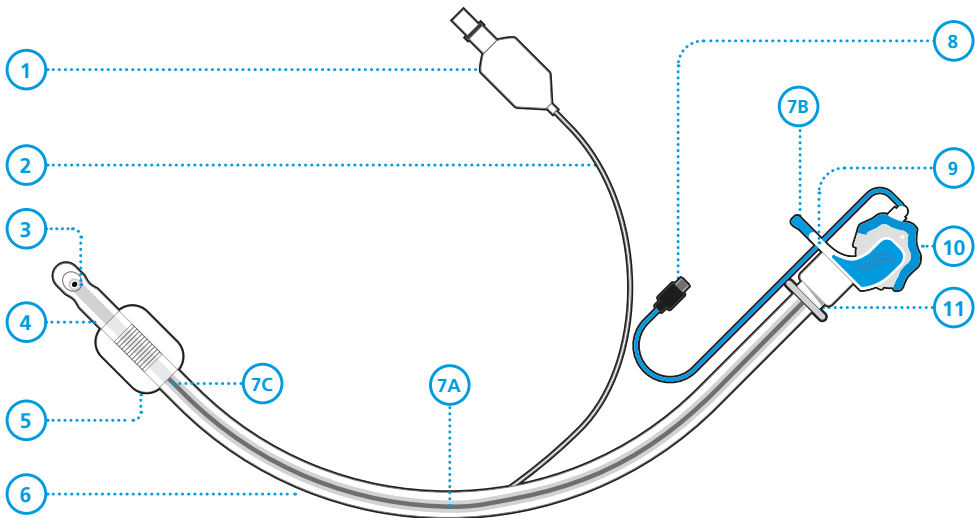




VIDEO STYLET AND ENDOTRACHEAL TUBE INSTRUCTIONS FOR USE



PRODUCT KEY

1. Pilot Balloon
2. Inflation Line
3. Video Camera
4. Flexible Tip
5. Cuff
6. Endotracheal Tube (ETT)
- 7A. Removable Malleable Rod
- 7B. Removable Malleable Rod Tab
- 7C. Distal End of Removable Malleable Rod
8. Camera Line with Display Connector
9. Control Platform
10. Control Wheel
11. 15mm Connector

**THIS INSTRUCTIONS FOR USE COVERS PROVU
VIDEO STYLET AND ENDOTRACHEAL TUBE PRODUCTS:**

- **038-990-065U** ProVu Video Stylet Size 6.5
- **038-990-070U** ProVu Video Stylet Size 7.0
- **038-990-075U** ProVu Video Stylet Size 7.5
- **038-990-080U** ProVu Video Stylet Size 8.0

Intended Use

The ProVu Video Stylet (ProVu VS) is a sterile, single-use, video-enabled stylet and ETT intubation system with malleable and directional control intended to assist with oral and nasal intubations and designed for use in adults in a hospital environment. The device consists of a control wheel at the proximal end and an incorporated light source and video camera at the distal end. The ProVu VS is connected to a ProVu Display to provide a video stream from the distal end of the ETT.

A malleable rod is pre-loaded to facilitate curvature of the ETT and can be removed to make the ETT more flexible. The ProVu VS is designed to assist placement of the ETT by providing video images of the patient's airway anatomy during intubation. The directional ETT tip allows for controlled flexion and retroflexion enabling precise placement through the vocal cords and video confirmation of the correct ETT placement within the trachea.

Precautions















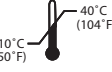





- Ensure there is adequate room for easy operation.
- Make sure the stylet portion of the ProVu VS is fully seated on the ETT connector prior to use.
- Always remove the malleable rod when performing nasal intubation or when using with an Intubating Supraglottic Airway (ISGA) or Intubating Oral Airway (IOA).
- Do not put any traction on the ProVu VS control wheel while bending the ProVu VS's malleable rod.
- The ProVu VS ETT must not be cut to length by the user.
- Deflate cuff prior to repositioning the ETT.
- If the patient's position is altered after intubation, verify that the ETT position remains correct.
- Cuff pressure should be monitored. Any deviations from the selected seal pressure should be investigated and corrected immediately. Diffusion of nitrous oxide mixture, oxygen or air may either increase or decrease cuff volume and pressure. To decrease such diffusion, inflating the cuff with the same gas mixture that will contact the cuff's external surface is recommended.
- Do not place any other device or object in the ETT's lumen while using the ProVu VS.
- If lubricating the ProVu VS ETT, do not lubricate the camera lens of the ProVu VS.
- Ensure that you always have easy access to the power cord, plug or adapter to disconnect this device from the power.
- The user must check the product for any manufacturing defects before use.
- Ensure there is no glare on the screen before and / or during use.

