rti surgical®

Cortiva® Allograft Dermis

for Plastic and Reconstructive Surgery

Cortiva®
ALLOGRAFT DERMIS

Cortiva®1mm
TAILORED
ALLOGRAFT DERMIS

Cortiva®1mm
ALLOGRAFT DERMIS

Cortiva
Silhouette™
ALLOGRAFT DERMIS

Cortiva®1mm
PERFORATED
ALLOGRAFT DERMIS

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 tissue-based grafts—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 tissue-specific 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. RTI has a facility in Neunkirchen, Germany.

1969 – 1989

1969

Tutoplast® Tissue Sterilization Process developed.

TUTOPLAST® TISSUE STERILIZATION PROCESS

1971

First clinical use of Tutoplast Dura.

1990 – 1999

1998

CE Approval for Tutopatch®.

Tutopatch® BOVINE PERICARDIUM

2000 – 2009

2002

CE Approval for Tutomesh®.

Tutomesh® FENESTRATED BOVINE PERICARDIUM

2008

510(k) granted for Tutopatch® and Tutomesh® Bovine Pericardium

MORE THAN **11 MILLION** TISSUE-BASED IMPLANTS

RTI Surgical offers a complete portfolio of three different tissue types: allograft dermis, bovine pericardium and porcine dermis.

2010 – 2020

2013
510(k) Clearance granted for Fortiva Porcine Dermis.

Fortiva®
PORCINE DERMIS

2013
Cortiva® Allograft Dermis Launched.

Cortiva®
ALLOGRAFT DERMIS

2021 –

2021
Cortiva Silhouette™ Allograft Dermis Launched.

Cortiva
Silhouette™
ALLOGRAFT DERMIS

2024
Cortiva® 1mm Perforated Allograft dermis launched.

Cortiva® 1mm
PERFORATED
ALLOGRAFT DERMIS

HOMOLOGOUS USE

Cortiva® Allograft Dermis implants are regulated as 361 human cell and tissue products (HCT/Ps) as defined in US FDA 21 CFR 1271 and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician).

Homologous use means the repair, reconstruction, replacement, or supplementation of a recipient's cells or tissues with an HCT/P that performs the same basic function or functions in the recipient as in the donor.

The FDA has not cleared or approved any acellular dermal matrix (ADM) or mesh for use in breast reconstruction.

have been processed through RTI's proprietary validated sterilization processes with **zero confirmed incidence** of implant-associated infection.

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

MAINTAINS IMPLANT CHARACTERISTICS

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.

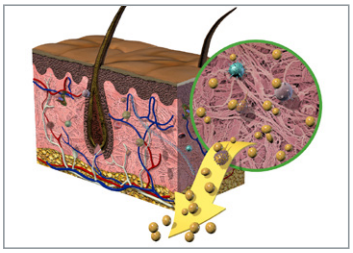
VALIDATED VIRAL INACTIVATION

Validated to inactivate and/or remove a panel of viruses, bacteria and fungi and spores, including enveloped and non-enveloped viruses as well as DNA and RNA viruses.

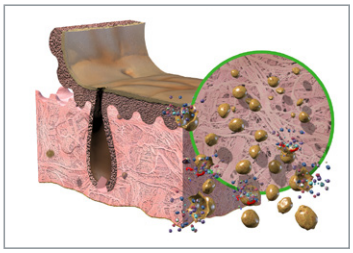
HOW THE TUTOPLAST PROCESS WORKS

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 assurance level (SAL) of 10^{-6} of the final packaged graft.

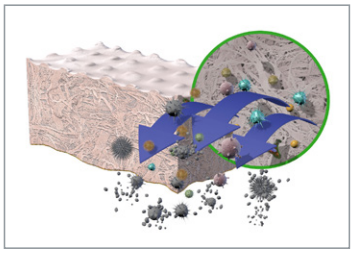
PROCESSING MAKES THE DIFFERENCE



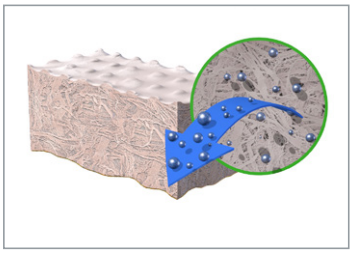
1. Alkaline Treatment
Removes cells and lipids which interfere with healing.



