NEVELIA®

BI-LAYER MATRIX

The choice for aesthetic and functional results in loss of substances[1]

SKIN EXPERTISE WITH A NEW COLLAGEN TECHNOLOGY

SYMATESE: OUR EXPERTISE IN THE FIELD OF COLLAGEN AND SKIN

SYMATESE GROUP is recognized for the **QUALITY AND EXPERTISE OF ITS TECHNOLOGIES** by some leading companies in cosmetics and dermatology. The key features of NEVELIA® have been developed to achieve dermal reconstruction close to native skin thanks to:

- ✓ Our expertise in the field of **SKIN AND DERMAL REGENERATION**
- ✓ Our **SCIENTIFIC APPROACH** to development and manufacturing
- ✓ Our know-how in **COLLAGEN TRANSFORMATION**

The Collagen extraction and purification are the key for the quality of the implant and guarantee

- Collagen quality
- Product safety
  - Calf hides from animal less than 6 months, coming from safe countries
  - Viral and BSE safety by selection of sourcing and several chemical inactivation processes
  - Conformity to current ISO-22442 and Eur. Pharmacopeia, Monograph N°1482

NEVELIA® Collagen Matrix design and crosslinking is the result of our **expertise in the field of collagen**

- The extraction procedure and the freeze-drying process allow to structure the collagen into a matrix with optimal hydrophily, pore structure and pore size.
- The collagen is then crosslinked to adjust the collagen degradation rate while the dermis is regenerated and therefore optimizes the neodermis quality.

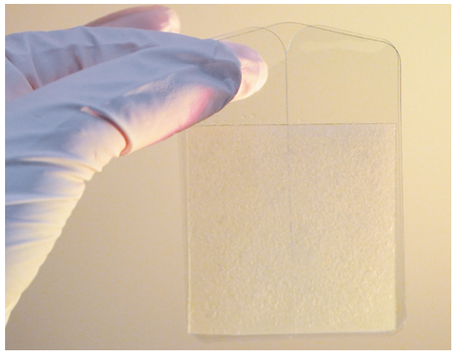
The goal is to obtain an optimal quality of collagen and a matrix structure to allow the neodermis formation.

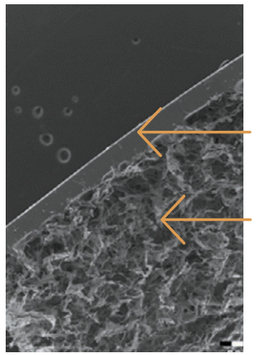
NEVELIA® BI-LAYER MATRIX

NEVELIA® Bi-Layer Matrix is a sterile medical device consisting of a collagen porous layer to promote and guide regeneration and a reinforced silicone layer acting as a pseudo-epidermis.

This matrix serves as a support for cell infiltration, thus contributes to the natural tissue regeneration process. It is resorbed, becoming a vascularized tissue that is histologically very close to the normal dermis, from 2 to 3 weeks after it is implanted[2].

The silicone layer is removed after dermal regeneration, at the time of the thin split thickness skin graft.





Silicone sheeting reinforced with a polyester

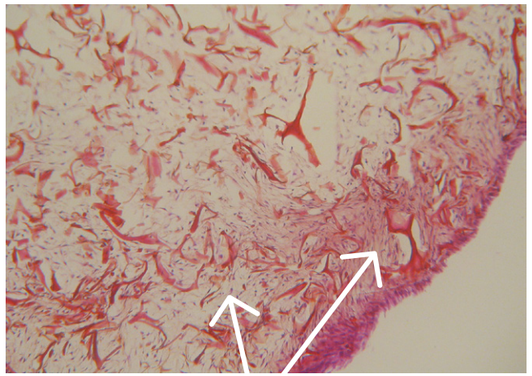
Three-dimensional porous matrix of bovine collagen, Type I

SYMATESE know-how in collagen extraction and transformation over 30 years has permitted to develop and manufacture successfully collagen-based medical devices and components like bone substitutes, hemostatic compresses or coatings for vascular grafts.

