

# **USER MANUAL**

Small Animal Endoscope

## ***Declaration***

The Manufacturer owns the copyright of this unpublished User Manual and reserves the right to treat it in a confidential manner. The Manual only serves as a reference for operating, maintaining and repairing the product with no open use of the Manual allowed.

The Manual contains exclusive materials protected under the copyright law with the copyright reserved. No part of the Manual shall be photographed, copied or translated into any other language without the written approval of the manufacturer.

The contents in the Manual are subject to changes without prior notice.

The product shall only be used as the insertion tube, and any consequences caused by any other use shall be borne by the operator.

## ***Responsibilities of the Manufacturer***

The Manufacturer will be responsible for the safety, reliability and performance of the product on the following prerequisite:

- The installation, maintenance and upgrading of the product are all carried out by the personnel authorized or approved by the Manufacturer;
- The storage, working and electrical environments of the product are in conformity with the product specifications;
- The product is used under the instructions of the User Manual.

## ***Summary of the Manual***

### **◆ Main components**

This product is composed of Small Animal Endoscope optional accessory suction button, T type Luer adapter and waterproof cap.

### **Applications**

Applicable for small and medium animal endoscopy.

### **◆ Cautions, warnings and indicative instructions**

- 1) This product does not contain any user repairable part; the internal maintenance of the instrument must be done by technical personnel authorized by the Manufacturer.
- 2) The image processor must be plugged out before the cleaning of the product.
- 3) Operation and use of the product must be strictly in accordance with the User Manual provided by the Manufacturer.
- 4) The service life of this product depends on the environment for storing and

using it. Generally it is valid for five years if it works for no more than eight consecutive hours each day. (Please refer to the Manual for other details)

- 5) Using other accessories, sensors or cables than those provided by the Manufacturer of the equipment may lead to increased or decreased electromagnetic immunity of the equipment, thus leading to improper operations.

### ***About the Manual***

The Manual provides a detailed introduction of the use, function and operating methods of the product. Please carefully read and comprehend the contents contained before using the product to ensure the proper use of it and the safety of animals and users.

The Manual is based on the most complete configuration, and parts of the contents may not be applicable to the product you have purchased. Please contact the Company for any inquiry.

Please place the Manual near the product for easy and immediate reference when you need it.

The Manual shall be read by clinical professionals, who should have the knowledge and working experience in medical procedures, practice and terms necessary for animal endoscopy.

All the figures in the Manual only serve as a reference, and the settings or data in the figures may not be fully consistent with those seen on the actual product.



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# Description of marks

The marks on the package, back cover of the Manual or the product are described below:



Refer to the Manual



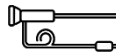
With BF type application part



Caution



Serial number



Endoscope



Lot number



Manufacturer



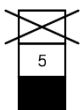
Separate handling mark of waste electrical and electronic equipment please abide by local laws and regulations)



Fragile, handle with care



Keep dry



Stacking limit by 5



This way up



Temperature limit



Humidity limitation



Atmospheric pressure limitation

# ***Essentials (description prior to use)***

## ***Instructions for Use***

This Manual contains basic information for the safe and effective use of this product. Prior to use, please carefully read this Manual and the manuals of other instruments and operate as prescribed.

Please keep all relevant manuals in safe and easily accessible place. If you have any questions or suggestions, please contact us.

This Manual describes by the top configuration. The functions are subject to the actual model.

## ***User qualification***

The operators of this product must be veterinarians that have passed the review of medical safety supervisor of the hospital, or the veterinarians that are appointed by department director according to the skill difficulty and can perform given operations safely according to official regulations.

## ***Matching devices***

Please refer to Chapter 1 “Confirmation of items in the box” and check if this product is compatible with the matching device being used. Incompatible device will cause injury to the animal or operator or damage to the device.

## ***Cleaning, disinfecting and sterilizing prior to first use/cleaning, disinfecting, sterilizing and storage after use***

The product has not gone through cleaning, disinfection or sterilization before its delivery. Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and sterilizing: Overview” to Chapter 7 “Steps of cleaning, disinfecting and sterilizing” to clean, disinfect and sterilize the product prior to the first use.

Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and

sterilizing: Overview” to Chapter 7 “Storage, handling and treatment out of hospital” to clean, disinfect, sterilize and store the product after use. Incomplete cleaning, disinfecting and sterilizing or improper storage will cause infection and result in equipment damage or reduce its performance.

## ***Backup equipment***

It is necessary to prepare backup equipment or equipment with similar functions to avoid accidents when equipment failure or function exception occurs in the operating process.

## ***Maintenance and care***

The failure rate of Small Animal Endoscope and the matching equipment increases with the operating times and accumulated operating duration. In addition to the check prior to use every time, the personnel responsible for the maintenance of medical instrument also need to regularly check the parts mentioned in this Manual. Do not use the Small Animal Endoscope if it has any exception; instead, check according to 9.1 “Troubleshooting guide”. Please contact us if there is any exception still.

## ***Improper repair and refitting prohibited***

This product doesn't contain any user repairable part; do not disassemble, refit or try to repair, or else it will lead to animal injury or equipment damage. The equipment disassembled, repaired or refitted by unauthorized technical personnel will void the warranty.

## ***Description of symbols***

This Manual uses the following symbols:

**DANGER**

Indicates emergency hazard that may cause death or serious injury.

**WARNING**

Indicates potential hazard that may cause death or serious injury.

**CAUTION**

Indicates potential hazard that may cause light or moderate injury. It is also used to prompt to avoid insecure operation or potential equipment damage.

**NOTE**

Indicate additional help information.

## **Warnings and cautions**

Please abide by the following warnings and cautions prior to use. Supplementary information is also available in subsequent chapters.

### **WARNING**

- Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and sterilizing: Overview” to Chapter 8 “Storage, handling and treatment out of hospital” to clean, disinfect, sterilize and store the product

after use. Incomplete cleaning, disinfecting and sterilizing or improper storage will cause cross infection of animals.

- Do not use high frequency electrotome to carry out electrocautery or argon plasma coagulation.
- Do not knock, impact or drop the tip, insertion section, bending section or operating section of Small Animal Endoscope; also do not bend, pull or twist the tip, insertion section, bending section or operating section, or else it will damage the Small Animal Endoscope or make the parts fall into animal's body.


### **NOTE**

- Do not perform bending operation forcibly or abruptly. Do not pull, twist or rotate angled bending section, or else it will cause injury to the animal and the bending part can't be straightened in the process of checking.
- If the bending part is angled, do not insert or pull out the insertion section of the Small Animal Endoscope, or else it will cause injury to the animal.
- The bending section only can be bent upwards or downwards. Fully consider the bending direction of Small Animal Endoscope when inserting, pulling out or operating the Small Animal Endoscope, and do not apply too much force to the left or right, or else it will cause injury to the animal.
- Do not operate the bending section, insert or pull out the insertion section of the Small Animal Endoscope, or use accessories before clear image of Small Animal Endoscope is acquired, or else it may cause injury to the animal.
- Do not operate the bending section, insert or pull out the

insertion section of the Small Animal Endoscope, or use accessories when the image is frozen, or else it may cause injury to the animal.

- Do not insert or pull out the insertion section abruptly or forcibly, or else it may cause injury to the animal.
- If it is difficult to insert Small Animal Endoscope, stop the operation, or else it will cause injury to the animal.
- Abide by the following notice during lighting.
  - Do not observe continuously, or contact living tissues for a long time with the tip of Small Animal Endoscope.
  - If any liquid enters Small Animal Endoscope, immediately remove the batteries to prevent fire and electric shock. If liquid has infiltrated into the Small Animal Endoscope, do not use it as the internal structure may have been damaged.

**CAUTION**

- Do not make the bending diameter of the insertion tube smaller than 12cm, or else it will damage the equipment.
- Do not bend the insertion section of Small Animal Endoscope forcibly, or else it will damage the insertion section.
- Do not impact the tip of the insertion section, especially the object lens surface of the tip, or else it will cause viewing failure.
- Do not twist or bend the bending section, or else it will cause equipment damage.
- Do not squeeze the bending section, or else it will cause deformation or cracking of the surface rubber and lead to water leaking.
- Using this product near the equipment with the following symbol or portable and removable RF communication devices (e.g. mobile phone) may cause electromagnetic interference. In this case, take necessary mitigation measures, e.g. adjusting orientation or position of this instrument or shield the space. 
- To check the electromagnetic interference from other equipment (any equipment other than this equipment and

the parts constituting this system), check if this system works normally in the operating environment.

- Please remove the battery if Small Animal Endoscope are not used for a long time. Otherwise, the heat produced by the battery or battery leakage may lead to fire.
- Please DO NOT open the battery/screw cap when Small Animal Endoscope are on. Otherwise, they will be damaged.

## ***Examples of improper operation***

Senior experts have the responsibility to teach the clinical technique of Small Animal Endoscope in detail. The safety of animals in the process of examination and treatment with Small Animal Endoscope is ensured by proper operation of veterinarians and reliable medical equipment. Below are some examples of improper operation.

- Inserting, pulling out or using accessories when the visual field of Small Animal Endoscope is not clear will cause injury to the animal.
- If the front tip is contacted with the mucosal surface for too long or the suction pressure is too big under a long time of suction, it leads to hemorrhage or injury.
- Inserting or pulling out Small Animal Endoscope or operating the bending section when the visual field is not clear will cause injury to the animal.

## ***LED***

The LED is built in the device and is basically safe for the eyes, but watching on the light for long time emitted by the LED may hurt the eyes. The maintenance personnel, dealers and other persons in need shall read this manual in details.

### **WARNING**

- Failure to use, control or adjust the device or perform operations according to the instructions may cause harmful radiation.

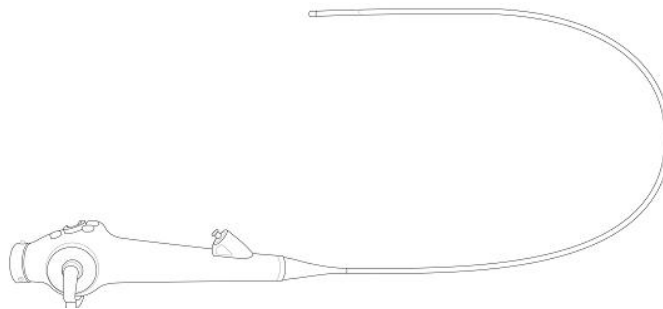
### **CAUTION**

- Avoid eye or skin exposure to direct or scattered light.

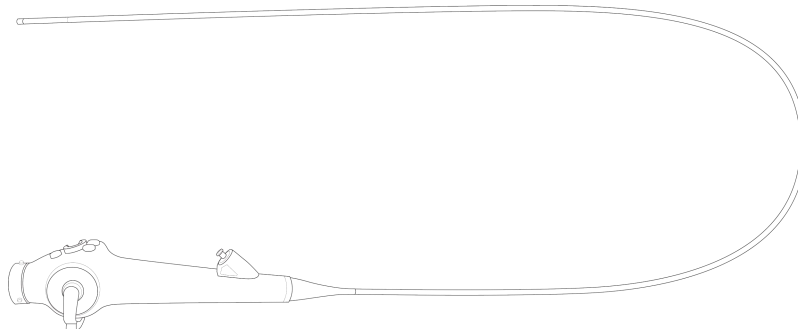
# Chapter 1 Confirmation of items in the box

Please confirm the items in the box by referring to the following pictures and check if there is any damage to any of them. Please do not use the product and immediately contact us if you find any instrument damage or part missing, or have any question. The product has not gone through disinfection or sterilization before its delivery.

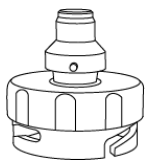
Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and sterilizing: Overview” to Chapter 7 “Steps of cleaning, disinfecting and sterilizing” to clean, disinfect and sterilize the product prior to the first use.



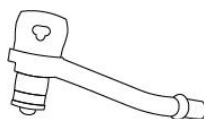
Endoscope operating part



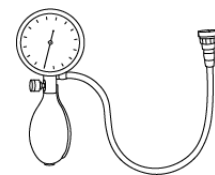
Endoscope operating part



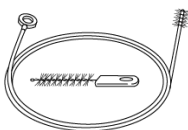
Waterproof cap



Suction button



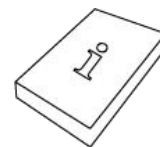
Portable air pressure leak detector



Cleaning brush



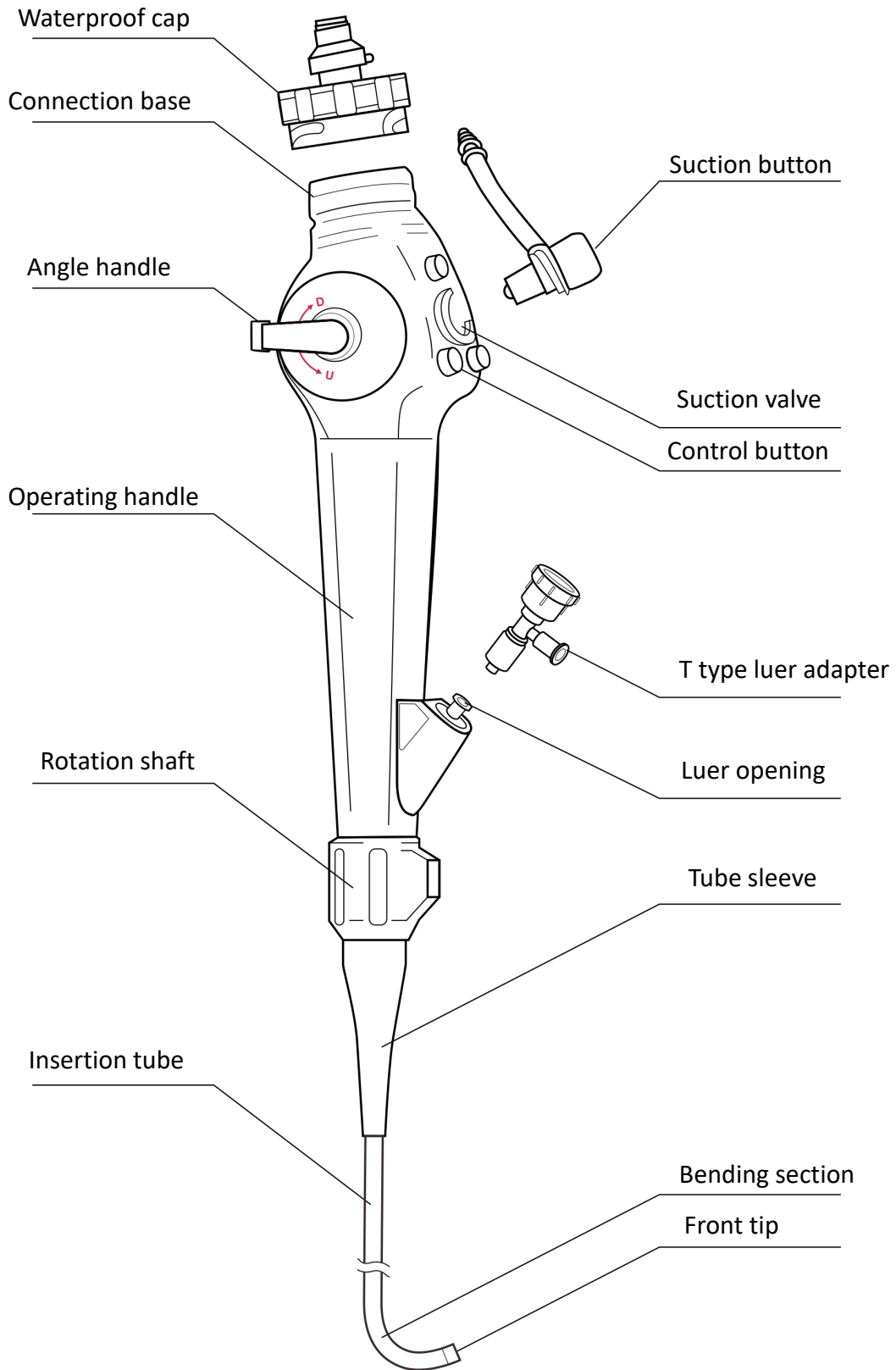
T type luer adapter



User manual

# Chapter 2 Part names and specifications

## 2.1 Part names



## **2.2 Functions of Small Animal Endoscope**

### **1. Leakage detector connecting base**

The leakage detector connecting base is used for connecting the portable air pressure leakage detector, which detects whether the operating handle leaks water.

### **2. Handle button**

The function of the handle button 1 is as follows:

-- Short press the button once for changing the displayed image size on the image processor;

The functions of the handle button 2 are as follows:

-- Short press the button once for photographing the image being displayed;

-- Long press the button for two seconds for videotaping the image being displayed, and the subsequent short pressing of the handle button for exiting this function.

The function of the handle button 3 is as follows:

-- Short press the button once for freezing the displayed image, and the subsequent short pressing of the button may unfreeze it.

### **3. Suction button**

When using the product, press the suction button for sucking and release it for stopping the suction. The button is used for removing any fluid or scrap that blocks the eyesight.

### **4. Waterproof cap**

This cap is used to seal and protect the Small Animal Endoscope.

- Remove the waterproof cap before connecting the Small Animal Endoscope to the image processor.
- The waterproof cap must be removed before disinfection with gas.

### **5. Connection base**

Connected to the waterproof cap or the video connector:

-- Connected to the waterproof cap before the liquid sterilization or the seal test on the product;

-- Connected to the video connector for transmitting image signals to image processor before the use of the product.

### **6. Angle handle**

Used to control the direction of the bend:

- When the angle handle is rotated to the "U" direction, the bending section is bent upward.
- When the angle handle is rotated to the "D" direction, the bending section

is bent downward.

#### **7. Suction base**

- Used for installing the suction button during the use of the product.
- Used for connecting the sterilizer connector during the sterilization.

#### **8. T type luer adapter**

- Used to lock the inserted instruments.

#### **9. Luer opening**

The function of the Luer opening is as follows:

- Used for the insertion of endoscope accessories or instruments.
- Used for installing the T type luer adapter.
- If necessary, an injection can be done through the direct connection with the injecting apparatus (such as an injector).

