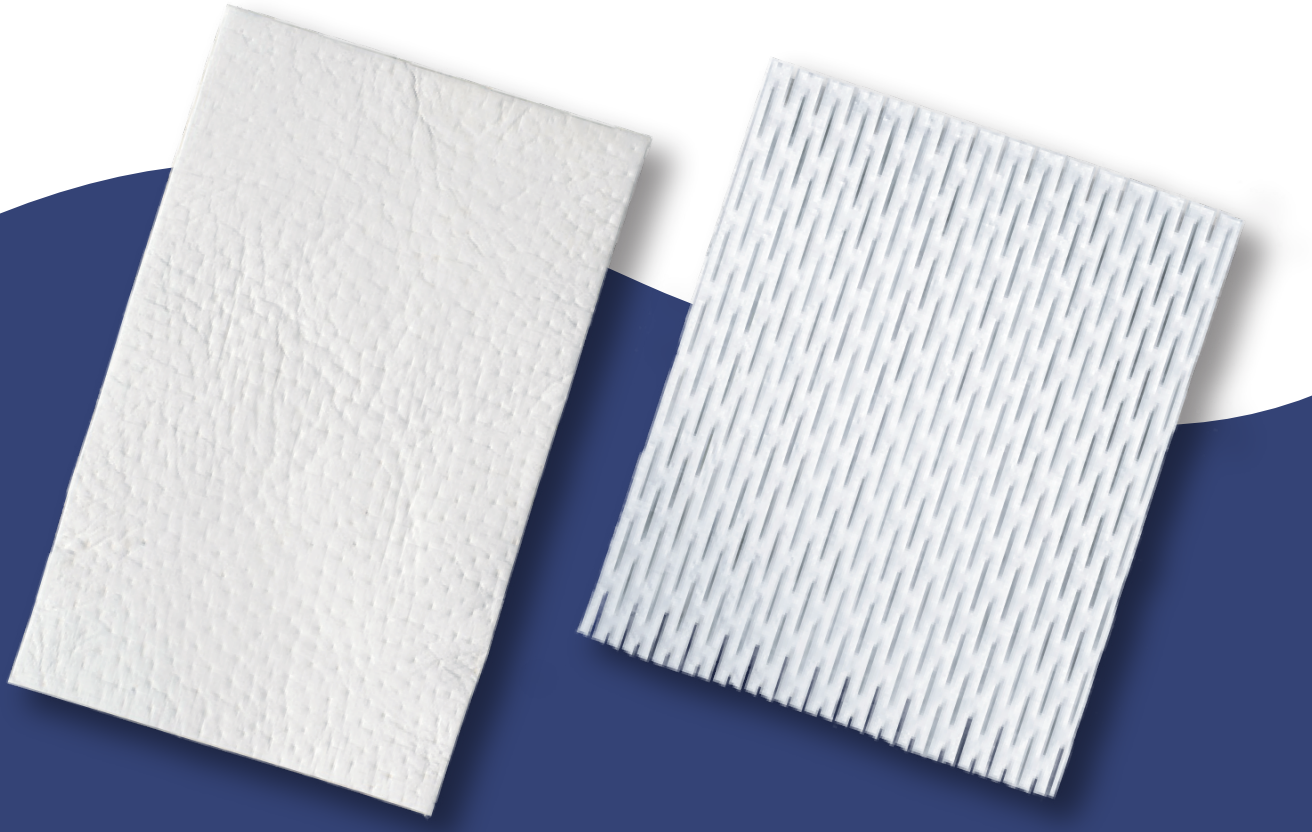
ROYAL

Derm-Maxx™

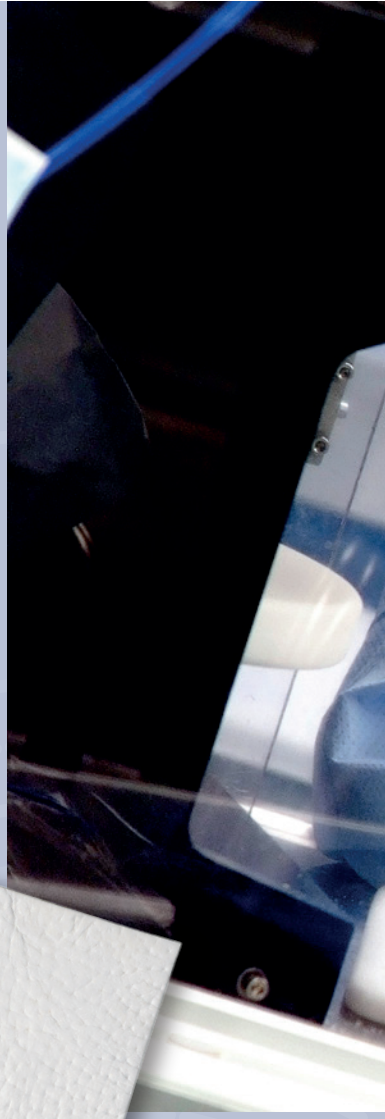
DERMAL MATRIX



Derm-Maxx™ Dermal Matrix for Wound Covering

OVERVIEW & APPLICATION GUIDE

Sterile, Room Temperature Human Dermis Graft



Derm-Maxx™ Dermal Matrix is an acellular human dermis graft sterilized using the Tutoplast® Tissue Sterilization Process. This proprietary process retains the three dimensional intertwined multidirectional fibers and mechanical properties of the native tissue. Derm-Maxx™ Dermal Matrix provides a natural scaffold to support the body's regenerative processes.

Derm-Maxx™ Dermal Matrix at a Glance

STERILE

Terminally sterilized to a Sterility Assurance Level (SAL) 10^{-6}
Via the Tutoplast® Process

BIOCOMPATIBLE

- Preserved vascular channels
- Preserved key components of the native matrix
- Revascularization evident in as early as 7 days in an animal model[1]

CONVENIENT

- ***Five year shelf life***

  The Tutoplast® Process uses solvent dehydration to allow for a five year on-the-shelf storage.

