



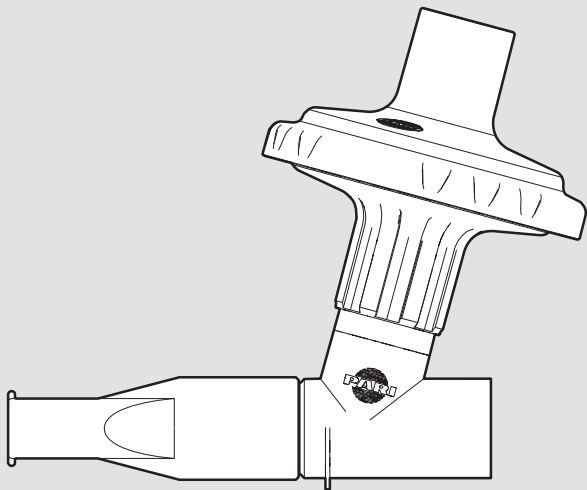
Instructions for use

PARI Filter Valve Set

(Type 041)

Accessories for PARI inhalation systems

Accessories for the PARI PEP S System



Read the instructions for use

Read these instructions for use carefully before using the product. Follow all instructions and safety instructions. Keep the instructions for use in a safe place.

Validity of instructions for use

PARI Filter Valve Set (Type 041)

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Disclaimer

These instructions for use describe the components of PARI products and optional accessories. For this reason, these instructions for use also describe and illustrate features not present in your PARI product because they are, for instance, country-specific and/or optional. When using the systems, products and functions, the applicable country-specific regulations must be observed.

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1 IMPORTANT INFORMATION

1.1 Intended purpose

The PARI Filter Valve Set is an accessory for PARI nebulisers or the PARI PEP S System.

The PARI Filter Valve Set reduces the release of the exhaled aerosol into the ambient air.

This PARI product can be used in a home environment, as well as in professional health institutions. When used in a home environment, this PARI product is intended for single-patient use only (no patient change). In a professional environment, the device can be used with different patients as long as the corresponding hygiene reprocessing measures are complied with.

This product must be used only by individuals who understand the contents of the instructions for use and are able to use the product safely. This product may only be used by individuals who are able to inhale with a mouthpiece without assistance. Individuals in the following groups must be supervised by a person who is responsible for their safety:

- Children
- Individuals with limited capabilities (e.g. physical, mental, sensory)

If the patient is not able to use this product safely on their own, then the treatment must be carried out by the responsible person.

This PARI product is suitable only for patients who are able to breathe by themselves and are conscious.

1.2 Indication













The indication for this PARI product is based on the indication for the PARI nebuliser used or the PARI PEP S System.

1.3 Contraindications

There are no contraindications known to PARI GmbH.

1.4 Labelling

The following symbols can be found on the product and/or the packaging:

| | |
|--|---|
|  | Medical device |
|  | Legal manufacturer |
|  | Date of manufacture |
|  | This product conforms to the EU Medical Device Regulation 2017/745. |
|  | Consult instructions for use |
|  | Item no. |
|  | Production batch number, lot number |
|  | Unique Device Identifier (UDI) |
|  | Exhalation filter |
|  | Y-connection |
|  | PARI filter pad |
|  | Mouthpiece without expiratory valve |

1.5 Safety instructions

The present instructions for use contain important information, safety instructions, and precautionary measures. The user must follow these in order to guarantee safe operation of this PARI product.

This PARI product must be used only as described in these instructions for use.

Please also follow the instructions for use of the nebuliser and compressor you are using.

Labelling and classification of warning instructions

In these instructions for use, safety-critical warnings are categorised according to the following hazard levels:

DANGER

DANGER indicates a hazardous situation which will lead to very severe injuries or death if it is not avoided.

WARNING

WARNING indicates a hazardous situation which can lead to very severe injuries or death if it is not avoided.

CAUTION

CAUTION indicates a hazardous situation which can lead to mild or moderate injuries if it is not avoided.

