MYKUTIS®

INTERACTIVE SKIN SUBSTITUTE

MD

PLANT-BASED

RI.MOS. CARE

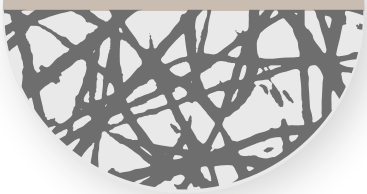
Interactive lattice support [1,2,3]

MYKUTIS® is designed to **promote cell proliferation and accelerate tissue repair**, in granulating wounds, with slowed growth factors.

Formulation [5,7,8,9]

MYKUTIS® is composed of **Poly-L-L-Lactic Acid (PLLA)** and an **oil solution** based on the **extract of St. John's Wort flower in Neem oil**.

PLLA
Poly-L-L-Lactic Acid



Supporting structure for the **tissue regeneration. Biocompatible and eco-friendly.**

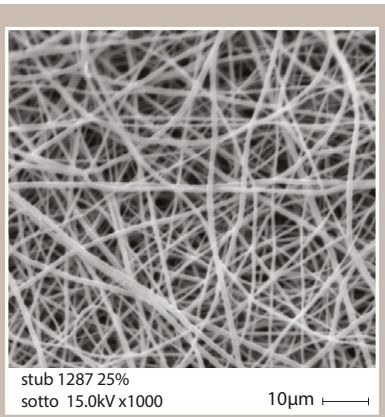
+

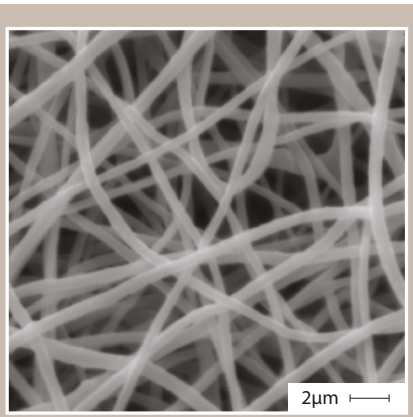
Neem
+
St. John's Wort

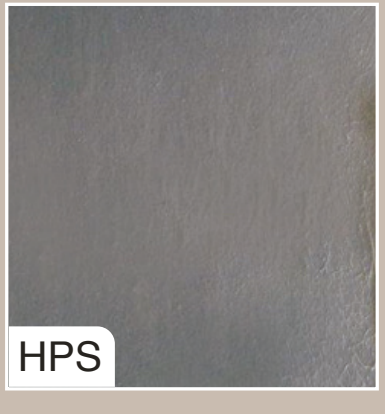
Synergistic Activity
Regenerating, Re-epithelializing, Soothing

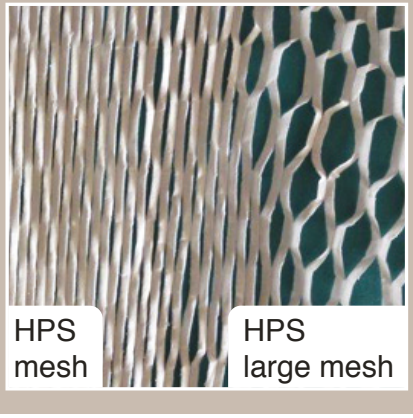
Antiseptic, Antimicrobial, Anti-inflammatory

Production Technology [4]









Electrospinning
High porosity scaffold.
Promotes cell substrate formation.

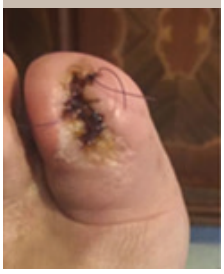
Mesh Structure
Reticular, expandable struture designed to facilitate the flow of exudate.

Clinical cases

Diabetics Ulcers

16/05

23/05



13/06

Traumatic injury resulting from a poorly performed pedicure.
The patient is an 84 years old woman with a history of diabetes, hypertension, heart disease and dialysis dependency.
16/05 Deep curettage of the toe, with MYKUTIS® applied to the phalanx and surrounding edges. The wound flaps were approximated with sutures.
23/05 Follow-up. The patient continues self-administered medication every other day, with outpatient evaluations every 15 days.
13/06 Suture removal at 30 days post-injury.

