



Instructions for Use of Single-use Rhinolaryngoscope



Please read the Instructions for Use of the product carefully before use.

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Version: 1.0

Date of Issue: May 13, 2025

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Declaration

The Manufacturer has the right of final interpretation to this Instruction for use.

The Manufacturer does not bear any responsibility for software and equipment that are not provided by the Manufacturer and Endo-Therapeutics.

The Manufacturer will bear responsibilities for the safety, reliability and performance of products only when the following requirements are met at the same time:

- Assembly, extension, readjustment, improvement and maintenance must be carried out by the professionals approved by the Manufacturer;
- All replaced components, supporting accessories and consumables during maintenance are original or are approved by the Manufacturer;
- Relevant electrical equipment conforms to the requirements of MDR and FDA standards and this Instruction for use.
- Product operation is carried out in accordance with this Instruction for use.

1. Important Information - Please Read Before Use

Please read these safety instructions carefully before using the single-use Rhinolaryngoscope series. The Instructions for Use are subject to change without prior notice. A copy of the latest version can be provided as required. Please note that these instructions do not constitute an explanation or discussion of clinical procedures. These instructions involve only the basic operation of single-use Rhinolaryngoscope series and operation-related precautions.

Prior to the first use of single-use Rhinolaryngoscope series, the operator should be adequately trained on the use of clinical endoscopes, and familiar with the intended use, warnings and precautions described in the Instructions for Use. In the Instructions for Use, the term endoscope refers to a certain product of the single-use Rhinolaryngoscope series. The Instructions for Use applies to the endoscopes and provides system-related information.

1.1. Intended use

The product is a single-use sterile flexible endoscope for endoscopic surgery and examination in the anatomy of nasal cavity and upper respiratory tract. The endoscope is used to provide images through an endoscopy video processor distributed by Endo-Therapeutics. The single-use flexible Rhinolaryngoscope is connected to the endoscopy video processor and used in conjunction with other endoscopic accessories for nasal and respiratory tract examination and treatment in adults.

The endoscope is indicated for use in a hospital, and for the treatment of adults.

1.2. Contraindication

Uncontrolled bleeding disorder

Unable or unwilling to cooperate (eg, too young)

Acute epiglottitis and croup

Acute epistaxis

Recent facial trauma or surgery

Note: This Rhinolaryngoscope should be used without interference of environmental and other factors and operated in strict accordance with the instructions.

1.3. Clinical advantages

The Rhinolaryngoscope is designed to be disposable to minimize the risk of cross-contamination.

1.4. Warnings and precautions

Failure to observe these warnings and precautions may result in injury to the patient or damage to the equipment. The Manufacturer assumes no responsibility for any system damage or patient injury caused by improper use.

Warnings

- 1. It can only be used by physicians who have received training on the use of clinical endoscopy and surgery.**
- 2. The endoscope is single-use and must be handled and disposed of in accordance with generally accepted standards of medical practice for such devices to avoid contamination before insertion.**
- 3. Do not soak, clean or disinfect the device as doing so may leave harmful residues or cause device malfunction. Repeated use of the endoscope can cause contamination and lead to infection.**
- 4. Do not use the endoscope if its sterile barrier or packaging is damaged.**
- 5. Do not use the endoscope if any damage occurs or if it fails the pre-use inspection.**
- 6. Do not take the image as the sole basis for any pathological diagnosis. Physicians must interpret and confirm any findings by other means and with respect to the clinical characteristics of the patient.**
- 7. Do not use the endoscope in conjunction with active endoscopic accessories (e.g., laser probe and electrosurgical device) as this may cause injury to the patient or damage to the endoscope.**
- 8. Do not use the endoscope when delivering highly flammable anesthetic gas to the patient as this may cause harm to patients.**
- 9. The patient should be closely observed during the use of the device as there is a**

risk of patient injury.

10. Make sure the bendable portion is in a straight position when inserting and withdrawing the endoscope. Do not apply excessive force when manipulating the control lever as this may cause injury to the patient and/or damage to the endoscope.

11. Do not apply excessive force when pushing, manipulating or withdrawing the endoscope as this may cause injury to the patient or damage to the endoscope.

12. Heat dissipation from the light emitting portion may cause an increase in temperature at the distal end of the endoscope. Avoid long-time contact between the head of the device and mucosa as this may injure the mucosa.

