

Gastrostomy Tube

ENFit™

Read all instructions carefully before use!



Gastrostomy Tube

3 Port
ENFit™



STERILE

Rx Only **CAUTION:** Federal (USA) law prohibits this device to sale by or on the order of a physician.

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1. DESCRIPTION

The **Dynarex Gastrostomy Tube** (Figure A) is a 100% silicone feeding tube comprised of a double lumen tube (shaft) with proximal retention disk, balloon, and distal open flow-through tip.

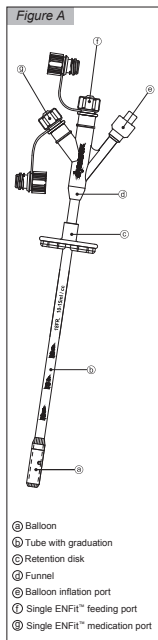
The tube has external graduations (cm) and a radiopaque marker at the distal end. The tube size and balloon capacity are clearly indicated on the shaft and pouch of each device. The tube is made without use of natural rubber latex, BPA, or phthalates plasticizers.

The tube size and balloon capacity are indicated on the shaft and packaging of each device. (See Table 1).

Gastrostomy Tubes are recommended for adult and pediatric patients (excluding neonates).

Available Size Range (Fr/Ch)	12-14	16	18-24
Balloon Capacity (mL)	5	10	15

Table 1

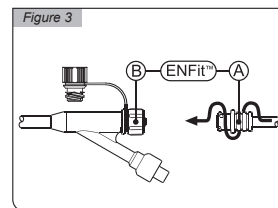
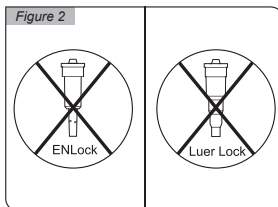


2. INDICATIONS FOR USE

Gastrostomy Tubes are indicated for use in a well-established gastrostomy tract for feeding and/or administration of medications. They also may be used for gastric decompression.

3. ⚠️ WARNINGS

- **Gastrostomy Tubes** are for single use only. Do not reuse, reprocess or resterilize. Reuse may cause a risk of infection and compromise functional reliability. Do not use if the package is open or damaged.
- For enteral/gastrostomy use only.
- Verify expiration date. Do not use after this date.
- A **Gastrostomy Tube** has the potential to misconnect with small bore connectors of other healthcare applications
- Use only administration feeding sets with the ENFit™ connection system. Feeding sets with different system connections, e.g. ENLock or Luer Lock, are not compatible with the **Gastrostomy Tubes**. (Figure 2)



- When using feeding sets with the ENFit™ connection system, screw the feeding set (A) clockwise into the ENFit™ feeding port (B) firmly by hand (Figure 3).
- Always confirm that the feeding set is connected to the enteral port only and NOT to an IV set.

- Do not nick, cut, tear, puncture, or otherwise damage the device.

4. CAUTION

- Placement should be performed by/or under directions of physician.
- Federal (USA) law and similar laws around the world restrict this device to sale by, or on the order of, a licensed healthcare practitioner.
- A single **Gastrostomy Tube** may remain in a well-established gastrostomy tract for more than 30 days, unless the tube comes out or becomes clogged. In such instances the patient should immediately contact their physician.
- Dependable: durable silicone balloon encourages up to 90 days of service life. However the life span of the **Gastrostomy Tube** can vary according to several factors including, but not limited to, volume of filled water in the balloon, gastric pH, and tube care.
- Always keep a replacement **Gastrostomy Tube** available for use. Do not remove device until a replacement **Gastrostomy Tube** is available, to prevent the stoma from closing.
- Follow good clinical practice as well as all local and national regulations for transportation and disposal.

5. CONTRAINDICATIONS FOR USE

Do not use the tube for patients with the following conditions:

- Nonestablished stoma tract
- Infection or irritation of the stoma
- Gastrocutaneous fistulas
- Evidence of granulation tissue
- Allergy to silicone

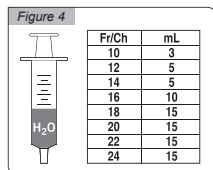
6. POTENTIAL COMPLICATIONS

Potential complications may include, but not limited to: wound infections or irritation at stoma site, fever, gastric distention, tube blockage and tissue necrosis.