#### **10. Bending section**

The position of the endoscope tip can be adjusted by changing the vertical direction of the bending section by adjusting the angle handle.

#### **11. Front tip**

The imaging section of the endoscope and the terminal outlet of the suction opening. Prevent it from collision or pressing and keep it clean.

## 2.3 Specifications

<b>NOTE</b>
-------------

- Small Animal Endoscope is intended to be used with product image processor. Small Animal Endoscope integrates image sensor in the Front tip to obtain images, convert to electrical signals, transfer to the video processing circuit through cable, and display the real-time image on the LCD screen of image processor. This product does not contain optical fiber bundles.

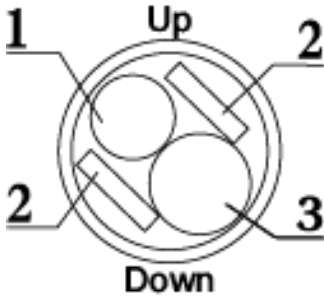
### ***Environmental conditions:***

<b>Normal operating conditions</b>	<b>Ambient temperature:</b>	15°C ~ 37°C
	<b>Atmospheric pressure:</b>	700hPa ~ 1060hPa
	<b>Relative humidity:</b>	30% ~ 85%
<b>Storage and transport</b>	<b>Ambient temperature:</b>	-47°C ~ +70°C
	<b>Atmospheric pressure:</b>	700hPa ~ 1060hPa
	<b>Relative humidity:</b>	10% ~ 95%

### ***Safety specifications***

By type of electric shock protection	/
By level of electric shock protection	Equipment with BF type application
By level of explosion protection	Equipment that is not suitable for use in places with flammable anesthetic gas
By level of protection against incoming harmful fluid	Regular equipment (sealed equipment without protection against incoming fluid)
By sterilization method	Equipment sterilized as recommended by the manufacturer
By sterilization and disinfection	See the relevant chapter in this Manual for details
By operation mode	Equipment that can run continuously
By level of mobility	Hand-held equipment

## Specification:

Model	1	2	3	4
<b>Outer diameter</b> ( $\pm 0.5\text{mm}$ )	2.8mm	3.1mm	3.8mm	5.2mm
<b>Suction channel</b> ( $\pm 0.3\text{mm}$ )	1.2mm	1.2mm	1.5mm	2.8mm
<b>Viewing angle</b> ( $\pm 15\%$ )	120°	120°	120°	120°
<b>Direction of view</b> ( $\pm 10^\circ$ )	0°	0°	0°	0°
<b>Depth of field</b>	3~200mm	3~200mm	3~200mm	3~200mm
<b>Bending angle</b> ( $\pm 15^\circ$ )	Up210°, Down130°	Up210°, Down130°	Up180°, Down130°	Up180°, Down130°
<b>Rotation angle</b> ( $\pm 10\%$ )	Left 120°, Right 120°	Left 120°, Right 120°	Left 120°, Right 120°	Left 120°, Right 120°
<b>Insertion tube length</b> ( $\pm 10\%$ )	610mm	610mm	1000mm	1000mm
<b>Front tip</b>	 <p>1. Object lens 2. LED light source 3. Working / Biopsy channel outlet</p>			

# ***Chapter 3 Preparation and examination***

Prior to each use, prepare and check the instrument as described below, and check other equipment used in conjunction with this instrument according to the provisions of Instructions for Use. If any problem is found on the equipment, refer to Chapter 9 “Troubleshooting” for troubleshooting. If the problem can’t be solved, do not use this instrument, and follow the instructions in 9.3 “Repair of Small Animal Endoscope” to return the instrument to us.

## **WARNING**

- Using malfunction Small Animal Endoscope will compromise the safety of animals and aggravate equipment damage.
- The product has not gone through cleaning, disinfection or sterilization before its delivery. Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and sterilizing: Overview” to Chapter 7 “Steps of cleaning, disinfecting and sterilizing” to clean, disinfect and sterilize the product prior to the first use.

## ***3.1 Preparing the equipment***

Prior to each use, please prepare the operating handle and personal protective equipment such as goggles, masks, waterproof clothes and protective gloves according to the actual conditions. Personal protective equipment should be of proper sized and long enough to avoid skin exposure. Please refer to the Instructions for Use of the respective equipment.

## 3.2 Checking Small Animal Endoscope

Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and sterilizing: Overview” to Chapter 7 “Steps of cleaning, disinfecting and sterilizing” to clean, disinfect and sterilize the product.

### Checking Small Animal Endoscope

1. Check the operating section for scratches, deformations, loose parts and other abnormalities.
2. Check the protective sleeve and the insertion section near the protective sleeve for bending, twisting and other abnormalities.
3. Check whether the surface of the entire insertion section including the bending section and the tip has depression, bulge, swell, scratches, holes, loosening, deformation, bending, attached foreign matters, part shedding, foreign matter protrusions and other abnormalities.
4. Hold the operating section with one hand and gently stroke the entire surface of the insertion section with the other hand in both directions (see Fig. 3.1). Make sure that there is no object or wire protruding from the insertion section. Make sure that the insertion tube is not exceptionally rigid.

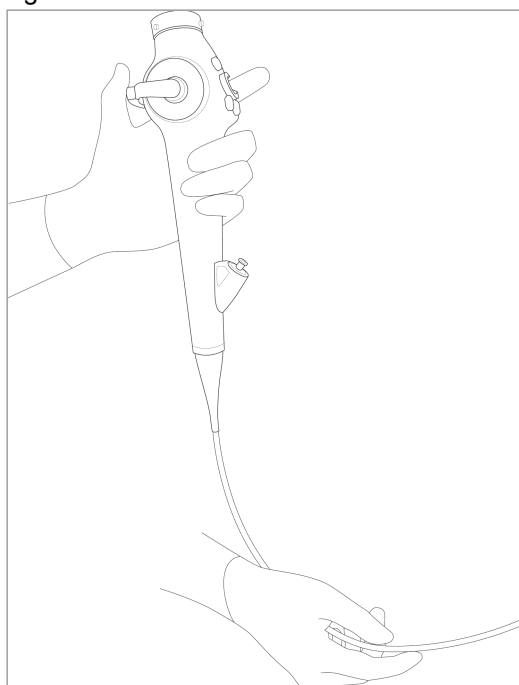


Fig. 3.1

5. Check if the surface rubber of the bending section has loosening, swell, cut, holes and other abnormalities.

6. Bend the insertion tube of Small Animal Endoscope into a semicircle with both hands. Then, move the hands as indicated by the arrows shown in Fig. 3.2 to confirm that the entire bending tube can be bent smoothly.

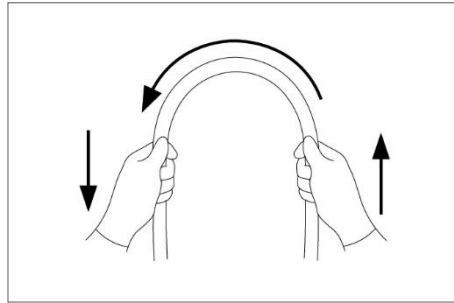


Fig. 3.2

7. Gently hold the middle and the position 10cm from the tip, gently push and pull, and make sure that the bending section and the insertion tube are connected firmly.
8. Check whether there are scratches, cracks and stains on the insertion section of Small Animal Endoscope and whether there are gaps and other abnormalities around the lens.

## ***Checking bending function***

Perform the following checks when the bending section is in extended state.

- If the angle control handle is too loose or not smooth, or the bending section cannot bend smoothly, the bending function may be abnormal. In this case, do not use Small Animal Endoscope as the bending section can't be straightened during checking.
1. Slowly rotate the up/down angle control handle to the end of each direction and then return to respective natural position. Make sure that the bending operation is smooth and normal, and can reach the maximum amplitude and restore to the natural position.
  2. As shown in Fig. 3.6, when the up/down angle control handle is moved to the natural position, make sure that the bending section can return to straight condition smoothly.

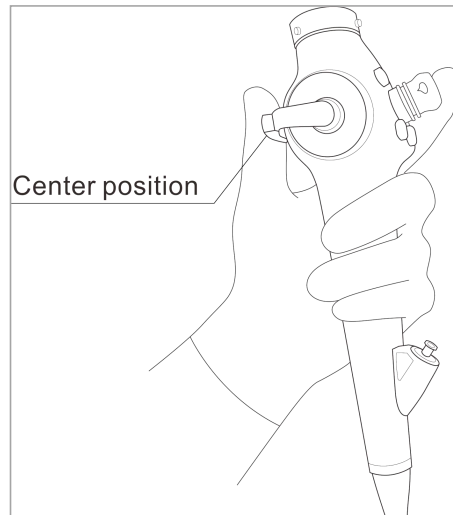


Fig. 3.6

### ***3.3 Preparing and checking accessories***

#### ***Checking and installing instrument port accessories***

Suction button (applicable only to operating handles with channels), T type luer adapter, tube fixing sleeve.

Please follow the instructions stated from Chapter 5 “Cleaning, disinfecting and sterilizing: Overview” to Chapter 7 “Steps of cleaning, disinfecting and sterilizing” to clean, disinfect and sterilize the instrument port accessories.

### ***3.4 Checking and mounting medical accessories***

#### ***Installing the suction button***

**WARNING**

- Firmly install the suction button to the suction base. If the installation of the button on the handle is incorrect, and there is gap between the button base and the top of the suction base, the button may fall off the handle, leading to the leakage of the animal’s residue, or the spill out from the gap.
- The suction button does not need to be lubricated, as the lubricant will cause the expansion of the button gasket, thus affecting the function of the button.

1. As shown in Fig. 3.10, put the suction button into the suction base, and direct the arm of the suction button at the white mark on the handle.
2. Press down the top of the suction button with your thumbs until there is a clicking sound.
3. Check to confirm that the button bottom is in close contact with the suction base, and there is no gap between the button bottom and the top of the suction base.

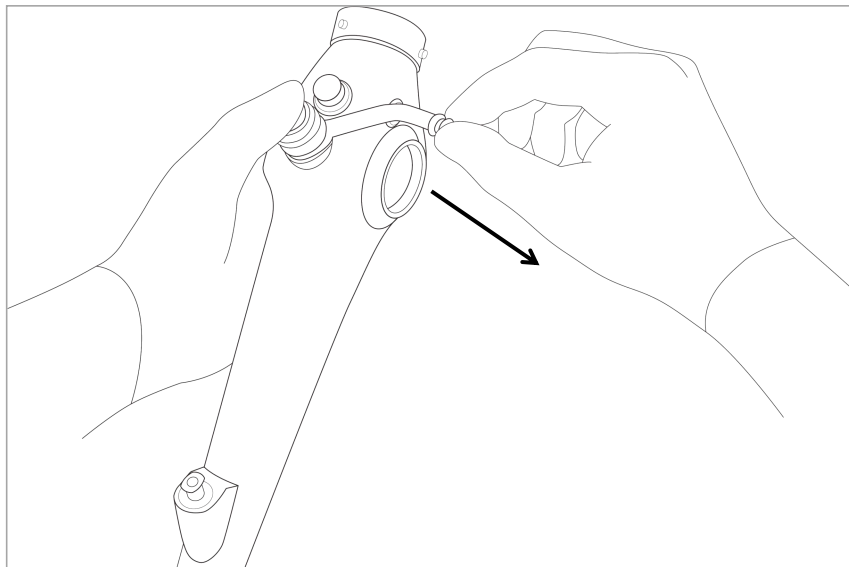


Fig. 3.10

## ***Installing the T type luer adapter***

### **WARNING**

- Incorrect installation of the T type luer adapter to the fluid feeding channel opening will lead to a decreased effect of the suction system, and result in leakage and spill out of the animal's residue, which in turn results in the risk of infection.
- If the T type luer adapter is not properly sealed, there will be no pressure difference during the suction, leading to the failure in suction.

1. install the T type luer adapter to the luer opening and insert it to the end to fix it onto the operating handle.
2. Make sure the bonnet is firmly fixed to the luer opening and well sealed.

## 3.5 Checking and connecting accessory equipment

### Connecting the operating handle and the suction pump

**WARNING**

- Firmly connect the tube of the suction pump to the connector of the suction button. Improper connection will lead to leakage of the residue out of the channel, thus resulting in the risk of infection, equipment damage or reduced suction performance.
1. As shown in Fig. 3.13, install the suction button to the suction base, and connect the tube of the suction pump to the connector of the suction button.

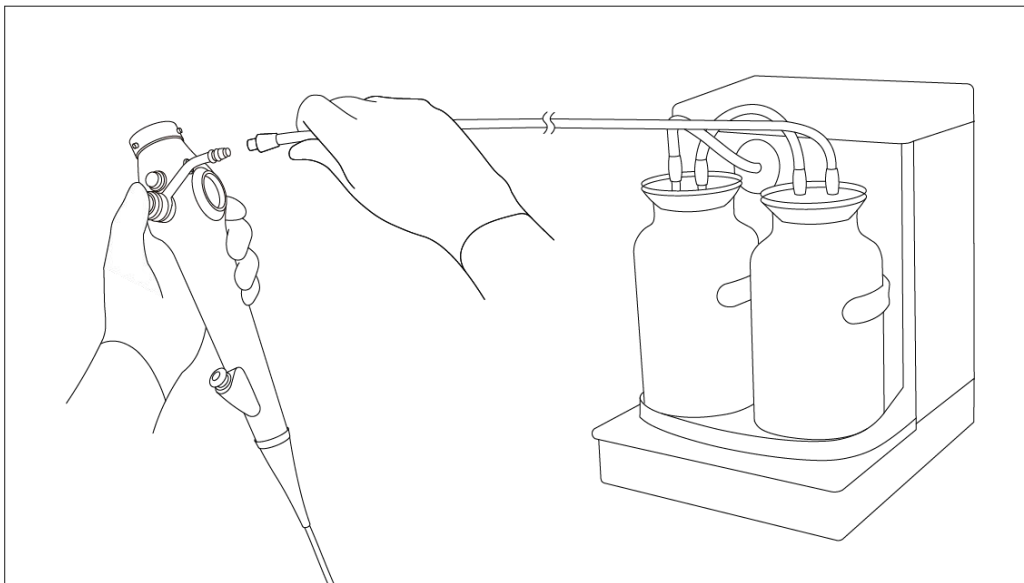


Fig. 3.13

## 3.6 Checking the Small Animal Endoscope system

### Checking the suction function

**WARNING**

- Set the negative pressure of the suction device between -35 kPa and 0 kPa. Over high suction pressure may make it difficult to stop the suction.
- If the suction button cannot be operated smoothly, please take it off and install it once again, or replace it with a new one.
- If the suction button does not work properly, please stop using the Small Animal Endoscope. Otherwise, the suction may not be able to stop, resulting in injury to the animal. If the button still cannot be operated smoothly after the re-installation or the replacement, there is probably some fault with the Small Animal

Endoscope, In that case, please stop using the system and contact with us.

1. Adjust the suction pressure to the level required for the operation.
2. Soak the front end of the Small Animal Endoscope into sterile water and press the suction button. Make sure the water can be continuously sucked into the bottle of the suction pump.
3. Release the suction button. Make sure the suction stops and that the suction button returns to the original position.
4. Take out the front end of the Small Animal Endoscope. Press the suction button to suck the air for seconds and remove all the water from the channel.

### ***Checking the water feeding through the luer opening***

1. Insert the injector filled with sterile water into the luer opening or the T type luer adapter opening (with the T type luer adapter installed), and push down the handspike.
2. Make sure water flows out of the front end.

**NOTE**

- Under the correct operation, the injector must be fully inserted and perpendicular to the injection port. An

inclined angle or incomplete insertion may lead to leakage.

- Please DO NOT press the suction button when feeding fluid. Otherwise, it will suck the water into the suction tube, instead of sending it out through the front end of the Small Animal Endoscope.
- If no fluid comes out of the front end of the Small Animal Endoscope, please inject air into the biopsy channel.

### ***Checking the biopsy channel***

**WARNING**

- Keep your eyes away from the front tip when inserting the accessories, as the accessories sticking out of the tip may hurt your eyes.

1. Insert the accessories through the luer opening. Make sure they smoothly stick out of the front tip and that there is no dirt on the tip.

2. Make sure the accessories can be smoothly drawn out of the luer opening.

## Chapter 4 Operation

This Instructions for Use does not explain or discuss any clinical operations with Small Animal Endoscope, but only describes the basic operation and precautions regarding the use of this instrument. Therefore, the operator of the instrument must be a veterinarian or medical staff under the supervision of a veterinarian, and they must have received adequate training on clinical technologies of Small Animal Endoscope.

### **WARNING**

- Surface temperature above 41°C (106°F) can cause mucosal burns. Try to use the shortest time and the appropriate distance that can meet the needs of exact observation. Do not observe statically in close distance, and do not keep the tip of Small Animal Endoscope close to the mucosa for too long.
- Do not insert or pull out Small Animal Endoscope under the following conditions, or else it will cause injury to the animal.
  - When accessories protrude from the tip of Small Animal Endoscope.
  - When the bending section is angled.
  - When Small Animal Endoscope is inserted or pulled out with excessive force.
- The bending section will only bend up or down, never bend left or right. Fully consider the bending direction of Small Animal Endoscope when inserting, pulling out or operating it, and do not apply excessive force to the left and right direction, or else it will lead to injury.
- If any of the following conditions occur during the checking, stop immediately and pull out Small Animal Endoscope from the animal's body in accordance with the contents of Section 9.2 " Pulling out exceptional Small Animal Endoscope".

- Function problem of Small Animal Endoscope is found.
- Image on the LCD screen of image processor disappears or freezes unexpectedly.
- Angle control handle is locked.
- Angle control function is abnormal.

Continued use of Small Animal Endoscope in these cases may result in injury to the animal.

**WARNING**

- If the image or function of Small Animal Endoscope is abnormal but resumes normal quickly, Small Animal Endoscope may have failure. In this case, immediately stop using Small Animal Endoscope, as the abnormalities may occur again, which may make Small Animal Endoscope unable to resume its normal state. Therefore, please stop the checking immediately, and observe the image of image processor while pulling out Small Animal Endoscope slowly, or else it will cause injury to the animal.

