SUMMARY OF SAFETY AND CLINICAL PERFORMANCE

(SSCP)

NEVELIA®

SSCP date	2022/11/14
SSCP version	1
SSCP EUDAMED version	Rev 0

SECTION B: SSCP FOR PATIENTS

A Summary of the Safety and Clinical Performance (SSCP) of the device, intended for patients, is given below:

Manufacturer's reference number for the SSCP: SSCP-MCMDR

Summary of safety and clinical performance Document revision: Rev 0

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions for Use to provide information on the safe use of the device.

1 DEVICE IDENTIFICATION AND GENERAL INFORMATION

1.1 DEVICE TRADE NAME

NEVELIA®

1.2 MANUFACTURER: NAME AND ADDRESS

SYMATESE SAS
ZI LES TROQUES
69630 CHAPONOST – France

1.3 BASIC UDI-DI

Basic UDI-DI for NEVELIA®: 376017216MCSGZ

1.4 YEAR WHEN THE DEVICE WAS FIRST CE-MARKED

NEVELIA® is CE-certified since 2013 (legacy device).

2 INTENDED USE OF THE DEVICE

2.1 INTENDED PURPOSE

NEVELIA® is intended for dermal regeneration.
NEVELIA® can be used with a split thickness skin graft (STSG) during a second-stage procedure to restore an epidermal coverage.

2.2 INDICATIONS AND INTENDED PATIENT GROUPS

NEVELIA® is indicated in patient with skin loss for reconstructive surgery in case of:
- burn wounds (third and deep second-degree burns),
- traumatic wounds,
- iatrogenic wounds,
- chronic wounds.

NEVELIA® Bi-layer matrix is used for patients requiring dermal substitution.
There are few clinical data dealing with NEVELIA® in paediatric population and none in pregnant women. Caution should be exercised when envisaging its use in these population.

2.3 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.

3 DEVICE DESCRIPTION

3.1 DEVICE DESCRIPTION AND MATERIAL/SUBSTANCES IN CONTACT WITH PATIENT TISSUES

NEVELIA® Bi-layer matrix is a sterile implantable medical device consisting of a collagen layer and a reinforced silicone layer.
NEVELIA® collagen layer part is an absorbable freeze-dried cross-linked collagen of about 2 mm thick. The collagen used in NEVELIA® is Type 1-collagen extracted from calf hides. It promotes dermal regeneration.

NEVELIA® silicone layer part is a silicone sheet about 200 µm thick reinforced with a polyester fabric. It acts as a physical protection of the wound, preventing dryness and limiting external contamination.
NEVELIA® Bi-layer matrix as dermal substitute allows the reduction of the wound surface as well as the complete closure of the wound.
NEVELIA® Bi-layer matrix is supplied hydrated in a physiological saline solution and placed between two protective plastic sheets. It is unitarily packed in double pouches placed in a box.
NEVELIA® Bi-layer matrix is sterile, biocompatible and ready-to-use.
Several matrices can be used to cover the entire surface of a wound provided that they do not overlap.
NEVELIA® Bi-layer matrix is not intended for repeated applications.

NEVELIA® Bi-layer matrix is sterilized by E-beam radiation (beta irradiation).
NEVELIA® Bi-layer matrix does not contain medicinal substance, human tissues or blood products.

The components of NEVELIA® are:

- Bovine Type I collagen layer
- Reinforced silicone layer
- Silicone adhesive
- 0.9% sterile saline solution

The duration of contact of NEVELIA® with the human tissues is around 4 weeks after the placement. The collagen layer is resorbed to leave the place to autologous neodermis.
NEVELIA® is a single-use product, it must not be re-sterilized.

3.2 INFORMATION ABOUT MEDICINAL SUBSTANCES IN THE DEVICE, IF ANY

The device does not contain any medicinal substances.

3.3 DESCRIPTION OF HOW THE DEVICE IS ACHIEVING ITS INTENDED MODE OF ACTION

NEVELIA® is implanted in order to support new dermal formation (neodermis). The collagen layer promotes dermal regeneration by cellular colonization of the patient's cells. The neodermis is obtained between 3 and 4 weeks. At this time, the silicone layer can be removed and a split thickness skin graft (STSG) is performed to restore an epidermal coverage. The reinforced silicone layer acts as a temporary barrier limiting external contamination. The polyester fabric guarantees that the matrix will not tear around staples or sutures. The silicone layer is transparent allowing dermal regeneration or potential signs of infection to be monitored.

3.4 DESCRIPTION OF ACCESSORIES, IF ANY

NEVELIA® device is not supplied with accessories. During a surgery, other instruments and accessories can be used to manage the procedure, depending on the user expertise and decision (surgical scissors, surgical staples, suture, sterile compress, scalpel, negative Pressure Wound Therapy Device).

4 RISKS AND WARNINGS

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional.

4.1 HOW POTENTIAL RISKS HAVE BEEN CONTROLLED OR MANAGED

The residual risks are acceptable since the benefit/risk ratio is favourable and corresponds to the state of art / technology. All the residual risks have been evaluated as Low residual risks or medium residual risk and considered as acceptable according to SYMATESE policy.