13. Do not use the endoscope during defibrillation as this may causes harm to users.

Precautions

1. Prepare an appropriate stand-by system ready in the event of a malfunction.

2. Be careful not to damage the insertion tube or the distal end. Avoid collision of other objects or sharp devices such as needle with the endoscope.

3. The device can only be sold to or ordered by physicians according to the Code of Federal Regulations.

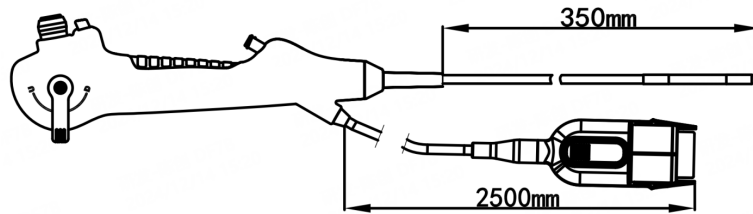
4. The color representing blue dye is indicative of possible impairment on the real-time endoscopic image.

5. Manipulating the single-use Rhinolaryngoscope by holding the handle upside down will make the image inverted on the display.

2. System Description

The endoscope is connected to the compatible endoscopy video processor. See the corresponding instructions for use for information about compatible endoscopy video processor.

2.1 System components



The endoscope system is available in 10 models: RH-M58, RH-M52, RH-M50, RH-M40, RH-M32, RH-M32A, RH-M58H, RH-M52H and RH-M40H.

2.2 Specifications

Models	RH-M58	RH-M52	RH-M50	RH-M40	RH-M32	RH-M32A	RH-M22
Field of view	120°±10%	120°±10%	120°±10%	120°±10%	120°±10%	120°±10%	120°±10%
Direction of view	0°±10°	0°±10°	0°±10°	0°±10°	0°±10°	0°±10°	0°±10°
Depth of field	3-50mm	3-50mm	3-50mm	3-50mm	3-50mm	3-50mm	3-50mm
Maximum insert outer diameter	5.8±10%mm	5.2±10%mm	5.0±10%mm	4.4±10%mm	3.2±10%mm	3.2±10%mm	2.2±10%mm
Length of insertion tube	350mm±10%	350mm±10%	350mm±10%	350mm±10%	350mm±10%	350mm±10%	350mm±10%
Minimum working channel inner diameter	≥2.50mm	≥2.1mm	2.8±10%mm	≥1.1mm	1.2±10%mm	/	/
Bendable portion	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)
Overall length of product	605±10%mm	605±10%mm	605±10%mm	605±10%mm	605±10%mm	605±10%mm	605±10%mm

Models	RH-M58H	RH-M52H	RH-M40H
Field of view	120°±10%	120°±10%	120°±10%
Direction of view	0°±10°	0°±10°	0°±10°
Depth of field	3-50mm	3-50mm	3-50mm
Maximum insert outer diameter	5.8±10%mm	5.2±10%mm	4.4±10%mm
Length of insertion tube	350mm±10%	350mm±10%	350mm±10%
Minimum working channel inner diameter	≥2.50mm	≥2.1mm	≥1.1mm
Bendable portion	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)	210° (upwards) and 210° (downwards), with a deviation of -5% (excluding upper limit)
Overall length of product	605±10%mm	605±10%mm	605±10%mm

It cannot be ensured that the instrument combination applying only to the minimum insertion channel width is compatible.

It cannot be ensured that the instrument combination applying only to the maximum insertion portion width and working length is compatible.

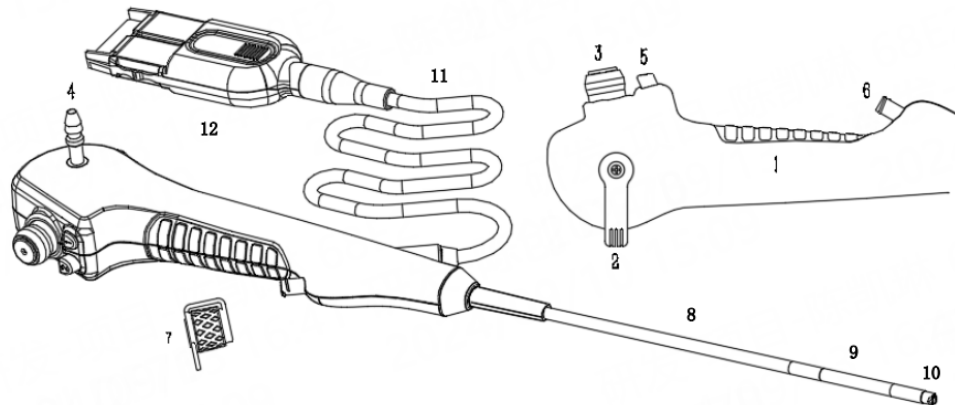
2.3 Environmental specifications

Operational Environment Temperature	5-40°C (41-104°F)
Relative humidity	≤93%
Air pressure	70-106kPa
Altitude	≤2000m
Storage and Transport Temperature	0-45°C (32-113°F)
Relative humidity	30-95%
Sterilization Sterilizing method	EO (ethylene oxide sterilization)

