

FUJIFILM

Water Tank

WT-603

OPERATION MANUAL

Thank you for purchasing our product. Read this manual carefully before use to avoid unexpected accidents, and take full advantage of the product's capabilities.

Important Safety Information

1. Intended Use

This product is a water tank connected to a FUJIFILM 700 system scope intended to supply water in combination with an endoscopic processor or light source under the management of physicians in medical facilities. Do not use this product for any other purpose.


2. Safety

Read and understand this manual carefully before using the product according to the instructions given. Items important for the safe use of this product are summarized in Chapter 1, “Safety.”

Safety precautions associated with individual operations or procedures are provided separately by “**▲WARNING**” or “**▲CAUTION**.”

3. WARNING

Items that must be observed for safety when using this product are identified by “**▲WARNING**” or “**▲CAUTION**.” Read and understand the precautions carefully to ensure that procedures are performed correctly.

| |
|--|
|  WARNING |
| Read and understand this manual carefully before operating the equipment. |
| Improper use or operation of the equipment may injure patients, physicians, or people in the vicinity. |

Improper operations that will damage the equipment only are indicated by “CAUTION.”

4. When Using this Product for the First Time

This product has not been sterilized. When using it for the first time, disinfect or sterilize this product to the level suitable for the application, in accordance with Chapter 5 “Maintenance Method.”

5. Clinical Procedures

This manual assumes that the product will be used by medical specialists who have received proper training in endoscopic procedures. It does not provide information about clinical procedures. Proper clinical judgment should be exercised for all clinical procedures.

6. Main Adverse Events

The following adverse events may occur while using this product: infection, electric shock, injury, inflammation and chemical injury.

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Preface

This manual describes how to use this product as well as how to clean, disinfect, sterilize, and store it.




The water tank is used in combination with a FUJIFILM 700 system scope. For the combination, read also the Operation Manual of the endoscope.

This manual describes the reprocessing and storage methods for this product according to ISO 17664.

Conventions Used in This Manual

This manual uses the following conventions for easier understanding.

■ General Conventions

| Convention | Description |
|---|---|
|  | Indicates a potential danger that may cause harm to people. |
|  WARNING | Explains dangerous situations that may cause death or serious injury if not avoided. |
|  CAUTION | Explains situations that may cause injury if not avoided. |
| CAUTION | Explains situations that may cause damage to equipment if not avoided. |
| (1), (2), (3), ... | Indicates consecutive numbers in operating procedures for the order in which successive steps in the procedure should be taken. |
| [Note] | Indicates a comment or supplementary information. |
| → | Indicates a reference. |

Chapter 1 Safety

1. Precautions in using this product

1) Preparation and inspection before use

Prior to using this product, prepare a spare one to avoid unexpected accidents such as equipment failure. If a replacement is not available, you may not be able to continue endoscopic procedures.

Make sure to check this product before use according to the procedures provided in this manual, to avoid unexpected accidents, and take full advantages of this product's capabilities.

If the inspection result shows any defects, do not use this product.

2) Combination of equipment

Use this product only in combination with a FUJIFILM 700 system scope.

In order to avoid unexpected accidents and take full advantage of the equipment's capabilities, read the operation manual of the components used in combination carefully before using it.

2. Reprocessing

Reprocess this product with an understanding of reprocessing guidelines. Not doing so may increase a risk of infection.

This product has not been sterilized. When using this product for the first time, reprocess to a level suitable for the application.

When reusing this product, reprocess it according to the procedures described in this manual. Inadequate cleaning may cause an infection.

Wear personal protective equipment when performing chemical reprocessing to protect your skin and to prevent infection.

When using this product for a patient with Creutzfeldt-Jakob disease, use it exclusively for a patient with the same disease, or properly discard this product after use. Since the reprocessing methods described in the manual of this product cannot eliminate the causal agents of Creutzfeldt-Jakob disease, the product could be a source of infection. For the treatment of Creutzfeldt-Jakob disease, refer to the guidelines for it available.

3. Disposal of this Product

When disposing of this product, comply with local laws and regulations in your area. Determine whether or not the product is to be treated as a biohazard, then handle and dispose of accordingly.

4. Prohibition of Disassembly and Modification

Do not disassemble or modify this product.

4. “WARNING” and “CAUTION” Messages Appearing in Individual Chapters

Chapter 4 Method of Use

Change the sterile water inside water tank every day. There is a risk of infection.

If the inspection result shows any defects, do not use this product. There is a risk of causing misdiagnosis or disability.

4.2. Attaching and Detaching to the Endoscope

When opening/closing the tank cover, do not place your hand or fingers in the rotation direction of the hook. There is a risk of hand/finger injury by the hook.

Chapter 5 Maintenance Method

Reprocess this product properly according to the procedures described in this manual, immediately after all examinations of the day are completed. Remove the O ring when reprocessing this product. There is a risk of infection and/or damaging this product.

When opening/closing the tank cover, do not place your hand or fingers in the rotation direction of the hook. There is a risk of hand/finger injury by the hook.

5.2 Disinfection

Reprocess this product properly according to the procedures described in this manual, immediately after all examinations of the day are completed. Remove the O ring and tank cover and open the protective cap when disinfecting the water tank. There is a risk of infection and/or damaging this product.

Provide adequate ventilation during disinfection. Close the cover of the immersion tub when immersing the tank into the disinfectant solution. Vapor of the disinfectant solution may adversely affect the human body.

After the immersion into the chemical solution, rinse off the remaining chemicals with sterile water. There is a risk of the remaining disinfectant solution flowing into a patient's body cavity.

5.3 Sterilization

Reprocess this product properly according to the procedures described in this manual, immediately after all examinations of the day are completed.

Remove the cleaning adapter when sterilizing this product. There is a risk of infection.

Chapter 6 Storage

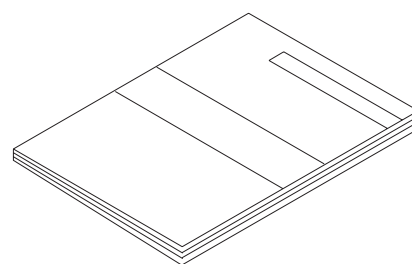
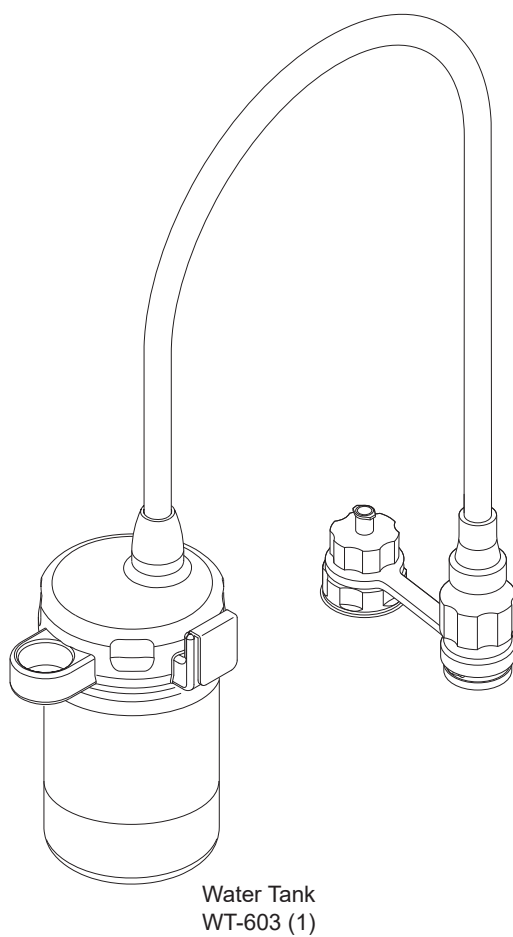
Dry this product before storing it. There is a risk of infection.

Chapter 2 Composition

2.1 Composition

Water Tank WT-603 consists of the following items.