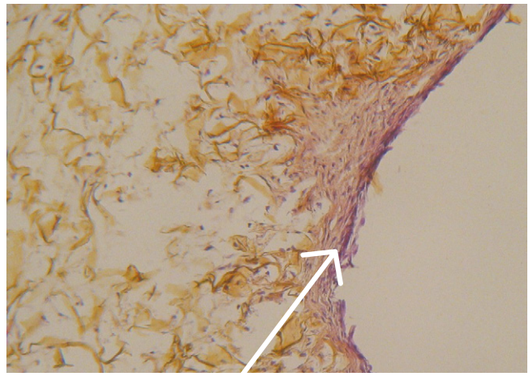
NEVELIA® STRUCTURE

NEVELIA® is a three-dimensional porous matrix of stabilized bovine origin type I Collagen.

NEVELIA® is made of a specific native collagen with a large fibrous proportion to keep cell adhesion signals and mechanical structure to support regeneration.
In vitro tests demonstrate an optimized colonization as fibroblasts recognize collagen fibers.



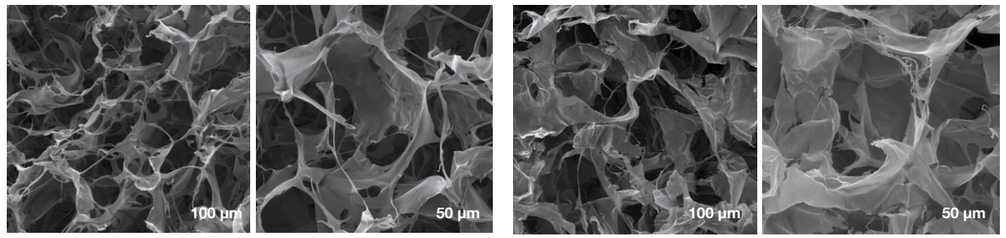
NEVELIA®
Colonization in the matrix thickness, many cells, strong collagen neosynthesis



OTHER BI-LAYER MATRIX
Colonization mainly on the surface, few cells, poor collagen neosynthesis

Additional NEVELIA® features are:

- ✓ Optimized pore size[3] (average pore size 100 µm) and open-cell structure promoting nutrients flow and fibroblasts migration

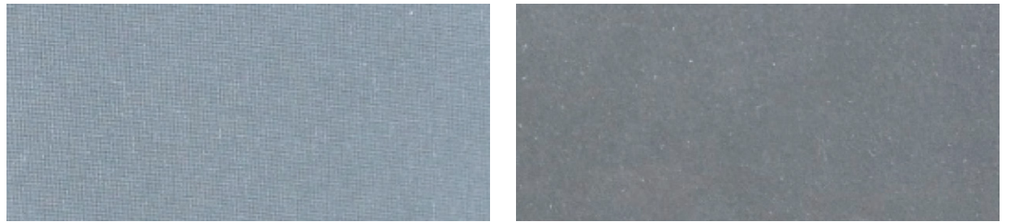


NEVELIA® MATRIX SEM photography

OTHER BI-LAYER MATRIX SEM photography

- ✓ Crosslinking rate for a balanced absorption / regeneration process
- ✓ No GAG added to keep cells attachment potential

NEVELIA® is composed of medical-grade silicone elastomer reinforced with a polyester material.



NEVELIA®
Reinforced silicone sheeting

OTHER BI-LAYER MATRIX
Non-Reinforced silicone sheeting

NEVELIA® UTILIZATIONS

NEVELIA® is used for dermal regeneration in skin loss, especially in:

- Burns surgery (third and deep second degree burns and burns sequelae)
- Chronic wounds surgery (including leg ulcers and diabetic foot)
- Traumatology
- Skin tumors surgery
- Reconstructive plastic surgery

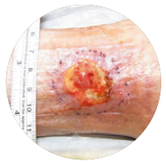
NEVELIA® can also be used in children.
NEVELIA® is used in combination with a thin split thickness skin graft to recreate skin close to normal skin in terms of function and appearance.