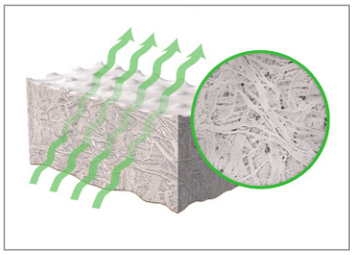
2. Osmotic Treatment
Disrupts cell membranes to allow easier removal of cellular components.



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.

Peace of Mind

Allograft Sterility

U.S. FDA RECOMMENDATION FOR MEDICAL DEVICES

"The sponsor should state the sterility assurance level (SAL) of 10^{-6} for devices labeled as sterile unless the device is intended only for contact with intact skin. FDA recommends a SAL of 10^{-3} for devices intended only for contact with intact skin."[1]

The Cortiva allograft portfolio is held to the same sterility standards as medical devices and materials.

RTI employs redundant safeguards to provide the highest level of confidence that patients receive safe, high-quality tissue.

RTI's proprietary Tutoplast Tissue Sterilization Process is validate to achieve a sterility assurance level (SAL) of 10^{-6}, meaning there is a 1 in one million chance that there is any viable microorganism on the tissue after sterilization. The process is also validated to inactivate a panel of relevant and model viruses as outlined in Q5A.

There are different levels of allograft sterility.

Category	Cortiva® Allograft Dermis	Some Sterilized Dermis	Aseptically Processed Dermis
Sterility Assurance Level (SAL)	10^{-6}	10^{-3}	**Aseptic** (There is no sterility assurance level associated with aseptic processing.)
The Difference	1 in 1,000,000 chance a viable microorganism survives the sterilization process	1,000 times more likely to contain microorganisms than SAL 10^{-6}	Up to 1,000,000 times more likely to contain microorganisms than SAL 10^{-6}

Cortiva Allograft Dermis is terminally sterilized via low dose gamma irradiation in order to achieve SAL 10^{-6} which is the highest level of sterility for surgical implants.

Non-crosslinked Acellular Dermal Matrices

The Cortiva Allograft Dermis implants offer three important components of a tissue-based implant: consistency* and handling, reliable supply and sterility.*

Tutoplast® processed allograft dermis has been shown to be biocompatible with a low inflammatory response,[2]** making it suited for repair, replacement, reconstruction or augmentation of soft tissue.

Cortiva allograft and AlloDerm had similar perioperative wound complications in abdominal wall reconstruction with zero explantations.[3]***

**Data on file at RTI Surgical.*

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

****Clinical cases are unique and individual results may vary.*

CONSISTENT

The Cortiva allograft portfolio has best-in-class thickness consistency.

RAPID REHYDRATION

Cortiva Allograft Dermis implants rehydrate in approximately 30 seconds.

- Results in reduced preparation time compared to some other ADMs.

PRESERVATIVE FREE

Cortiva allograft implants are preservative and antibiotic free.

RELIABLE SUPPLY

RTI has invested significantly in increased processing capacity and optimization to provide a consistent supply.

- Tissue will be available where and when it is needed without delay to surgeries.

PROVEN CLINICAL DATA

Cortiva Allograft Dermis is referenced in multiple publications. Most publications are head-to-head against AlloDerm and showed Cortiva allograft to be comparable to AlloDerm.[4-8]

Multiple implant options provide consistent thickness to meet individual patient needs:

- Cortiva allograft = 0.8 – 1.8mm
- Cortiva 1mm allograft = 0.8 – 1.0mm
- Cortiva 1mm perforated allograft = 0.8 – 1.0mm
- Cortiva 1mm Tailored allograft = 0.8 – 1.0mm
- Cortiva Silhouette allograft = 0.45 – 0.7mm

