SIA
SURGICAL INNOVATION ASSOCIATES

# DuraSorb® | Biosynthetic Mesh

An advancement in soft tissue repair

A clinically-proven material trusted for over 30 years

**TO ORDER TODAY, CONTACT YOUR AREA SALES REPRESENTATIVE**


EMAIL
orders@sia.health

PHONE
+1 847 769 7824

FAX
+ 1 888 851 1456

www.sia.health

# EVIDENCE-BASED ENGINEERING, CLINICALLY-DRIVEN NEED

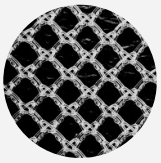
Macroporous scaffolds encourage early soft tissue ingrowth and immunological surveillance[1].

Monofilament fibers such as those used in DuraSorb® exhibit decreased surface area and decreased propensity for bacterial adhesion compared to multifilament alternatives[2,3].

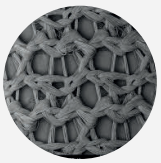
## INNOVATION IN SOFT TISSUE REINFORCEMENT

DuraSorb® is a biosynthetic mesh scaffold composed of polydioxanone, a material used clinically for over 30 years, in contrast to newer polymers with less extensive clinical history.

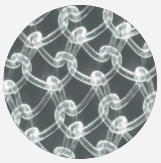
Compare the macroporous, open-knit structure of DuraSorb® with the patterns of other resorbable materials.



**DuraSorb®**
Monofilament
Digital Microscope, 20x



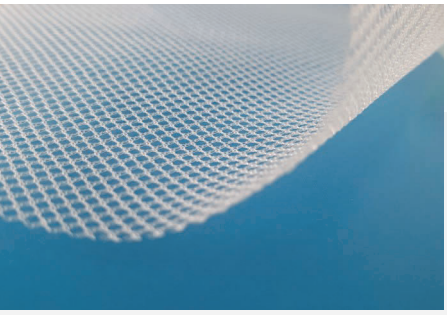
**TIGR® Matrix**
Multifilament
SEM Photo, 20x

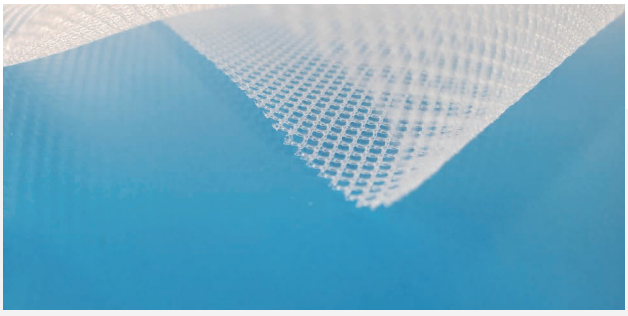


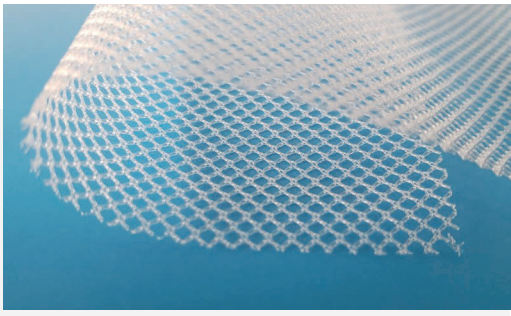
**Phasix® and GalaFlex®**
Monofilament derived
from P4HB SEM Photo, 20x

**Seri® Scaffold**
Multifilament derived from Silk
SEM Photo, 17x

- **FULLY RESORBS OVER A PREDICTABLE TIMELINE THROUGH HYDROLYSIS[6]**
- **LARGE, OPEN PORE CONSTRUCTION (>1.0 MM)**
- **MONOFILAMENT FIBERS WARP KNIT INTO A UNIFORM PATTERN**







Delivered in flat, sterile sheets, DuraSorb® may be trimmed to the desired shape and size.