  This proprietary processing step eliminates the need for freezing or refrigeration of the graft. The storage characteristics of Derm-Maxx™ Dermal Matrix provide convenient, on-the-shelf storage between 1 °C and 37 °C for easy access and use.

- ***Simple single step rehydration***

  Derm-Maxx™ Dermal Matrix's single rehydration step* in room temperature sterile saline requires minimal effort and time. The quick rehydration of the Derm-Maxx™ Dermal Matrix can reduce OR time and costs.

*Please refer to labeling for complete instructions for use.

TUTOPLAST®
TISSUE STERILIZATION PROCESS

The Tutoplast® 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

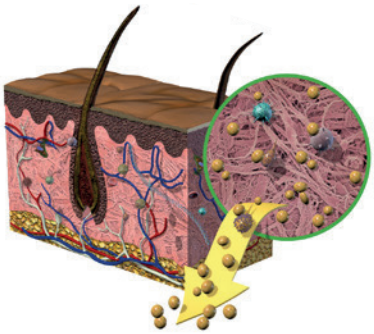
Osmotic treatments disrupt cell membranes to allow for full penetration of the graft.

VALIDATED VIRAL INACTIVATION

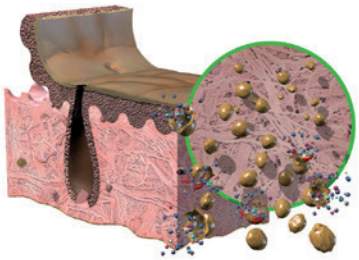
- Ability to inactivate or remove HIV, hepatitis, fungi, and spores
- Validated by individual tissue type based on most difficult case testing using most difficult to kill organisms

How does the Tutoplast® Process work?

