Repliform™ Tissue Regeneration Matrix

Refer to the device directions for use for complete instructions on device use.

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.

Repliform matrix is compliant with the AATB Standards for Tissue Banking and the state guidelines of California, Florida, New York, Maryland, and Illinois.

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.

Repliform matrix is not indicated for use as a dural substitute.

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.

Warnings

- 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.
- 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.

**Adverse Effects**

Potential adverse effects which may result from placement of an implant or 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; sloughing or failure of the graft. Adverse outcomes potentially attributed to Repliform matrix must be reported promptly to Boston Scientific 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.

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