## ***4.1 Preparing and turning on the instrument***

1. Prepare the instrument and its accessories as described in Chapter 3.
2. When the instrument is ready, and it is well-connected with image processor, press the power button to turn image processor on and make sure that the image of the tip of SMALL ANIMAL ENDOSCOPE can be displayed on the LCD screen of IMAGE PROCESSOR.
3. Check the instrument in strict accordance with the contents of Chapter 3 to confirm that the instrument is normal.

**CAUTION**

- For abnormal instrument, refer to Chapter 9 “Troubleshooting” for troubleshooting. If the problem of SMALL ANIMAL ENDOSCOPE can’t be solved, stop using immediately, or else it will cause injury to the animal.

## ***Tip bending angle***

### **CAUTION**

- Do not apply too much force to the angle, or else the wire controlling the bending section will bear a greater load. This may cause the wire to be stretched or broken, affecting the function of the bending section.

Operate the angle control handle as needed to guide the insertion and observation of the tip.

## ***Sending fluid or cleansing***

### **WARNING**

- Please DO NOT inject too much air or non-flammable gas into the animal's body, or it will lead to air embolism.

### **CAUTION**

- Please do not press the suction button when feeding the fluid, or it will be sucked into the suction pump.

1. Make sure the suction button has been installed.

2. Open the T type luer adapter installed to the biopsy channel opening and firmly insert the injector into the injector opening.

3. Push down the injector handspike.

## ***Suction***

### **WARNING**

- Avoid sucking any solid substance or sticky fluid, or it may block the channel, the biopsy channel, the suction channel or the suction button. If the blocking occurs, or the suction cannot be stopped, take off the suction tube from the suction connector on the

suction button, close the suction pump, take off the suction button and remove the blockage.

### **CAUTION**

- Please do the suction with the minimum suction pressure required for
- completing the examination. Too much suction pressure will lead to the suction of mucosa, or result in injury to the mucosa. In addition, the animal's fluid may leak or spill out of the biopsy channel opening, resulting in the risk of infection.

- Please install the T type luer adapter to the main body during the suction. Failure to block the clamping tube opening may weaken the effect of the Small Animal Endoscope suction system, and may lead to the animal's residue or fluid leaking or spilling out, bringing in the risk of infection.
- Do not fully inject the suction bottle during the examination, or it will lead to faulty functions of the suction pump.

As shown in Fig. 4.1, press the suction button to carry out the suction, the excess fluid at the front tip or other residues that block the view of the video Laryngoscopes will be sucked away.

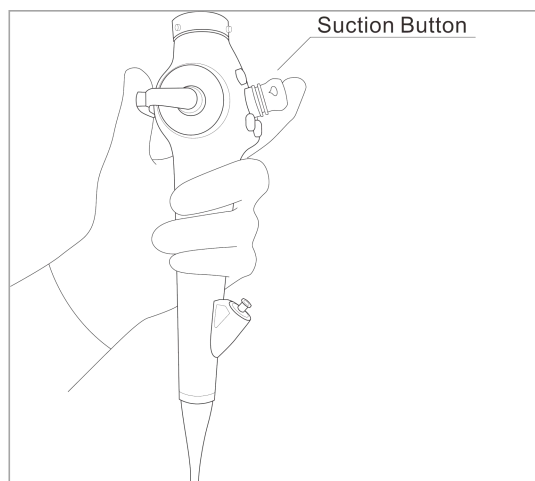


Fig. 4.1

## ***Insertion of the endoscope***

If necessary, apply a medical grade, water-soluble lubricant to the insertion tube.

### **CAUTION**

- Do not apply olive oil or products containing petroleum-based lubricants (e.g., Vaseline). These products may cause stretching and deterioration of the bending section's covering.
- Do not allow the insertion tube to be bent within a distance of 10 cm or less from the junction of the boot. Insertion tube damage can occur

## ***If the access sheath is used***

Refer to the instruction manual of access sheath.

### **CAUTION**

- Do not insert or withdraw the endoscope from the sheath while the bending section is angulated, and

do not perform angulation control while the bending section is in the sheath. Otherwise, the insertion tube could be damaged.

- Use a sheath with an proper inner diameter that is larger than the insertion tube outer diameter. Forcibly inserting the insertion tube into a sheath that is too small could damage the insertion tube.

## ***Insertion tube operation***

### **WARNING**

- Before operating the angulation control lever, make sure to check the position of the knob indicator of the insertion tube knob and the insertion tube. Otherwise, the bending section may bend to a different direction as intended and animal injury, bleeding, and/or perforation could result.

### **CAUTION**

- Do not apply excessive force (especially twisting force) to the insertion tube knob. Otherwise, the knob can be damaged which will make it impossible to free the insertion tube.
- Once the insertion tube and the insertion tube knob hits against the stopper, do not apply excessive additional force. Otherwise the knob and the insertion tube can be damaged, which makes it impossible to free the insertion tube.
- Do not turn the insertion tube by holding the insertion tube, always hold the boot when turning the insertion tube.
- Do not turn the insertion tube with excessive force when the insertion tube indicator is set to the Instrument channel opening indicator on the control section . The insertion tube could be damaged .

1. Turn the insertion tube knob until its knob is aligned with the “Middle” indicator on the control section.

2. Turn the insertion tube as necessary to guide the endoscope for insertion and observation while holding the boot in the hand.

3. The maximum angle of the Up / down rotation of the insert tube are Up210° and down130°, turn the insertion tube until the knob on the control section to return the insertion tube to the neutral position after using the endoscope .

## 4.2 Using accessories

Please refer to Chapter 1 “Confirmation of items in the box” for details on the use of this instrument and dedicated accessories.

### WARNING

- Please DO NOT use the equipment with the high-frequency electric knife, or use it for laser therapy or argon plasma coagulation therapy. The product is not applicable to those treatments, or it will damage the Small Animal Endoscope and lead to injury to the animal.
- When using accessories, keep the distance between the tip of Small Animal Endoscope and the mucous membrane greater than the minimum visual distance of Small Animal Endoscope in order to observe the accessories in the master unit image of image processor. If the tip is placed within the minimum visual distance, the accessories will be invisible in the master unit image of image processor, resulting in severe injury to the animal or equipment damage. The minimum visual distance of the equipment is 3mm.
- When inserting or pulling out an accessory, make sure that the accessory tip is closed or fully retracted into the sheath. Slowly insert or retract the accessory into the seam of the instrument channel opening. Failure to do so may result in damage to the instrument channel opening and part dropping.
- If it is difficult to insert or pull out the accessory, please straighten the bending section as much as possible without the image of image processor disappearing. Inserting or pulling out with excessive force can cause damage to biopsy channel or accessories and part dropping, or injury to the animal.
- If the tip of the accessory is not visible in the display window of image processor, do not open the tip of the accessory or extend the tip of the instrument. This can result in injury to the animal or equipment damage.

### CAUTION

- When using a biopsy forceps with a needle, make sure that the needle is not overly bent. The bent needle protrudes from the closed biopsy forceps. Using biopsy forceps with needle protruding can damage the biopsy channel or cause injury to the animal.
- When injection needle is used, it is only possible to extend the needle from or retract it to the sheath when the needle is extended from the tip of the Small Animal

Endoscope. If the needle protrudes from the inside of the biopsy channel, or if the syringe is inserted or pulled out when the needle is extended, the needle may damage the biopsy channel opening.

## ***Accessory operation***

Operate the accessories of Small Animal Endoscope according to their respective Instructions for Uses.

## ***Pulling out accessories***

### **WARNING**

- When an accessory is pulled out from the endoscope channel opening, the animal debris may be splashed. You can cover around the accessory and endoscope channel opening with gauze to prevent splashing.
- Do not remove the accessory if the accessory tip is open or protrudes from the sheath, or else it may result in injury to the animal or equipment damage.
- Please pull the accessories out of the biopsy channel opening in a slow manner and along the vertical direction. Otherwise, it will damage the gap or small hole of the opening, which will reduce the effect of the Small Animal Endoscope suction system, leading to the animal's residue or fluid leaking or spilling out, bringing in the risk of infection.
- If the accessory can't be pulled out from Small Animal Endoscope, close the accessory or retract it into the sheath, and then pull out Small Animal Endoscope and the accessory carefully while observing the image on the LCD screen of image processor. Be careful to avoid damaging cavity tissue of the body.

Close the accessory tip or retract it into the sheath and then pull out the accessory slowly.

## ***Using the injector to lavage***

### **CAUTION**

- Incorrect installation direction or incomplete installation may lead to the fluid leaking out of the biopsy channel opening.
1. Firmly insert the injector filled with lavage fluid (such as saline) into the biopsy channel opening, and press down the injector handspike to inject the lavage fluid (as shown in Fig. 4.6 (a)).
  2. After installing the injector, slowly pull out the handspike to suck the lavage fluid (as shown in Fig. 4.6(b)).

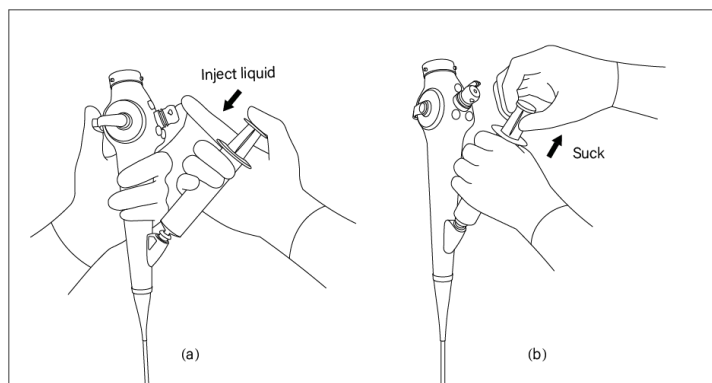


Fig. 4.6

### 4.3 Pulling out the Small Animal Endoscope

**WARNING**

- If the surface of the insertion section is stained with blood when Small Animal Endoscope is pulled out, the animal should be examined carefully.
- If you can't pull out Small Animal Endoscope smoothly from the animal's body, do not apply too much force, or else it may cause injury to the animal.

1. Press the suction button to suck blood, mucus or other residues.
2. Observe the image on the LCD screen of image processor while slowly taking out the Small Animal Endoscope. Take the guiding tongue piece out of the animal's mouth if it is used.
3. Press the power button of image processor, turn off the Small Animal Endoscope, and turn off the matching equipment.

## Chapter 5 Cleaning, disinfecting and sterilizing: Overview

### 5.1 Key points for cleaning, disinfection and sterilization

Medical literature has recorded reports of cross-infection caused by improper cleaning, disinfection or sterilization. It is strongly recommended that all personnel engaged in cleaning, disinfection or sterilization must operate carefully according to the instructions for use of this manual and the instructions for use of all ancillary equipment and fully understand the following:

- Occupational health and safety regulations in the hospital
- Cleaning, disinfection and sterilization procedures for individual equipment

- Structure and operation of Small Animal Endoscope
- Use of chemicals

Please make a judgment from a professional point of view for the type and conditions of the cleaning, disinfection and sterilization methods used.

Please refer to the cleaning, disinfection and sterilization standard of your country/region. Contact local health authorities for local standards and regulations.

## 5.2 Precautions

### **WARNING**

- If Small Animal Endoscope isn't effectively cleaned, disinfected and sterilized after each examination, it will endanger the safety of animals. In order to reduce the risk of cross-infection, thoroughly clean Small Animal Endoscope and then disinfect or sterilize in accordance with Chapter 7 "Steps of cleaning, disinfecting and sterilizing" after each examination. The external surface and all channels of Small Animal Endoscope should be cleaned, disinfected and sterilized.
- All channels of Small Animal Endoscope must be cleaned, disinfected or sterilized during each cleaning, disinfection and sterilization process, even if some of the channels hadn't been used by the previous animal. Otherwise, the improper cleaning, disinfection and sterilization of Small Animal Endoscope may cause infection to the next animal or operator who uses Small Animal Endoscope.
- If Small Animal Endoscope is not thoroughly cleaned, it can't be effectively disinfected or sterilized. Before disinfection or sterilization, cleaned Small Animal Endoscope and accessories thoroughly in order to remove the microorganisms or organic matters that affect the disinfection or sterilization effect.

### **CAUTION**

- Before using the cleaning machine of Small Animal Endoscope, make sure that it is able to clean, disinfect and sterilize Small Animal Endoscope and all channels. If you are not sure, please contact the manufacturer to confirm the specific instructions or connector information. Improper cleaning, disinfection and sterilization of Small Animal Endoscope may cause infection to the next

animal who uses Small Animal Endoscope.

- This Instructions for Use specifies chemicals suitable for cleaning, disinfecting and sterilizing, and can be used in combination with Small Animal Endoscope, as well as those chemicals that can't be used in combination with Small Animal Endoscope, and cleaning machine. For chemicals and Small Animal Endoscope cleaning and disinfection machines that are not available in this manual, please contact us or designated service centers and sales representatives. Improper use of chemicals or Small Animal Endoscope cleaning and disinfection machines will damage Small Animal Endoscope. When using these chemicals and the cleaning and disinfection machines, please follow respective Instructions for Use. We can't ensure the cleaning, disinfection and sterilization effects of these chemicals and Small Animal Endoscope cleaning and disinfection machines. Please contact the manufacturers of the disinfectants and Small Animal Endoscope cleaning and disinfection machines.
- Animal debris and chemicals for cleaning, disinfection and sterilization are dangerous. Wear personal protective equipment such as goggles, masks, waterproof clothes and protective gloves to protect against encroachments of dangerous chemicals and potentially contaminated substances during cleaning, disinfection and sterilization.
- Be sure to rinse the chemicals thoroughly. Use deionized water (Aq.Dest.) to thoroughly rinse the surface of Small Animal Endoscope, all channels and the cleaning equipment to remove any residual chemicals.
- The room of cleaning and disinfection must be ventilated. Full ventilation helps prevent the accumulation of harmful chemical vapor.
- Store alcohol in a sealed container. It is easy to cause a fire and will become invalid due to volatilization if it is stored in open container.
- Before manual cleaning, ensure that Small Animal Endoscope has been checked for leakage; if leakage is detected, do not use Small Animal Endoscope, or else it may cause sudden disappearing of image, bending function damage or other malfunctions.
- Before each use, make sure that the equipment has been properly cleaned, disinfected or sterilized. If it is found that the equipment hasn't been properly cleaned, disinfected, sterilized, it should be cleaned, disinfected and sterilized again according to the instructions in this

manual.

- The cleaning, disinfecting and sterilization methods described in this Instructions for Use can't eliminate or inactivate the pathogenic substances of Creutzfeldt-Jacob disease (CJD). To use this product on animals with CJD or variant CJD (vCJD), ensure that appropriate measures will be taken immediately after using this product. For methods of handling CJD, follow the regulations in your country.
- This equipment is not a durable product or does not have the durability specified in the regulations that violate the destruction or protection site of each country. Please contact us for information on the durability of each method. If you have taken the cleaning, disinfection and sterilization methods not mentioned in this manual, we can't guarantee the efficacy, safety and durability of this product. Make sure that the equipment is free from exceptions and use it under the direction of the veterinarian. Do not use malfunctioning equipment.

# ***Chapter 6 Suitable cleaning, disinfection and sterilization methods and chemicals***

## ***6.1 Compatibility overview***

The materials and structures used by Small Animal Endoscope may not be suitable for certain methods of cleaning, disinfection and sterilization. We discern whether it is an effective method based on the following two points.

### ***Microbial efficacy***

If it is declared that this method has been “certified” on microbial efficacy, the standard method described in this Instructions for Use can successfully clean, disinfect and sterilize this instrument.

### ***Material durability***

If it is declared that this method has been “verified” on the durability of the material, it can be used to carry out repeated cleaning, disinfection and sterilization. Verified durability of the material only does not indicate that the efficacy of microbial level has been certified.

## ***Selecting cleaning, disinfection and sterilization methods***

The organization using the product shall select the actual cleaning, disinfection and sterilization method in accordance with national and local regulations, and the method shall be determined by the disinfection control committee of the hospital.

Please contact your local infection control institution to determine the appropriate cleaning method for the specified instrument.

### ***Monitor***

Check and certify the cleaning, disinfection and sterilization methods of reusable instruments in accordance with national and local regulations and record the cleaning, disinfection and sterilization results at regular intervals or procedures.

Although no biological indicator is available to confirm the disinfection process, the test strip can be used to monitor the concentration of the disinfectant. Monitoring

the concentration of daily used agents ensures that the solution is not below the effective concentration.

In order to monitor the sterilization process, appropriate biological or chemical indicators should be used.

## ***Compatible methods and list of chemicals***

The cleaning, disinfection and sterilization methods and agents listed in this table have been validated in Small Animal Endoscope and its accessories.

	multienzyme cleaning solution	O-phthalaldehyde (OPA)	2% glutaraldehyde	Ethylene oxide gas sterilization
<b>Operating section</b>	○	○	○	○
<b>T type luer adapter</b>	○	○	○	○
<b>Suction button</b>	○	○	○	○
<b>Leak detector</b>	○ <sup>*2</sup>	○ <sup>*2</sup>	○ <sup>*2</sup>	-
<b>Channel cleaning brush</b>	■	■	■	-
<b>Channel port cleaning brush</b>	■	■	■	-
<b>Accessory cleaning brush</b>	■	■	■	-
<b>Channel flusher</b>	■	■	■	■

○ Compatible    — Incompatible    ■ Compatible, efficacy unacknowledged

Table 6.1

\*1 This product is compatible with some commercially available cleaning/disinfecting machines. For details, please refer to the Instructions for Use of the disinfecting machine.

\*2 Only the channel fittings and joints of the leak detector can be immersed.

### **WARNING**

- Do not use steam sterilization (high temperature autoclave) for the Small Animal Endoscope, as it may damage Small Animal Endoscope.

## ***6.2 Washing liquid***

Use medical low foam detergent (neutral detergent or enzyme detergent) and follow the manufacturer's recommended dilution method and temperature.

