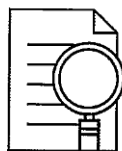


Channel Cleaner

(Ball Brush, disposable balls for cleaning endoscopic channels)

User manual



Read carefully before use

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Safe use

Special instructions

Manual cleaning and brushing of the endoscope prior to disinfection is extremely important, even when performed with automated equipment. If dirt, blood or mucus remain in the channels and/or on the surfaces of the endoscopes, good disinfection performance cannot be expected. In addition, aldehyde-based disinfectants are known to bind proteins to surfaces. For this reason, manual cleaning and brushing is an essential requirement to ensure a high level of disinfection.

However, the quality of manual cleaning and brushing may vary from operator to operator. This device was designed and developed to improve manual cleaning, including brushing. It is recommended to follow local manual cleaning and brushing guidelines and the endoscope manufacturer's instructions regarding these guidelines when using this device.

Parts that cannot be brushed by the device must be cleaned and brushed according to local guidelines and the endoscope manufacturer.

Indication for the use of the device

This device is used for brushing and cleaning the inner walls of endoscope channels using ball suction. It is recommended that the device not be used for any purpose other than that specified. Only trained personnel should use it.

User manual

This user manual contains important information for the safety and effective use of the device. Before using the device, read this user manual and the manuals of other devices used together with the device completely and follow the instructions carefully.

Keep these operating instructions and the operating instructions for the other devices in one place so that they are immediately available when needed.

If any part of this manual is unclear, please contact the authorized service center or the nearest sales office.

To user

This device is intended for use by healthcare professionals, therefore it is assumed that users are adequately trained in endoscope cleaning. For this reason, the entire cleaning technique of the endoscope is not discussed in these instructions for use.

Compatible endoscopes

This device must be used on the endoscopes listed in the table "2.2 Specifications". Use on endoscopes other than those listed may result in clogging of the channels by the balls, insufficient cleaning or breakage of the device, so that the specific functions cannot be guaranteed.

Maintenance, storage and deterioration

Since the device is a brush for cleaning endoscopes, it is neither disinfected nor sterilized. Store the device according to the instructions in this manual. Improper storage may result in loss of balls, deformation of containers and cartridges, so that the specific functions cannot be guaranteed. The cartridges, containers and bullets are intended for single use only. It is recommended not to reuse them. The device can be used for 5 years from the date of manufacture.

To read the serial number

Example: E1-14 12 04

E→for the European market, 1→1st production, 14→14/2 = 07 (year, 2007), 12→12/2=06 (month, June), 04→04/2=02 (day). The production date is indicated on the packaging.

How to assemble the device

This device consists of a cartridge (with 3 balls) and a container. Do not use the cartridge until you have secured it in a suitable place in the container. Assemble the device according to the instructions in the user manual. Incorrect assembly may result in breakage or deformation of the reservoir and loss of the balls. In addition, the balls may not be able to be sucked in.

Warnings in the manual

The following warnings are included in this manual:

Warning: The contents refer to possible malfunction, impossibility of cleaning and breakage of the appliance if not used properly.

Caution: Contents if improperly cleaned or clogged by balls or breakage of the device if used improperly.

Reference: Contents such as current knowledge and information for the application of the device.

Handling warnings and general precautions

The following recommendations should be strictly observed when handling the device. In addition, each chapter contains specific warnings that should be observed in conjunction with the following points.

Warning: - Do not brush and clean the endoscope with this device only. The section from the inlet of the biopsy channel to the main tube of the suction channel and the section where the air/water and suction valves are attached should be cleaned with special brushes other than this device.

- Follow the instructions in "Chapter 3 Instructions for Use" for the cleaning method of this unit.
- The beads must be aspirated together with a cleaning solution and 3 beads are required for brushing an endoscope. For more information, refer to Chapter 3 "Operation" of this manual.

Caution. - Cartridges, balls and containers should only be used once and should not be reused.

