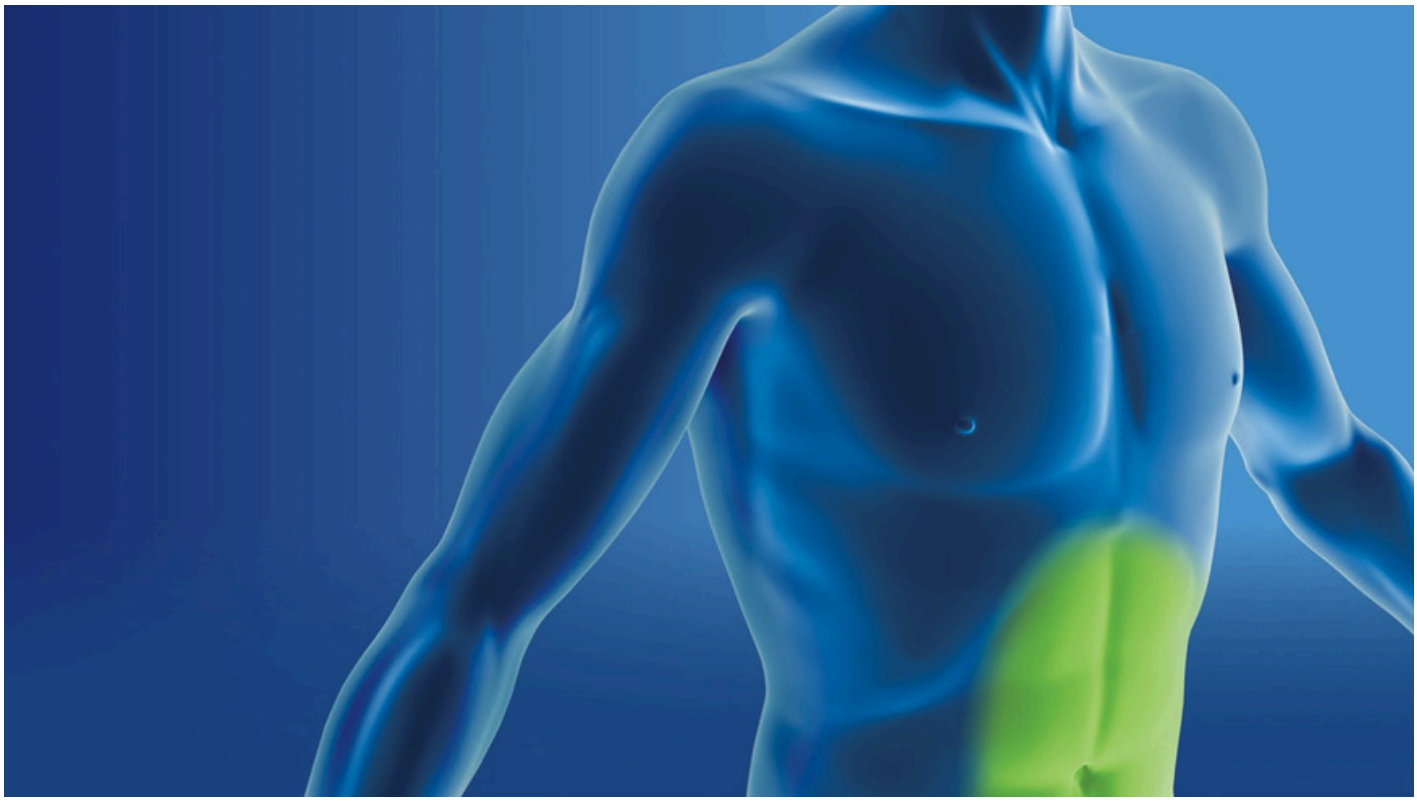
HOSPITAL INNOVATIONS

Fortiva® 1.5mm

Tissue Matrix Options for General Surgery



Tutomesh®

Fortiva®
Tissue Matrix 1.5mm

Fortiva®
Tissue Matrix 1.5mm Perforated

Speak to your local Business Development Manager for further information or contact us using the details below:

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CF72 9FG

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The Tutoplast® Tissue Sterilisation Process is a validated chemical sterilisation methodology specifically developed to sterilise and preserve tissue for implantation.

STERILE

TUTOPLAST PROCESS

Overall the structure, biomechanics and remodelling characteristics of the implant are maintained.

