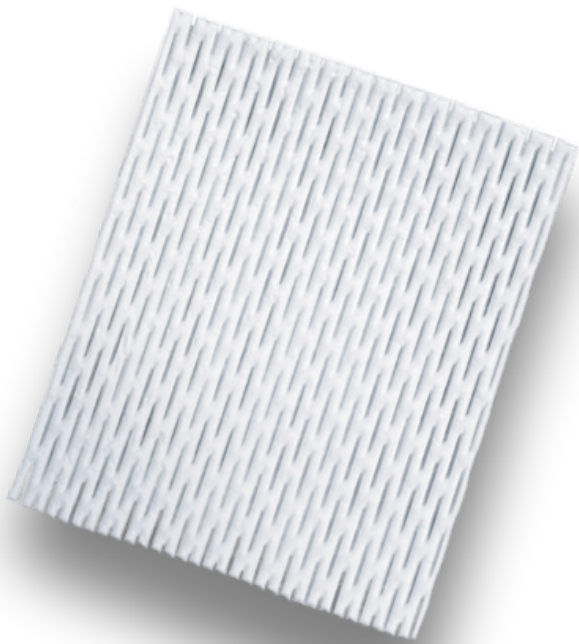


MATRIX^{HD}

DERMAL FENESTRATED MATRIX



Matrix HD Dermal Fenestrated Matrix for Wound Covering

OVERVIEW & APPLICATION GUIDE

CLINICAL BENEFITS

Oxygenation	Allows for increased oxygen diffusion, promoting cellular repair
Hemoglobin Activity	Improved blood flow, faster revascularization
Wound pH Stability	Faster healing environment, better bacterial control
Fluid Drainage / Management	Enables drainage of exudate preventing seroma / hematoma formation
Flexibility and Conformity	Conforms easily to the wound

DERMAL FENESTRATE MATRIX

Matrix HD Dermal Fenestrated Matrix is an acellular human dermis that is provided with on-the-shelf storage 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 wound and surgical wounds.

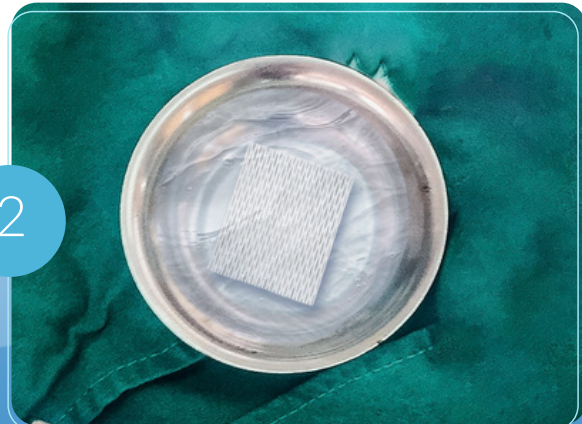


WOUND COVERING APPLICATION GUIDE

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

Matrix HD Dermal Fenestrated 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.

MATRIX^{HD}

DERMAL FENESTRATED MATRIX

4



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



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. Matrix HD Dermal Fenestrated 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.

ORDERING INFORMATION - Q4345

Code	Description
MHD-11	Matrix HD Dermal Fenestrated Matrix 1cm x 1cm
MHD-22	Matrix HD Dermal Fenestrated Matrix 2cm x 2cm
MHD-24	Matrix HD Dermal Fenestrated Matrix 2cm x 4cm
MHD-44	Matrix HD Dermal Fenestrated Matrix 4cm x 4cm
MHD-46	Matrix HD Dermal Fenestrated Matrix 4cm x 6cm
MHD-48	Matrix HD Dermal Fenestrated Matrix 4cm x 8cm
MHD-510	Matrix HD Dermal Fenestrated Matrix 5cm x 10cm
MHD-1020	Matrix HD Dermal Fenestrated Matrix 10cm x 20cm
MHD-2020	Matrix HD Dermal Fenestrated Matrix 20cm x 20cm

REFERENCES

1.Data on file at RTI Surgical, Inc.



Marketed by Royal Wound-X
401 Hackensack Ave, Suite 604
Hackensack NJ 07601
Phone: 201-488-1549

Sterile, Room Temperature Human Dermis Graft

Matrix HD Dermal Fenestrated Matrix is a sterilized acellular human dermis graft, processed using the Tutoplast® Tissue Sterilization Process. This specialized method preserves the tissue's three-dimensional, multidirectional fiber structure and mechanical integrity. Designed to support the body's natural regenerative processes, Matrix HD Dermal Fenestrated Matrix serves as a biologically compatible scaffold for tissue repair and reconstruction.

Matrix HD Fenestrated Dermal Matrix at a Glance

STERILE

Terminally sterilized to a Sterility Assurance Level (SAL) 10⁻⁶ Via the Tutoplast® Process

BIOCOMPATIBLE

- Maintains preserved vascular channels for optimal integration
- Retains essential components of the native matrix
- Demonstrates revascularization as early as 7 days in an animal model¹

CONVENIENT

- **Five year shelf life**

The Tutoplast® Process utilizes solvent dehydration, enabling a five-year shelf life without the need for freezing or refrigeration. This proprietary method ensures Matrix HD Dermal Fenestrated Matrix can be conveniently stored at temperatures between 1°C and 37°C, allowing for easy access and use.