Vascular Ulcers

14/08

12/09

25/09

Accidental traumatic injury
An 81 years old woman with chronic venous insufficiency, currently on treatment with new oral anticoagulants.
14/08 MYKUTIS® applied to the base of the granulating lesion, combined with a 15-21 mmHg compression bandage. Weekly follow-ups.
12/09 70% reduction in lesion size.
25/09 Complete healing at 7 weeks.

Autoimmune Ulcers

14/08

28/08

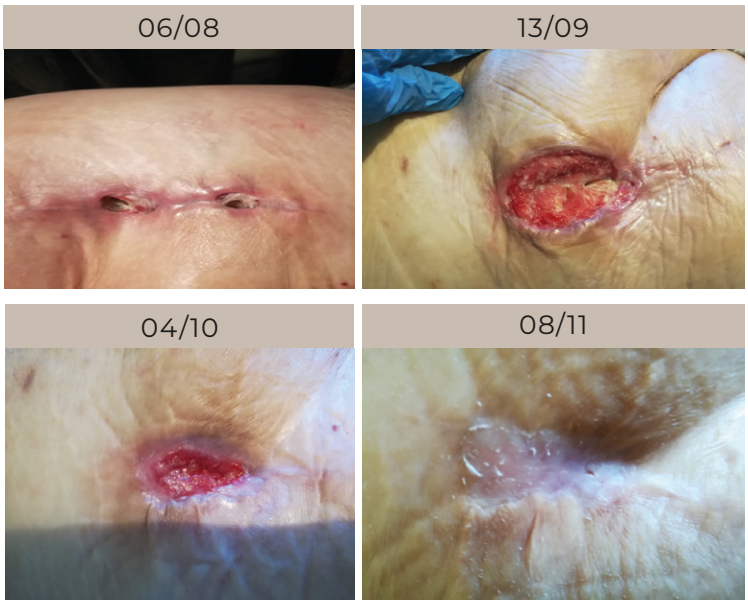
29/10

Vasculitic lesion
A 46 years old woman with a history of breast carcinoma, previous liver disease, mastectomy, chemotherapy, portal hypertension, bilateral pneumonia and sepsis secondary to port infection. She also has moderate chronic venous insufficiency and a histological diagnosis of pyoderma gangrenosum.
14/08 MYKUTIS® applied to the base of the granulated lesion.
28/08 Lesion size reduced by 40%; pain decreased from 8 to 6 (VAS scale). Weekly dressings.
29/10 Lesion size reduced by 96%; pain reduced further from 6 to 4 (VAS scale).

Site of skin graft removal

Autologous skin grafting
A 64 years old woman with chronic venous insufficiency and moderate renal infufficiency presents with a chronic lesion persisting for 5 years. Autologous skin graft.
04/07 Follow-up 3 days post-collection
08/07 Additional MYKUTIS® applied to the necessary areas.
12/07 90% re-epithelialization achieved.

Surgical Wounds



Hip dehiscence following prosthesis
06/09 MYKUTIS® applied to the dehisced area.
13/09 Continued application of MYKUTIS® where needed. Follow-up every 5 to 7 days to assess exudate and scaffold absorption.
04/10 80% reduction in dehiscence.
08/11 Complete recovery achieved.

Product benefits

Injury management
Promotes cell proliferation and accelerates healing

Rapidity
Promotes a faster regeneration process

Versatility
Suitable for outpatient and home use

Patient at the center
Caring is also taking care

Quality of life
Allows patients to quickly resume their daily activities

Features

- Protective barrier to prevent infections and maintain optimal wound conditions
- Promotes tissue regeneration and re-epithelialization
- Suitable for outpatient use
- Quick and easy to apply
- Expands and adapts to accommodate wound irregularities
- Does not require fixation with staples or sutures
- Use of breathable secondary dressings is recommended

Indications for use [5]

For stalled wounds that fail to progress in the healing process.
Promotes cell proliferation and accelerates healing.

