



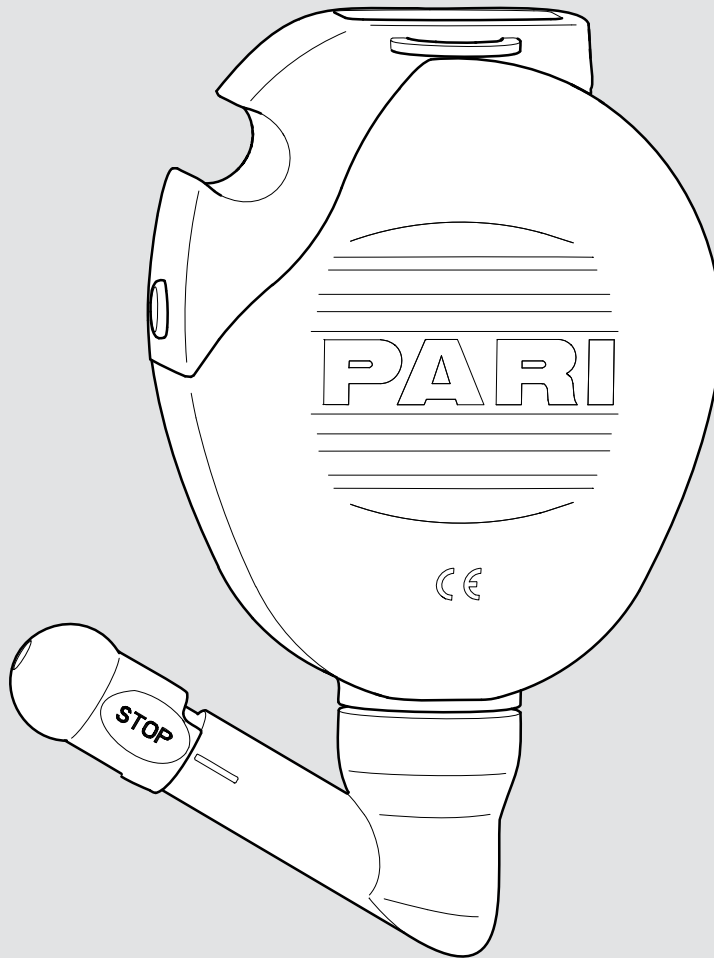
# Instructions for use

## PARI MONTESOL nasal douche

Model: PARI MONTESOL (Type 177)

**Important:** Read these instructions carefully before using the product for the first time. Follow all instructions and safety instructions!

Keep the instructions in a safe place.



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## **Identification, validity, version**

These instructions for use are valid for the PARI MONTESOL nasal douche (Type 177) in the following countries:

GB and countries outside the EU

Version of these instructions for use: Version A – 2020-04,  
Approved version dated 2020-04-21

Information as of: 2020-03

The current version of the instructions for use can be downloaded from the internet as a PDF file:

[www.pari.com](http://www.pari.com) (on the respective product page)

## **Formats available for visually impaired patients**

The instructions for use available in PDF format on the internet can be enlarged for printing.

## **Conformity**

The product conforms to the EU regulation 2017/745 on medical devices.

## **Trade marks**

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## **Legal manufacturer**

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# 1 IMPORTANT INFORMATION

## 1.1 Intended purpose

The PARI MONTESOL nasal douche is a medical device designed for flushing the main nasal cavity. Using a nasal douche with a nasal rinse moistens the mucous membranes of the nose and cleans the nasal cavity.

The PARI MONTESOL nasal douche can be used:

- by children aged 4 years and older after consultation with a healthcare professional<sup>1</sup>
- by children aged 7 years up to adults

Only solutions that are approved for use as nasal rinses may be used.

This PARI product must only be used in home environments and only by a single patient (no change of patient).

This product must only be operated by individuals who understand the contents of the instructions for use and are able to operate the product safely. 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 operate the product safely himself, the therapy must be carried out by the responsible person.

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

A nasal rinse lasts about 5 minutes.

The frequency and duration of use will be determined by healthcare professionals<sup>1</sup> according to the individual needs of the patient.

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1) Professional medical staff: Doctors, pharmacists and physiotherapists.

