EndoVive™
Standard Balloon Replacement Kit Straight and Right-Angle Bolsters
Prescriptive Information

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

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.

Intended Use/Indications for Use
The replacement tube is intended to provide gastric access for Enteral feeding, medication administration, and gastrointestinal decompression. The replacement tube is indicated in adult and pediatric populations for use in percutaneous placement of an Enteral feeding tube for feeding and/or administration of medication in conjunction with an established GI stoma tract. Typical uses include the replacement of existing gastrostomy feeding tubes. The replacement tube may also be used for decompression.

Contraindications
Placement is also contraindicated for patients with evidence of granulation tissue, infection, and/or irritation at the stoma site.

Warnings
- Excessive tension, tissue necrosis and tube dislodgement may cause separation of the gastric and abdominal wall.
- This product must never be used in the vasculature.

Precautions
The replacement tube should only be used by or under the supervision of physicians trained in percutaneous gastrostomy tube placement. A thorough understanding of the technical principles, clinical applications and risks associated with percutaneous gastrostomy tube placement is necessary before using this device. Any use of this device, other than those indicated in these instructions, is not recommended.

Adverse Events
The following may be associated with the use of Gastrostomy Tubes: aspiration, reflux, sepsis, ascites, bleeding, granulation tissue, pressure necrosis, ulcers, severe gastroesophageal reflux or diffuse inflammatory, infectious or neoplastic disease involving the walls of the abdomen or anterior stomach,

gastrointestinal obstruction, tube occlusion, tube clogging, peritonitis, perforation, malposition, leakage, kinking, tube migration, inadvertent tube removal, proximal small bowel obstruction (fistulae), irritation and infection such as redness, edema or purulent drainage.