

CAUTION: BEDSIDE MISCONNECTION RISKS

The Gabriel® Feeding Tube with Balloon has a caution label attached at its proximal end stating "Enteral Feed/Use Only, MR Conditional" along with instructions on deflating the balloon before removal. This label is to alert staff that the **Gabriel Feeding Tube with Balloon is for enteral use only** and to be aware of potential bedside misconnections. Bedside misconnections can cause serious injury to the patient. The connectors listed below are known to potentially engage and connect to the Gabriel Feeding Tube with Balloon. Please ensure that connections with the following and similar items are not made:

- Misconnection can occur with tracheostomy tube;
- Ensure that any transitional connectors are connected to an enteral port and not to an IV set.

This Gabriel Feeding Tube's connector is intended to connect to enteral feeding pump lines, enteral feeding gravity set lines, and the Lopez 3-way Valve (ICU Medical K915171).

PRECAUTIONS

- Tube balloon (3 ml) and pilot balloon (3 ml) must be deflated before removal from patient. Please remove all 6 ml.
- Please read all illustrated instructions for the procedure prior to use.
- For technical questions please call (478) 335-8311.

MRI SAFETY INFORMATION

Non-clinical testing has demonstrated that the Gabriel Feeding Tube with Balloon Size 12 Fr is MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5-Tesla (1.5 T) or 3-Tesla (3 T).
- Maximum spatial field gradient of 3,000 G/cm (30.0 T/m).
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg.

RF Heating - Under the scan conditions defined above, the Gabriel Feeding Tube with Balloon Size 12 Fr is expected to produce a maximum temperature rise of less than 5.0 °C after 15 minutes of continuous scanning. Caution: The RF heating behavior does not scale with static field strength. Devices that do not exhibit detectable heating at one field strength may exhibit high values of localized heating at another field strength. The breaking of the tube and exposure of the coil could lead to greater rise in RF heating during MRI scan.

MR Artifact - In non-clinical testing, the image artifact caused by the device extends approximately 14 mm from the Gabriel Feeding Tube with Balloon Size 12 Fr when imaged with a gradient-echo pulse sequence in a 3 T MRI system.

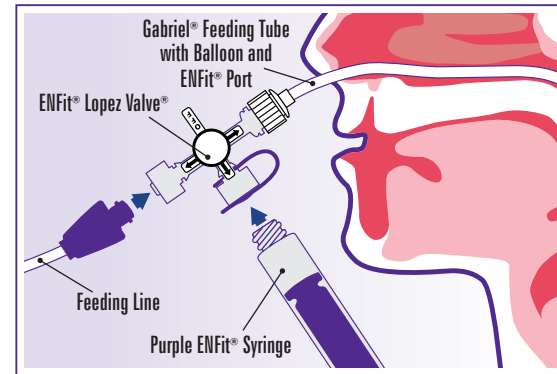
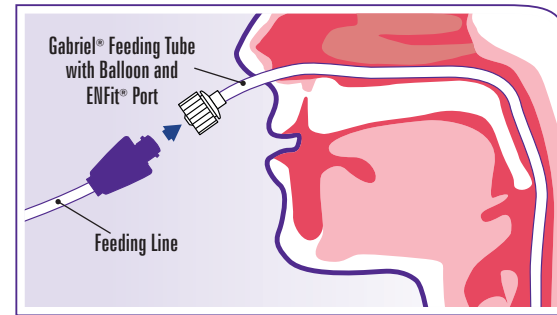
Expiration date: August 2021

Print date: February 2020

U.S. Patent #9,713,578 Japan Patent #6357311
China Patent #ZL201310710594.0
European Patent #2 745 828

CPT Code 43761

CE 0197



CONTENTS

- Gabriel Feeding Tube with Balloon, preassembled with stylet
- Cotton swab
- Numbing gel
- CO2 Sampling Line
- Lubricating gel
- Silk suture thread
- 10 cc Luer Lock syringe
- Skin adhesive
- Butterfly-tape to secure tube at end of procedure
- ENFit® Lopez Valve®