THOROUGHLY PENETRATES TISSUE

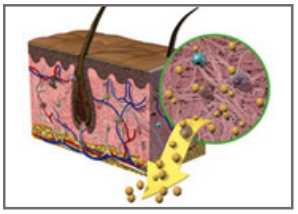
Osmotic treatments disrupt cell membranes to allow for full penetration of the graft.

VALIDATED VIRAL INACTIVATION

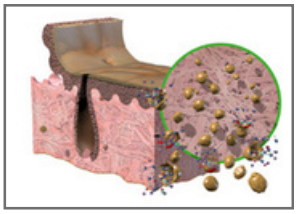
Validated for a broad spectrum of viruses relevant for the type of tissue, including enveloped and non-enveloped viruses as well as DNA and RNA viruses.

HOW DOES THE TUTOPLAST PROCESS WORK?

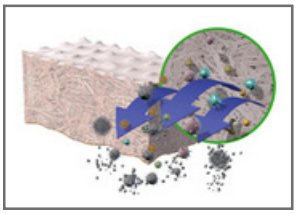
Osmotic, oxidative and alkaline treatments break down cell walls, inactivate pathogens and remove bacteria. Solvent dehydration allows for room-temperature storage of tissue without damaging the native tissue structure. Terminal gamma irradiation ensures a sterility level (SAL) of 10-6 of the final packaged graft.



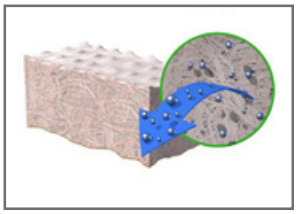
1. Alkaline Treatment
Removes cells and lipids which interfere with healing.



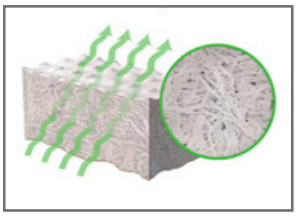
2. Osmotic Treatment
Disrupts cell membranes to allow easier removal of cellular components.



3. Oxidative Treatment
Removes immunogenic structures, enveloped and non-enveloped viruses.



4. Solvent Treatment
Removes water from tissue, preserves the natural tissue matrix.



5. Irradiation
Irradiation produces a terminally sterile graft, while preserving structural integrity.

Images depict dermal processing.

50 Years of Proven History

RTI SURGICAL, INC. IS A LEADING GLOBAL PROVIDER of tissue-based implants for surgeries with a commitment to advancing science, safety and innovation.

RTI's innovations continuously raise the bar of science and safety for biologics - from being the first company to offer precision-tooled bone implants and assembled allograft technology to maximise each gift of donation, to inventing fully validated sterilisation processes that include viral inactivation steps. These processes are scientifically proven to address donor-to-recipient disease transmission risk while preserving natural tissue characteristics and biocompatibility.

RTI's worldwide corporate headquarters is located in Alachua, Fla., and RTI has additional manufacturing facilities in Greenville, NC, Marquette, Mich., and Neunkirchen, Germany.

1969 – 1989

1969
Tutoplast® Tissue Sterilisation Process developed.

1971
First clinical use of Tutoplast Dura.

TUTOPLAST®
TISSUE STERILIZATION PROCESS

MORE THAN 11 MILLION TISSUE-BASED IMPLANTS

1990 – 1999

1992
Pioneer Surgical Technology formed.

1992
Tutogen Medical® opens facility in Germany.

1998
CE approval for Tutopatch®.

Tutopatch®

1998
Regeneration Technologies, Inc. (RTI) spins off from University of Florida Tissue Bank.

2000 – 2009

2002
CE Approval for Tutomesh®.

Tutomesh®

2008
Regeneration Technologies merges with Tutogen Medical to form RTI Biologics®.

2010 – 2020

2013
RTI Biologics acquires Pioneer Surgical Technology to create RTI Surgical®.

2014
CE approval for Fortiva® 1.5mm.

Fortiva®
TISSUE MATRIX

2018
CE approval for Fortiva® 1mm Perforated.

Fortiva®
TISSUE MATRIX

2020
Montagu Private Equity acquires RTI Surgical's OEM business.

Have been processed through RTI's proprietary validated sterilisation processes with zero confirmed incidence of implant-associated infection.