1. Klinge U, Klosterhalfen B, Birkenhauer V, Junge K, Conze J, Schumpelick V (2002) Impact of polymer pore size on the interface scar formation in a rat model. J Surg Res 103:208
2. Engelsman AF, van Dam GM, van der Mei HC, Busscher HJ, Ploeg RJ (2010) In vivo evaluation of bacterial infection involving morphologically different surgical meshes. Ann Surg 251:133–137
3. Klinge U, Junge K, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V (2002) Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacteria adherence, and the in vivo consequences in a rat model. J Biomed Mater Res 63:765–771
4. Surgical Mesh Electronic IFU. TIGR Matrix, https://novusscientific.com/
5. GalaFLEX Scaffold IFU. GalaFLEX Scaffold, https://galateasurgical.com/, "Phasix SEM" PHASIX Mesh, https://crbard.com/CRBard/Media
6. Martins J, Lach A, Morris H, Carr A, Mouthuy, PA (2019) Polydioxanone implants: A systematic review of safety and performance in patients

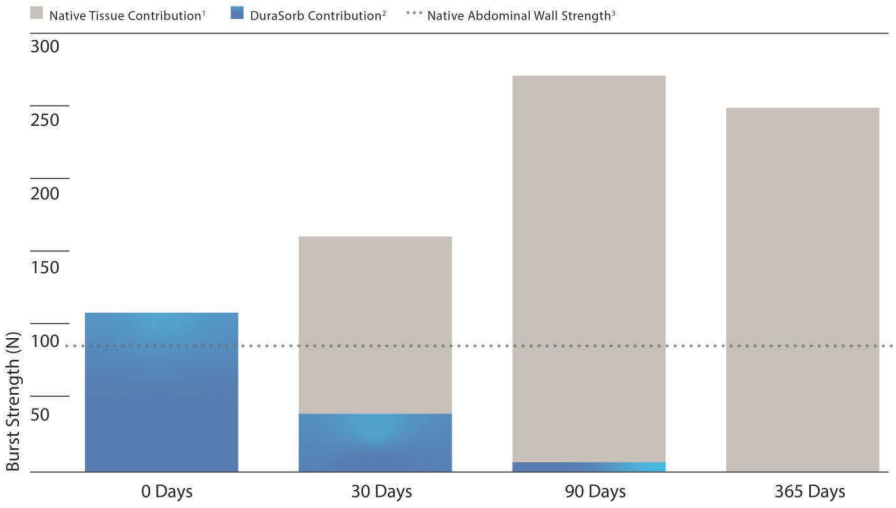

**To learn more, contact your local DuraSorb® sales representative or call 1.847.769.7824**

# RAPID TISSUE INTEGRATION + LONG-TERM SUPPORT

DuraSorb® is designed to provide the remodeling characteristics of a biologic, with the repair strength of a synthetic device.

In a large animal model, complete integration was achieved by 1 month, with maintenance of repair strength and full absorption at one year.

## DURASORB® TISSUE STRENGTH DATA FROM 1-YEAR LARGE ANIMAL MODEL




**As DuraSorb® is integrated, native tissue strength increases naturally**

1. Native Tissue Contribution: Differential between DuraSorb strength and compound repair strength.
2. DuraSorb Contribution: Based on temporal strength changes in physiologic conditions.
3. Native Abdominal Wall Strength: Based on 30-day native fascia samples immediately adjacent to repair site.

Data on File. Pre-clinical and animal model results may not necessary translate directly to clinical use.

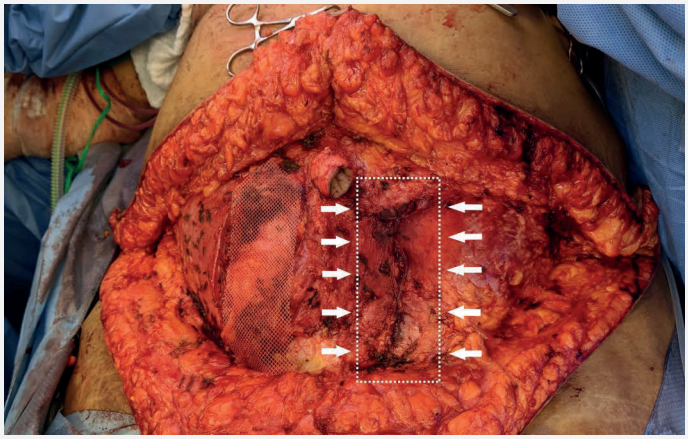
## DuraSorb® Case Review

### DIEP PERFORATOR FLAP DONOR SITE REINFORCEMENT

DuraSorb® tailored and positioned for reinforcement of a repair at the donor site of a concurrent deep inferior epigastric perforator (DIEP) procedure

