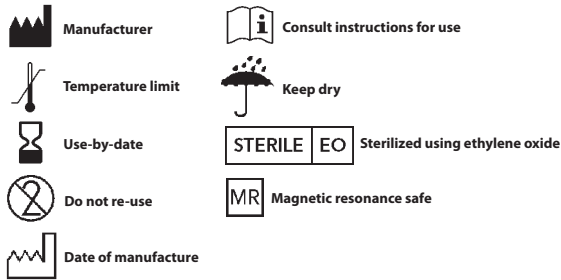


FORTIFY TRG™

Tissue Repair Graft

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FORTIFY TRG™ TISSUE REPAIR GRAFT

DEVICE DESCRIPTION

The FORTIFY TRG™ Tissue Repair Graft is a dried multi-layered small intestinal submucosa (SIS) sheet. The graft is used to reinforce soft tissue and can be cut to size to accommodate the patient's anatomy. The FORTIFY TRG™ Tissue Repair Graft is provided sterile for single use only. Prior to use, the device is hydrated with saline or autologous body fluids, such as blood, bone marrow aspirate or blood concentrates such as platelet concentrate.

INTENDED USE

The FORTIFY TRG™ Tissue Repair Graft is intended for implantation to reinforce soft tissue. The graft is supplied sterile in peel-open packages and is intended for one-time use.

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 physician.

This product is intended for use by trained medical professionals.

CONTRAINDICATIONS

The graft is derived from a porcine source and should not be used for patients with known sensitivity to porcine materials.

PRECAUTIONS

- The graft is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device failure and/or transmission of disease.
- Do not resterilize.** Discard all open and unused portions.
- The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date.
- The graft may not have sufficient strength to support stresses encountered in some ventral hernias or large-area, body-wall repairs.
- Ensure that the graft is hydrated prior to suturing or stapling.
- Hydration of ECM-based materials with autologous fluids has only been studied in animal models. Clinical benefit has not been established.
- Patients undergoing radiation therapy may not experience normal wound healing.
- Graft performance has not been evaluated with suture spacing greater than 2 mm.**
- Ensure that all layers of the graft are secured when suturing or stapling.**

POTENTIAL COMPLICATIONS

Complications that can occur with the use of any surgical graft material may include, but are not limited to:

- Abscess
- Adhesion
- Allergic reaction
- Bleeding
- Delayed or failed incorporation
- Erosion
- Extrusion
- Fever
- Fistula formation
- Induration
- Infection
- Inflammation
- Migration
- Pain
- Recurrence of tissue defect
- Seroma formation
- Tissue trauma

If any of the following conditions occur and cannot be resolved, device removal should be considered:

- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction
- Infection
- Seroma formation

Use of autologous body fluids may introduce other potential complications. Please consult the Instructions for Use of the autologous fluid preparation device.

STORAGE

Store the graft in a clean, dry location at room temperature.

STERILIZATION

This graft has been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- A sterile basin
- Sterile, smooth forceps
- Hydration fluid: room temperature sterile saline, sterile lactated Ringer's solution, or autologous body fluids such as blood, bone marrow aspirate, or blood concentrates.

Use the table below for guidance as to the approximate amount of hydration fluid needed for each device size.

Size (cm)	Approximate Amount of Hydration Fluid
1x10	1 cc
4x7	1 cc
7x10	2.5 cc
7x20	5 cc

NOTE: Consult autologous fluid preparation device labeling for instructions on how to prepare the autologous fluid.

NOTE: Handle the graft using aseptic technique, minimizing contact with latex gloves.

- Remove the graft inner pouch from its outer pouch, and place the inner pouch onto the sterile field.
- Open the inner pouch and aseptically remove the graft with the sterile, smooth forceps.
- Place the graft into the sterile dish in the sterile field. Multiple grafts may be hydrated simultaneously in the same basin.
- Add the hydration fluid to the basin.
- Hydrate the graft in the fluid until the desired handling characteristics are achieved. Do not hydrate the graft for longer than 5 minutes.
- Prepare the implant site using standard surgical techniques.
- Trim the graft to fit the implant site, providing a small allowance for overlap.
- After hydration, suture or staple the graft into place, avoiding excess tension.
 - NOTE:** Suturing or stapling grafts with close tissue approximation produces better outcomes.
- Complete the surgical procedure.
- Discard any unused portions of the graft according to institutional guidelines for medical waste.