Instructions for Use
**Indications for Use**

Gastrostomy tube feeding may be indicated for patients needing long-term enteral support or hydration secondary to a primary condition relating to the head and/or neck. These conditions include stroke; cancer; head and neck tumors, injuries, or trauma; and neurological disorders resulting in a chewing or swallowing abnormality. This device (sold in a kit) is intended as an initial placement device. The device is placed by one of two techniques, the PULL technique and the over-the-guidewire technique (PUSH technique). This guidance covers the PUSH technique.

**Contraindications**

1. Esophageal stenosis
2. Portal hypertension

**Warnings**

Do not reuse, reprocess, or resterilize this medical device. Reuse, reprocessing, or resterilization may 1) adversely affect the known biocompatibility characteristics of the device, 2) compromise the structural integrity of the device, 3) lead to the device not performing as intended, or 4) create a risk of contamination and cause the transmission of infectious diseases resulting in patient injury, illness, or death.

After MIC* PEG Tube placement, proper positioning of the internal bumper against the gastric mucosa must be verified endoscopically. Tension on the MIC* PEG Tube should be avoided to minimize the risk of complications.

Failure to comply with these warnings may result in pressure necrosis of the gastric mucosa with subsequent erosion, perforation, and/or leakage of gastric contents into the peritoneum. Migration of the internal bumper into the stoma tract or embedding into the stomach wall may also occur over time.

Dispose of all sharps according to facility protocol.

**Caution:** Verify package integrity prior to opening. Do not use if package is damaged or sterile barrier compromised.
Placement Procedure

1. Use a clinically approved method to prep and sedate the patient for an endoscopic procedure.

2. Use a clinically approved procedure to perform the gastric endoscopy.

3. With the patient in a supine position, insufflate the stomach with air and transilluminate the abdominal wall. △ Caution: Proper selection of the insertion site is critical to the success of this procedure.

4. Select gastrostomy site. This site (typically the upper left quadrant) should be free of major vessels, viscera, and scar tissue.

5. Prep and drape the skin at the selected insertion site. Locally anesthetize the insertion site.

6. Following local anesthesia, make a 1 cm (approximate) incision through the skin with the scalpel.

7. Insert the introducer needle system through the incision, advancing through the peritoneum and the stomach wall. Fig. 1

8. When the introducer needle is observed in the stomach, remove the introducer needle from the introducer cannula by firmly holding the cannula hub and pulling back on the needle hub.

9. Place the guidewire through the introducer cannula into the stomach. Grasp the guidewire with a retrieval snare. Withdraw the retrieval snare into the endoscope channel. Fig. 2

10. Remove the endoscope and the guidewire through the oropharynx. Pull approximately 45 inches (114 cm) of the guidewire from the mouth.

11. Before advancing the MIC* PEG Tube into the oropharynx, feed the tapered end of the MIC* PEG Tube over the guidewire until the wire exits the opposite end of the MIC* PEG Tube. Fig. 3

12. Once the guidewire is approximately 45 inches (114 cm) from the mouth, slide the introducer cannula out of the incision site.

13. Lubricate the MIC* PEG Tube with a water-soluble lubricant. Keep the guidewire taut and push the MIC* PEG Tube in an antegrade method until the tapered tip of the tube dilates the stoma tract through the abdominal wall. Fig. 4

14. Re-enter the esophagus with the endoscope and visually follow the gastrostomy tube as it enters the stomach. Grasp the tapered tip of the MIC* PEG Tube as it penetrates the abdominal wall and pull the PEG tube so that the internal bumper moves into the stomach. Remove the guidewire.

15. Use a rotating motion to slowly work the tube up and out until the internal bumper gently rests against the gastric mucosa. Note: Graduated markings on the body of the tube will assist in determining the progress of the tube as it exits the abdomen. △ Caution: Do not use excessive force to pull the tube into place. This could harm the patient and damage the tube.

16. Cleanse the tube and stoma site and apply a sterile gauze dressing.

17. Slide the external bolster over the proximal end of the MIC* PEG Tube and push the external bolster into place next to the sterile gauze dressing. Visually verify that the internal bumper is properly placed. Remove the endoscope. The external bolster should be positioned approximately 2 mm above the skin. △ Caution: Do not apply excessive tension. There should be no compression of the gastric mucosa or the skin. Optionally, a suture loop (not supplied) may be tied around the external bolster to minimize movement of the MIC* PEG Tube while the stoma is healing.

18. Cut the MIC* PEG Tube at approximately 90 degrees, leaving an appropriate length to attach a MIC* Feeding Adapter on the proximal end of the MIC* PEG Tube. This adapter will accept a catheter tip syringe or a standard feeding connector. Fig. 5 Discard the removed portion of the tubing.

Skin and Stoma Care

1. Keep the skin around the MIC* PEG Tube stoma site clean, dry, and free of drainage.

2. The stoma and surrounding skin area should be inspected at each feeding. Wash the area at least once daily with a mild soap and water solution. Be sure to clean under the external bolster. Rotating the tube in place while cleaning helps to promote tube independence. Always rinse and thoroughly dry the skin.

3. After the stoma is healed, a dressing is not necessary with the MIC* PEG Tube and may even cause moisture retention resulting in skin irritation.

Removal of the MIC* PEG Tube

△ Caution: The MIC* PEG Tube should be removed by either traction removal through the stoma or through endoscopic retrieval. We do not recommend that a portion of the tube be cut to allow the internal bumper to pass.
Caution: When the 14 Fr PEG is used, use endoscopic removal method only.

1. When the physician determines that the tract is formed (usually within 4-6 weeks after placement of PEG), the MIC* PEG Tube may be replaced with an alternative feeding device. We recommend using one of the following:
   - MIC-KEY® Low-Profile Gastrostomy Tube
   - MIC® Gastrostomy Tube

2. To remove the tube, prep the patient for MIC* PEG Tube removal using standard procedure. Lubricate the skin and tube around the stoma with a water-soluble lubricant. Rotate the tube 360° and move the tube in and out slightly.
   Warning: If the tube does not move without restriction in the tract, do not attempt to use traction as a method of removal. Removal of feeding tubes using traction may result in tract separation and associated complications. Feeding tubes that have been in place for several months may have an increased potential for internal bumper separation during traction removal.

Caution: When the 14 Fr PEG is used, use endoscopic removal method only.

3. Position one hand on the abdomen around the stoma with the thumb and forefinger approximately two inches apart to stabilize the abdominal wall.

4. Grasp the tube with the opposite hand next to the stoma site. Firmly, but gently, pull the MIC* PEG Tube until the internal bumper emerges through the stoma.

5. Replace the MIC* PEG Tube with the appropriately sized gastrostomy tube.

6. If the tube cannot be removed with a reasonable amount of traction, it should be removed by endoscopic retrieval.

For Enteral Nutrition Only
Verify package integrity prior to use.