Pierson Surgical Ltd.

Kerecis™ Omega3 WOUND

Acellular, reconstructive tissue matrix for chronic wound repair
Piscine origin, Icelandic, decellularized, Omega3 rich

Chronic wound repair with Kerecis Omega3

Kerecis Omega3 Wound is intact decellularized fish skin that contains natural Omega3 and dermal-matrix proteins that are compatible with human tissue. Chronic wounds are stuck in an inflamed stage and fail to progress through the normal stages of healing. Kerecis Omega3 Wound effectively salvages the wound from the inflammation stage and allows for regular healing to ensue.

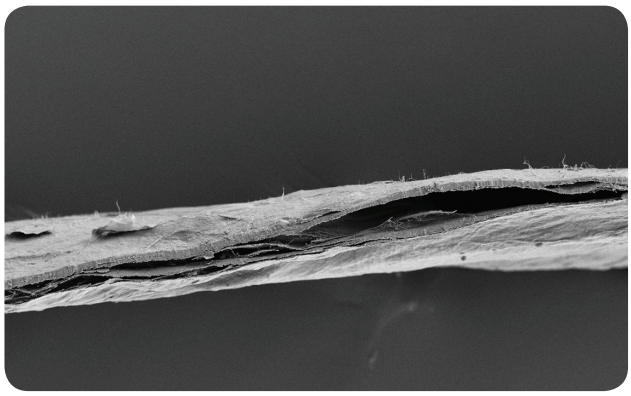
When applied to a chronic wound, Kerecis™ Omega3 Wound facilitates wound healing by providing a frame-work for cells to proliferate.

Technical Overview

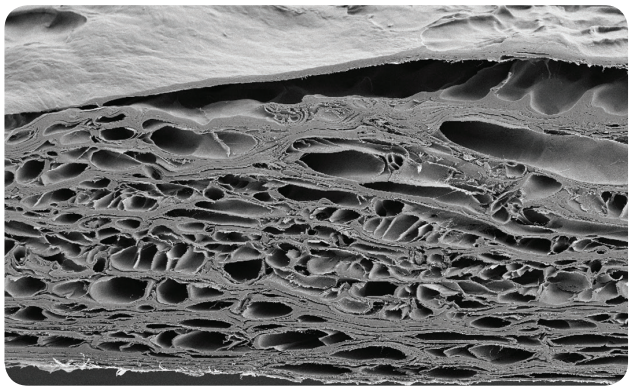
Kerecis Omega3 products are decellularized sheets of intact fish-skin, where all cells and antigenic materials have been removed, leaving behind the skin's extra-cellular materials. The literature uses the term Acellular Dermal Matrix (ADM) to describe porous scaffolds of this type when made from skin, and Extra Cellular Matrix (ECM) when sourced from non-skin tissues.

Traditional mammalian ADM/ECM products contain proteins such as collagen and fibrin as well as other compounds. In addition to those compounds, Kerecis Omega3 importantly contains EPA- and DHA-type Omega3 fatty acids, which exist in fish and have been connected to various health benefits mostly attributed to anti-inflammatory properties.[1]

The patented Kerecis Omega3 Wound material is the only product on the market that contains natural fish Omega3 fatty acids as well as being the only product made from intact, decellularized fish skin. The fish is sourced from the pristine waters of North Iceland, close to the Arctic Circle.



Scanning Electronic Microscope (SEM) image of currently marketed porcine (pig) matrix, 300 times magnification.



Kerecis fish-skin matrix, 300 times magnification. The Kerecis fish-skin matrix is thicker and more porous, providing proliferating cells with a sophisticated structure to bind to and proliferate in.

KERECIS

Technical Benefits

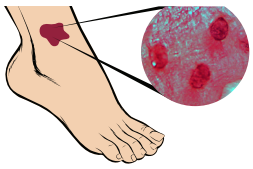
When wounds heal, they go through three distinct stages: inflammation, proliferation and remodeling. Chronic wounds do not progress through these stages, and remain stuck in the inflammation stage.