NOTE

NOTE indicates a hazardous situation which can lead to material damage if it is not avoided.

Hazard due to small parts which can be swallowed

The product contains small parts. Small parts can block the airways and lead to a choking hazard. Keep all components out of the reach of babies and infants at all times.

Hygiene

Comply with the following hygiene instructions:

- Use only components that have been thoroughly cleaned and dried. Contamination and residual moisture encourage bacterial growth, which increases the risk of infection.
- Before every use and reprocessing cycle, wash your hands thoroughly.
- Make absolutely sure you also carry out reprocessing before using the device for the first time.
- Always use drinking water for reprocessing.
- Make sure all components are dried properly after each reprocessing step.
- Do not keep the components in a damp environment or together with damp objects.

Reporting serious incidents

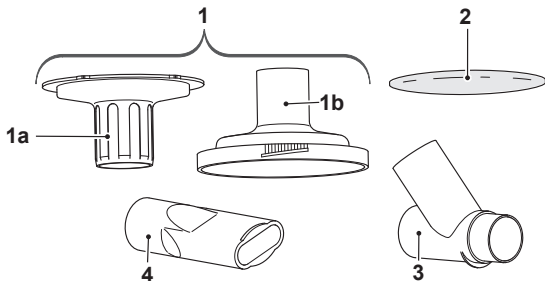
Report serious adverse incidents to the manufacturer and to the competent authority.

2 PRODUCT DESCRIPTION

2.1 Components

Please refer to the package for information on the supplied components.

2.2 Overview and product designations



| | |
|------|---------------------------------------|
| (1) | Exhalation filter |
| (1a) | Lower part |
| (1b) | Upper part (with exhalation valve) |
| (2) | PARI Filter Pad |
| (3) | Y-connection |
| (4) | Mouthpiece (without exhalation valve) |

2.3 Product combinations

The PARI Filter Valve Set can be combined with the following PARI products:

- PARI jet nebulisers, except PARI LC SPRINT SINUS
- PARI membrane nebulisers, such as eFlow®rapid nebuliser. Information about the accessories to be used is included in the instructions for use of the nebuliser.
- PARI PEP S system

2.4 Description of function

With the PARI Filter Valve Set, the exhaled air must pass through the exhalation filter before it leaves the nebuliser. During exhalation, the PARI Filter Pad in the exhalation filter reduces the release of aerosol ¹ into the ambient air to less than 1 %. The reduction in aerosol release depends on the nebuliser.

2.5 Material information

| Component | Material |
|--|--------------------------------------|
| Mouthpiece, lower part and upper part of the exhalation filter, Y-connection | Polypropylene |
| Exhalation valve | Silicone |
| PARI Filter Pad | Polypropylene-based synthetic fibres |

1) Aerosol: Small particles of solid, liquid, or mixed composition (fine “mist”) suspended in gases or air.

2.6 Operating life

The individual product components have the following expected lifetimes:

| Product component | Service life |
|--|--|
| PARI Filter Valve Set (exhalation filter, Y-connection, mouthpiece) | in a home environment [see: Processing limits, page 16] |
| PARI Filter Valve Set (exhalation filter, Y-connection, mouthpiece) | in a professional environment [see: Processing limits, page 22] |
| PARI Filter Pad | Single use |

3 USE

WARNING

Choking hazard from breathing in small parts

The product is not completely closed. As a result, there is a danger that small parts can get inside it, and may be breathed in during inhalation.

- Therefore, before every use it is imperative to make sure there are no foreign bodies inside the product.

All the steps described below must be carried out correctly.

3.1 Preparing for treatment

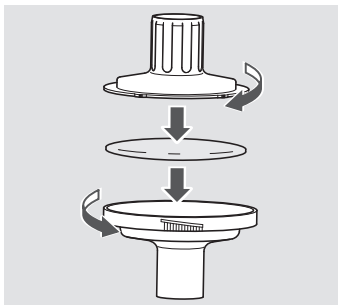
Use a PARI Filter Pad for the PARI Filter Valve Set

Using accessories

Information on assembling accessories is included in the instructions for use of the respective accessory².

