



Overview

OverTube™ Endoscopic Access System – IFU # 51931777

Product

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Reuse Warning

For single use only. Do not reuse, reprocess or sterilize. Reuse, reprocessing or sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or sterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

Intended Use/Indications for Use

The OverTube is intended to be used in conjunction with an endoscope for foreign body removal or endoscopic procedures requiring multiple insertions of the endoscope into the upper gastrointestinal tract.

Contraindications

Contraindications include those specific to use of an overtube and any endoscopic procedure, which may include, but not be limited to, the following:

- Esophageal bleeding, ulceration and/or laceration
- Laryngeal perforation and/or stenosis
- Existing trauma to teeth, gums and/or pharynx which could be aggravated during the procedure
- Non reversible bleeding disorders with coagulopathy
- The patient has any other condition or anatomical limitation that would contraindicate them from a gastrointestinal endoscopic procedure
- Varices

Warnings

- Lubrication required. Generously lubricate inner and outer surfaces of the OverTube with water soluble lubricant prior to use
- During insertion or removal of the OverTube and/or endoscope and accessory devices, do not advance or retract against resistance. Doing so may result in patient injury.
- Do not advance, remove, or reposition the OverTube unless under endoscopic visual guidance. Doing so may result in patient injury.

- Once placed, the OverTube should not be advanced beyond the endoscope as tissue entrapment and mucosal injury could occur. For any repositioning required, refer to Endoscope Removal and Reinsertion.
- Reuse or reprocessing of the OverTube could result in device malfunction or patient consequences to include:
 - Infection or the transmission of disease
 - Damage to the polymer extrusion, compromising safe access
 - Impaired sealing when using insufflation
 - Accumulation of lubricant and debris

Precautions

- Prior to use, performing a baseline esophagogastroduodenoscopy (EGD) can identify contraindications of the use of the OverTube.
- Endoscopic procedures and foreign body retrieval should only be performed by clinicians with adequate training and familiarity with endoscopic techniques. Use of the OverTube should not be attempted unless proficiency in technique has been developed.
- Do not try to remove specimens or foreign bodies that are larger than the OverTube can accommodate (inner diameter 17.5 mm).
- The OverTube is a single-use device intended to support one endoscopic procedure. As the number of endoscopic passes increases, the endoscope may need to be relubricated to ensure smooth passage down the OverTube. Additionally, the cuff may need to be reinflated periodically during the procedure.
- If the seal is over-inflated, endoscope and accessory movement can be affected. If required, reduce the seal force by opening the seal valve and withdrawing a small volume of air back into the syringe.

Adverse Events

Possible complications that may result from using the OverTube include, but may not be limited to:

- Allergic reaction
- Gastrointestinal Symptoms
- Hemorrhage
- Infection / Sepsis
- Inflammation
- Laceration
- Pain
- Perforation
- Respiratory Distress
- Tissue damage

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