BURNS

CHRONIC WOUNDS

TRAUMATOLOGY

SKIN TUMORS



OTHERS

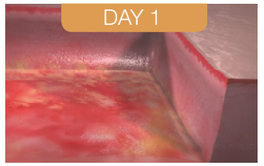
NEVELIA®, AN ALTERNATIVE TO

- Skin Expansion (Single or sequential)
- Flaps (Local, distant, free ...)
- Split-Thickness or Full-Thickness skin autograft
- Dermal graft (Allografts, Xenografts...)

NEVELIA® DERMAL REGENERATION PROCESS

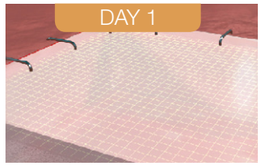
CONTRACTED SCAR

The surgery can be scheduled as soon as the patient is stabilized.



EXCISION OF THE WOUND

All the dead tissue on and around the graft zone must be removed. For the succes of NEVELIA® Bi-layer Matrix, all necrotic and scar tissues must be excised down to the viable tissue.



NEVELIA® BI-LAYER MATRIX APPLICATION

NEVELIA® Bi-Layer Matrix must be cut to fit the excised wound size exactly. The collagen matrix must be in direct contact with the excised wound. The matrix will be fixed in place with surgical slaples or sutures.

NEODERM FORMATION

The collagen matrix is quickly colonized by the patient's cells and is gradually replaced by an autologous neoderm.

REMOVAL OF THE SILICONE LAYER

When the neoderm is formed, the silicone layer is removed. The reconstructed dermis has a distinctive orange-yellow or light yellow colour and may present with slightly reddish areas, sign of a good revascularization.

HARVESTING OF THE GRAFT

A thin split thickness skin graft must be token, if possible from an area similar in colour to the reconstructed area. It must be removed with dermatome and may be meshed.

THIN SPLIT THICKNESS SKIN GRAFT

The graft is placed on the neoderm and it is fixed with staple or suture.

REGENERATED SKIN

Epidermization.
Complete hecling of the wound.

NEVELIA® BENEFITS

NEVELIA® provides immediate wound closure and promotes dermal regeneration.

NO GAG
Glycosaminoglycan

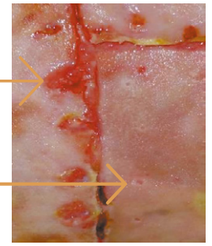
- Collagen hemostatic properties
  The hemostatic effect may reduce the risk of hematoma formation under or in the device

NATIVE COLLAGEN AND ITS 3D OPEN-CELL STRUCTURE

- Good neo-dermis colonization[4]
- Adequate management & medical care in mobile areas
- Good trophicity especially necessary in areas of friction, pressure, loss of substance, instable scar

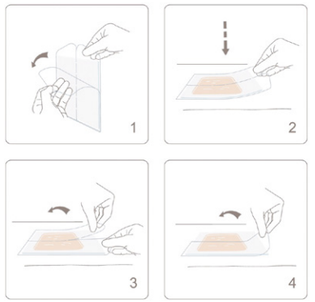
REINFORCED SILICONE SHEETING

- Possible prolonged placement of NEVELIA® for a better management of certain indications especially in chronic wounds or in case of skin graft lack in extended deep burns



- Reduction of the risk of certain side effects
  The matrix will not tear around the staples or sutures
  • Neodermis formation over all the surface without any granulation tissue
  • Treated area totally covered, thus reducing the risk of infection.

PRE-HYDRATED MATRIX PLACED BETWEEN 2 RIGID PLASTIC PROTECTIVE SHEETS



- Ready for use and ease of aseptic handling "no touch"

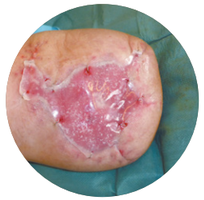
NEVELIA® BI-LAYER MATRIX CLINICAL BENEFITS FOR SPECIFIC INDICATIONS

BURNS SURGERY

- Waiting donor site availability for extended burns

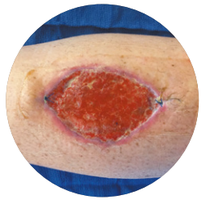
CHRONIC WOUNDS SURGERY

- Good trophicity especially necessary in areas of friction, pressure
- Adapted to prolonged healing time



TRAUMATOLOGY

- Good trophicity especially necessary in areas of friction, pressure
- Adapted to prolonged healing time to combine other treatments



SKIN TUMORS SURGERY

- Wise choice awaiting anatomopathologist results
- Facilitates monitoring of cancer recurrence
- Ease of care for the elderly through faster mobilization

ADDITIONAL BENEFITS

NEVELIA® by-layer matrix can improve treatment in a number of situations.

