

Brief Summary Document

Overview

Product Single-Use Broncho Videoscope – IFU 97354355

Rx Statement

***CAUTION:** Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner. Prior to use, please refer to all applicable “Instructions for Use” for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator’s Instructions.*

Content

INTENDED USE AND INDICATIONS FOR USE

This Single-use Broncho Videoscope is intended for use in conjunction with an Endoscopic Image Processor to provide images through a video monitor for observation, diagnosis, imaging, and treatment of respiratory system parts such as the trachea, bronchi, and lungs.

Do not use this product for any other purposes.

Based on a thorough understanding of the Single-use Broncho Videoscope specifications and functions listed in this instruction manual, select a Single-use Broncho Videoscope corresponding to the endoscopy and treatment goals.

CONTRAINDICATIONS

- Severe superior vena cava obstruction syndrome;
- Newly occurring myocardial infarction, or patients with unstable angina;
- Patients with a suspected aortic aneurysm;
- The trachea is too narrow for the Single-use Broncho Videoscope to pass through, which can lead to severe obstructive ventilatory disorder in patients;
- Patients with uremia, as severe bleeding may occur during endoscopy;
- Patients with severe pulmonary hypertension, as severe bleeding may occur during endoscopy;
- Patients with severe cardiopulmonary disease that cannot tolerate surgery;
- Patients with uncorrected diabetes and hypertension;
- Patients with uncontrolled coagulopathy;

- Do not use any equipment that is not compatible with this device for the diagnosis or treatment of proposed contraindications in any medical or health administrative institution or endoscopic society, or for cases that do not fall within their prescribed indications.

WARNING

- Do not install or operate the Single-use Broncho Videoscope in the following locations:
 - Area with a high oxygen concentration;
 - Area with oxidizing agents (such as nitrous oxide) in the atmospheric environment;
 - Area with flammable detergents or anesthetics in the atmospheric environment;
 - Area with flammable liquid nearby.

Use in such areas may cause an explosion or fire, as the Single-use Broncho Videoscope is not an explosion-proof device. Additionally, use in such areas may result in adverse events impacting the patient as described in Warnings and Cautions.
- Do not attempt to clean, disinfect, and reuse the device in different patients. This product is a single-use device.
- Do not prepare, inspect, or use the Single-use Broncho Videoscope with wet hands, otherwise, it may cause an electric shock.
- This product is not to be used with high-frequency surgical equipment.
- When the Single-use Broncho Videoscope is used with energized endotherapy devices, patient leakage current may be additive.
- Mains power quality should be that of a typical commercial or hospital environment. If the user of the Single-use Broncho Videoscope and Endoscopic
- Image Processor requires continued operation during power mains interruptions, it is recommended that they be powered from an uninterruptible power supply.
- Before each use or after a change of viewing modes / settings, check needed to ensure the view observed through the Single-use Broncho Videoscope provides a live image (rather than a stored one) and has the correct image orientation.
- Interconnections conditions require the applied parts of other ME equipment used within the configuration for endoscopic application to be type BF applied parts.
- This product should only be used by doctors who are skilled in clinical endoscopy techniques and procedures.
- No modification of this equipment is allowed.
- This product can only be used with the Endoscopic Image Processor specified by the product.
- Do not use excessive force or make sudden bending operations. Do not pull, twist, or rotate the angled bend section. Failure to comply may result in adverse events to the patient as described in Warnings and Cautions. Failure to comply may also cause the inability to straighten the bend section during the endoscopy process.
- Personal protective equipment (such as goggles, face masks, waterproof clothing, and chemical-resistant gloves) should be worn during operation to protect the operator from dangerous chemical preparations and potentially infectious materials. Personal protective equipment should fit properly and should be long enough to prevent skin exposure.
- When the endoscopic image is not displayed or the image is unintentionally frozen, do not operate the bend section, perform suction, insert or withdraw the insertion section of the Single-use Broncho Videoscope, or use an endoscopic treatment accessory. Failure to comply may result in adverse events to the patient as described in Warnings and Cautions.
- Do not perform a procedure inserting or withdrawing the Single-use Broncho Videoscope with excessive force or force the distal end of the Single-use Broncho Videoscope against the mucosa when the field of vision is poor or the accessory is outside the field of view, as this may result in adverse events to the patient as described in Warnings and Cautions.