ABDOMINAL WALL OPTIONS

Tutomesh® is a thin yet strong bovine pericardium Natural Collagen Tissue Matrix

Tutomesh® is a natural collagenous matrix that offers three important components of a biologic implant: safety, strength and support for revascularisation and remodelling.

PERFORATED

Tutomesh® provides an option for improved fluid movement (such as seroma) away from the implant. This may result in the use of fewer drains during abdominal wall reconstruction techniques.1

EXCELLENT PLIABILITY

The thin yet strong bovine pericardium provides superior tissue durability and conformability to patient anatomy.

OPTIMAL REMODELING

The nature of the thin tissue combined with the collagen structure allows very rapid conversion to vascularized host tissue.

Tutomesh®

Fortiva®

TISSUE MATRIX
1.5mm PERFORATED

Fortiva® Tissue Matrix Options for Abdominal Wall Reconstruction

- Strong out of the package and at the interface
- Perforated for increased integration1 and fluid management
- Consistent thickness for predictable handling
- Multiple sizes to meet your reconstruction needs
- Ready to use

REVASCULARISATION AND REMODELING (ANIMAL MODEL)*

Tutoplast bovine pericardium demonstrated rapid revascularisation, repopulation and remodeling.[2]

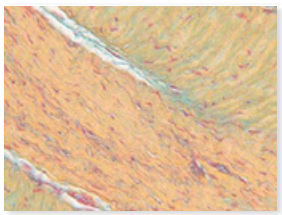
Explant gross evaluation revealed that Tutoplast bovine pericardium integrated well with surrounding host tissue at four, eight and 12 weeks.[3]

Histologic analysis revealed that Tutoplast bovine pericardium had more favorable remodeling characteristics when compared to Veritas.[3]

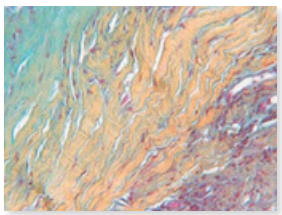
In an animal model, the Tutoplast® bovine pericardium implants have demonstrated fast tissue integration via cell repopulation and rapid revascularisation in addition to remodelling over time.

TUTOPLAST BOVINE PERICARDIUM (CLINICAL BIOPSY)[2]

Pre-Implantation
Collagen is stained in yellow, elastin fibres appear in red

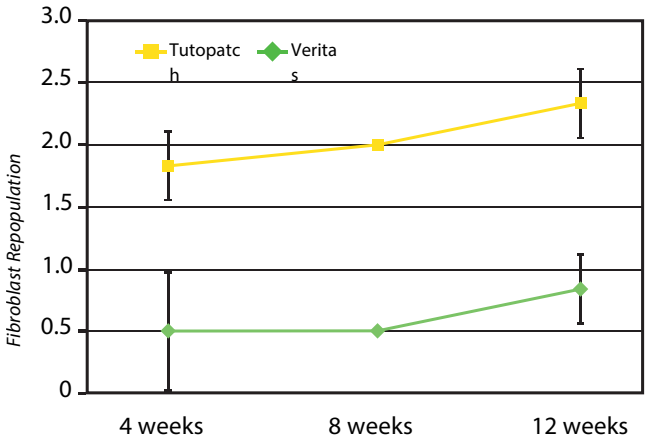


Nine Months After Implantation
Collagenous tissue with blood vessels proves revascularisation

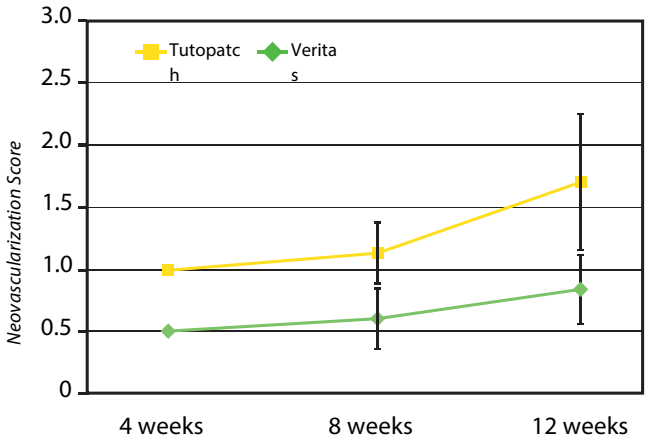


36 Months After Implantation
Tissue shows revascularisation with blood vessels and cells, completely remodelled

HISTOLOGICAL SCORES FOR FIBROBLAST REPOPULATION AND REVASCULARISATION (ANIMAL MODEL)[3*]



Histological scores for fibroblast repopulation of Tutoplast bovine pericardium and Veritas at four, eight and 12 weeks post implantation.