With basement membrane

Cortiva®
ALLOGRAFT DERMIS

Cortiva® 1mm
ALLOGRAFT DERMIS

Cortiva® 1mm
PERFORATED
ALLOGRAFT DERMIS

Without basement membrane

Cortiva® 1mm
TAILORED
ALLOGRAFT DERMIS

Cortiva
Silhouette™
ALLOGRAFT DERMIS

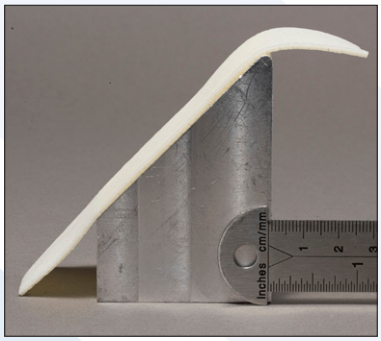
*Clinical cases are unique and individual results may vary.

Same Portfolio
Different Characteristics

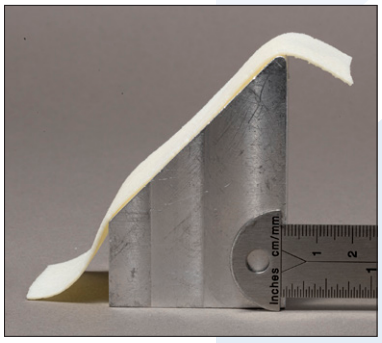
Your patients are unique, therefore your requirements should be unique too.

Cortiva Allograft Dermis implants are available in multiple sizes and thicknesses for all of your patients' needs.

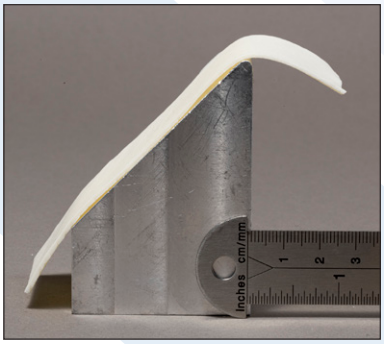
Cortiva®
ALLOGRAFT DERMIS



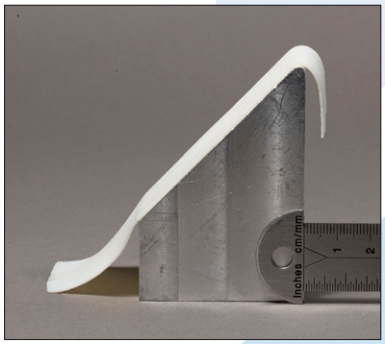
Cortiva® 1mm
TAILORED
ALLOGRAFT DERMIS



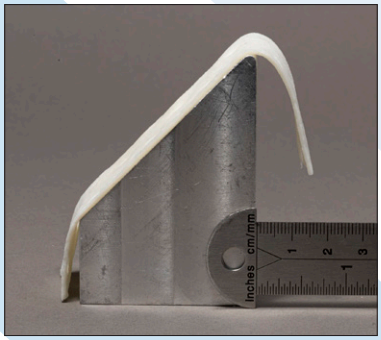
Cortiva® 1mm
ALLOGRAFT DERMIS



Cortiva
Silhouette™
ALLOGRAFT DERMIS



Cortiva® 1mm
PERFORATED
ALLOGRAFT DERMIS

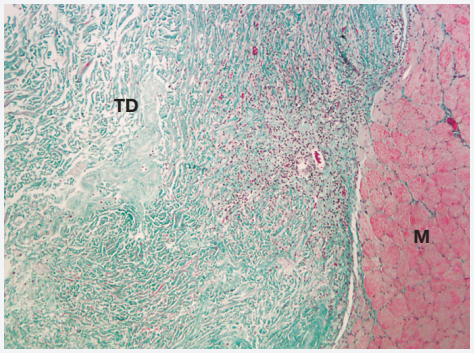


REVASCULARIZATION AND REMODELING (ANIMAL MODEL)*

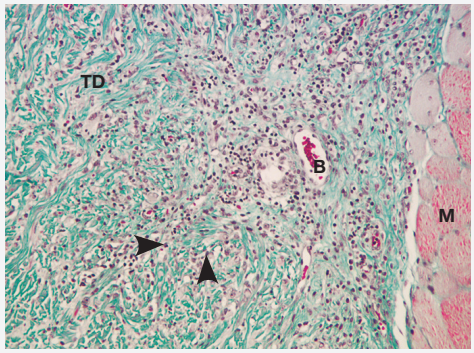
Cortiva Allograft Dermis demonstrated rapid revascularization and remodeling.[8]