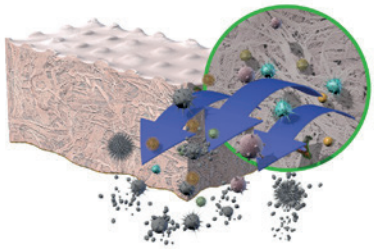
Osmotic, oxidative and alkaline (if indicated) treatments break down cell walls, inactivate pathogens, and remove bacteria. Solvent dehydration allows for room-temperature storage of tissue without damaging the native tissue structure. Low-dose gamma irradiation ensures a sterility level (SAL) of 10^{-6}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



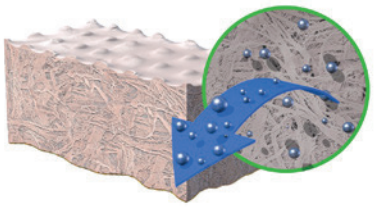
1. Alkaline Treatment
Removes cells and lipids which interfere with healing.



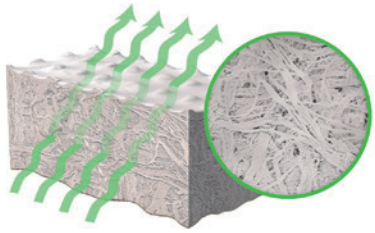
2. Osmotic Treatment
Disrupts cell membranes to allow easier removal of cellular components.



3. Oxidative Treatment
Inactivates pathogens and removes bacteria.



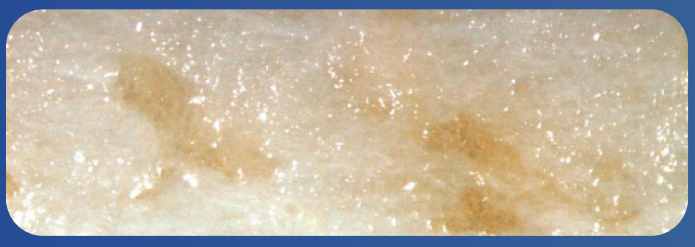
4. Solvent Treatment
Removes water from tissue, preserves the natural tissue matrix and allows for room-temperature storage without damaging the native structure.



5. Irradiation
Low-dose irradiation produces a terminally sterile graft, while preserving structural integrity.

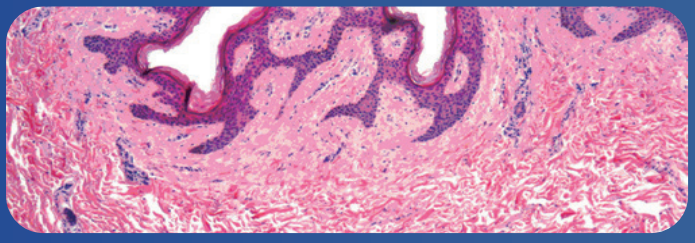
Images depict dermal processing.

Pre-Processed vs. Tutoplast® Processed Human Dermis

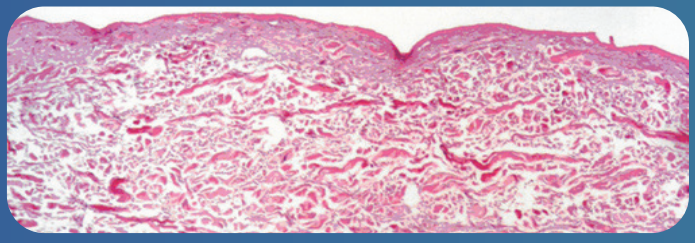


Pre-processed Human Dermis
Note presence of intact epidermis.

Tutoplast® Processed Human Dermis
Note epidermis has been removed and underlying matrix has been preserved.



Pre-processed Human Dermis
Note the presence of cellular debris throughout (purple cell nuclei).



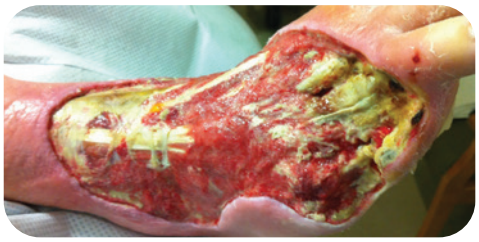
Tutoplast® Processed Human Dermis
Note the absence of cellular debris and the intact tissue matrix.