In that stage the white blood cells secrete degradative enzymes called MMPs in the wound bed, to clean up the wound and prepare for healing. Studies show that the concentration of MMPs increases in the chronic wound, resulting in less formation of the new tissues needed for the wound to heal.[2, 3]

When applied to the wound bed, the Kerecis Omega3 Wound facilitate the wound healing process, assisting chronic wounds to proceed from the inflammation stage. The matrix subsequently acts as a substrate for the overactive MMPs.

Once the concentration of the MMPs in the wound has been lowered, the body's own cells migrate into the matrix framework and repopulate. Ultimately the matrix is converted into functional, living tissue, and remodeling ensues.

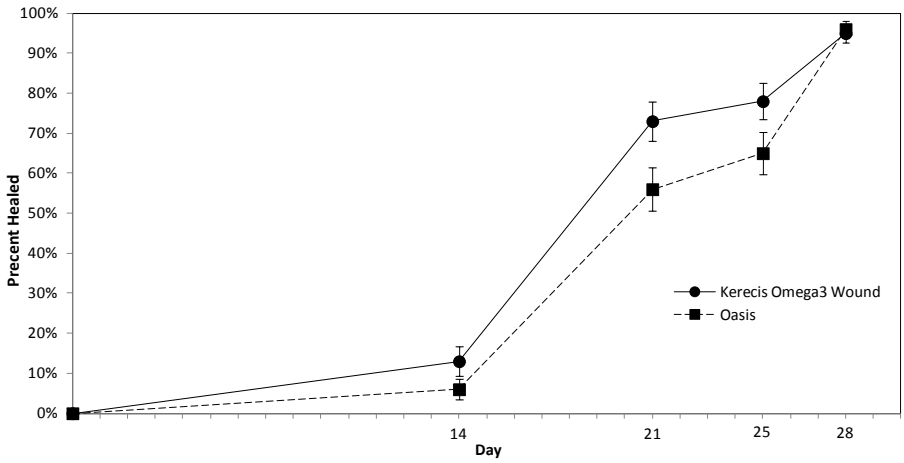
Kereics™ Omega3 Wound provides a basis for Cell-ingrowth and normal wound healing process



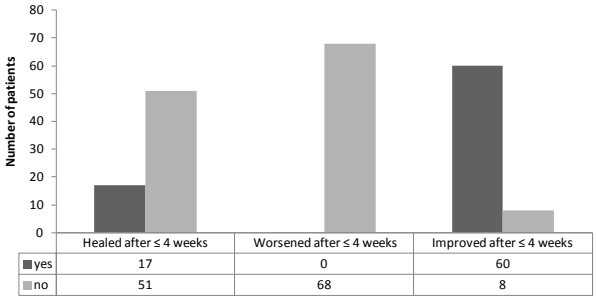
Naturally contains EPA- and DHA- type Omega3 fatty acids

The body´s own cells migrate into the product, divide and lay down new tissue

Studies with Kerecis™ Omega3 Wound

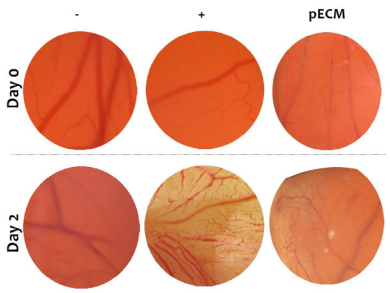


The fish skin Kerecis Omega3 Wound product was compared with Oasis, a porcine derived small intestinal submucosa, in a randomized controlled study on 140 punch wounds. The study demonstrated accelerated closure rate for Kerecis Omega3 Wound. [6, 7]



	Healed after ≤ 4 weeks	Worsened after ≤ 4 weeks	Improved after ≤ 4 weeks
yes	17	0	60
no	51	68	8

