



Integra® Flowable Wound Matrix

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Description

Integra® Flowable Wound Matrix is an advanced wound care device comprised of granulated cross-linked bovine tendon collagen and glycosaminoglycan. The granulated collagen-glycosaminoglycan is hydrated with saline and applied in difficult to access wound sites and tunneled wounds. It provides a scaffold for cellular invasion and capillary growth.

Integra Flowable Wound Matrix is supplied sterile, in single use kits containing one syringe with granular collagen, one empty sterile syringe, one luer lock connector, and one flexible injector.

Indications

Integra Flowable Wound Matrix 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/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 sulfate derived from shark cartilage.
- The device is not indicated for use in third-degree burns.

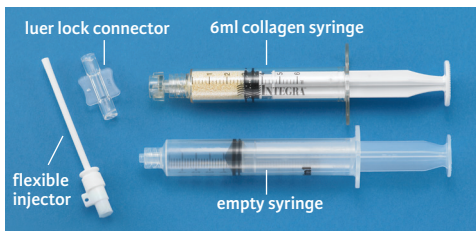
Precautions

- Do not resterilize. Discard all opened and unused portions of Integra Flowable 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 Flowable 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.
- The following complications are possible with the use of wound management products: infection, chronic inflammation (initial application of wound dressings may be associated with transient, mild, localized inflammation), allergic reaction, excessive redness, pain, or swelling. If any of these conditions occur, the device should be removed.

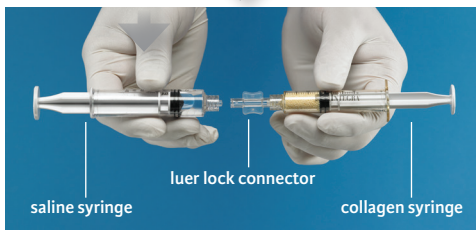
Instructions for Use

1. Always handle Integra Flowable Wound Matrix using aseptic techniques. Inspect all packaging integrity including protective wrapping, syringes and tip caps. **Do not use if packaging is damaged, or tip cap is missing or not fully attached to syringe. Visually inspect the empty syringe. Do not use if empty syringe contains cracks or visible particulate matter.**
2. 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. Peel open all three pouches (dry granulated collagen syringe pouch, empty sterile syringe pouch and the luer lock connector accessory pouch).
3. Pour saline into sterile container and draw 3.0ml of saline into the empty syringe.
4. Remove tip cap from the 6ml dry collagen syringe and attach luer lock connector to the collagen syringe.
5. Attach the syringe containing saline to the other end of the luer lock connector.
6. Hold both syringes in your hands securely.
7. Dispense all saline fluid into the dry collagen syringe.
8. Depress plungers back and forth at least 15 times to prepare the Integra Flowable Wound Matrix.
9. Consider the flowable wound matrix mixed when product appearance is consistent and homogeneous and all the product can be moved from one syringe to the other.

Steps 2/3



Steps 4/5



Steps 6/7



Instructions for Use (continued)

10. Ensure all the mixed material is moved into the 6ml collagen syringe (white plunger).
11. Remove the luer lock connector and the empty syringe while holding the 6ml syringe.
12. Attach flexible injector tip securely to the 6ml syringe.
13. Slowly depress plunger to 3ml to remove air pockets.
14. When dispensing Integra Flowable Wound Matrix, first determine the location of the base of the wound bed utilizing the flexible injector. Upon dispensing product into the wound, avoid pressing the injector tip directly against the base of the wound to ensure the product is not prevented from exiting the flexible injector.
15. After application, use an optimal secondary dressing to maintain matrix adherence and protect the wound area. The optimum dressing is determined by wound location, size, depth and user preference.
16. Change the dressing as needed. Frequency of dressing changes 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.
17. On inspection, if the wound is not completely filled, use an additional dose of the Integra Flowable Wound Matrix to complete the procedure.

Steps 8/9



Steps 10/11



Step 12



How Supplied

Integra Flowable Wound Matrix is supplied sterile, in single use kits containing one syringe with granular collagen, one empty sterile syringe, one luer lock connector, and one flexible injector.

Product Code	Size	Quantity
FWD301	3cc	1 Unit/Box





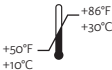




Storage

Store at room temperature (+50°F - +86°F / +10°C - +30°C). Avoid excessive heat. Avoid freezing.




Product Information Disclosure

INTEGRA HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. INTEGRA EXCLUDES ALL WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. INTEGRA SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THIS PRODUCT. INTEGRA 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 Glossary

Symbols	Title	Explanatory Text	Standard	Reference Number
	Catalog number	To identify the manufacturer's catalog number.	ISO 7000, Graphical symbols for use on equipment	2493
	Consult Instructions for Use	To indicate the need for the user to consult the Instructions for Use.		1641
	Sterilized using ethylene oxide	To indicate that the device is provided sterile and has been sterilized using ethylene oxide.		2501
	Manufacturer	To identify the manufacturer of the device.		3082
	Temperature limit	To indicate the maximum and minimum temperature limits at which the device shall be stored, transported or used.		0632
	Lot number	To identify the manufacturer's batch or lot code.		2492
	Do not re-use	To indicate that the device is for single use only and must not be used more than once.		1051
	Do not re-sterilize	To indicate that the device should not be re-sterilized after it once has been sterilized.		2608
	Use-by date (YYYY-MM-DD)	To indicate that the device should not be used after the date accompanying the symbol.		2607

Symbols Glossary (continued)

Symbols	Title	Explanatory Text	Standard	Reference Number
	Do not use if package is damaged	To indicate that the device must not be used if the package holding the device is damaged.	ISO 7000, Graphical symbols for use on equipment	2606
	Sterilized using irradiation	To indicate that the device is provided sterile and has been sterilized using irradiation		2502
	Not made with natural rubber latex	To indicate that the device is not made with natural rubber latex	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	Derived from 5.4.5
Rx ONLY	Prescription use only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.	Guidance for Industry Alternative to Certain Prescription Device Labeling Requirements	N/A

Caution:

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

For product ordering information, technical questions, or reimbursement issues, please call:

(USA) 800-654-2873 or (outside USA) 609-936-5400

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Manufacturer:



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Made in USA

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

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