ExceFil™ Wound Matrix IFU

DEVICE DESCRIPTION

ExceFil™ Wound Matrix is a porcine-derived extracellular matrix (urinary bladder matrix, UBM) Non-chimical crossed linked that preserves the native collagen and elastin structure. It is available in sizes up to 20 × 30 cm. ExceFil® offers flexible treatment options through both 1 mm one-step and 2 mm two-step procedures. The 1 mm one-step approach is recommended for well-vascularized wounds requiring immediate skin grafting, while the 2 mm two-step approach is ideal for complex or poorly vascularized wounds, allowing optimal wound bed preparation before skin graft placement.

INDICATIONS

Excefil™ Wound Matrix ExceFil® is indicated for use with autologous split-thickness skin grafts (STSG) in the reconstruction of deep dermal defects and full-thickness skin wounds. It is suitable for plastic and reconstructive surgery, burn management, traumatic injuries, dermatologic procedures, and the treatment of chronic or poorly healing wounds requiring skin grafting.are intended for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/ undermined wounds, surgical wounds, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears), and draining wounds. The device is intended for one time use.

One-step Procedure

The one-step procedure involves immediate coverage of ExceFil® with an autologous split-thickness skin graft (STSG). This technique enables prompt wound closure, supports early patient mobilization, and has shown excellent clinical outcomes in burn and reconstructive surgery.

Two-step procedures

In the two-step procedure, ExceFil® is first applied and secured to the prepared wound bed. Once adequate vascularization of the collagen-elastin matrix has been achieved, definitive coverage with an autologous split-thickness skin graft (STSG) is performed during a second procedure.

Skin grafting is typically carried out after 5–12 days, once healthy granulation tissue has developed throughout the matrix. If granulation tissue extends beyond the matrix surface, it should be gently trimmed to create an optimal wound bed before graft placement.

Split-Thickness Skin Graft (STSG) Placement

Optimal results are generally achieved with unmeshed split-thickness skin grafts (STSG). Fenestration may be used to facilitate fluid drainage and help reduce the risk of seroma formation. Clinical experience also suggests that slightly overlapping the graft beyond the wound margins may improve coverage and integration.

When a meshed skin graft is required, care should be taken to minimize shear forces between the graft and ExceFil®. Proper fixation and immobilization are recommended to ensure close contact between the graft and the matrix during the initial healing phase.

DEVICE APPLICATION

1. Clean wound bed and irrigate to remove exudate and debris.
2. Perform standard debridement procedures in line with internal institutional protocols.
3. Using standard aseptic/sterile technique, open device pouches and remove device from inner pouch.
4. Hydrate device in a sterile dish with room temperature sterile saline (0.9%) or sterile lactated Ringer's solution prior to use.

Minimum hydration time: 2 min

Cut device to the desired size, ensuring complete wound coverage.

NOTE: When using ExceFil® Powder with an ExceFil® Wound Matrix, always apply the powder to the wound before placing the ExceFil® Wound Matrix, following the Instructions for Use (IFU).

Cover device with non-adherent dressing. Secure dressings to wound site. **Wet Wound**: Apply an absorptive dressing. Secure dressings to wound site. **Dry Wound**: Apply a hydrogel dressing to keep wound moist. Secure dressings to wound site.

Discard any unused portion of the device.

NOTE: Keep device and wound bed moist.

WOUND CARE MANAGEMENT Application

1. Inspect primary dressing at least every 7 days.
   - Remove exudate and apply new device to any non-covered wound areas as necessary.
   - During new device application, cover device with a new and appropriate secondary dressing, as described above.
2. Change all secondary dressings as appropriate for the wound type.
   - During secondary dressing changes, do not remove any remaining device that is present on wound surface.
   - As device is resorbed and incorporated, it may form a caramel-colored gel and emit a pungent odor.
3. Rinse wound surface gently leaving any existing caramel-colored gel on wound surface.
4. Repeat wound care management process weekly until wound has epithelialized or until desired wound state is achieved.

STORAGE

Store in a clean, dry environment at room temperature in unopened and undamaged package. Protect from freezing, excessive heat, and high humidity.

STERILIZATION

Excefil™ Wound Matrix devices are supplied sterile by electron beam irradiation in double peel-open pouches. Device is sterile if device pouch is unopened and undamaged.

1. Exposure to contaminated or infected field can lead to rapid breakdown of device.
2. If active infection is present, treat patient to resolve infection prior to device application.
3. Do not use if cracked, broken, or otherwise damaged.

POTENTIAL COMPLICATIONS

Complications and reactions are possible with any soft tissue repair, including but not limited to: infection, increased chronic inflammation, allergic reaction, unexplained fever or chills, excessive redness, pain, or swelling.

The following procedures only serve as a suggested guideline for the management of wounds with Excefil™ Wound Matrix. The provided suggestions are not intended to supersede internal institutional protocols and sound clinical judgment.

CONTRAINDICATIONS

1. Patients with known sensitivity or allergy to porcine materials.
2. Third-degree burns.

PRECAUTIONS

Always use aseptic technique when handling device.

NOTE: Maintain moist wound environment throughout wound care management procedures.

Excefil™ Wound Matrix Sizes

size cm	Thickness	Procedure
5x7	1mm	One-Step
10x15	1mm	One-Step
20x30	1mm	One-Step
10x15	2mm	Two-Step
20x30	2mm	Two-Step

SYMBOLS GLOSSARY

The below symbols conform with the following standards:

ISO 15223 —1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements

ISO 7000: — Graphical symbols for use on equipment — Registered symbols

Title of Symbol/ Explanatory Text		ISO 7000 Reference
LOT	Batch Code	2492
REF	Catalogue Number	2493
	Consult Instructions for Use	1641
	Do Not Re-sterilize	2608
	Do Not Reuse	1051
	Do Not Use if Package is Damaged	2606
	Manufacturer	3082
	Non– Pyrogenic	2724
SN	Serial Number	2498
STERILE R	Sterilized Using Irradiation	2502
	Use By Date	2607
Rx Only	**CAUTION**! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.	21 CFR 801

Rx Only

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