Preparing the exhalation filter

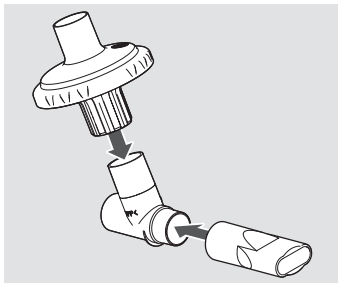
- Insert the PARI Filter Pad into the upper part of the exhalation filter.
- Place the lower part of the exhalation filter with the snap locks in the holes provided in the upper part, and turn the lower part as far as it will go.



2) Instructions for use of accessories are included with the respective accessory. They can also be ordered from the manufacturer or distributor.

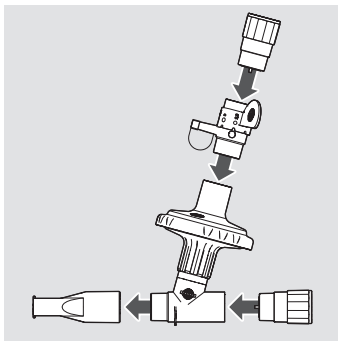
Assembling the PARI Filter Valve Set

- Push the exhalation filter onto the Y-connection.
- Push the mouthpiece (without exhalation valve) onto the Y-connection.



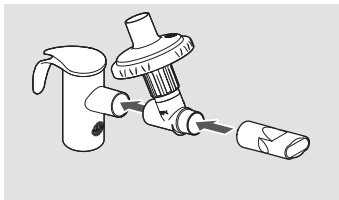
Connecting the PARI Filter Valve Set with the PARI PEP S System

- Assemble the PARI PEP S system without mouthpiece, as described in the instructions for use of the PARI PEP S system.
- Push the PARI PEP S system with the PARI PEP S inhalation valve onto the exhalation filter.
- Push an additional PARI PEP S inhalation valve onto the Y-connection.



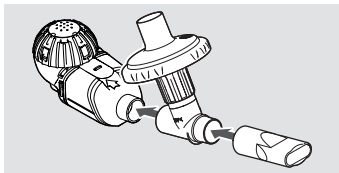
Connecting the PARI Filter Valve Set with a jet nebuliser

- Assemble the nebuliser as described in the instructions for use of the nebuliser.
- Push the PARI Filter Valve Set onto the nebuliser.



Connecting the PARI Filter Valve Set with a membrane nebuliser

- Assemble the nebuliser as described in the instructions for use of the nebuliser.
- Push the PARI Filter Valve Set onto the nebuliser.



3.2 Performing treatment

All of the safety instructions in these instructions for use must have been read and understood before any treatment is carried out.

[see: Safety instructions, page 7]

Performing inhalation therapy

- Before therapy, ensure that all parts are firmly connected to each other.
- Fill the nebuliser as described in the instructions for use of the nebuliser.
- Perform the inhalation as described in the instructions for use of the nebuliser.

Inhalation with accessories (e.g. masks) is described in the instructions for use of the respective accessory.

Performing PEP therapy

- Before therapy, ensure that all parts are firmly connected to each other.
- Carry out the PEP treatment as described in the instructions for use of the PARI PEP S.

3.3 Ending the treatment

End the treatment as described in the instructions for use of the nebuliser or the PARI PEP S system which you are using.

4 REPROCESSING IN A HOME ENVIRONMENT

The product components must be cleaned thoroughly immediately after each use, and disinfected at least once a week.

