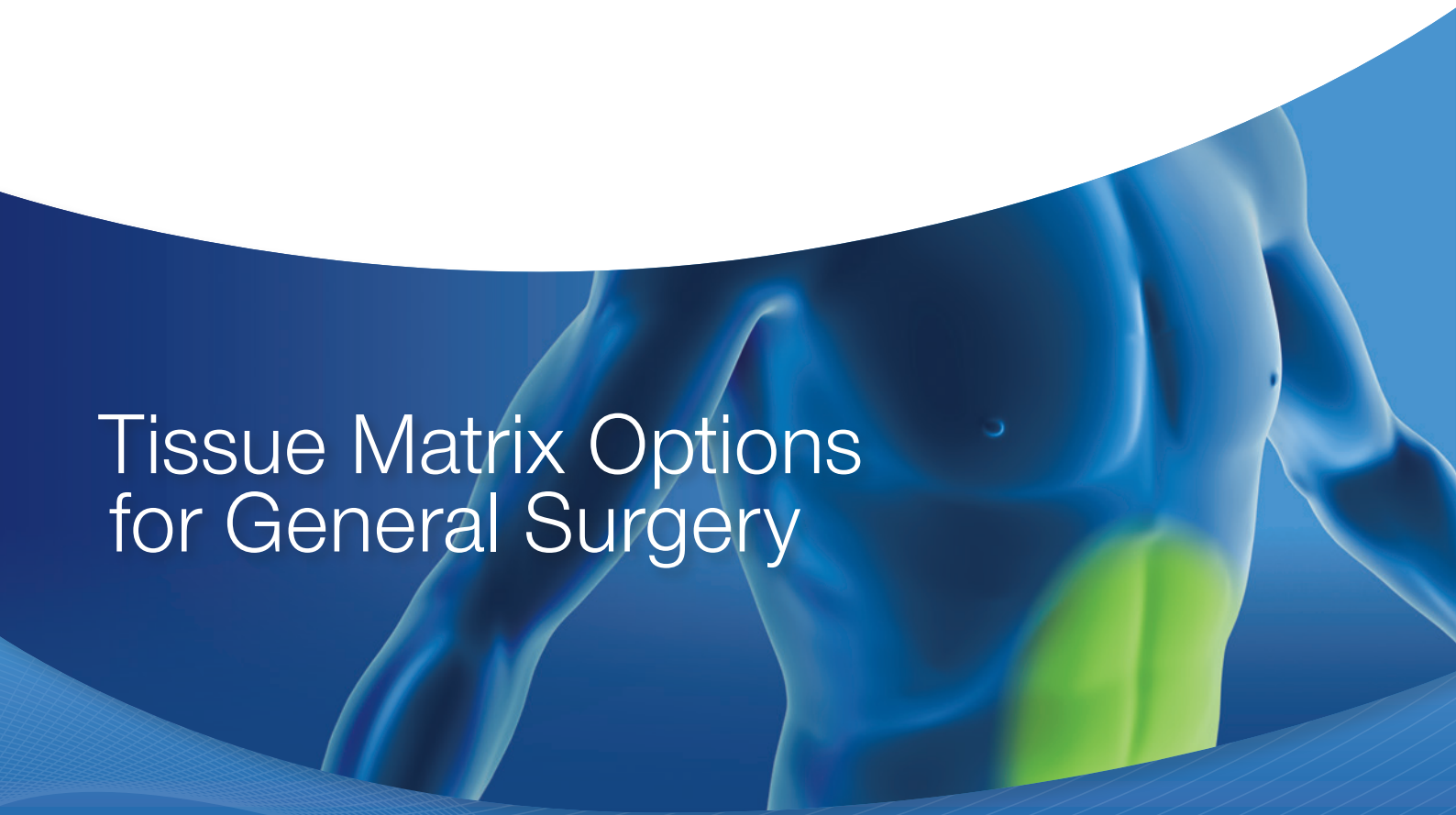
rti surgical®

Tissue Matrix Options for General Surgery



Tutomesh®

Fortiva®
TISSUE MATRIX
1.5mm

Fortiva®
TISSUE MATRIX
1.5mm PERFORATED

TABLE OF CONTENTS

The Tutoplast® Tissue Sterilization Process is a validated chemical sterilization methodology specifically developed to sterilize and preserve tissue for implantation.

