SIA
SURGICAL INNOVATION ASSOCIATES

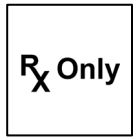
DuraSorb®

BioSynthetic Mesh

Instructions for Use

SYMBOL DEFINITIONS

5.3.4 - Keep Dry

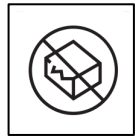


Prescription Only

5.1.5 – Batch Code

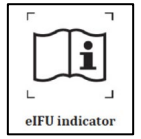
5.1.6 - Catalog Number

5.1.1 - Manufacturer



5.2.8 - Do Not Use If Package Is Damaged

5.4.2 – Do Not Reuse



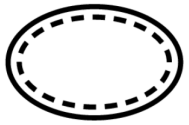
5.4.3 - Consult Instructions For Use

5.1.4 - Use By Date

5.4.4 - Caution

5.2.6 - Do Not Resterilize

5.2.3 - Sterilized Using Ethylene Oxide



5.2.13 – Single Sterile Barrier with Protective Packaging Inside

5.3.8 – Humidity Limitation

5.3.7 – Temperature Limit

Numbers indicate symbol reference # from ISO 15223-1:2022

DEVICE DESCRIPTION

DuraSorb™ is a resorbable monofilament knit surgical mesh. DuraSorb™ is packaged individually and is provided sterile as flat sheets of mesh that can be cut to the desired shape and size. DuraSorb™ is made entirely of polydioxanone (PDO) thread, which is similar in form to PDO sutures. The threads degrade via bulk hydrolysis once implanted. Strength retention decreases followed by mass loss in the threads. In vitro tests show that DuraSorb™ Monofilament Mesh itself retains some burst strength for 3 months, but not beyond that time. In vivo investigations in swine show that DuraSorb™ is fully integrated by 1 month and takes up to 9 months to fully absorb.

Device Product Numbers: PTM0616, PTM1025, PTM2025

INDICATIONS FOR USE

DuraSorb™ Monofilament Mesh is intended for use in reinforcement of soft tissue where weakness exists.\

Intended for use by licensed medical professionals.

CONTRAINDICATIONS

DuraSorb™ Monofilament Mesh must always be separated from the abdominal cavity by peritoneum. Not for use following planned intra-operative or accidental opening of the gastrointestinal tract. Use in these cases may result in contamination of the mesh, which may lead to infection. Not suitable for reconstruction of cardiovascular defects.

PRECAUTIONS

1. Carefully check that the packaging is undamaged and unopened and that the seals are intact before use.
2. Dispose of product if packaging is damaged or opened prematurely outside the sterile field.
3. The mesh should be large enough to extend beyond the margin of the defect. Users should be familiar with strength requirements and scaffold size choices for the repair.
4. Improper selection, placement, positioning, and fixation of DuraSorb™ can cause subsequent undesirable results
5. Infections should be treated according to acceptable surgical practice to minimize the need for removal of the mesh.

WARNINGS

1. Do not use if the outer or inner package has been damaged or if any of the seals appear not to be intact.
2. Do not use after the expiration date.
3. Do not use on contaminated and/or infected wounds.
4. For single use only. Do not resterilize.
5. Because DuraSorb™ is fully resorbable, it should not be used in repairs where permanent support from the mesh is required.
6. The safety and effectiveness of DuraSorb™ has only been established with either permanent or absorbable sutures.
7. DuraSorb™ has not been studied for use in:
    a. the repair of direct inguinal hernias
    b. intraperitoneal use
    c. contaminated and/or infected wounds
    d. breast reconstructive surgeries
8. The safety and effectiveness of DuraSorb™ have not been established for urogynecological use. Refer to safety communications from the FDA and from UK's National Institute for Health and Clinical Excellence (NICE) for guidance.
9. The safety and effectiveness of DuraSorb™ Monofilament Mesh has not been established for use in tendon repair

ADVERSE REACTIONS

Possible adverse reactions with DuraSorb® are those typically associated with any implantable mesh prosthesis, including, but not limited to, infection of wound from contaminated mesh, reoperation for mesh removal, seroma formation, mechanical mesh failure or general or mucocutaneous mesh erosion/extrusion. Further, possible adverse reactions include pain, allergic reaction, infection, scarring, or risks related to the potential unknown impact of mesh used in conjunction with tissue expander or breast implant on breast implant outcomes listed.

Possible risks associated with surgery include soft tissue infection, bleeding/hematoma, seroma formation, wound healing issues, a need for re-operation and other complications.

SERIOUS ADVERSE EVENT REPORTING

In case of serious adverse events caused by DuraSorb®, please follow local vigilance reporting procedures to submit a report of the event to the competent authority, and report event to SIA by calling +1-872-870-0520 or writing productcomplaints@integralife.com.

PREPARATION FOR USE

1. Open the outer aluminum foil pouch and aseptically remove the inner pouch containing the product. The inner pouch and the DuraSorb™ Monofilament Mesh contained within are both sterile.
2. Place the inner pouch in the sterile field. The pouch will provide protection from contamination of the DuraSorb™ until the time of use.
3. At appropriate time during operation, open inner pouch, remove DuraSorb™, and follow directions for use below.

DIRECTIONS FOR USE

1. Prepare the implantation site using standard surgical techniques.
2. Trim DuraSorb™ so as to allow an adequate overlap of the defect area.
3. Device may be used in a dry state, but it is recommended that it is dipped briefly in aqueous solution in accordance with institutional implant preparation procedures, in order to remove any particulate debris from cutting.
4. Implant DuraSorb™ Monofilament Mesh according to currently accepted surgical mesh procedures.
5. If trimming DuraSorb™ further in situ, it is recommended that surgical site be rinsed and aspirated to remove any device particulate debris that may have been generated.
6. Fixate DuraSorb™ according to currently accepted surgical practices.
7. Affix the traceability label in the patient's medical record.

STORAGE, PACKAGING AND DISPOSAL

1. Store at room temperature (18 - 28°C) with humidity conditions of 20 - 40%, and away from direct heat.
2. Sterile in unopened and undamaged package with sterile barrier intact.
3. A traceability label which identifies the lot number of the prosthesis is enclosed in every package for placement in the patient's medical record.
4. Dispose of contaminated units, components, and packaging materials in accordance with standard hospital procedures, universal precautions for biohazardous waste, and applicable local, state, and federal laws.

ACCESSING THE ELECTRONIC IFU (EIFU)

Requirements for eIFU download: internet connection and Adobe Acrobat version X, Adobe Reader version X, or OSX Preview version X. Other PDF readers may work but have not been verified.

Manufactured by:
Surgical Innovation Associates, Inc.
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Chicago, IL 60654

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