Histological scores for revascularisation of Tutoplast bovine pericardium and Veritas at four, eight and 12 weeks post implantation.

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

Fortiva® Fortiva®

TISSUE MATRIX
1.5mm

TISSUE MATRIX
1.5mm PERFORATED

CONSISTENT MATRIX THICKNESS FOR EXTRA CONFIDENCE WHEN NEEDED

A tissue matrix derived from porcine dermis. The perfect choice for when the patient requires a thicker barrier between the implant and the surrounding tissue. More consistent thickness means less patient to patient variance. Ideal for patients that require long lasting implant strength.

PERFORATED 1.5mm

Fortiva® Tissue Matrix 1.5mm perforated combines the features of Fortiva® Tissue Matrix 1.5mm with the ability to improve the circulation of fluids.[1]

PERFORATION OF ACELLULAR DERMAL MATRICES INCREASES THE RATE OF CELLULAR INVASION1

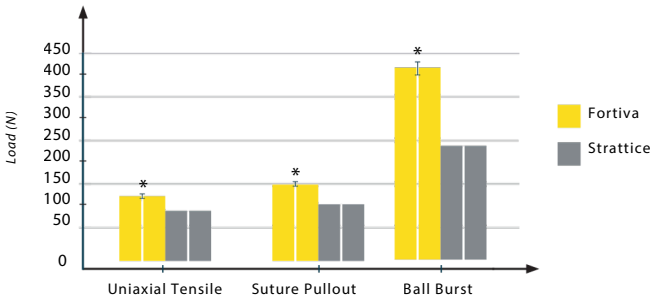
- Perforated ADMs have a significant advantage in cellular invasion and density when implanted in a suitable host.
- Perforating the ADM did not significantly diminish it's tensile strength.
- Perforations can also lead to a decreased risk of seroma and infection, drastically decreasing patient morbidity.

NO PRESERVATIVES. READY TO USE.

Our matrices are processed through a delicate proprietary system, which retains key implant properties. Fortiva® Tissue Matrix 1.5mm is ready to use and is stored in pharmaceutical grade water, eliminating the need to rinse away harsh chemicals, polysorbate 20 or phosphate buffers.

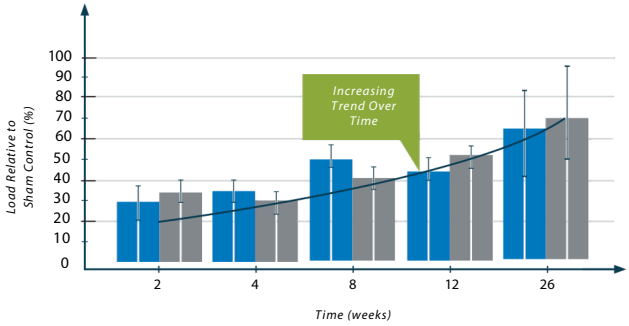
- Save time. No need for lengthy rinsing.
- Reduced risk of patient reaction or sensitivity to preservation chemicals, polysorbate 20 or phosphate buffers.

IN VITRO MAXIMUM LOADS AT FAILURE[4*]



In vitro maximum loads at failure of Fortiva® and Strattice reconstructive tissue matrix during uniaxial tensile, suture pullout and ball burst testing. Error bars show standard error. (*indicates superiority)

INTERFACE STRENGTH OVER TIME [4*]

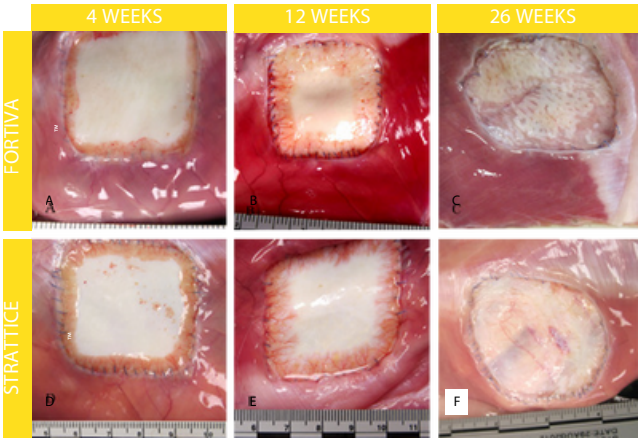


Interface strength of implant and host in explants over time relative to a sham control for Fortiva® and Strattice reconstructive tissue matrix. Black line indicates trend of interface strength over time. Error bars show standard error.