- **Simple single step rehydration**

Matrix HD Dermal Fenestrated Matrix rehydrates in a single step using room temperature sterile saline, requiring minimal time and effort. Its rapid rehydration process helps reduce time and associated costs.





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

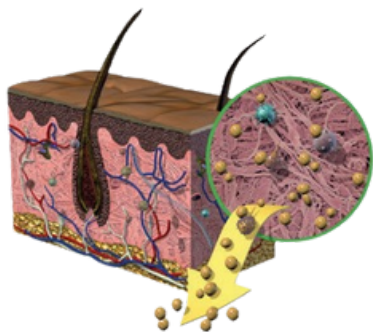
Osmotic treatments disrupt cell membranes to allow for full penetration of the graft.

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

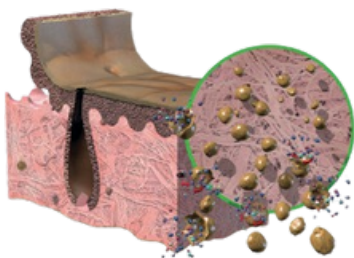
How does the Tutoplast® Process work?

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.



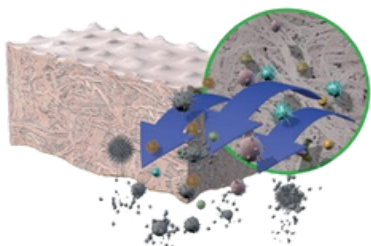
1. Alkaline Treatment

Removes cells and lipids which interfere with healing.



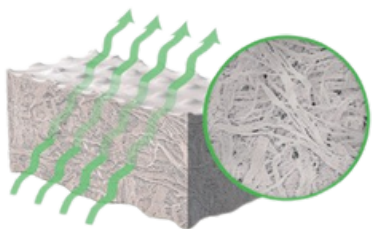
2. Osmotic Treatment

Disrupts cell membranes to allow easier removal of cellular components.



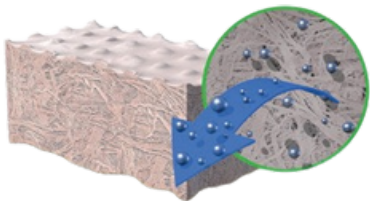
3. Oxidative Treatment

Inactivates pathogens and removes bacteria.



5. Irradiation

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



4. Solvent Treatment

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

Images depict dermal processing.

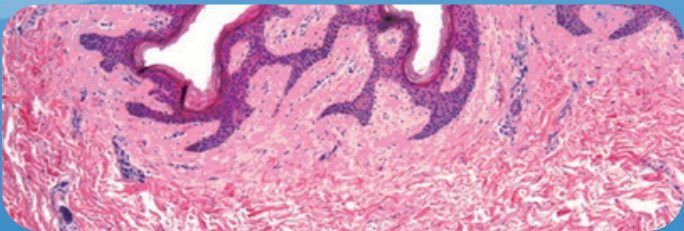
Pre-Processed vs. Tutoplast® Processed Human Dermis



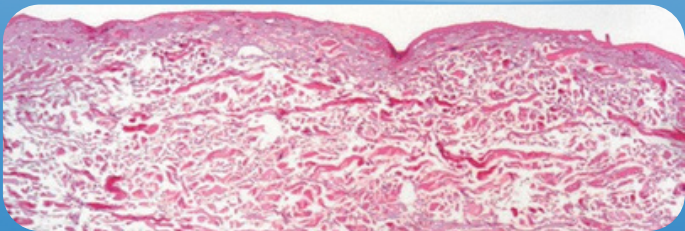
Pre-processed Human Dermis
Note presence of intact epidermis.



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.

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

Clinical cases are unique and individual results may vary

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



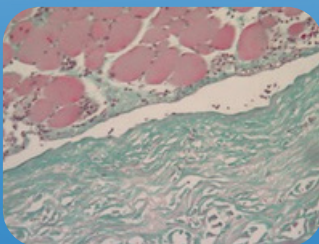
10 Weeks

Biocompatibility

The donated human tissue source of Matrix HD Dermal Fenestrated 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.

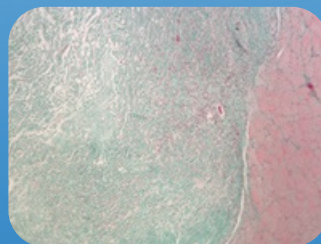
IN-VIVO ANIMAL MODEL STUDY

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



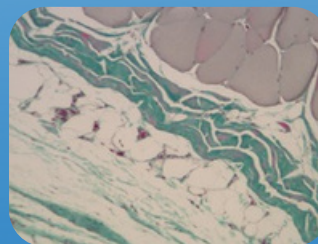
Day 1

Beginning of cellular infiltration of the graft by host tissue.



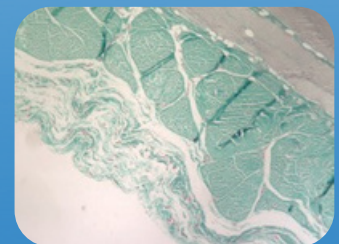
Day 7

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.



¹Performance data from animal studies may not be representative of performance in humans.