POST-IMPLANTATION HISTOLOGY

7 DAYS POST-IMPLANTATION (40X)



7 DAYS POST-IMPLANTATION (100X)

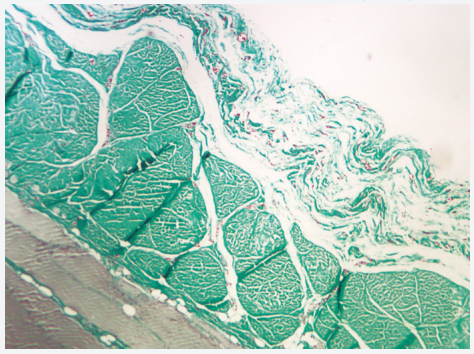


KEY

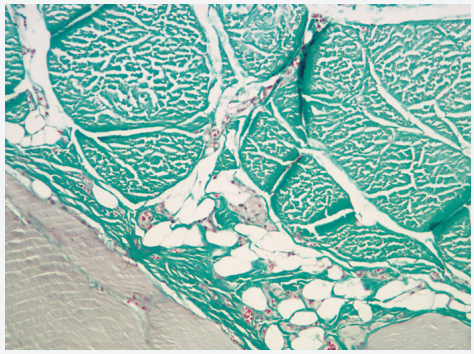
TD = Tutoplast Dermis
M = Muscle
B = Blood Vessels
➤ = Polymorphoneutrophils

Representative Masson's Trichrome histology photos of Cortiva Allograft Dermis at seven days post-implantation show fibroblasts and capillaries have begun infiltration into the implant.

16 WEEKS POST-IMPLANTATION (40X)



16 WEEKS POST-IMPLANTATION (100X)



Representative Masson's Trichrome histology photos of Cortiva Allograft Dermis at 16 weeks post-implantation demonstrate progressive tissue remodeling.

Implants were completely replaced by mature granulation tissue. The implant areas were partially compartmentalized by branching capillaries in an animal model.

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

Room Temperature Storage
Sterilized through the Tutoplast® Tissue Sterilization Process

CORTIVA® ALLOGRAFT DERMIS

Thickness Range: 0.8 - 1.8mm
Basement Membrane

Code	Size
DH0204	2cm x 4cm
DH0412	4cm x 12cm
DH0416	4cm x 16cm
DH0420	4cm x 20cm
DH0508	5cm x 8cm
DH0510	5cm x 10cm
DH0612	6cm x 12cm
DH0616	6cm x 16cm
DH0620	6cm x 20cm
DH0710	7cm x 10cm
DH0816	8cm x 16cm
DH1010	10cm x 10cm
DH1015	10cm x 15cm
DH1220	12cm x 20cm
DH1315	13cm x 15cm
DH1620	16cm x 20cm

CORTIVA® 1MM ALLOGRAFT DERMIS

Thickness Range: 0.8 - 1.0mm
Basement Membrane

Code	Size
DH2412	4cm x 12cm
DH2416	4cm x 16cm
DH2508	5cm x 8cm
DH2612	6cm x 12cm
DH2616	6cm x 16cm
DH2710	7cm x 10cm
DH2812	8cm x 12cm
DH2816	8cm x 16cm
DH2820	8cm x 20cm
DH3015	10cm x 15cm
DH3620	16cm x 20cm