*Lab data may not be representative of effects or performance in humans.

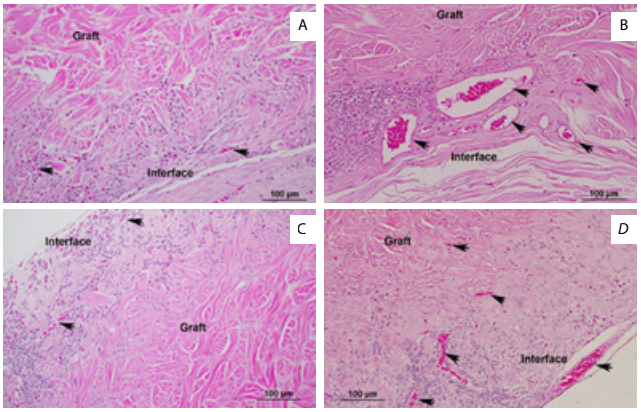
Comparison of Fortiva® Porcine Dermis and Strattice Reconstructive Tissue Matrix for Abdominal Wall Defect Repair in a Rabbit Model[5]

MACROSCOPIC OBSERVATION*



Gross examination. Macroscopic views of peritoneal side of the implants at 4, 12 and 26 weeks (from left to right) post implantation. (A)-(C) Fortiva®, (D)-(F) Strattice reconstructive tissue matrix.

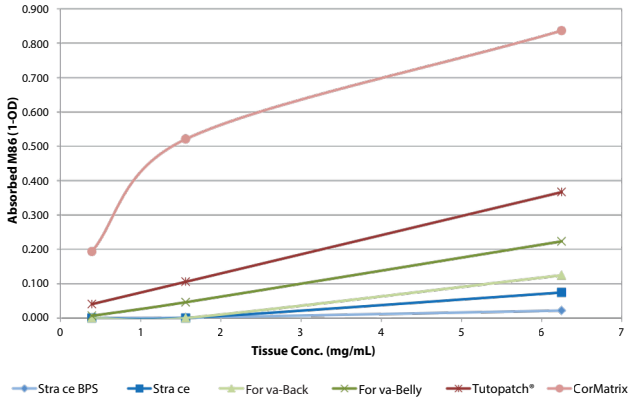
REVASCULARISATION*



Histological images representing graft revascularization of Fortiva® at 4 (A) and 12 (B) weeks, and Strattice reconstructive tissue matrix at 4 (C) and 12 (D) weeks post implantation. Arrows point to blood vessels. H&E at 200X magnification.

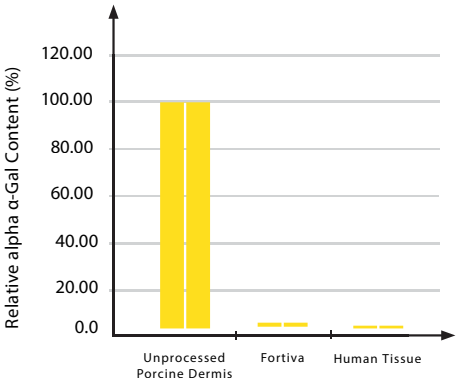
Viral Inactivation, Sterilisation and α-Gal Removal of Fortiva® Porcine Dermis[6]

α-GAL ANALYSIS



α-GAL CONTENT

RELATIVE TO UNPROCESSED PORCINE DERMIS CONTROL



Relative α-Gal content in unprocessed porcine dermis, Fortiva®, and human tissue. Fortiva® contains less than 2% of α-Gal found in unprocessed porcine dermis (>98% removal).