- Do not insert or pull out the insertion section suddenly or forcefully. If it is difficult to insert the Single-use Broncho Videoscope, do not insert it forcefully; instead, stop the operation immediately. Failure to comply may result in adverse events to the patient as described in Warnings and Cautions.
- If the endoscopic image becomes dark during operation, it may be because blood or mucous membranes have adhered to the distal end of the Single-use Broncho Videoscope. The Single-use Broncho Videoscope should be carefully withdrawn from the patient's body to remove the blood or mucous membranes, ensuring optimal illumination and safe operation. If the user continues operations under such conditions, the temperature of the distal end will rise, causing burns to the patient's mucous membranes. It may also cause adverse events to the patient as described in Warnings and Cautions.
- Long-term suction operations will cause the distal end to contact the mucosal tissue. If the suction pressure is too high or the distal end contacts the mucosal surface for too long, it may cause adverse events to the patient as described in Warnings and Cautions.
- When the endoscopic image is not displayed on the monitor, one of the endoscopic image components may be damaged. The Endoscopic Image Processor should be turned off immediately. If the equipment remains powered for a prolonged period in such a situation, the distal end of the Single-use Broncho Videoscope will become hot, causing adverse events to the patient as described in Warnings and Cautions.
- If the user encounters significant resistance due to anatomical reasons during insertion, do not forcefully insert or withdraw the Single-use Broncho Videoscope. Failure to comply may result in adverse events to the patient as described in Warnings and Cautions.
- Do not look directly into the light emitted from the Single-use Broncho Videoscope. Doing so may result in eye injury.
- The temperature of the Single-use Broncho Videoscope's distal end may exceed 41°C (106°F) as a result of endoscopic illumination. As surface temperatures over 41°C (106°F) may cause tissue burns, always ensure a distance appropriate for adequate viewing and utilize the minimum illumination level for the minimum length of time. Do not use stationary viewing in close proximity to the tissue or place the distal end of the Single-use Broncho Videoscope in close proximity to the tissue for an extended length of time unless necessary.
- Do not expose the Single-use Broncho Videoscope to strong electromagnetic radiation (such as microwave treatment devices, MRI, wireless transmitter, and high-frequency wave therapy equipment); otherwise, the performance of the Single-use Broncho Videoscope will be affected.
- Portable radio-frequency (RF) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Single-use Broncho Videoscope, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection against RF communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- Use of this equipment adjacent to or stacked on top of other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be monitored to verify that they are operating normally.
- If the movement of the up/down angulation control knob is slack or unsmooth, or the bending of the bending section is not smooth, the bending function may be abnormal. In this case, do not use the Single-use Broncho Videoscope as the bending section may not straighten during the endoscopy, resulting in adverse events to the patient as described in Warnings and Cautions.
- If any abnormality is found during the inspection of an accessory, replace the Single-use Broncho Videoscope with a new one. A damaged or deformed accessory will reduce the effectiveness of the air/water supply function and may also cause leakage or spillage of liquid from the port(s) of the accessory.

- The suction button is sterile in preparation for single use. Do not reuse it or repeat sterilization.
- If the product's plug section and Endoscopic Image Processor are not connected properly, the endoscopic image may flicker or may not be displayed at all. Continued use of the Single-use Broncho Videoscope under such conditions may result in adverse events to the patient as described in Warnings and Cautions
- Securely connect the suction tube extending from the suction pump to the suction joint near the suction button. If the suction tube is not properly connected, debris will leak from the tube. Failure to establish a secure connection may result in contamination to the patient, operator, or device, and to the abnormal functioning of the equipment.
- Check whether the product is set to provide normal, live image output before use.
- Do not look directly into the distal end of the Single-use Broncho Videoscope when the LED light source is on. Failure to comply may result in eye injury.
- Keep your eyes away from the distal end when inserting the Single-use Broncho Videoscope accessories. Otherwise, an endoscopic treatment accessory that protrudes from the distal end may cause adverse events as described in Warnings and Cautions.
- Do not press the suction button while any liquid is being conveyed. Otherwise, the liquid will be suctioned in the suction pump.
- Avoid sucking solid pus or high-viscosity liquids to prevent the blockage of pipes or buttons. If the suction button is clogged and the suction process cannot be stopped, slowly remove the suction tube from the suction button to prevent liquids from splashing. Stop the suction and the endoscopy and withdraw the Single-use Broncho Videoscope from the patient while observing the endoscopic image.
- The suction pressure set by the suction pump should be in the range of -50 kPa to 0 kPa. Excessive pressure can make it difficult to stop the suction. If it cannot be stopped, remove the suction tube from the suction joint of the suction button, and turn off the suction pump. When there is splashed liquid, slowly remove the suction tube and remove all solid matter.
- Do not forcefully or suddenly insert endoscopic treatment accessories. Otherwise, the endoscopic treatment accessories may abruptly protrude from the distal end of the Single-use Broncho Videoscope, which may result in adverse events to the patient as described in Warnings and Cautions.
- When the Single-use Broncho Videoscope is used in conjunction with a powered Single-use Broncho Videoscope accessory, the patient's leakage current will increase, so the device needs to meet the leakage current requirements, otherwise, the patient may be at risk.
- Do not perform laser treatment when supplying oxygen, otherwise it will cause burns during laser treatment.
- To avoid injury, burns, bleeding, or perforation to the patient and damage to the Single-use Broncho Videoscope, make sure that the target is a sufficient distance from the distal end of the Single-use Broncho Videoscope. Additionally, do not activate the laser before the laser probe tip is in the correct position in the endoscopic image.
- Activating a laser generator within close proximity to the Single-use Broncho Videoscope distal end can damage the distal end.
- If the tip and aiming beam of the laser probe cannot be seen in the endoscopic image, do not emit laser light, as doing so may cause adverse events to the patient as described in Warnings and Cautions, and the working channel may be damaged.
- Do not withdraw the laser probe when laser light is emitted, as doing so may cause adverse events to the patient as described in Warnings and Cautions, and/or the Single-use Broncho Videoscope may be damaged.
- When performing laser treatment, wear suitable protective filtering spectacles or goggles, otherwise the operator may be injured.
- Do not use damaged laser probes. Using a laser probe with a damaged sheath or tip may cause adverse events to the patient as described in Warnings and Cautions and/or damage to the equipment.