ADDITIONAL MATERIALS NEEDED

1 Cup / Gloves / 2x2 Gauze

RE-ORDER INFORMATIONS

Size	Length	Balloon Size	Reorder #
12 Fr	130 cm	3 ml	GFTB 512

Design and specification developed by:
Syncro Medical Innovations, Inc.
515 Mulberry Street, Suite 200
Macon, Georgia 31201, USA
gabrielfeedingtube.com / Tel: 888-980-9159 / Fax: (716) 806-3504

GABRIEL®

FEEDING TUBE WITH BALLOON

12 Fr

Tube Length, 130 cm (52 in)

Reorder # GFTB 512

Preassembled with Stylet

- Radio-opaque and disposable (Intended for single-patient use only, non-sterile tube)
- Proximal male ENFit® connector
- Purple colored 3 ml pilot balloon at proximal end and 3 ml inflatable balloon at distal end.
- Single line mark at 50 cm (Corresponds to placement at lower end of esophagus)
- Double line mark at 80 cm (Corresponds to placement at duodenal bulb)
- Triple line mark at 110 cm (Corresponds to distal duodenal placement)
- Preassembled with stylet
- Read all precautions and instructions for use before use.



MR conditional. (See last page for MRI safety information.)

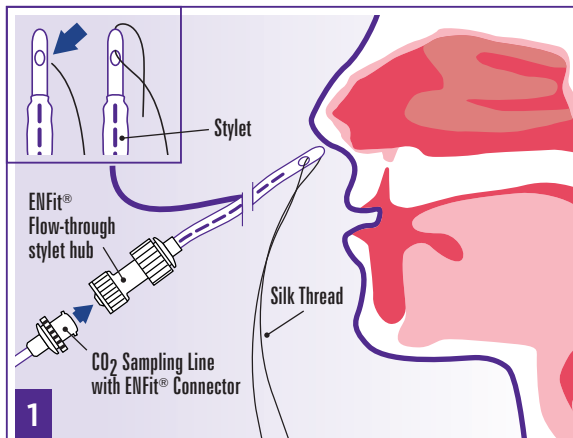
Caution: Federal law restricts this device to sale by or on the order of a physician.

Indications for Use: The Gabriel Feeding Tube with balloon functions as a conduit to facilitate enteral feeding and may be used in adult or elderly patients who cannot consume an adequate diet orally. Small bowel feeding may be indicated for patients with functioning gut who require short to moderate term feeding support such as post-trauma patients, burn patients, general trauma patients, high-risk patients prone to tube misplacement complications, and patients in whom malnutrition exists—or may result—secondary to an underlying disease or condition.

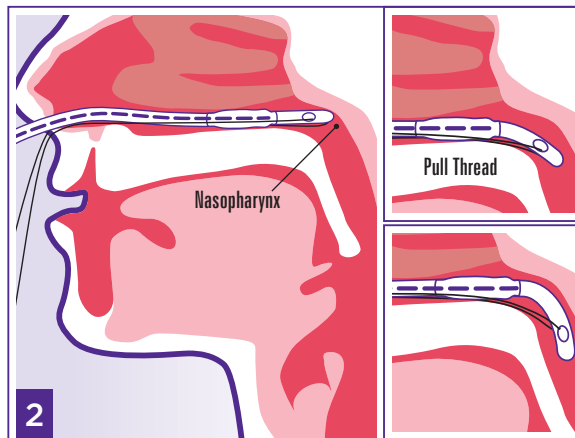
MADE IN CHINA

Syncro Medical Innovations, Inc.
515 Mulberry Street, Suite 200
Macon, Georgia 31201, USA