Data on file at RTI Surgical. H&E Stain. 50x magnification.

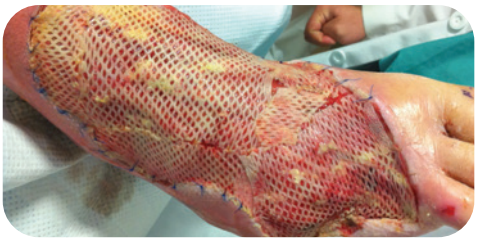
Wound Care Cases

DIABETIC FOOT ULCER

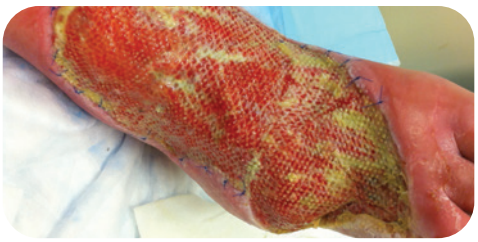
Patient presented with a diabetic ulcer with exposed tendon and bone on the dorsal aspect of the foot. The surgeon used multiple grafts to cover the entire surface of the wound. At three weeks the wound showed a decrease in wound depth and significant granulation tissue present.[1]



Initial Presentation



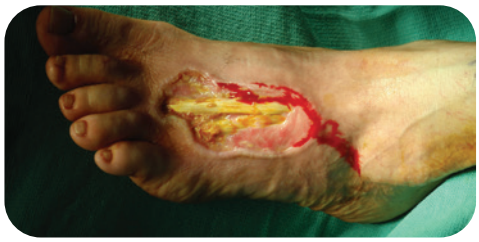
Graft Application



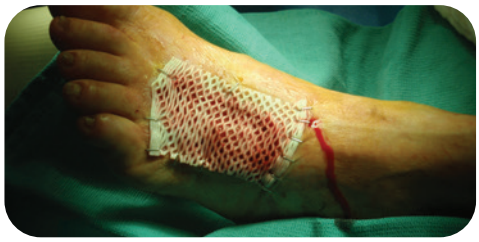
3 Weeks

INSECT BITE

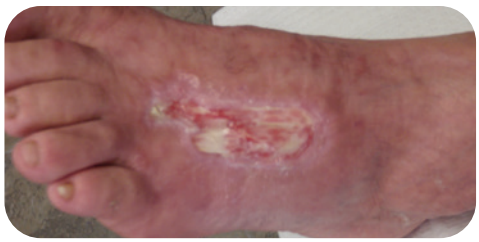
Patient presented with an infected insect bite with exposed tendon and bone on the dorsal aspect of the foot. The wound required two graft applications. At 10 weeks the wound showed 70 percent decrease in size and 80 percent granulation tissue coverage.[1]



Initial Debridement



Graft Application



10 Weeks

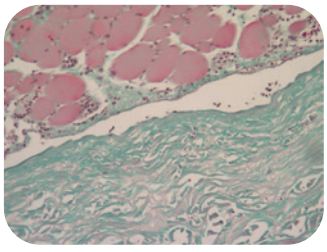
Clinical cases are unique and individual results may vary

Biocompatibility

The donated human tissue source of Derm-Maxx™ Dermal Matrix produces a biocompatible intact porous scaffold to support cellular proliferation and revascularization. The Tutoplast® Process preserves the key components of the native matrix that support the body's regenerative processes.

