Repliform®
Tissue Regeneration Matrix

Instructions for Use

Distributed by:

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752

Processed from Donated Human Tissue by:
LifeCell Corporation
One Millennium Way
Branchburg, NJ 08876
DESCRIPTION

Repliform® Tissue Regeneration Matrix is donated allograft human dermis, aseptically processed to remove cells and freeze-dried to remove moisture while preserving biologic components and structure of the dermal matrix.

Repliform matrix is white to buff colored and is uniform in appearance.

REGULATORY CLASSIFICATION

Repliform matrix is regulated by the US Food and Drug Administration (FDA) as human tissue for transplantation. All tissue is processed and provided in accordance with the FDA’s requirements for banked human tissue (21 CFR Part 1271) and Standards for Tissue Banking of the American Association of Tissue Banks (AATB). The tissue processor is compliant with the AATB Standards for Tissue Banking and applicable state requirements.

DONOR SCREENING AND TESTING

LifeCell has determined the donor of this tissue graft to be an eligible donor based on the results of donor screening and testing records. Donor screening includes, but may not be limited to, review of relevant medical records including a current donor risk assessment interview; a physical examination of the donor; laboratory test results; existing coroner and autopsy results; as well as other information pertaining to risk factors for relevant communicable diseases.

Comprehensive donor screening and testing is performed on all tissue donors in accordance with FDA regulations, AATB standards and applicable state requirements. Refer to the Summary of Records label provided with each graft for details of the testing.

Samples of the donor skin are tested for and shown to be free of bacterial and fungal pathogens; non-pathogenic skin bacteria may be present.

Due to limitations in testing technology, testing and donor screening cannot totally eliminate the risk that human source material will transmit disease.

INDICATIONS FOR USE

Repliform matrix is used for repair or replacement of damaged or inadequate integumental tissue such as in the treatment of urinary incontinence, to repair enteroceles, rectoceles and/or cystoceles and for pelvic floor reinforcement or other conditions resulting from inadequate or damaged integumental tissue.

Each package of Repliform matrix is intended for use in one patient, on a single occasion only.

Repliform matrix is not indicated for use as a dural substitute.
Repliform matrix is not intended for use in veterinary applications.

**CONTRAINDICATIONS**

Repliform matrix is contraindicated for use in any patient who is sensitive to any of the antibiotics listed on the package or polysorbate 20.

**WARNING**

Processing of the tissue, laboratory testing, and careful donor screening minimize the risks of the donor tissue transmitting disease to the recipient patient. As with any processed donor tissue, the graft cannot be guaranteed to be free of all pathogens. No long-term studies have been conducted to evaluate the carcinogenic or mutagenic potential or reproductive impact of the clinical application of Repliform matrix.

**DO NOT STERILIZE** Repliform matrix.

**DO NOT USE** Repliform matrix if either the outer foil bag or the inner (Tyvek®) pouch is perforated or torn. A damaged foil bag or inner (Tyvek) pouch may result in degradation or contamination of the product.

**DO NOT USE** after product expiration date on the label.

The inner (Tyvek) pouch that contains the Repliform matrix is NOT STERILE; **DO NOT PLACE** THE INNER (Tyvek) POUCH IN THE STERILE FIELD.

Transfer Repliform matrix from packaging aseptically. **DO NOT PLACE** either the foil bag or the inner (Tyvek) pouch in the sterile field. (See **INSTRUCTIONS FOR REHYDRATION**.)

**PRECAUTIONS**

Poor general medical condition or any pathology that would limit the blood supply and compromise healing should be considered when selecting patients for implanting Repliform matrix as such conditions may compromise successful clinical outcome.

Repliform matrix must be placed within two well-vascularized layers of tissue to minimize potential complications such as dehiscence and/or necrosis.

Whenever clinical circumstances require implantation in a site that is contaminated or infected, appropriate local and/or systemic anti-infective measures should be taken.
Repliform matrix has a distinct basement membrane (upper) and dermal surface (lower). (See ORIENTATION.) When applied as an implant, it is recommended that the dermal side be placed against the most vascular tissue.

Prior to rehydration, **DO NOT BEND** because this may cause the Repliform matrix to fracture. **DO NOT USE** the Repliform matrix if it is bent, broken or cracked.

**DO NOT USE** the Repliform matrix if prior to rehydration it is not uniformly white to buff in coloration.

Patients must be advised to avoid:

- Postoperative physical vaginal activity, including sexual intercourse, douching, and tampon use, for six to eight weeks;
- Postoperative physical strain, such as heavy lifting, for two to three months.

If any hair is visible, remove before implantation.

Use of Repliform matrix is limited to specific health professionals (e.g., physicians).

Once a package or container has been compromised, the tissue shall be either transplanted, if appropriate, or otherwise discarded.

Discard all open and unused portions of the product or expired product according to local institutional requirements.

**ADVERSE REACTIONS**

Potential adverse reactions which may result from surgical procedures associated with the implant of a tissue graft include, but are not limited to the following: wound or systemic infection; dehiscence, including dehiscence caused by loss of suture support; necrosis; hypersensitive, allergic or other immune response; and sloughing or failure of the graft.

