Integra® Meshed Bilayer Wound Matrix

DESCRIPTION

Integra® Meshed Bilayer Wound Matrix is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan with a polysiloxane (silicone) layer. The meshed bilayer matrix allows drainage of wound exudate and provides a flexible adherent covering for the wound surface. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

INDICATIONS

Integra Meshed Bilayer Wound Matrix is indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. Integra Meshed Bilayer Wound Matrix may be used in conjunction with negative pressure wound therapy. The device is intended for one-time use.

CONTRAINDICATIONS

- This device should not be used in patients with known sensitivity to bovine collagen or chondroitin materials.
- This device is not indicated for use in third-degree burns.

When **used with Negative Pressure Wound Therapy**, follow **Contraindications** for the specific Negative Pressure Wound Therapy device utilized, such as in the presence of:

- Exposed arteries, veins, organs, anastomotic sites or nerves
- Malignancy in the wound
- Untreated osteomyelitis
- Untreated malnutrition
- Necrotic tissue (with or without eschar present)
- Non-enteric and unexplored fistulas
- Sensitivity to silver (if silver dressings are used)

WARNINGS AND PRECAUTIONS

- Do not resterilize. Discard all opened and unused portions of Integra Meshed Bilayer Wound Matrix.
- Device is sterile if the package is unopened and undamaged. Do not use if the package seal is broken.
- Discard device if mishandling has caused possible damage or contamination.
- Integra Meshed Bilayer Wound Matrix should not be applied until excessive exudate, bleeding, acute swelling and infection are controlled.
- Debridement or excision must be done thoroughly to remove any remaining necrotic tissue that may cause infection.
- Do not stretch, expand, spread or remesh the device.
- The following complications are possible with the use of wound dressings. If any of the conditions occur, the device should be removed: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain or swelling.

When **used with Negative Pressure Wound Therapy**, follow **Warnings and Precautions** for the specific Negative Pressure Wound Therapy device utilized, such as:

- Precautions for patients who are or may be receiving anticoagulant therapy or suffering from difficult hemostasis;
- Excessive bleeding is a serious risk associated with the application of suction to wounds and may result in death or serious injury. Careful patient selection, in view of the above-stated contraindications, warnings and precautions, is essential. Carefully monitor the wound and collection circuit for any evidence of a change in the blood loss status of the patient. Notify the Physician of any sudden or abrupt changes in the volume or the color of exudate.

INSTRUCTIONS FOR USE - Integra Meshed Bilayer Wound Matrix (Without Negative Pressure Therapy)

Application

1. Using aseptic technique, peel open the outer pouch and gently drop the inner foil pouch onto a sterile field or surface.
2. Using sterile technique, place foil pouch flat and peel open the inner pouch.
3. Remove product, including the protective polyethylene sheets.
4. While holding the product with the tab, remove one polyethylene cover sheet. Turn the product and remove the second polyethylene cover sheet.
5. Using the tab, the product can now be placed into a basin containing a sterile saline solution. Carefully remove the tab from the product while rinsing for 1–2 minutes.
6. Keep product in the basin until application.
7. Prepare wound bed using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
8. Cut the device to size and apply immediately following wound bed preparation.

Note: It is critical that the collagen layer be in direct contact with the prepared wound. The silicone layer, identified by the black threads, must be placed out (away from the wound bed). Do not apply upside down; the black threads must be clearly visible.

9. Integra Meshed Bilayer Wound Matrix should be firmly secured using surgical staples, sutures, or other mechanical means. Any air bubbles should be carefully removed to maintain contact with the wound.
10. After application, use appropriate secondary dressings to maintain device adherence and protect the wound area. The optimum secondary dressing is determined by wound location, size, depth and user preference.

Post-Application

1. Change the secondary dressings as needed. Frequency of secondary dressing change will be dependent upon volume of exudate produced, type of dressing used and the clinician's need to inspect the wound bed for signs of infection or healing.

Removal of silicone layer from Integra Meshed Bilayer Wound Matrix

1. If edges of Integra Meshed Bilayer Wound Matrix are loose before full healing has occurred, the silicone can be trimmed away from the loose areas until the entire wound has healed.
2. Remove the silicone layer of the Integra Meshed Bilayer Wound Matrix when the tissue underneath is healed, typically 14 to 28 days. The Matrix may be loose in spots.
3. Remove by starting at one corner and pull gently. The silicone layer will peel off healed tissue relatively easily.

Caution: If bleeding occurs, or if patient complains of excessive pain, stop and wait 1 to 2 additional days. Forced removal may result in wound re-injury.