- Diabetic ulcers
- Acute and chronic vascular ulcers
- Traumatic injuries (including abrasions and lacerations)
- Surgical wounds (dehiscence or failure to heal after surgery)

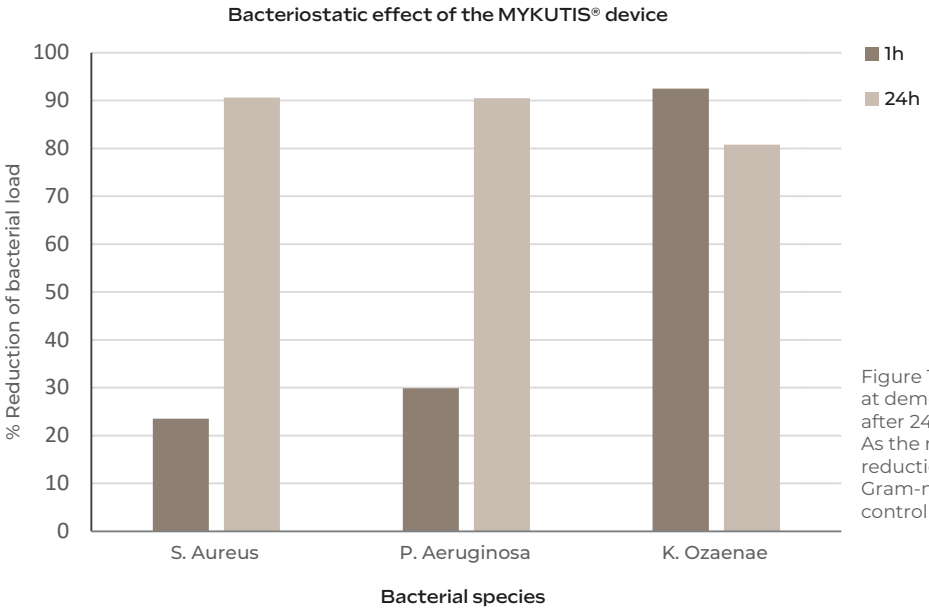
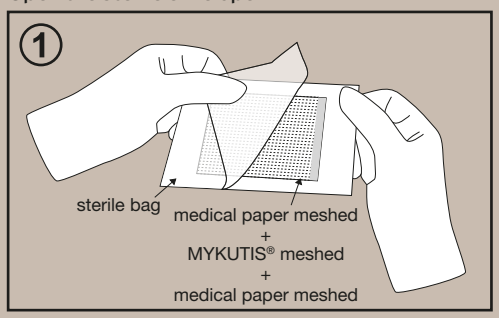


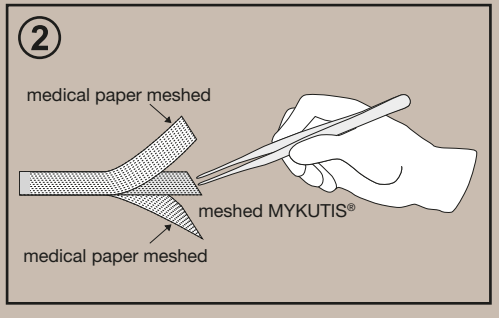
Figure 1: The graphic shows the results of an in vitro study aimed at demonstrating the bacteriostatic effect of the MYKUTIS® device after 24 hours of treatment.
As the results show, treatment with MYKUTIS® promotes the reduction of microbial load for both Gram-positive (S. Aureus) and Gram-negative (P. Aeruginosa) bacteria. The bacterial proliferation control effect is, moreover, also evident on K. Ozaenae species.[10]

Methods of use and application

Open the sterile envelope



CAUTION. Separate and pull out MYKUTIS® sandwiched between 2 sheets of meshed



PROCEDURE AT FIRST APPLICATION

- Debridement
- Hemostasis
- Application of MYKUTIS® on the bed of the granulating wound, even beyond the edges of the wound
- Covering with Hyperoil® medicated gauze and sterile TNT gauze (secondary dressing)
- Fixing with suitable medical adhesive backings

FIRST CHECK (on day 1 or day 2)

- Replacement of secondary dressing
- Checking for any signs of infection
- If necessary, add MYKUTIS® in uncovered areas.

SECOND AND SUCCESSIVE CHECK (every 7 days)

- Replacement of secondary dressing
- If necessary, add MYKUTIS® in uncovered areas.

DESCRIPTION	DATA	PACKAGING	REF.	UDI CODE
SIZE SINGLE SCAFFOLD	10X7 cm	BOX OF 5 ALUMINIUM ENVELOPES (n.10 MYKUTIS® scaffold)	120015SC05	8 007279 016352
STERILIZATION	EO			
EXPIRATION	4 years			

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Medical device CE class IIb
MATERIAL FOR PROFESSIONAL USE ONLY

CE 0051

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ISO 13485: 2016

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