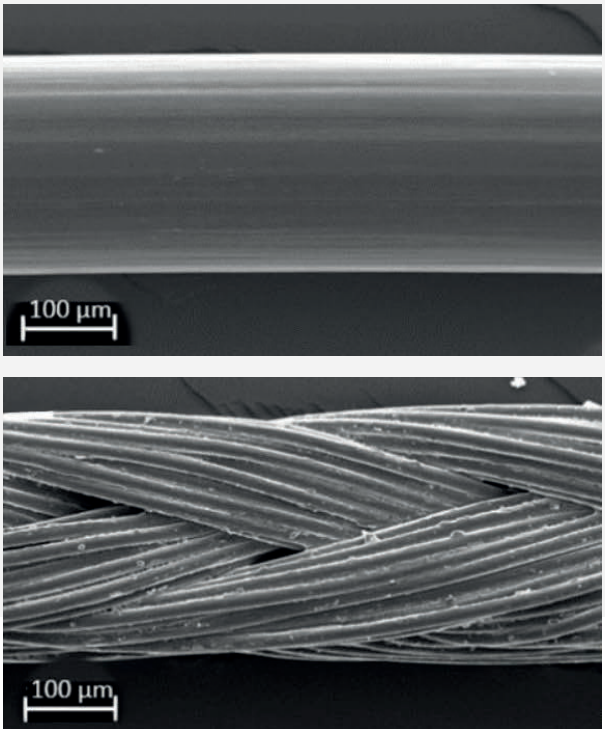
**PHOTO RIGHT :** Primary closure of anterior rectus sheath with DuraSorb® inlay design.

**PHOTO LEFT :** DuraSorb designed to fit large fascial defect from flap harvest, in preparation for a spanning underlay.



# MONOFILAMENT MESH DISCOURAGES BACTERIAL ADHESION

Monofilament mesh products are well known to exhibit decreased surface area and decreased propensity for bacterial adhesion[1, 2]




SEM image of uncoated monofilament (top) and uncoated multifilament sutures (bottom)[3]

## DuraSorb® Indication For Use

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

## Contraindications

DuraSorb® must always be separated from the abdominal cavity by peritoneum and is 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. DuraSorb is not suitable for reconstruction of cardiovascular defects.

## Peer-Reviewed Preclinical Studies

Multiple preclinical studies confirm the safety and performance of DuraSorb®, and validate the well-documented evidence of the benefits of macroporous, monofilament absorbable meshes[4].

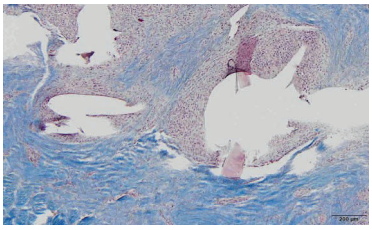
**STUDY OBJECTIVE:** Evaluation of DuraSorb® strength and histopathology in a hernia model

**STUDY DESIGN:** Two full-thickness, 1.5 cm-diameter excisional defects were created bilaterally in the abdominal wall of Yucatan mini swine through a midline approach. DuraSorb was fixated over the defect in the preperitoneal plane with (Suture Method)

**RESULTS:** Tissue integration including vascularization within 30 days. Mesh fully incorporated at one year, and repair sites had higher strength than surrounding native abdominal tissue. No device-associated complications were found clinically, upon gross examination or histologically.

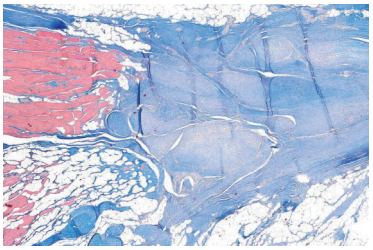
### DuraSorb® at 30 Days

Trichrome stain from swine model of abdominal wall repair at 30 days, indicating active tissue integration, cellular penetration, and early collagen deposition throughout DuraSorb®.

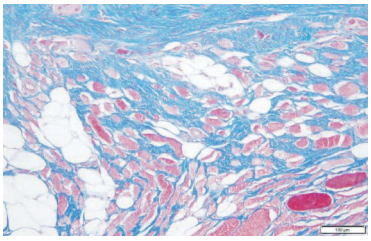


### DuraSorb® at 1 Year

Trichrome stain from swine model of abdominal wall repair at 1 year, demonstrating more than 1 mm of collagenous tissue at the site of the surgically created muscular defect, where DuraSorb® was previously placed.