### **WARNING**

- Excessive foam of washing liquid will prevent full contact of the liquid and the cavity (e.g. channels), which reduces the cleaning effect.
- Use certified detergents in accordance with national and

local regulations. Insufficient cleaning agent may result in an infection risk.

- Do not reuse the washing liquid.

**CAUTION**

- Only use the washing liquid that the compatibility with Small Animal Endoscope cleaning equipment has been confirmed by the manufacturer and has been certified by the authorities. Incompatible detergents can cause significant damage to Small Animal Endoscope and accessories.

## 6.3 Disinfectant

Under normal circumstances, 2% glutaraldehyde and O-phthalaldehyde (OPA) solution is suitable for Small Animal Endoscope according to the manufacturer's instructions. If the disinfectant is used repeatedly, its effectiveness should be checked regularly with the test paper recommended by the manufacturer. Do not use any expired solution.

**WARNING**

- Do not use Small Animal Endoscope disinfected with alcohol for examination.

**CAUTION**

- Only use the disinfectants that the compatibility with Small Animal Endoscope cleaning equipment has been confirmed by the manufacturer and has been certified by the authorities. Incompatible disinfectants can cause significant damage to Small Animal Endoscope and accessories.
- For information on concentration, temperature and immersing time, refer to the instruction manual of the disinfectant manufacturer. Do not exceed the level specified by the manufacturer.

## 6.4 Flushing water

Flushing water should be sterile deionized water (Aq. Dest.) complying with EN 285 standard or treated water (such as filtration) that the quality of microorganisms has been improved. If you rinse with non-sterile water after manual, gently wipe the endoscope and rinse the channels with 70% ethanol, then allow the channels to dry to avoid residual bacteria. The quality of the water selected by the organization shall be confirmed by national and local regulations and the infection control

committee of the hospital.

**WARNING**

- Do not use tap water to rinse the equipment due to possible chlorination.
- Do not reuse flushing water.

## **6.5 Ethylene oxide gas sterilization**

This Small Animal Endoscope and other accessories listed in Table 6.1 are suitable for ethylene oxide gas sterilization (note: the waterproof cap of the operating section must be removed before gas disinfection) and ethylene oxide gas sterilization and ventilation can be carried out under the parameters specified in Table 6.2. Ethylene oxide gas sterilization should comply with the cleaning, disinfection and sterilization regulations of the hospital, and the Instructions for Use of sterilization equipment.

**WARNING**

- Before sterilization, the equipment must be thoroughly cleaned and dried to remove microbes and organic substances. Residual debris or water vapor will reduce the sterilization effect.
- Sterilization effect depends on a variety of factors, such as packing or placing of sterilization equipment, placement methods and load in sterilization equipment. Use a biological or chemical indicator to confirm the sterilization effect, and follow the guidelines for sterilization and operating instructions for sterilization equipment issued by medical authorities, public organizations or medical institutions.
- Proper ventilation is required for all equipment after ethylene oxide gas sterilization in order to remove the residual harmful ethylene oxide gas.
- Ethylene oxide gas is toxic and may be hazardous to health. Please follow applicable domestic medical regulations.
- Use a package suitable for ethylene oxide gas sterilization, or else it may reduce the effect of sterilization.

**CAUTION**

- Exceeding recommended parameters may cause damage to the equipment. Do not exceed the parameter range listed in Table 6.2.
- Before ethylene oxide gas sterilization, the waterproof cap should be removed from Small Animal Endoscope. If not,

the air in the Small Animal Endoscope may expand, resulting in damage to the surface rubber of bending section or the angle control function.

- Do not seal Small Animal Endoscope together with other devices in the package, or else it will damage the Small Animal Endoscope.

## 6.6 Conditions for ethylene oxide gas sterilization

Processing stage	Parameters	Values
<b>Sterilization</b>	Temperature	55°C (130°F)
	Vacuum (absolute pressure)	0.05-0.07 MPa (7.25-10.15 psia)
	Relative humidity	50-80%
	Ethylene oxide gas concentration	0.735-0.740 mg/cm <sup>3</sup> (735-740 mg/L)
	Sterilization time	60 minutes
<b>Ventilation</b>	Minimum ventilation parameters	12 hours at 50-57°C (122-135°F) in ventilation chamber or 7 days at room temperature

Table 6.2

# ***Chapter 7 Steps of cleaning, disinfecting and sterilizing***

## **WARNING**

- All channels of the Small Animal Endoscope must be cleaned and disinfected or sterilized during each cleaning, disinfection and sterilization treatment, even if some of the channels hadn't been used by the previous animal. Otherwise, the improper cleaning, disinfection and sterilization of the Small Animal Endoscope may cause infection to the next animal or operator who uses the Small Animal Endoscope.

## **CAUTION**

- Do not make the bending diameter of the insertion section of the Small Animal Endoscope less than 12cm, or else it may cause damage to the equipment.
- For proper cleaning, sterilization, and disinfection, do not make the bending diameter of the insertion section less than 40cm, or else it will be difficult to insert the channel cleaning brush, resulting in damage to the biopsy channel or unthorough cleaning.
- When the channels of the Small Animal Endoscope are ventilated or laved, the air pressure or water pressure should not exceed 0.2MPa. Excessive pressure can damage the Small Animal Endoscope
- Before immersing the Small Animal Endoscope in detergent or disinfectant, make sure that the leakage cover has been mounted on the Small Animal Endoscope, or else the water will penetrate the Small Animal Endoscope and cause damage.

This chapter includes the steps of cleaning, disinfecting and sterilizing the Small Animal Endoscope, which are associated with animal safety and health. Refer to Section 7.12 "Maintenance steps of cleaning, disinfection and sterilization accessories" for the maintenance steps of cleaning, sterilizing and disinfecting medical equipment.

## 7.1 Required cleaning, disinfecting and sterilizing equipment

### Preparing equipment

Before cleaning, disinfecting or sterilizing, prepare the equipment shown in Table 7.1.

**WARNING**

- Use a basin with a size at least 50cm×50cm (20"x 20") and a depth sufficient to completely immerse the electronic entire Small Animal Endoscope. If the Small Animal Endoscope can't be immersed completely, it may reduce the cleaning, disinfection and sterilization effect.

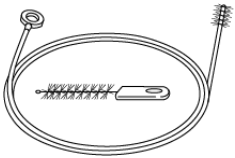
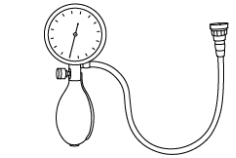
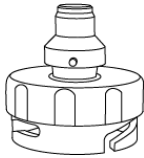
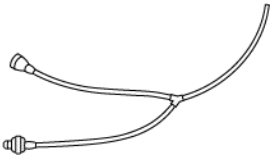
Items in the box	Picture	Items in the box	Picture
Channel cleaning brush		Portable air pressure leak detector	
Waterproof cap		Channel flusher (applicable to models with channels)	
Personal protective equipment		Sterile water (sterile water rinse)	
500cm <sup>3</sup> (500ml) container		70% ethanol or isopropyl alcohol (non-sterile water rinse)	
Soft hair brush		Clean lint-free cloth, or paper towel	
Flushing water		Sterile lint-free cloth	
Washing liquid		Sterile cotton swab	
Disinfectant		30 cm <sup>3</sup> (30ml) syringe	
A basin with a cap, of a size at least 40cmx40cm (16"x 16")		A basin with a cap, of a size at least 30cmx30cm (12"x 12")	
Deionized water (Aq.Dest)		Small basin	

Table 7.1

## ***Parts and functions of cleaning, disinfection and sterilization equipment***

For inspection of other equipment not mentioned below, refer to respective Instructions for Use.

### ***Waterproof cap***

1. When carrying out ethylene oxide gas sterilization, the waterproof cap must be removed from the operating section interface (as shown in Fig. 7.1).

2. When carrying out liquid sterilization, the waterproof cap must be mounted on the operating section interface.

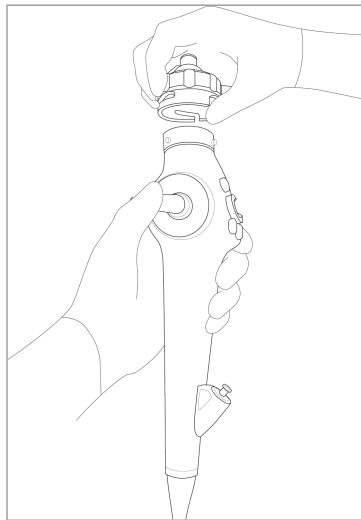


Fig. 7.1

### ***Channel flusher***

The Channel flusher is used for irrigating the cleaning, disinfecting and sterilizing fluid through the injection channel and the suction channel, and eliminating fluid from channels (as shown in Fig. 7.2).

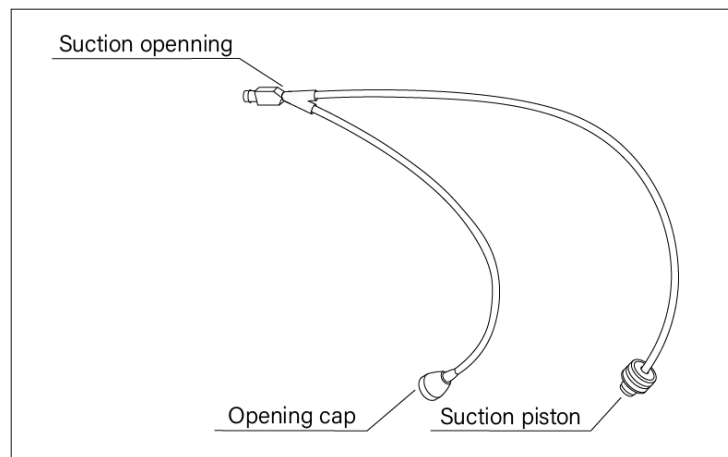


Fig. 7.2

## ***Channel cleaning brush***

The channel cleaning brush is used to brush the channels (as shown in Fig. 7.3).

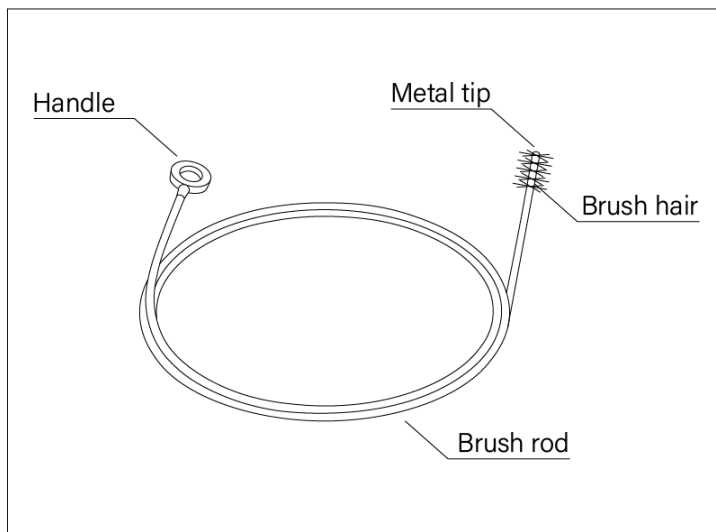


Fig. 7.3

### **WARNING**

- Do not use channel cleaning brush for cell tissue sampling, or other diagnostic purposes, or else it may result in injury, cross infection or equipment damage.

## ***Channel opening cleaning brush***

The channel opening cleaning brush is used to clean the instrument channel opening (as shown in Fig. 7.4).

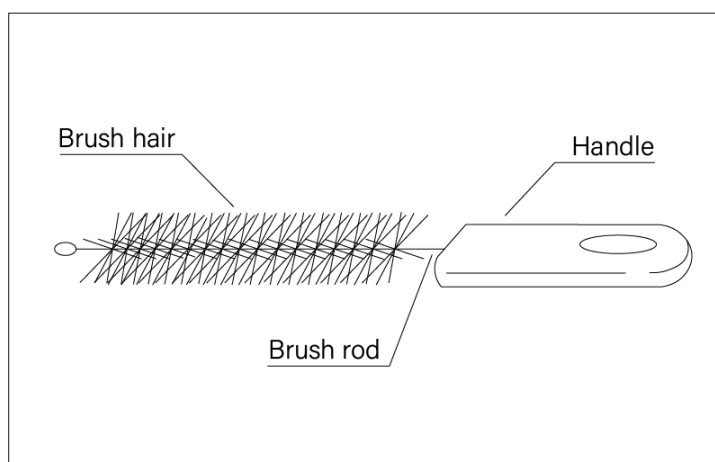


Fig. 7.4

## ***Leak detector***

When the Small Animal Endoscope is tested for leaks, mount the leak detection cover on the connector of the leak detector and press the airbag to check for leaks (as shown in Fig. 7.5).

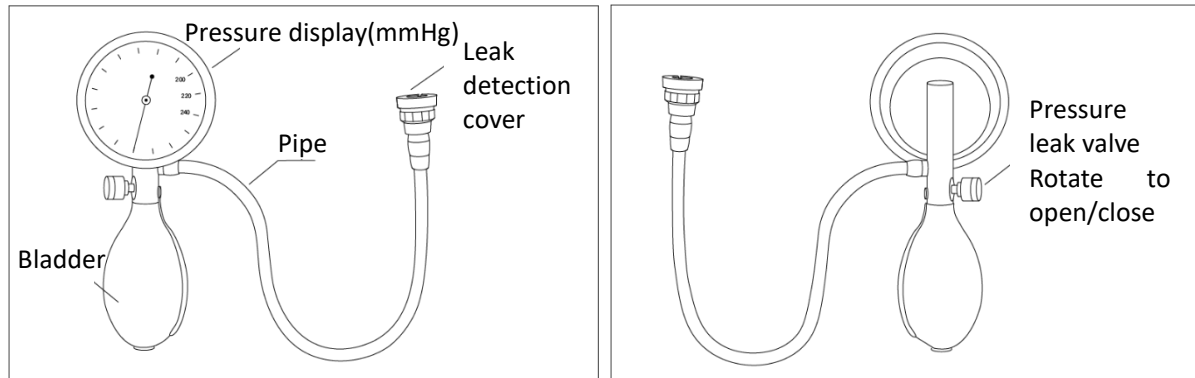


Fig. 7.5

## ***Checking reusable equipment***

For inspection of other instruments not mentioned below, refer to respective Instructions for Use.

### **WARNING**

- All of the instruments mentioned below are consumables. If any problems are found, use a backup device. Using defective devices will make it difficult to effectively clean, disinfect and sterilize the Small Animal Endoscope and cause damage to the Small Animal Endoscope or other equipment.

## ***Checking waterproof cap***

Make sure that the waterproof cap is free of scratches, cracks and debris (as shown in Fig. 7.1).

## ***Checking Channel flusher***

Check for seams, scratches, cracks, debris, and other damage (as shown in Fig. 7.2).

## ***Checking channel cleaning brush and channel opening cleaning brush***

1. Make sure that the brush tip and the metal tip are securely connected and check if the brush hair are loose or peeled off.

2. Check the brush rod for bending, scratches and other damage.
3. Check if the brush rod or brush hair is stained with debris.

## ***Checking leak detector***

1. Check for seams, scratches, cracks, debris, and other damage (as shown in Fig. 7.6).
2. Press the bladder to confirm that the leak detector discharges air from the joint (as shown in Fig. 7.6).

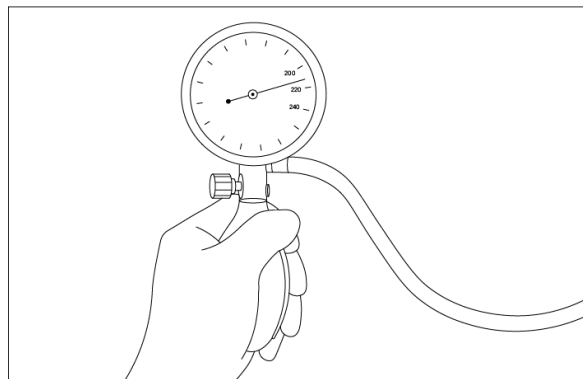


Fig. 7.6

## ***Inspection of single-use equipment***

### **WARNING**

- All equipment mentioned below is single-use only. Do not clean, disinfect or sterilize the equipment prior to use and/or after use, or it may damage the equipment. Using damaged equipment may make it difficult to effectively reprocess the endoscope, and could cause endoscope and/or equipment damage.
- Do not store the equipment outside its packaging, or it would damage the equipment. Before use, inspect the bristles for any damage. If the bristles are crushed, gently straighten them with your fingers. Using a brush with crushed bristles may make it difficult to effectively reprocess the endoscope.
- Before use, inspect the equipment for any irregularity. Should any irregularity be observed, use a spare instead. Using defective equipment may make it difficult to effectively reprocess the endoscope, and could cause endoscope and/or equipment damage

## ***Inspection of the single-use channel opening cleaning brush***

1. Open the packaging right before use (as shown in Fig. 7.7).
2. Check for loose or missing bristles.
3. Check for bends, scratches and other damage to the shaft.
4. Check for debris on the shaft and/or in the bristles of the brush.

