

# Kerecis® Omega3 SurgiBind™

Intact fish-skin grafts for reinforcing soft tissue



## SurgiBind Product

**Kerecis® Omega3 SurgiBind™** is an FDA-approved medical device for soft tissue reinforcement.

#### SurgiBind is gently processed

- Because there is no risk of viral transfer from north Atlantic cod to humans, the skin needs only mild processing for medical use without harsh detergents or mechanical pressing.
- This unique processing maintains the grafts' natural threedimensional structure and skin elements, including Omega3 fatty acids.<sup>1,2</sup>

#### SurgiBind is a rapidly integrating graft

- With its rapid cell ingrowth and neovascularization, surgical procedures that are at risk of delayed healing can be reinforced with a one-step implantable graft.
- Fast integration reduces time to full tissue remodeling.<sup>3,4</sup>

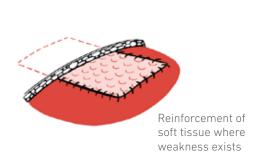
### SurgiBind provides an optimal structure for cell and vascular ingrowth

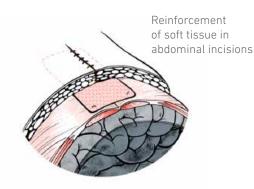
- The fish-skin graft uniquely limits the risk of tissue failure by providing structure for cell and vascular ingrowth, reinforcing the tissue and providing a natural bacterial barrier.
- The product has shown to facilitate 20x faster ingrowth
  of cells compared to amniotic tissue and to promote
  revascularization and remodeling faster than mammaliansourced scaffold tissue.<sup>1</sup>

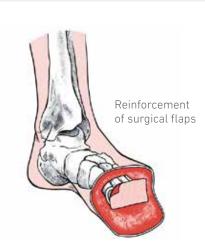
#### SurgiBind is based on a market proven technology

 Kerecis Omega3 SurgiBind is intact fish skin that is used for soft tissue reinforcement and grafting. It is based on the Kerecis Omega3 graft technology that is FDA approved and one of the leading products in the market for tissue regeneration and treatment of chronic, trauma and burn wounds.

### Different ways of application







#### Indications for use

For implantation to reinforce soft tissue where weakness exists, in patients requiring soft tissue repair, or reinforcement in plastic or reconstructive surgery.

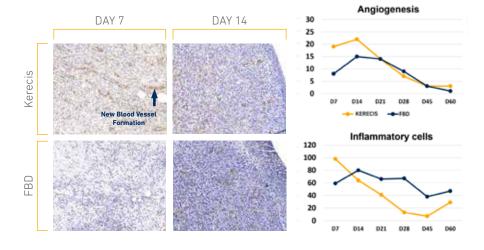
#### Contraindications

**Kerecis Omega3 SurgiBind** is derived from a fish source and should not be used in patients with a known allergy or other sensitivity to fish material. Kerecis Omega3 SurgiBind is not indicated for repairs where load bearing support from the mesh is required such as in the repair of any hernia. The device is not indicated for intraperitoneal organ contact. The device is not indicated for bridging defects.

#### Research and clinical studies

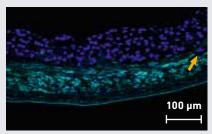
#### **Expedited Revascularization**

Animal model showing integration and neovascularization of Kerecis Fish-Skin Graft compared to fetal bovine dermis (FBD) in pig injury. Immunohistochemistry with alpha-smooth muscle actin. Positive brown staining is outlining the newly formed blood vessels.<sup>3</sup>



#### Kerecis® Omega3 fish skin

Human amnion/chorion membrane



### Accelerated Cell Ingrowth

Confocal microscopy images following cell seeding and fluorescent labeling, indicated with red arrows, show examples of cell infiltration in fish skin and amnion/chorion membrane.<sup>1</sup>

Scanned electron microscopy images of fish skin show a pore size of ~10-150  $\mu$ m. This is suitable for human cell infiltration because typical human cells range from ~10-100  $\mu$ m in diameter.