2.4 Product compatibility

The endoscope can only be used in conjunction with the endoscopy video processor distributed by Endo-Therapeutics.

2.5 Endoscope components



No.	Components	Function
1	Handle	For product holding
2	Manual lever	Control the bending direction and angle of the bendable portion by moving the lever forward and backward
3	Air Suction button	Button controlling the Air Suction switch
4	Suction outlet	Connect the suction source
5	Button1 Button2	Button1: short press for photo, long press for video Button2: Freeze image Their function can be customized on the image processor
6	Working channel entrance	The insertion port of the accessories or the connecting port of the injection pump and other equipment, it can also be connected to the biopsy valve
7	Biopsy valve	For sealing or connecting devices
8	Insertion tube	Flexible braided tube
9	Bendable portion	Controllable bendable portion
10	Distal end	Located at the distal end of the endoscope, including the camera LED and working channel
11	Handle connecting cable	For transferring image data to the image processor
12	Cable connector	Connect the cable to the image processor

3. Pre-use Inspection

This endoscope must be inspected in accordance with the following rules before use. In addition, the inspection should be performed in accordance with the Instructions for Use and the rules for other devices used in conjunction with the endoscope.

3.1 Inspection of packaging integrity

Before use, please check whether the outer packaging of the endoscope is complete and whether the product model and specifications are consistent with those on the label.

Warning

- Do not use the endoscope if its sterile barrier or packaging is damaged.
- The endoscope has been sterilized with ethylene oxide, with the expiration date printed on each layer of packaging. Do use products beyond the expiration date in clinical practice.
- Do not open the bag or box with knives or other sharp tools.

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3.2 Inspection of endoscope

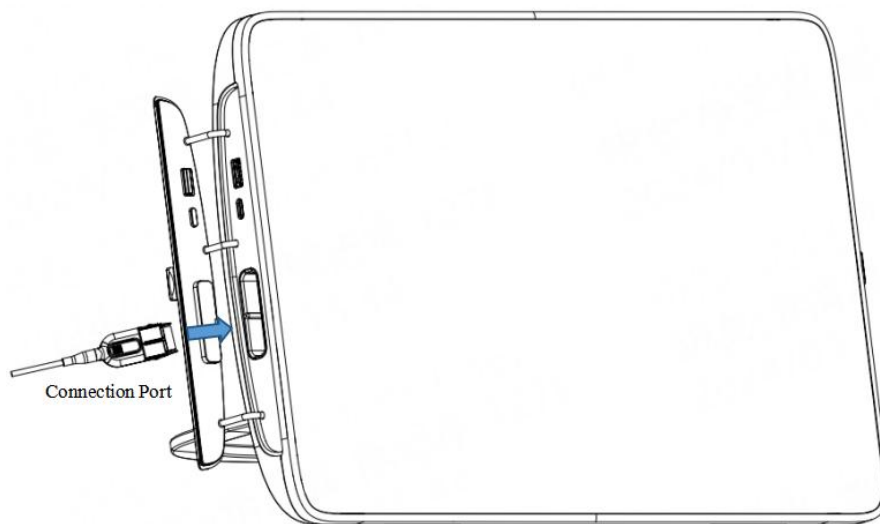
Check for shipping damage or other damages, such as rough surfaces, sharp edges or protrusions, which may harm the patient.

3.3 Inspection of endoscope end

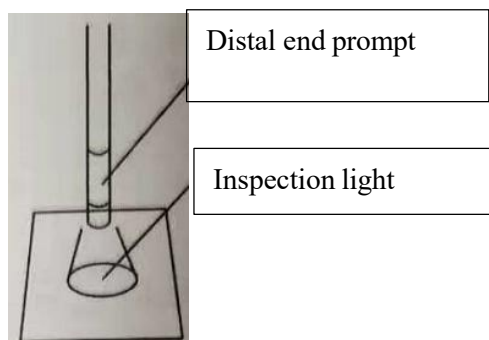
Warning ⚠

· Do not look directly into the distal end of the endoscope while inspecting the light source as this may cause eye injury.

