



Tutopatch[®] Tutomesh[®]

Bovine Pericardium Implant Overview



ABOUT RTI SURGICAL ■

Since the company's founding, RTI Surgical, Inc. has remained at the forefront of a changing industry, becoming one of the largest processors of biologic implants and a global leader in tissue-based innovations. We continue to break new ground with developments that are changing regenerative medicine.

The Germany-based company Tutogen Medical has been a part of this global success story, being a subsidiary of Florida/US-based RTI Surgical since 2008.

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TUTOPATCH[®] BOVINE PERICARDIUM ■ TUTOMESH[®] FENESTRATED BOVINE PERICARDIUM ■

Natural Collagen Matrix

Tutopatch[®] bovine pericardium and Tutomesh[®] fenestrated bovine pericardium are natural collagenous matrices. Processed through the Tutoplast[®] Tissue Sterilization Process, both implants offer a safe and natural biologic option for soft tissue repair.

The Tutopatch[®] and Tutomesh[®] implants offer three important components of a biologic implant: safety, strength and

support for revascularization and remodeling. Additionally, the material properties of bovine pericardium allow the implants to conform to anatomic structures, making it suited for surgical applications.

OVERALL IMPLANT FEATURES

- ▶ Available in:
 - Fenestrated and non-fenestrated
 - Rectangular and oval shapes
- ▶ Conforms to anatomical structures



SAFETY ■

Tutopatch® bovine pericardium and Tutomesh® fenestrated bovine pericardium are processed through the Tutoplast® Tissue Sterilization Process.

- ▶ Validated multi-step chemical preservation and sterilization process that removes antigenic properties and inactivates pathogens
- ▶ Validated low dose gamma irradiation achieves terminal sterility of SAL 10⁻⁶ (Sterility Assurance Level)

Tutoplast® processed bovine pericardium is utilized in a number of application fields including neurosurgery, ophthalmology, ENT procedures and abdominal surgery.

TUTOPLAST® Tissue Sterilization Process

The Tutoplast® process was originally developed more than 40 years ago by Tutogen Medical.

During the Tutoplast® process, osmotic, oxidative and alkaline treatments break down cell walls, inactivate pathogens and remove bacteria. Solvent dehydration results in room temperature storage without damaging the native tissue structure. Overall the structure, biomechanics and remodeling characteristics of the implant are maintained. Low dose gamma irradiation ensures sterility of the final packaged graft.



STRENGTH

Despite the naturally thin texture of bovine pericardium, it is inherently strong. The material's strength comes from the composition of the tissue's structure. Native bovine pericardium is

comprised of multi-directional collagen fibers that are approximately 90% Type I collagen. Many three-stranded Type I collagen molecules pack together side-by-side forming fibrils, which results in

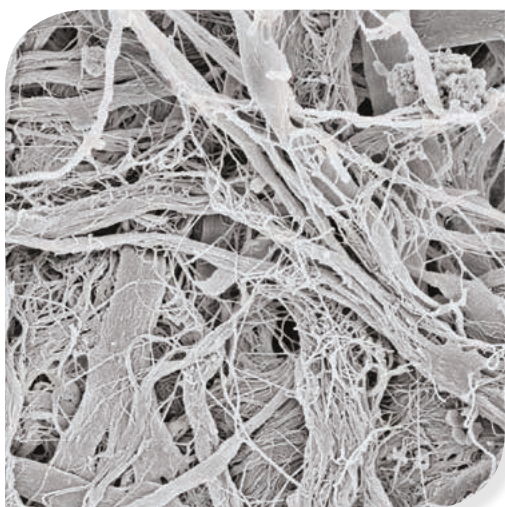
high tensile strength. In fibrils, adjacent collagen molecules are displaced from one another thus creating a staggered, striated effect that can be seen in scanning electron micrographs (SEM).

TUTOPATCH® bovine pericardium has been shown to preserve the native multi-directional network of collagen fibers¹

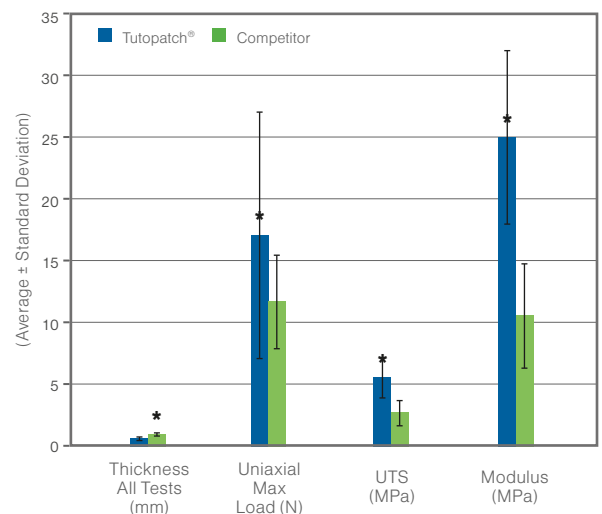
If the network of collagen fibers is altered during processing, mechanical strength could be compromised. Tutopatch® bovine pericardium has been shown to preserve this network of collagen fibers after processing as shown in the SEM image below.¹ It is important to preserve the material characteristics that are well

suited to resist the tensile forces placed on it during soft tissue repair. In a head-to-head comparison against a competitor's collagen matrix, Tutopatch® bovine pericardium was shown to have a defined collagen structure similar to non-processed bovine pericardium, whereas the competitor's

solution exhibited dramatically altered collagen structure. Further, preimplant, out of the package testing revealed Tutopatch® bovine pericardium demonstrated significantly greater uniaxial max load, UTS and modulus than the competitor's solution.¹



Bovine pericardium after the Tutoplast® Tissue Sterilization Process, Smooth surface, 5000x magnification.



