Integra® Wound Matrix
Integra® Wound Matrix (Thin)

DESCRIPTION
Integra® Wound Matrix and Integra® Wound Matrix (Thin) are collagen-glycosaminoglycan wound dressings that maintain and support a healing environment for wound management. Integra Wound Matrix (Thin) has 50% less collagen compared to each of the corresponding sq cm sizes of Integra Wound Matrix.

INDICATIONS
Integra Wound Matrix and Integra Wound Matrix (Thin) are 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/grafts, 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 Wound Matrix and Integra Wound Matrix (Thin).
- 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 Wound Matrix and Integra Wound Matrix (Thin) 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.

SINGLE-USE DEVICE
Integra Wound Matrix and Integra Wound Matrix (Thin) is supplied in a single-use package and is guaranteed to be sterile and non-pyrogenic unless opened or damaged. The product is intended for use as an absorbable implant and is not to be reused. Any attempt to resterilize or reuse the product/components will damage the matrix and impair its ability to function as intended. All unused pieces must be discarded.

INSTRUCTIONS FOR USE

Application
1. Always handle Integra Wound Matrix and Integra Wound Matrix (Thin) 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 Wound Matrix and Integra Wound Matrix (Thin) 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 Wound Matrix and Integra Wound Matrix (Thin) may gradually peel and may be removed during dressing changes. Do not forcibly remove sections of Integra Wound Matrix or Integra Wound Matrix (Thin) that may adhere to the wound. On inspection, if Integra Wound Matrix or Integra Wound Matrix (Thin) is no longer covering the wound, place an additional piece of Integra Wound Matrix or Integra Wound Matrix (Thin) over the wound.

HOW SUPPLIED
Integra Wound Matrix and Integra Wound Matrix (Thin) is supplied sterile, in single use, double peel packages containing phosphate buffer. Integra Wound Matrix and Integra Wound Matrix (Thin) are available in the following sizes:

Product Codes	Size		Quantity
52021	2 inch x 2 inch	(5 cm x 5 cm)	1 unit/box
52021T (Thin)	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
52025T (Thin)	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
54051T (Thin)	4 inch x 5 inch	(10 cm x 12.5 cm)	1 unit/box
54055T	4 inch x 5 inch	(10 cm x 12.5 cm)	5 units/box
54055T (Thin)	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
54101T (thin)	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
54105T (Thin)	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
58101T (Thin)	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
58105T (Thin)	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 re-use		LOT	Lot number
Consult Instructions for Use		Expiration date	
+30°C / +2°C	Temperature limitation	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	Not made with natural rubber latex
Do not re-sterilize		Manufacturer	
REF	Catalog number		Do not use if package is damaged

Manufactured by:
Integra LifeSciences Corporation
1100 Campus Road
Princeton, NJ 08540
800-654-2873
609-275-0500
integralife.com
Made in USA

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