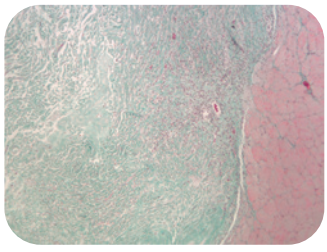
IN-VIVO ANIMAL MODEL STUDY

The graft functioned successfully as a scaffold and is fully incorporated and remodeled by the host tissue.[1]



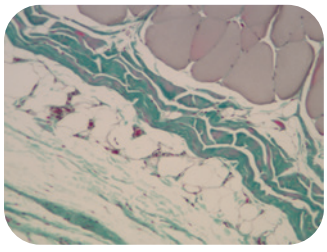
Day 1

Beginning of cellular infiltration of the graft by host tissue.



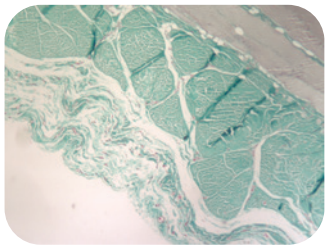
Day 7

Vascularization evident, invasion of fibroblasts and other cells found in normal healing cascade of the graft by host tissue.



Week 8

Difficult to distinguish implant from host tissue; graft is well incorporated.

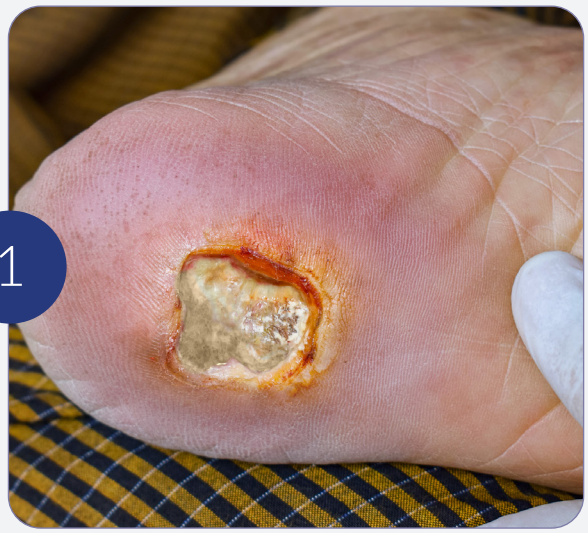


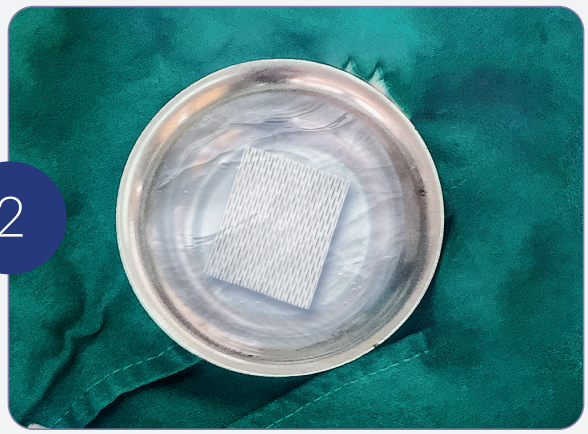
Week 16

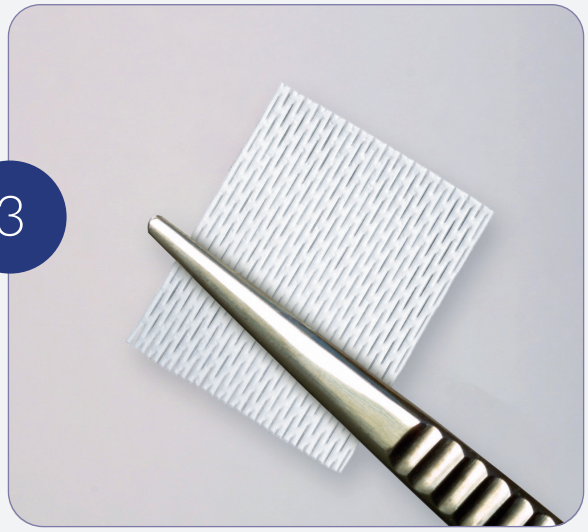
Nearly complete incorporation and remodeling of the graft has occurred.