PRECAUTIONS

- Before using the Single-use Broncho Videoscope, please read the product manuals and the instruction manuals for the optional accessories.
- Before using the Single-use Broncho Videoscope, check that the sterile packaging of the product is complete and not damaged. Do not use it if the package is damaged.
- Check whether the product is within the indicated shelf life before use.
- Before using this device, check that the device operates properly. Check that no damage or defects have occurred in all sections. If the appearance of the device is damaged or there are defects on other surfaces, please contact Scivita Medical Technology Co., Ltd.
- This product is a precision device. Please pay special attention to problems such as bending, impact, falling, or collision, which may cause equipment failure.
- Before inserting the Single-use Broncho Videoscope into the patient, check that the entire structure of the Single-use Broncho Videoscope is complete and intact, and confirm that the distal end can move freely without hindrance.
- Please connect the signal cable correctly. An incorrect connection will result in image loss or image errors. When the plug section of the signal cable is wet and/or contaminated, do not insert it into the Endoscopic Image Processor, as this may cause an electric shock, resulting in serious damage to the Single-use Broncho Videoscope, and cause adverse events to the patient as described in Warnings and Cautions.
- Do not use sharp objects to puncture the bending section and the distal end of the insertion section.
- Do not attempt to bend or twist the insertion section of the Single-use Broncho Videoscope, as this may result in damage to the insertion section.
- When the device is running, do not pull or tie the connection cable, which may result in image loss.
- Whenever a Single-use Broncho Videoscope is found to not be working properly, stop using it immediately and slowly withdraw it. Using a faulty Single-use Broncho Videoscope can cause adverse events to the patient as described in Warnings and Cautions.
- When the user operates the bending function, the distal end can be flexibly manipulated to the maximum bending angle by operating it with ordinary force. If the force exerted on the up/down angulation control knob is too large, it may damage the Single-use Broncho Videoscope or cause adverse events to the patient as described in Warnings and Cautions.
- Pay attention to the following when using accessories:
 - Replace deformed accessories promptly;
 - If the accessory has operational or appearance abnormalities, replace it with a new one;
 - Excessive force or forced passage may cause trauma to the operating channel and other adverse events to the patient as described in Warnings and Cautions.
- Turn off the Endoscopic Image Processor before connecting or disconnecting the product plug section to it. The Endoscopic Image Processor should only be turned ON or OFF when the product plug section is connected to it, otherwise the device may be damaged.
- Environmental protection: The Single-use Broncho Videoscope should be handled in accordance with medical waste after use, and all applicable national and local laws and regulations should be followed.
- This product can be affected by electromagnetic interference. Keep it away from magnetic objects and strong magnetic fields ($\geq 1\text{mT}$).
- This product generates and emits electromagnetic energy, which does not interfere with other equipment during normal use. However, if the device is installed incorrectly, or is not used according to the user manual, it may influence the efficacy of other devices.
- Federal law restricts this device to sale by or on the order of a physician.
- Any serious incident that has occurred associated with the Single-use Broncho Videoscope should be reported to Scivita Medical and the competent authority of the nation or state in which the user is established and/or the patient is located.

