SYMATESE

NEVELIA®

BI-LAYER MATRIX

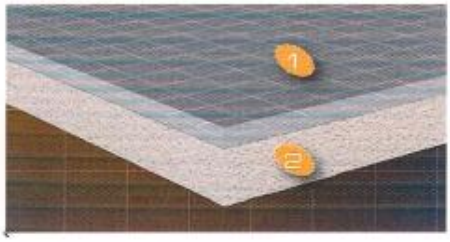
for Dermal Regeneration

The choice of efficiency and convenient use
for dermal reconstruction

NEVELIA® Bi-Layer Matrix **OUTLINE**

SYMATESE is introducing NEVELIA® Bi-Layer Matrix which is a sterile medical device consisting of a collagen layer to promote dermal regeneration and a reinforced silicone layer acting as a pseudo-epidermis.
The type I, purified, stabilised, bovine origin collagen is supplied as a porous matrix. This matrix serves as a support for cell infiltration, thus contributes to the natural tissue regeneration process. It is resorbed, becoming a vascularised tissue that is histologically very close to the normal dermis, from 2 to 3 weeks after it is implanted.
NEVELIA® Bi-Layer Matrix is manufactured, and packaged under ISO 13485 quality standards applicable to medical devices. Quality controls are performed at all stages of the production. The NEVELIA® Bi-Layer Matrix is sterilized by radiation.

STRUCTURE of NEVELIA® Bi-Layer Matrix



1. Silicone layer consists of medical-grade silicone elastomer reinforced with a polyester material – **Exclusive technology patented by SYMATESE[1].** It is a « pseudo-epidermis », protecting the wound from bacterial infection and other damages while regulating water vapour loss.
2. Three-dimensional porous matrix of purified stabilized bovine collagen. It permits cell migration and growth of a new dermis.

NEVELIA® Bi-Layer Matrix **CLINICAL ADVANTAGES**

The choice of efficiency and convenient use for dermal reconstruction

SAFE & READY TO USE

- NEVELIA® Bi-Layer Matrix is presented hydrated and ready-to-use, into a physiological saline solution. There is no need to proceed extra manipulation before the implementation of the product.
- NEVELIA® Bi-Layer Matrix is packaged between 2 rigid plastic protective sheets for ease of aseptic handling.

RELIABLE & EASIER

- NEVELIA® Bi-Layer Matrix has an **exclusive** reinforced silicone layer with a polyester material that reduces tearing around staples or sutures and thus limits the risk of early wrenching of it and the risk of infection.
- NEVELIA® Bi-Layer Matrix transparency of the pseudo-epidermis facilitates the monitoring of the dermal regeneration and the possible presence of complications.

EFFICIENCY DEMONSTRATED [2]

- General assessment of surgeon and patient regarding **FUNCTIONAL** results at 18 months.
The results satisfactory and very satisfactory represent :

90 % of surgeons' opinion — **93 %** of patients' opinion

- General assessment of surgeon and patient regarding **AESTHETIC** results at 18 months.
The results satisfactory and very satisfactory represent :

87 % of surgeons' opinion — **93 %** of patients' opinion

[1] *Patent n° EP 2083751 – « Device for regenerating human skin and method for manufacturing said device ».*
[2] *Clinically proved on 35 patients – bi center study in France, on an equivalent dermal regeneration Bi-Layer*

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NEVELIA® Bi-Layer Matrix
INDICATION

NEVELIA® Bi-Layer Matrix 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® Bi-Layer Matrix is used in combination with a thin split thickness skin graft (STSG) 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.

DERMAL REGENERATION PROCESS

Day 0

Contracted Scar

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

Day 21+

Removal of the Silicone Layer

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

Day 1

Excision of the Wound

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

Day 21+

Harvesting of the Graft

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

Day 1

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 staples or sutures.

