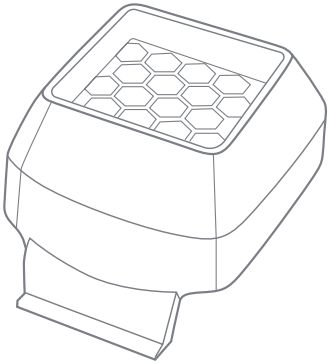
wound spacer

(EN) Instructions for Use



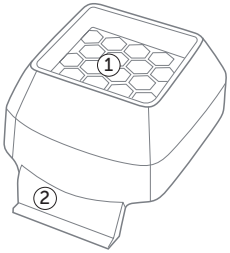
Content

Before using the wound 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.

CE 0197

1. Product Description

The wound spacer is a sterile, non-active medical device that is used with the active medical device plasma care.
The spacer is shown in the illustration on the right.



1 Grid
2 Flap with RFID-Tag

2. Intended Purpose

The wound spacer is a sterile 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 healthcare professionals and is suitable for patients aged 12 and over with chronic and acute wounds. The spacer is in brief contact with the patients wound or intact skin.

3. Warnings & Precautions

Risks due to contamination / infection

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

Injured skin and wounds must only be treated with a sterile spacer.

For each application, ensure that the sterility of the spacer is maintained during and after the connection process with the device.

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

Dispose of the wound spacer safely in accordance with the applicable regulations for contaminated disposable items.

Clean and disinfect the plasma care device and the plama 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 wound treated with plasma care should be treated no more than once every 24 hours. The same area of the wound must not be treated for longer than 3 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.

Plasma treatment can lead to stimulation of granulation (= therapeutic success). However, if a wound pocket is present, purely superficial wound closure must be avoided by mechanical measures, if necessary, so that wound germs remain accessible for antimicrobial measures.

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.

Before treatment with the plasma care, all wound dressings must be removed and the wound must be cleaned. In order to remove avital tissue, necrosis, coatings and/or foreign bodies, the wound must be thoroughly cleaned (with active substance-free wound irrigation solutions or debridement if necessary) before treatment with the plasma care .
Otherwise the plasma treatment may not be effective.

Wound irrigation solutions with added active ingredients must not be used immediately before treatment with the plasma care. If used, ensure that the wound is rinsed with an active ingredient-free wound irrigation solution immediately before treatment with the plasma care.

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.

Avoid superficial closure of wound pockets/fistula tracts. Keep open mechanically if necessary.

4. Medical Application

The aim of the plasma care in combination with the wound spacer is to reduce the bacterial or fungal load in wounds and to improve wound healing by modifying the microenvironment. The plasma care can also be used for the prophylactic treatment to prevent infections in wounds. Plasma species reduce the bacterial and fungal load in wounds. Eukaryotic (human) tissue is not damaged in the process.

4.1 Indications

Chronic and acute skin wounds which are not contraindicated.

4.2 Contraindications

- Wounds in the eye and mouth/nose area
- Children under 12 years

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

5. Operation

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.

For each application, ensure that the sterility of the spacer is maintained during and after the connection process with the device.

5.1 Preparation of the Therapy

Before plasma treatment, the wound must be adequately cleaned mechanically or with a sharp instrument. To do this, it should be cleaned with a neutral rinsing solution (e.g., NaCl 0.9%) and any deposits carefully removed. If a wound antiseptic is required, it should only be applied after plasma treatment.

Open a wound spacer by completely peeling off the film.
To maintain sterility, do not remove the spacer from the blister.

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

One therapy unit lasts 1 minute. Up to 6 units can be performed in one therapy session using one spacer. The therapy session is limited to 10 minutes. After that, the spacer is expired.

A wound treated with plasma care should be treated no more than once every 24 hours. The same area of the wound must not be treated for longer than 3 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 10 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 1 minute. Each segment of the LED ring flashes in succession for 15 seconds.

Therapy is complete after 1 minute. 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 5 more skin areas (6 units within 10 minutes in total).

For larger wounds, the spacer can now be moved up to 5 times (6 times in total) to treat as much of the wound area as possible. Please note the session duration of 10 minutes.

5.3 Completion of the Therapy

Once 10 minutes have elapsed or a total of 6 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 6 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 (see chapter 8).

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.

Avoid superficial closure of wound pockets/fistula tracts. Keep open mechanically if necessary.

At the end of the treatment, a new bandage should be applied.

6. Problem Solving

If the plasma care device malfunctions when used in combination with the wound 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 wound spacer meets all relevant requirements of Regulation (EU) 2017/745 (MDR) and the necessary standards.

8. Disposal

The wound spacer is intended for single use only. Therefore, dispose of it safely in accordance with applicable regulations.
After use, the wound spacer falls under the following waste code: (AS 18 01 03). Other waste that requires special collection and disposal measures to prevent infection (AS 18 01 03).
The spacer must therefore be disposed of in accordance with the currently applicable enforcement guidelines for the disposal of waste from healthcare facilities issued by the Federal/State Working Group on Waste (LAGA) 18.

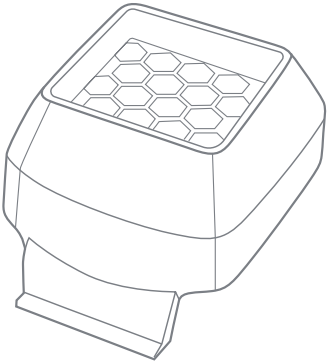
9. Symbols

Warning	Note	Do not use when damaged
REF Article-Reference	LOT LOT-Number	Store in a dry place
CE 0197 CE mark with notified authority	MD Medical Device	Protect from direct light
Read the Instruction Manual	STERILE EO EO sterilized	Do not reuse
Date of Manufacture	Can be used until	Do not re-sterilize

10. Technical Data

Trade name	wound spacer
Dimensions	7 cm (L) x 6 cm (W) x 4 cm (H); 14 g
REF	VB319002
Applicable with	plasma care

wound spacer



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