3.3.1 Connect the endoscope power connector to the matching endoscopy video processor and press the Power button. Both the power indicator and the endoscope image will be displayed on the monitor.

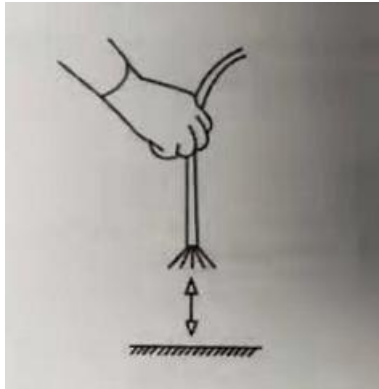


3.3.2 Confirm that there is a beam of light emitted from the end of the endoscope (dual LED)



3.3.3 Point the distal tip of the endoscope at the object to be measured and move it

between 3-50 mm. Verify on the monitor that the image quality and brightness of the object to be measured are basically stable.



Note:

- Please refer to "White Balance Calibration " in case of abnormal color of endoscopic image.

3.3.4 Observe the distal tip of the endoscope by aligning it to the palm of your hand to ensure that the endoscopic image is free from noise, blur or other abnormalities.

3.4 Inspection of bending function

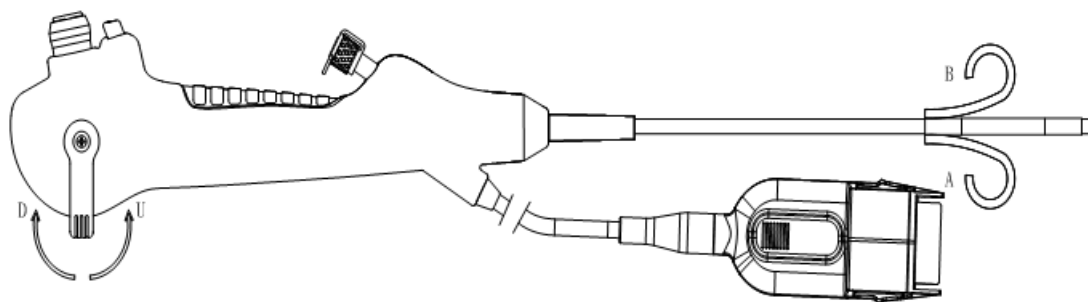
Perform the following inspections when the bendable portion is in a straight state.

Warning ⚠

- Bending function abnormality may occur if the bending control lever slides with a clicking sound or the bendable portion does not achieve a smooth bending. In this situation, an endoscope should not be used because abnormalities may occur during the surgery.

3.4.1 Slowly slide to bend the control lever and confirm that the bendable portion is bent smoothly and normally and can achieve the maximum bending amplitude

3.4.2 Slide the bending control lever to bend the bendable portion upward and downward respectively



3.4.3 Slowly slide the bending control lever to the neutral position and confirm that the bendable portion can be smoothly restored to a nearly straight line

3.5 Inspection of the suction function (skip this inspection if suction is not required during the surgery)

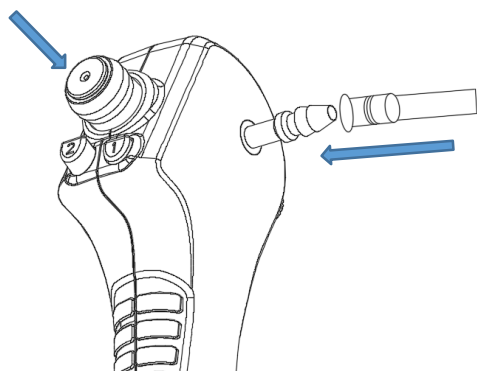
Warning

- Do not continue to use the endoscope if the suction valve cannot work properly as continued suction may occur, leading to patient injury.

Note

- The pressure of the negative-pressure device system should be less than 70 kpa.

3.5.1 Connect the pipeline of the vacuum system to the suction joint and adjust the suction pressure to the level that should be reached during surgery.