INSTRUCTIONS FOR USE - Integra Meshed Bilayer Wound Matrix (With Negative Pressure Therapy)

Application

1. Using aseptic technique, peel open the outer pouch and gently drop the inner foil pouch onto a sterile field or surface.
2. Using sterile technique, place foil pouch flat and peel open the inner pouch.
3. Remove product, including the protective polyethylene sheets.
4. While holding the product with the tab, remove one polyethylene cover sheet. Turn the product and remove the second polyethylene cover sheet.
5. Using the tab, the product can now be placed into a basin containing a sterile saline solution. Carefully remove the tab from the product while rinsing for 1–2 minutes.
6. Keep product in the basin until application.

7. Prepare wound bed using standard methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride the wound to ensure the wound edges contain viable tissue.
8. Cut the device to size and apply immediately following wound bed preparation.

Note: It is critical that the collagen layer be in direct contact with the prepared wound. The silicone layer, identified by the black threads must be placed out (away from the wound bed). Do not apply upside down; the black threads must be clearly visible.

9. Integra Meshed Bilayer Wound Matrix should be firmly secured using surgical staples, sutures, or other mechanical means. Any air bubbles should be carefully removed to maintain contact with the wound.
10. Apply Negative Pressure Wound Therapy Device according to manufacturer's instructions for use, paying specific attention to contraindications, warnings, and precautions.
    - Where applicable, follow instructions for "Meshed Grafts and Bioengineered Tissues"
11. For pressure settings, refer to instructions for use for the specific device utilized and type of wound, if applicable.

Post-Application

1. Utilize Negative Pressure Wound Therapy Device according to manufacturer's instructions paying special attention to wound monitoring.
2. During dressing changes, carefully remove the Negative Pressure Wound Therapy device and secondary dressing, foam or film, using caution to not disrupt the Integra Meshed Bilayer Wound Matrix.
3. Discontinue Negative Pressure Wound Therapy when the collagen matrix has been integrated and the silicone has separated from the Integra Meshed Bilayer Wound Matrix (typically 14-28 days).
    - When using Negative Pressure Wound Therapy, this time frame may be reduced.

Removal of Silicone Layer from Integra Meshed Bilayer Wound Matrix

1. If edges of Integra Meshed Bilayer Wound Matrix are loose before full healing has occurred, the silicone can be trimmed away from the loose areas until the entire wound has healed.
2. Remove the silicone layer of the Integra Meshed Bilayer Wound Matrix when the tissue underneath is healed, typically 14 to 28 days. The Matrix may be loose in spots.
3. Remove by starting at one corner and pull gently. The silicone layer will peel off healed tissue relatively easily.

Caution: If bleeding occurs, or if patient complains of excessive pain, stop and wait 1 to 2 additional days. Forced removal may result in wound re-injury.

HOW SUPPLIED

Integra Meshed Bilayer Wound Matrix is supplied sterile, in single use, double peel packages containing phosphate buffer. Integra Meshed Bilayer Wound Matrix is available in the following sizes:

Product Codes	Size		Quantity
MWM2021	5 cm x 5 cm	(2 inch x 2 inch)	1 unit/box
MWM4051	10 cm x 12.5 cm	(4 inch x 5 inch)	1 unit/box
MWM4101	10 cm x 25 cm	(4 inch x 10 inch)	1 unit/box
MWM8101	20 cm x 25 cm	(8 inch x 10 inch)	1 unit/box

STORAGE

Store flat at room temperature: (+ 10°C to + 30°C)

DISPOSAL

Product to be disposed according to institutional procedures.

PRODUCT INFORMATION DISCLOSURE

INTEGRA LIFESCIENCES CORPORATION HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA LIFESCIENCES EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA LIFESCIENCES SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA LIFESCIENCES NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME FOR IT ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS. INTEGRA INTENDS THAT THIS DEVICE SHOULD BE USED ONLY BY PHYSICIANS SKILLED IN THE USE OF THE DEVICE.

SYMBOLS USED ON LABELING

Do not re-use	LOT Lot number
Consult Instructions for Use	Expiration date
+30°C / +10°C Temperature limitation: +10°C to +30°C	STERILE R Sterilized using irradiation
Rx ONLY Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner	LATEX This product is not manufactured with Dry Natural Rubber or Natural Rubber Latex
Manufacturer	REF Catalog Number
Do not re-sterilize	Do not use if package is damaged
Date of Manufacture	

CAUTION: Federal law restricts this device to sale by or on the order of a physician or practitioner.

For product ordering information, technical questions, or reimbursement issues please call: (USA) 877-444-1122 (Outside USA) 609-936-5400 or (Fax) 866-800-7742

INTEGRA®

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