RESTRATA®

MINIMATRIX

DESCRIPTION:
Restrata® MiniMatrix is a sterile, single patient use device intended for the local management of wounds. Restrata® MiniMatrix is a form of Restrata® Matrix that can be dispersed at the wound site during application. The device is made from synthetic biocompatible materials and was designed to include a fibrous structure with high porosity similar to native extracellular matrix. Restrata® MiniMatrix completely degrades via hydrolysis. The device does not contain any human or animal materials or tissues.

Restrata® MiniMatrix is supplied in a nested pouch configuration, placed within a shelf-box. The product is terminally sterilized. Contents of the package are guaranteed sterile and non-pyrogenic unless the package has been opened or damaged.

INTENDED USE:
Restrata® MiniMatrix is intended for use in the management of wounds, including:

- Partial and full thickness wounds
- Pressure sores / ulcers
- Venous ulcers
- Diabetic ulcers
- Chronic vascular ulcers
- Tunneled / undermined wounds
- Surgical wounds (e.g., donor site / grafts, post-laser surgery, post-Mohs surgery, podiatric wounds, dehisced wounds)
- Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, skin tears)
- Draining wounds

PRECAUTIONS:

- Do not use the product if there is evidence of container damage.
- Do not use the product after the expiration date listed on the packaging.

CONTRAINDICATIONS:

- This device should not be used in patients with known sensitivity to resorbable suture materials.

STORAGE:
Store at room temperature. Avoid excessive heat or humidity. Refrigeration of Restrata® MiniMatrix is not necessary.

WARNINGS:

- Do not resterilize.
- Device is sterile if the package is unopened and undamaged. Do not use if the product package is damaged or opened.
- Discard device if mishandling has caused possible damage or contamination.
- Restrata® MiniMatrix should not be applied until excessive exudate and bleeding is controlled.
- Complications are possible with any soft tissue repair procedure, such as chronic inflammation, infection, or allergic reaction. If any of these occur, the device should be removed as a precaution. Report any serious incident that has occurred in relation to this device to the manufacturer and the authority having jurisdiction in the user's locale.

SYMBOLS:

STERILE E-BEAM	Sterile unless package is opened or damaged. Sterilization Method: E-Beam
	Do not reuse after opening
	See instructions for use
Rx ONLY	For prescription use only
MR	MR Safe
	Expiration Date *Product labels: YYYY-MM-DD* *Patient labels: YYMMDD*
LOT	Lot Number
Customer Service	844-879-2237 Ext 0
Manufactured for:	Acera Surgical, Inc. 1650 Des Peres Rd. Ste. 120 St. Louis, MO 63131
	Electronic Instructions For Use (eIFU)

SUGGESTED INSTRUCTIONS FOR USING RESTRATA® MINIMATRIX
NOTE: Always handle Restrata® MiniMatrix using aseptic technique.

1) WOUND BED PREPARATION:

- Prepare the wound bed using standard methods and debride, if necessary, to ensure it is free of exudate and non-viable and devitalized tissue.

2) APPLICATION OF RESTRATA® MINIMATRIX:

- Measure the wound and select the appropriate amount of Restrata® MiniMatrix. Restrata® MiniMatrix should be applied using 5 to 10 mg per square centimeter of wound surface area.
- Restrata® MiniMatrix is packaged in a two-pouch configuration. Using standard aseptic technique, open the outer foil pouch and remove the inner clear pouch.
- Cut open the inner clear pouch.
- Apply Restrata® MiniMatrix to the wound bed, covering the entire wound.
- Alternatively, prior to applying to the wound bed, Restrata® MiniMatrix can be hydrated with sterile saline to form a slurry to aid in the application of the device where the location or geometry of the wound may make it difficult to apply dry. To make a slurry, dispense Restrata® MiniMatrix into a separate sterile container. Slowly add drops of sterile saline until desired consistency is achieved.
- To prevent dislodgement of the device, a non-adherent dressing can be placed over Restrata® MiniMatrix, followed by additional dressings and/or compression as needed.
- Discard any unused portion of Restrata® MiniMatrix.

3) DRESSING CHANGES:

- To prevent damage to the newly incorporating Restrata® MiniMatrix, it is recommended that clinicians manage dressing changes as appropriate.
- Take care to avoid dislodging Restrata® MiniMatrix when the dressings are changed.

4) WOUND ASSESSMENT:

- Restrata® MiniMatrix persists in the wound bed to help create an environment conducive to wound healing until it completely degrades via hydrolysis, typically within 30 days. It is not meant to be removed.
- Change all dressings as necessary.
- Carefully reassess the wound and record healing progression such as wound type, wound dimensions or length, width, depth, volume and other relevant information.

5) REAPPLICATION OF RESTRATA® MINIMATRIX:

- If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared Restrata® MiniMatrix over previously absorbed application (see step 2). Reapply Restrata® MiniMatrix as needed, based on physician or provider discretion, repeating application steps.

NOTE: If using a Restrata® device (or a wound dressing sheet of similar composition) in conjunction with Restrata® MiniMatrix, apply Restrata® MiniMatrix directly to the wound prior to applying Restrata® as described in the devices' Instructions for Use.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

For patent information, visit www.acera-surgical.com/patents
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