4.1 Reprocessing cycles

| | |
|-----------------------|--|
| PARI Filter Valve Set | – Clean immediately after every use – Disinfect once a week |
|-----------------------|--|

4.2 Processing limits

| | |
|-------------------------------------|------------------------------------|
| PARI Filter Valve Set, disinfection | 300 processing cycles, max. 1 year |
|-------------------------------------|------------------------------------|

4.3 Preparation

- Detach the PARI Filter Valve Set from the nebuliser.
- Dismantle the PARI Filter Valve Set into all individual parts.
- Dispose of the PARI filter pad.

4.4 Cleaning

Precleaning

All individual parts must be precleaned immediately after use.

EQUIPMENT:

- Drinking water temperature of about 15 °C

PROCEDURE:

- Rinse all parts used for 2 minutes in running drinking water.

Manual cleaning

EQUIPMENT:

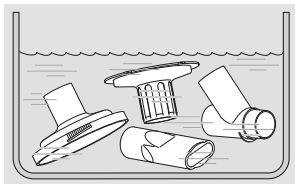
- Drinking water temperature of at least 40 °C
- Standard washing-up liquid³
- Receptacle with at least 3 l capacity

PROCEDURE:

- Add about 1 teaspoon of washing-up liquid to 3 l warm drinking water.
- Place all the parts in the washing-up water.

Application time: 5 minutes

- Occasionally move the parts back and forth.
- If there is visible soiling, use a medium-soft brush (such as a toothbrush) which is used exclusively for this purpose.



RINSING:

- Rinse all individual parts thoroughly under running drinking water at approx. 15 °C for 3 minutes.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

3) Validated with Palmolive®.

In the dishwasher

The individual parts can be cleaned in a standard household dishwasher, provided it is connected to a mains water supply of drinking water quality.

To ensure safety when handling the cleaning agent used, follow the corresponding instructions for use, particularly the accompanying safety instructions.

PROCEDURE:

i *Do not clean the individual components together with very dirty dishes.*

- Place all components in the crockery basket so that no water can collect in them.
- Select a program running at 50 °C minimum.

DRYING:

Ensure that there is no residual moisture remaining in the components. If necessary:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface and allow them to dry completely.

4.5 Disinfecting

Disinfect all individual components after cleaning. Only components that have been cleaned can be disinfected effectively. The validated disinfection procedures are described below.

In boiling water

EQUIPMENT:

- Clean saucepan
- Drinking water

PROCEDURE:

CAUTION

Risk of infection due to moisture

Moisture encourages the growth of bacteria.

- Remove all parts from the saucepan as soon as the disinfection process is complete, and allow them to dry.
- Place all the individual parts in water at a rolling boil for at least 5 minutes. **NOTE! Risk of damage to plastic parts!** Plastic will melt if it comes into contact with the hot base of the pan. Make sure there is enough water in the pan to prevent the individual parts from touching the pan base.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface, and allow them to dry completely.

Using a standard thermal disinfecter for baby bottles (not a microwave oven)

EQUIPMENT:

- Thermal disinfecter with a runtime of at least 6 minutes

PROCEDURE:

 **CAUTION**

Risk of infection due to inadequate disinfection

Inadequate disinfection encourages the growth of bacteria and thus increases the risk of infection.

- Make sure that the disinfectant is clean and operating properly before every disinfection process.
- Allow the disinfection to continue until the disinfectant switches off automatically or the minimum disinfection time stated in the instructions for use of the disinfectant has elapsed. Do not switch the device off prematurely.

 **CAUTION**

Risk of infection due to moisture

Moisture encourages the growth of bacteria.

- Remove all parts from the disinfectant as soon as the disinfection process is finished, and allow them to dry.

Regarding the performance of the disinfection, the duration of the disinfection procedure and the quantity of water required, follow the instructions for use of the disinfectant you are using.

DRYING:

- After the disinfection process is complete, place all parts on a dry, clean and absorbent surface and allow them to dry completely. Or else leave all individual parts in the closed thermal disinfectant for max. 24 hours until the next use.

4.6 Inspecting

Inspect all product components after each cleaning and disinfection. Replace any broken, deformed or seriously discoloured parts.