Warnings & Cautions

- Do not modify the device.
- The ProVu VS should only be used by trained medical professional.
- Intubation and extubation should be performed using currently accepted medical techniques.
- Apply good medical judgment when using this product.

- Do not reuse this device. Reuse may result in hazards such as, but not limited to; cross contamination, damage to device, patient injury and/ or suboptimal performance.
- Only use the ProVu VS with the ETT it is provided with as they are specifically designed and correctly sized for the system.
- ProVu VS is designed for use only with ProVu Displays.
- Do not use any part of the system with other stylets.
- Do not advance the ETT in the trachea without having the ProVu stylet fully inserted.
- Do not bend the fully inserted malleable rod at any point distal to the proximal end of the ETT cuff.
- To protect the ProVu VS from damage, use with a bite block when indicated.
- Do not use in procedures which will involve the use of a laser beam or electro-surgical active electrode in the immediate area of the ProVu VS.
- Do not place anything other than the ProVu VS's malleable rod through the opening in the platform for the Malleable Rod.
- Do not use with highly flammable anesthetics.
- Do not attempt to use directional control of the ProVu VS with ISGAs and IOAs until the ETT cuff of the ProVu VS has passed the distal opening of the ISGA or IOA.
- Do not over inflate the cuff.
- Do not use with a defibrillator.
- Do not exert excessive force on the stylet.
- Do not use with ISGAs that have an inflexible airway tube.
- If device stops working, continued use could cause harm to the patient.
- Check that the ProVu Display correctly displays video from the stylet with clarity and the correct orientation.
- Do not use within Magnetic Resonance Imaging (MR/MRI) environments or with other high interference sources.
- Any serious incident that occurs in relation to the device should be reported to the manufacturer and the competent authority of the Member State of the user and/or patient.
- After Extubation, dispose of all single-use components of the ProVu VS intubation system in accordance with local hospital policies.
- Do not over inflate the cuff. Over inflation can result in tracheal damage, or herniation of the cuff, which may cause airway blockage. As airways may vary in size & compliance, the recommended volume of air for inflation is the amount required to achieve a cuff pressure of 20-30cm of H₂O.
- Measurement of the cuff inflation using palpation of the pilot balloon as the sole method of evaluation is not recommended.
- Minimal Occluding Volume or Minimum Leak Techniques should be used in conjunction with a manometry, monitored throughout the process, and adjusted as necessary to ensure the selected seal pressure is maintained. Failure to do so could result in tracheal damage or herniation of the cuff, which may cause airway blockage.

Symbols Glossary

									
Catalog number	Batch Code	Use-By-Date	Product conforms with Directive 93/42/EEC	Do Not Re-use	Refer to instruction manual/booklet	Do not use if packaging is open or damaged.	Sterilized using Ethylene Oxide	Caution: US Federal Law Restricts this device to sale by, or on the order of, a physician.	Product not made with Phthalate DEHP
									
Separate Collection	Manufactured by	Do not re-sterilize	USB / Mirco USB	Temperature Limit 10 to 40°C (50°F to 104°F)	Do not use blade to open	Keep dry	Keep away from sunlight	Recycle	Country of origin