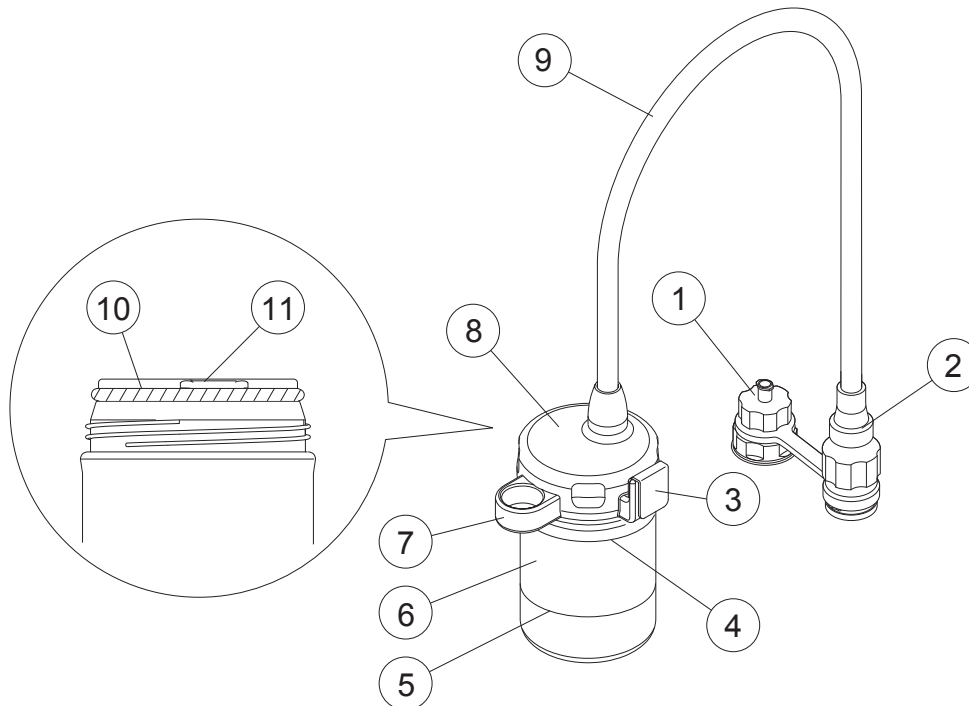
[Note] The figures in parentheses indicate the quantities.



Operation Manual (1)

Chapter 3 Names and Functions of Parts

3.1 Names and Functions of Parts



① Cleaning adapter

Used to clean and disinfect the water tank.
Attached to the connector of the water tank.

② Connector

Connected to the water supply connector of the endoscope.

③ Hook

Used to mount the water tank to the light source, processor or cart.

④ Intended water level mark

Pour in sterile water up to this mark.

⑤ Lower limit water level mark

Indicates the lower limit of the sterile water volume. Water cannot be supplied to the endoscope if the sterile water volume is lower than this mark.

⑥ Tank

Holds the sterile water to be supplied. When filled up to the intended water level, approximately 230 mL of water is stored in the tank.

⑦ Connector holder

Holds a connector attached to it.

⑧ Tank cover

Open this cover to supply and discharge water.

⑨ Channel tube

Tubing between the connector and tank cover.

⑩ O ring














Creates a seal between the tank cover and tank.

[Note] To seal them together tightly, attach the O ring to the specified position.

⑪ Notch

Used to remove the O ring.

3.2 Symbols

| Symbol | Description |
|---|---|
|  | Lot number |
|  | Caution, consult accompanying documents |
|  | Manufacturer |
|  | Authorised representative in the European Community |
|  | Authorised representative domiciled in Switzerland |
|  | Temperature limitation |
|  | Keep dry |
|  | Non-sterile |
|  | CE marking |
|  | Applicable for autoclave |
|  | Humidity limitation |
|  | Atmospheric pressure limitation |
|  | Quantity |

Chapter 4 Method of Use

! WARNING

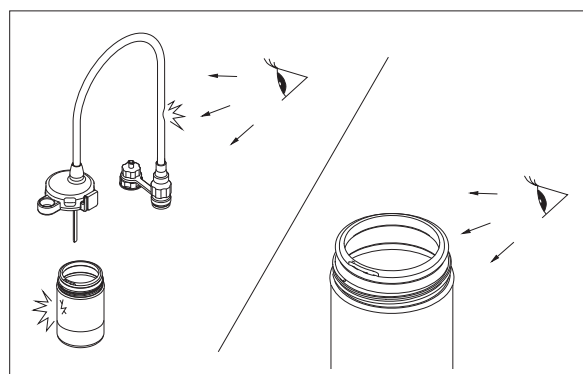
Change the sterile water inside water tank every day. There is a risk of infection.

! CAUTION

If the inspection result shows any defects, do not use this product. There is a risk of causing misdiagnosis or disability.

4.1 Preparation and Inspection

- (1) Prepare the water tank that has been disinfected or sterilized to the level suitable for the application.
- (2) Ensure that the exterior of water tank and the tube are free from significant distortion.
- (3) Ensure that the O ring is attached to the designated position and that it is free from cuts or twisting.



4.2 Attaching and Detaching to the Endoscope

CAUTION

When opening/closing the tank cover, do not place your hand or fingers in the rotation direction of the hook. There is a risk of hand/finger injury by the hook.

CAUTION

Do not drop or strongly bump the tank. There is a risk of damaging the water tank.

Do not apply an excessive force such as bending, twisting or straining to the tube. There is a risk of damaging the tube.

[Note] Make sure to refill the sterile water regularly in order not to allow the water level to fall below the minimum level. If the water level falls below the minimum level, water supply may become impossible.

4.2.1 Attaching this product

- (1) Fill the tank with sterile water up to the intended water level mark.

[Note]

Use only sterile water in the water tank, and change the water every day.

[Note]

Refill sterile water up to the intended water level mark after each examination.

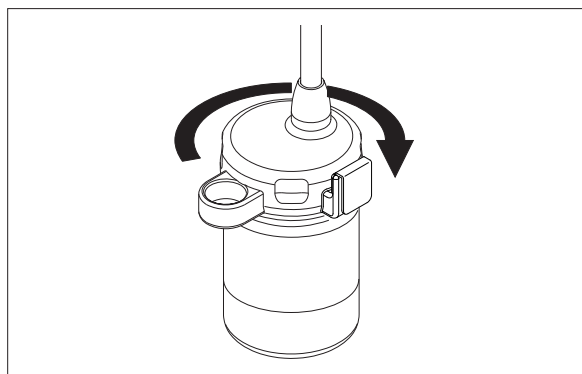
[Note]

Make sure to refill sterile water regularly in order not to allow the water level to fall below the minimum level.

[Note]

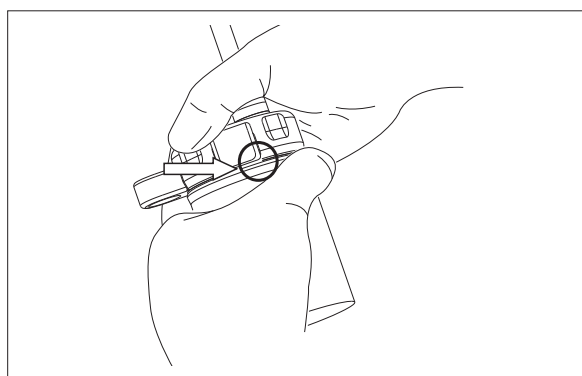
Do not replace or refill sterile water above an electrical device. Sterile water dripping onto an electrical device may cause a device failure.

- (2) Turn the tank cover clockwise and close it.
Turn it until it closes completely.



[Note]

When opening/closing the tank cover, do not place your hand or fingers in the rotation direction of the hook. There is a risk of hand/finger injury by the hook.

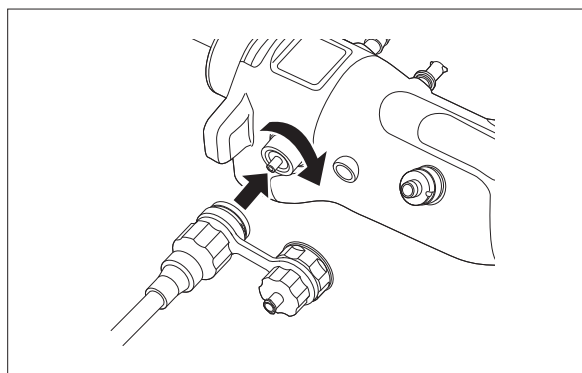


- (3) Mount the hook of the water tank onto the hook of the light source, processor, or cart.
- (4) Insert the connector of the water tank to the water supply connector of the endoscope.