CORTIVA® 1MM PERFORATED ALLOGRAFT DERMIS

Thickness Range: 0.8 - 1.0mm
Basement Membrane

Code	Size
DP1620	16cm x 20cm

CORTIVA® 1MM TAILORED ALLOGRAFT DERMIS

Thickness Range: 0.8-1.0mm
No Basement Membrane

Code	Size
DMS087	Small, 7.3 x 15.1cm (87cm^2)
DMM140	Medium, 9.2 x 19.2cm (140cm^2)
DML170	Large, 10.2 x 21.1cm (170cm^2)

CORTIVA SILHOUETTE™ ALLOGRAFT DERMIS

Thickness Range: 0.45 - 0.70mm
No Basement Membrane

Code	Size
UTD0204	2cm x 4cm
UTD0407	4cm x 7cm
UTD0412	4cm x 12cm
UTD0416	4cm x 16cm
UTD0508	5cm x 8cm
UTD0612	6cm x 12cm
UTD0616	6cm x 16cm
UTD0710	7cm x 10cm
UTD0812	8cm x 12cm
UTD0816	8cm x 16cm
UTD0820	8cm x 20cm
UTD1015	10cm x 15cm
UTD1620	16cm x 20cm

To coordinate implant availability with your local representative:
Call: 877-612-4287 or Email: rticustomerservice@rtix.com

CORTIVA & CORTIVA 1MM ALLOGRAFT DERMIS

DESCRIPTION

Cortiva® and Cortiva® 1mm allograft dermis are dehydrated dermis from donated human tissue processed through the Tutoplast® Tissue Sterilization process. The implants are preserved by the Tutoplast® tissue sterilization process which retains the three-dimensional collagen structure responsible for the multidirectional, mechanical properties of the original dermal tissue.

These implants are regulated as 361 human cell and tissue product (HCT/Ps) as defined in US FDA 21 CFR 1271 and are restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). These implants are provided sterile and require rehydration prior to use.

WARNINGS

The same potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, it is not possible to guarantee freedom from transmission of infectious agents or other adverse reactions such as hypersensitivity, allergic or immune response.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant; as such conditions may compromise outcomes.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to the success of the surgical procedure.

CORTIVA® 1MM PERFORATED ALLOGRAFT DERMIS

DESCRIPTION

Cortiva® 1mm Perforated Allograft Dermis is dehydrated dermis from donated human tissue processed through the Tutoplast® tissue sterilization process. The implant is preserved by the Tutoplast® tissue sterilization process which retains the three-dimensional collagen structure responsible for the multidirectional, mechanical properties of the original dermal tissue.

The implant is regulated as 361 human cell and tissue product (HCT/Ps) as defined in USFDA 21 CFR 1271 and is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). The implant is provided sterile and requires rehydration prior to use.

WARNINGS

The same potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, it is not possible to guarantee freedom from transmission of infectious agents or other adverse reactions such as hypersensitivity, allergic or immune response.

Do not use the implant for abdominal wall repair, hernia repair or for other procedures that require substantial tensile strength. The implant should be used only where it is under minor to moderate tension.

Do not further perforate the implant. Additional perforations may affect implant performance.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant as such conditions may compromise outcomes.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. The implant should be used with caution in surgical procedures where it is under moderate to high tension. Appropriate placement and fixation of the implant are critical to the success of the surgical procedure.

CORTIVA 1MM TAILORED ALLOGRAFT DERMIS

DESCRIPTION

Cortiva 1mm Tailored allograft dermis is dehydrated dermis from donated human tissue processed through the Tutoplast® tissue sterilization process. The implant is preserved by the Tutoplast® tissue sterilization process which retains the three-dimensional collagen structure responsible for the multidirectional, mechanical properties of the original dermal tissue.

Cortiva® 1mm Tailored allograft dermis is regulated as a 361 human cell and tissue product (HCT/P) as defined in US FDA 21 CFR 1271 and is restricted to homologous use for the repair, replacement, reconstruction or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). This implant is provided sterile and requires rehydration prior to use.

WARNINGS

The same medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, the potential for transmission of infectious agents may exist. A small number of patients may experience localized immunological reactions to the implant. Successful treatment is dependent upon the patient's host tissue response. Resorption of the implant and commensurate substitution with functional host tissue is required to restore function.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant; as such conditions may compromise outcomes.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to the success of the surgical procedure.