## 1.2 Indications

The PARI MONTESOL nasal douche can be used for rinsing the nose in the following cases:

- Acute and chronic inflammation of the paranasal sinuses (rhinosinusitis)
- Allergic rhinitis (pollen allergy)
- Dry or blocked nose and encrustations
- Period spent in a dry or polluted atmosphere and with high dust load
- For preventing and as auxiliary treatment for cold infections
- Following surgery on the nasal cavity, the paranasal sinuses or the nasal septum (only after consultation with a health-care professional<sup>1</sup>)

## 1.3 Contraindications

The PARI MONTESOL nasal douche must not be used:

- in cases of injury to the nasal roof, the walls of the paranasal sinuses and the skull base if such injuries allow direct connection with the fluid spaces of the brain
- in the event of frequent and heavy nosebleeds

If you are uncertain whether you can use the PARI MONTESOL nasal douche, ask your doctor before use.

## 1.4 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 only be used as described in these instructions for use.

The instructions for use of the rinse solution you use must also be followed.

**If your health condition is not improved, or even worsens as a result of the treatment, seek advice from a healthcare professional<sup>1</sup>.**

## **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 of the product out of the reach of babies and infants at all times.

## **Hygiene**

Observe the following hygiene instructions:

- Do not use product components unless they have been thoroughly cleaned and dried. Contamination and residual moisture encourage the growth of bacteria, 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 product components in a damp environment or together with damp objects.

## **Treatment of children and anyone who requires assistance**

For individuals who are not able to perform the therapy session without assistance or cannot appreciate the hazards, there is a risk of injury. Such individuals include for example children and people with limited capabilities. For these individuals, a person responsible for safety must supervise or carry out the application.



## Reporting serious adverse events

Serious incidents which occur in connection with this PARI product must be reported promptly to the manufacturer and/or the distributor as well as to the competent authority. Any event which has led or might lead directly or indirectly to death or an unexpected serious worsening of the health condition of a person is to be considered serious.

## Identifying and classifying warning instructions

Safety-critical warnings are categorised according to the following hazard levels in these instructions for use:

### **DANGER**

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

### **WARNING**

WARNING indicates a hazardous situation which can lead to 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.

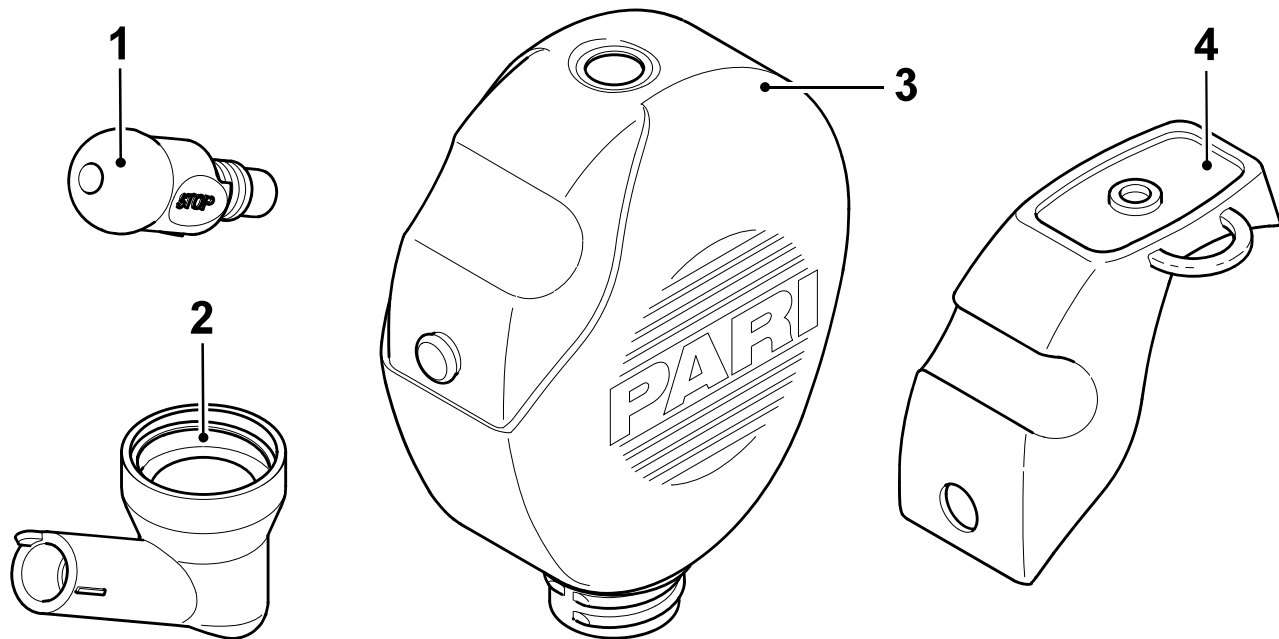
### **NOTE**

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

## 2 PRODUCT DESCRIPTION

### 2.1 Components

The following components are included in the package:



(1)	Nasal insert
(2)	Bend
(3)	Reservoir (250 ml fill volume)
(4)	Valve

### 2.2 Description of function

The PARI MONTESOL nasal douche is used to cleanse and moisturise the nasal mucosa.