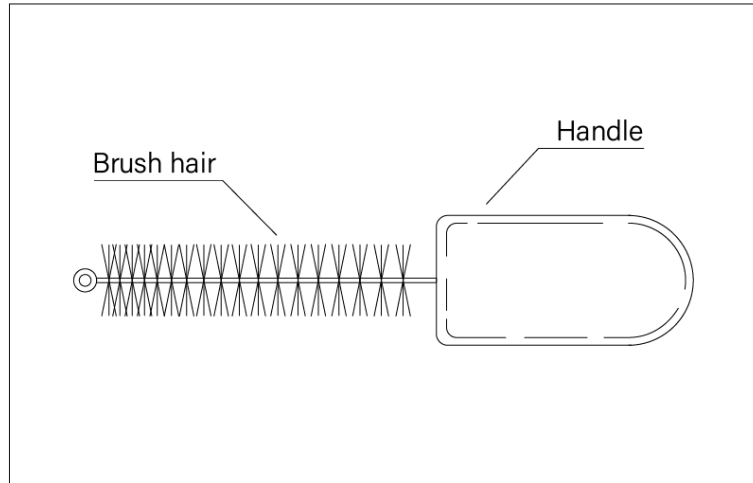
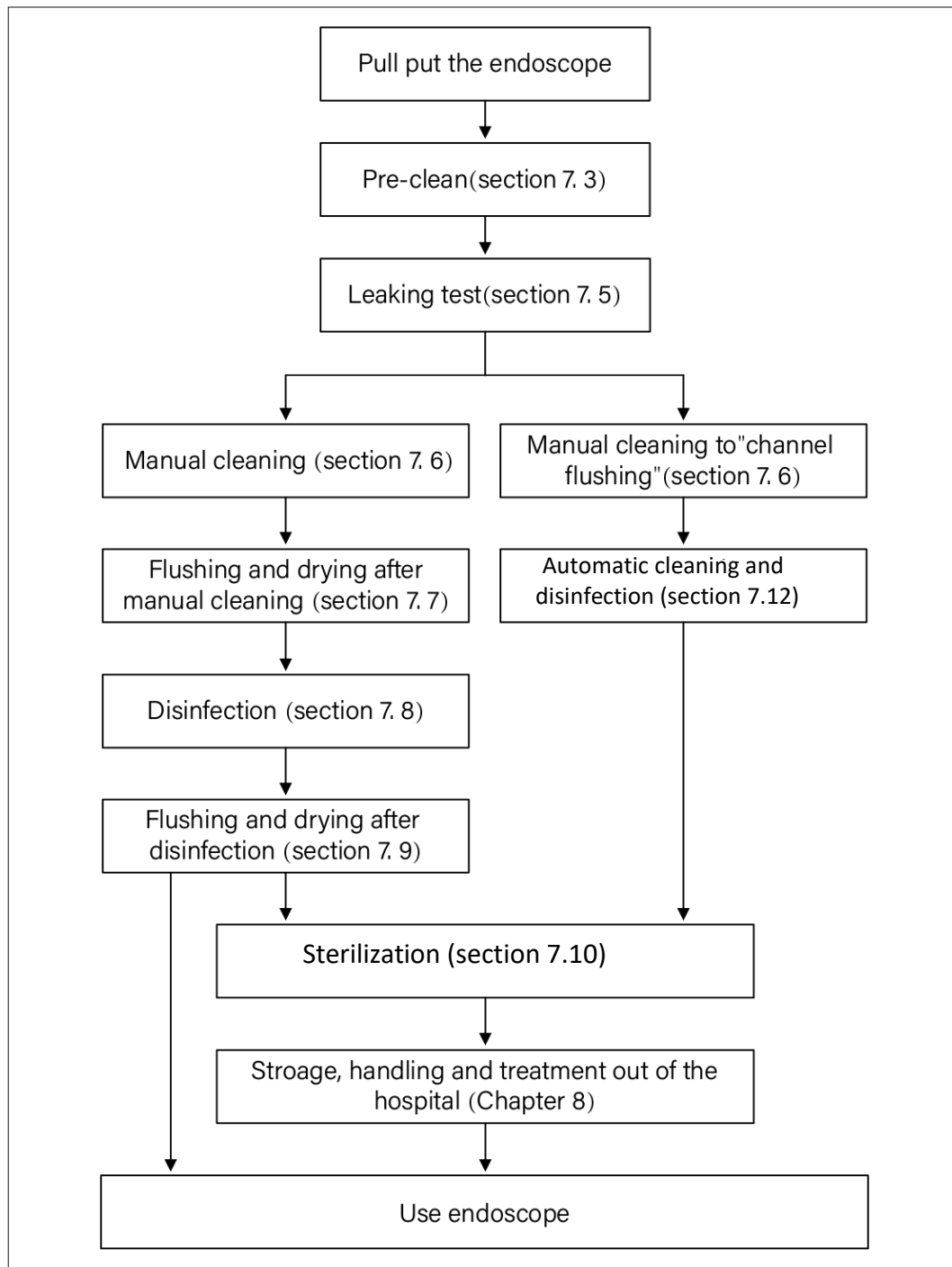


Fig. 7.7

## 7.2 Cleaning, disinfection and sterilization steps

After use, follow the steps below to clean, disinfect and sterilize the Small Animal Endoscope.

### **Cleaning, disinfection and sterilization steps of the Small Animal Endoscope**



Select whether to use sterilized or sterilized methods in accordance with all applicable national and local laws and regulations.

**WARNING**

- All channels of the Small Animal Endoscope must be cleaned, disinfected and sterilized during each cleaning, disinfection and sterilization treatment. Otherwise, the improper cleaning, disinfection and sterilization of the Small Animal Endoscope may cause infection to the next animal or operator who uses the Small Animal Endoscope.
- Do not skip any of the steps described below, or else it may cause infection.
- Do not store disinfected devices. Use it immediately after disinfection or send it to sterilization room. To use stored instruments, please refer to local regulations and guidelines.
- Do not immerse the equipment in any liquid for more than 60 minutes, or else it will cause function failure of the Small Animal Endoscope.
- If the local regulations/guidelines require disinfection before sterilization, complete the steps in or Section 7.8 “Disinfection” before sterilization treatment.

## ***7.3 Pre-cleaning***

### ***Washing***

**WARNING**

- If the Small Animal Endoscope isn’t cleaned immediately after each operation, the residual tissue debris will solidify, making it difficult to effectively clean, disinfect and sterilize the Small Animal Endoscope.

The Small Animal Endoscope should be pre-cleaned immediately after each inspection.

### ***Required equipment***

Prepare the following equipment

- Personal protective equipment
- Clean lint-free cloth

- 500cm<sup>3</sup> (500ml) container
- Detergent
- Deionized water (Aq.Dest.)
- 30cm<sup>3</sup> (30ml) syringe

## ***Preparation***

1. Wear suitable personal protective equipment.
2. Turn off the instrument.
3. Remove the master unit and battery of image processor from Small Animal Endoscope.
4. Prepare the washing liquid in a 500cm<sup>3</sup> (500 ml) container at the recommended temperature and concentration of the detergent manufacturer.
5. Prepare deionized water (Aq.Dest.) in a 500cm<sup>3</sup> (500ml) container.

## ***Gently wipe the insertion section***

### **CAUTION**

- Hold the insertion section carefully. Holding the insertion section or bending section with excessive force or bending too much will cause serious damage to the surface rubber of the insertion section and bending section.

1. Rinse thoroughly under flowing water, scrub the debris on the insertion section with gauze repeatedly, and clean the operating section.

## ***Suction washing liquid(enzyme wash)***

Please refer to the product manual provided by the manufacturer for the formulation and the soak time of the multi-enzyme cleaner.

1. Turn on the suction pump/connect to the negative pressure bottle.
2. Install the T type luer adapter to the biopsy channel opening and cover the biopsy channel opening.
3. Soak the front end of the Small Animal Endoscope into the washing liquid. Press the suction button and suck the solution for 30 seconds towards the suction channel (as shown in Fig. 7.8).

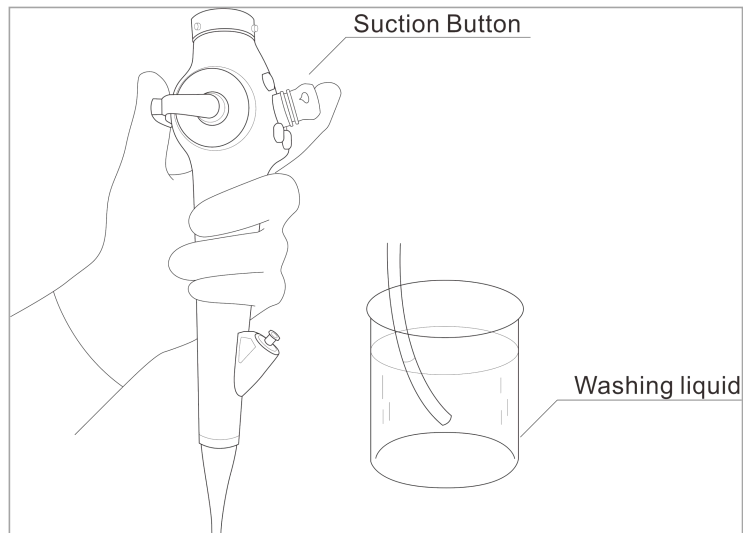


Fig. 7.8

4. Take the front end of the Small Animal Endoscope out of the washing liquid and soak it into the aqua distillata (Aq. Dest). Press the suction button to suck the Aq. Dest to the suction channel for 10 seconds.
5. Take the front end of the insertion tube out of the Aq. Dest. Press the suction button to suck the air for 10 seconds.

## ***7.4 Handling the Small Animal Endoscope***

### **WARNING**

- Do not spill debris and pre-wash liquid during handling.

### **NOTE**

- Please use handling equipment to transport the Small Animal Endoscope to the cleaning, disinfection and sterilization areas.

### ***Handling in the hospital***

1. To handle the Small Animal Endoscope with hands, pick up the operating section with one hand and carefully hold the tip of the insertion tube with the other hand, but do not squeeze it (as shown in Fig. 7.9).

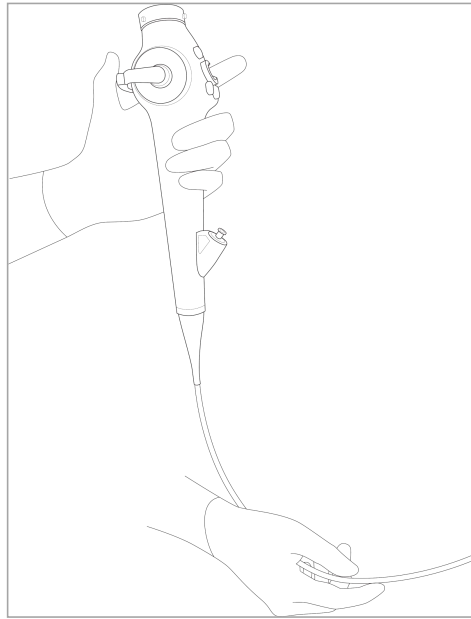


Fig. 7.9

2. Transfer the Small Animal Endoscope from the site of use to the cleaning, sanitizing and sterilizing areas.

**CAUTION**

- The instrument should be cleaned, sterilized and sterilized immediately after use. Do not allow used instrument that has not been cleaned, sterilized and sterilized overnight. If the instrument is placed for a long time without cleaning, disinfection and sterilization, the debris on it becomes hard and difficult to remove. If the instrument is immersed in the liquid for a long time without cleaning, disinfection and sterilization, the internal humidity of the Small Animal Endoscope will be too high and will lead to damage.
- Do not impact the tip of the Small Animal Endoscope during handling, or else it will damage the tip.
- Do not lift the Small Animal Endoscope by holding the insertion section, or else it will damage the Small Animal Endoscope.

## 7.5 Leakage test

After pre-cleaning, use leak detector on the Small Animal Endoscope for leakage test to confirm its waterproofness.

### **Required appliances**

Please prepare the following equipment.

- Personal protective equipment
- Basin, size at least 50cm×50cm (20"×20"), and depth sufficient to completely immerse the entire the Small Animal Endoscope
- Deionized water (Aq.Dest.)
- Waterproof cap
- Leak detector

#### **CAUTION**

- The waterproof cap must be mounted before immersing, or else the water will enter the Small Animal Endoscope and cause damage to the device.
- Attach the leak detection cover of the leak detector to the waterproof cap and screw the cover to the end. If it isn't screwed in place or connection is improper, the interior of the Small Animal Endoscope can't be pressurized, and accurate leak detection will be impossible.
- If a certain part of the Small Animal Endoscope continuously emits bubbles during leakage detection, it means that this position has leakage and water can enter the Small Animal Endoscopes here. If any leakage is found, remove the Small Animal Endoscope from the water and contact us.
- When mounting the leak detection cover of the leak detector to the waterproof cap, make sure that the inside and outside of the leak detection cover are completely dry. Otherwise, the residual water on the component may cause abnormal function of the Small Animal Endoscope
- Remove the master unit and the battery of image

processor from the Small Animal Endoscope before immersing, as the master unit of image processor mustn't be immersed, or else it will lead to abnormal function or

battery short circuit due to water infiltration.

**NOTE**

- When the leak detection cover is connected in place, the surface rubber of the bending section will expand with the increase of the internal pressure of the Small Animal Endoscope. This is a normal phenomenon.

## ***Leak detection using bladder***

**CAUTION**

- Always keep the leak detector completely dry. Otherwise, the residual water on the leak detector will cause damage to the Small Animal Endoscope.
- Open the air pressure relief valve before removing the leak detection cover. Discharge the air in the Small Animal Endoscope until the display shows 0mmHg, or else it will lead to damage to the Small Animal Endoscope.
- Only the connection pipe and leak detection cover of the leak detector can be immersed (as shown in Fig. 8.10). Immersing other parts may damage the leak detector.
- The barometer pressure should not exceed 220mmHg; if the pressure is too large, it may damage the Small Animal Endoscope. Rotate the air pressure relief valve to discharge the air (as shown in Fig. 7.10).

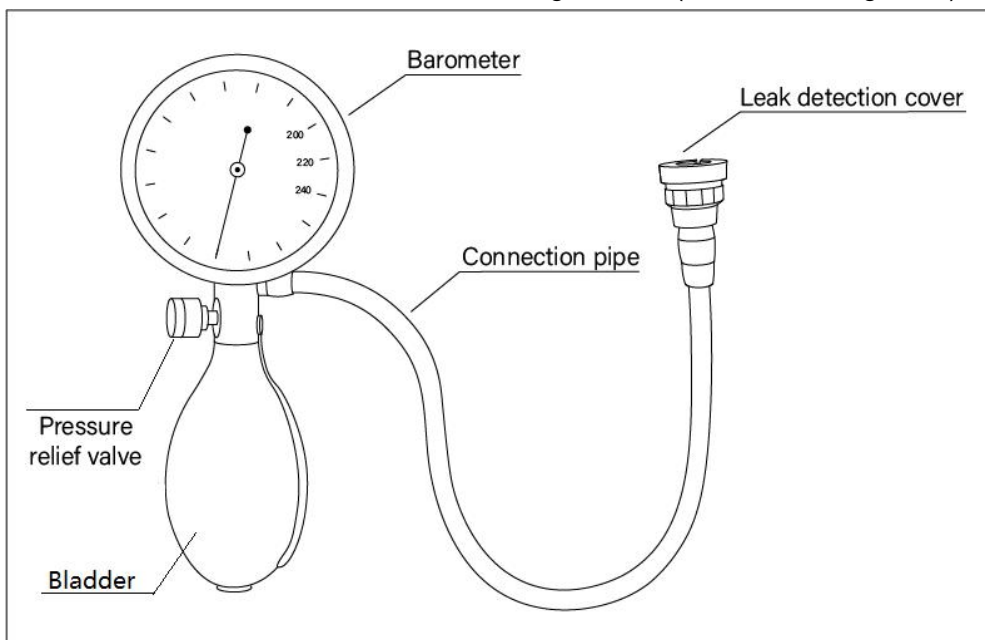


Fig. 7.10

1. Wear suitable personal protective equipment.
2. Fill up the basin with deionized water (Aq.Dest.). The size of the basin is at least 50cmx50cm (20"x20"), and the depth is sufficient to completely immerse the

entire the Small Animal Endoscope.

3. Turn the waterproof cap clockwise to the end, as shown in Fig. 7.11.

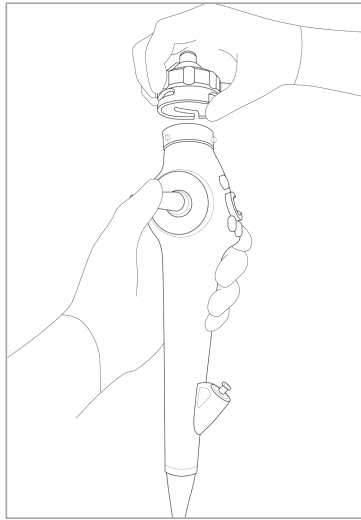


Fig. 7.11

4. Align the seam in the leak detection cover with the pin on the waterproof cap of the Small Animal Endoscope. Push the cover and turn it clockwise (as shown in Fig. 7.12).

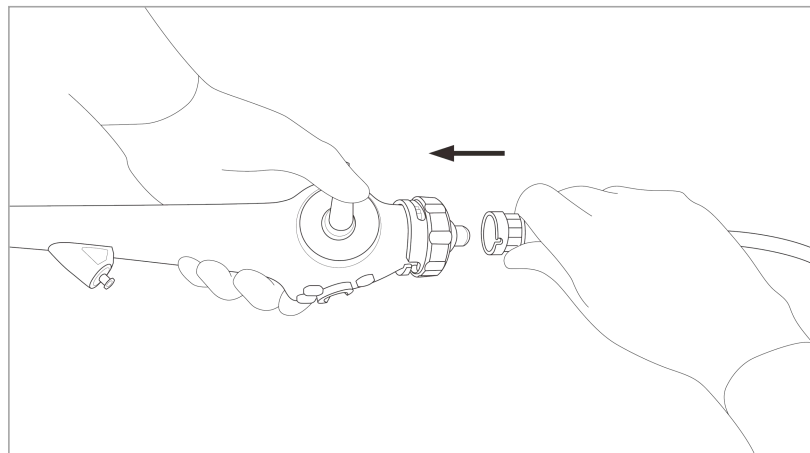


Fig. 7.12

5. Make sure that the pressure relief valve has been closed.

6. Press the bladder until the pressure display indicates between 180-200mmHg. The pointer must be in the “green area” of the barometer. To test a slight leak, apply pressure to about 200mmHg. Stabilize the pointer for a few seconds after applying pressure and read the pressure when the pointer is stable.

**CAUTION**

- If the pointer continues to drop to 0mmHg, the Small Animal Endoscope may have serious leakage, or the leak detector is damaged. The leakage test should be stopped immediately. If the Small Animal Endoscope is still

immersed in water and there is no pressure in the Small Animal Endoscope, the water will enter the Small Animal Endoscope, resulting in serious problems and even causing irreversible damage to the Small Animal Endoscope.

