

# derma spacer

## (EN) Instructions for Use



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Before using the derma spacer with the plasma care, read the instructions for use carefully and completely.

Damage can be avoided by following the instructions for use. The warnings and precautions must be observed, as disregard may result in serious injury or even life threatening situations. Keep these instructions for use in a safe place.

## 1. Product Description

The derma spacer is a non-sterile, non-active medical device that is used as with the active medical device plasma care.

The spacer is shown in the illustration on the right.



- ① Grid
- ② Flap with RFID-Tag
- ③ Applicator

## 2. Intended Purpose

The derma spacer is a disposable product intended to ensure a defined distance and a reproducible volume between the plasma source and the application area during cold plasma therapy and is used with the plasma care medical device.

It must be used by medical professionals and is suitable for patients aged 12 and over. It is used exclusively on intact skin to improve the appearance of the skin or treat skin diseases that are triggered or aggravated by bacteria, fungi or viruses (e.g. acne).

## 3. Warnings & Precautions



### Risks due to contamination / infection

Only use the derma spacer for one patient. Otherwise cross contamination may occur. The spacer must not be reprocessed.

The derma spacer is not sterile and must not be used on injured skin or wounds.

Ensure that the plasma does not come in direct contact with nitrile and latex protective gloves. These can be damaged by prolonged exposure.

Clean and disinfect the plasma care device and the plasma source unit after each patient treatment with an agent approved by the manufacturer to avoid cross contamination.



### Risks which lead to health impairments or serious injuries

A skin area treated with plasma care should be treated no more than once every 24 hours. The same area of the skin must not be treated for longer than 4 minutes per treatment.

Never place a spacer in a position that overlaps the nostrils, mouth or eyes. If plasma is applied in the immediate vicinity of these areas, care must be taken to ensure that there is no air gap between the skin surface and the spacer. The species (e.g. ozone) generated by the plasma can irritate the respiratory tract and eyes.

Treatment with the plasma care generates very low-intensity UV radiation. Avoid treatments on the eyes.

Treatment with the plasma care produces low concentrations of ozone. When used as intended, the legal limits are not exceeded, but the „olfactory limit“ may be exceeded. The ozone is sufficiently diluted by the ambient air.

When used in small rooms and/or with several devices and/or for longer treatment times, ensure adequate ventilation (e.g. by opening windows or doors). Individual sensitivity to ozone varies greatly.

When using the plasma care in the presence of people with chronic respiratory illnesses as well as infants and small children, particular care must be taken to ensure adequate ventilation due to their particular sensitivity.



### Further safety instructions

Always use the plasma care with a spacer. It is not possible to use the plasma care without a spacer.

The plasma care is sensitive to liquids. If liquid enters the device, especially when it is facing upwards, this may cause malfunctions or damage to the device.

Before using a spacer, check whether the packaging is damaged or has already been opened.

## 4. Medical Application

The aim of the derma spacer in combination with the plasma care is to treat skin diseases caused by bacteria, fungi or viruses, or whose symptoms are worsened by them, and to improve the skin appearance.

Reactive plasma species reduce the burden of bacteria, fungi and viruses without damaging human tissue.

### 4.1 Indications

Treatment with the derma spacer in is primarily aimed at improving the skin situation. The therapeutic and diagnostic indications and specifics for plasma treatment with the derma spacer in combination with the plasma care are skin diseases caused or aggravated by bacteria, fungi or viruses as well as neurodermatitis and viral skin diseases with bacterial superinfection.

### 4.2 Contraindications

- Wounds in the eye and mouth/nose area
- Children under 12 years
- Treatment of injured skin or wounds

Cardiac support systems such as pacemakers or defibrillators, whether implanted or external, are not a contraindication. Areas in the direct vicinity of osteosynthesis material (e.g. external fixator) can also be treated with the plasma care.

## 5. Operation



One therapy unit lasts 2 minutes. Up to 10 units can be performed in therapy session using one spacer. The therapy session is limited to 45 minutes. After that, the spacer is expired.

Before you use a spacer for the therapy, you can try out plasma care with the (colored) training spacer supplied.

Never use the training spacer for patient treatment.

This special training spacer can be used for practice/demonstration for 24 practice sessions, whereby one practice session allows 6 plasma units of 1 minute each within a timeframe of 10 minutes.