STERILE

TUTOPLAST PROCESS

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

THOROUGHLY PENETRATES TISSUE

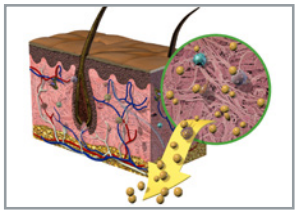
Osmotic treatments disrupt cell membranes to allow for full penetration of the graft.

VALIDATED VIRAL INACTIVATION

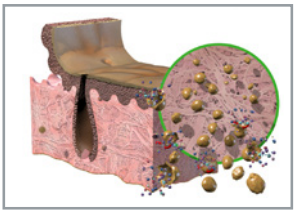
Validated for a broad spectrum of viruses relevant for the type of tissue, including enveloped and non-enveloped viruses as well as DNA and RNA viruses.

HOW DOES THE TUTOPLAST PROCESS WORK?

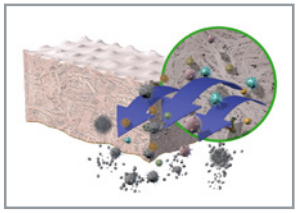
Osmotic, oxidative and alkaline treatments break down cell walls, inactivate pathogens and remove bacteria. Solvent dehydration allows for room-temperature storage of tissue without damaging the native tissue structure. Terminal gamma irradiation ensures a sterility level (SAL) of 10^{-6} of the final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



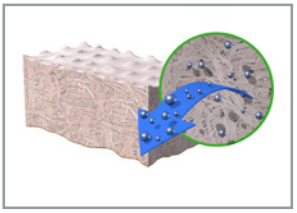
1. Alkaline Treatment
Removes cells and lipids which interfere with healing.



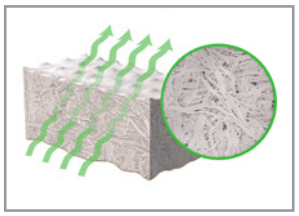
2. Osmotic Treatment
Disrupts cell membranes to allow easier removal of cellular components.



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 maximize each gift of donation, to inventing fully validated sterilization 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 Sterilization Process developed.

1971

First clinical use of Tutoplast Dura.

TUTOPLAST®
TISSUE STERILIZATION PROCESS

MORE THAN 8 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 sterilization processes with **zero confirmed incidence** of implant-associated infection.

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 revascularization and remodeling**.

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 integration[1] and fluid management
- **Consistent thickness** for predictable handling
- **Multiple sizes** to meet your reconstruction needs
- **Ready to use**

REVASCULARIZATION AND REMODELING (ANIMAL MODEL)*

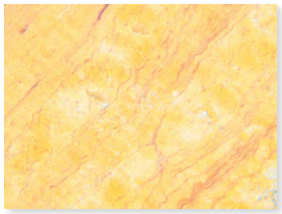
Tutoplast bovine pericardium demonstrated rapid revascularization, repopulation and remodeling.[2]

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

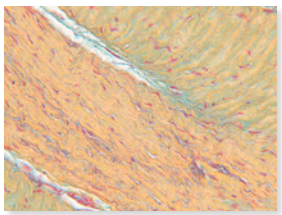
Histologic analysis revealed that Tutoplast bovine pericardium had more favorable remodeling characteristics when compared to Veritas.[3]

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

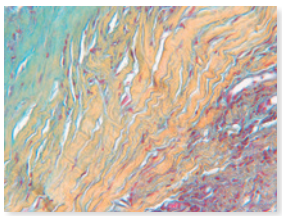
TUTOPLAST BOVINE PERICARDIUM (CLINICAL BIOPSY)[2]



