EICKVIEW SD
SEMI-DISPOSABLE ENDOSCOPES

USER MANUAL

Art. No. 307010, 307020, 307030

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veterinary technology for life

Eickemeyer®

CE 2797

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

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Intellectual Property

Declaration

EICKEMEYER® has the right of final interpretation to this Instruction for use.
EICKEMEYER® does not bear any responsibility for software and equipment that are not provided by EICKEMEYER® and its distributors.
EICKEMEYER® 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 EICKEMEYER®;
- All replaced components, supporting accessories and consumables during maintenance are original or are approved by EICKEMEYER®;
- 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 EickView SD “semi-disposable” Endoscpoee series manufactured by EICKEMEYER®. 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 operations of EickView SD “semi-disposable” Endoscpoe series and operation-related precautions.

Prior to the first use of EickView SD “semi-disposable” Endoscpoe 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 this Instructions for Use, the term endoscope refers to a certain product of the EickView SD “semi-disposable” Endoscpoe series, and the term system refers to a certain product of the EickView SD “semi-disposable” Endoscpoe series and a compatible EickView SD Endoscopy Monitor manufactured by EICKEMEYER®. 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 manufactured by EICKEMEYER®. The EickView SD “semi-disposable” Endoscpoe is connected to an endoscopy video processor manufactured by EICKEMEYER®, and used in conjunction with other endoscopic accessories for the examination and treatment of trachea and bronchus in adults

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

Indications

1. Chronic cough with unknown cause.

2. Hemoptysis or blood in sputum with unknown cause.

3. Localized wheezing sound with unknown cause.

4. Hoarseness with unknown cause.

5. Cancer cells or suspected cancer cells found in sputum.

6. Chest X-ray and/or CT examination indicated atelectasis, pulmonary nodules or mass shadows, obstructive pneumonia, pulmonary inflammation not absorbable, diffuse pulmonary nodules, hilar and (or) mediastinal lymphadenopathy, tracheobronchial stenosis and pleural effusion of unknown cause.

7. Preoperative examination of lung is of reference value to guide the resection site and scope and evaluate prognosis.

8. Chest trauma, for which tracheobronchial laceration or rupture is suspected, and bronchoscopy examination can make a definite diagnosis.

9. Etiological diagnosis of pulmonary or bronchial infectious diseases (including bronchopulmonary infections in immunosuppressed patients), such as culture of specimens obtained by tracheal aspiration, protective specimen brush, or bronchoalveolar lavage (BAL).

10. Airway management during mechanical ventilation.

11. Diagnosis of suspected trachea and bronchial fistula.

1.2. Contraindication

1. Those with cervical vertebra disease;

2. Those who are allergic to narcotics;

3. Those with ventilatory dysfunction causing CO_2 retention without ventilatory support;

4. Those with gas exchange dysfunction, whose arterial blood oxygen partial pressure is still below the safe range after oxygen inhalation or mechanical ventilation;

5. Those with cardiac insufficiency, severe hypertension or arrhythmia;

6. Those with elevated intracranial pressure;

7. Those with aortic aneurysm;

8. Those with coagulation disorder;

9. Those with recent asthma attacks or uncontrolled asthma.

10. Those with severe bleeding tendencies and impaired coagulation.

Note: EickView SD "semi-disposable" Endoscpoe should be used without interference of environmental and other factors and operated in strict accordance with the instructions.

1.3. Clinical advantages

The EickView SD "semi-disposable" Endoscpoe is designed to be disposable to minimize the risk of cross-contamination.

1.4. Warnings and precautions

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.

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 relevant regulations.

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

5. Manipulating the EickView SD “semi-disposable” Endoscpoe by holding the handle upside down will make the image inverted on the display.

2. System Description

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

2.2 Specifications

Model	EickView 60SD	EickView 60SD-XS
Field of view	120°±10%	120°±10%
Direction of view	0°±10°	0°±10°
Depth of field	3-50mm	3-50mm
Maximum insert outer diameter	3.2±10%mm	2.5±10%mm
Length of insertion tube	600mm±10%	600mm±10%
Minimum working channel inner diameter	1.2±10%mm	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)
Overall length of product	860±10%mm	860±10%mm

Model	EickView 150SD
Field of view	120°±10%
Direction of view	0°±10°
Depth of field	3-50mm
Maximum insert outer diameter	6.0±10%mm
Length of insertion tube	1500mm±10%
Minimum working channel inner diameter	2.9±10%mm
Bendable portion	180° (upwards) and 180°(downwards), with a deviation of -5% (excluding upper limit)

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.

