DuraSorb® Monofilament Mesh – Instructions for Use

BioSynthetic Mesh

Device Description

DuraSorb® is a resorbable, monofilament, macroporous scaffold designed to support early soft tissue ingrowth. DuraSorb® is packaged individually and is provided sterile as a flat sheet mesh that can be trimmed by the surgeon to meet the individual patient's needs. DuraSorb® is composed of 100% polydioxanone (PDO) monofilaments, which is similar in form to PDO sutures. The mesh degrades via bulk hydrolysis once implanted. Strength retention decreases followed by mass loss. In vivo investigations in swine show that DuraSorb® is fully integrated at 1 month, load bearing is transferred to native tissue at 3 months and is fully resorbed at 12 months.

Table 1: DuraSorb® Product Numbers and Descriptions

Product Number	Product Description
PTM0616	DuraSorb® Monofilament Mesh, 6 x 16cm
PTM1025	DuraSorb® Monofilament Mesh, 10 x 25cm
PTM2025	DuraSorb® Monofilament Mesh, 20 x 25cm

Indications for Use

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

DuraSorb® is 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.

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Precautions

- The device is limited to use by physicians who are trained to perform the required surgical procedure.
- DuraSorb® has not been studied for use in:
  - the repair of direct inguinal hernias
  - intraperitoneal use
  - breast reconstruction surgeries
- DuraSorb® is sterile if the foil pouch is unopened and undamaged.
- Do not use after the expiration date.
- The mesh should be large enough to extend beyond the margin of the defect.
- Improper selection, placement, positioning, and fixation of DuraSorb® may cause unintended results.
- The safety and effectiveness of DuraSorb® has been established with permanent and absorbable sutures, but has not been established with other fixation methods.
- For single use only. Do not re-sterilize.

Warnings

- Do not use on contaminated and/or infected wounds.
- DuraSorb® is fully resorbable and should not be used in repairs where permanent support from the mesh is required.
- The safety and effectiveness of DuraSorb® has 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.
- 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, including, but not limited to, infection, re-operation for mesh removal, inflammation, extrusion, erosion, adhesion, fistula formation, seroma formation, hematoma, mechanical mesh failure, dehiscence, necrosis, and recurrence of the hernia or tissue defect.

Serious Adverse Event Reporting

In case of serious adverse events with the use of 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.

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Instructions for Use (IFU)

Note: These are recommendations for use. The surgeon should always accommodate the specific needs of the patient. Always handle DuraSorb® Monofilament Mesh using aseptic technique.

Selection of the Device

1. Select the DuraSorb® device size appropriate for the defect area and surgical reconstruction plan.

Device Removal from Packaging

1. Inspect the sterile barrier and verify that it is undamaged and unopened and the seals are intact before use. Do not use the device if the sterile barrier is damaged or opened.
2. Open the outer foil pouch and aseptically present the inner pouch containing the device. The inner pouch and the DuraSorb® Monofilament Mesh contained within are both sterile.
3. Place the inner pouch in the sterile field. The pouch will provide protection from contamination of the DuraSorb® until the time of use.
4. At appropriate time during operation, aseptically open inner pouch and remove DuraSorb®.

Device Preparation

1. Prepare the implantation site using standard surgical techniques.
2. Trim and prepare DuraSorb® to prevent any particulate debris from entering the defect site. Device should not remain in aqueous solution for more than 1 hour.
3. When trimming DuraSorb®, ensure an adequate overlap of the defect site.

Device Placement

1. Implant DuraSorb® Monofilament Mesh according to currently accepted surgical mesh procedures.
2. If trimming DuraSorb® in situ, it is recommended that the surgical site be rinsed and aspirated to remove any remnant material that may have been generated.
3. Fixate DuraSorb® according to currently accepted surgical practices.
4. Affix the device traceability label to the patient's medical record. The traceability label identifies the lot and serial number.

Storage and Disposal

1. Store DuraSorb® following standard medical device control and storage procedures for sterile products.
2. 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.

Intended Clinical Benefit

- A resorbable scaffold that can be implanted to buttress a wound or defect and remain during the critical stages of healing and degrade via bulk hydrolysis over a predicable time horizon.
- A sterile medical device intended for use in open surgical procedures.

