EndoVive™ One Step Button

Low Profile Percutaneous Endoscopic Gastrostomy Kit

Prescriptive Information

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

Caution/Rx Only:

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

Warnings:

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 One Step Button Device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Contraindications:

The One Step Button Device is not indicated for the following:

- Children under 10 Kilos/22 pounds.
- The 24F is not indicated in children under 15 kilos/33 pounds.
- Not recommended in individuals with abnormally high intra-abdominal pressures.
- Obstruction of the esophagus which may prevent the introduction or removal of the feeding tube.
- Inability to identify transabdominal illumination or needle placement.
- Multiple surgical procedures near the gastrostomy site.
- Patients on anticoagulant drugs.
- High medical risk patients.

Precautions:

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

Adverse Events:

The following complications may occur with the use of direct feeding devices: fever, gastric distention, infection, blockage/ occlusion, tissue necrosis, migration, peritonitis, sepsis, erosion/embedding into the gastric wall (“Buried Bumper Syndrome”), aspiration, bleeding, fistula, gastroparesis, GE reflux, pain, perforation, ulceration, tube clogging, malposition, leakage, kinking, inadvertent removal, small bowel obstruction, granulation tissue, and pneumoperitoneum.

Caution:

- Carefully examine the unit to verify that the contents have not been damaged in shipment. DO NOT USE if damaged. Immediately return damaged product to Boston Scientific Corporation.
- 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.

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