer reinforcement

Did you know?

OviTex RTM costs 10-20% less than market leading synthetic resorbable devices and 20-35% less than market leading biologic devices.[8]

Consistently Low Recurrence Rates

Backed by 7+ years of clinical experience and 30+ published or presented works

VENTRAL / AWR

Ankney, Szotek, et al.[9]
2022
259 Patients / 1-59 m
0.8%

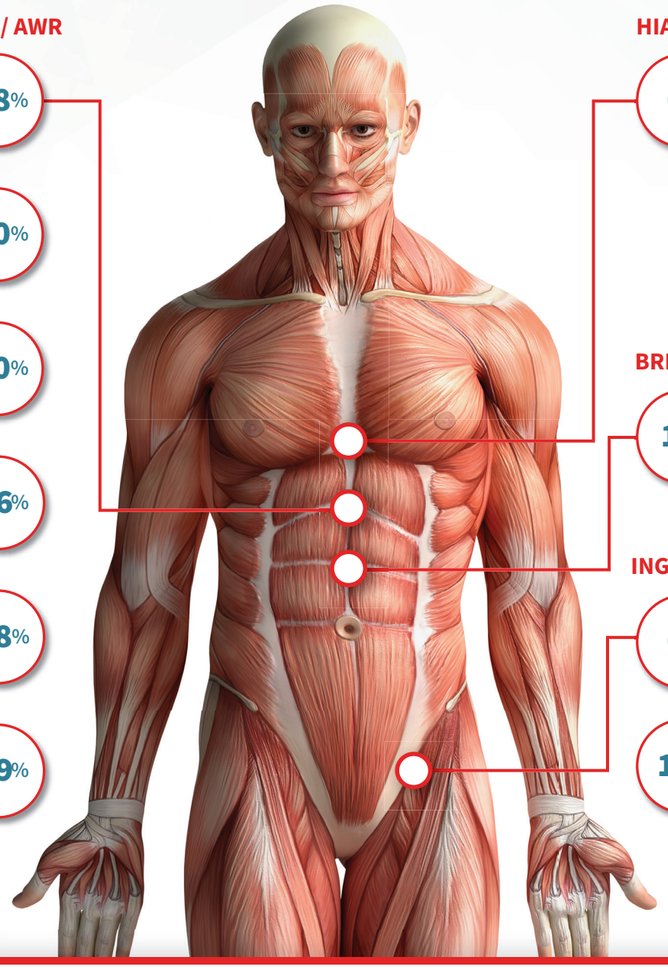
Sivaraj, Nazerali, et al.[10]
2022
50 Patients / 29-34m
4.0%

Parker, et al.[11]
2021
50 Patients / 12m
6.0%

DeNoto, et al. [12]
2022
92 Patients / 24m
2.6%

Sivaraj, Nazerali, et al.[13]
2022
36 Patients / 29m
2.8%

Ankney, Szotek, et al.[9]
2022
54 Patients / 3-39m
1.9%



HIATAL

0%
Sawyer[14]
2018
25 Patients / 14m

BRIDGED

16%
DeNoto[15]
2022
19 Patients / 23m

INGUINAL

0%
Ferzoco[16]
2018
31 Patients / 13m

1.6%
Ankney, Szotek, et al.[9]
2021
306 Patients /1-36m

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Or visit ovitex.com

Lower Recurrence Rates Than Other Leading Hernia Devices**

	DeNoto, 2022 (BRAVO)[12]	Roth, 2021 (Phasix)[17]	Hope, 2022 (ATLAS)[18]	Harris, 2021 (PRICE)[19]	
Trade Name	**OVITEX™ 1S PERMANENT**	**PHASIX™ MESH**	**PHASIX-ST™ MESH**	**STRATTICE**	**VENTRALIGHT ST OR SOFT MESH**
Total Pts	92	121	120	82	83
Mesh Type	Reinforced Tissue Matrix	Resorbable Synthetic	Resorbable Synthetic	Biologic	Permanent Synthetic
Mesh Composition	Ovine forestomach matrix and polypropylene	Poly-4-hydroxybutyrate (P4HB)	Poly-4-hydroxybutyrate (P4HB) with a hydrogel barrier	Porcine dermis	Polypropylene with hydrogel barrier or polypropylene
Follow-Up	24 Months	36 Months	24 Months	26 Months	
Surgical Approach	Open (65%)	Open		Open	
	Laparoscopic (13%)		Laparoscopic (55.8%)		
	Robotic (22%)		Robotic (44.2%)		
Plane of Placement	Retrorectus (53%)	Retrorectus (73%)			
			Intrabdominal		
	Intraperitoneal (46%)				
				Sublay/Retrorectus (38%)	Sublay/Retrorectus (30%)
	Retrofascial/ Pre-Peritoneal (1.1%)				
				Underlay (30%)	Underlay (31%)
	Onlay (1.1%)	Onlay (26%)		Onlay (17%)	Onlay (28%)
Primary Closure	92%	94%	N/A	85%	89%
Component Separation	51%	43.8%	1.7%	35%	46%
BMI (kg/m2)	31.0 ± 4.51	32.2 ± 4.5	33.2 ± 4.5	36.1 ± 9.6	35.0 ± 7.7
CDC Wound Class	I (80%)	I (100%)	I (100%)	I (67%)	I (70%)
	II (15%)			II (23%)	II (23%)
	III (4%)			III (1%)	III (0%)
				IV (9%)	IV (7%)
Incidence of Surgical Site Occurence/ Complications	38% SSO (including SSI)	6.6% (Seroma required intervention only)	0.8% a<45 Days	21% SSO (excluding SSI)	22% SSO (excluding SSI)
		15.7% (Device related AEs)	0.0% a>45 Days (required intervention)		
Incidence of Surgical Site Infection	20.7%	9.3 ± 0.03%	0%	39%	34%
Recurrence Rate (Final Follow-Up Population)	**4.5%** (3/66)	–	–	**40%** (25/63)	**22%** (14/64)
Recurrence Rate (Kaplan Meier estimate)	**2.6%**	**17.9%**	**31.7%***	–	–