- The product is for single use. Before the sterile packaging is opened, the product packaging should be confirmed to be complete and not damaged, otherwise it must not be used.
- When the endoscopic treatment accessory is inserted into the working channel, the irrigation fluid volume will decrease. Under these conditions, please confirm the irrigation fluid volume in advance.
- Do not press the suction button during the water injection process, otherwise the water will be suctioned into the suction tube and will not flow out from the distal end of the Single-use Broncho Videoscope.
- Do not allow suction pressure to exceed -70 kPa. Please note that it is difficult to stop suction when the suction pressure is too high.
- If the suction button does not work smoothly, remove the device and reinsert it, or replace it with a new Single-use Broncho Videoscope. Continuous use of the Single-use Broncho Videoscope when the suction button does not work properly may make it impossible to stop suction during use, which can result in adverse events to the patient as described in Warnings and Cautions. Stop using the device immediately, and contact Scivita Medical Technology Co., Ltd.
- Use an endoscopic treatment accessory that is no wider in inner diameter than the Single-use Broncho Videoscope's working channel. Failure to comply may result in damage to the Single-use Broncho Videoscope and/or endoscopic treatment accessories.
- If accessory insertion is met with obvious resistance, straighten the bending section as much as possible to avoid losing the endoscopic image. Forced insertion of an endoscopic treatment accessory may result in damage to the Single-use Broncho Videoscope and/or endoscopic treatment accessory.
- Confirm that the tip of the endoscopic treatment accessory is closed or has been retracted into the sheath and slowly insert the endoscopic treatment accessory into the working channel. When inserting into the channel, do not open the tip of the endoscopic treatment accessory or extend it from the sheath. Failure to comply may result in damage to the Single-use Broncho Videoscope and/or endoscopic treatment accessories.
- Hold the Single-use Broncho Videoscope treatment accessory near the insertion port of the working channel, and insert it slowly and vertically into the insertion port of the working channel. Failure to do so may result in bending or damage to the sheath of the endoscopic treatment accessory.
- Adjust the Single-use Broncho Videoscope white balance to its normal color display mode before use.
- The Single-use Broncho Videoscope is important for observation and diagnosis. Be careful when using it. The movement of the device should be gentle and progressive. It must not be forced, bumped, or bent.
- When the Single-use Broncho Videoscope is in use, please observe the monitor image in real-time.
- When the Single-use Broncho Videoscope insertion section has been inserted into the patient's body, do not disconnect the signal line connected to the Endoscopic Image Processor.
- If any malfunction occurs during the endoscopic diagnosis, stop the diagnosis to ensure that the bending section is straight, not bent, and slowly withdraw it.
- When bending the insertion section do not bend past the safety zone, which is 14 cm from the front soft rotation section (as shown below). Failure to comply may result in damage to the insertion section.
- Make sure that the liquid in the suction bottle does not overflow during the endoscopy. Suctioning liquid into a suction bottle already filled with liquid can cause the pump to work abnormally and endanger the patient and the operator.
- During operation, make sure that the cap of the disposable biopsy valve is covered on the valve body; the connectors or knobs of the irrigation valve should be sealed.
- Recommended suction tube: silicone tube with 8 mm outer diameter and 5 mm inner diameter. Recommended waste bottle: volume ≥ 1000 ml.
- Before inserting or withdrawing the endoscopic treatment accessory, confirm that the distal end is closed or fully retracted into the sheath. The endoscopic treatment accessory should be inserted slowly and not at an angle into or out of the working channel port. Failure to do so may result in damage to the working channel or in component detachment.

- If the distal end of the endoscopic treatment accessory is not visible in the endoscopic image, do not open the distal end of the endoscopic treatment accessory.
- When bending the bending section, do not insert the laser probe into the working channel, as this may result in damage to the working channel and/or laser probe.
- When inserting the laser probe into the working channel, do not bend the bending section with force, otherwise, the laser probe may be damaged.
- Cool the laser probe before pulling it out of the working channel. If the laser probe is pulled out at a high temperature, the working channel may be damaged.
- Do not store the Single-use Broncho Videoscope in places subject to direct sunlight, X-rays, radiation, or strong electromagnetic radiation (such as near microwave therapy equipment, MRI equipment, short-wave therapy equipment, radio equipment, or cell phones). Failure to comply may result in damage to the device.

POTENTIAL ADVERSE EVENTS

Possible complications include, but are not limited to:

- Perforation;
- Bronchospasms;
- Electric shock;
- Infection;
- Inflammation;
- Laceration;
- Laryngospasms;
- Obstruction;
- Ocular injury;
- Hemorrhage;
- Tissue damage;
- Burns;
- Pain;
- Pneumothorax.