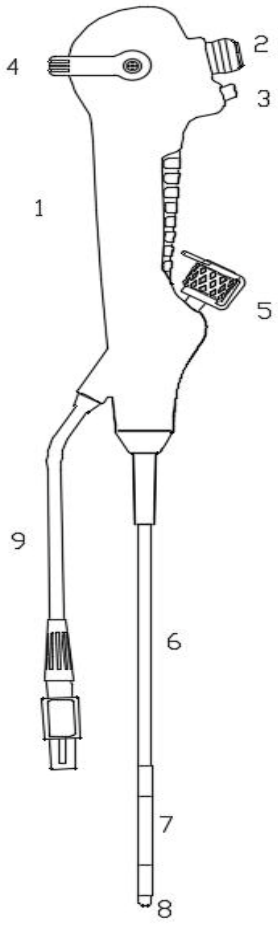
2.3 Environmental specifications

Operational Environment Temperature	5-40℃（41-104℉）
Relative humidity	≤93%
Air pressure	70-106kPa
Altitude	≤2000m
Storage and Transport Temperature	0-45℃（32-113℉）
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 manufactured by EICKEMEYER®, and the model of VLM is for intended use.

2.5 Endoscope components



No.	Components	Function
1	Handle	Indicated for use by the left or right hand
2	Air Suction button	Button controlling the Air Suction switch
3	Buttons 1 and 2	Used for photographing, video, white balance, graphics freezing and white balance
4	Manual lever	Control the bending direction and angle of the bendable portion by moving the lever forward and backward
5	Luer connector port	Used for connecting the irrigation system
	Biopsy valve	For sealing and connecting devices
6	Insertion tube	Flexible braided tube
7	Bendable portion	Controllable bendable portion
8	Distal end	Composed of the camera, light source (two LEDs)
9	Handle connecting wire	For transferring image data to the host

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.

3.2 Inspection of endoscope

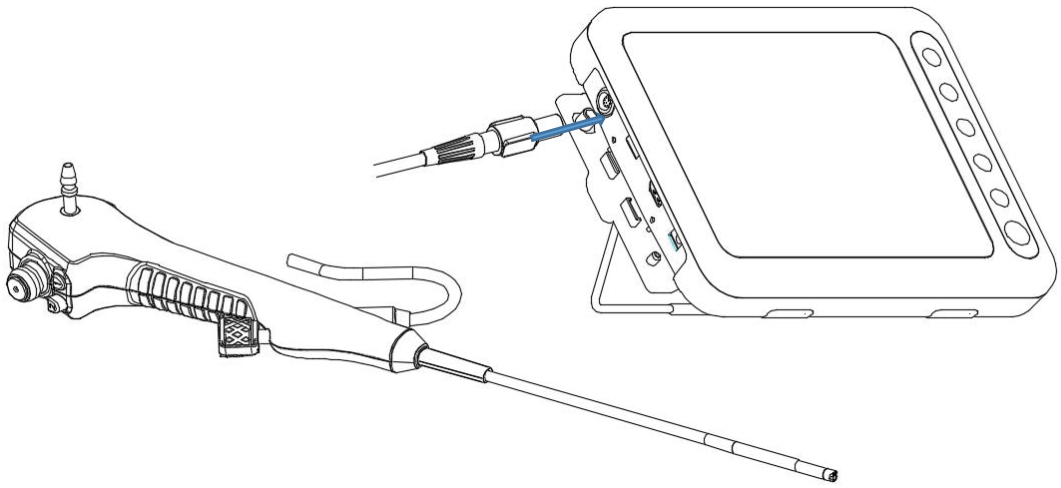
Check for shipping damage or other damages, such as rough surfaces, sharp edges or protrusions, which may harm the patient.

3.3 Inspection of endoscope end

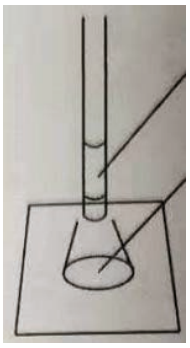
Warning ⚠

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

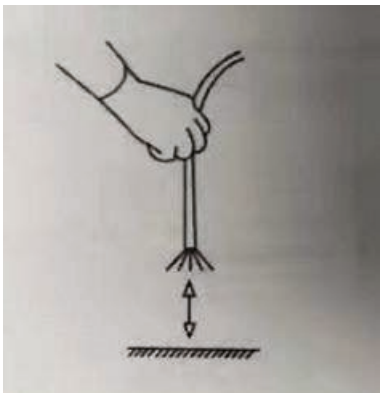
3.3.1 Connect the endoscope power connector to the matching endoscopy video processor and press the Power button. Both the power indicator and the endoscope image will be displayed on the monitor.



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

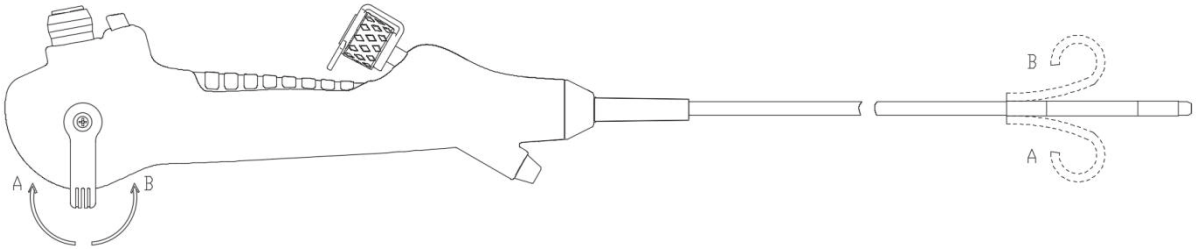
Perform the following inspections when the bendable portion is in a straight state.