- This device must not be used for purposes other than those specified here.
- Use this device to clean contaminated endoscopes immediately after the endoscopic procedure and do not use it if contaminants (mucus, blood) have dried in the channels.
- Immediately after the endoscopic examination, aspirate a certain amount of cleaning solution from the container and remove impurities (mucus, blood) in the canal before aspirating the beads for brushing and cleaning.
- If a ball gets stuck in the channels when cleaning with this instrument, push it out of the channel with a brush. Follow the instructions in "Chapter 4 Ball Blockage".
- If the inlet of the biopsy channel is damaged, the suction power is less effective. The capacity of the suction pump must be greater than -45kPa.

Chapter 1 Packaging test

1.1 Testing the device

Use the illustrations below to make sure that all main parts and accessories are present and undamaged. Also check that the balls are firmly seated in the cartridge. In case of missing or broken parts, or in case of doubt, please contact the nearest authorized service center or sales office.

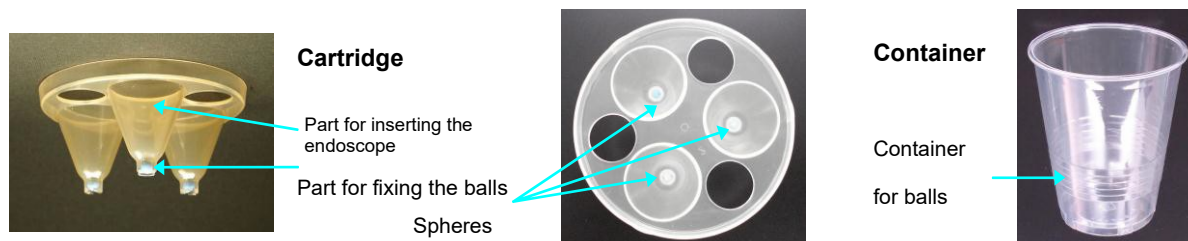


Chapter 2 Description, function and specifications of the individual components

2.1 Description and functions of the individual components

The device must be used in conjunction with a cartridge and a container.

Sewer cleaning device (for single use)



1) Cartridge

This cartridge can hold 3 balls for brushing and cleaning endoscopes and allows simultaneous suction of the ball and cleaning solution by inserting the endoscope tip into the corresponding part of the cartridge container.

Caution! - The cartridge must be correctly positioned in the container.

- Avoid any impact on the cartridges. If this happens, for example if the cartridge falls on the ground, the bullets may be displaced from their correct position.

2) Container

The reservoir facilitates the aspiration of balls and cleaning solution for endoscope cleaning after inserting the cartridge into the reservoir, while keeping the cartridge in the most suitable position.

Caution. - The cartridge must be firmly connected to the container at the correct height. If the cartridge is lower, the container may break.

- Avoid impacts and pressure on the containers so that they do not break or become deformed.
- When a cartridge is fixed in the container, it is possible that the balls move out of their seat. Follow the recommendations in the chapter "Mounting the device" and make sure that the balls are held in the correct position after mounting.

3) Ball Collection Trap

The trap is designed so that the ejection of the balls can be checked.

When the spheres are aspirated, they are collected in the trap to confirm leakage. It is possible to exclude the trap when aspirating fluids and organic material during endoscopic procedures.



Attention: After completing the daily work, immerse the trap in a cleaning solution and then wash it ultrasonically. After washing, disinfect the siphon, rinse and dry. The trap is reusable.

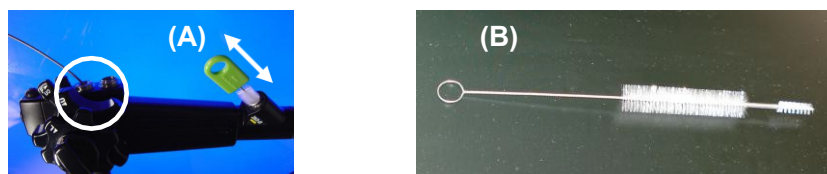
4) Brushing of inlets for biopsy, suction, air/water channel

The maneuver is performed with a brush (B) placed on the parts of the endoscope such as the biopsy (A), suction and air/water channel inlets where brushing with balls is not possible.