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

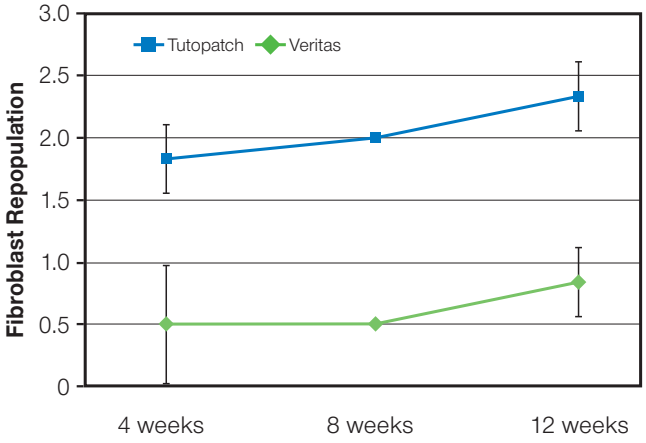


Nine Months After Implantation
Collagenous tissue with blood vessels proves revascularization

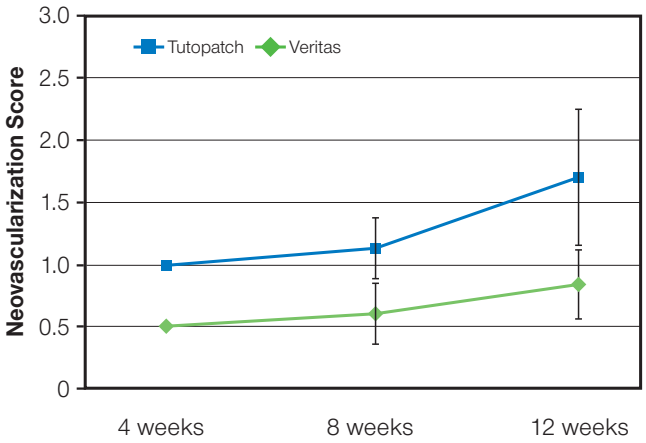


36 Months After Implantation
Tissue shows revascularization with blood vessels and cells, completely remodeled

HISTOLOGICAL SCORES FOR FIBROBLAST REPOPULATION AND REVASCULARIZATION (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 revascularization 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® TISSUE MATRIX 1.5mm

Fortiva® 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 INVASION[1]

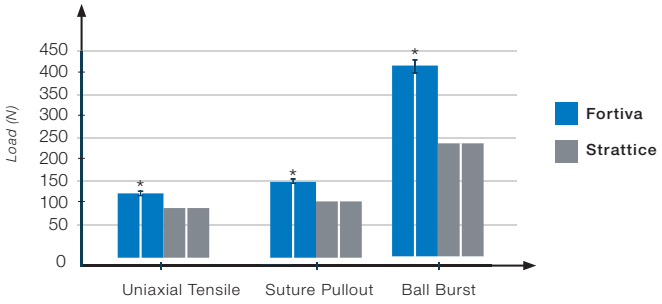
- Perforated ADMs have a significant advantage in cellular invasion and density when implanted in a suitable host.
- Perforating the ADM did not significantly diminish its tensile strength.
- Perforations can also lead to a decreased risk of seroma and infection, drastically decreasing patient morbidity.

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.

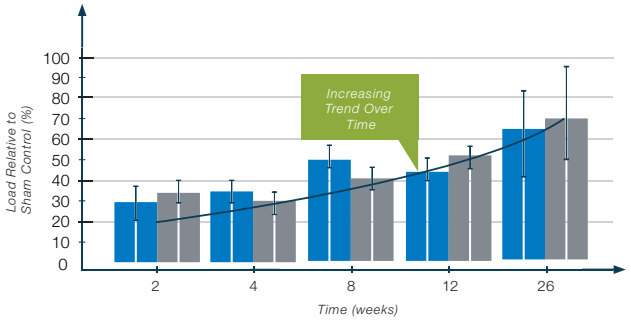
- Save time. No need for lengthy rinsing.
- Reduced risk of patient reaction or sensitivity to preservation chemicals, polysorbate 20 or phosphate buffers.

