

EndoVive™ Jejunal Feeding Tube 3-Port Through-the-PEG J-Tube Kit

REFER TO THE DEVICE DIRECTIONS FOR USE FOR COMPLETE INSTRUCTIONS ON DEVICE USE. RX ONLY.
CAUTION: FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

Warning

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

For single 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 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.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

Caution

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

Caution

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

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.
- Do not use without reading and understanding the complete instructions enclosed herein.

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3-Port Through-the-PEG J-Tube Kit

Adverse Events

Possible complications of TTP J-Tubes, include, but may not be limited to, those associated with gastrostomy tubes. Complications include: infection, blockage/occlusion, tissue necrosis, migration, aspiration, bleeding, fistula, GE reflux, pain, perforation, ulceration, peritonitis, diarrhea, tube clogging, malposition, leakage, kinking, inadvertent removal, small bowel obstruction, granulation tissue, and pneumoperitoneum.

Caution

This device is intended to connect to enteral feeding devices. Care should be taken to avoid the potential harm of misconnection with non-enteral feeding connectors