RESTRATA®

DESCRIPTION:
Restrata® is a sterile, single use device intended for use in local management of wounds. Restrata® is a soft, white, conformable, non-friable, absorbable matrix that provides a moist environment for the body's natural healing process to occur. Restrata® is made from synthetic biocompatible materials and was designed to include a fibrous structure with high porosity, similar to native extracellular matrix. Restrata® is a porous matrix with a defined rate of resorption that provides a scaffold for cellular infiltration and vascularization before completely degrading via hydrolysis. The device permits the ingress of cells and soft tissue formation in the defect space / wound bed. The device does not contain any human or animal materials or tissues.

Restrata® is terminally sterilized, in a single use double peel package in a variety of sizes in non-meshed and meshed configurations. Contents of the package are guaranteed sterile and non-pyrogenic unless the package has been opened or damaged.

INTENDED USE:
Restrata® 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

CONTRAINDICATIONS:
- This device is not indicated for use in third degree burns.
- 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® 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.
- Debridement or excision must be done thoroughly to remove any remaining non-viable or necrotic tissue that may cause infection.
- Restrata® should not be applied until excessive exudate, bleeding, acute swelling, and infection is controlled.
- Complications are possible, such as chronic inflammation, infection, or allergic reaction. If any of these occur, the device should be removed. 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.

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.
- Restrata® has not been studied in wounds that extend into the tendon, muscle, joint capsule, or bone.
- Restrata® has not been studied in children under the age of 18 years or in pregnant women.

SYMBOLS:

STERILE | E-BEAM	Sterile unless package is opened or damaged. Sterilization Method: E-Beam
	Do not reuse after opening
	See instructions for use
℞ 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® (NON-MESHED AND/OR MESHED)
NOTE: Always handle Restrata® using aseptic technique.

1) WOUND BED PREPARATION:
- Prepare the wound bed using standard methods to ensure it is free of exudate and non-viable and devitalized tissue. An initial excision or debridement of the wound may be necessary to ensure the wound edges contain viable tissue.
- Wait for any bleeding to stop before applying Restrata®.
- Cleanse the wound thoroughly with sterile saline prior to application of Restrata®.

2) PREPARATION OF RESTRATA®
- Measure the wound and select the appropriate size sheet of Restrata®. If necessary, the product may be fenestrated or meshed with a scalpel.
- Restrata® is packaged in a nested pouch configuration. Peel open the outer foil pouch starting from the chevron sealed edge. The inner TyVek® pouch is sterile and may be placed on the sterile field.
- Rinse surgical gloves, if necessary, to remove any glove powder prior to touching the product.
- Restrata® can be cut to the desired shape of the wound bed in a wet or dry state. In order to increase pliability of the product, if desired, hydrate Restrata® in sterile, room temperature, hypertonic solution (i.e. saline, water, etc.) for a minimum of 1 minute.

3) APPLICATION OF RESTRATA®:
- Apply Restrata® with either side towards the wound bed, and position to completely contact the entire surface of the wound bed and extend slightly beyond wound margins. Restrata® can be repositioned as necessary.
- As required, securely anchor non-meshed Restrata® with physician's preferred fixation method based on the type of wound, location of wound, patient's mobility, and patient compliance. Given the resorbable nature of Restrata®, it is recommended to use a method of fixation that is absorbable as well (e.g., absorbable sutures, tissue sealant, dissolvable clips, or other appropriate fixation method).
- For meshed Restrata®, physician may secure with mechanical means, if necessary.
- Rehydrate Restrata® by applying sterile saline, as needed.
- A non-adherent primary wound dressing can be placed over Restrata®.
- To prevent dislodgement of device, apply appropriate secondary dressing or compression to maintain dressing adherence (e.g., multi-layer compression bandage system, or other appropriate dressing), manage the wound exudate, keep Restrata® moist, and keep all layers securely in place. The optimum secondary dressing is determined by wound location, size, depth and physician or provider preference.
- Discard any unused pieces of Restrata®.

4) DRESSING CHANGES:
- To prevent damage to the newly incorporating Restrata®, it is recommended that clinicians manage primary and secondary dressing changes as appropriate. 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.
- Take care to avoid dislodging Restrata® when the primary or secondary dressings are changed.

5) WOUND ASSESSMENT:
- Restrata® persists in the wound bed acting as a protective covering to promote natural wound healing until it completely degrades via hydrolysis, typically within 30 days. It is not meant to be removed.
- As healing occurs, sections of Restrata® may gradually peel. Carefully trim any remaining loose edges that are not in contact with the wound. Take care not to disturb the area of Restrata® that is in contact with the wound bed.
- In the event the material does need to be removed from the wound bed, use warm (37°C) sterile saline to continuously rinse the wound site to help detach the material, so as not to cause further damage to the wound bed. Forced removal may result in wound reinjury.
- Change all primary and secondary dressings every 7 days, or 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.

6) REAPPLICATION OF RESTRATA®:
- Change primary or secondary dressings as needed (see step 4).
- If the wound is free of infection and necrosis but not fully epithelialized, reapply newly prepared Restrata® over previously absorbed application (see step 2 & 3). Reapply Restrata® as needed, based on physician or provider discretion, repeating application steps.

NOTE: If excess exudate collects under the sheet, a small opening can be cut in the sheet to allow the exudate to drain.

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.
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