Day 21+

Thin Split Thickness Skin Graft

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

Day 1 to 21

NeoDerm Formation

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

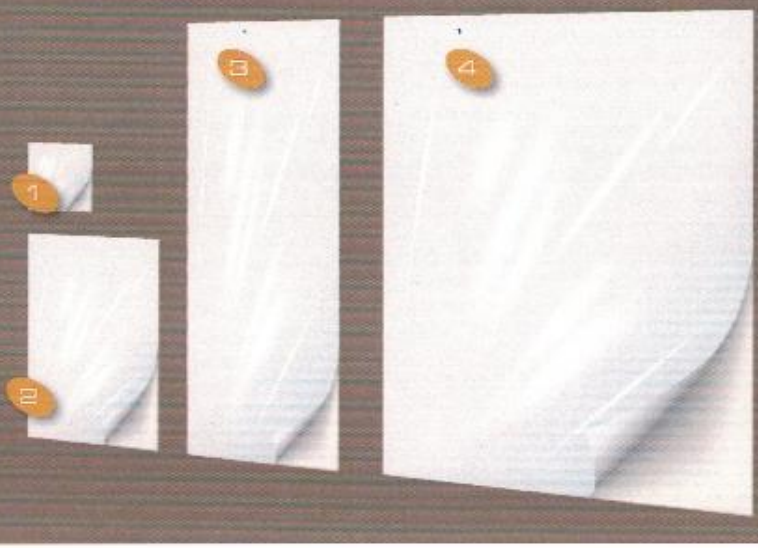
Day 45+

Regenerated Skin

Epidermization.
Complete healing of the wound.

NEVELIA® Bi-Layer Matrix **REFERENCES**

	REFERENCES	DESCRIPTION	PACKAGING
1	**MCS0505**	NEVELIA®, Bi-Layer Matrix for dermal regeneration, **5 x 5 cm**	1
2	**MCS1015**	NEVELIA®, Bi-Layer Matrix for dermal regeneration, **10 x 15 cm**	1
3	**MCS1030**	NEVELIA®, Bi-Layer Matrix for dermal regeneration, **10 x 30 cm**	1
4	**MCS2030**	NEVELIA®, Bi-Layer Matrix for dermal regeneration, **20 x 30 cm**	1



PRECAUTIONS FOR USE

The surgeon must establish the risk/benefit ratio for each patient before using NEVELIA® Bi-Layer Matrix. There have been no clinical studies evaluating NEVELIA® Bi-Layer Matrix in pregnant women. Caution should be exercised when envisaging their use in this population.

The surgeon must respect certain precautions for use when implanting NEVELIA® Bi-Layer Matrix:

- All the dead tissue on and around the area receiving the graft must be carefully removed, leaving only viable tissue. For NEVELIA® Bi-Layer Matrix to take successfully and to prevent infection, all necrotic and scar tissues must be excised.
- It is important to make sure that haemostasis is complete before applying NEVELIA® Bi-Layer Matrix, to prevent the development of hematomas which may cause local failure of NEVELIA® Bi-Layer Matrix, to take.
- The matrix can be meshed if used for highly exudative wounds or to improve the fit of the bi-layer matrix to an irregular surface. NEVELIA® Bi-Layer Matrix must not be expanded.
- NEVELIA® Bi-Layer Matrix must be applied on the day the necrotic or dead tissue is excised or when a viable, vascularised wound bed has been obtained. Delayed application after excision may jeopardize integration of the matrix into the wound bed.
- NEVELIA® Bi-Layer Matrix must be cut to fit the excised wound exactly. This will minimise scarring. It is important to ensure that the matrix is inserted into the wound with the collagen layer directly against the viable wound bed, **and the silicone layer facing outwards.**
- When it is used in mobile areas, NEVELIA® Bi-Layer Matrix must be implanted in such a way as to prevent its mechanical dislodgement.
- The wound bed and changes in the colour of the dermis should be monitored regularly through the transparent pseudo-epidermis to detect any emerging complications and decide on the appropriate time to remove the silicone layer and perform the thin split thickness skin graft.
- Care must be taken not to accidentally remove the newly formed dermal tissues when removing the silicone layer. The reconstructed dermis **must not** be excised.
- After opening, NEVELIA® Bi-Layer Matrix must not be stored for later use as this could cause a risk of infection.

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.

The criteria used to select patients are entirely the responsibility of the surgeon.

NEVELIA® Bi-Layer Matrix is CE marked by the notified body LNE / G-MED n°0459 and is a Class III Medical Device

Distributor

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

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