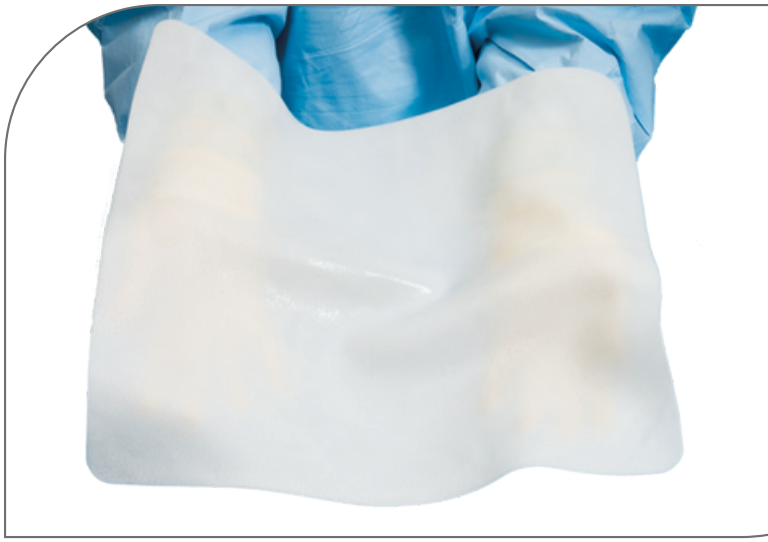
*Performance data from animal studies may not be representative of performance in humans.

Fortiva®

TISSUE MATRIX
1.5mm

SOFT

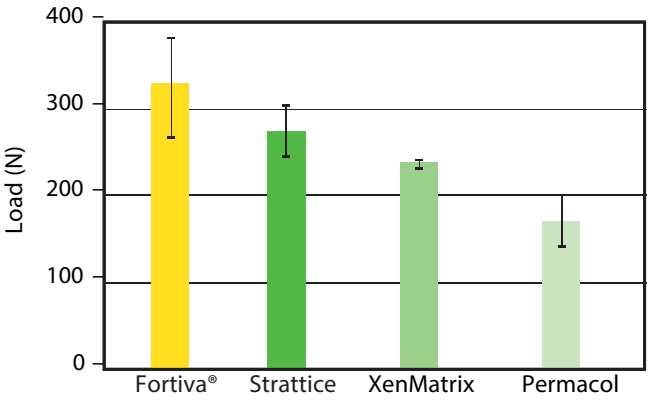
Fortiva® Tissue Matrix 1.5mm has a consistent thickness of 1.5mm for predictable handling. The implant is pliable and contours to the shape of the abdominal wall.



STRONG

In a head-to-head benchtop biomechanical comparison, Fortiva® Tissue Matrix 1.5mm demonstrated greater ball burst strength than Strattice, XenMatrix and Permacol (pre-implant, out of the package).[7]

BALL BURST STRENGTH[6*]



LOW SEROMA AND RECURRENCE RATES**

In a prospectively maintained database, Fortiva® Tissue Matrix 1.5mm demonstrated low seroma and recurrence rates compared to Strattice and AlloDerm.[8]

RECURRENCE AND SSO STRATIFIED BY MESH TYPE

Variable	Fortiva® (n=72)	Strattice (n=98)	AlloDerm (n=59)	P
Recurrence, n(%)	5 (6.9)	10 (10.2)	12 (20.3)	0.040†
Any SSO, n(%)	41 (56.9)	48 (49.0)	29 (49.2)	0.540
Delayed healing	16 (22.2)	24 (24.5)	15 (25.4)	0.900
Skin necrosis	4 (5.6)	8 (8.2)	6 (10.2)	0.570
Fistula	7 (9.7)	5 (5.1)	6 (10.2) 7	0.400
Seroma	1 (1.4)	13 (13.3)	(11.9) 2	0.021†
Hematoma	3 (4.2)	3 (3.1)	(3.4) 17	0.900
SSI	20 (27.8)	23 (23.5)	(28.8)	0.710

† Denotes significance of (greater than or equal to) P 0.05. Significance determined by ANOVA.

*Lab data may not be representative of effects or performance in humans.
**Clinical cases are unique and individual results may vary.