The brush shown in Figure B can be used to clean the entrance of the biopsy channel, the area where the biopsy channel and the suction channel meet, the entrance of the suction channel, and the air/water channel without having to change brushes of different sizes.

Attention: After completing the daily work, immerse the trap in a cleaning solution and then wash it ultrasonically. After washing, disinfect the siphon, rinse and dry.

The toothbrush is reusable, however, frequent use may cause the fibers to wear or detach, reducing brushing efficiency. If local guidelines do not allow the toothbrush to be reused, proceed with disposal.



2.2 Specifications

The diameters of the insertion tube and the biopsy channel of the endoscopes to which the product is adapted are as follows:

Diameter of the biopsy channel: 1.8 - 2.2 mm; 2.8 mm; 3.2 mm
 - 3.8 mm Outer diameter of the endoscope: 8 - 18 mm

Applies only to devices with frontal view.

Note: This device must be used for introducer tubes and biopsy channels with the diameters specified above. If endoscopes of different sizes are used, insufficient cleaning, inability to aspirate the ball, clogging or damage to the endoscope by the ball may occur. This device cannot be used for duodenoscopes.

Chapter 3 Application procedure

Warning: - Prepare and check the components before using the device to avoid malfunctions. Also check the equipment on which the device is to be used (endoscope) according to the instructions in the relevant operating manual. If in doubt, do not use the device and contact an authorized service center or your local sales office. If the device is used in doubt, it may not only fail to function properly, but may also result in insufficient cleaning, clogging by a ball, damage to the device, or impairment of its function.

- This device can be used to clean endoscopes before disinfection; it is not sterilized.
- When using this device, perform manual cleaning as recommended in the guidelines and by the endoscope manufacturer and then disinfect.

Caution. - Keep the endoscope as straight as possible during ball aspiration. Otherwise, insufficient cleaning or blockage of the channel by the bullet may occur.

- When the endoscope is placed in the container, remove any mucus adhering to the outer surface of the endoscope insertion tube with a clean cloth.
- Before vacuuming the ball, suck up a sufficient amount of detergent and remove any remaining slime, then vacuum the ball.
- Vacuum the balls together with a sufficient amount of cleaning solution, such as enzyme cleaner. If air is sucked in during operation, the balls may become clogged or insufficiently cleaned.
- Perform the suction procedure with the maximum pressure of the endoscope. If the suction pressure is too weak, the beads may get stuck in the channels or the cleaning may be insufficient. In addition, if the inlet of the biopsy channel is damaged, the suction capacity in the channel may be reduced, resulting in beads clogging the channels or inadequate cleaning.

3.1 Preparation before use

Equipment to be used simultaneously and protective measures

Prepare the equipment for cleaning the channels, the endoscope cleaner, the brush for the entrance of the biopsy channel, the bullet trap, the brush for cleaning the outer surface of the endoscope, the basin or sink for cleaning the endoscope, the protective equipment for cleaning (goggles, face mask, gown and waterproof gloves).

Disinfection of the device by brushing the biopsy channel inlet and the bead trap

Prepare the cleaning solution, cleaning trays, brushes, ultrasonic bath filled with the cleaning solution, disinfectant in a tray, protective equipment to facilitate the cleaning and disinfection procedures at the end of the use of the biopsy channel entry brush (do not reuse if it is a disposable brush) and the bead trap.

Devices to be used in the event of obstruction by a bullet

Prepare endoscope cleaning brushes or biopsy forceps that can be inserted through a bullet into the channels in the event of a blockage.

3.2 Sewer Cleaner Inspection

Check the cartridge and bullet trap as follows:

Checking the external appearance:

If the cartridges or containers are defective, it is recommended not to use them.

Warning: - In the event of a defect, e.g. a broken container, the cleaning solution to be aspirated may spread and damage the insertion tube of the endoscope.

- In the event of deformation, breakage or other damage to the cartridges, bead aspiration may be impaired or damage to the endoscope insertion tube may occur.