Rinsing the nose clears germs, dust and dirt out of the nasal passages and supports the natural cleaning function of the nose.

## 2.3 Material information

The individual product components are made from the following materials:

Product component	Material
Reservoir	Polypropylene
Bend	Polypropylene
Valve	Thermoplastic elastomer
Nasal insert	Thermoplastic elastomer

## 2.4 Operating life

The product has an expected lifetime of 300 disinfection cycles (max. 1.5 years). After that, the product must be replaced with a new one.

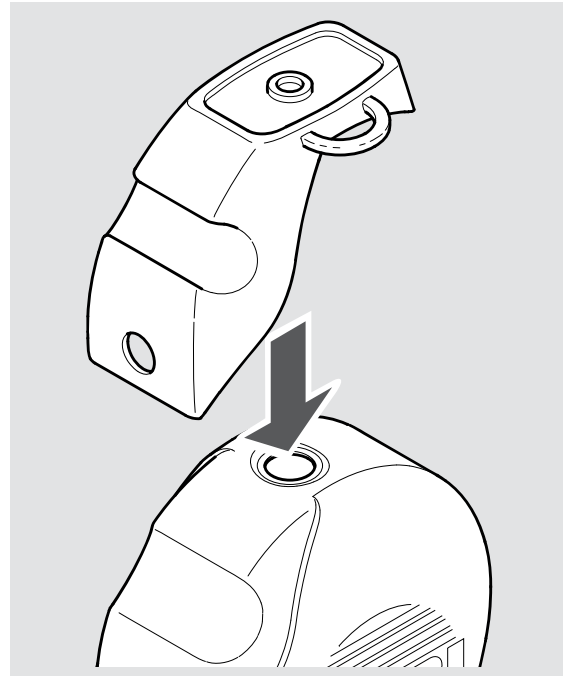
### 3 APPLICATION

People who assist others in carrying out the therapy must ensure that all of the steps described below are carried out correctly.

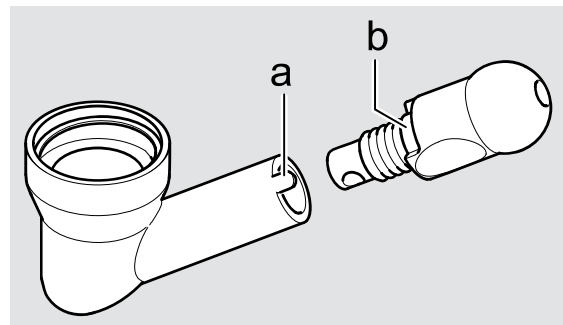
#### 3.1 Preparing to rinse the nose

##### Assembling the nasal douche

- Attach the valve to the reservoir.



- Place the nasal insert on the bend.  
Make sure that the small pin (a) on the bend engages in the hole (b) in the nasal insert.



## Fill the nasal douche

The following section describes how to fill the nasal douche for use with the PARI MONTESOL nasal rinse. If you use a different rinse solution, fill the nasal douche as instructed in the associated instructions for use.

### CAUTION

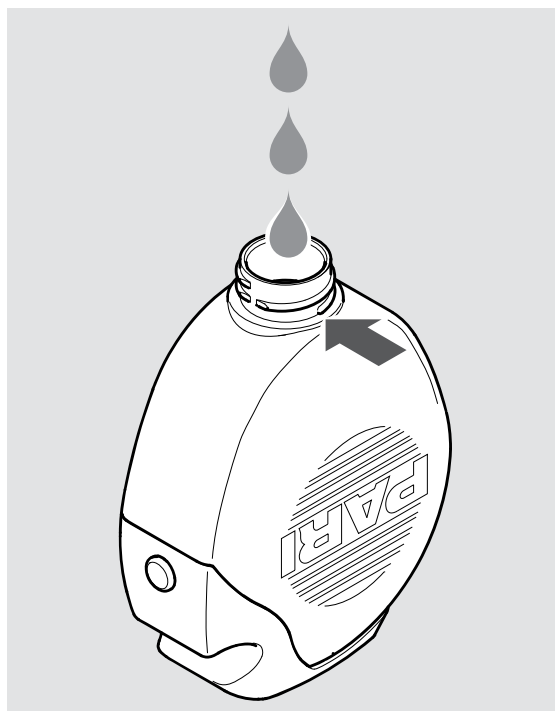
#### **Risk of infection from contaminated water**

If contaminated water is used to prepare the rinse solution, rinsing can lead to infections of the nose.