Mechanical testing data from Tutopatch® bovine pericardium and competitor's collagen matrix pre-implant. *Indicates statistical significance (p < 0.05).

REVASCULARIZATION AND REMODELING

(Animal Model*)

Tutopatch® bovine pericardium and Tutomesh® fenestrated bovine pericardium have demonstrated rapid revascularization, repopulation and remodeling.^{1,2}

Explant gross evaluation revealed that Tutopatch® bovine pericardium integrated well with surrounding host tissue at four, eight and 12 weeks.

Histologic analysis revealed that Tutopatch® bovine pericardium had more favorable remodeling characteristics when compared to a competitor's collagen matrix.

In an animal model, the Tutopatch® and Tutomesh® implants have demonstrated fast tissue integration via cell repopulation and rapid revascularization in addition to remodeling over time.

Histological scores for fibroblast repopulation and revascularization

(Animal Model*)



Histological scores for fibroblast repopulation of Tutopatch® bovine pericardium and competitor's collagen matrix at four, eight and 12 weeks post implantation.



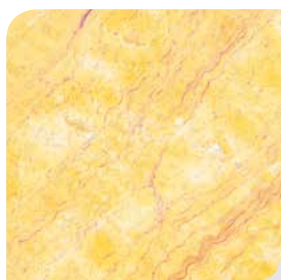
Histological scores for revascularization of Tutopatch® bovine pericardium and competitor's collagen matrix at four, eight and 12 weeks post implantation.

* Performance data from animal studies may not be representative of performance in humans.

TUTOPATCH® and TUTOMESH® Implant Histology³

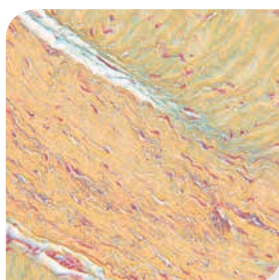
(Clinical Biopsy)

Pre-Implantation



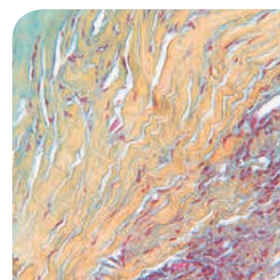
Collagen is stained in yellow, elastin fibers appear in red

Nine Months After Implantation



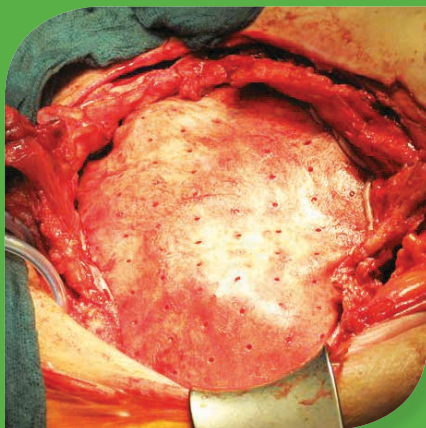
Collagenous tissue with blood vessels proves revascularization

36 Months After Implantation



Tissue shows revascularization with blood vessels and cells, completely remodeled

CLINICAL EVIDENCE



Demonstrated low recurrence rate and minimal complications clinically,³ resulting in a proven technology for hernia repair.

- ▶ 43 Implant Recipients
- Post-Surgery Follow Up, Complicated Incisional Hernia Repair Diameter > 4cm
- ▶ No implant infections, no implant migration, no implant shrinkage
- ▶ No implant was explanted in five year follow up
- ▶ 5.3% wound infection rate
- ▶ 7.9% rate of seroma
- ▶ 9.3% recurrence rate at five years

TUTOPATCH® BOVINE PERICARDIUM AND TUTOMESH® FENESTRATED BOVINE PERICARDIUM IMPLANTS

TUTOPATCH® bovine pericardium		UNITS
68366	140 mm x 200 mm	1
68355	120 mm x 160 mm	1
68367	80 mm x 110 mm	1
68362	70 mm x 80 mm	1
68354	60 mm x 140 mm	1
68353	60 mm x 80 mm	1
68360	50 mm x 110 mm	1
68352	40 mm x 100 mm	1
68351	40 mm x 50 mm	1
68358	30 mm x 40 mm	1
68357	20 mm x 100 mm	1
68350	20 mm x 30 mm	1
68361	15 mm x 30 mm	1
68356	15 mm x 20 mm	1
68364	3 mm x 120 mm	1
68359	ø 14 mm	1