- If air bubble emit continuously from the leak detection cover during the leakage test, the leak detection cover or leak detection joint may be damaged. Please replace the leak detection cover or contact the manufacturer for repair.

7. Make sure that the pointer is stable. After connecting the leak detector, immerse the Small Animal Endoscope in the water, bend the bending section and observe about 30 seconds. Make sure there is no air bubble emitting from the Small Animal Endoscope.

8. Remove the Small Animal Endoscope from the basin.

9. Rotate the air pressure relief valve to release air from the Small Animal Endoscope.

10. Rotate the leak detection cover counterclockwise to remove the cover from the leak detection joint of the Small Animal Endoscope.

11. Dry the leak detector thoroughly.

## **7.6 Manual cleaning**

### **WARNING**

- The Small Animal Endoscope must be thoroughly cleaned before disinfection or sterilization. Thorough cleaning should remove microbes and organic tissue, and unthorough removal will reduce the effect of disinfection or sterilization. If the Small Animal Endoscopes isn't pre-cleaned immediately, the residual tissue debris on the device will solidify, making it difficult to effectively clean, disinfect and sterilize the Small Animal Endoscope

### **CAUTION**

- In order to avoid leakage, do not apply too much force when cleaning the Small Animal Endoscope.
- Put the waterproof cap on the Small Animal Endoscope. If not, water may enter and damage the Small Animal Endoscope.
- For details on the washing liquid, refer to Section 6.2

“Washing liquid”.

- When the leak detection is completed, perform the manual cleaning according to the following procedure.

## ***Required equipment***

- Personal protective equipment
- Basin, size at least 50cm×50cm (20”×20”), and the depth sufficient to completely immerse the entire the Small Animal Endoscope
- Clean lint-free cloth
- Medical low-foam washing liquid(neutral detergent or enzyme detergent)
- 30cm<sup>3</sup> (30ml) syringe
- Cotton swabs
- Channel cleaning brush
- Suction opening cleaning brush
- Joint cleaning brush
- Channel opening cleaning brush
- Soft brush
- Channel flusher

### **CAUTION**

- In order to avoid damage to the Small Animal Endoscope, do not immerse it with other devices other than the above mentioned.

## ***Preparation***

1. Wear suitable personal protective equipment.
2. Fill washing liquid in into the basin at the temperature and concentration recommended by the detergent manufacturer. The size of the basin is at least

50cmx50cm (20"x20"), and the depth is sufficient to completely immerse the entire the Small Animal Endoscope.

## ***Cleaning all outer surfaces***

1. Immerse the Small Animal Endoscope in the washing liquid.
2. Rinse and wipe all external surfaces of the Small Animal Endoscope with a soft brush or a lint-free cloth before immersing the Small Animal Endoscope. In particular, pay attention to the object lens, and ensure that all surfaces of the tip are thoroughly cleaned.
3. Visually check if there is residual debris on the surface of the Small Animal Endoscope.

## ***Channel cleaning***

### **WARNING**

- Always clean the inside of the biopsy channel. Otherwise, improper cleaning, disinfection and sterilization of the Small Animal Endoscope may cause infection to the next animal or operator who uses the Small Animal Endoscope.
- In order to prevent the washing liquid from splashing out when the channel cleaning brush is pulled out, the Small Animal Endoscope should be kept immersed in the washing liquid.
- Channel cleaning brush and joint cleaning brush are consumables. Disposable brush is non-reusable. Repeated use may cause the brush to bend or twist, which may result in falling off during use. Before and after use, make sure that the cleaning brush is not damaged and has no other problems. If any brush part falls off into the Small Animal Endoscope, find it immediately and pass through the channel with a new channel cleaning brush or other accessory to confirm that there is no part left inside the channel of the Small Animal Endoscope. Otherwise, the part that remains in the channel will fall into the animal's body

during the next operation. Due to the location, the new channel cleaning brush or other accessory passing through the channel may not be able to remove the part. In this case, please contact us as soon as possible.

- When using a disposable channel cleaning brush, do not rub the instrument channel with the brush rod when removing the brush from the channel, or else it will

damage the brush hair and leave the hair in the channel.

**CAUTION**

- Gently pull out the channel cleaning brush from the biopsy channel. Make sure that the brush rod doesn't rub the external opening of the instrument opening, or else it may damage the brush or grind into groove at the opening.
- Do not attempt to pass the channel cleaning brush from the tip of the insertion section, or else it will cause the cleaning brush to be stuck and can't be pulled out.

Follow all the steps below to clean all channels and channel openings when the Small Animal Endoscope is still immersed in the washing liquid (as shown in Fig. 7.13)

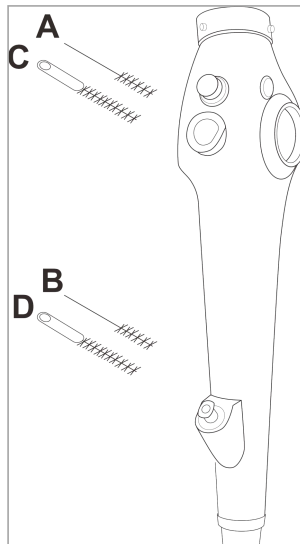


Fig. 7.13

### ***Scrubbing the suction channel of the operating section***

1. Soak the Small Animal Endoscope in the washing liquid to prevent the fluid from spilling out.
2. Straighten the bending section of the Small Animal Endoscope and hold the channel cleaning brush 3cm away from the bristle.
3. As shown in Fig. 7.13 A, insert the channel cleaning brush into the suction button opening, and push it in through the insertion section until it sticks out of the Small Animal Endoscope.
4. Clean the bristle in the washing liquid with finger tips, and carefully put the brush through the channel to pull it back beyond the suction opening.

5. Clean the bristle in the washing liquid once more.
6. Repeat the steps from 2 to 5 until all the residues are removed.

### ***Cleaning biopsy channel***

1. Hold the channel cleaning brush at 3cm from the brush hair.
2. As indicated by B in Fig. 7.13, insert the channel cleaning brush vertically into the biopsy channel. Tap gently and pass the cleaning brush through the biopsy channel until it extends from the tip of the Small Animal Endoscope.
3. Clean the brush hair with your fingertips in the washing liquid. Pull out the brush from the channel carefully and return to the outside of the channel.
4. Clean the brush again in the washing liquid.
5. Repeat steps 1 through 4 until all debris is removed.

### ***Scrubbing the suction base opening***

**WARNING**

- Insert the channel opening cleaning brush into the suction base opening, and DO NOT forcefully insert the brush to more than half of its depth. Otherwise, it will lead to the brush stuck in the suction piston.

1. As shown in Fig. 7.13 C, insert the channel opening cleaning brush into the suction base opening until it can reach more than half of its depth.
2. Insert the cleaning brush in a rotary manner once.
3. Pull out the brush and clean the bristle in the washing liquid with finger tips.
4. Repeat steps from 1 to 3 until all the residues are removed.

### ***Scrubbing the biopsy channel opening***

1. As shown in Fig. 7.13 D, insert the channel opening cleaning brush into the biopsy channel opening until the brush handle contacts the channel opening.
2. Insert the cleaning brush in a rotary manner once.

3. Pull out the brush and clean the bristle in the washing liquid with finger tips.
4. Repeat steps from 1 to 3 until all the residues are removed.

### ***Injecting the washing liquid into channels***

1. Install one end of the Channel flusher to the biopsy channel opening and the other end to the suction base (as shown in Fig. 7.14).
2. Connect the suction tube of the suction pump/negative pressure bottle to the suction opening of the Channel flusher. Open the suction pump/negative pressure bottle.
3. Soak the front tip of the Small Animal Endoscope in the washing liquid.
4. Suck the solution for around 30 seconds.
5. Close the suction pump/unplug the negative pressure bottle connector.
6. Take the suction tube off the Channel flusher.

### ***Soaking the Small Animal Endoscope in the washing liquid***

1. Fully soak the endoscope and the suction cleaning connector in the washing liquid.
2. Install the 30cm<sup>3</sup> (30ml) injector to the suction opening on the Channel flusher.
3. Pull up the injector handspike and fill in the washing liquid in the channel, the suction channel and the suction cleaning connector. (as shown in Fig. 7.14)
4. Fully soak the apparatus and the suction cleaning connector in the washing liquid, and take off the injector and the suction cleaning connector.

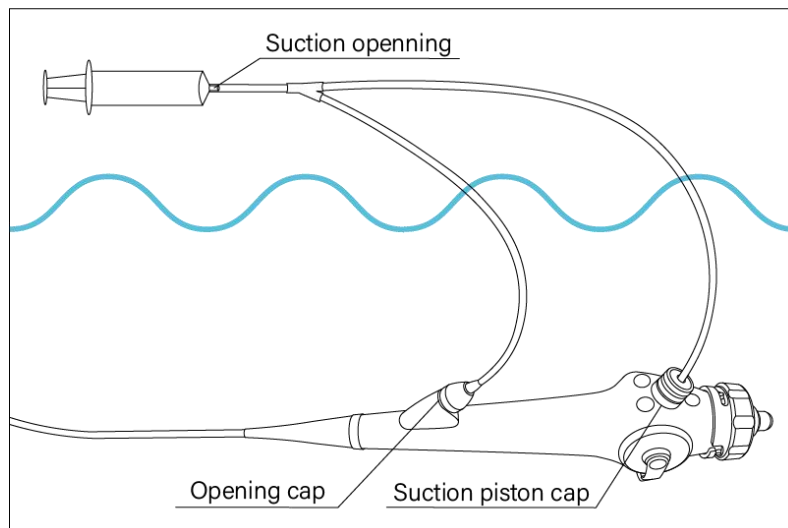


Fig. 7.14

5. When the Small Animal Endoscope is soaked in the solution, use a piece of lint-free cloth to wipe off all the residues on its external surface.
6. Use a seal cover to cover the basin to minimize the volatilization of the detergent steam.
7. Soak the Small Animal Endoscope and the Channel flusher for certain duration with the temperature and the concentration recommended by the detergent manufacturer.
8. Take the Small Animal Endoscope and the Channel flusher out of the washing liquid.

### ***Pre-soaking for delayed cleaning, disinfecting and sterilizing***

The following steps should be carried out only in the case of delayed cleaning, disinfecting and sterilizing. Unnecessary soaking should be avoided, since a long time of soaking will damage the Small Animal Endoscope.

1. Put in the washing liquid in a basin with the temperature and the concentration recommended by the detergent manufacturer. The size of the basin should be at least 50cmX50cm (20"X20"), and the depth should be enough for fully soaking the entire the Small Animal Endoscope.
2. Carefully roll up the insertion section of the Small Animal Endoscope, and fully soak the Small Animal Endoscope in the washing liquid.
3. After completing the steps specified in "Soaking the Small Animal Endoscope in the washing liquid" in this section, inject the washing liquid into all the channels.
4. Use a seal cover to cover the basin to minimize the volatilization of the detergent steam.
5. Soak Small Animal Endoscope for one hour with the temperature and the concentration recommended by the detergent manufacturer.
6. Take the Small Animal Endoscope out of the washing liquid.
7. After the soaking, manually clean the Small Animal Endoscope by following the steps in this section.

## ***7.7 Rinsing and drying after manual cleaning***

### **WARNING**

- Rinse the external surface and channels of the Small Animal Endoscope, and rinse the cleaning equipment thoroughly with flushing water to remove residual washing liquid, or else it may cause mucosal inflammation.

### **CAUTION**

- Disinfectant contains a variety of corrosive hazardous compounds (such as chlorine) that could damage the equipment. To remove all residues, rinse the equipment thoroughly using deionized water (Aq.Dest.). Do not use tap water to rinse the equipment due to possible chlorination.

### ***Required equipment***

Please prepare the following equipment

- Personal protective equipment
- Basin, size at least 50cm×50cm (20"×20"), and depth sufficient to completely immerse the entire instrument.
- Deionized water (Aq.Dest.)
- Clean lint-free cloth or paper towel
- Channel flusher

### ***Cleaning outer surface***

1. Wear suitable personal protective equipment.
2. Fill up the basin with deionized water (Aq.Dest.). Use a basin at least 50 cmx50 cm (20"x20") and the depth is sufficient to completely immerse the entire the Small Animal Endoscope.
3. Immerse the Small Animal Endoscope and the Channel flusher in deionized water (Aq.Dest.), stir gently and rinse thoroughly.

### ***Removing washing liquid from all channels***

1. Mount the Channel flusher on the Small Animal Endoscope. Connect the suction pipe of the suction pump to the suction opening of the Channel flusher.
2. Turn on the suction pump and suck deionized water (Aq.Dest.) for 30 seconds.
3. Remove the Small Animal Endoscope connected to the Channel flusher from the deionized water (Aq.Dest.) and suck air for 20 seconds.
4. Turn off the suction pump.

5. Remove the Channel flusher from the Small Animal Endoscope.
6. Remove the suction pipe from the Channel flusher.

## ***Drying outer surface***

1. Use a clean lint-free cloth to wipe and dry the outer surface of the Small Animal Endoscope and the Channel flusher.
2. Check if the Small Animal Endoscope and Channel flusher have residual debris. If yes, repeat the steps described in this section.

## ***7.8 Disinfection***

### **WARNING**

- In the whole process of disinfection, the Small Animal Endoscope and all the devices should be completely immersed in the disinfectant. If the devices are not removed from the Small Animal Endoscope or all parts are not completely immersed, the disinfectant can't be in full contact with all surfaces of the devices, which may reduce the effect of disinfection.

### **CAUTION**

- For details on disinfectant, refer to Section 6.3 "Disinfectant".

After cleaning, follow the steps below to disinfect the Small Animal Endoscope.

## ***Required equipment***

Please prepare the following equipment.

- Personal protective equipment
- Basin with a sealed lid, size at least 50cm×50cm (20"×20"), and the depth sufficient to completely immerse the entire the Small Animal Endoscope
- Disinfectant
- Clean lint-free cloth

- 30cm<sup>3</sup> (30ml) syringe
- Channel flusher

## ***Preparation***

1. Wear suitable personal protective equipment.
2. Fill up disinfectant into the basin according to the temperature and concentration recommended by the disinfectant manufacturer. The basin size should be at least 50cmx50cm (20"x20") and the depth is sufficient to completely immerse the entire the Small Animal Endoscope.

## ***Filling disinfectant into all channels***

### **WARNING**

- Remove all air bubbles from all channels, or else it will reduce the disinfection effect on the channel surface.

### **NOTE**

- It is easy to remove the air bubbles by injecting disinfectant into the channel forcibly.

1. Immerse the Small Animal Endoscope and the Channel flusher in the disinfectant.
2. Mount the Channel flusher to the Small Animal Endoscope.
3. Mount the 30cm<sup>3</sup> (30ml) syringe into the Channel flusher.
4. Unplug the syringe plunger and inject the disinfectant into all channels and Channel flusher.

## ***Immersing the Small Animal Endoscope and all devices in the disinfectant***

### **CAUTION**

- In the whole process of disinfection, the Small Animal Endoscope and all devices should be completely immersed in the disinfectant. If the devices are removed before being completely immersed, the disinfectant can't fully contact with all the surface of the devices, which will reduce the disinfection effect.

1. Immerse the Small Animal Endoscope and Channel flusher completely in the disinfectant, remove the syringe, and then remove the Channel flusher from the Small Animal Endoscope.

2. If there is air bubbles attached to the surface of the Small Animal Endoscope or Channel flusher, wipe thoroughly with a clean lint-free cloth.
3. Cover the basin with a sealing cap to minimize the volatilization of the disinfectant vapor.
5. Immerse the Small Animal Endoscope and Channel flusher in the disinfectant according to the time, temperature and concentration recommended by the disinfectant manufacturer.

## ***Removing the Small Animal Endoscope and all devices from the disinfectant***

1. Connect the Channel flusher to the Small Animal Endoscope before removing the Small Animal Endoscope from the disinfectant.
2. Remove the Small Animal Endoscope and Channel flusher from the disinfectant.
3. Use a 30cm<sup>3</sup> (30ml) syringe to inject air into the channel through a Channel flusher until disinfectant isn't discharged from the tip of the Small Animal Endoscope any longer.
4. Remove the Channel flusher and the syringe from the Small Animal Endoscope.

## ***7.9 Flushing and drying after disinfection***

### **WARNING**

- After cleaning, disinfecting and sterilizing, thoroughly clean and dry the channels of the Small Animal Endoscope. Otherwise, the bacteria will breed in the channels, which may cause infection to the animal or operator who uses the Small Animal Endoscope next time.
- Rinse the outer surface of the Small Animal Endoscope and the channels, and rinse thoroughly with flushing water to remove residual disinfectant, or else it will cause mucosal inflammation.

### **CAUTION**

- Disinfectant contains a variety of corrosive hazardous

compounds (such as chlorine) that could damage the equipment. To remove all residues, rinse the instrument thoroughly with deionized water (Aq.Dest.). Do not use tap water to rinse the equipment due to possible chlorination.

- Be careful that alcohol is flammable.
- For the quality of the flushing water, refer to Section 6.4 “Flushing water”.

After disinfection, follow the steps below to rinse and dry the Small Animal Endoscope and all devices.

## ***Required equipment***

Please prepare the following equipment.

- Personal protective equipment
- Sterile water basin, size at least 50cm×50cm (20”×20”), and the depth sufficient to completely immerse the entire the Small Animal Endoscope
- Sterile deionized water for sterile water rinsing
- Sterile lint-free cloth
- Suction pump with sterile suction pipe
- Channel flusher

If there is no sterile water, please prepare the following equipment.

- Deionized water (Aq.Dest.) for non-sterile water rinsing
- Small pot
- 70% isopropyl alcohol or ethanol
- Sterile cotton swab

### **WARNING**

- If the device is used directly on the animal after this operation, the device and the water used for flushing must be sterile water.
- Do not reuse flushing water.