4.2 REMAINING RISKS AND UNDESIRABLE EFFECTS

The following complications and associated average occurences have been identified by clinical data on NEVELIA®:

- haematoma/ bleeding (< 10%),
- seroma/collection (< 5%),
- early detachment of the collagen layer/ partial loss of dermal substitute (< 5%),
- wound infection (< 5%),
- loss of epidermal graft (< 5%).

Based on the state of the art, the following events have been identified that may occur with the use of NEVELIA®:

- allergic reaction,
- bone exposure,
- hyperkeratosis.

These events have never been reported before with NEVELIA®.

Other adverse events related to the split thickness skin graft (STSG) procedure may occur and are those commonly reported during surgical procedure.

Transmissible spongiform encephalopathy (TSE) diseases and viral infections are residual risks related to the use of substances of animal origin. It is unlikely they occur as many measures are taken to reduce them as far as possible. These risks have never been reported during the history of NEVELIA® or similar devices.

Please be aware that any serious incident that might have been caused by NEVELIA® should be reported directly or through the distributor to the manufacturer or the Competent Health Authority.

4.3 WARNINGS AND PRECAUTIONS

a) Warning

NEVELIA® is not recommended to be used in nose ala due to the specific thickness of this body area

b) Precautions for use

The surgeon must establish the risk/benefit ratio for each patient before using NEVELIAÒ.

- Necrotic and scar tissues must be excised for NEVELIA® to take successfully and to prevent infection. Delayed application after excision may jeopardize integration of the matrix into the wound bed.
- A complete haemotasis must be performed before NEVELIA® implantation to prevent the formation of haematomas which may cause local failure of NEVELIA®.
- NEVELIA® must not be expanded. NEVELIA® can be meshed if used for highly exudative wounds or to improve the fit of NEVELIA® to an irregular surface.
- NEVELIA® must be cut to fit the excised wound exactly. This will minimize scarring and improve aesthetic result.
- NEVELIA® must be implanted and fixed in such a way to prevent its mechanical dislodgement when it is used in mobile areas.
- All inadvertent movement-related disturbance of the NEVELIA® should be avoided as this may cause it to separate from the wound bed. Physiotherapy and joint mobility exercises are possible as soon as the patient is well enough, and with the physician's approval.
- Caution must be taken not to accidentally remove or excised the newly formed dermal tissues when removing the silicone layer.

4.4 SUMMARY OF ANY FIELD SAFETY CORRECTIVE ACTION, (FSCA INCLUDING FSN)

Not applicable.

5 SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP

5.1 CLINICAL BACKGROUND OF THE DEVICE

The skin is the largest organ of the body by weight. It functions as a protective barrier and thermoregulatory organ but also provides the means for perceiving a myriad of tactile, thermal, and chemical sensory inputs. The complexity of the dermal layer means that damage to this section can result in permanent impairment of function. This is particularly so for deep, partial thickness and full thickness wounds, where the dermal component of skin is often completely lost, such as burn, traumatic, iatrogenic or chronic wounds. These are devastating injuries and need urgent treatment. Autografts is considered as the gold standard. More particularly split-thickness skin graft (STSG) allow effective and minimally invasive skin reconstruction. However, STSG without adequate dermal support are prone to contraction and restrictive scarring, and are not suitable to cover poorly vascularized tissues. These shortcomings led to the development of tissue-engineered dermal substitutes, like bovine matrix bilayer as NEVELIA®, that has been widely applied in various full-thickness skin defects. These dermal substitutes have been shown to optimize healing and improve the quality of scar tissue. Dermal matrices provide many benefits, including the ability to expedite healing, decrease length of stay, and provide coverage that is flexible, supple, and mobile. Therefore, dermal substitutes as NEVELIA® is a real option to treat full thickness defects.

5.2 THE CLINICAL EVIDENCE FOR THE CE-MARKING

NEVELIA® promotes healing with good functional and aesthetic results. Clinical evidence for CE-marking is based on laboratory testing, scientific literature, market feedback and clinical data with the devices from clinical studies.

5.3 SAFETY

The use of NEVELIA® is based on the grounds of safety and efficacy of clinical data sourced from dermal regeneration. According to the analysis of the market feedback, the data generated in a clinical study with implants, the scientific literature and the analysis from the implant registries, no systematic failures or major complications related to NEVELIA® were observed. The adverse events possibly related to NEVELIA are reversible, relatively low in frequency, common to similar devices and not life-threatening. The benefit/risk ratio is acceptable and favourable for the use of the NEVELIA® dermal substitute in skin regeneration. Thus, the safety of NEVELIA® is confirmed.
Undesirable side effects identified in the literature correspond to those listed in the risk assessment. They are acceptable under normal conditions of use when weighed against benefits to the patient.
In order to reinforce clinical data on NEVELIA® as well as to generate ones on the paediatric population, SYMATESE planned two post market follow-up activities.

- Activity 1: prospective study with an objective to generate new clinical data on safety and performance, for each intended indication, reinforcing existing data.
- Activity 2: retrospective study with an objective to generate new clinical data on safety and performance on the paediatric population, demonstrating the favourable benefit/ risk balance on this population.

6 POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

General description of therapeutic alternatives

Others dermal substitute can be used such as:

- Autograft
- Allograft
- Xenograft
- Amnion
- Cultured epidermal autograft

- Single layer dermal substitute
- Double layer dermal substitute (other than NEVELIA®)

7 SUGGESTED TRAINING FOR USERS

Not applicable. The device is not intended to be handled directly by the patient.