1. Check all parts of the container from top to bottom for deformation, cracks or other damage.
2. Check all parts of the cartridges from top to bottom for deformation, cracks or other damage.
3. Check that the cartridge contains 3 bullets.

3.3 Mounting the device

The cartridge and container must be assembled as follows:

Caution. - Avoid excessive pressure when inserting the cartridge into the container to prevent breakage or deformation of the container.

- Do not push the cartridge from the corners to the center of the container. Doing so may cause the container to break or become deformed.

- ① Place a container on the table with the lower part facing upwards and place a white cartridge holder on top.
- ② Insert a cartridge into the cartridge holder.
- ③ Place another container on the cartridge and carefully push it up to the filling lines.
- ④ Fill approx. 200 ml of the cleaning solution into the assembled container.



①②③④

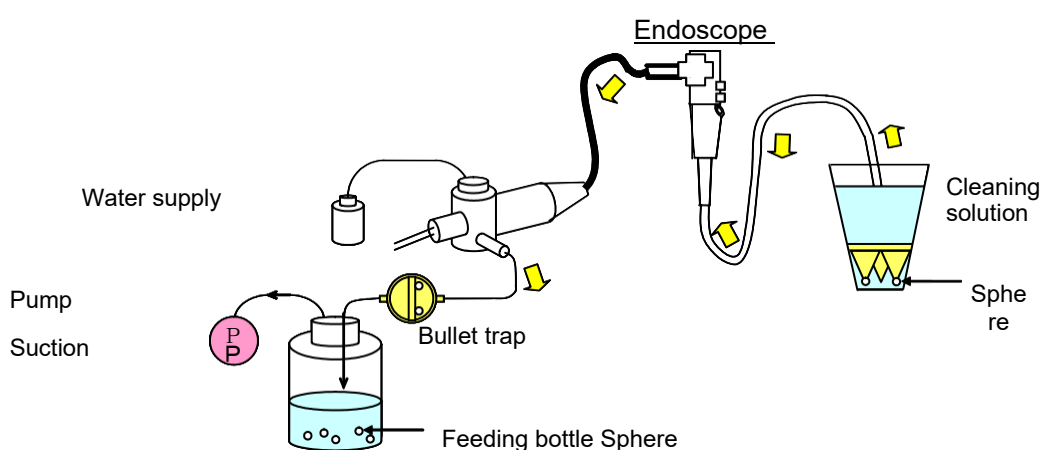
3.4 Method of application

This device is intended for use by well-trained healthcare professionals who are believed to be adequately trained and knowledgeable about the cleaning and disinfection techniques to be followed before using the device. For this reason, the user manual does not address topics related to cleaning and disinfection techniques.

Note: - The device must not be used for duodenoscopes, echo endoscopes and other special endoscopes.

- At the end of aspiration with the device, ensure that the brush ball has passed through the endoscope channel and has been ejected into a container or collection device.
- Parts that cannot be brushed with this device must be cleaned with a special brush for the biopsy, suction and air-water channel inlets.
- Hold the endoscope insertion tube straight when inserting it into the cleaning device container.
- To aspirate the beads, insert the tip of the endoscope straight into the concave part of the cartridge so that there is no distance between the tip and the surface of the cartridge. Otherwise, the bead cannot be sucked into the channel.
- The brush balls can be aspirated together with a sufficient amount of cleaning solution (approx. 40 ml per ball). The second ball should be aspirated when the first has been collected in the water bottle and the third after the second has been collected.
- This sewer cleaning device is intended for single use only. Do not reuse after cleaning and disinfection.
- When pouring the cleaning solution into the container, be careful not to pour it directly onto the part containing the beads, but carefully along the walls of the container. If you pour the solution directly onto the part containing the beads, the beads may come out of their seats, making suction difficult.

Caution. - When cleaning by suction of the balls, it is possible to follow the movement of the ball on a monitor. It is recommended to check if the balls are sucked correctly.