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

Derm-Maxx™ Dermal Matrix is acellular human dermis that is provided sterile with on-the-shelf sorage and has a five-year shelf life. Tutoplast® processed allografts have been used as a wound covering in diabetic ulcers, Charcot foot ulcers, venous ulcers, trauma wounds, pressure sores/ulcers, partial and full thickness wounds and surgical wounds.







WOUND COVERING APPLICATION GUIDE

IMPORTANT: Read the entire instructions for use (IFU), provided with the graft, before using the following quick reference guide.

1. WOUND PREPARATION

Prepare the wound bed per standard protocol. Remember proper debridement is crucial in wound healing. All dead or devitalized tissue should be removed from the wound prior to grafting.

2. GRAFT PREPARATION

Derm-Maxx™ Dermal Matrix needs to be rehydrated prior to use by soaking in sterile, room temperature saline solution for at least 30 seconds. Use promptly after rehydration (refer to IFU provided with the graft).

NOTE: *The graft is sterile as packaged, but antibiotics agents prescribed by the surgeon may be added to the soaking solution as a precaution against incidental infection. The prescribing surgeon is responsible for selecting an appropriate antibiotic agent at a suitable concentration. Other rehydration methods such as blood and platelet-rich plasma (PRP) have also been used.*

3. SIZE & TRIM GRAFT

The graft should be sized according to the tissue defect. An excess border is recommended for adequate fixation of viable tissue.

Derm-Maxx™
DERMAL MATRIX

4. GRAFT ORIENTATION

Some physicians may prefer to apply the graft to the wound bed with the rough side down (rough side making the contact with the wound bed). The rough side of the graft can be determined by dropping a small amount of blood on both sides. (The side that absorbs the blood is considered the “rough” or “down” side.)

5. GRAFT FIXATION

Use the appropriate suture and needle for the surgical procedure. If absorb-able sutures are used, it is recommended to select the longest lasting materials available. Derm-Maxx™ Dermal Matrix must be securely placed to prevent displacement and to aid in incorporation to the wound bed.

6. WOUND DRESSING

To maintain a clean and moist wound environment, application of a non-adherent dressing directly over the graft is recommended. Sterile gauze may be applied to maintain “dressing to wound” contact and help keep the graft fixation secure.

REIMBURSEMENT

HCPCS CODE FOR Derm-Maxx™ Dermal Matrix

The Centers for Medicare & Medicaid Services (CMS) assigned a brand-specific Level II HCPCS code, Q4238, to Derm-Maxx™ Dermal Matrix.

CMS has indicated that these brand-specific HCPCS codes are applicable for all sites of service that use the Derm-Maxx™ Dermal Matrix.

CODE DESCRIPTION

Q4238 Derm-Maxx™, per square cm

Use of the HCPCS Q-code does not guarantee payment. You should select the most appropriate codes for the procedures performed. Coding practices will vary by the site of care, patient condition, range of services provided, local carrier instructions, and other factors. The decision about how to complete a reimbursement claim form, including billing amounts, is exclusively the responsibility of the provider. Coding regulations are subject to change at any time.

ORDERING INFORMATION

Code	*Description*
MDRMF-11	Derm-Maxx™ Dermal Matrix, Fenestrated 1cm x 1cm
MDRMF-22	Derm-Maxx™ Dermal Matrix, Fenestrated 2cm x 2cm
MDRMF-24	Derm-Maxx™ Dermal Matrix, Fenestrated 2cm x 4cm
MDRMF-44	Derm-Maxx™ Dermal Matrix, Fenestrated 4cm x 4cm
MDRMF-48	Derm-Maxx™ Dermal Matrix, Fenestrated 4cm x 8cm
MDRMF-510	Derm-Maxx™ Dermal Matrix, Fenestrated 5cm x 10cm

- Royal Biologics is ISO 13485:2016 Certified

REFERENCES

1. Data on file at RTI Surgical, Inc.

ROYAL

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