Stain from swine model, (Left cranial abdominal wall). Image demonstrates fine collagen fibers (blue) at the site of the device. DuraSorb® is completely resorbed at year. (MT, 10X)

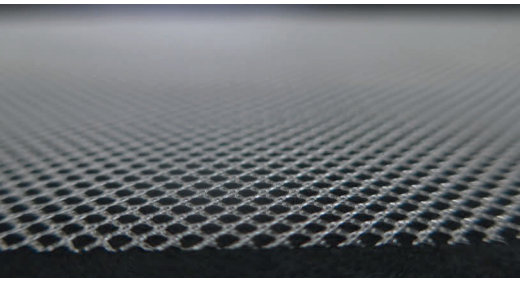



1. Engelsman AF, van Dam GM, van der Mei HC, Busscher HJ, Ploeg RJ (2010) In vivo evaluation of bacterial infection involving morphologically different surgical meshes. Ann Surg 251:133–137
2. Klinge U, Junge K, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V (2002) Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacteria adherence, and the in vivo consequences in a rat model. J Biomed Mater Res 63:765–771
3. Reinbold J, Uhde A-K, Müller I, Weindl T, Geis-Gerstorfer J, Schlensak C, Wendel H-P, Krajewski S. Preventing Surgical Site Infections Using a Natural, Biodegradable, Antibacterial Coating on Surgical Sutures. Molecules. 2017; 22(9):1570
4. Data on file. Pre-clinical and animal model results may not necessary translate directly to clinical use.

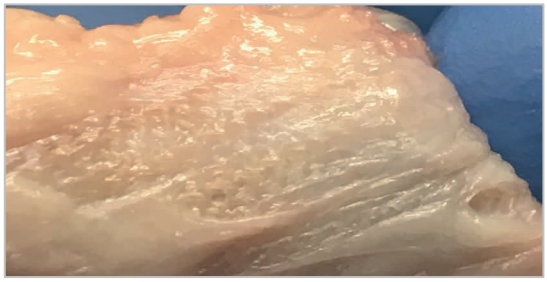

**To learn more, contact your local DuraSorb® sales representative or call 1.847.769.7824**

# DURASORB® CONFORMS, INTEGRATES, DISSIPATES

The macroporous knit structure allows DuraSorb® to drape and conform as needed. Demonstrated tissue integration within one month, with neocollageneous tissue observed throughout[1].



The DuraSorb® open-pore knit pattern is designed to conform for the desired clinical situation and anatomic area.



Gross pathology demonstrating tissue integration into DuraSorb®. Sample from porcine abdominal wall implantation, 45-day endpoint (middle)

25x SEM image of DuraSorb® fibers with surrounding neocollagenous tissue. Sample from porcine abdominal wall at 91 days (at right).

## DuraSorb® Case Review

### LAPAROSCOPIC PARAESOPHAGEAL HERNIA REPAIR

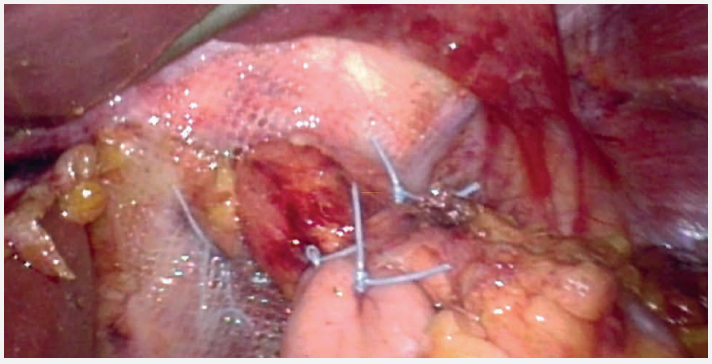
Durasorb applied for crural reinforcement following esophageal mobilization in a laparoscopic hiatal hernia repair