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*]

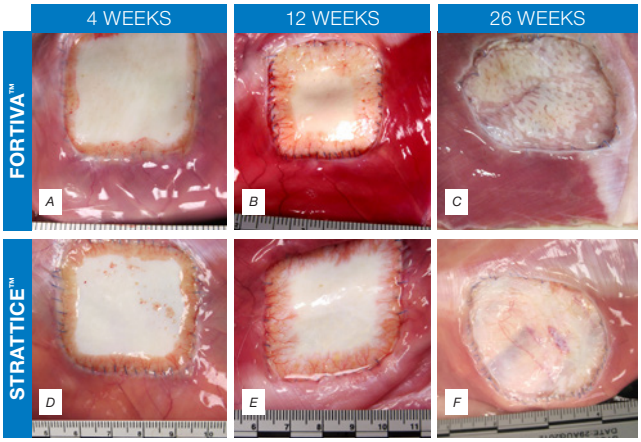


Interface strength of implant and host in explants over time relative to a sham control for Fortiva® and Strattice reconstructive tissue matrix. Black line indicates trend of interface strength over time. Error bars show standard error.

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

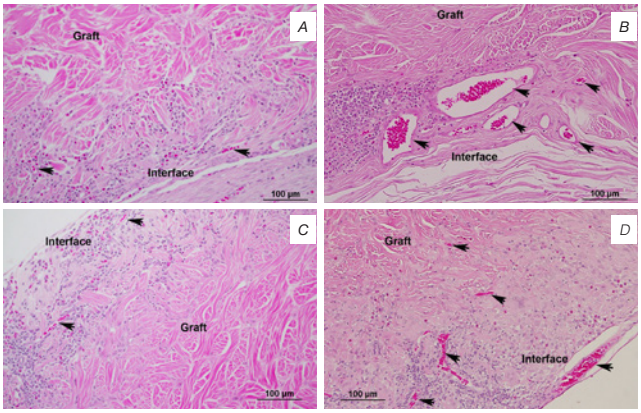
Comparison of Fortiva® Porcine Dermis and Strattice Reconstructive Tissue Matrix **for Abdominal Wall Defect Repair in a Rabbit Model**[5]

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.

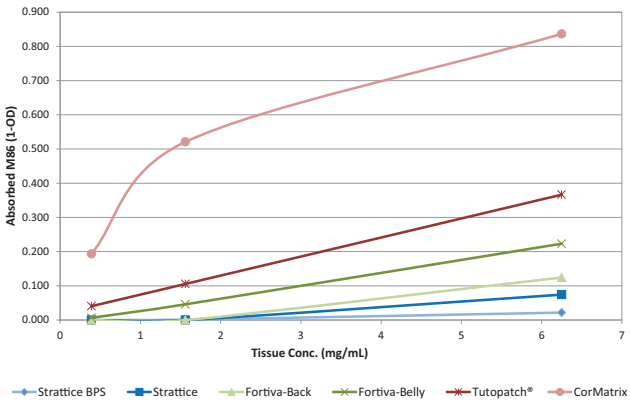
REVASCULARIZATION*



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.

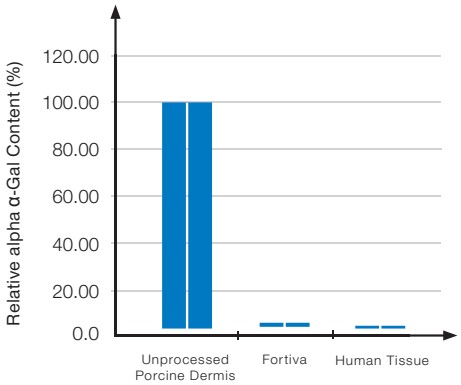
Viral Inactivation, Sterilization and α-Gal Removal of Fortiva® Porcine Dermis[6]

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).

