INTEGRA® BILAYER MATRIX WOUND DRESSING

DESCRIPTION

Integra® Bilayer Matrix Wound Dressing is an advanced wound care device comprised of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable polysiloxane (silicone) layer. The semi-permeable silicone membrane controls water vapor loss, provides a flexible adherent covering for the wound surface and adds increased tear strength to the device. The collagen-glycosaminoglycan biodegradable matrix provides a scaffold for cellular invasion and capillary growth.

INDICATIONS

Integra Bilayer 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, 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. The device is intended for one-time use.

CONTRAINDICATONS

- 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 Bilayer 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 Bilayer 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. While holding the product with the tab remove one polyethylene cover sheet. Turn the product and remove the second polyethylene cover sheet.
6. 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
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. 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.
11. Integra Bilayer Matrix Wound Dressing should be firmly secured using surgical tapes, or other mechanical means. Any air bubbles should be carefully removed by moving them to the edge of the sheet
12. 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.

Removal

1. If edges 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 Bilayer Matrix Wound Dressing when the tissue underneath is healed, typically 14 to 28 days. The dressing 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 reinjury.

HOW SUPPLIED

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

Product Codes	*Size*		*Quantity*
BMW2021	2 inch x 2 inch	(5 cm x 5 cm)	1 unit/box
BMW202	2 inch x 2 inch	(5 cm x 5 cm)	5 units/box
BMW4051	4 inch x 5 inch	(10 cm x 12.5 cm)	1 unit/box
BMW405	4 inch x 5 inch	(10 cm x 12.5 cm)	5 units/box
BMW4101	4 inch x 10 inch	(10 cm x 25 cm)	1 unit/box
BMW410	4 inch x 10 inch	(10 cm x 25 cm)	5 units/box
BMW8101	8 inch x 10 inch	(20 cm x 25 cm)	1 unit/box
BMW810	8 inch x 10 inch	(20 cm x 25 cm)	5 units/box

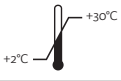
STORAGE

Store flat at room temperature. Avoid excessive heat. Avoid freezing.

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.

SYMBOLS USED ON LABELING

	Do not reuse after opening	LOT	Lot number
	See instructions for use		Expiration date
 +30°C +2°C	Storage temperature range +2°C- +30°C	STERILE R	Sterile-method of sterilization: irradiation
Rx ONLY	Federal (USA) law restricts this device to sale by or on the order of a physician or practitionar		

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 877-444-1122 or 609-275-0500.

Integra LifeSciences Corporation
1100 Campus Road, Princeton, NJ 08540
800-654-2873 609-275-0500
integralife.com

Integra and the Integra logo are registered trademarks of Integra LifeSciences Corporation or its subsidiaries in the United States and/or other countries.

©2020 Integra LifeSciences Corporation. All Rights Reserved.

U.S. Patent www.integralife.com/patentmarking

7100012072 Rev 01 2020-05 1541883-1