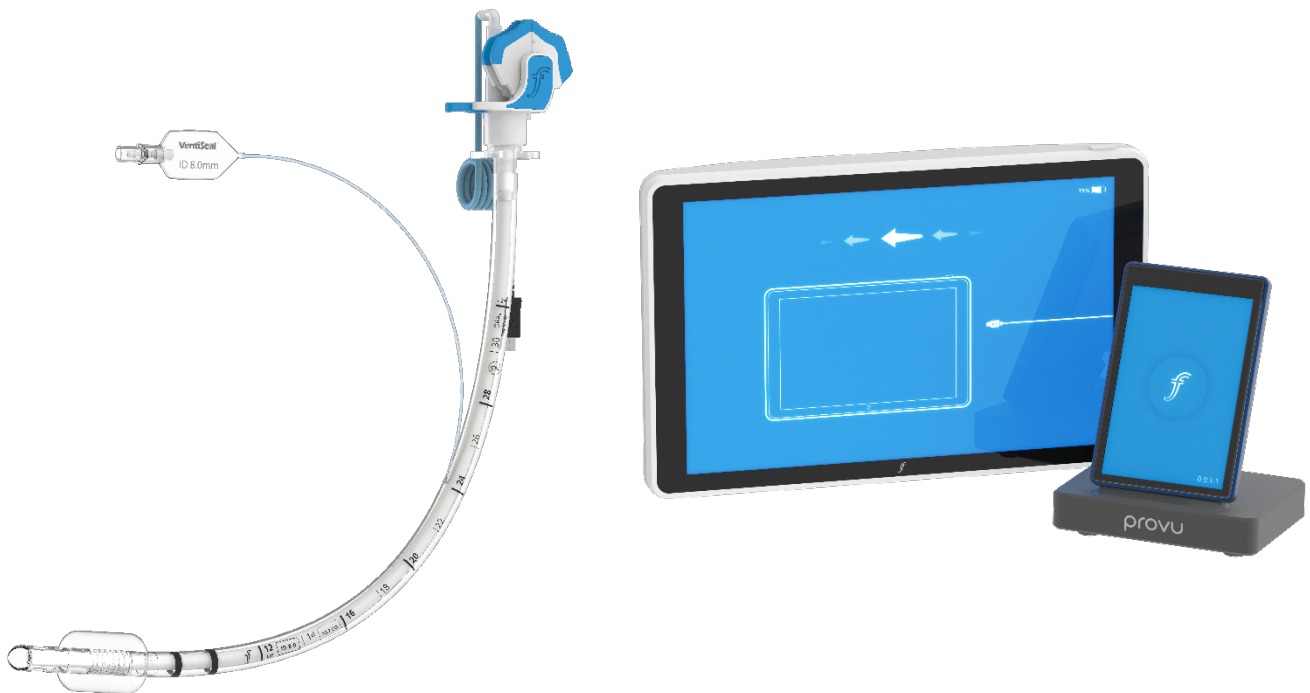


# ProVu Video Stylet

Product Data Sheet

**PRODUCT:** ProVu Video Stylet and Displays**DESCRIPTION / FUNCTION**

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. 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.

**WARNINGS / 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.
- 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 devices or objects in the ETT's lumen while using 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.
- Do not modify the device.
- The ProVu VS should only be used by trained medical professionals.
- Intubation and extubation should be performed using currently accepted medical techniques.
- Apply good medical judgement 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 with Magnetic Resonance Imaging (MR/MRI).
- 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 and 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.

## SPECIFICATION / KEY FEATURES

- Connection of ProVu video stylet to display allows video-guided viewing of the airway from the distal end of the ET tube.
- Removable malleable rod enables the ET tube to be shaped as required.
- Articulated ET tube tip can be flexed and retroflexed to conform with patient's anatomy using the control wheel. An auto-lock function maintains the desired tip position.
- VentiSeal cuff enables pressure to be distributed over a larger area, reducing the pressure placed on the tracheal wall.
- Ventilation eyes reduce the risk of occlusion.
- Standard 15 mm male connector provides universal connections.
- Display sizes available in 3.5" and 8" with various display accessories.