Contraindications

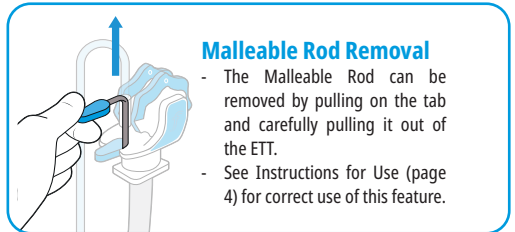
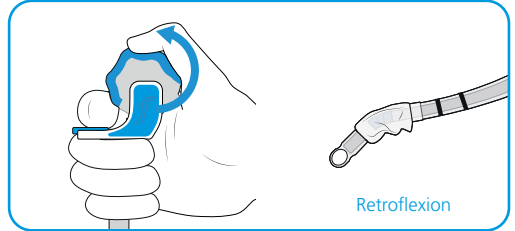
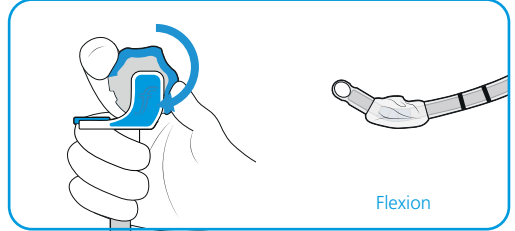
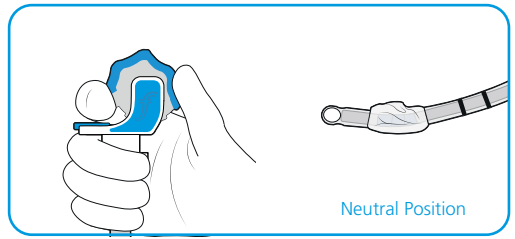
- Laryngeal edema (oedema), acute airway inflammation, laryngeal abscess/compression of trachea and severe bleeding or thoracic aortic aneurism
- Do not use with patients with the following:
 - Nasal polyp
 - Nasopharyngeal hemangioma

Controlling the Tip

- The ProVu VS should be held with the thumb and index finger placed on the control wheel for flexion and retroflexion of the distal tip of the ETT.
- Rotation of the control wheel towards the user results in flexion of the ETT tip.
- Rotation of the control wheel away from the user results in the retroflexion of the ETT tip.

Before Use

- When using the ProVu VS with the malleable rod, make sure the malleable rod is fully inserted in the ProVu VS so that the proximal portion is flush with the control platform and secured in place.
- Inflate the cuff and check for leaks, once satisfied, deflate the cuff.
- Check that ProVu VS is not damaged and that the flexion and retroflexion mechanisms are working.
- Make sure the stylet portion of the ProVu VS is fully seated on the ETT connector prior to use.
- Unplug the ProVu Display (refer to ProVu Display instructions for use) from the charger and check that it has sufficient charge to complete the procedure. Place the ProVu Display in view – either in the Wrist Mount, Display Table Stand or Pole Stand.
- Connect the ProVu VS camera line to the ProVu Display, or Amplifier Cable if used, and make sure an image appears on the display with proper orientation, and that the ProVu VS camera LED lights turn on.
- Use good clinical judgment to determine if the ETT of the ProVu VS is the correct size and length for the intended patient.



Technical Specifications

	6.5, 7.0 ETT	7.5, 8.0 ETT
WEIGHT (WITH ETT)	56g	63g
WEIGHT (WITHOUT ETT)	39g	42g
OUTER DIAMETER	5mm	6mm
USB LENGTH	600mm	600mm
RESOLUTION	480 x 320 px	480 x 320 px
VIEWING ANGLE (FIELD OF VIEW)	60°	60°
ILLUMINATION TEMPERATURE	5500K-6000K	5500K-6000K
ILLUMINATION LUX	200 - 500 Lux	200 - 500 Lux
DEPTH OF FIELD	20 - 50mm	20 - 50mm
OPERATING TEMPERATURE	10 - 40°C	10 - 40°C

Recommended Size by Patient

- ProVu Video Stylet Size 6.5 - Adult
- ProVu Video Stylet Size 7.0 - Adult
- ProVu Video Stylet Size 7.5 - Adult
- ProVu Video Stylet Size 8.0 - Adult