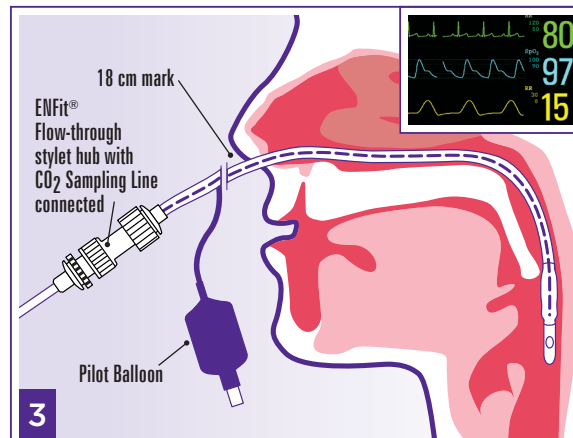
888-980-9159
gabrielfeedingtube.com



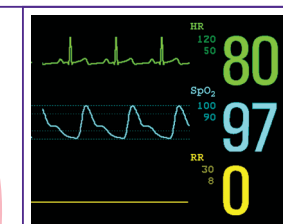
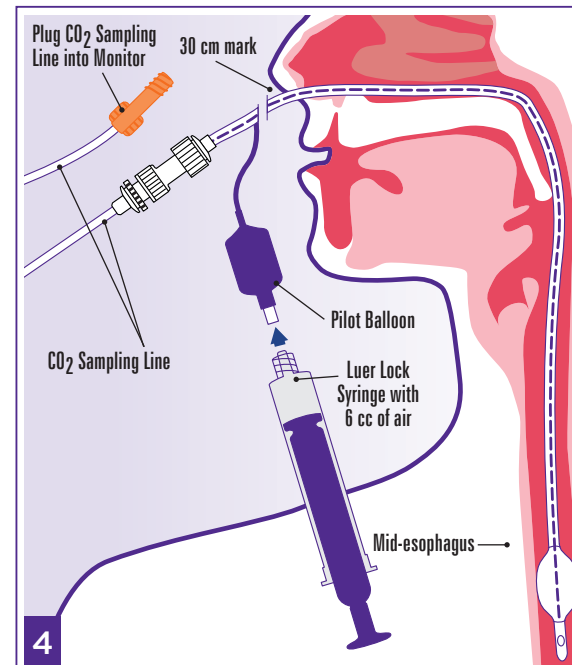
- Connect CO₂ Sampling Line to ENFit® flow-through stylet hub.
 - Apply provided numbing gel to nostril using the cotton-tipped swab provided. Wait two minutes.
 - Insert silk thread into the distal end holes.
 - Apply lubricating gel to the tube distal tip and nostril.



- Hold both ends of silk thread at six o'clock position and insert the tube toward the back of the head to the nasopharynx.
 - Pull both ends of thread to flex the tip and guide the tube downward to the oropharynx.
 - Remove the thread completely. (The use of thread steering technique is optional.)

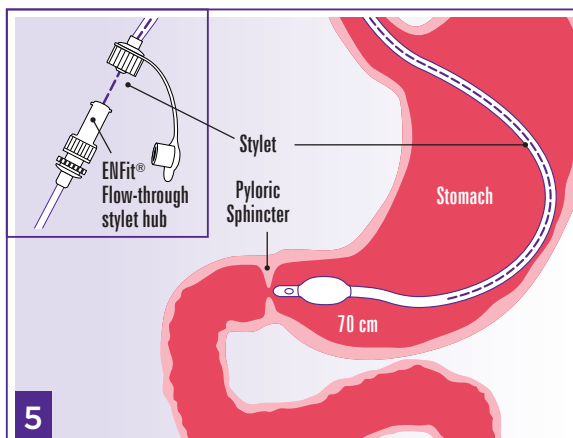


- When the 18 cm mark is at the nostril, ask the patient to swallow in order to advance the tube into the esophagus.
 - When the 30 cm mark is at the nostril, the tube tip should be in mid-esophagus. Cough should be absent in conscious patients.