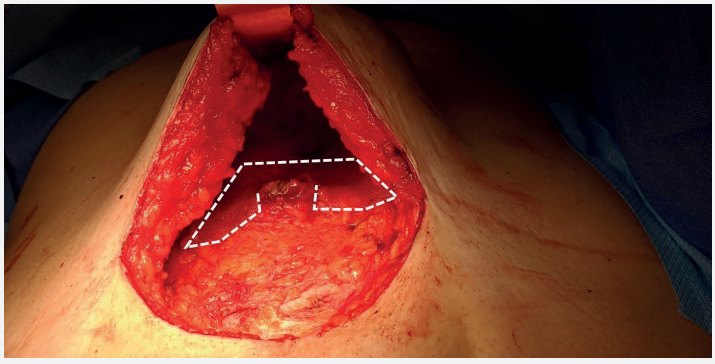
- DuraSorb's handling characteristics support easy introduction, positioning and fixation with the laparoscopic repair
- The macroporous, open knit design supports growth of new vascular, collagenous tissue[2], which is required for strengthening the crural closure

### UMBILICAL HERNIA REPAIR

A sheet of DuraSorb, trimmed to size for the repair of an umbilical herniation

- The proprietary design of DuraSorb delivers a material that conforms naturally, but also provides adequate support for abdominal wall closure[3]
- DuraSorb can be cut to defect-specific shapes without unraveling





1. Performance from pre-clinical investigation; Data on File. Pre-clinical and animal model results may not necessary translate directly to clinical use.

**To learn more, contact your local DuraSorb® sales representative or call 1.847.769.7824**

# IDEAL BALANCE OF STRENGTH RETENTION AND MASS DISAPPEARANCE

## PRODUCT CHARACTERISTIC COMPARISON

| PROPERTY | DURASORB® | TIGR® MATRIX | GALAFLEX® PHASIX® | VICRYL® | SERI® SCAFFOLD | ADM |
|---|---|---|---|---|---|---|
| MATERIAL | Polydioxanone | PGLA/PLA | P4HB | PLGA | Silk | Human Dermis |
| STRUCTURE | Monofilament | Multifilament | Monofilament | Multifilament | Multifilament | Decellularized Tissue |
| ABSORPTION (MONTHS) | < 12 months | 24 - 36 | 18 - 24 | 3 | 24 | NA |

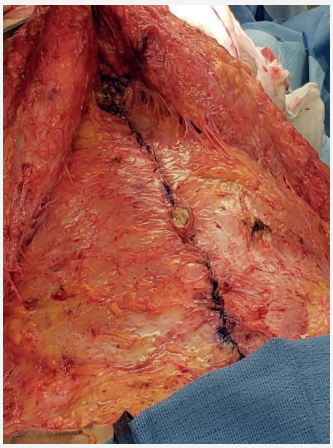
## DuraSorb® Case Review

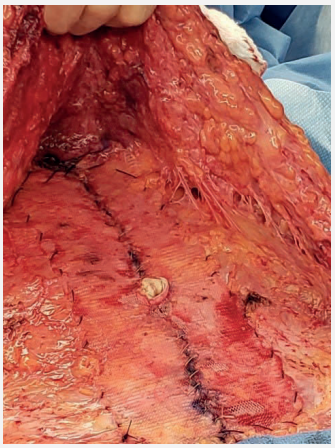
### ABDOMINOPLASTY PLICATION REINFORCEMENT

The macroporous design of DuraSorb® facilitates free fluid flow between tissue planes prior to integration, which is complete by 1 month[1]

DuraSorb exhibits full absorption and natural remodeling within one year[1]. PICTURED LEFT, abdominal diastasis repaired and ready for mesh reinforcement

PICTURED RIGHT: A no-drain abdominoplasty was done using DuraSorb® as onlay to provide secondary reinforcement of the plication.





### FULLY RESORBABLE

- 100% resorbable scaffold
- FDA 510(k)-cleared for soft tissue reinforcement where weakness exists