- Always use fresh drinking water, after boiling if necessary, to prepare the rinse solution.
- Place the nasal douche on the valve.
- Fill the nasal douche with the rinse solution.  
Instructions regarding dosage are included in the instructions for use of the nasal rinse you are using.
- Fill the nasal douche with **lukewarm** drinking water up to the bottom edge of the screw thread.

### CAUTION! Risk of injuring the nasal mucosa if water is

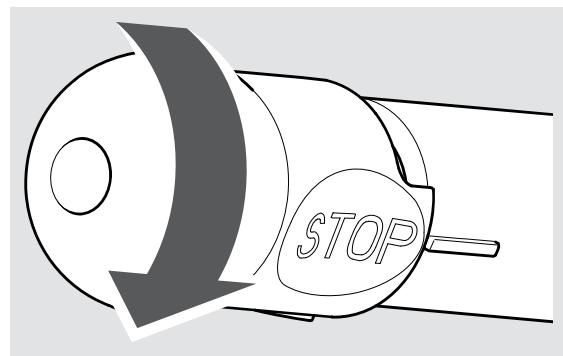
**too hot or too cold.** The nasal mucosa can be injured by liquids at a temperature above 41 °C, or also by frequent rinsing with liquids that are too cold. Therefore, use only lukewarm water to prepare the rinse solution. If necessary, allow the rinse solution to cool down a little or warm up to room temperature before rinsing with it.



- Screw the bend onto the reservoir tightly.



- Twist the nasal insert to the STOP position, to ensure that no liquid can escape yet (the line on the bend points to "STOP").
- Shake the nasal douche gently back and forth so that the nasal rinse is mixed with the drinking water.



## 3.2 Rinsing the nose

### CAUTION

#### **Risk of aspiration (breathing in the rinse solution)**

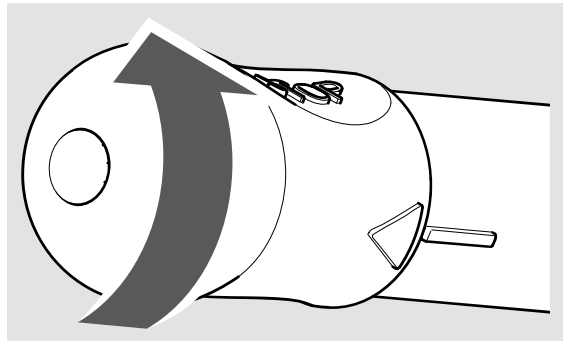
Motor skills may vary widely from one patient to another. If the patient's coordination is inadequate, the rinse solution can get into the windpipe (by swallowing).

- If this happens regularly: Do not rinse the nose again until the requisite coordination is possible.

- Rinsing the **left nostril**:  
Hold the nasal douche in the **left hand**.  
Rinsing the **right nostril**:  
Hold the nasal douche in the **right hand**.
- Rest your index finger lightly on the valve.



- With your free hand, twist the nasal insert to the rinse position (the line on the bend will point to the triangle).



- Bend your head slightly over the basin and open your mouth wide.
- Breathe in and out calmly through your mouth.
- Place the nasal insert against your nostril so as to block it completely.
- Tilt your head slightly to one side (in the direction of the nostril that is not currently being treated).



- Press your index finger gently against the nasal douche valve.  
Rinsing of the nose begins. The rinse solution flows in one nostril, through the nasal sinuses and back out of the other nostril.

- If necessary, you can interrupt the rinsing process by taking your index finger off of the valve.

**i** *Some residual fluid will remain in the nasal douche after rinsing.*

**i** *Small quantities of rinse solution may run down the throat. Tilt your head slightly forwards and to one side while rinsing so that this small quantity can flow quite naturally out of your mouth.*

*If larger quantities get into your throat, open your mouth as wide as possible.*

*If one side of your nose is blocked, start the rinsing process with the blocked nostril.*



## 4 REPROCESSING

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

### 4.1 Preparation

Dismantle the nasal douche into its individual parts:

- Unscrew the bend from the reservoir.
- Pull the nasal insert off from the bend.
- Remove the valve from the reservoir.