 Do not use cleaning solutions with added active ingredients immediately before treatment with the derma spacer. Otherwise, no statement can be made about the effectiveness of the plasma treatment and/or adjuvant treatment. A possible interaction between plasma and other active ingredients is unknown.

After skin cleansing, the treatment with the plasma care is carried out.

### 5.1 Preparation of the Therapy

Before treatment, the skin is cleaned with neutral cleansing solution, rinsing solution and then dabbed dry with a clean cloth.

Deposits such as skin flakes are carefully removed. In some cases, the skin can be cleaned or mechanically abraded before treatment. The decision is up to the practitioner.



Open a derma spacer by carefully tearing open the bag. Make sure that the spacer does not fall out of the bag.

Put the opened bag aside.



Now switch on the plasma care.

To do this, place your thumb on the touch button for 2–3 seconds.



The device is switched on as soon as the touch button lights up white. Remove your thumb from the button, otherwise the device will switch off again.



Now plug the plasma care and the spacer together until you hear a clicking sound and the spacer holds onto the device. Make sure that the tab on the spacer is pointing forwards. Make sure that the spacer is in the packaging until it is fixed to the device.



The device immediately starts the initialization phase as soon as the spacer is fixed. During this phase, the LED ring flashes blue and the characteristic noise can be heard.



After about 15–45 seconds, initialization is complete and the LED ring lights up solid blue. The device has now successfully tested the quality of the plasma and is ready for therapy.

## 5.2 Performing the Therapy



A skin area treated with plasma care should be treated no more than once every 24 hours. The same area must not be treated for longer than 4 minutes per treatment.

The plasma care is sensitive to liquids.

If liquid enters the device, especially when it is facing upwards, this may cause malfunctions or damage to the device.



Position the spacer on the skin area to be treated. Ensure that the spacer forms a closed volume with the skin area as far as possible. Uneven surfaces can be closed with a bandage.



Start the therapy by briefly touching the button. With the start of the first therapy-unit, the 45 minute limit of the therapy-session has started.



As soon as you hear the characteristic noise, remove your finger from the button. The therapy now runs for 2 minutes. Each segment of the LED ring flashes in succession for 30 seconds.



Therapy is complete after 2 minutes. This can be recognized by the fact that the LED ring lights up blue continuously and sound can no longer be heard. You can now treat up to 9 more skin areas (10 treatment-units within 45 minutes in total).



For larger areas, the spacer can now be moved up to 9 times (10 treatments in total) to treat as much of the wound area as possible. Please note the session duration of 45 minutes.

### 5.3 Completion of the Therapy



Once 45 minutes have elapsed or a total of 10 therapy units have been completed, the spacer is used up. This is indicated by a red flashing LED ring. If the patient does not require 10 therapy units, the treatment can be stopped between each unit.



To remove the spacer, press down on the tab with your thumb. Please do not use force or pull on the spacer.



Dispose of the contaminated spacer according to the regulations.



The device can now be switched off by holding the button for 2–3 seconds. The light of the LED ring and the button switches off.

## 6. Problem Solving



If the plasma care device malfunctions when used in combination with the derma spacer, follow the instructions for problem solving in the plasma care device user manual.

If a different spacer is attached during a therapy session than the one with which the session was started, the current session is terminated.

## 7. Feedback & Regulatory Compliance

Complaints, problems and safety concerns should be reported to the manufacturer or its distribution partners. In accordance with Regulation (EU) 2017/745 (MDR) on medical devices, serious incidents related to the product must be reported to both the manufacturer and the competent authority of the Member State in which the user is located.

The derma spacer meets all relevant requirements of Regulation (EU) 2017/745 (MDR) and the necessary standards.

## 8. Disposal

The derma spacer is intended for single use only. Therefore, dispose of it safely in accordance with applicable regulations. Expired/used derma spacers can be disposed of safely for humans and the environment (residual waste).

Please observe the applicable national regulations and your regional public waste disposal system.

## 9. Symbols

 Warning	 Note	 Do not use when damaged
 Article-Reference	 LOT-Number	 Store in a dry place
 CE-Mark	 Medical Device	 Protect from direct light
 Read the Instruction Manual	 Non-sterile product	 Do not reuse
 Date of Manufacture	 Can be used until	

## 10. Technical Data

<b>Trade name</b>	derma spacer
<b>Dimensions</b>	7 cm (L) x 6 cm (W) x 4 cm (H); 14 g
<b>REF</b>	VB319007
<b>Applicable with</b>	plasma care

# derma spacer



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