Accessing the Electronic IFU (EIFU)

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

Table 2. Symbols Glossary

Symbol	Title of Symbol	Meaning of Symbol	Standard	Reference Number
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.1
	Use-by date (YYYY-MM-DD)	Indicates the date after which the medical device is not to be used.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.4
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.5
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.1.6
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied.	5.1.7
	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.2.3

Table 2. Symbols Glossary				
Symbol	**Title of Symbol**	**Meaning of Symbol**	**Standard**	**Reference Number**
	Single sterile barrier with protective packaging inside	Indicates a single sterile barrier system with protective packaging inside	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.2.13
	Do not resterilize	Indicates a medical device that is not to be resterilized.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.2.6
	Do not use if package is damaged and consult *instructions for use*	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the *instructions for use* for additional information.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.2.8
	Do not re-use	Indicates a medical device that is intended for one single use only.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1 Medical Devices – Symbols to be used with medical device labels, labelling and information to be supplied	5.4.3
℞ Only	Prescription use only	Caution: Federal (US) law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.	Guidance for Industry: Alternative to Certain Prescription Device Labeling Requirements, dated January 21, 2000	N/A

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CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.

Manufactured by:
Surgical Innovation Associates, Inc.
445 W Erie St
Suite 111
Chicago, IL 60654
United States of America
www.sia.health

LS-0002 (DOC-349) Ver. 9

Approved By:

(CO-223) CCP-24-039

Description

Implementation of CCP-24-039: Study HHY00002, “GLP Evaluation of an Absorbable Mesh Repair of an Abdominal Wall Defect in the Porcine Model” was conducted with the objectives to confirm the safety, performance, and degradation of DuraSorb over time in an in vivo large animal model. An additional study, HHY00003, “Non-GLP Evaluation of an Absorbable Mesh Repair of an Abdominal Wall Defect in the Porcine Model” was conducted to provide further performance and degradation data at a long-term, chronic-phase time point to supplement previous data. Based on these in vivo investigations in swine (HHY00002 and HHY00003), it was determined that DuraSorb should be fully absorbed in 6-9 months. This language was included in DuraSorb’s IFU. However, SIA received feedback from the FDA that the resorption timeline for DuraSorb should be updated to state that DuraSorb can take “up to 9 months to absorb.” Per HHY00002, the mesh was fully incorporated by host tissue at the 30- and 91-day timepoints. Additionally, the strength at the surgical site was similar or greater to the native abdominal wall. It was identified that in the marketing claims matrix, the language is DuraSorb takes up to 12 months to absorb. Upon further review of the in vivo studies, there is no objective evidence of the full absorption of DuraSorb within the 9 months timeframe. Therefore, the decision has been made to update the resorption timeline to accurately reflect the study data and to align with the marketing claims matrix. This will be updated in the device description section of the IFU. During the design review process per PDPROJ-3-DRW18, the device description of DuraSorb was updated to: DuraSorb® is a resorbable, monofilament, macroporous scaffold designed to support early soft tissue ingrowth. DuraSorb® is packaged individually and is provided sterile as a flat sheet mesh that can be trimmed by the surgeon to meet the individual patient’s needs. DuraSorb® is composed of 100% polydioxanone (PDO) monofilaments, which is similar in form to PDO sutures. The mesh degrades via bulk hydrolysis once implanted. Strength retention decreases followed by mass loss. In vivo investigations in swine show that DuraSorb® is fully integrated at 1 month, load bearing is transferred to native tissue at 3 months and is fully resorbed at 12 months.” These changes, focusing on the timeline and transfer of strength from primarily the mesh to the native tissue reforming, more accurately depicts how the device functions. The Use Specification contained within the Design and Development Plans for DuraSorb also need to be updated. This change does not impact the Design Verification and Validation testing completed as the change is to align the statement with the available pre-clinical data. A 510k Note to File was completed. Design Review, PDPROJ-3-DRW18, was conducted to review the change and to confirm the appropriate wording change.

Justification

Necessary to accurately reflect study data and align with the marketing claims matrix.

Assigned To:	Initiated By:	Priority:	Impact:
Stephanie Lietz	Stephanie Lietz	Medium	Major

Version History:

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Stephanie Lietz	August 6, 2024 4:14 PM CDT	CO-223	9	Published
Mayna Muenchow	March 1, 2024 9:49 AM CST	CO-174	8	Superseded
Mayna Muenchow	January 16, 2024 9:56 PM CST	CO-131	7	Superseded
Nelson Torres	August 28, 2023 12:49 PM CDT	CO-118	6	Superseded
Nelson Torres	August 17, 2022 10:18 PM CDT	Not Available	5	Superseded
Nelson Torres	August 17, 2022 10:16 PM CDT	Not Available	4	Superseded
Nelson Torres	August 17, 2022 10:16 PM CDT	Not Available	3	Superseded
Nelson Torres	August 17, 2022 10:15 PM CDT	Not Available	2	Superseded
Nelson Torres	August 17, 2022 10:15 PM CDT	Not Available	1	Superseded
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