### 4.2 Cleaning

EQUIPMENT:

- Drinking water at a temperature from 40 °C to max. 50 °C
- Standard commercial dishwashing liquid<sup>2</sup>
- Receptacle with at least 3 l capacity

PROCEDURE:

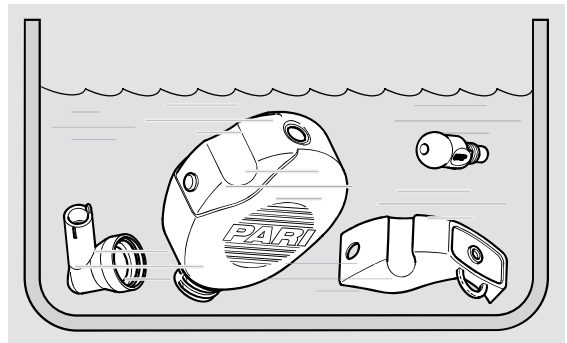
- Add about 1 teaspoonful dishwashing liquid to 3 l warm drinking water.
- Place all the parts in the rinsing water.

Treatment time: at least  
5 minutes

- Occasionally move the parts back and forth.
- In the case of heavy soiling, use a soft brush (e.g., a medium toothbrush which is used exclusively for this purpose).

RINSE:

- Rinse off all parts thoroughly in drinking water.  
Water temperature: approx. 15 °C, duration: 2 minutes



<sup>2</sup>) Validated with Palmolive®.

DRY:

- 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.

### 4.3 Disinfecting

After cleaning, disinfect all of the **disassembled parts** (only parts that have been cleaned can be disinfected effectively).

The validated disinfection procedures are described below.

#### In boiling water

EQUIPMENT:

- Clean cooking pot
- Drinking water

PROCEDURE:

#### CAUTION

##### **Risk of infection due to moisture**

Moisture encourages the growth of bacteria.

- Remove all parts from the pot as soon as the disinfection process is finished 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 pot. Make sure there is enough water in the pot to prevent the individual parts from touching the pot base.

DRY:

- 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 disinfecter is clean and operating properly before every disinfection process.
- Allow the disinfection to continue until the disinfecter switches off automatically or the minimum disinfection time stated in the instructions for use of the disinfecter 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 disinfecter 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 disinfecter you are using.

### DRY:

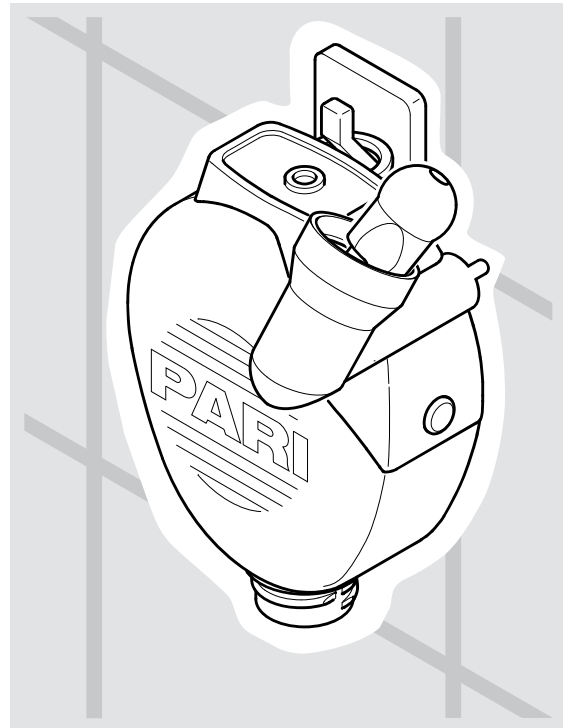
- After the disinfection process is complete, place all parts on a dry, clean and absorbent surface and allow them to dry completely.

## 4.4 Inspecting

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

## 4.5 Storage

- Attach the valve to the reservoir.
- Insert the bend in the hole in the valve.
- Insert the nasal insert in the aperture in the bend.
- Hang the nasal douche up by the strap on the valve.
- If the nasal douche is not used every day, store it in a dry, dust-free place.











## 5 MISCELLANEOUS

### 5.1 Disposal

All product components can be disposed of with domestic waste unless this is prohibited by the disposal regulations prevailing in the respective member countries.

### 5.2 Labelling

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

	Medical device
	Legal manufacturer
	Date of manufacture
	Consult instructions for use
	Item number
	Production batch number, lot
	This product conforms to the EU Medical Device Regulation 2017/745.
	Use for a single patient – multiple applications possible