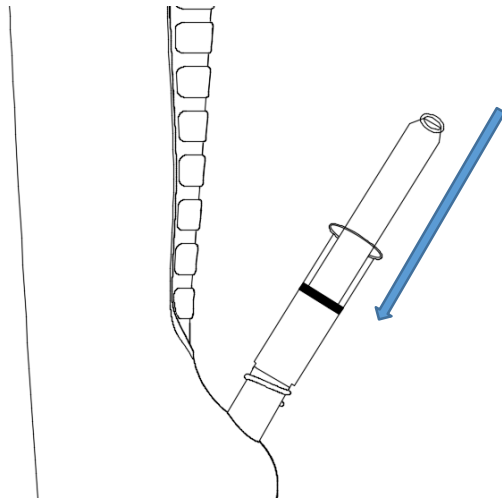
3.5.2 Immerse the distal tip into sterile water and press the suction valve. Confirm that the bottle of the water sucking device can enable continuous water absorption.

3.5.3 Release the Air Suction button, confirm that the air suction stops and that the Air Suction button returns to its original position

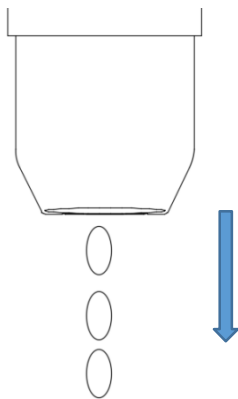
3.5.4 Take the end of the endoscope out of water. Press the Air Suction button to suction for a few seconds so that all water in the pipeline is removed

3.6 Inspection of the working channel

3.6.1 Insert a syringe filled with sterile water into the working channel port of the endoscope and press the plunger.



3.6.2 Confirm that the injection is flowing out from the end of the endoscope.



Warning ⚠

- The syringe must remain perpendicular to the working channel port when inserting into it. Otherwise, the device will be damaged.

Note

- The syringe must be entirely inserted into the working channel port for the purpose of proper operation.

3.7 Inspection of endo-therapy accessories

Warning ⚠

The head of endo-therapy accessories such as biopsy forceps must be closed at the time of insertion, failing to do so may result in damage to the working channel and detachment of endo-

therapy accessories.

- Do not insert endoscopic accessories forcibly in case of any difficulty in their insertion. Forcible insertion can result in damage to the working channel and detachment of endo-therapy accessories.
- The endo-therapy accessory must be inspected for abnormalities in appearance or operation before use and should be replaced if not functioning properly.

3.7.1 Endo-therapy accessories are inserted from the working channel port and pushed slowly to ensure that the accessory can extend smoothly from the distal-end working channel port.

3.8 White balance

Warning

- A pure white object should be used when performing white balance calibration, but it should never come into contact with the endoscope.
- The distal tip of the endoscope should not be exposed to an external light source whilst performing white balance calibration. Otherwise, white balance calibration may end in failure.

3.8.1 Press the Power button of the endoscopy video processor, connect it to the compatible endoscope, and press the power switch of the video processor. When the distal end of the endoscope is directed at the white object, the White Balance button on the video processor screen or the Handle button with the white balance function should be gently pressed for white balance calibration.

3.8.2 Repeat step 1 in case of calibration failure

4. Use of Endoscope

The endoscope can only be operated by physicians or medical personnel under the supervision of a physician, and operators must receive clinical and technical training on the endoscope.

Warning

- This device cannot be used together with the high-frequency electric knife or argon plasma for possible device damage or patient injury.
- The endoscope cannot be withdrawn in advance in the following situation. Otherwise, the patient will be injured.
 - When an accessory extends from the distal end; or
 - When the bendable portion is bent to a certain angle.

4.1 Insertion of endoscope

Warning

- Do not use excessive force in either the left or right directions at the time of endoscope insertion as this may cause injury to the patient.
- Do not slide the bending control lever forcibly as this may impose an excessive load on the steel wire, leading to stretching or breaking of the steel wire and affecting the bending function.

Note

- When the endoscope is inserted into the mouth, it is recommended that a bite block be placed in the patient's mouth to prevent the patient from biting the insertion portion during examination.
- The insertion tube should be lubricated with medical lubricants before endoscope insertion to minimize friction produced when inserting the endoscope into a patient's body.
- Whether there is an appropriate stand-by device available for immediate use in the event of malfunction.

4.1.1 The endoscope can be held in either hand. The insertion tube can be pushed into the patient's mouth or nose with the hand that does not hold the endoscope. Move the control lever by thumb. The control lever can be used to bend and extend the distal end of the endoscope vertically. Moving the control lever downward will bend (curve) the distal end forward. Moving it upward will bend (extend) the distal end backward. The insertion tube should always be held as straight as possible to ensure the optimal bending angle of the distal end. Be sure to observe the real-time video displayed on the monitor when the endoscope enters the patient's body.

