

BAEHR PodoPlasma® Spacer

EN User Manual

1. Product Description
2. Intended Purpose
3. Warnings & Precautions
4. Medical Application
 - 4.1 Indications
 - 4.2 Intended patient population
 - 4.3 Contraindications
5. Operation
 - 5.1 Preparation of Therapy
 - 5.2 Performing the Therapy
 - 5.3 Completion of Therapy
6. Problem Solving
7. Feedback & Regulatory Compliance
8. Purchasing & Disposal
9. Symbols
10. Technical Data



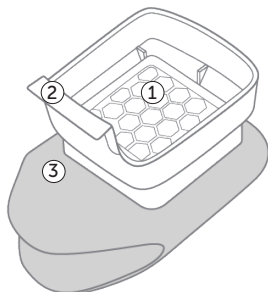
Before using the PodoPlasma spacer with the Baehr PlasmaCare, read the instructions for use carefully and completely. Damage can be avoided by following the instructions for use. The warnings and precautions must be observed, as disregard may result in serious injury or even life threatening situations. Keep these instructions for use in a safe place.

1. Product Description

The PodoPlasma spacer is a non-active medical device that is used with the active medical device Baehr PlasmaCare.

The spacer is shown in the illustration on the right.

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



2. Intended Purpose

The PodoPlasma 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 Baehr PlasmaCare 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 Baehr PlasmaCare 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 Baehr PlasmaCare 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 Baehr PlasmaCare 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 Baehr PlasmaCare 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 Baehr PlasmaCare with a spacer. It is not possible to use the Baehr PlasmaCare without a spacer.

The Baehr PlasmaCare 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 PodoPlasma spacer for one patient. Otherwise cross contamination may occur.

The PodoPlasma 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 Baehr PlasmaCare device and the plasma 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 PodoPlasma spacer in combination with the Baehr PlasmaCare 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 Baehr PlasmaCare are diseases of the skin and nails caused or aggravated by bacteria, fungi or viruses.

The special indication for the PodoPlasma spacer is the treatment of nail fungus (onychomycosis).

4.2 Intended patient population

The product is intended for use in patients aged 12 years and older.

4.3 Contraindications

- Wounds in the eye and mouth/nose area
- Cardiac support systems such as pacemakers or defibrillators, whether implanted or external, are not a contraindication. Wounds in the direct vicinity of osteosynthesis material (e.g. external fixator) can also be treated with the Baehr PlasmaCare.

5. Operation



Before you use a spacer for the therapy, you can try out Baehr PlasmaCare 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 Baehr PlasmaCare 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 PodoPlasma spacer by carefully opening the blister pack. Make sure that the spacer does not fall out of the blister pack.



Now switch on the Baehr PlasmaCare.

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 Baehr PlasmaCare 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 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 Baehr PlasmaCare 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 Baehr PlasmaCare 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 Baehr PlasmaCare 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 Baehr PlasmaCare device malfunctions when used in combination with the PodoPlasma spacer, follow the instructions for problem solving in the Baehr PlasmaCare 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 PodoPlasma spacer meets all relevant requirements of Regulation (EU) 2017/745 (MDR) and the necessary standards.

8. Disposal

The PodoPlasma spacer is intended for one patient and six sessions. Dispose of it safely in accordance with applicable regulations. Expired/used PodoPlasma 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	PodoPlasma spacer
Dimensions	12cm (L) x 11 cm (W) x 7 cm (H); 40 g
REF	VB319005
Applicable with	Baehr PlasmaCare PodoPlasma



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