

INTEGRA™ MATRIX WOUND DRESSING

DESCRIPTION

INTEGRA™ Matrix Wound Dressing is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

INDICATIONS

INTEGRA™ Matrix Wound Dressing is indicated 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 (donor sites/grfts, post-Moh's 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.

CONTRAINDICATIONS

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

PRECAUTIONS

- Do not resterilize. Discard all opened and unused portions of INTEGRA™ Matrix Wound Dressing.
- 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™ Matrix Wound Dressing 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.
- 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.

INSTRUCTIONS FOR USE

Application

1. Always handle INTEGRA™ Matrix Wound Dressing using aseptic technique.
2. Peel open the outer pouch and remove the inner foil pouch.
3. Place foil pouch flat on sterile surface and peel it open.
4. Remove product, including the protective polyethylene sheets.
5. Separate product from the polyethylene sheets by slowly and carefully peeling back from one of the corner edges. Handle with care as product is fragile.
6. Place product into basin containing a sterile saline solution. Rinse the product free of storage buffer by immersion in sterile saline for 1-2 minutes.
7. Keep product in the basin until application.
8. 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.
9. Cut the device to size and apply immediately following wound bed preparation.
10. Smooth INTEGRA™ Matrix Wound Dressing into place to ensure the sheet is in contact with the underlying wound bed.
11. After application, use appropriate secondary dressings to maintain dressing 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 dressing 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.

Note: If hematoma or excess exudate collect under the sheet, small openings can be cut in the sheet to allow fluid to drain.

2. As healing occurs, sections of INTEGRA™ Matrix Wound Dressing may gradually peel and may be removed during dressing changes. Do not forcibly remove sections of INTEGRA™ Matrix Wound Dressing that may adhere to the wound. On inspection, if INTEGRA™ Matrix Wound Dressing is no longer covering the wound, place an additional piece of INTEGRA™ Matrix Wound Dressing over the wound.

HOW SUPPLIED

INTEGRA™ Matrix Wound Dressing is supplied sterile, in single use, double peel packages containing phosphate buffer. INTEGRA™ Matrix Wound Dressing is available in the following sizes:

Product Codes	Size	Quantity
52021	2 inch x 2 inch (5 cm x 5 cm)	1 unit/box
52025	2 inch x 2 inch (5 cm x 5 cm)	5 units/box
54051	4 inch x 5 inch (10 cm x 12.5 cm)	1 unit/box
54055	4 inch x 5 inch (10 cm x 12.5 cm)	5 units/box
54101	4 inch x 10 inch (10 cm x 25 cm)	1 unit/box
54105	4 inch x 10 inch (10 cm x 25 cm)	5 units/box
58101	8 inch x 10 inch (20 cm x 25 cm)	1 unit/box
58105	8 inch x 10 inch (20 cm x 25 cm)	5 units/box









STORAGE

Store flat at room temperature. Avoid excessive heat (greater than 40°C). Avoid freezing.

PRODUCT INFORMATION DISCLOSURE

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SYMBOLS USED ON LABELING

 Do not reuse after opening	 LOT Lot number
 See instructions for use	 Expiration date
 Storage temperature range +2°C–+30°C	 STERILE  Sterile—method of sterilization: irradiation
 Federal (USA) 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 877-444-1122 or 609-275-0500.

For training and certification, please visit www.ilstraining.com.

Integra LifeSciences Corporation
311 Enterprise Drive, Plainsboro, NJ 08536, USA
www.integra-ls.com

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