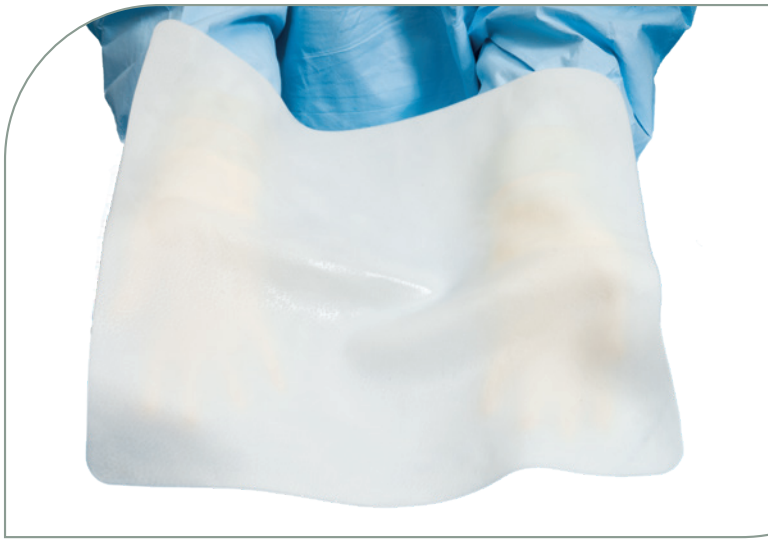
**Performance data from animal studies may not be representative of performance in humans.*

Fortiva®

TISSUE MATRIX
1.5mm

SOFT

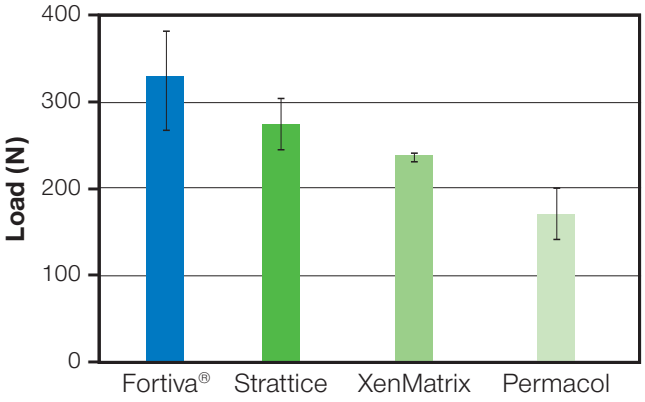
Fortiva® Tissue Matrix 1.5mm has a consistent thickness of 1.5mm for predictable handling. The implant is pliable and contours to the shape of the abdominal wall.



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)	0.400
Seroma	1 (1.4)	13 (13.3)	7 (11.9)	0.021†
Hematoma	3 (4.2)	3 (3.1)	2 (3.4)	0.900
SSI	20 (27.8)	23 (23.5)	17 (28.8)	0.710

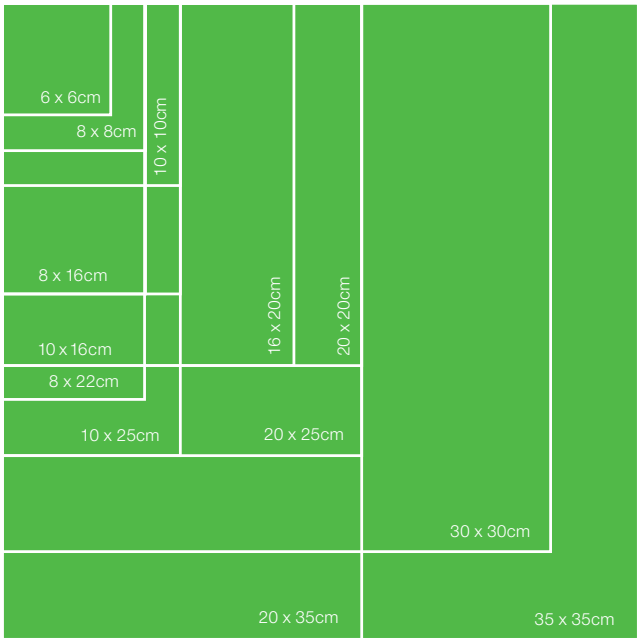
† Denotes significance of (greater than or equal to) P 0.05. Significance determined by ANOVA.