Item No.	Item Description
61113	Fortiva® Porcine dermis 1.0mm (20 cm x 25 cm)
61114	Fortiva® Porcine dermis 1.0mm (16 cm x 20 cm)
61115	Fortiva® Porcine dermis 1.0mm (10 cm x 16 cm)
61116	Fortiva® Porcine dermis 1.0mm (10 cm x 10 cm)
61118	Fortiva® Porcine dermis 1.0mm (8 cm x 16 cm)
61211	Fortiva® Porcine dermis 1.0mm perforated (20 cm x 25 cm)
61212	Fortiva® Porcine dermis 1.0mm perforated (16 cm x 20 cm)
61213	Fortiva® Porcine dermis 1.0mm perforated (10 cm x 16 cm)
61214	Fortiva® Porcine dermis 1.0mm perforated (10 cm x 10 cm)
61216	Fortiva® Porcine dermis 1.0mm perforated (8 cm x 16 cm)
61100	Fortiva® Porcine dermis 1.5mm (35 cm x 35 cm)
61101	Fortiva® Porcine dermis 1.5mm (30 cm x 30 cm)
61102	Fortiva® Porcine dermis 1.5mm (20 cm x 35 cm)
61103	Fortiva® Porcine dermis 1.5mm (20 cm x 25 cm)
61104	Fortiva® Porcine dermis 1.5mm (20 cm x 20 cm)
61105	Fortiva® Porcine dermis 1.5mm (16 cm x 20 cm)
61106	Fortiva® Porcine dermis 1.5mm (10 cm x 25 cm)
61107	Fortiva® Porcine dermis 1.5mm (8 cm x 22 cm)
61108	Fortiva® Porcine dermis 1.5mm (10 cm x 16 cm)
61109	Fortiva® Porcine dermis 1.5mm (10 cm x 10 cm)
61110	Fortiva® Porcine dermis 1.5mm (8 cm x 8 cm)
61111	Fortiva® Porcine dermis 1.5mm (6 cm x 6 cm)
61119	Fortiva® Porcine dermis 1.5mm (8 cm x 16 cm)
61200	Fortiva® Porcine dermis 1.5mm perforated (35 cm x 35 cm)
61201	Fortiva® Porcine dermis 1.5mm perforated (30 cm x 30 cm)
61202	Fortiva® Porcine dermis 1.5mm perforated (20 cm x 35 cm)

ORDERING INFORMATION

Item No.	Item Description
61203	Fortiva® Porcine dermis 1.5mm perforated (20 cm x 25 cm)
61204	Fortiva® Porcine dermis 1.5mm perforated (20 cm x 20 cm)
61205	Fortiva® Porcine dermis 1.5mm perforated (16 cm x 20 cm)
61206	Fortiva® Porcine dermis 1.5mm perforated (10 cm x 25 cm)
61207	Fortiva® Porcine dermis 1.5mm perforated (8 cm x 22 cm)
61208	Fortiva® Porcine dermis 1.5mm perforated (10 cm x 16 cm)
61209	Fortiva® Porcine dermis 1.5mm perforated (10 cm x 10 cm)

References

1.Osoria, H., Jacoby, A., et. al. "Perforation of Acellular Dermal Matrices Increases the Rate of Cellular Invasion" Plastic & Reconstructive Surgery. 2014.
2. Urbach V., Linderman M., Shaheen I., Paolucci V. Data on file. Department of General Surgery and Visceral Surgery, Kettler Hospital, Offenbach, Germany.
3. Qiu, Q., Zhukauskas, R., Wachs, R., Ely, A. "In Vitro and In Vivo Comparison of Tutopatch Bovine Pericardium and Veritas Collagen Matrix for Hernia Repair." Research and Development, RTI Surgical, Inc. 2014.
4. Wachs, R., Michaelson, J., Faleris, J., Mangual, E., Moore, S. "In Vitro and In Vivo Mechanical Characterization of Fortiva® Porcine Dermis." Research and Development, RTI Surgical, Inc. 2013.
5. Mangual, E., Zhukauskas, R., Faleris, J., Michaelson, J., Moore, S., Qiu, Q."Comparison of Foritva Porcine Dermis and Strattice Reconstructive Tissue Matrix for Abdominal Wall Defect Repair in a Rabbit Model." Research and Development, RTI Surgical, Inc. 2013.
6. Mangual, E., Qui, Q., Schreiner, S., Ely, A. "Viral Inactivation, Sterilization and a-Gal Removal of Fortiva® Porcine Dermis" Research and Development, RTI Surgical Inc. July 2013.
7. Data on file at RTI Surgical, Inc.
8. Maxwell, D., et. al., "A Comparison of Acellular Dermal Matrices in Abdominal Wall Reconstruction." Annals of Plastic Surgery. 2018

Speak to your local Business Development Manager for further information or contact us using the details below:

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