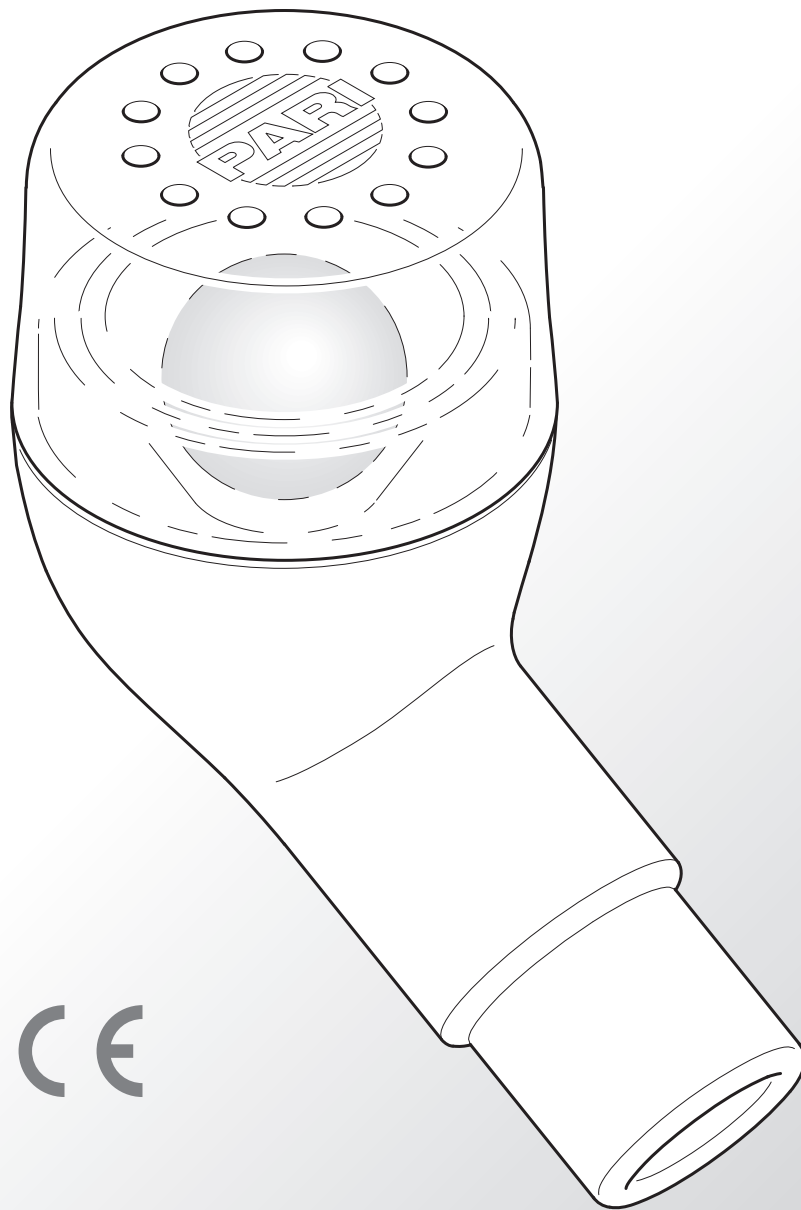




O-PEP Hygiene-Beileger



Hygienic re-use in the professional setting

Information as of: 2013-02. We reserve the right to make technical changes.

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1 General

In a professional setting, do not use the support strap or the storage pouch, because neither of these items can be disinfected or sterilised.

NOTICE

Ensure that the system is processed for re-use only with the application of adequately validated device- and product-specific procedures, and that the validated parameters are maintained during each cycle. The equipment used must be maintained regularly.

Follow the schedule defined below for hygienic re-use:

- Single patient use:
Clean the PARI O-PEP **after every application**.
Disinfect it at least once a month.
- Multiple patient use:
Clean, disinfect and sterilise the PARI O-PEP **before every change in patient**.

The PARI O-PEP must be processed for re-use with the application of suitable, validated methods in such manner that the success of these methods can be monitored reliably and the safety and health of patients is not threatened.

CAUTION

Ensure that the components are allowed to dry sufficiently after each processing step. Condensation or residual wetness can present an increased risk through the growth of bacteria.

The following text describes the methods validated by PARI, with which plastic PARI parts can be processed effectively.

