RESTRATA®
SOFT TISSUE REINFORCEMENT

DESCRIPTION:
Restrata® Soft Tissue Reinforcement (STR) is an electrospun fiber matrix intended for implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery. Restrata® Soft Tissue Reinforcement is composed of resorbable synthetic fibers engineered from biocompatible materials. Contents of the package are provided sterile. The device is intended for one-time use.

INDICATIONS FOR USE:
Restrata® Soft Tissue Reinforcement is indicated for implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

CONTRAINDICATIONS:
This device should not be used in patients with known sensitivity to resorbable suture materials. Restrata® Soft Tissue Reinforcement is not indicated for repairs where load bearing support from the device is required such as in the repair of any hernia. The device is not indicated for intraperitoneal organ contact. The device is not indicated for bridging defects.

PRECAUTIONS:
- This device is designed for single patient use only. Do not reprocess, re-sterilize, or re-use.
- This device is fully resorbable, it should not be used in repairs where permanent support from the device is required.
- Sterile if package is unopened and undamaged.
- Do not use if the package seal is broken or if handling has caused damage or contamination.
- Discard unused portions of the medical device.
- Do not use after printed expiration date.
- Failure to securely suture the device to healthy, well-vascularized tissue may result in lack of incorporation of device.
- The device may not have sufficient strength to support stress encountered in all ventral hernias or large-area, body-wall repairs.
- No studies have been done to evaluate the reproductive impact with the clinical use of the device.
- The device has not been studied for use in the repair of direct inguinal hernias, ventral hernias, intraperitoneal use, central nervous system, contaminated and/or infected wounds, breast surgery or breast reconstruction. The safety risk of use in these other situations are unknown.
- The safety and effectiveness of the device has not been established for urogynecology use.

POTENTIAL COMPLICATIONS:
- Complications that can occur with the use of any device of this type may include, but are not limited to infection, chronic inflammation, allergic reaction, or seroma. If any of these occur and cannot be resolved, device removal should be considered. 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.

MRI SAFETY INFORMATION:
- The Restrata® Soft Tissue Reinforcement device is MR Safe.

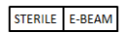
SUGGESTED INSTRUCTIONS FOR USE
NOTE: Handle Restrata® Soft Tissue Reinforcement using aseptic technique in the surgical setting.

1. Prepare the defect site using standard surgical techniques.
2. Determine the size of the defect and select the appropriate size sheet of Restrata® Soft Tissue Reinforcement.
3. Peel open the outer foil pouch starting from the chevron sealed edge. Remove the inner TyVek® pouch, which is sterile and may be placed on the sterile field.
4. Rinse surgical gloves, if necessary, to remove any glove powder prior to touching the product.
5. Carefully remove the product from the inner TyVek® pouch using aseptic technique so as not to crush the material.
6. Cut Restrata® Soft Tissue Reinforcement if needed to fit the defect site, providing a small allowance for overlap. The non-meshed device can also be cut/meshed to include slits if desired. The product can be cut in a wet or dry state. Restrata® Soft Tissue Reinforcement may be hydrated in standard sterile solution (i.e. saline, etc.) until desired handling characteristics are achieved.
7. Transfer the device to the defect site with either side oriented as desired.
8. It is recommended that the device be securely anchored using sutures or other method chosen by the clinician, avoiding excess tension.
9. Complete the standard surgical procedure and postoperative measures.
10. Place suction drains or the postoperative measures in place as per institutional guidelines for the procedure. The liberal use of drains is recommended until output is less than 15cc in 24 hours.
11. Discard any unused portions of Restrata® Soft Tissue Reinforcement.

STORAGE:
- Store at room temperature. Avoid excessive heat or humidity. Refrigeration of the device is not necessary.

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

SYMBOLS:



Sterile unless package is opened or damaged.
Sterilization Method: E-Beam


Do not reuse after opening


See instructions for use


For prescription use only

MR Safe


Expiration Date
Product labels: YYYY-MM-DD
Patient labels: YYMMDD

Lot Number

Customer Service: 844-879-2237 Ext 0

Manufactured for:
Acera Surgical, Inc.
1650 Des Peres Rd.
Ste. 120
St. Louis, MO 63131, USA


Electronic Instructions For Use (eIFU)

For patent information, visit www.acera-surgical.com.
MKG-20005-04. Issued 06/2025.