Adverse outcomes potentially attributed to Repliform matrix must be reported promptly to Boston Scientific Corporation Customer Service at 1-888-272-1001.

**STORAGE**

Refrigerate upon receipt between 1 - 10°C (34 - 50°F ) in its original packaging. It is the responsibility of the tissue dispensing service, tissue distribution intermediary, and/or end-user clinician to maintain tissue intended for transplantation in appropriate storage conditions prior to further distribution or transplant. The expiration date for the Repliform matrix is recorded on the product container labeling as a month and year. In products where expiration date is indicated as year (4 digits) and month (2 digits), the product expires on the last day of the month indicated.
Expiration date printed on the labeling is valid as long as product is stored refrigerated and in an unopened foil bag.

**HOW SUPPLIED**

Repliform matrix is supplied on a printed paper backing and is sealed in an inner (Tyvek) pouch, which is enclosed within an outer foil bag. Product thickness range and size are clearly marked on the label located on the outer foil pouch.

**Important:** It is the responsibility of the healthcare practitioner to maintain recipient records for the purpose of tracing tissue post-implantation. Patient tracking labels are provided for convenience.

**INSTRUCTIONS FOR REHYDRATION**

When preparing to use Repliform matrix in the operating room (OR), the following rehydration procedure should begin at least ½ hour ahead of intended use.

For best results when rehydrating Repliform matrix, use liberal amounts of warmed saline solution in a two-step bath with light agitation.

Normal rehydration of Repliform matrix is usually accomplished in 10-40 minutes, depending on thickness.

**Equipment required**
- 2 sterile dishes large enough to accommodate the Repliform matrix without bending
- Sterile saline or sterile lactated Ringer’s solution that is sufficient to completely submerge the graft
- Sterile atraumatic forceps

**Rehydration Step 1**

Tear open the foil bag at the notch and remove the inner (Tyvek) pouch. (Keep both the foil bag and inner (Tyvek) pouch OUT of the sterile field.)

Peel open the inner (Tyvek) pouch and aseptically remove the tissue. **Do not peel the printed paper backing at this point in the process.**

Submerge the tissue completely and soak for a minimum of 5 minutes or until the backing separates from the Repliform matrix.

**Tip:** Warming saline up to 37°C and using gentle movement of Repliform matrix in the solution speeds the rehydration process. However, do not heat saline above 37°C.
**Tip:** When rehydrating multiple pieces, ensure the pieces are not overlapping or clumping together as this may slow down the process. Use multiple bowls if necessary.

**Tip:** Keep Repliform matrix fully submerged by weighing it down, e.g., with sterile forceps.

**Tip:** If you are having a problem with rehydration, gently wipe/rub both sides of Repliform matrix, with a sterile gloved hand, to remove any excess cryoprotectant that may be creating a barrier between the Repliform matrix and the rehydration fluid.

**Rehydration Step 2**

Using a sterile gloved hand or forceps, remove and discard the backing once it separates from the tissue. Then, aseptically transfer the tissue to a second bath sufficiently filled with rehydration fluid.

**Submerge completely and soak until the tissue is fully rehydrated (thicker grafts may take up to 40 minutes).**

**Tip:** Keep Repliform matrix fully submerged by weighing it down, e.g., with sterile forceps.

When Repliform matrix is fully rehydrated, it is soft and pliable throughout. At this stage, it is ready for application to the surgical site. Repliform matrix may be aseptically trimmed to required dimensions.

**Important: Use Repliform matrix within 4 hours of rehydration.**

**Considerations**

If not completely rehydrated, Repliform matrix will appear to be of uneven thickness and have a mottled appearance.

Antibiotics may be added to the second rehydration solution.

**Orientation**

Repliform matrix has a distinct basement membrane (upper) and dermal surface (lower). When applied to the wound bed in a grafting procedure, the dermal side should be placed against the wound bed, with the basement membrane side facing up. When applied as an implant, the dermal side should be placed against the most vascular tissue.

**Procedure for determining orientation**

To determine proper orientation once the graft has been rehydrated, add a drop of blood to both sides of the graft and rinse with rehydration solution. The dermal side will have a bloody appearance, whereas the basement membrane side will appear pink.
Preparing to Implant Repliform Matrix

Repliform matrix can be shaped with sterile scissors or scalpel.

When Repliform matrix is ready, store in the second saline wash until surgical site is prepared.

**Important: Use Repliform matrix within 4 hours of rehydration.**

TISSUE TRANSPLANT RETURN RECORD

The Tissue Transplant Return Record (TTRR) is attached to the “Instructions for Use.” Please separate the TTRR from the “Instructions for Use” and follow the directions provided on the form for completion and return to LifeCell Corporation.
WARRANTY STATEMENT

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Contact Boston Scientific Corporation’s Customer Service at 1-888-272-1001 for additional information, to place an order, or to report adverse reactions.

Repliform® Tissue Regeneration Matrix is a trademark of LifeCell Corporation.

Tyvek is a registered trademark of DuPont.

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This product and certain methods are covered by U.S. and foreign patents and patents pending, including: US 8,323,352; US 8,007,531; and US 7,476,249.

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