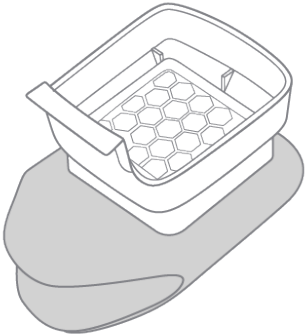
podo spacer

(EN) Instructions for Use



Content

Before using the podo 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

1. Product Description

The podo spacer is a 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
③ Applicator

2. Intended Purpose

The podo 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 is intended for patients aged 12 and over with nail fungus (onychomycosis or nail mycosis). The application must be carried out by medical professionals.
A spacer can be used several times to treat the same patient. Several toenails can be treated at the same time.

3. Warnings & Precautions

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 5 minutes per treatment.
The species 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.
It is not permitted to remove the spacer bag and treat without it.

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.

When removing a spacer, check whether the packaging is damaged or has already been opened.

Risks due to contamination / infection

Only use the podo spacer for one patient. Otherwise cross contamination may occur.

The podo 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 plama source unit after each patient treatment with an agent approved by the manufacturer to avoid cross contamination.

If the spacer has already been used, make sure it's clearly assigned to the patient.

4. Medical Application

The aim of the podo spacer in combination with the plasma care is to treat skin and nail diseases caused by bacteria, fungi or viruses or whose symptoms are worsened by them.
Reactive plasma species reduce the burden of bacteria, fungi and viruses in dermatological diseases. Human tissue is not damaged.

4.1 Indications

Therapeutic and diagnostic indications and specifications, that form the basis for plasma treatment with the plasma care are diseases of the skin and nails caused or aggravated by bacteria, fungi or viruses.
The special indication for the podo spacer is the treatment of nail fungus (onychomycosis).

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 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.

If the spacer has already been used, it must be ensured that it is clearly assigned to the patient. There is a risk of cross-contamination or infection.

5.1 Preparation of the Therapy

Podiatric treatment with the plasma care is an antifungal therapy that can be easily integrated into the treatment process. It is recommended to file down the nails affected by the fungus to make the nail more permeable to cold plasma therapy.

Open a podo spacer by carefully opening the blister pack. Make sure that the spacer does not fall out of the blister pack.

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 position the spacer on the toes to be treated. The number of toes treated simultaneously may vary depending on the size of the foot.

Use the protective grid to check that the toenails to be treated are below the grid and are not covered by the fabric so that maximum therapeutic success can be achieved.

Make sure that the pouch encloses the foot as much as possible and that there is no opening in order to achieve maximum therapeutic success.

Now plug the plasma care and the spacer together until a clicking sound is heard and the spacer holds onto the device.
Make sure that the tab on the spacer is pointing forwards.

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

After 15-45 seconds, the initialization is complete and the LED-ring lights up blue continuously. The device has now successfully checked the quality of the plasma and is ready for therapy.

5.2 Performing the Therapy

One therapy unit lasts 5 minutes. Up to 4 therapy units within one therapy session can be performed, whereby a therapy session is limited to 60 minutes.
With one spacer, a total of 6 therapy sessions can be carried out. After the sixth session, the spacer is invalid and must be disposed.

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 5 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.

Start the therapy by briefly touching the button. With the start of the first therapy-unit, the 60 minute limit of the therapy-session has started.

As soon as you hear the characteristic beep remove your thumb from the button. The therapy unit will now run for 5 minutes. Each segment of the LED ring flashes for 75 seconds.

The therapy unit is completed after 5 minutes. This can be recognized by the LED ring lighting up blue continuously and the sound is no longer audible. You can now perform up to 3 more therapy units (4 therapy-units within 60 minutes in total).

If you would like to perform a therapy unit on another foot or toe, remove the device from the spacer and reposition the spacer/pouch.

Now plug plasma care and spacer together until you hear a „click" and the spacer is firmly connected to the device. Initialization is no longer carried out and the device lights up blue continuously.

Start the therapy unit by briefly touching the button. As soon as you hear the characteristic beep remove your thumb from the button. The therapy unit will now run for 5 minutes. Each segment of the LED ring flashes for 75 seconds.

5.3 Completion of the Therapy

Once 60 minutes have elapsed or a total of 4 therapy units have been completed, the session is terminated. This is indicated by a red flashing LED ring. If the patient does not require 4 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.

If the spacer is to be used for further therapy sessions, place it back in the blister pack, seal it, and enter the patient's name (if not already done) and the date of the therapy session in the fields provided.

Make sure that the spacer is never stored damp in the blister.

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

8. Disposal

The podo spacer is intended for one patient and six sessions. Dispose of it safely in accordance with applicable regulations. Expired/used podo 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	One patient only
Read the Instruction Manual	Non-sterile product	Patient name
Date of Manufacture	Can be used until	Protect from direct light
Date		

10. Technical Data

Trade name	podo spacer
Dimensions	12cm (L) x 11 cm (W) x 7 cm (H); 40 g
REF	VB319009
Applicable with	plasma care

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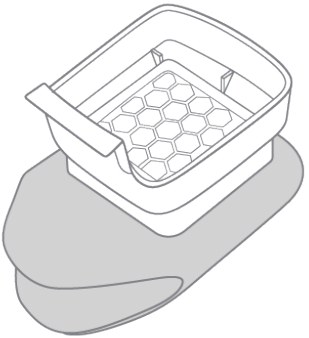

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