## ***Sterile water rinsing***

1. Put on the suitable personal protective equipment.
2. Put sterile water in a basin with a size of at least 50cmX50cm(20"X20"), and a depth enough for soaking the entire the Small Animal Endoscope.
3. Soak the Small Animal Endoscope and the Channel flusher in the sterile water. Use a piece of sterile lint-free cloth to thoroughly irrigate and wipe all the external surfaces.
4. Connect the Channel flusher and the suction pump to the Small Animal Endoscope.
5. Open the suction pump to suck the sterile water for 30 seconds.
6. Take the Small Animal Endoscope out of the sterile water and suck the air for 60 seconds.
7. Close the suction pump.
8. Put the Small Animal Endoscope and the Channel flusher in the sterile basin.
9. Hold the operating section so that the biopsy channel opening face downwards, and take the Channel flusher off the Small Animal Endoscope. As shown in Fig. 7.15.

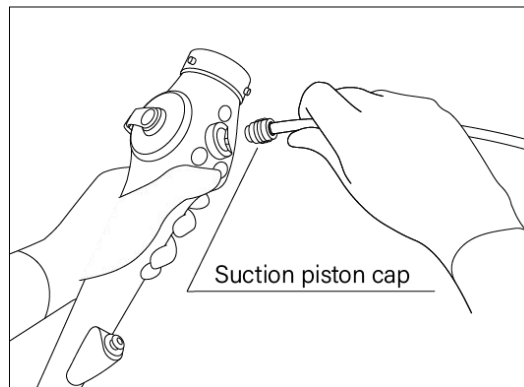


Fig. 7.15-1

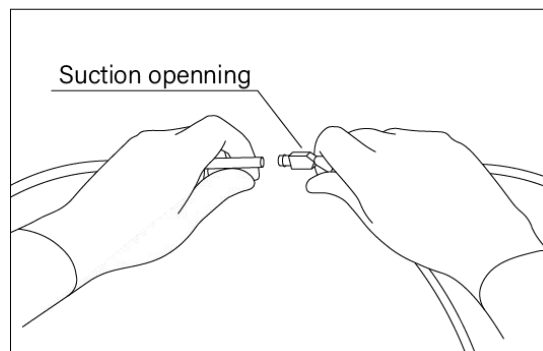


Fig. 7.15-2

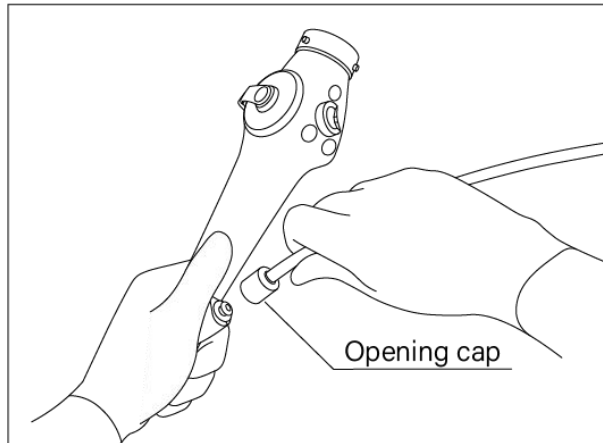


Fig. 7.15-3

10. Use a sterile lint-free cloth to wipe and dry the outer surface of the Small Animal Endoscope and the Channel flusher thoroughly.

11. Dry the Small Animal Endoscope and Channel flusher.

12. Store the components as described in Chapter 8 "Storage, handling and treatment out of hospital".

**NOTE**

- Rinse with sterile water and then rinse the channels with 70% isopropyl alcohol or ethanol to easily dry the inside of the channels.

## ***Using non-sterile water and alcohol for rinsing***

1. Wear suitable personal protective equipment.

2. Fill deionized water in the basin (Aq.Dest.). The basin size should be at least 50cmx50cm (20"x20"), and the depth is sufficient to immerse the entire the Small Animal Endoscope.

3. Immerse the Small Animal Endoscope and the Channel flusher in deionized water. Use a sterile lint-free cloth to rinse and wipe all outer surfaces thoroughly and operate according to steps 4 through 10 in "Sterile water rinsing".

4. Fill 70% ethanol or isopropyl alcohol into the basin.

5. Connect the Channel flusher and suction pump to the Small Animal Endoscope.

6. Turn on the suction pump.

7. Immerse the tip of the Small Animal Endoscope in 70% isopropanol or ethanol and suck alcohol for 5 seconds.

8. Remove the Small Animal Endoscope tip from the alcohol and suck air for 20 seconds.
9. Turn off the suction pump. Hold the operating section, keep the biopsy channel opening downwards and remove the Channel flusher from the Small Animal Endoscope, as shown in Fig. 7.14.
10. Wipe and dry the outer surface of the Small Animal Endoscope and the Channel flusher thoroughly with a sterile lint-free cloth dipped in alcohol.
11. Dry the interior of suction opening and the biopsy channel opening with a sterile cotton swab dipped in alcohol.
12. Dry the Small Animal Endoscope and the Channel flusher.
13. Store the components as described in Chapter 8 “Storage, handling and treatment out of hospital”.

## **7.10 Sterilization**

### ***Ethylene oxide gas sterilization***

The Small Animal Endoscope be sterilized with ethylene oxide gas. Perform the following steps after manual cleaning and drying according to Section 7.3 “Pre-cleaning” and Section 7.6 “Manual cleaning”.

#### **WARNING**

- For the conditions for ethylene oxide gas sterilization, refer to Section 6.6 “Conditions for ethylene oxide gas sterilization”.
- In order to ensure the sterilization effect, the Small Animal Endoscope and all devices should be dried before performing ethylene oxide gas sterilization.

#### **CAUTION**

- Exceeding the recommended parameters may cause damage to the equipment.
- Remove the waterproof cap before gas sterilization. If not, vacuum formed inside the sterilization chamber may cause the surface rubber of the bending section to crack or cause other damage to the endoscope.
- The master unit and the battery of image processor should be removed from the Small Animal Endoscope before sterilization, or else the master unit of image processor may be damaged.

1. The Small Animal Endoscope and all devices should be completely dried before ethylene oxide gas sterilization.
2. Remove the waterproof cap from the operating section by rotating it counterclockwise.
3. Seal the instrument in a package suitable for ethylene oxide gas sterilization according to the hospital's regulations.
4. Sterilize the package according to the ethylene oxide gas sterilization parameters recommended by Section 6.5 "Ethylene oxide gas sterilization" and instructions of the manufacturer sterilizer.
5. Ventilate the part according to the minimum parameters recommended in Section 6.5 "Ethylene oxide gas sterilization".
6. Store the components according to the instructions in Chapter 8 "Storage, handling and treatment out of the hospital".

## ***7.11 Steps of cleaning, disinfecting and sterilizing reusable parts***

### **WARNING**

- All reusable parts must be cleaned, disinfected or sterilized after each use, or else it may cause infection risk to the animal or the operator.

This section contains the reusable parts listed below and the cleaning, disinfection and sterilization steps of cleaning, disinfection and sterilization equipment.

- T type luer adapter
- Suction button

### ***Required equipment***

Please prepare the following equipment.

- Personal protective equipment
- A basin with sealed lid, at least 30cmx30cm (12"x12") and a depth sufficient to completely immerse the reusable parts
- Deionized water (Aq.Dest.)
- Sterile deionized water (Aq.Dest.) for sterile water rinsing
- Detergent

- Channel opening cleaning brush
- Soft brush
- Clean lint-free cloth
- 30cm<sup>3</sup> (30ml) syringe
- Disinfectant
- Sterile lint-free cloth

If there is no sterile water, please prepare the following supplies.

- 70% isopropyl alcohol or ethanol

## ***Manual cleaning***

### **WARNING**

- Reusable parts must be thoroughly cleaned before disinfection or sterilization. Thorough cleaning will remove microbes and organic tissue, while incomplete removal of organic tissue reduces the effect of disinfection or sterilization. If the reusable parts are not pre-cleaned immediately, the residual tissue debris on the device will solidify, making it difficult to effectively clean, disinfect and sterilize the device.

### **CAUTION**

- Make sure that the instruments immersed in the washing liquid won't come into contact with each other.
- For details on the washing liquid, refer to Section 6.2 "Washing liquid".
- Disinfectant contains a variety of corrosive hazardous compounds (such as chlorine) that could damage the equipment. To remove all residues, rinse the instrument thoroughly using deionized water (Aq.Dest.). Do not use tap water to rinse the equipment due to possible chlorination.
- For the quality of the flushing water, refer to Section 6.4 "Flushing water".

1. Wear suitable personal protective equipment.

2. Fill washing liquid into the basin according to the temperature and concentration recommended by the disinfectant manufacturer. The basin size should be at least 30cmx30cm (12"x12") and the depth is sufficient to completely immerse the entire reusable part.
3. Fill up the basin with deionized water (Aq.Dest.). The basin size should be at least 30cmx30cm (12"x12") and the depth is sufficient to completely immerse the entire reusable part.
4. Immerse all reusable parts in the washing liquid.
5. Use a soft brush or a clean lint-free cloth to clean the outer surface of all reusable parts in the washing liquid.
6. Use the channel opening cleaning brush to thoroughly clean the leak detection cover until no debris is visible.
7. If debris is attached to the inside of the T type luer adapter, wash the bonnet in the washing liquid and rub it from the outside until no debris is visible.
8. Flush the interior and opening of all reusable parts with a 30 cm<sup>3</sup> (30 ml) syringe until no air bubbles are visible.
9. Cover the basin with a sealing cap to minimize the volatilization of the detergent vapor. Immerse all reusable parts at the temperature and concentration recommended by the detergent manufacturer.
10. Remove all reusable parts from the washing liquid and check.
11. Immerse all reusable parts in deionized water (Aq.Dest.).
12. Gently stir all reusable parts for thorough rinsing.
13. Remove all reusable parts from deionized water (Aq.Dest.).
14. Wipe and dry all outer surfaces thoroughly with a clean lint-free cloth.
15. Check if all reusable parts have residual debris. If yes, repeat all steps until debris is removed.

## ***Disinfection***

### **WARNING**

- Remove all air bubbles from all devices as bubbles may impair the disinfection effect.

### **CAUTION**

- Completely immerse all devices before all disinfection steps can be carried out. If any device is not completely

immersed during the sterilization step, the disinfectant may not be able to fully contact all surfaces.

- For information on disinfectant, refer to Section 6.3 “Disinfectant”.

1. Fill the disinfectant into the basin according to the temperature and concentration recommended by the disinfectant manufacturer. The basin size should be at least 30cmx30cm (12”x12”) and the depth is sufficient to completely immerse the entire reusable part.

2. Immerse all reusable parts in the disinfectant.

3. Wipe all outer surfaces with a lint-free cloth and rinse with a 30 cm<sup>3</sup> (30 ml) syringe to remove all air bubbles.

4. When immersed in the disinfectant, rinse the inside and the recesses of all devices with a 30cm<sup>3</sup> (30ml) syringe. Make sure that all bubbles are excluded.

5. Cover the basin with a sealing cap to minimize the volatilization of the

disinfectant vapor. Immerse all reusable parts with the time, temperature and concentration recommended by the disinfectant manufacturer.

6. Remove all reusable parts from the disinfectant.

## ***Rinsing after disinfection***

### **WARNING**

- Rinse the outer surface of the reusable parts with flushing water to remove residual disinfectant, or else the residual disinfectant can cause mucosal inflammation.

### **CAUTION**

- Disinfectant contains a variety of corrosive hazardous compounds (such as chlorine) that could damage the equipment. To remove all residues, rinse the instrument thoroughly using deionized water (Aq.Dest.). Do not use tap water to rinse the equipment due to possible chlorination.
- Be careful that alcohol is flammable.
- For the quality of the rinsing water, refer to Section 6.4 “Flushing water”.

After disinfection, rinse all reusable parts according to the following steps.

## ***Sterile water rinsing***

1. Fill sterile water into the basin, which has a size at least 30cmx30cm (12”x12”) and a depth sufficient to completely immerse the entire reusable part.

2. Immerse all reusable parts into sterile water.
3. Gently stir to thoroughly rinse all reusable parts.
4. When immersed in the disinfectant, rinse the inside and the recesses of all devices with a 30cm<sup>3</sup> (30ml) syringe. Make sure that all bubbles are excluded.
5. Remove all reusable parts from sterile water.
6. Wipe and dry all outer surfaces thoroughly with a sterile lint-free cloth.
7. Completely dry all reusable parts.
8. Store the parts as described in Chapter 8 “Storage, handling and treatment out of the Hospital”.

## ***Using non-sterile water and alcohol for rinsing***

### **CAUTION**

- Be careful that alcohol is flammable.

1. Fill deoxygenated water (Aq.Dest.) into the basin. The basin size used is at least 30cmx30cm (12”x12”) and the depth should be sufficient to completely immerse the entire reusable part.
2. Immerse all reusable parts in deoxygenated water (Aq.Dest.) and operate according to Step 3 to Step 6 of “Sterile water rinsing.”
3. Fill 70% ethanol or isopropanol into the basin. The basin size used is at least 30cmx30cm (12”x12”) and the depth should be sufficient to completely immerse the entire reusable part.
4. Immerse all reusable parts in alcohol.
5. Gently stir all reusable parts in alcohol.
6. Use a 30cm<sup>3</sup> (30ml) syringe to rinse alcohol and remove all air bubbles from the inside and the recesses of all appliances.
7. Remove all reusable parts from alcohol.
8. Wipe and dry all outer surfaces thoroughly with sterile lint-free cloth.
9. Thoroughly dry all reusable parts.

10. Store the components as described in Chapter 8 “Storage, handling and treatment out of the Hospital”.

## ***Sterilization***

### **CAUTION**

- Some parts accept several sterilization methods. But sterilization method may be inapplicable to some parts, or else it will cause equipment damage.

In this section, the sterilization method of the equipment is applicable to the equipment compatible with ethylene oxide gas sterilization or steam sterilization listed in Table 7.1.

## ***Ethylene oxide gas sterilization***

### **WARNING**

- For the conditions for ethylene oxide gas sterilization, refer to Section 6.6 “Conditions for ethylene oxide gas sterilization”.
- To ensure the sterilization effect, dry the reusable parts and all equipment before performing ethylene oxide sterilization.

### **CAUTION**

- Exceeding the recommended parameters may result in damage to reusable parts.

1. Dry the reusable parts before ethylene oxide sterilization.

2. Seal the reusable parts in the ethylene oxide gas sterilization package according to the provisions of the hospital.

3. Sterilize the package according to the recommended ethylene oxide sterilization parameters in Section 6.5 “Ethylene oxide gas sterilization” and manufacturer’s instructions.

4. Ventilate the reusable parts in accordance with the minimum ventilation parameters specified in Section 6.5 “Ethylene oxide gas sterilization”.

5. Store the components as described in Chapter 8 “Storage, handling and treatment out of the hospital”.

## ***7.12 Automatic cleaning and disinfection***

This endoscope is compatible with some endoscope automatic washer-disinfector that meet EN ISO 15883-1. For compatibility confirmation and connection operation details of the endoscope and the automatic washer-disinfector, please refer to the operating manual of the automatic washer-

disinfector and the endoscope manual.

**WARNING**

- Before cleaning and disinfecting the endoscope in the automatic washer-disinfector, thoroughly manually clean the endoscope according to the instructions in section 7.3 "pre-cleaning" to section 7.6 "manual cleaning".
- Use of a cleaning/ disinfection machine that is not compatible with the endoscope may cause damage to the endoscope. Do not force the use of the endoscope without detailed instructions proving that it is compatible with the intended automatic washer-disinfector.
- If an endoscope that has not been thoroughly cleaned by hand is placed in a automatic washer-disinfector, debris attached to the endoscope may impair the effect of the automatic washer-disinfector and pose infection risk to the next animal or operator.
- Failure to do pre-cleaning immediately after use will cause coagulation of the animal debris and reduce the cleaning and disinfection effect of the endoscope.
- Before using the automatic washer-disinfector, be sure that the machine is capable of cleaning and disinfecting the endoscope and all its tubes. If it is not possible to determine whether the cleaning machine/disinfector is capable of cleaning and disinfecting the endoscope and all its ducts, contact the manufacturer of the endoscope cleaning machine to confirm its details, as well as the connector information.
- When cleaning and disinfecting the endoscope in the automatic washer-disinfector, use a connector compatible with the type of the endoscope. Otherwise, inadequate cleaning and disinfection of the endoscope poses an infection risk to the next animal or operator.
- Do not overload the automatic washer-disinfector.
- To prevent corrosion, the endoscope should be removed from the automatic washer-disinfector immediately after the automatic cleaning/disinfection.

### ***Disinfection conditions***

- Liquid temperature: less than 45 °C
- Liquid pressure: 0.2mpa - 0.5mpa
- Gas pressure: 0.02mpa - 0.04mpa
- Process water: rinsing water should be sterile deionized water (Aq. Dest.) conforming to EN 285.
- Disinfectant: O-phthalaldehyde (OPA)

**WARNING**

- Do not rinse the equipment with tap water due to possible chlorination.

- In general, O-phthalaldehyde (OPA) solution is suitable for the disinfection of this endoscope. Special formula disinfectants should be prepared according to the manufacturer's instructions. If the disinfectant is reused, its effectiveness should be regularly tested with a dipstick recommended by the manufacturer of the disinfectant.
- Do not use solutions that exceed expiry dates.

### ***Test before cleaning/disinfection***

1. Make sure that the endoscope and all accessories are firmly fixed in the instrument basket of the automatic washer-disinfector, and no touching each other.
2. An endoscope with a lumen (working channel) must connect the port of the lumen to the flushing outlet of the automatic washer-disinfector and ensure that all lumens are adequately flushed/disinfected.
3. Before the endoscope is cleaned/disinfected, the leak detector of the endoscope should be connected with the test port of the automatic washer-disinfector. Set the leakage test pressure of the automatic washer-disinfector to 0.03MPa, and maintain the leakage test status throughout the cleaning/disinfection process.
4. After the completion of the leakage test, the unobstructed lumen of the endoscope shall be tested to ensure the unobstructed lumen.