18.6% defects < 7.1 cm2 and 43.3% defects > 7.1 cm2

***No head-to-head clinical studies have been conducted. Due to differences in patient population, surgeons, surgical technique, and other variables, no direct comparisons of results can be made. For a comparative discussion of these studies, please see G. DeNoto, E.P. Ceppa, S.J. Pacella, M. Sawyer, G. Slayden, M. Takata, G. Tuma, J. Yunis, 24-Month results of the BRAVO study: A prospective, multi-center study evaluating the clinical outcomes of a ventral hernia cohort treated with OviTex® 1S permanent reinforced tissue matrix, Ann Medicine Surg 2022, 83,*

	OviTex		OviTex 1S		OviTex 2S		OviTex LPR	
Construct	6 mm Grid 4 layers		6 mm Grid 1 smooth side (25 mm Grid) | 6 layers		25 mm Grid 2 smooth sides | 8 layers		3 mm Grid 1 smooth side (25 mm Grid) | 4 layers	
Viscera Contact	Not Recommended		Yes		Yes		Yes	
Thickness	~0.9 mm		~1.1 mm		~1.6 mm		~ 0.9 mm	
	POLYMER REINFORCEMENT		POLYMER REINFORCEMENT		POLYMER REINFORCEMENT		POLYMER REINFORCEMENT	
	Permanent	Resorbable	Permanent	Resorbable	Permanent	Resorbable		Permanent
4 x 8 cm	F10244-0408P	F10254-0408G	F10246-0408P	F10256-0408G	–	–	**9 cm circle**	F10244-0909L
6 x 10 cm	F10244-0610P	F10254-0610G	F10246-0610P	F10256-0610G	–	–	**12 cm circle**	F10244-1212L
10 x 12 cm	F10244-1012P	F10254-1012G	F10246-1012P	F10256-1012G	F10248-1012P	–	**15cm circle**	F10244-1515L
10 x 20 cm	F10244-1020P	–	F10246-1020P	F10256-1020G	F10248-1020P	–	**12x18 cm ellipse**	F10244-1218L
16 x 20 cm	F10244-1620P	–	F10246-1620P	F10256-1620G	F10248-1620P	–	**15x20 cm ellipse**	F10248-1520L
18 x 22 cm	–	–	F10246-1822P	–	F10248-1822P	–	**15x25 cm ellipse**	F10248-1525L
20 x 20 cm	F10244-2020P	F10254-2020G	F10246-2020P	F10256-2020G	F10248-2020P	F10258-2020G		
25 x 30 cm	F10244-2530P	–	F10246-2530P	–	F10248-2530P	–		
25 x 40 cm	F10244-2540P	–	F10246-2540P	–	F10248-2540P	–		

Permanent Reinforcement: All suture is 5-0 Polypropylene (PP) – blue and clear

Resorbable Reinforcement: All suture is 6-0 Polyglycolic Acid (PGA) – clear only

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To learn more about OviTex RTM, call

US: 1-844-835-2246 (1-844-TELABIO)
EU: 00800 03577753 or visit telabio.com

Aroa Biosurgery. 2 Kingsford Smith Place, Airport Oaks, Auckland 2022, New Zealand

CMRP S4M Europe. 59, rue Castellion. 01100 Oyonnax – France

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.
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 the use of surgical mesh): pain, infection, hernia recurrence, 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 and OviTex are registered trademarks of TELA Bio, Inc. All other trademarks are trademarks of their respective owners or holders.

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