TUTOPATCH® ET (Extra Thin) bovine pericardium		UNITS
68342	ø 80 mm 0,1 - 0,4 mm	1
68341	ø 60 mm 0,1 - 0,4 mm	1
68349	ø 20 mm 0,1 - 0,25 mm	1
68348	ø 14 mm 0,1 - 0,25 mm	1
68347	ø 10 mm 0,1 - 0,25 mm	1

TUTOMESH® oval - bovine pericardium		UNITS
68542	130 mm x 220 mm	1
68541	120 mm x 200 mm	1
68540	110 mm x 180 mm	1
68543	100 mm x 160 mm	1

TUTOMESH® bovine pericardium		UNITS
68443	120 mm x 160 mm	1
68442	80 mm x 120 mm	1
68444*	120 mm x 200 mm	1
68441*	60 mm x 80 mm	1
68440*	40 mm x 50 mm	1

*Special Products | available only on request



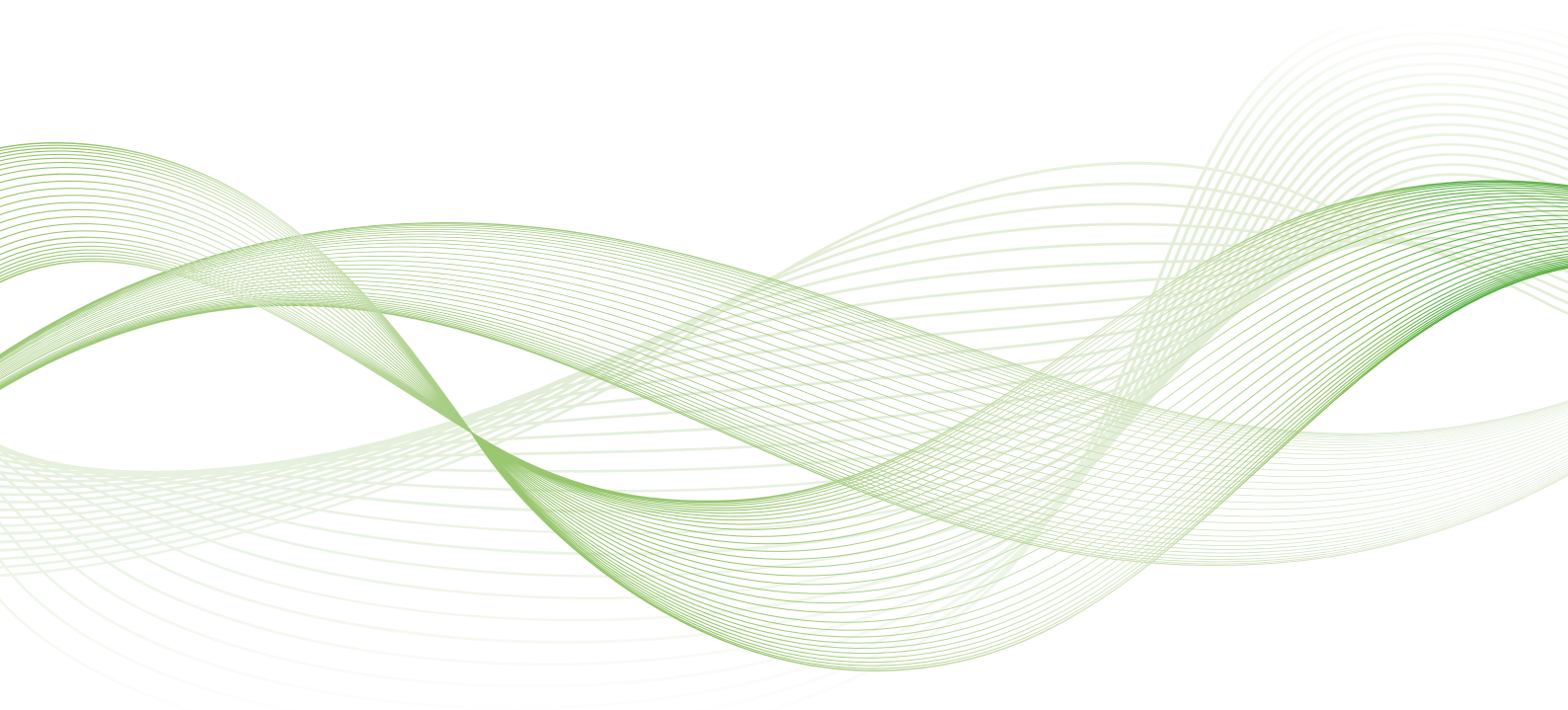
¹ Qiu Q.Q., Zhukauskas R., Wachs R.A., Ely A. Data on file, 2014.

² Van Tuil C., Saxena A.K., Willital G.H., Experience with management of anterior abdomen wall defects using bovine pericard. Hernia. 2006 10:41-47.

³ Urbach V., Lindemann M., Shaheen I., Paolucci V. Data on file, 2009. Department of General Surgery and Visceral Surgery, Kettler Hospital, Offenbach, Germany.



QUALITY & SAFETY
GENERATE TRUST



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