#### **WARNING**

- During the operation of the automatic washer-disinfector, the endoscope shall be tested for leakage in the whole process. If the low-pressure alarm is issued by the leakage test during the operation, the endoscope is at risk of liquid damage. The cleaning/disinfection operation shall be stopped immediately and the liquid in the disinfection shall be emptied.
- The pressure recommended for leakage testing of the endoscope is 0.03mpa, up to a maximum of 0.04mpa. Otherwise, the epidermis may be damaged by the endoscope.
- When blockage is detected, the working channel of the endoscope should be checked. Failure to do so may result in failure of cleaning/disinfection and may pose an infection risk to the next animal or operator.

### ***Cleaning***

1. Use medical, low-foam cleaning agent (PH neutral or enzymatic detergent) and follow the dilution method recommended by the manufacturer.

2. Start the washing function of the automatic washer-disinfector. Use the cleaning detergent to wash the surface and working channel. In principle, the initial rinse time should be no less than 5 minutes, flush temperature is no less than 25 °C , and the flushing water pressure should be maintained within the range of 0.2mpa to 0.5mpa.

3. The cleaning procedure of the automatic washer-disinfector shall be followed after rinsing. Set the initial rinse time should be no less than 10 minutes, flush temperature is no less than 40 °C . The endoscope shall be cleaned with sterilized deionized water in accordance with EN 285.

4. After cleaning, the rinsing procedure of the cleaning/disinfectant machine shall be performed, final rinsing temperature as 40 °C , the time is no less than 10 minutes and the endoscope shall be rinsed with sterilized deionized water in accordance with EN 285.

#### **WARNING**

- The dosage of the cleaning agent should comply with the regulations of the cleaning agent manufacturer, and should avoid repeated use. In case of repeated use, the method in line with the regulations of the cleaning agent manufacturer should be adopted to confirm the effectiveness of the cleaning agent.
- The pressure of the flushing liquid agent is lower than 0.2mpa, which may result in impurity of flushing and weaken the cleaning/disinfection effect. Flushing liquid at a pressure above 0.5MPa can have a damaging effect on the endoscope.
- In the process of washing, cleaning and rinsing fluid temperature shall not be higher than 45 °C. Temperature is higher than 45 °C will cause clotting protein clean caused difficulties.

## ***Disinfection***

After the above cleaning procedure, O-phthalaldehyde (OPA) could be utilized to sterilize the endoscope.

The steps are as follows:

1. In the preparation and use of disinfectants, the concentration and additives should be prepared according to the method recommended by the manufacturer, and the temperature should be controlled according to the recommended.

2. Set the parameters of the automatic washer-disinfector, and confirm the parameters of the disinfection process according to the instructions of the automatic washer-disinfector. In general, the disinfection time shall not be less than 20 minutes, temperature shall not be less than 40 °C and the circulating pressure of disinfectant shall be controlled within the range of 0.2mpa to 0.5mpa.

3. Disinfect the endoscope according to the preset disinfection procedure of the automatic washer-disinfector. During disinfection, all surfaces of the endoscope should be exposed to the O-phthalaldehyde (OPA) disinfectant cycle. Temperature, pressure and leakage shall be tested during disinfection to ensure that the above parameters are within the set range.

**WARNING**

- Disinfectants should be avoided reusing, and if they are reused, they must be tested for effectiveness in accordance with the manufacturer's instructions. Otherwise, it may weaken the disinfection effect and increase the risk of cross-infection among animals or operators using the endoscope next time.
- After disinfection, gloves should be changed before further treatment, otherwise it may lead to secondary contamination of the disinfected endoscope, increasing the risk of infection.

## ***Flushing and drying***

1. After disinfection, the endoscope shall be rinsed with sterilized deionized water conforming to EN 285, and the rinsing process shall follow the instructions of the automatic washer-disinfector. The rinsing process shall be performed on all surfaces of the endoscope, including the outer surface and the working channel. In principle, the time should be no less than 10 minutes, temperature shall not be less than 25 °C and the water pressure should be maintained within the range of 0.2mpa to 0.5mpa.

2. After rinsing, thoroughly dry the outer surface and working channel of the endoscope with the drying procedure of the automatic washer-disinfector. Drying temperature shall not be higher than 60 °C, endoscope surface should be no residual water after drying, using crepe paper test, should be no black spots.

**WARNING**

- Disinfectant contains a variety of corrosive and harmful compounds (such as chlorine) that can damage equipment. To remove all residues, thoroughly rinse using Aq.Dest. Deionized water. Do not rinse the equipment with tap water as chlorination may occur.
- Rinse water should not be reused, or it may lead to excessive residue of endoscope disinfectant.
- After cleaning, disinfection and sterilization, failure to thoroughly dry the endoscope may result in bacterial growth in the tube, posing an infection risk to the animal or operator using the endoscope the next time.
- The cleaning and disinfection effect of the automatic washer-disinfector shall be tested regularly, and the test results shall meet the requirements of EN ISO 15883-5 standard.

## ***7.13 Maintenance steps for cleaning, disinfection and sterilization accessories***

The following cleaning, disinfection and sterilization equipment should be cleaned, disinfected and sterilized separately from the Small Animal Endoscope.

- Channel opening cleaning brush
- Joint cleaning brush
- Channel flusher
- Leak detector

### **CAUTION**

- Refer to Section 6.1 “Compatibility overview” for applicable cleaning, disinfection and sterilization methods.

### ***Brush and Channel flusher maintenance***

1. Clean and disinfect these devices after use.
2. If necessary, perform ultrasonic cleaning or sterilization.

### ***Leak detector maintenance***

#### **CAUTION**

- Only immerse the channels and fittings of leak detector, or else it will cause damage.

1. Wipe the surface of the leak detector with a clean lint-free cloth immersed in washing liquid.
2. Wipe off the washing liquid on the surface of the leak detector with a clean lint-free cloth immersed in deionized water (Aq.Dest.).
3. Clean and disinfect the pipes and fittings of the leak detector.
4. Dry the leak detector thoroughly.

# **Chapter 8 Storage, handling and treatment out of the hospital**

After cleaning, disinfection and sterilization, the clean Small Animal Endoscope and the accessories should be kept away from any contaminated equipment. If the clean Small Animal Endoscope or accessory is contaminated between the two examinations, it may cause infection to the next animal or operator.

## **CAUTION**

- To prevent contamination of Small Animal Endoscope and the accessories after cleaning, disinfection and sterilization, be sure to keep the storage cabinet clean.
- The storage cabinet must be clean, dry, well ventilated and kept at room temperature. Do not store the Small Animal Endoscope in an environment subject to direct sunlight, high temperature or high humidity, or expose it to ozone, X-ray or ultraviolet light, or else it will damage the Small Animal Endoscope or cause infection.
- Do not store Small Animal Endoscope in the transport case, which is only used to transport the Small Animal Endoscope; storing the Small Animal Endoscope in a wet unventilated environment such as the transport box will lead to infection.

## **8.1 Storage of Small Animal Endoscope**

1. Remove all devices from Small Animal Endoscope, such as the waterproof cap.
2. Make sure that all surfaces of the Small Animal Endoscope (especially the inside of the channel, the tip, the lens, and the electronic contact) are completely dry.
3. Carefully wipe the tip lens with a cotton swab dipped in 70% alcohol.
4. Keep the tip of the catheter pendulous naturally in the storage cabinet. Make sure that the insertion section is vertically suspended and straightened as far as possible.
5. Store Small Animal Endoscope at a room temperature (10-40°C, humidity 30-85%) in a clean and dry place.

## **NOTE**

- The storage time of the sterilization equipment is different depending on the type of packaging and the storage

conditions (see DIN 58953, Part 9, or local regulations).

- Using a double sterile package according to DIN 58946, Part 9 can extend the storage time.

Package	On the baffle	In the cabinet
Single sterile packaging	Immediately	6 weeks
Double sterile packaging	6 weeks	6 months

Table 8.1

## ***8.2 Storage of reusable parts, cleaning, disinfection and sterilization equipment and leak detector***

1. Make that all reusable parts and cleaning, disinfection and sterilization equipment are completely dry.
2. Keep all reusable equipment in the storage cabinet. Make sure that these parts are not in contact with each other during storage.
3. Store all cleaning, disinfection and sterilization equipment in the box, and place the box in the storage cabinet.

## ***8.3 Handling of Small Animal Endoscope out of the hospital***

The Small Animal Endoscope should be placed in the shipping box for handling.

### **WARNING**

- The Small Animal Endoscope must be cleaned, disinfected or sterilized before being handled out of the hospital, or else it will cause infection.

### **CAUTION**

- The shipping box can't be cleaned, sterilized or disinfected. Before placing Small Animal Endoscope into the shipping box, please clean and disinfect or sterilize Small Animal Endoscope.

## ***8.4 Treatment***

When handling Small Animal Endoscope and any parts (such as cleansing brush), all applicable national and local laws and regulations should be followed.

# Chapter 9 Troubleshooting

If it is found that the Small Animal Endoscope has been damaged and does not function properly, or if there are other abnormalities found during the examination according to the method described in Chapter 3 “Preparation and examination”, do not use the Small Animal Endoscope, and contact us.

Some nonfunctional faults can be solved according to the contents of Section 9.1 “Troubleshooting guide”. If the fault still can’t be ruled out, please stop using the Small Animal Endoscope and return it to us for repair.

We are not responsible for the repair of the accessories. If any accessory is damaged, please contact us to purchase a new one.

## **WARNING**

- If any problem is found in the Small Animal Endoscope, do not use it for the animal, or else it will endanger the safety of animals and users and cause more serious damage to the equipment.
- If any part of the Small Animal Endoscope falls off into the animal's body due to equipment damage or malfunction, immediately stop using the Small Animal Endoscope and take appropriate measure to recover the part.

If there is any problem in the Small Animal Endoscope, stop the examination immediately and carefully pull out the Small Animal Endoscope from the animal as described in Section 9.2 “Pulling out the exceptional Small Animal Endoscope”.

## 9.1 Troubleshooting guide

The following table shows the problems caused by improper setting or damaged consumables and the countermeasures.

The problems caused by the following causes should be repaired. Repairs by unauthorized service personnel may result in injury to the animal or the user and/or equipment damage, so be sure to contact us for maintenance in accordance with Section 9.3 “Repair of the Small Animal Endoscope”.

### ***Suction***

<b>Problem</b>	<b>Possible cause</b>	<b>Solution</b>
No suction or insufficient suction force	The biopsy channel opening is not sealed by the T type luer adapter	Seal the opening with the bonnet
	The T type luer adapter cannot reach the sealing effect due to damage	Replace it with a new one
	Inappropriate suction pump settings	Set according to the manual for the suction pump
	Damage to the suction button	Replace it with a new one
The suction button cannot be installed	Damage to the suction button	Replace it with a new one
The suction button cannot return to the original position	Over high suction pressure	Reduce the suction pressure

Table 9.1

### ***Liquid delivery***

<b>Problem</b>	<b>Possible cause</b>	<b>Solution</b>
Channel opening leaks	Channel clogged	Clean the channel with channel cleaning brush
	Injection nozzle damage	Replace new syringe
Leakage between the injection joint and the syringe	Channel clogged	Clean the channel with channel cleaning brush
	Syringe isn't inserted firmly	Inserted the syringe firmly

Table 9.2

## **9.2 Pulling out the exceptional Small Animal Endoscope**

If there is any problem in the Small Animal Endoscope in the course of use, take appropriate measures as described in “Pulling out the Small Animal Endoscope when image appears on the LCD screen of image processor” or “Pulling out the Small Animal Endoscope when there is no image on the LCD screen of image processor or frozen image can’t be restored”. After pulling out, return the Small Animal Endoscope for repair according to Section 9.3 “Repair of the Small Animal Endoscope”.

### **WARNING**

- If the Small Animal Endoscope or accessories can’t be pulled out of the animal’s body smoothly, do not try to force out; if there is any abnormality, immediately contact us. Forcibly pulling out the Small Animal Endoscope or accessories may cause injury to the animal.

### ***Pulling out the Small Animal Endoscope when image appears on the LCD screen of image processor***

1. Turn off the power supply for all devices except the master unit of image processor and the suction pump.
2. When using the accessory, close the accessory tip or retract it into the sheath and slowly pull out the accessory.
3. Observe the Small Animal Endoscope image while carefully pulling out the Small Animal Endoscope.

### ***Pulling out the Small Animal Endoscope when there is no image on the LCD screen of image processor or frozen image can’t be restored***

1. Turn off the power supply for all devices except the master unit of image processor and the suction pump.
2. Turn off the master unit of the image processor, and then turn it on. If the image of the image processor appears or the frozen image is restored, proceed to step 2 and subsequent operation of “Pulling out the Small Animal Endoscope when image

appears on the LCD screen of image processor". If the image still does not appear or the frozen image isn't restored, perform the following steps.

3. Turn off the power of the Small Animal Endoscope, image processor and the suction pump.
4. When using the accessory, close the accessory tip and retract it to the sheath, and then slowly pull out the accessory.
5. Rotate the up/down angle control handle to the middle position.
6. Release the angle control handle and carefully pull out the Small Animal Endoscope.

### ***9.3 Repair of the Small Animal Endoscope***

#### **WARNING**

- Thoroughly clean and disinfect or sterilize the Small Animal Endoscope before repair. Improper cleaning, disinfection and sterilization will cause infection to the personnel of the hospital or the company handling the equipment.

#### **CAUTION**

- We are not responsible for damage to equipment and personal injury due to repair by unauthorized personnel.

Please contact us before sending the Small Animal Endoscope for repair. Please attach the description of the failure or damage of the Small Animal Endoscope, the name and contact phone number of the person most familiar with the failure, and the warranty card. When repairing the Small Animal Endoscope, follow the instructions in Section 9.3 "Handling of the Small Animal Endoscope out of the hospital".

# Appendix

## EMC information

This model is intended for use in the electromagnetic environments specified below. The user and the medical staff should ensure that it is used only in these environments.

### Magnetic emission compliance information and recommended electromagnetic environments

Emission standard	Compliance	Guidance
RF emissions CISPR 11	Group1	This instrument uses RF (radio frequency) energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated emissions CISPR 11	Class B	This instrument's RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Main terminal conducted emissions CISPR 11		
Harmonic emissions IEC61000-3-2	Class A	This instrument's harmonic emissions are low and are not likely to cause any problem in the typical commercial power supply connected to this instrument.
Voltage fluctuations/flicker emissions IEC61000-3-3	Complies	This instrument stabilizes its own radio variability and has no affect such as flicker in lighting apparatus.

## Electromagnetic immunity compliance information and recommended electromagnetic environments

Immunity test	IEC60601-1-2 test level	Compliance level	Guidance
Electrostatic discharge (ESD) IEC61000-4-2	Contact: $\pm 2, \pm 4, \pm 6, \pm 8\text{kV}$ Air: $\pm 2, \pm 4, \pm 8, \pm 15\text{kV}$	Same as left	Floors should be made of wood, concrete, or ceramic tile that hardly produces static. If floors are covered with synthetic material that tends to reduce static, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC61000-4-4	$\pm 2\text{kV}$ For power supply lines $\pm 1\text{kV}$ For input/output lines	Same as left	Mains power quality should be that of atypical commercial (original condition feeding the facilities) or hospital environment.
Surge IEC61000-4-5	Differential mode: $\pm 0.5, \pm 1\text{kV}$ Common mode: $\pm 0.5, \pm 1, \pm 2\text{kV}$	Same as left	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	$< 5\% U_T$ ( $> 95\%$ dip in $U_T$ ) for 0.5 cycle <hr/> $40\% U_T$ ( $60\%$ dip in $U_T$ ) for 5 cycle <hr/> $70\% U_T$ ( $30\%$ dip in $U_T$ ) for 25 cycle <hr/> $< 5\% U_T$ ( $> 95\%$ dip in $U_T$ ) for 5 seconds	Same as left	Mains power quality should be that of atypical commercial or hospital environment. If the user of this instrument requires continued operation during power mains interruptions, it is recommended that this instrument be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	3 A/m	Same as left	It is recommended to use this instrument by maintaining enough distance from any equipment that operates with high current.


**NOTE**

$U_T$  is the AC mains power supply prior to application of the test level.

## Cautions and recommended electromagnetic environment regarding portable and mobile RF communications equipment such as cellular phones

Immunity test	IEC60601-1-2 test level	Compliance level	Guidance
Conducted RF IEC61000-4-6	3 Vrms (150 kHz – 80 MHz)	3 V (V <sub>1</sub> )	Formula for recommended separation distance (V <sub>1</sub> =3 according to the compliance level)  $d = \left[ \frac{3.5}{V_1} \right] \sqrt{P}$
Radiated RF IEC61000-4-3	3 V/m (80 MHz– 2.5GHz)	3 V/m(E <sub>1</sub> )	Formula for recommended separation distance (E <sub>1</sub> =3 according to the compliance level)  $d = \left[ \frac{3.5}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">80 MHz – 800MHz</p> $d = \left[ \frac{7}{E_1} \right] \sqrt{P}$ <p style="text-align: right;">800 MHz– 2.5GHz</p>

**NOTE**

- Where “P” is the maximum output power rating of the transmitter in watts(W) according to the transmitter manufacturer and “d” is the recommended separation distance in meters(m).
- This instrument complies with the requirements of IEC60601-1-2. However, under electromagnetic environment that exceeds its noise level, electromagnetic interference may occur on this instrument.
- Electromagnetic interference may occur on this instrument near a high-frequency electrosurgical equipment and/or other equipment marked with the following symbol: 

**Recommended separation distance between portable and mobile RF communications equipment and this instrument**

Rated maximum output power of transmitter P (W)	Separation distance according to frequency of transmitter (m) (calculate as $V_1=3$ and $E_1=3$ )		
	150 kHz –80 MHz	80 MHz – 800 MHz	800 MHz– 2.5 GHz
	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$

0.01	0.12	0.12	0.23
0.1	0.38 0.73	0.38	
1	1.2	1.2	2.3
10	3.8 7.3	3.8	
100	12 23	12	

**NOTE**

The guidance may not apply in some situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Portable and mobile RF communications equipment such as cellular phones should be used no closer to any part of this instrument, including cables than there commended separation distance calculated from the equation applicable to the frequency of the transmitter.