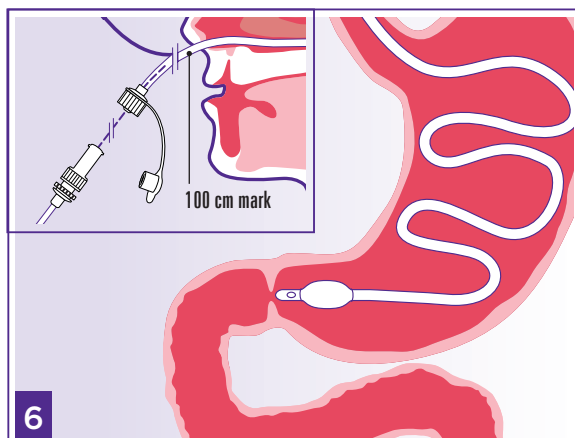


Sedated patients who are unresponsive to trachea misplacement should be connected to pulse-oximetry and CO₂ monitor compatible with the provided CO₂ sampling line. **Using the Luer Lock syringe, inflate the tube distal end balloon and pilot balloon with 6 cc of air and observe end-tidal CO₂ wave and pulse-oximetry.** Detection of end-tidal CO₂ wave or drop in pulse-oximetry by 5 or more points indicates misplacement in the trachea. Deflate balloon and withdraw to 18 cm mark then reinsert into esophagus.

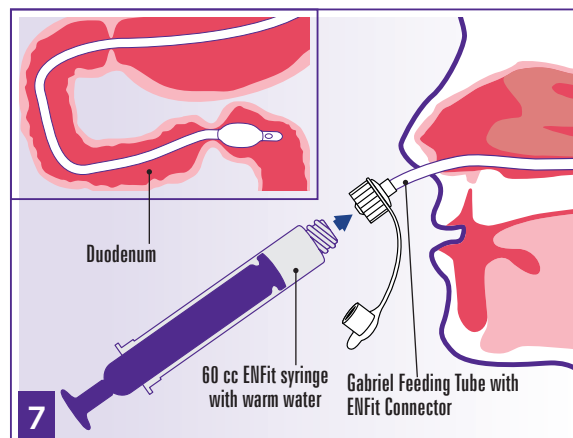
Optional: Tube balloons can be inflated with 6 cc water and patient turned on right side down to facilitate distal tube placement.



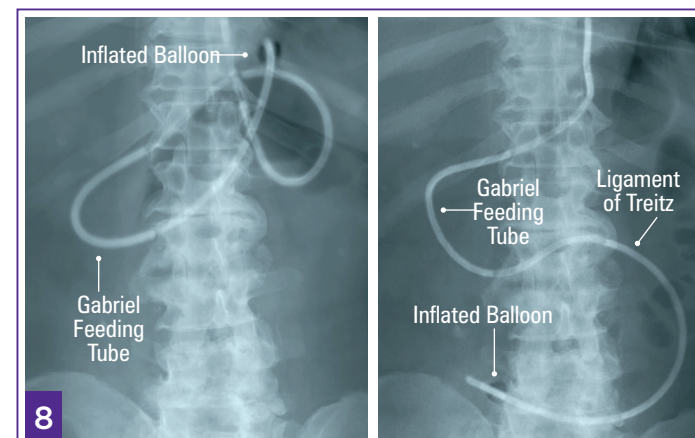
- Once esophageal placement is confirmed, continue advancing the tube down the esophagus and into the stomach.
 - When the tube reaches the 70 cm mark, pull the stylet out gradually as you advance more tube.



- Continue advancing the tube until the 100 cm mark is at the nostril then remove the stylet completely.
 - Apply skin prep-site adhesive solution to the nose, then secure the tube at 100 cm using the nasal butterfly-tape provided.



- Connect ENFit syringe directly to the Gabriel Feeding Tube.
 - Inject 60 cc of warm water to stimulate gastric peristalsis to help the tube migrate deeper into the small intestine.



Obtain abdominal x-ray to confirm gastric or intestinal placement before initiating feeding. X-ray is the gold standard to confirm final tube placement. Tube migration can be monitored by abdominal x-ray as needed. X-rays above show (on left) tube in the stomach shortly after placement and (on right) the tube in jejunum 12 hours after insertion.

- Initiate feeding and maintain as tolerated by the patient.
- Deflate tube balloons after 48 hours or before removal.
- **Precaution: Do not use with feeding pumps that can generate pressure greater than 40 psi.**
- Flush tube with warm water (20-30 ml) prior to and after administering medications, every 3-4 hours during continuous feeding, and after intermittent feedings.
- **Precaution: Do not use a syringe smaller than 30 cc when irrigating the feeding tube.**

GABRIEL
FEEDING TUBE WITH BALLOON