Assembly of the sewer cleaning and disinfection device

Place a container on a table and place the white cartridge holder on the bottom of the container. Insert a cartridge into the holder.

Place another container on the cartridge and press lightly until the fill lines are reached.

1. Preparation of the cleaning solution for endoscope cleaning

Carefully pour the cleaning solution down the walls of the container.

The amount of solution should not exceed the recommended amount to avoid spillage when inserting the endoscope tip.

2. Ball suction

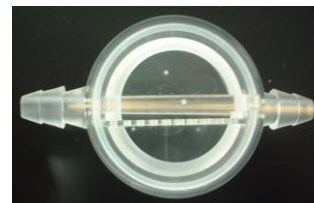
① Remove dirt from the insertion tube with a clean cloth or similar.

② Insert the tip of the endoscope into the container and aspirate the cleaning agent 5-6 times (by pressing the suction plunger).

Then insert the endoscope tip into the concave part of the cartridge holder.

Press the suction plunger so that the first ball is sucked in. After making sure the first ball is in the water bottle or ball trap, prime the second ball, etc.

④ When the third ball has landed in the trap (if there is no trap, the balls fall directly into the water bottle), proceed as described in point ⑤) and check whether all three balls are in the trap. If so, open the siphon and drain the water or balls into the water bottle as shown in the photos. Then completely siphon off the water or cleaning solution remaining in the container to release the three beads from the water bottle.



⑤ (When the third bullet has been recovered), disconnect the light source from the endoscope and move to a sink. Clean the parts not cleaned by the bullets with a brush suitable for biopsy, aspiration and air/water channel entrances; the entire endoscope, including the surface and control knobs, etc., should be cleaned normally (see illustrations, manual cleaning and brushing as recommended by local guidelines and the endoscope manufacturer).



Caution. - It is recommended to wash the endoscopes after you have read the topics on cleaning in the instructions for use of the endoscope.

- Cleaning of parts that cannot be cleaned with this equipment must be carried out in accordance with the instructions for use and any cleaning and disinfection procedure in accordance with the guidelines recommended by professionals in the field.

3. After cleaning the endoscope, it must be disinfected.

Chapter 4 Countermeasures in the event of a bullet blockage

4.1 Countermeasures in case of blockage by a bullet

If a bullet lodges in a channel of the endoscope during suction and causes restricted suction, take the following measures:

Reference: -The causes of constipation can be attributed to the following reasons:

- 1) Different diameter of the ball in relation to the channel.
- 2) Low suction power
- 3) Residual material or biofilm in the channel.
- 4) Damage or deformation of the duct.
- 5) Low volume of detergent solution aspirated.
- 6) Insufficient suction due to degradation or damage of the biopsy channel inlet.

Countermeasures:

If a ball is clogging a duct, push it out with a conventional brush of the appropriate diameter, inserting it from the universal side as in standard duct cleaning. In this case, the duct is brushed at the same time.

Method of restoring the ball with a channel brush:

- 1) Remove the suction piston from its seat.
- 2) Insert the brush from the entrance of the suction channel to the tip of the endoscope.
- 3) When the tip of the brush exits the biopsy channel at the tip of the endoscope, remove the brush.
- 4) Then guide the brush from the inlet of the suction channel to the outlet of the universal part.
- 5) When the tip of the brush comes out of the suction channel on the universal side, remove the brush.
- 6) Brush the entrance of the biopsy channel with a suitable brush.

After performing the entire procedure, verify that the bullet has been removed from the biopsy or aspiration channel.

Chapter 5 Conservation

5.1 Preservation

This device should be stored in a clean place, away from direct light, at room temperature and normal humidity. It is recommended to store it in a suitable container to keep it clean and not to expose it to water or heat sources.

1. Cartridges and containers must be stored in suitable boxes to prevent sagging due to weight, etc.
2. The bullets contained in a cartridge may shift. It is recommended to store the boxes in a place protected from shocks.

Chapter 6 Disposal of the device

6.1 Disposal

Subject to local regulations.

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