Align the groove on the connector of the water tank and the pin on the endoscope and attach them firmly by turning the connector clockwise until it stops.

[Note]

Make sure the light source and processor have been turned off.



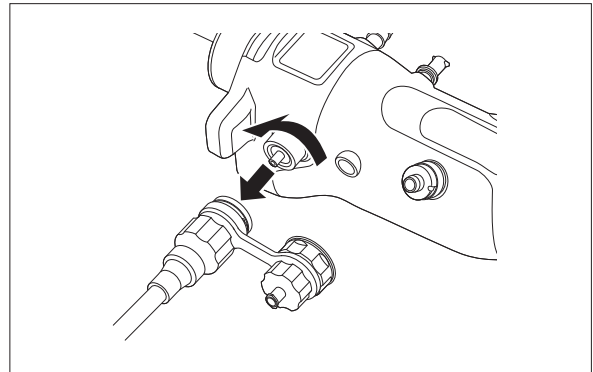
- (5) Ensure that the sterile water and air are supplied according to the Operation Manuals of the endoscope and light source.

4.2.2 Detaching the water tank

- (1) Turn the connector of the water tank counterclockwise to pull out the water supply connector of the endoscope.

[Note]

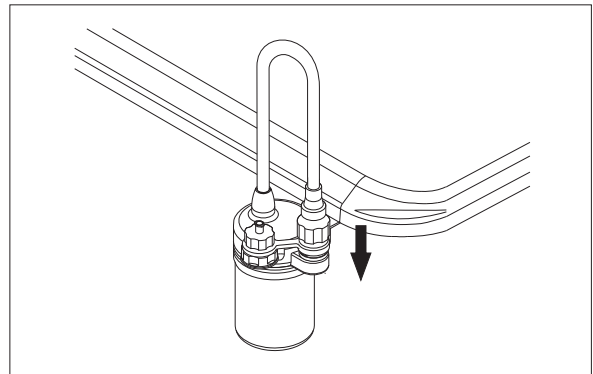
Make sure the light source and processor have been turned off.



- (2) Attach the connector of the water tank to the connector holder.

[Note]

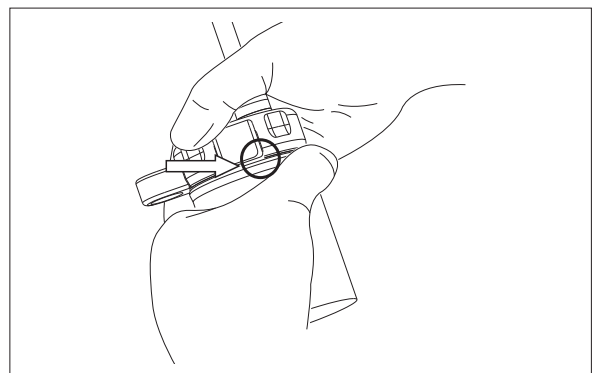
After the connector of the water tank is detached from the water supply connector of the endoscope, be sure to attach it to the connector holder of the water tank. If the sterile water remaining in the water tank drips from the connector of the water tank, it may cause a failure of the peripheral device.



- (3) Detach the water tank from the hook of the light source, processor or cart, and discharge the water remaining inside the water tank.

[Note]

When opening/closing the tank cover, do not place your hand or fingers in the rotation direction of the hook. There is a risk of hand/finger injury by the hook.



Chapter 5 Maintenance Method

WARNING

Reprocess this product properly according to the procedures described in this manual, immediately after all examinations of the day are completed. Remove the O ring when reprocessing this product. There is a risk of infection and/or damaging this product.

Reprocess the water tank with an understanding of reprocessing guidelines. Not doing so may increase a risk of infection.

This product is not compatible with automated endoscope reprocessors. Use of an automated endoscope reprocessor for this product may pose an infection risk and/or cause injury or equipment failure.

CAUTION

When opening/closing the tank cover, do not place your hand or fingers in the rotation direction of the hook. There is a risk of hand/finger injury by the hook.

CAUTION

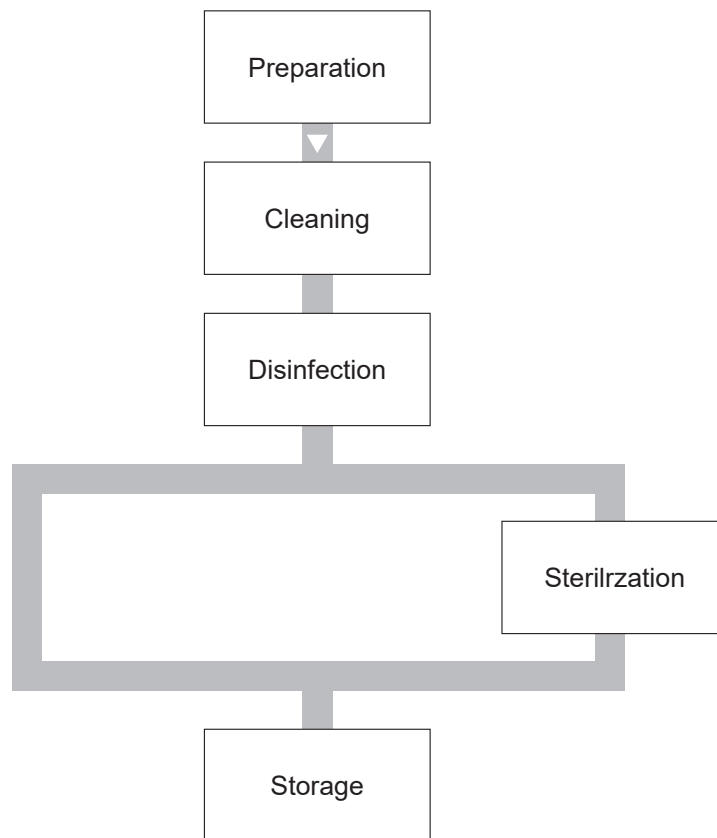
Reprocess this product according to the specified method. There is a risk of failure.

The reprocessing methods applicable to the part are described in Table 5.1.

Table 5.1 Applicable reprocessing methods

| | Cleaning method | | Disinfection/Sterilization method | | |
|------------|-------------------|---------------------|-----------------------------------|-----------|-------------------|
| | Chemical cleaning | Ultrasonic cleaning | Chemical disinfection | Autoclave | Gas sterilization |
| Water Tank | Yes | No | Yes | Yes | No |