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

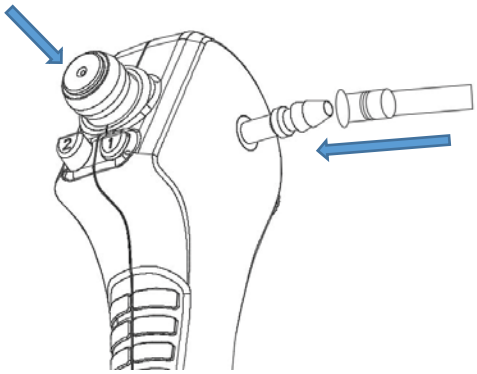
3.5 Inspection of the suction function

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.



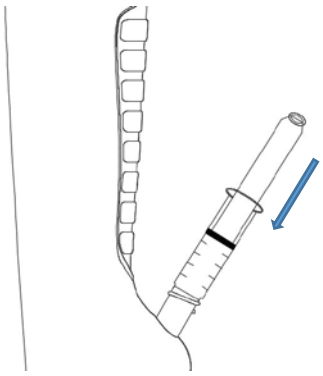
3.5.2 Immerse the distal tip into sterile water and press the suction valve. Confirm that the bottle of the water sucking device can enable continuous water absorption.

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.

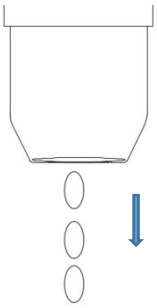
3.5.4 Take the end of the arthroscope out of water. Press the Air Suction button to suction for a few seconds so that all water in the pipeline is removed.

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.

· Do not press the suction valve when conveying liquid. Otherwise, the liquid will be attached to the tube instead of being discharged through the end of the endoscope.

3.7 Inspection of endo-therapy accessories

Warning ⚠

· The compatibility between the endoscope and any accessories should be inspected according to [Compatible Equipment and Accessories] before each use to ensure safe use.

· The head of endo-therapy accessories such as biopsy forceps must be closed at the time of insertion, otherwise the working channel will be damaged and parts will fall off.

· 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 in time if any.

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 HiVisu 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 manufactured by EICKEMEYER®, 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 Insert the endoscope into the trachea and bronchi through the patient's mouth or nose. 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 trachea and bronchi for observation.

4.2 Suction

Warning ⚠

· Excessive suction pressure may cause mucosal aspiration or injury.

· Make sure that biopsy valve cap is closed at the time of pumping. If not closed, the effect of the endoscopic suction system will be reduced

· Do not press the suction valve for a long time during the suction process

4.2.1 Connect the catheter of the negative-pressure device system to the suction joint of the endoscope, and adjust the suction pressure to the level that should be reached during surgery

4.2.2 Close the biopsy valve cap, press the Suction button, and operate the suction system

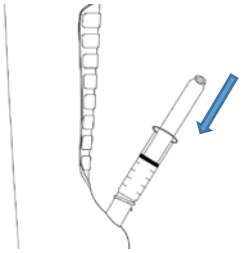
4.3 Injection or flushing of drugs

Warning ⚠

· The liquid will be sucked into the bottle of the vacuum system if the Suction button is pressed during liquid delivery.

4.3.1 Confirm that the suction function is closed.

4.3.2 Insert either syringe into the working channel port.



4.4 Insertion of the 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.

4.4.1 Please refer to [Compatible Equipment and Accessories] in the Instructions for Use for the selection of endoscopic accessories.

4.4.2 Withdraw the endoscope back to the bendable portion in a natural straight line, with the bending control lever kept still.

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

4.4.4 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. 4.4.5 Operate the bending control lever to slowly move the distal end to the expected position for surgery.

4.5 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.

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

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

4.6 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.

4.6.1 Observe the real-time endoscopic video displayed on the monitor and operate the bending control lever to slowly withdraw the endoscope from the patient's body.

4.6.2 Withdraw the endoscope and disconnect it from the endoscopy video processor

4.7 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.

4.8 Disposal of Endoscope

The used endoscope is considered infected and must be handled according to local guidelines, rather than using infected medical equipment with electronic components. The product and the materials used have undergone strict cleaning and disinfection procedures. Do not reuse.

5. Others

[Service Life]

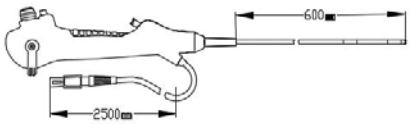
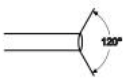
The date of manufacture and expiration date should be indicated on the label, and the aseptic shelf life is 3 years.

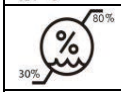
[Customer Service]

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

If you have any questions in the use of this product, please contact EICKEMEYER®.

Symbols and description

	Working length
Max. OD	Maximum outer diameter of the insertion portion
Min. ID	Minimum inner diameter of the working channel
	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 30-80% 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

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veterinary technology for life

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