

EndoVive™ Through the PEG Jejunal Feeding Tube Kit

Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

Intended Use/Indications for Use

The Through the PEG (TTP) Jejunal Feeding Tube (J-Tube) Kit is intended to provide enteral access for decompression and delivery of nutrition and/or medication.

Contraindications

None known.

Precautions

- The TTP J-Tube Kit should only be used by or under the supervision of physicians trained in percutaneous gastrostomy/jejunostomy tube placement. A thorough understanding of the technical principles, clinical applications and risks associated with percutaneous gastrostomy/jejunostomy tube placement is necessary before using this device.
- Any use of this device, other than those indicated in these instructions, is not recommended.
- The TTP J-Tube is designed for use with EndoVive™ Gastrostomy Tubes. Verify the proper TTP J-Tube Kit is selected for the appropriate gastrostomy tube.

Potential Adverse Events

Possible complications of TTP J-Tubes, include, but may not be limited to, those associated with gastrostomy tubes. Complications include: bleeding, tube occlusion, tube clogging, infection, peritonitis, perforation, malposition, leaking, kinking, tube migration, diarrhea, inadvertant removal, and small bowel obstruction.

Warnings

Contents supplied STERILE using an Ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, contact your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization 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 resterilization may also create a risk of contamination 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.

Cautions

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

The 8.5F (2.8 mm) TTP J-Tube is only compatible with 20F (6.7 mm) Boston Scientific Endoscopy Initial Placement gastrostomy tubes.

The 12F (4.0 mm) TTP J-Tube is only compatible with 24F (8.0 mm) Boston Scientific Endoscopy Initial Placement gastrostomy tubes.