4.7 Drying

After each cleaning and disinfection, place all components on a dry, clean and absorbent surface, and let them dry completely.

4.8 Storage

Store your PARI Filter Valve Set as described below:

- Wrap all individual components in a clean, lint-free cloth (e.g. a tea towel).
- Store all individual components in a dry, dust-free place.

5 REPROCESSING IN PROFESSIONAL HEALTH INSTITUTIONS

5.1 Reprocessing cycles

Single patient use

| | |
|-----------------------|---|
| PARI Filter Valve Set | <ul style="list-style-type: none">– Clean immediately after every use– Disinfect once a week |
|-----------------------|---|

Before a change of patient

| | |
|-----------------------|---|
| PARI Filter Valve Set | <ul style="list-style-type: none">– Cleaning– Disinfection– Sterilisation |
|-----------------------|---|

5.2 Processing limits

| | |
|--------------------------------------|------------------------------------|
| PARI Filter Valve Set, disinfection | 300 processing cycles, max. 1 year |
| PARI Filter Valve Set, sterilisation | 100 processing cycles, max. 1 year |

5.3 PARI Filter Valve Set

Separated parts for processing

 **CAUTION**

Risk of infection due to cross-contamination in the event of a change in patients

If a product is used for more than one patient, there is a risk that germs may be transmitted from one patient to the next.

- Clean, disinfect and sterilise all separated parts before every patient change.

All components of the PARI Filter Valve Set without PARI filter pad can be cleaned, disinfected and sterilised according to the procedures described below.

Preparation

Dismantle the product into its individual parts.

Precleaning

All individual parts must be precleaned immediately after use.

EQUIPMENT:

- Drinking water temperature of about 15 °C

PROCEDURE:

- Rinse all parts used for 2 minutes in running drinking water.

Cleaning and disinfecting

Manual cleaning

EQUIPMENT

The method has been validated in Europe using:


- pH-neutral, enzymatic cleaning agent:
Bode Bomix® plus (concentration: 0.1%)
- Drinking water temperature of about 15 °C
- Application time: 10 minutes

PROCEDURE:

CAUTION

Risk of infection due to growth of bacteria

Inadequate disinfection encourages the growth of bacteria and thus increases the risk of infection.

- Observe the specified mixing proportions and the specified treatment time.
- Ensure that all components are completely submerged in the solution for the whole of the treatment time. There must not be any air pockets or bubbles.
- Clean all individual parts with a solution prepared according to the manufacturer's instructions.
For visible soiling, use a medium-soft brush (e.g. a tooth-brush) which is used exclusively for this purpose.
 *If the recommended application period is exceeded significantly, the plastic parts may take on the smell of the medium used.*

RINSING:

- Rinse all individual parts thoroughly under running drinking water at approx. 15 °C for 3 minutes.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface, and allow them to dry completely.

Cleaning with disinfection

Cleaning and disinfection can be carried out in a single cycle using chemical reprocessing.

To ensure safety when handling chemicals, observe the instructions for use for the disinfectant.

| | |
|---|--|
| Mechanical cleaning with disinfection: | <p>EQUIPMENT:</p> <p>The method has been validated in Europe using:</p> <ul style="list-style-type: none">– Alkaline cleaning agent: Dr. Weigert neodisher® MediClean forte (concentration: 0.5%)– Deionised water– Cleaning and disinfection device: Steelco DS800 in conformance with DIN EN ISO 15883-1 and 15883-2 <p><i>Info:</i> <i>If a different alkaline cleaning agent is used, it may also be necessary to use a neutralising agent. Follow the recommendations of the manufacturer of the chemical.</i></p> <p>PROCEDURE:</p> <p>Program for cleaning and disinfecting according to manufacturer's instructions.</p> <p>DRYING:</p> <p>Ensure that there is no residual moisture remaining in the components.</p> <ul style="list-style-type: none">• Shake the water out of all of the parts.• Place all parts on a dry, clean, and absorbent surface, and allow them to dry completely. |
|---|--|