Ensure that the desired results are achieved consistently by the processing methods employed by your staff with the equipment and chemicals used. Take particular care to ensure that the processing procedure you select is effective if it must differ from our validated procedures (e.g., because the equipment and chemicals described are not available). When selecting the chemicals for use, make sure that they are suitable for cleaning or disinfecting medical products made from the materials indicated. Bear in mind the manufacturer's dosing information and instructions for safe handling of chemicals.

2 Material information

POM (polyoxymethylene)	Lower part with mouthpiece, funnel, upper part
Polyester	Pouch, support strap
Stainless steel	Ball

3 Processing limits

The PARI O-PEP can be sterilised up to 300 times and used for up to one year.

Do not expose the PARI O-PEP to temperatures above 137 °C. The support strap and storage pouch cannot be hygienically treated.

4 Preparation

Dismantle the PARI O-PEP into its individual parts:

- Unscrew the upper part from the lower part.
- Take the ball out of the funnel. Place it carefully on one side so that it cannot roll away.
- Take the funnel out of the lower part.

5 Cleaning and disinfection

Clean and disinfect immediately after use. Ideally, a mechanical procedure (instrument dishwasher) is to be used.

NOTICE

When selecting the cleaning agent and/or disinfectant, ensure that it is compatible with the materials used, **otherwise damage to the product components** cannot be ruled out.

5.1 Mechanical cleaning and disinfection

EQUIPMENT

- Cleaning and disinfection device in conformance with DIN EN ISO 15883
- Cleaning agent
- Neutralising agent if necessary

PROCEDURE

- Arrange the components so that they can be cleaned most effectively.
- Select a suitable cleaning programme and agent.

VALIDATION

The method has been validated using:

- G7836 CD cleaner-disinfector produced by Miele, programme Vario TD.
- Standard baskets manufactured by Miele
- Neodisher Mediclean forte 0.5% and Neodisher Z for neutralisation (from Dr. Weigert)

DRYING

Even if the cleaner-disinfector is equipped with a drying function, make sure that no residual moisture is left in the components. If necessary, remove any residual moisture by shaking the parts and allow them to dry completely.

5.2 Manual cleaning

As an alternative to mechanical cleaning and disinfection, the following manual method can be used:

EQUIPMENT

- Cleaning agent
- Brush
- Warm water

PROCEDURE

- Place all the parts in the cleaning solution.
- Clean the parts thoroughly with a brush.
- Thoroughly rinse the parts under hygienically tested water and leave them to dry completely on a clean, dry and absorbent surface.

VALIDATION

The method has been validated using:

- Bodedex[®] forte 0.5% (Block)
- Approx. 50 °C warm water
- Duration of cleaning procedure: approx. 5 minutes

5.3 Manual disinfection

For manual disinfection, select a suitable instrument disinfectant that has been proven to be effective and compatible with the cleaning agent used.

EQUIPMENT

- Disinfectant
- Water

CAUTION

PARI product components are not suitable for treatment with instrument disinfectants based on **quaternary ammonium compounds**. Quaternary ammonium compounds tend to become concentrated in plastic materials, which can cause **incompatibility reactions** in patients.

PROCEDURE

- Place all the parts in the disinfection solution.
- Allow the solution to take effect as indicated in the instructions for use of the disinfectant.
- Thoroughly rinse the parts under hygienically tested water and leave them to dry completely on a clean, dry and absorbent surface.

VALIDATION

The method has been validated using:

- Korsolex[®] Basic 4% (Bode)
- Treatment time: 15 minutes

6 Sterilisation

NOTICE

A validated sterilisation process can only be carried out on products that have been cleaned and disinfected.

EQUIPMENT

Steam steriliser – preferably with fractionated pre-vacuum – in accordance with DIN EN 285 or DIN EN 13060 (type B)

PROCEDURE

- Pack all of the disassembled parts in a sterile barrier system in accordance with DIN EN 11607 (e.g., foil-paper packaging).

Maximum sterilisation temperature and holding time:

121 °C, at least 20 min. or

132 °C / 134 °C, at least 3 min.

VALIDATION

The method has been validated according to DIN EN ISO 17665-1 using:

- Euro-Selectomat 666 from MMM (fractionated pre-vacuum method)
- Varioklav 400 E from H+P Labortechnik (gravitation method)

7 Visual inspection

Inspect all product components after each cleaning, disinfection and sterilisation. If any components have been damaged, the whole product must be replaced.

8 Storage

Store the PARI O-PEP in a dry, dust-free place away from sources of contamination.

9 Contact

For all product information and in the event of defects or questions about usage, please contact our Service Center:

Tel.: +49 (0)8151-279 279 (German-speaking)
+49 (0)8151-279 220 (international)