### Tissue Remodeling

In abdominal wall rat model, Kerecis Fish-Skin Graft was fully remodeled into site-appropriate connective tissue, while the Gentrix Urinary Bladder Matrix (UBM) tissue was easily identifiable from surrounding tissue.<sup>5</sup>

*In vivo* – Fish skin rapid integration and minimal inflammation

#### In vivo - Fish skin rapid integration and minimal inflammation







UBM - Implants were visible (arrows) after 4 weeks

#### References

1) Magnusson, et al. Regenerative and Antibacterial Properties of Acellular Fish Skin Grafts and Human Amnion/Chorion Membrane: Implications for Tissue Preservation in Combat Casualty Care. Mil. Med. 182, 383–388 (2017).

2) Magnusson, S. et al. Decellularized fish

skin: characteristics that support tissue repair. Laeknabladid 101, 567-573 (2015).

3) Stone R 2nd, Saathoff EC, Larson DA, et al. Accelerated Wound Closure of Deep Partial Thickness Burns with Acellular Fish Skin Graft. Int J Mol Sci. 2021;22(4):1590.

4) Patel, M. & Lantis II, J. C. Fish skin acellular dermal matrix: potential in the treatment of chronic wounds. Chronic Wound Care Manag. Res. 6, 59–70 (2019).

5) data on file

Composition Fish skin from north Atlantic cod

Pore size Intact three-dimensional skin structure

Appearance Flat, dry sheet with scale-textured surface and smooth underside

Solid or pre fenestrated

Storage Shelf stable for three years at room temperature

Rehydration Hydrate at least 60 seconds in room temperature sterile saline

Intraoperative handling Can be trimmed to size wet or dry. Place with textured side facing up

or towards distal aspect.

Lay graft flat in surgical plane, avoiding buckling of tissue or tenting.

Secure with sutures.

Sterilization Via exposure to ethylene oxide gas. Sterility assurance level (SAL) 10-6 with undetectable

ethylene oxide residuals.

Regulatory FDA 510(k) approved medical device indicated for soft tissue reinforcement. Not subject to

FDA Guidance on human cells, tissues, and cellular and tissue-based products (HCT/Ps).



Box of 10	Catalog # Single Unit	Description	Size Dimensions	Size Area cm²
SOLID				
50241S02D2D	50241S02D0D	Kerecis Omega3 SurgiBind	3 x 7 cm	21 cm <sup>2</sup>
50241S10D2D	50241S10D0D	Kerecis Omega3 SurgiBind	3 x 12 cm	36 cm²
50241S03D2D	50241S03D0D	Kerecis Omega3 SurgiBind	7 x 10 cm	70 cm²
50241S21D2D	50241S21D0D	Kerecis Omega3 SurgiBind	7 x 20 cm	140 cm²
50241S24D2D	50241S24D0D	Kerecis Omega3 SurgiBind	250 cm²	250 cm²
FENESTRATED 1:1				
50241G02D2D	50241G02D0D	Kerecis Omega3 SurgiBind Fenestrated 1:1	3 x 7 cm	21 cm²
50241G10D2D	50241G10D0D	Kerecis Omega3 SurgiBind Fenestrated 1:1	3 x 12 cm	36 cm²
50241G03D2D	50241G03D0D	Kerecis Omega3 SurgiBind Fenestrated 1:1	7 x 10 cm	70 cm²
50241G21D2D	50241G21D0D	Kerecis Omega3 SurgiBind Fenestrated 1:1	7 x 20 cm	140 cm²
50241G24D2D	50241G24D0D	Kerecis Omega3 SurgiBind Fenestrated 1:1	250 cm²	250 cm²



#### **OUR VISION**

To become the world leader in tissue regeneration by sustainably harnessing nature's own remedies FDA approved, U.S. and international patents and trademarks granted and pending.

#### KERECIS

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