4.1.2 The bending control lever is used to control the bending angle at the distal end and guide the distal end to go deeper into the mouth or ear canal and nose for observation.

4.2 Insertion of endo-therapy accessories into the endoscope

Warning ⚠

- Do not insert the endo-therapy aids forcibly or abruptly, as the endoscope accessories will extend from the distal end of the endoscope abruptly, which could cause patient injury.
- If endo-therapy accessories are used, it is necessary to keep the bendable portion of the endoscope in a straight line and make the distance between the distal end of the endoscope and the mucosa greater than the minimum visible distance of the endoscope.
- Do not operate the endoscope accessories if they are not visible in the endoscope image, as this could cause device damage.

4.2.1 First, withdraw the endoscope back to the bendable portion in a natural straight line, with the bending control lever kept still.

4.2.2 Check whether the head of the endo-therapy accessory is closed, and then slowly insert it into the working channel port.

4.2.3 Observe the real-time video displayed on the monitor when the endo-therapy accessory reaches the distal-end working channel, and slowly push the endo-therapy accessory forward from the distal end. Fix the accessory devices to keep fixation.

4.2.4 Operate the bending control lever and slowly move the distal end to the expected position for surgery.

4.3 Withdrawal of endo-therapy accessories

Warning

- Do not bend the bendable portion when withdrawing the endo-therapy accessories. Otherwise, device damage or patient injury may occur.
- Make sure that the endoscopic therapy accessory to be withdrawn is completely retracted to the working channel.
- Do not withdraw the endoscopic therapy accessory if its end is not closed, otherwise it may cause patient injury or device damage.

4.3.1 Put endoscopic accessories back into the working channel after they have been used.

4.3.2 Ensure that the control lever is in the neutral position, and then slowly withdraw the endo-therapy aids from the working channel.

4.4 Withdrawal of the endoscope

Warning

- The patient should be examined carefully if there is blood on the surface of the insertion portion when the endoscope is withdrawn from the patient's body.
- The endoscope cannot be withdrawn from the patient's body with excessive force in case of non-smooth removal, which may result in patient injury.

4.4.1 Observe the real-time video of the endoscope displayed on the monitor, and slowly withdraw the endoscope from the patient's body by operating the bending control lever.

4.4.2 Withdraw the endoscope and disconnect it from the endoscopy video processor.

4.5 Inspection of endoscope

Inspect the withdrawn endoscope for any missing part or other abnormalities to ensure that there is no foreign object left in the patient's body.

4.6 Disposal of endoscope

The used endoscope is considered infected and must be handled according to local guidelines. Do not reuse.

5. Others

[Service Life]

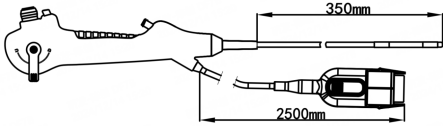
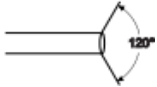
The date of manufacture and expiration date should be indicated on the label, and the aseptic shelf life is 3 years.

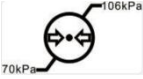
[Customer Service]

The endoscope is intended for single use only, for which maintenance services are not supported by the Manufacturer.

If you have any questions in the use of this product, please contact Endo-Therapeutics.

Symbols and description

	Working length
	Field of view
	Do not use the product if its sterile barrier or packaging is damaged.
	Natural rubber latex-free
	Type BF applied part
	Date of manufacture: followed by YYYY-MM-DD
	Expiration date: followed by YYYY-MM-DD
	Sterile product, sterilized with EO.
	For single use only. Do not reuse.
	Manufacturer
	Serial No.
	Warnings
	See the Instructions for Use

	Prescription
	Temperature limit: 0-45°C (32-113°F) for the storage and transportation environment.
	Humidity limit: Relative humidity of 30-95% for the storage and transportation environment.
	UDI code
	Medical device
	Fragile materials inside, handle with care
	Protect from moisture
	Face up during transportation
	Maximum 5 layers stacked with same package
	CE mark: indicates that the device complies with the EU 2017/745
	Authorized representative
	Storage pressure: 70–106 kPa
	WEEE logo
	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Maximum 5 layers stacked with same package