- ✓ **Immediate availability**
- ✓ **Efficiency** of the surgical technique
- ✓ **Creation of a thicker protective tissue and reestablishment of the gliding plan** in noble elements coverage like muscles, bones, tendons
- ✓ **Better functional and aesthetic results** compared to common dermo-epidermal graft
- ✓ **No additional scars in traumatology** (versus flaps)
- ✓ **Reduction risk sequelae of donor site**
- ✓ **Does not prevent alternative treatments**
- ✓ **Reduction of hypertrophic scars and keloids occurrence**
- ✓ **Faster procedure** which can be performed in ambulatory room for specific indications (hand, skin tumors)

Children : allows better adaptation of tissue to child growth (less tensions & flanges)

NEVELIA® RESULTS

CLINICAL CASE 1: **BURN**

- Male, 75 yrs old
- Third-degree burn (left foot)
- Burn date: 07 Jun 2014
- Enrollment date: 01 Jul 2014

Pr Vincent CASOLI
Bordeaux - France

3RD DEGREE BURN

WOUND BED PREPARATION

NEVELIA® GRAFT

FOLLOW UP

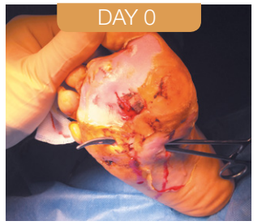
SILICONE REMOVAL, NEODERMIS FORMED

SPLIT DERMO EPIDERMAL GRAFT

CLINICAL CASE 2: **CHRONIC WOUND**

- Female, 60 yrs old
- Infected chronic wound (right foot)
- Wound date: 28 Nov 2014
- Enrollment date: 17 Feb 2015

Dr Sergiu FLUIERARU
Dr Luc TEOT
Montpellier - France



PREOPERATIVE

WOUND BED PREPARATION

NEVELIA® GRAFT

SILICONE REMOVAL, NEODERMIS FORMED

SPLIT DERMO EPIDERMAL GRAFT

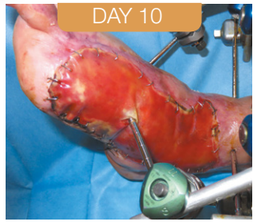
CLINICAL CASE 3: **TRAUMATOLOGY**

- Male, 66 yrs old
- Crush injury (right leg) with loss of soft tissue
- Accident date: 06 Mar 2014
- Enrollment date: 21 May 2014

Pr Vincent CASOLI
Bordeaux - France

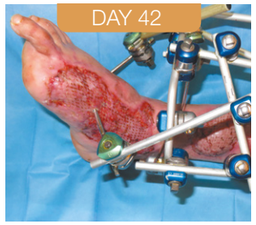
WOUND BED PREPARATION

NEVELIA® GRAFT



FOLLOW UP

SPLIT DERMO EPIDERMAL GRAFT



CLINICAL CASE 4: **SKIN TUMORS**

- Female, 62 yrs old
- Wound related to melanoma exeresis (right leg)
- Surgery date: 17 Dec 2014
- Enrollment date: 30 Jan 2014

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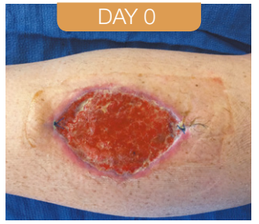
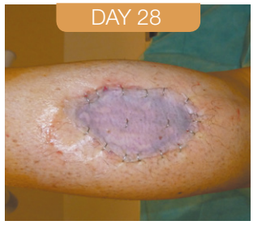
Bordeaux - France



WOUND BED PREPARATION

NEVELIA® GRAFT

FOLLOW UP



SPLIT DERMO EPIDERMAL GRAFT

CLINICAL CASE 5: **RECONSTRUCTIVE SURGERY**

- Male, 57 yrs old
- Open wound on amputation stump (right knee)
- Accident date: 18 Apr 2014
- Enrollment date: 23 May 2014

