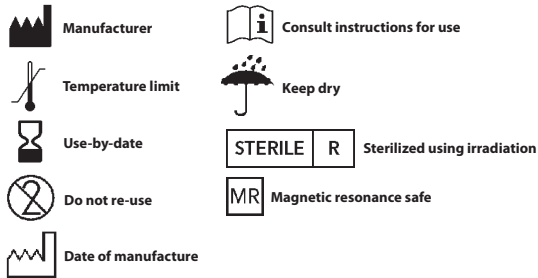


# FORTIFY FLOWABLE™

Extracellular Matrix

FP0138-01B



Distributed by:  
Wound Care Innovations, LLC, a Sanara MedTech Inc. Company  
1200 Summit Ave. Suite 414  
Fort Worth, TX 76102  
800-205-7719  
www.sanaramedtech.com

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## FORTIFY FLOWABLE™ EXTRACELLULAR MATRIX

### DESCRIPTION

The FORTIFY FLOWABLE™ Extracellular Matrix is an advanced wound care device comprised of particulate porcine small intestinal submucosa (SIS) and a natural carrier agent. The FORTIFY FLOWABLE™ Extracellular Matrix is mixed with hydration fluid within a syringe and then applied topically to wounds of various etiology. It provides a scaffold for cellular invasion and capillary growth. The FORTIFY FLOWABLE™ Extracellular Matrix is supplied sterile in peel-open packages and is intended for one-time use.

### INTENDED USE

The FORTIFY FLOWABLE™ Extracellular Matrix is indicated for the management of wounds including:

- Chronic vascular ulcers
- Diabetic ulcers
- Draining wounds
- Partial and full-thickness wounds
- Pressure ulcers
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Trauma wounds (abrasions, lacerations, second-degree burns, and skin tears)
- Tunneled/undermined wounds
- Venous ulcers

**Rx ONLY** This symbol means the following:

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

### CONTRAINDICATIONS

FORTIFY FLOWABLE™ Extracellular Matrix should not be used in patients with known sensitivity to porcine material or fructose. FORTIFY FLOWABLE™ Extracellular Matrix is not indicated for use in third degree burns.

### PRECAUTIONS

- FORTIFY FLOWABLE™ Extracellular Matrix is designed for single use only. Attempts to reprocess, resterilize and/or reuse may lead to device failure and/or transmission of disease.
- FORTIFY FLOWABLE™ Extracellular Matrix is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Use FORTIFY FLOWABLE™ Extracellular Matrix prior to the expiration date.
- Discard if mishandling has caused possible damage or contamination.
- FORTIFY FLOWABLE™ Extracellular Matrix should not be applied until excessive exudate, bleeding, acute swelling and infection is controlled.

### POTENTIAL COMPLICATIONS

The following complications are possible. If any of these conditions occur, the FORTIFY FLOWABLE™ Extracellular Matrix should be removed.

- Allergic reaction
- Excessive redness, pain, swelling or blistering
- Infection
- Inflammation

### STORAGE

FORTIFY FLOWABLE™ Extracellular Matrix should be stored in a clean, dry location at room temperature.

### STERILIZATION

FORTIFY FLOWABLE™ Extracellular Matrix has been sterilized with E-Beam radiation.

### INSTRUCTIONS FOR USE

#### Required Materials

- Sterile saline

**NOTE: Always handle the FORTIFY FLOWABLE™ Extracellular Matrix using aseptic technique.**

1. Prepare wound area using standard of care methods to ensure wound is free of debris and necrotic tissue. If necessary, surgically debride and treat the wound bed with standard of care techniques to ensure the wound shows granulation tissue and the edges contain viable tissue.

2. Using aseptic technique, open the package and remove the tray containing the FORTIFY FLOWABLE™ Extracellular Matrix.
3. Remove the plunger from a 3 mL syringe.
4. Place the cylinder in the 3 mL syringe.
5. Open the other 3 mL syringe and add 1 mL of sterile saline to the syringe.
6. Connect the two syringes with a luer-to-luer connector.
7. Depress plungers back and forth at least 15 times to prepare the FORTIFY FLOWABLE™ Extracellular Matrix.  
**NOTE:** Mixing is complete once the product is smooth and uniform and can be easily moved from one syringe to the other. If necessary, add more sterile saline.
8. Ensure all product is moved into one syringe. Disconnect the luer-to-luer connector from the syringes
9. Securely attach the cannula to the syringe containing the product and while pointing the syringe up, slowly depress the plunger to remove any air pockets.
10. Apply the FORTIFY FLOWABLE™ Extracellular Matrix to the wound. Smooth the FORTIFY FLOWABLE™ Extracellular Matrix into place to ensure the material is in full contact with the wound bed.  
**NOTE:** Additional product may be used to ensure the wound is completely covered. Do not over-fill defects.
11. Apply an appropriate non-adherent primary wound dressing over the FORTIFY FLOWABLE™ Extracellular Matrix.
12. Assess the wound and apply appropriate secondary dressings to maintain a moist wound environment. Change the secondary dressings as needed to maintain a moist, clean wound area.
13. Discard any unused portions of the FORTIFY FLOWABLE™ Extracellular Matrix according to institutional guidelines for biological waste.  
**NOTE:** Successful integration of FORTIFY FLOWABLE™ Extracellular Matrix may appear off-white or caramel-colored, similar to slough. This is usable extracellular matrix product and should not be removed. Any loose material around the wound edges may be removed as needed.
14. Gently cleanse the wound surface with sterile saline, leaving the FORTIFY FLOWABLE™ Extracellular Matrix intact.
15. At the follow-up visit, carefully reassess the wound and record healing progression and other relevant information.
16. If the wound is not healed, additional applications of the FORTIFY FLOWABLE™ Extracellular Matrix may be used over the previously applied material (follow steps 2-11 for instruction).