<Work flow of Reprocessing Water Tank and This Product>



5.1 Cleaning

5.1.1 Cleaning condition

<Clean Water (for Reprocessing)>

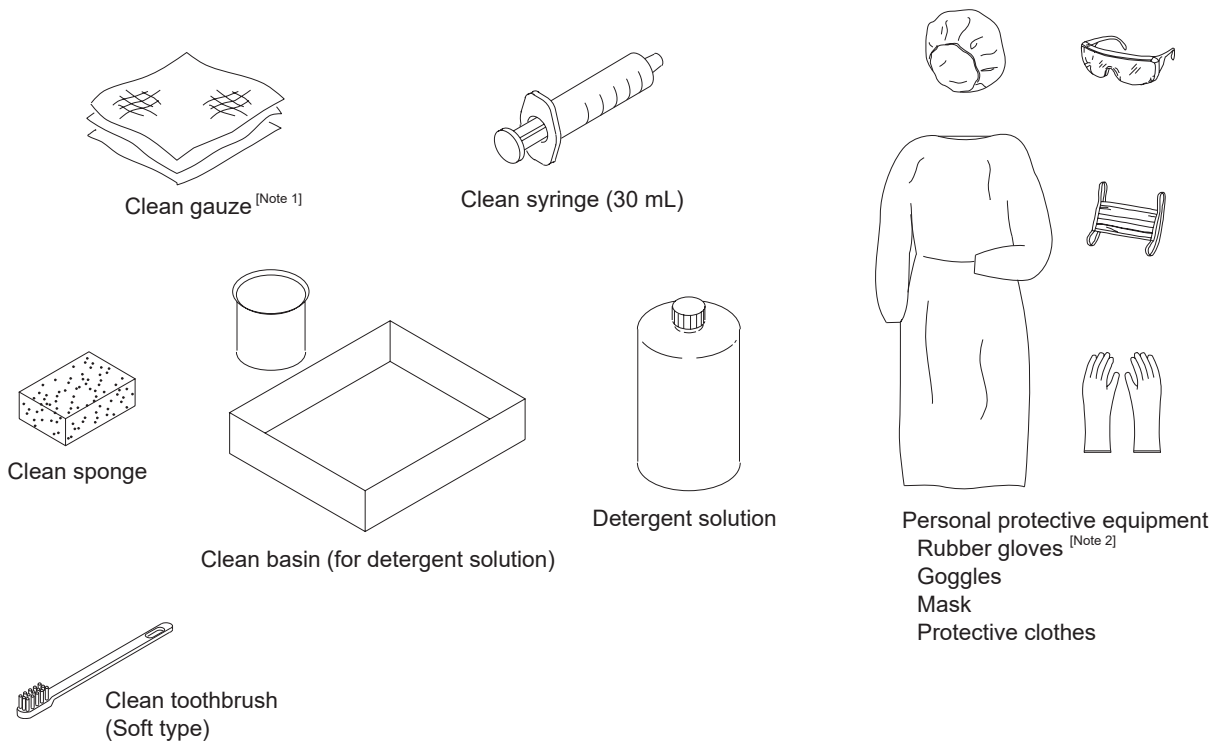
Water is used for rinsing after manual cleaning of the water tank and this product.
For these purposes, use water that is at least potable in quality.

<Detergent Solution>

Use a medical grade, low-foaming enzymatic detergent. For the names of specific brands of detergent solution that have been tested for compatibility with the water tank and this product, contact your local FUJIFILM dealer. Refer to the detergent manufacturer's instructions for preparation and use.

5.1.2 Necessary equipment

Prepare the necessary equipment.

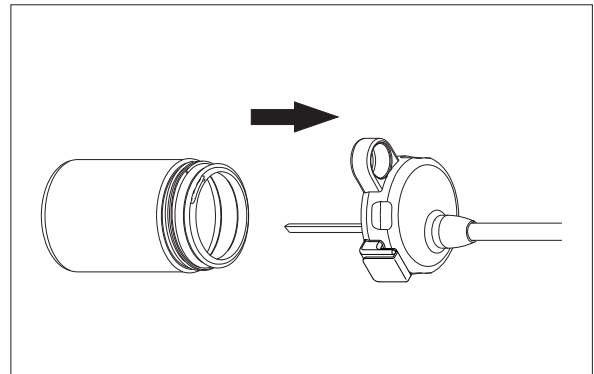


[Note 1] Prepare lint-free gauze.

[Note 2] Gloves are recommended to be long enough to prevent your skin from being exposed.

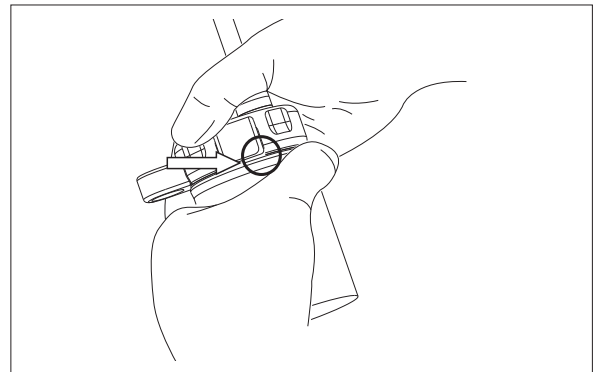
5.1.3 Cleaning procedure

- (1) Wear personal protective equipment.
- (2) Prepare cleaning supplies including fresh enzymatic detergent solution; follow detergent manufacturer's instructions for preparation and usage conditions.
- (3) Detach the water tank and dispose of the remaining water.
- (4) Separate components of the water tank (tank, tank cover with tubing).

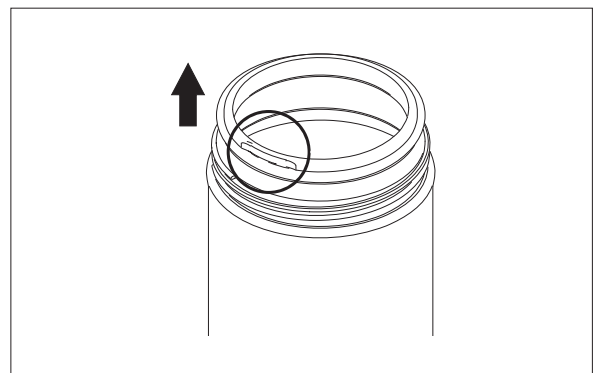


[Note]

When opening/closing the tank cover, to avoid risk of injury do not place your hand or fingers in the rotational direction of the hook.

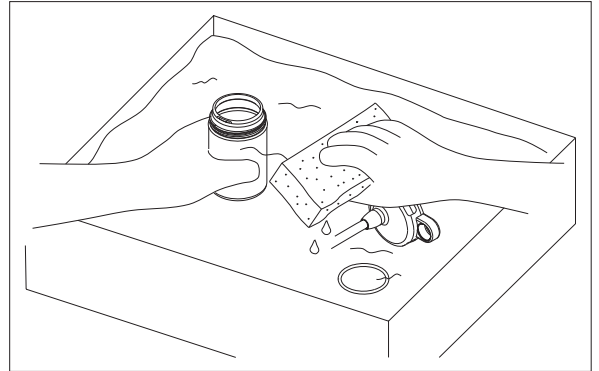


- (5) Detach the O ring by pulling it slowly over the notch of the tank.

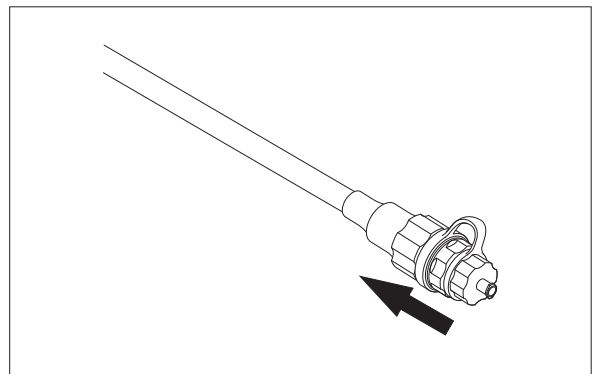


- (6) Completely immerse all water tank components. Leave the black rubber cleaning adapter strapped to the water tank connector.

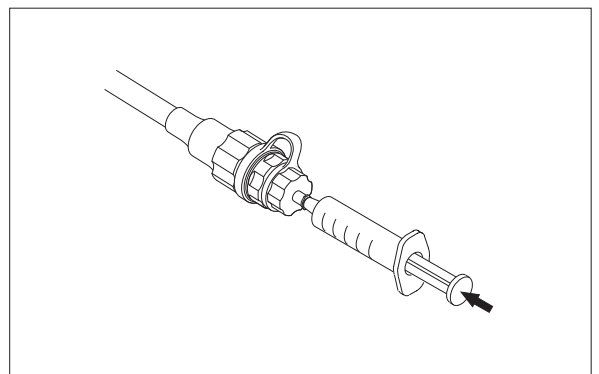
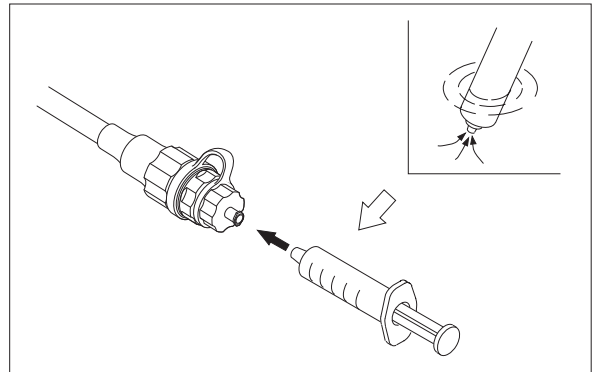
- (7) Thoroughly wash surfaces of the water tank components with a sponge and/or brush, ensure the water tank is completely filled with detergent solution and that it remains submerged.