Pr Vincent CASOLI
Bordeaux - France

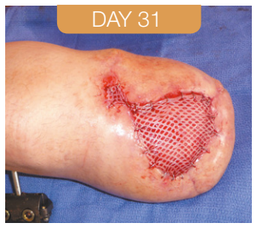
PREPARATION OF THE WOUND WITH NPWT

GRANULATION TISSUE

NEVELIA® GRAFT

FOLLOW UP

SILICONE REMOVAL, NEODERMIS FORMED



SPLIT DERMO EPIDERMAL GRAFT

CLINICAL CASE 6: **RECONSTRUCTIVE SURGERY**

- Female, 68 yrs old
- Necrotizing dermohypodermitis (right hand)
- Accident date: 07 Jul 2014
- Enrollment date: 30 Jul 2014

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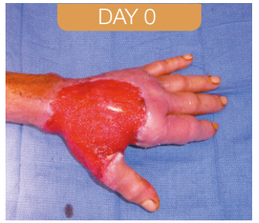

WOUND BED PREPARATION

NEVELIA® GRAFT

FOLLOW UP

BEFORE SILICONE REMOVAL

SILICONE REMOVAL, NEODERMIS FORMED

SPLIT DERMO EPIDERMAL GRAFT

REFERENCES	DESCRIPTION	SIZE	UNITS
MCS0505	NEVELIA® Bi-Layer Matrix for dermal regeneration	5x5 cm	1
MCS1015	NEVELIA® Bi-Layer Matrix for dermal regeneration	10x15 cm	1
MCS1030	NEVELIA® Bi-Layer Matrix for dermal regeneration	10x30 cm	1
MCS2030	NEVELIA® Bi-Layer Matrix for dermal regeneration	20x30 cm	1

NEVELIA® Bi-Layer Matrix is CE Marked by the notified body LNE/G-MED n°0459 and a Class III Medical Device made by SYMATESE-ZI les Troques-Chaponost-France.

Availability of the device can be subject to local regulatory registration. Please refer to appropriate Instructions for Use for complete product information. This product does not contain latex. Warning: Applicable laws restrict the sale of these devices by or on the order of a physician. NEVELIA® is a trademark of SYMATESE.

INDICATIONS

NEVELIA® is indicated for dermal regeneration in individuals with skin loss, particularly in the following fields:

- Burns surgery (third and deep second degree burns)
- Reconstructive plastic surgery
- Traumatology

NEVELIA® is used in combination with a thin split thickness skin graft to recreate skin resembling normal skin in terms of function and appearance.

NEVELIA® bi-layer matrix is particularly useful for:

- patients who are unable to supply sufficient donor skin for an autograft at the time of excision
- When the physiological condition of the patient does not allow the autograft

CONTRAINDICATIONS

NEVELIA® bi-layer matrix must not be used in patients presenting with:

- clinical signs of wound infection
- an allergic predisposition or known allergy to bovine collagen or silicone

BIBLIOGRAPHY

1 **Prospective evaluation of NEVELIA® in terms of safety and efficacy for third-degree burns treatment and reconstructive surgery in the University Hospital of Bordeaux: electronic poster presentation** at the EWMA 2017 conference in Amsterdam.

2 **Instructions for use MCSN01D** (May 2013)

3 **Yannas, I. V., E. Lee, et al. (1989). «Synthesis and characterization of a model extracellular matrix that induces partial regeneration of adult mammalian skin.»** Proc Natl Acad Sci U S A 86(3): 933-937.
Harley BA, Kim HD, Zaman MH, Yannas IV, Lauffenburger DA, Gibson LJ. Microarchitecture of three-dimensional scaffolds influences cell migration behavior via junction interactions. Biophys J. 2008 Oct;95(8):4013-24.

4 **CHAJRA Hanane [18-12-2006] , Mise au point de nouveaux biomatériaux à base de collagène pour la réparation tissulaire cutanée** Development of new collagen-based biomaterials for skin tissue repair

NOTES

For more information or to place an order, please contact:

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