CORTIVA SILHOUETTE™ ALLOGRAFT DERMIS

DESCRIPTION

Cortiva Silhouette™ allograft dermis is dehydrated dermis from donated human tissue processed through the Tutoplast® tissue sterilization process. The implant is preserved by the Tutoplast® tissue sterilization process which retains the three dimensional collagen structure responsible for the multidirectional, mechanical properties of the original dermal tissue.

The implant is regulated as a 361 human cell and tissue product (HCT/Ps) as defined in US FDA 21 CFR 1271 and is restricted to homologous use for the repair, replacement, reconstruction, or augmentation of soft tissue by a qualified healthcare professional (e.g., physician). The implant is provided sterile and requires rehydration prior to use.

WARNINGS

The same potential medical/surgical conditions or complications that apply to any surgical procedure may occur during or following implantation. The surgeon is responsible for informing the patient of the risks associated with their treatment and the possibility of complications or adverse reactions. As with any human tissue implant, it is not possible to guarantee freedom from transmission of infectious agents or other adverse reactions such as hypersensitivity, allergic or immune response.

Do not use the implant for abdominal wall repair, hernia repair or for other procedures that require substantial tensile strength. The implant should be used only where it is under minor to moderate tension.

Do not perforate the implant. Perforations may affect implant performance.

PRECAUTIONS

Prior to use, the surgeon must become familiar with the implant and the surgical procedure. Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for procedures using this implant; as such conditions may compromise outcomes.

The implant should be used with caution in surgical sites where an active infection is present or in sites with poor perfusion. If the surgeon determines that the clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken. Appropriate placement and fixation of the implant are critical to the success of the surgical procedure.

REFERENCES

1. Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for devices Labeled as Sterile. Guidance for Industry and Food and Drug Administration Staff. January 21, 2016. U.S. Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological health Center for Biologics Evaluation and Research.
2. Greenspan D. C., et al. "Histology of Surgically Implanted Tutoplast Processed Dermis." Unpublished data, 2008.
3. Lindsey et al., 2020. "AlloDerm and Cortiva Have Similar Perioperative Wound Complications in Abdominal Wall Reconstruction." Journal of Surgical Research. November 2020 (255) 255 - 260.
4. Rajiv P. Parikh, et al. 2018. "Cortiva versus AlloDerm ready to use in prepectoral and submuscular breast reconstruction: prospective randomized clinical trial study design and early findings." Plastic and Reconstructive Surgery Global Open. November 2018. doi: 10.1097/GOX.0000000000002013.
5. Keifer, et. al. 2016. "A complication analysis of two acellular dermal matrices in prosthetic based reconstruction." Plastic and Reconstructive Surgery Global Open. July 2016 4(7), e800. http://doi.org/10.1097/GOX.0000000000000790
6. Moyer, et. al. 2017. "A histological comparison of two human acellular dermal matrix products in prosthetic-based breast reconstruction." Plastic and Reconstructive Surgery Global Open, December 2017, 5(12) doi: 10.1097/GOX.0000000000001576
7. Urquia, et al. 2020. "Surgical Outcomes in Prepectoral Breast Reconstruction." Plastic and Reconstructive Surgery Global Open. 2020;8:e2744; doi: 10.1097/GOX.0000000000002744; Published online 23 April 2020.
8. Roth J. S., Diaz D. F. Laparoscopic Paraesophageal Hernia Repair with Acellular Dermal Matrix Cruroplasty. JSLS, Journal of the Society of Laparoendoscopic Surgeons. (2011) 15:355-360.

Please refer to the labeling for complete instructions for use.

Regulatory approvals vary by country. Therefore, we kindly ask you to contact the distributor in your region regarding availability of specific products, implants and / or instrumentation in your region.

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Distributed by:
RTI Surgical, Inc.
11621 Research Circle
Alachua, FL 32615 USA
t: 877.343.6832
www.rtisurgical.com
rticustomerservice@rtix.com

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