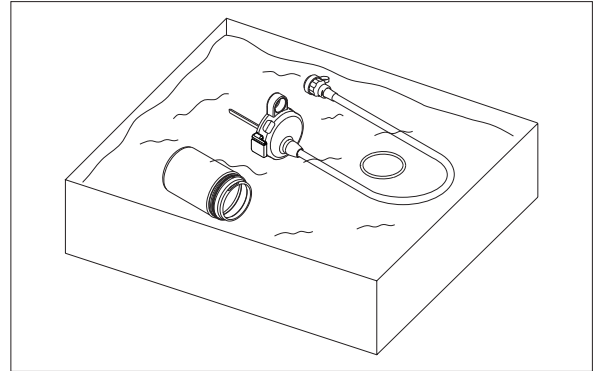
- (8) Attach the cleaning adapter to the distal metal water tank connector (to secure, push/slide the rubber adapter onto the end of the water tank connector).



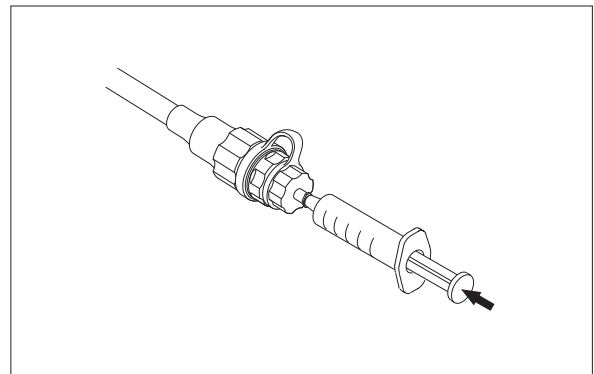
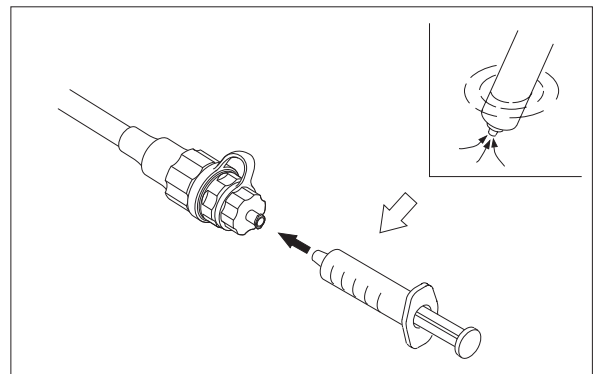
- (9) Using a syringe, flush at least 60 ml of detergent into/through the inlet port of the rubber cleaning adapter. Detergent should fill and flow out the ends of the two water tank channel tubes located under the water tank cover. (Fluid will exit the water tube intake tube as well as the opening to the air channel beneath the plastic tank cover/cap.)



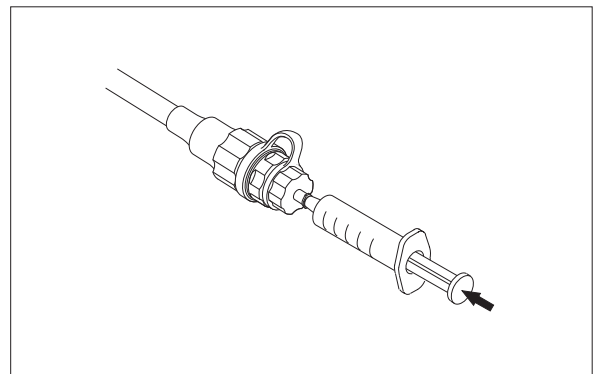
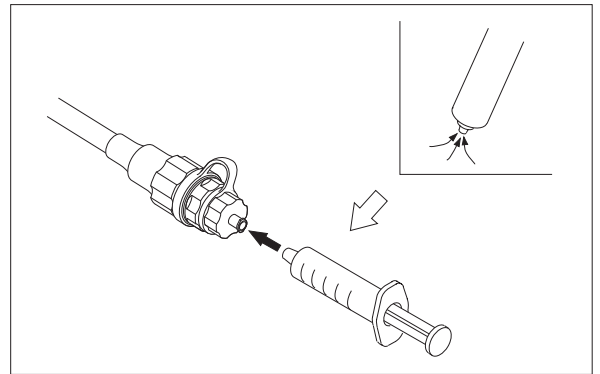
- (10) Detach the syringe and allow all items to soak for an appropriate time period (as per the detergent manufacturer's instructions).



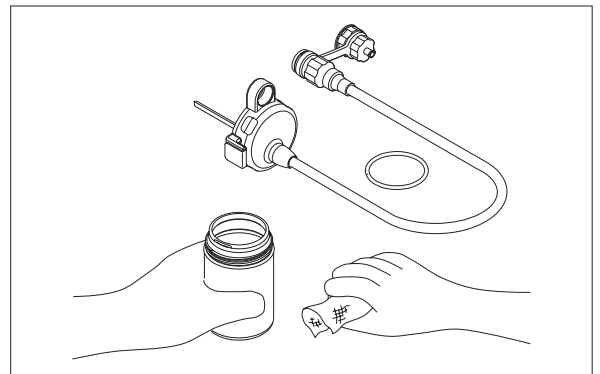
- (11) Remove the water tank from the detergent and rinse/soak in a basin of clean, potable tap water. Attach the cleaning adapter and flush 60 ml of water through the inlet port to rinse the two water tank channel tubes. Repeat rinsing two more times.



- (12) Remove water tank components and dry with gauze; using a syringe, flush air through the adapter to purge water/moisture from the tubing; repeat air purge as necessary until no fluid/moisture can be expelled from both tubes.



- (13) After components of the water tank are thoroughly dry, proceed with disinfection or sterilization.



5.2 Disinfection

WARNING

Reprocess this product properly according to the procedures described in this manual, immediately after all examinations of the day are completed. Remove the O ring and tank cover and open the protective cap when disinfecting the water tank. There is a risk of infection and/or damaging this product.

CAUTION

Provide adequate ventilation during disinfection. Close the cover of the immersion tub when immersing the tank into the disinfectant solution. Vapor of the disinfectant solution may adversely affect the human body.

After the immersion into the chemical solution, rinse off the remaining chemicals with sterile water. There is a risk of the remaining disinfectant solution flowing into a patient's body cavity.

CAUTION

Perform the reprocessing of the equipment by the specified method. There is a risk of damaging the equipment.

5.2.1 Conditions for disinfection

<Disinfectant Solution>

The material compatibility of FUJIFILM water tank and this product with legally marketed 3.0 to 3.5% glutaraldehyde disinfectant solutions has been verified.

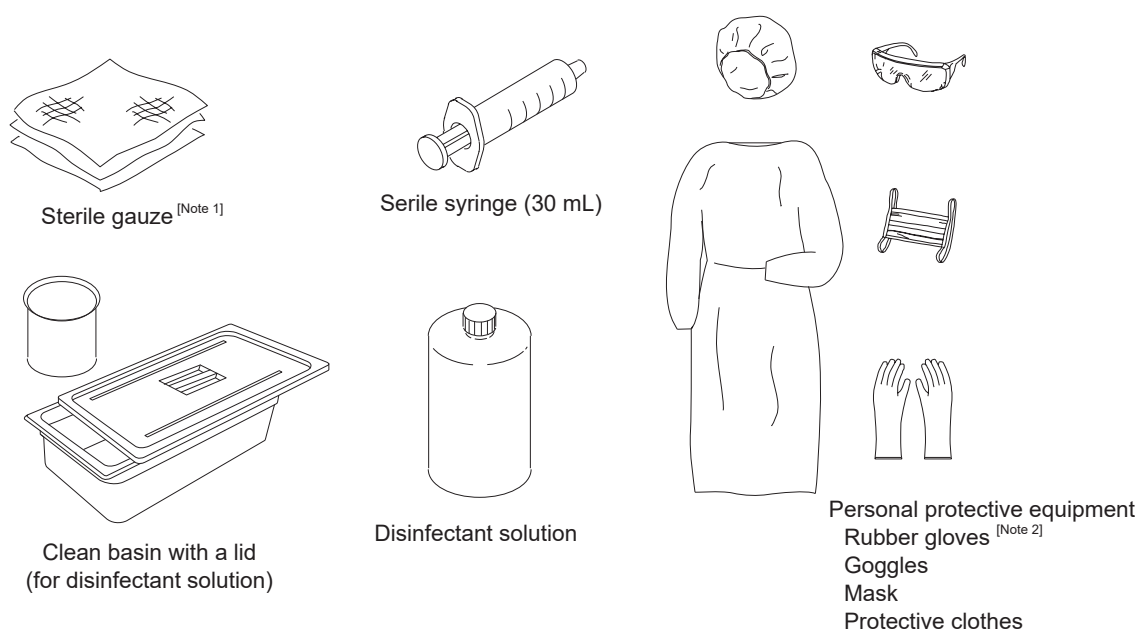
Use glutaraldehyde disinfectant solutions in accordance with the manufacturer's instructions. For the names of specific brands of disinfectant solution, contact your local FUJIFILM dealer.