Clinical Trials indicate that chronic wounds benefit from treatment with Kerecis Omega3 Wound. In a trial where participants had ulcers older than four weeks Kerecis Omega3 Wound was applied with good results.[4]



Chick chorioallantoic membrane (CAM) assay: There was a significant increase in the relative number of branch points counted in all groups compared to the untreated (saline) control ($p < 0.05$). There was a significant increase in the vascular area of Kerecis Omega3 treated membranes compared to untreated controls ($p < 0.01$).[5]

1. D. Mozaffarian and J. H. Y. Wu, "Omega-3 fatty acids and cardiovascular disease: effects on risk factors, molecular pathways, and clinical events.," J. Am. Coll. Cardiol., vol. 58, no. 20, pp. 2047–67, Nov. 2011. 2. M. Toriseva and V.-M. Kähäri, "Proteinases in cutaneous wound healing.," Cell. Mol. Life Sci., vol. 66, no. 2, pp. 203–24, Jan. 2009. 3. V. Maarit, L. Mattila, N. Johansson, A. Kariniemi, M. Karjalainen-Lindsberg, V.-M. Kähäri, and U. Saarialho-Kere, "Distinct populations of Stromal Cells Express Collagenase-3 (MMP-13) and Collagenase-1 (MMP-1) in Chronic Ulcers but Not in Normally Healing Wounds," J. Investig. Dermatology, no. 109, pp. 96–101, 1997. 4. Baldursson B et al. Poster presented at SAWC spring 2013, 5. Magnusson S. et al. Data on file. 2012, 6. Baldursson B et al. Poster presented at Wounds UK 2013, 7. Using mixed effects logistics regression model, the odds ratio of being healed using Kerecis Omega3 Wound at any given time-point was estimated 4.75. The difference between the treatments was significant (p=0,041). Two-sided 95% confidence interval confirmed non-inferiority. Data on file.

Product Indications

Kerecis™ Omega3 Wound is classified as a medical device and has been approved by multiple national regulatory bodies. The table below lists the approved indications in the USA and Europe. For a list of accepted indications in other jurisdictions, please contact Kerecis at info@kerecis.com.

USA

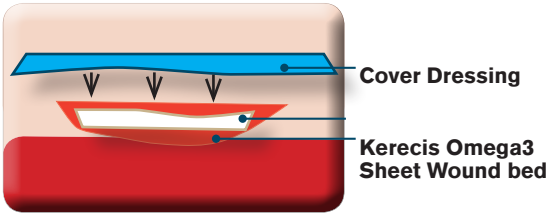
- Partial and full-thickness wounds
- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Trauma wounds (abrasions, lacerations, second-degree burns, skin tears)
- Surgical wounds (donor sites/grafts, post-Mohs surgery, post-laser surgery, podiatric, wound dehiscence)
- Drainage wounds

EUROPE

- Pressure ulcers
- Venous ulcers
- Chronic vascular ulcers
- Diabetic ulcers
- Traumatic ulcer
- Recurring ulcer in a burn scar
- Surgical wounds (after failed heel surgery)
- Necrotic wound (after injection, after infection, in a coagulopatic patient)
- Salvation of pinch graft

How to use

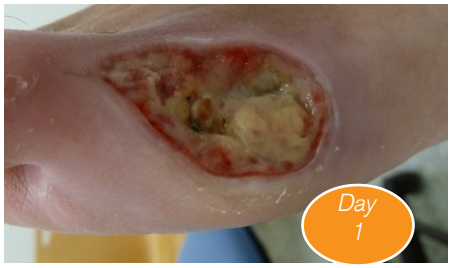
Remove Kerecis Omega3 Wound from the pouch, cut the sheet so that it fits into the wound, hydrate with a saline solution (NaCl) and apply into the wound without overlapping the wound edges. Apply a secondary dressing on top of the product and ensure that the wound bed and the Kerecis Omega3 sheet are moist at all times. Be careful to ensure that the Kerecis Omega3 sheet never dries out. Re-apply every 2-7 days, or when the previously applied sheet has been absorbed and is no longer visible. Do not remove partly absorbed product from the wound.