## PRODUCT RANGE & PART NUMBERS

Product Code	Product Description
038-990-001	ProVu Reusable 3.5" Video Stylet Display, Charging Dock and 1m Amplifier Cable
038-990-001U	ProVu Reusable 3.5" Video Stylet Display, Charging Dock and 1m Amplifier Cable
038-990-002	ProVu Reusable 8.0" Video Stylet Display, Charging Cable and 2m Amplifier Cable
038-990-002U	ProVu Reusable 8.0" Video Stylet Display, Charging Cable and 2m Amplifier Cable
038-990-010	ProVu Charging Dock for 3.5" Display
038-990-010U	ProVu Charging Dock for 3.5" Display
038-990-011	ProVu Video Stylet Reusable 1m Amplifier Extension Cable
038-990-011U	ProVu Video Stylet Reusable 1m Amplifier Extension Cable
038-990-012	ProVu Video Stylet Reusable 2m Amplifier Extension Cable
038-990-012U	ProVu Video Stylet Reusable 2m Amplifier Extension Cable
038-990-013	ProVu Dual Micro USB 1.0m Charging Cable
038-990-013U	ProVu Dual Micro USB 1.0m Charging Cable
038-990-065	ProVu Single Use Video Stylet with ET Tube Size 6.5
038-990-065U	ProVu Single Use Video Stylet with ET Tube Size 6.5
038-990-070	ProVu Single Use Video Stylet with ET Tube Size 7.0
038-990-070U	ProVu Single Use Video Stylet with ET Tube Size 7.0
038-990-075	ProVu Single Use Video Stylet with ET Tube Size 7.5
038-990-075U	ProVu Single Use Video Stylet with ET Tube Size 7.5
038-990-080	ProVu Single Use Video Stylet with ET Tube Size 8.0
038-990-080U	ProVu Single Use Video Stylet with ET Tube Size 8.0
038-990-100	ProVu Single Use Wrist Holder for 3.5" Display
038-990-100U	ProVu Single Use Wrist Holder for 3.5" Display
038-990-101	ProVu Display Pole Stand and Articulating Arm
038-990-101U	ProVu Display Pole Stand and Articulating Arm
038-990-102	ProVu Display Table Stand
038-990-102U	ProVu Display Table Stand

## MATERIALS

Component	Material
ET Tube Connector	Polypropylene
ET Tube	PVC
Video Stylet	Glass Filled Nylon, Thermoplastic Elastomer, EVA Shrink Sleeve
Malleable Rod	Stainless Steel, 304
Pole Stand	Aluminum
Wrist Strap	EVA
Display Casing	Polycarbonate
Charging Dock	Aluminum, Nylon
Table Stand	Aluminum, Polycarbonate

### LATEX CONTENT

Flexicare's ProVu Video Stylets do not contain natural rubber latex.

### DEHP CONTENT

Flexicare's ProVu VS does not contain phthalate DEHP.

### PRODUCT USE

Flexicare's ProVu Video Stylet, ET Tube, and wrist strap are single use devices.  
Flexicare's ProVu displays and accessories are reusable devices.

### STERILITY

Flexicare's ProVu Video Stylet and ET Tube are supplied sterile.  
Flexicare's ProVu displays and accessories are supplied non-sterile.

### STORAGE

Store in a cool, dry place out of direct sunlight.

### SHELF LIFE

Flexicare declares a shelf life of 5 years from the date of manufacture. This is based on the stability of the devices' components and raw materials sourced. Expiry date is clearly marked on individual product pouch.

### DISPOSAL CONSIDERATIONS

After use, dispose of in accordance with local policies and / or as advised by your local healthcare provider.

### PACKAGING MATERIALS

#### Non-Sterile

Primary – Carton / Box – Cardboard with Foam Inserts

#### Sterile

Primary – Top Web – EO Permeable Paper

Tray – Polyethylene Terephthalate (PET)

#### All variants

Secondary – Carton / Box - Cardboard