<Rinse Water>

After disinfection, rinse the water tank and this product using water for injection that complies with the European Pharmacopoeia and/or the International Pharmacopoeia or with the standards of the regulatory authority of your country.

5.2.2 Necessary equipment

Prepare the necessary equipment.

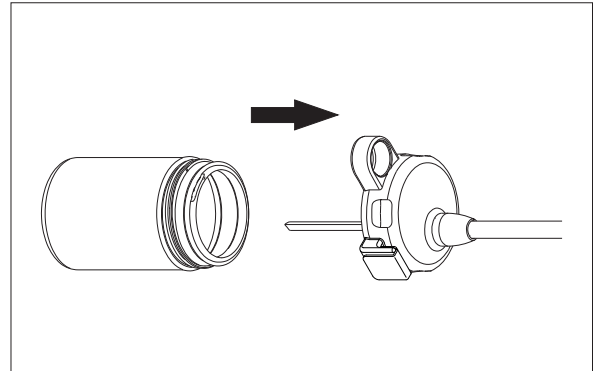


[Note 1] Prepare lint-free gauze.

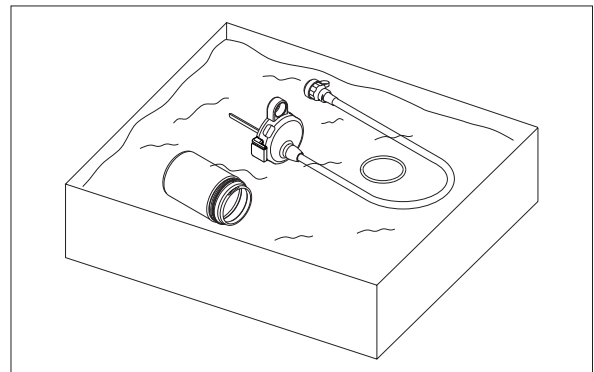
[Note 2] Gloves are recommended to be long enough to prevent your skin from being exposed.

5.2.3 Disinfection procedure

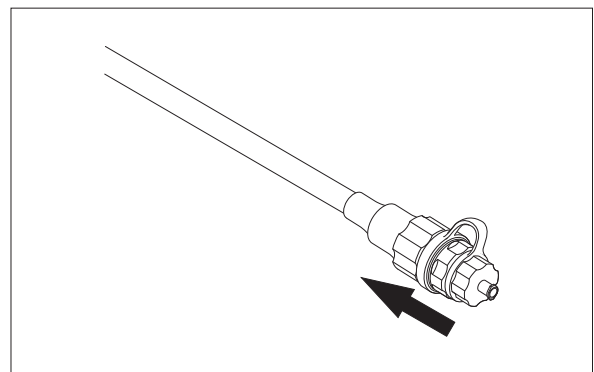
- (1) Wear personal protective equipment.
- (2) Prepare disinfection supplies including a disinfectant solution; follow disinfectant manufacturer's instructions for preparation and usage conditions.
- (3) Separate components of the water tank (tank, O ring and tank cover with tubing).



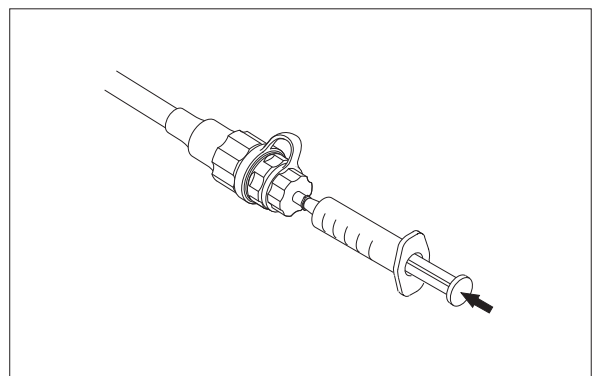
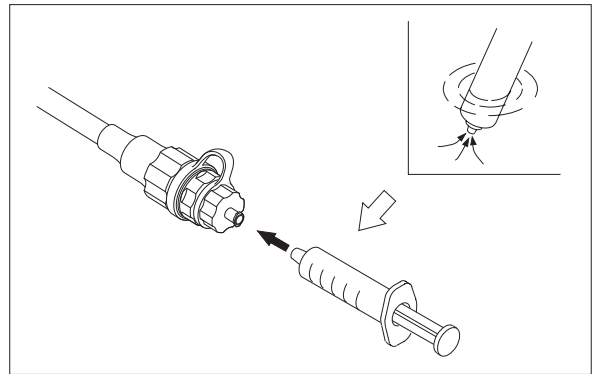
- (4) After ensuring that all components are dry, place all three items into a basin filled with disinfectant solution so all items are completely immersed.



- (5) Attach the cleaning adapter to the distal metal water tank connector (to secure, push/slide the rubber adapter onto the end of the water tank connector).

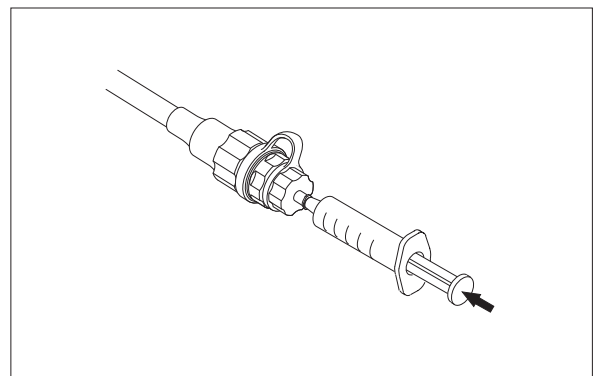
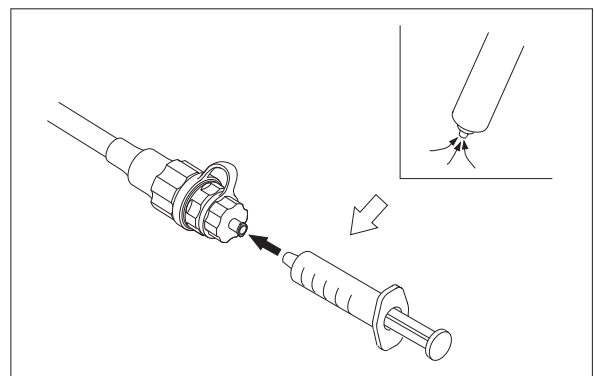
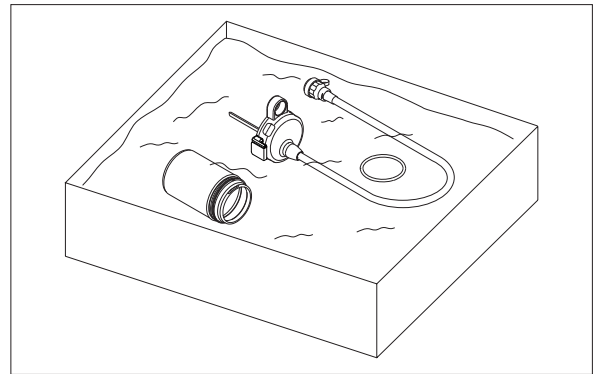


- (6) Using a syringe, flush at least 60 ml of disinfectant into/through the inlet port of the rubber cleaning adapter. Disinfectant should fill and flow out the ends of the two water tank channel tubes located under the water tank cover. (Fluid will exit the water tube intake tube as well as the opening to the air channel beneath the plastic tank cover/cap.)