Environmental Conditions

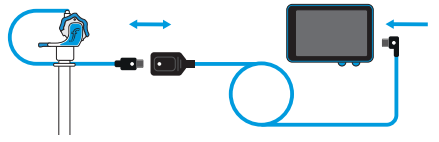
Operating & Storage Temperature: 10°C to 40°C
Transport Temperature: -5°C to 45°C

List of Accessories

- ProVu VS 3.5" Display
- ProVu VS 8" Display
- ProVu Wrist Mount
- ProVu Display Table Stand
- ProVu Display Intubation Station
- 1m Amplifier Cable
- 2m Amplifier Cable

Instructions for Use

1. Connect the ProVu VS to the ProVu Display using the camera line, or Amplifier Cable if used.
2. Check that the ProVu Display screen displays video from the camera with clarity and proper orientation.
- 3a. If using for nasotracheal intubation or using with an ISGA, IOA, or Video Laryngoscope with channels, guides or steerable mechanisms for the ETT; remove the malleable rod from the ProVu VS.
- 3b. If using for orotracheal intubation, including retromolar intubation, shape the pre-loaded malleable rod as necessary.
4. Use suction as needed to clear secretions from the patient's airway prior to inserting the ProVu VS.
5. Use currently accepted medical techniques for intubation, using the video stream of the ProVu VS on the Display as a guide for the intubation.
6. If directional control of the ETT tip is required, rotate the control wheel of the ProVu VS as needed (see page 3).
7. Once the ETT is correctly positioned, inflate the ETT cuff (taking care not to over inflate), and carefully remove the ProVu VS, then attach the ETT to the ventilation equipment while holding the ETT securely in place.



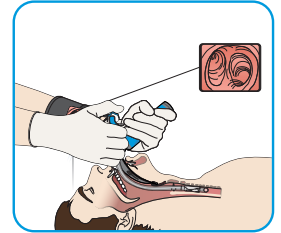
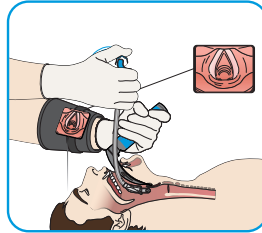
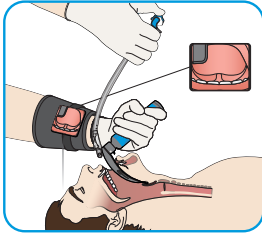
Extubation

- Before removing the ETT, completely deflate the cuff.
- Extubate using currently accepted medical techniques.

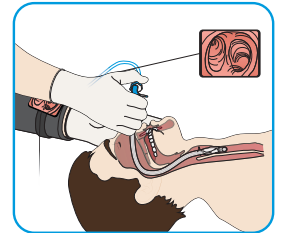
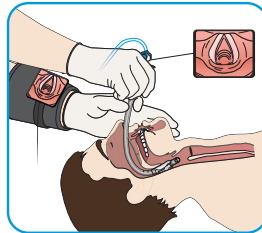
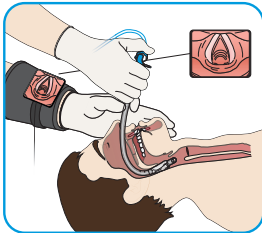
After Use

- After step 7, disconnect the ProVu VS from the Display.
- After Extubation, dispose of all single-use components of the ProVu VS intubation system in accordance with local hospital policies.

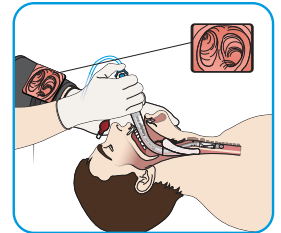
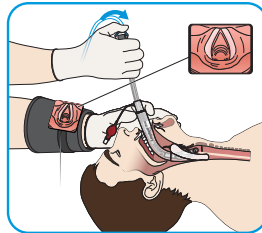
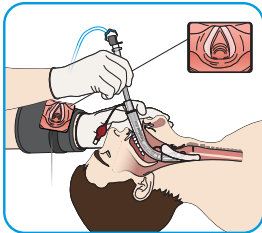
OROTRACHEAL
INTUBATION



NASOTRACHEAL
INTUBATION



ISGA
INTUBATION



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