**Chemical
cleaning with
disinfection:**

EQUIPMENT:


The method has been validated in Europe using:

- Aldehyde-free instrument disinfectant: Bode Bomix® plus (concentration: 2%)
Active agent basis: Quaternary ammonium compound
- Drinking water at about 15 °C
- Application time: 5 minutes

PROCEDURE:

- Clean and disinfect the individual parts in a single work step, using a solution prepared according to the manufacturer's instructions.
Info: *If the recommended treatment time is exceeded significantly, the plastic parts may take on the smell of the disinfectant.*

RINSING:

-  **CAUTION!** Disinfectant residues can cause allergic reactions or irritation of the mucous membrane. Rinse off all parts thoroughly in running drinking water at about 15 °C for 3 minutes.
- Dispose of the used solution (the diluted solution can be disposed of down the sink).

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean, and absorbent surface, and allow them to dry completely.

Chemical disinfection

To ensure safety when handling chemicals, observe the instructions for use for the disinfectant.

EQUIPMENT:

The method has been validated in Europe using:

- Aldehyde-containing disinfectant: Bode Korsorex® basic (concentration: 4%)
Active agent basis: Aldehyde donor, aldehyde
- Drinking water at about 15 °C
- Application time: 30 minutes

PROCEDURE:



CAUTION

Risk of infection due to growth of bacteria

Inadequate disinfection encourages the growth of bacteria and thus increases the risk of infection.

- Observe the specified mixing proportions and the specified treatment time.
 - Ensure that all components are completely submerged in the solution for the whole of the treatment time. There must not be any air pockets or bubbles.
 - Disinfect the individual parts with a solution prepared according to the manufacturer's instructions.
- i** *If the recommended application period is exceeded significantly, the plastic parts may take on the smell of the medium used.*

RINSING:



CAUTION

Risk of allergic reactions and irritation of the mucous membrane by disinfectants

Disinfectants can trigger allergic reactions or irritation of the mucous membrane on contact with the skin.

- Rinse the product thoroughly to ensure that no residues of the disinfectant remain on the PARI product.
- Rinse off all parts thoroughly in running drinking water at about 15 °C for 3 minutes.
- Dispose of the used solution. The diluted solution can be disposed of down the drain.

DRYING:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface, and allow them to dry completely.

Sterilising

CAUTION

Risk of infection by residual germs

If there is dirt on the parts, germs capable of reproduction may remain despite the sterilisation process. As a result, there is a danger of infection.

- Clean, disinfect, and dry all parts thoroughly before sterilising.
- Use only validated procedures for cleaning and disinfection.

EQUIPMENT:

The method has been validated in Europe using:

- Steam steriliser with fractionated pre-vacuum in accordance with DIN EN 285 or DIN EN 13060
- Sterile barrier system in accordance with DIN EN 11607-1
- Temperature: 132 °C/134 °C
- Holding time: min. 3 minutes

PROCEDURE:

- Place all the disassembled parts in a sterile barrier system which complies with DIN EN 11607-1 (e.g. foil-paper packaging).
- Carry out the sterilisation in a steam steriliser in accordance with the manufacturer's instructions.

Sterilisation temperature and holding time:

132 °C/134 °C, at least 3 minutes.

DRYING:

Ensure that there is no residual moisture remaining in the components. If necessary:

- Shake the water out of all of the parts.
- Place all parts on a dry, clean and absorbent surface, and allow them to dry completely.

5.4 Visual inspection and storage

Check all individual components. Replace any broken, deformed or seriously discoloured parts.

Storage location:

- dry
 - dust-free
 - protected from sources of contamination
- optional: use sterile packaging

6 FURTHER INFORMATION

All product components may be disposed of with normal domestic waste. The country-specific disposal regulations must be observed.

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PARI GmbH

Spezialisten für effektive Inhalation

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