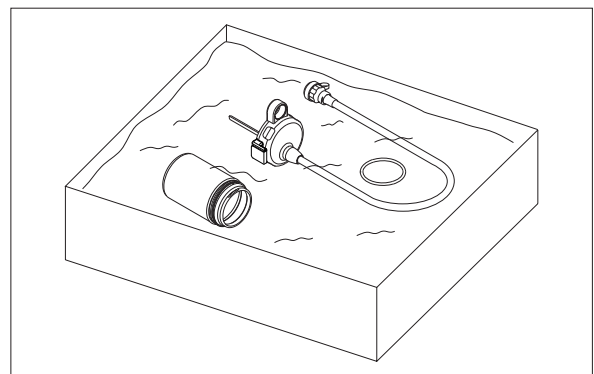


- (7) Allow all items to remain submerged, filled with and exposed to disinfectant solution; while soaking, leave the cleaning adapter attached to the water tank connector but remove the syringe.

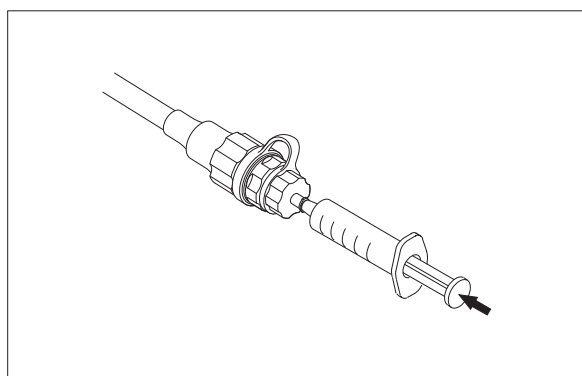
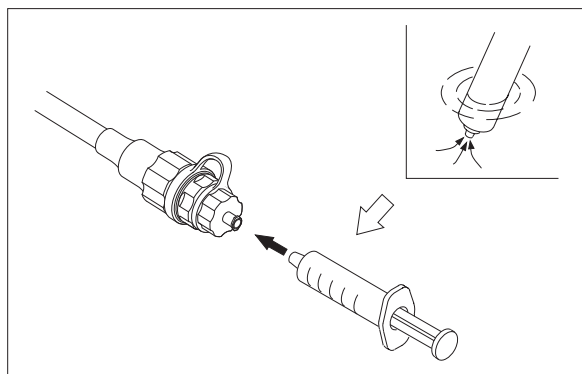
- (8) After allowing all items to remain exposed to the disinfectant for an appropriate time and temperature (per manufacturer's recommendations), use the syringe to flush air through the inlet port of the cleaning adapter to expel disinfectant from the tubing.



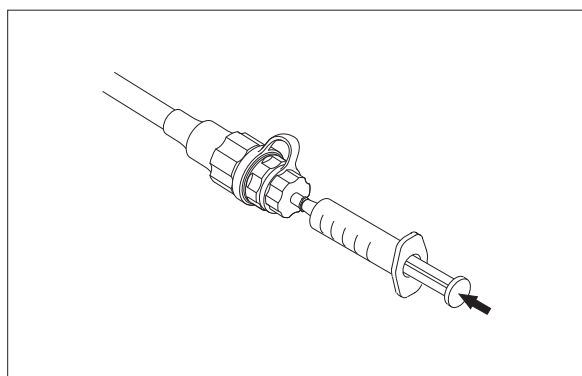
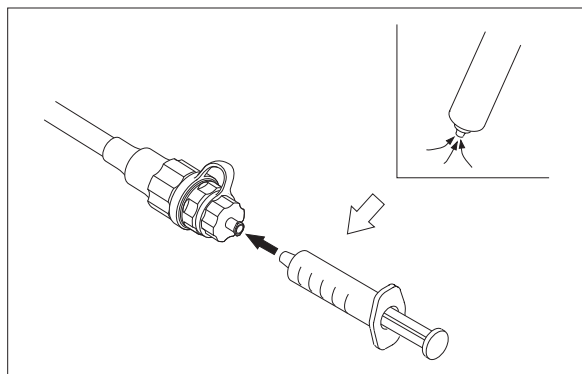
- (9) Remove items from disinfectant solution and immerse in sterile water; rinse all components.



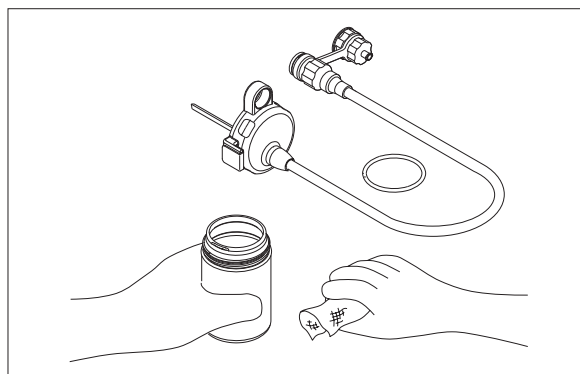
- (10) Flush at least 60 ml of sterile water through the inlet port on the cleaning adapter to rinse the lumens of the water tank tubing. Repeat rinsing two more times.




- (11) Remove all items from the sterile water, flush air through the water tank tubing until no more fluid/moisture can be expelled.



- (12) Inject at least 60 ml of 70% Ethyl or Isopropyl Alcohol into the cleaning adapter, water tank and tubing; follow by flushing with forced air to facilitate drying of the tubing and water tank surfaces.
- (13) Ensure that all surfaces of the water tank and tubing are thoroughly dry before storage and prior to filling bottle with sterile water for procedures.



5.3 Sterilization

| |
|---|
| <div> WARNING</div> <div>Reprocess this product properly according to the procedures described in this manual, immediately after all examinations of the day are completed. Remove the O ring and tank cover and open the protective cap when disinfecting the water tank. There is a risk of infection and/or damaging this product.</div> |
|---|

Autoclaving (high pressure steam sterilization) is used to sterilize this product.

5.3.1 Enclosing into a sterile pack

Enclose the tank, tank cover and O ring into a sterile pack and seal them tightly.
For the sealing procedure, follow the instructions of the sterile pack.

5.3.2 Autoclave

When performing autoclave sterilization of the water tank and this product, use a sterile pack or packaging material (compliant with ISO 11607) appropriate for to maintain sterility after sterilization.

If not used, the water tank or this product may be re-contaminated and it may be a source of infection.

After the water tank sealed in a sterile pack is placed in the autoclave equipment, perform autoclave operation according to the conditions specified in the following table.

When performing the autoclave operation, follow the guidelines of your facility. For the operation of the autoclave equipment, follow the operation manual of the equipment or the instructions of the manufacturer.

Table 5.2 Recommended steam sterilization (autoclaving) conditions

| | |
|---------------|--------------|
| Temperature | 132 to 134°C |
| Exposure time | 5 minutes |

[Note] When performing the autoclave sterilization in conditions other than those listed above, contact your local FUJIFILM dealer.

[Note] For France and Switzerland only:
Sterilization for the minimum of 18 minutes at temperature 134°C
Steam Sterilizer Class B according EN 13060

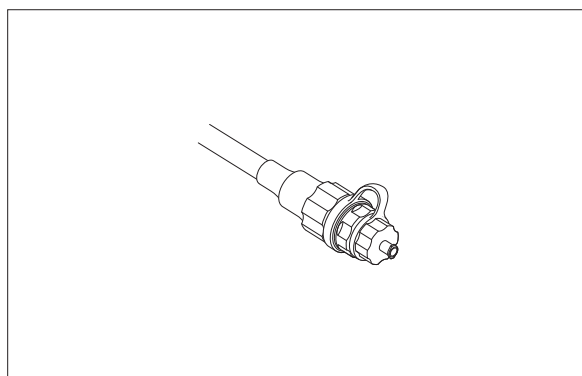
When performing autoclave sterilization, use a sterilizer that is installed and maintained in accordance with ISO 17665. Not doing so may cause inadequate sterilization and pose a risk of infection.