Application with Kerecis Omega3 Sheet
Material in contact with the wound bed, covered with a secondary wound dressing to maintain a moist wound environment

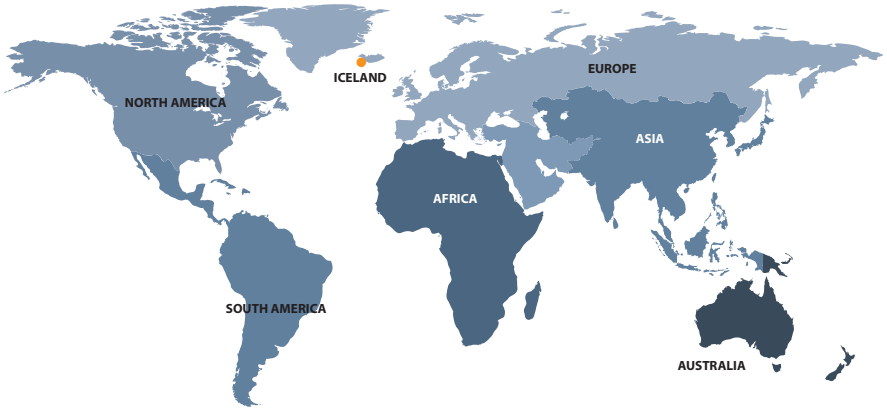
Case study

Type 2 diabetes. Insulin dependent. Badly controlled. Atherosclerosis was not significant and peripheral arterial blood flow considered sufficient for wound healing. Palpable pulses dorsalis pedis and ABPI is 0,94. Appeared with black necrotic wound on lateral part of foot (MT5). After debridement of eschar, treatment with Kerecis Omega3 Wound started.



Treatment with Kerecis Omega3 Wound starts.

After 10 weeks of treatment with Kerecis Omega3 Wound, further use was not needed for continuing healing process.



The origin of the product

Clean and environmentally sustainable

The fish skin used in Kerecis Omega3 technology is sourced from the pristine waters of North Iceland close to the Arctic Circle. The fish skin is processed immediately after harvesting. No penicillin or other antibiotics are used to reduce bioburden as is done with tissues of pig and cattle that are sourced from slaughterhouses. Kerecis, the company behind the Kerecis Omega3 technology, is committed to the responsible use of natural resources. All of our raw materials are sustainably harvested and no chemicals that are harmful to the environment are used in the manufacturing process. One step of the manufacturing process of Kerecis Omega3 calls for freeze drying. Freeze drying is an energy intensive process and the electricity that we use is 100% renewable (geothermal and hydro).

Ordering info

Item no	Description	size	Qty
50200S01B0	Kerecis Omega3 Wound	3 x 3,5 cm	1 pcs/box
50200S01B2	Kerecis Omega3 Wound	3 x 3,5 cm	10 pcs/box
50200S02B0	Kerecis Omega3 Wound	3 x 7 cm	1 pcs/box
50200S02B2	Kerecis Omega3 Wound	3 x 7 cm	10 pcs/box
50200S03B0	Kerecis Omega3 Wound	7 x 10 cm	1 pcs/box
50200S03B2	Kerecis Omega3 Wound	7 x 10 cm	10 pcs/box

KERECIS

Kerecis
Eyrargotu 2
400 Isafjordur
Iceland
Tel: +354 562 2601
sales@kerecis.com
www.kerecis.com

Pierson Surgical Ltd.

Pierson Surgical Ltd
sales@piersonsurgical.com
01225 766632
www.piersonsurgical.com

Fulfills United States and
ıl Device Regulations

CE
0123

KM-14-0306