NEVELIA® PATIENT PAGE

IMPLANT CARD

IMPLANT CARD: WHAT IS IT FOR?

Your healthcare practitioner has given you your personalized implant card because you have been treated with a NEVELIA® medical device.

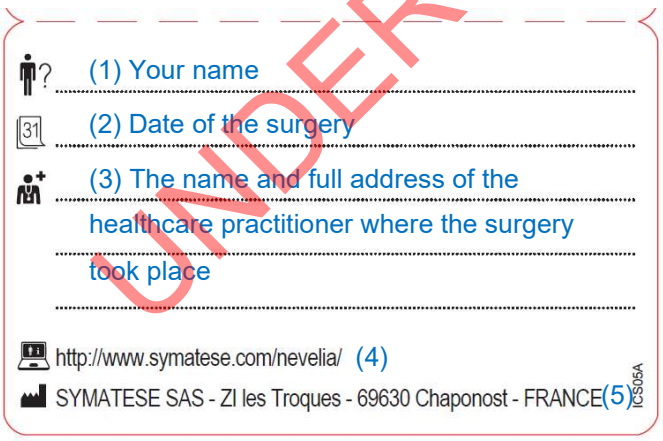
You must keep it and it is recommended to scan it to ensure preservation of information.

Your implant card is both-sided. The front side is intended to be completed with your personal information while the back side includes information about your device and its traceability.

IMPLANT CARD: CONTENT

IMPLANT CARD FRONT SIDE:

Make sure your healthcare practitioner has filled in the following fields (1), (2), (3) on the front side:



(4) Link to the website where all necessary information on your medical device are available

(5) Name and postal address of the manufacturer of your medical device

IMPLANT CARD BACK SIDE:

(1) Device type

(2) Device name

(3) Catalogue number

(4) Unique Device Identifier – Device identifier

(5) Batch code

(6) Unique Device Identifier

IMPORTANT INFORMATION CONCERNING YOUR NEVELIA® DEVICE

WARNING AND PRECAUTION WITH THE USE OF NEVELIA® DEVICE

- ❖ Remaining risks and undesirable effects

You must be informed of the possible adverse events related to the use of this product.
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 before been reported 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 of the country where the event occurred.

- ❖ Warnings and precautions

Precautions:

- 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 you are well enough, and with the physician's approval,
- Caution must be taken not to accidentally remove the silicone layer.

Considering the composition of NEVELIA®, there is no warning, precaution and/or measure to be taken as regards the exposure to reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, radiation associated with diagnostic or therapeutic procedures.

NECESSARY FOLLOW-UP AFTER IMPLANTATION OF NEVELIA® DEVICE

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

LIFETIME OF NEVELIA® DEVICE

NEVELIA® is implanted in order to support new dermal formation (neodermis).
The collagen part of NEVELIA® is absorbed in 3 weeks and the silicone layer is removed by the practitioner between 3 to 4 weeks after implantation. Therefore, the lifetime of NEVELIA® is of 4 weeks.

QUALITATIVE AND QUANTITATIVE INFORMATION ON THE MATERIAL USED FOR THE MANUFACTURING OF NEVELIA® DEVICE

Here are the details on the composition of your NEVELIA® device:

NEVELIA®	**Quantity (on dry weight)**
Bovine Type I collagen layer	16%
Reinforced silicone layer	73%
Silicone adhesive	7%
0.9% sterile saline solution	4%

After implantation, you are in contact with all these components.

LINKED DOCUMENTATION

- SSCP-MCMDR: Section B