5.4 Drying

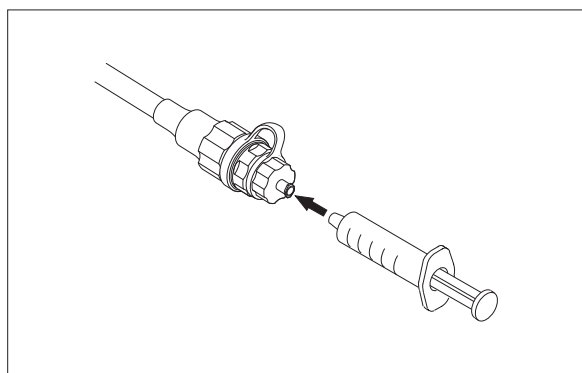
<Alcohol>

When performing final alcohol rinse followed by forced air for thorough drying, use medicalgrade ethyl alcohol (ethanol) or isopropyl alcohol (IPA) that complies with the European Pharmacopoeia and/or the International Pharmacopoeia or with the standards of the regulatory authority of your country.

- (1) Attach cleaning adapter to the connector of water tank.

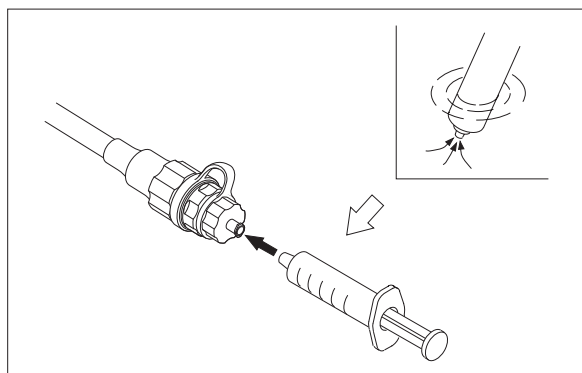


- (2) Using a sterile syringe, flush 60 ml of air into/through the cleaning adapter.

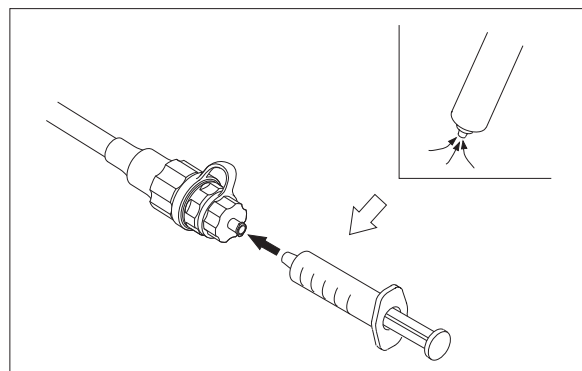


- (3) Fill the sterile basin with alcohol.

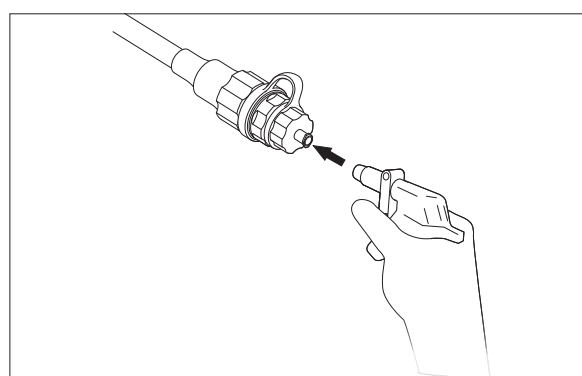
- (4) Using a sterile syringe, flush 60 ml of alcohol into/through the cleaning adapter.



- (5) Using a sterile syringe, flush 60 ml of air into/through the cleaning adapter.

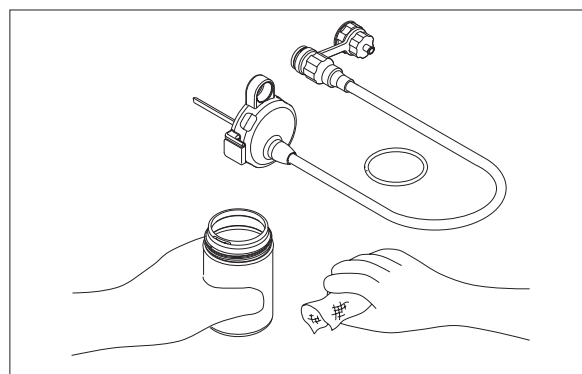


- (6) Flush filtered forced/compressed air at 200 to 250 kPa into/ through the cleaning adapter for 30 seconds three times.



- (7) Detach the cleaning adapter from the connector of water tank.

- (8) Wipe off alcohol remaining on the water tank and the tank cover with sterile gauze.



Chapter 6 Storage

WARNING

Dry this product before storing it. There is a risk of infection.

CAUTION

Do not store the equipment in locations that do not satisfy the storage conditions. There is a risk of damaging the equipment.

Store this product in a location that satisfies the following conditions. Disinfect or sterilize this product before storing it.

After disinfection or sterilization, store this product in a box.

Storage Conditions

Temperature: - 20 to +60°C

Humidity: 10 to 95%RH (no dew condensation)

Pressure: 70 to 106 kPa (within range of atmospheric pressure)

Main Specification

<WT-603>

| | |
|-------------------|---|
| Entire length | 630mm |
| External diameter | 72mm (Excluding hook and connector holder) |
| Volume | Approx. 230 mL |

<Operating Environment>

| | |
|-------------|--|
| Temperature | +10 to +40°C |
| Humidity | 30 to 85%RH (no dew condensation) |
| Pressure | 70 to 106 kPa (within range of atmospheric pressure) |

<Transport Environment>

| | |
|-------------|--|
| Temperature | -20 to +60°C |
| Humidity | 10 to 95%RH (no dew condensation) |
| Pressure | 70 to 106 kPa (within range of atmospheric pressure) |

<Storage Environment>

| | |
|-------------|--|
| Temperature | -20 to +60°C |
| Humidity | 10 to 95%RH (no dew condensation) |
| Pressure | 70 to 106 kPa (within range of atmospheric pressure) |

<Date of Minimum Durability (Expiration Date)>

The term of validity (durability) is one year after beginning of use, if this product is used according to the instructions in this manual.

<Applicable Endoscopes>

FUJIFILM 700 system scopes

<Medical Device Directive>

This product complies with the requirements of
European Directive 93/42/EEC.
Classification : Class II a



Warranty and After-Sales Service

If your equipment does not work properly and caused by the manufacturer's fault within the warranty period, we will exchange your equipment with a new one or equivalent.

The warranty period is one year from the date of purchase.

Note that the warranty is void in the following cases:

- a. Damage caused by fire or natural disaster such as storms or floods.
- b. Problems caused by careless handling or misuse of the product on the part of the user.
- c. Product modified by the user.

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Service Centers

Contact our regional representative below or the distributor from which you purchased the product.

<Europe>

FUJIFILM Europe GmbH

<http://www.fujifilm.eu/eu/>

See our website to locate our representative in your country.

<USA>

FUJIFILM Healthcare Americas Corporation

<http://www.fujifilmendoscopy.com/>

(800) 385-4666

<Australia>

FUJIFILM Australia Pty Ltd

<http://www.fujifilm.com.au/>

1800 060 209

<Asia>

FUJIFILM Asia Pacific Pte. Ltd.

<http://www.fujifilm.com.sg/>

6380-5540

If you are not a resident of the regions above, contact the distributor from which you purchased the product.

**FUJIFILM Corporation**

26-30, Nishiazabu 2-chome, Minato-ku, Tokyo 106-8620, Japan

**FUJIFILM Europe GmbH**

Balcke-Duerr-Allee 6, 40882 Ratingen, Germany

EU Importer:

FUJIFILM Europe B.V.

Oudenstaart 1, 5047 TK Tilburg, The Netherlands