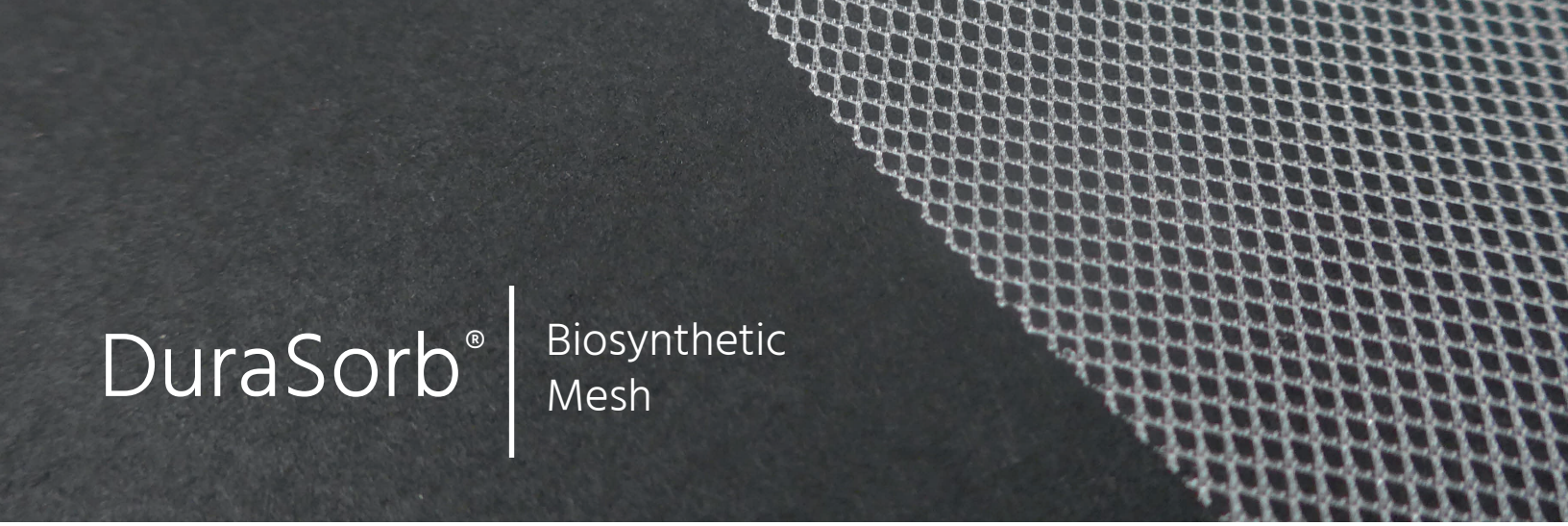
### EASY TO USE

- Evidence-based engineering, clinically-driven design
- Engineered for strength, handling and compliance

### TRUSTED MATERIAL

- Composed of a material trusted by surgeons for over 35 years
- Terminally sterilized and packaged for aseptic presentation

1. Performance from pre-clinical investigation; Data on File. Pre-clinical and animal model results may not necessary translate directly to clinical use.



# DuraSorb® | Biosynthetic Mesh

## ORDERING INFORMATION

| Reference | Size | Shape |
|---|---|---|
| PTM1015 | 10 x 15 cm | Rectangle |
| PTM1025 | 10 x 25 cm | Rectangle |
| PTM2020 | 20 x 20 cm | Square |

| Shapes | |
|---|---|
|  |  |
| Rectangle | Square |

## INDICATIONS FOR USE

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

## IMPORTANT SAFETY CONSIDERATIONS

Possible adverse reactions with the mesh are those typically associated with any implantable prosthesis, including, but not limited to, infection, inflammation, extrusion, erosion, adhesion, fistula formation, seroma formation, hematoma, and recurrence of the hernia or tissue defect. Because DuraSorb® is fully resorbable, it should not be used in repairs where permanent support from the mesh is required. The safety and effectiveness of DuraSorb® has only been established with either permanent or absorbable sutures. DuraSorb® has not been studied for use in, the repair of direct inguinal hernias, intraperitoneal use, contaminated and/or infected wounds, breast reconstructive surgeries. 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. The safety and effectiveness of DuraSorb® has not been established for use in tendon repair.

Please consult the DuraSorb® Instructions for Use (IFU) for complete prescribing information, including indications for use, warnings and precautions.

SIA
Surgical Innovation Associates

**TO LEARN MORE, CONTACT YOUR LOCAL DURASORB SALES REPRESENTATIVE OR CALL 1.847.769.7824**



**Surgical Innovation Associates, Inc**
800 Liberty Drive
Libertyville, IL, 60048, USA

**Telephone: +1 847 769 7824**
**Fax: + 1 888 851 1456**
**Email: info@sia.health**
**www.sia.health**