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

FORTIVA® TISSUE MATRIX 1.5MM AND 1.5MM PERFORATED

Part Number	Description
61111	Fortiva Tissue Matrix 1.5mm 6 x 6cm
61110	Fortiva Tissue Matrix 1.5mm 8 x 8cm
61119	Fortiva Tissue Matrix 1.5mm 8 x 16cm
61107	Fortiva Tissue Matrix 1.5mm 8 x 22cm
61109	Fortiva Tissue Matrix 1.5mm 10 x 10cm
61108	Fortiva Tissue Matrix 1.5mm 10 x 16cm
61106	Fortiva Tissue Matrix 1.5mm 10 x 25cm
61105	Fortiva Tissue Matrix 1.5mm 16 x 20cm
61104	Fortiva Tissue Matrix 1.5mm 20 x 20cm
61103	Fortiva Tissue Matrix 1.5mm 20 x 25cm
61102	Fortiva Tissue Matrix 1.5mm 20 x 35cm
61101	Fortiva Tissue Matrix 1.5mm 30 x 30cm
61100	Fortiva Tissue Matrix 1.5mm 35 x 35cm
61207	Fortiva Tissue Matrix 1.5mm Perforated 8 x 22cm
61209	Fortiva Tissue Matrix 1.5mm Perforated 10 x 10cm
61208	Fortiva Tissue Matrix 1.5mm Perforated 10 x 16cm
61206	Fortiva Tissue Matrix 1.5mm Perforated 10 x 25cm
61205	Fortiva Tissue Matrix 1.5mm Perforated 16 x 20cm
61204	Fortiva Tissue Matrix 1.5mm Perforated 20 x 20cm
61203	Fortiva Tissue Matrix 1.5mm Perforated 20 x 25cm
61202	Fortiva Tissue Matrix 1.5mm Perforated 20 x 35cm
61201	Fortiva Tissue Matrix 1.5mm Perforated 30 x 30cm
61200	Fortiva Tissue Matrix 1.5mm Perforated 35 x 35cm

Available in a wide range of sizes so valuable implant material is not wasted. From small defects of 6 x 6cm to the largest size of 35 x 35cm—Fortiva® Tissue Matrix 1.5mm has you covered.



TUTOMESH®

Part Number	Description
68440	Tutomesh 4 x 5cm
68441	Tutomesh 6 x 8cm
68442	Tutomesh 8 x 12cm
68443	Tutomesh 12 x 16cm
68444	Tutomesh 12 x 20cm
68445	Tutomesh 6 x 18cm
68446	Tutomesh 8 x 18cm
68540	Tutomesh 11 x 18cm, Oval
68541	Tutomesh 12 x 20cm, Oval
68542	Tutomesh 13 x 22cm, Oval
68543	Tutomesh 10 x 16cm, Oval

Call **+49 (0) 9134 99 88-400** or email **order@rtix.com** to coordinate product availability with your local representative.

Quality you can trust.

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1. Osoria, H., Jacoby, A., et. al. “Perforation of Acellular Dermal Matrices Increases the Rate of Cellular Invasion” Plastic & Reconstructive Surgery. 2014.
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8. Maxwell, D., et. al., “A Comparison of Acellular Dermal Matrices in Abdominal Wall Reconstruction.” Annals of Plastic Surgery. 2018

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9954 R03 8/3/2021