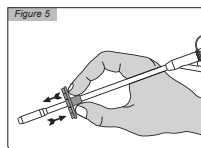
7. DIRECTIONS FOR PLACEMENT

7.1. Preparation of the tube

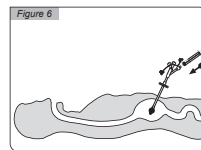
- Be sure to thoroughly wash and disinfect hands before handling the tube or its components.
- To prevent the stoma from closing, do not remove the current/defective device until a replacement **Gastrostomy Tube** is available.
- Select size of the **Gastrostomy Tube** according to the French size of the previous gastrostomy tube. Correct size helps prevent gastric leakage and skin irritation (Figure 4).
- Cleanse and disinfect skin around the stoma.



- Prior to use, inspect the tube for any damage. The retention disk should slide along the tube easily (*Figure 5*).



- Check the balloon for leakage by filling with water (*Figure 6*). Never inflate more than indicated inflation volume on the catheter. (*Figure 4*). Do not squeeze the inflated balloon. After checking, deflate the balloon using a Luer tip syringe.

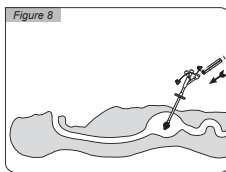
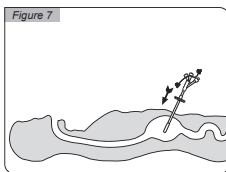


7.2. Removal of the current tube

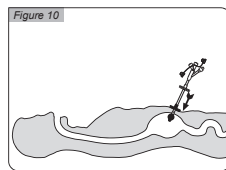
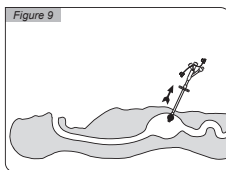
- Gently push the tube into the stoma approximately 1" (2.5 cm) and rotate to make sure it is freely movable.
- Deflate the balloon using a Luer tip syringe.
- Gently remove the gastrostomy tube without force.
- If the tube cannot be removed, apply a water-soluble lubricant and gently rotate and push the tube 1" (2.5 cm) into stoma and again try to remove.
- If unable to remove, stop the procedure, reinflate the balloon and report to the physician.
- **⚠ WARNING: Do not use excessive force to remove the tube.**

7.3. Replacement of the new tube

- Remove existing tube according to manufacturer's directions.
Note: the tube in place may be a tube from another company.
- Lubricate the tip of the tube with water or with a water-based lubricant. Never use oil or petroleum jelly.



- Gently guide the tube through the stoma into the stomach, about 2"-4" (50-100 mm) on adults and 1"- 1.5" (25-38 mm) on children, or until the entire balloon has passed through the tract (*Figure 7*).
- Hold the tube in place and inflate the balloon with the recommended volume of water (*Figures 4 & 8*). **Do not use air.** Never inflate more than indicated inflation volume on the inflation valve.



- Gently withdraw the tube until the balloon rests against the inner stomach wall (*Figure 9*). To prevent tissue necrosis, avoid excessive tension. Slide the retention bolster down into position until it gently touches the skin (*Figure 10*). **DO NOT suture.**
- Check for signs of gastric leakage.
- Flush the feeding lumen to verify there are no obstructions.

7.4. Placement confirmation

⚠ WARNING: Prior to the feeding tube use, confirm tube placement according to your institution's preferred procedures and authorization.

- After correct placement is confirmed, flush with 10 mL of water to verify tube function.
- Monitor tube position by using the external centimeter graduations on the tube shaft to record its position in the stomach. Refer to these markings daily to ensure that the tube has not migrated.

8. CARE AND MAINTENANCE

- Inspect stoma site frequently by lifting the edges of the retention disk. Gently clean with warm water and soap. If there is any evidence of infection, irritation or granulation consult a physician at once.
- After every use flush the tube with 10-20 mL of water for adults and 5-10 mL for children, before and after each feeding or administration of medication or every 4-8 hours if feeding is continuous.
- To ensure proper balloon inflation, check the balloon's fluid level every 7-10 days. It is normal for water to migrate out of the balloon. If the quantity is below the original inflated amount, refill the balloon to the proper quantity using fresh water. Replacing the balloon fluid every 7-10 days is the best way to maintain integrity of the balloon and the inflation channel. If the balloon continues to deflate, replace the tube.
- If deflation of the balloon with a syringe is difficult, it is possible that the inflation channel has become occluded. In case of occlusion, replace the tube.

9. MEDICATION ADMINISTRATION

- Any interaction of the patient's nutrients and medication should be discussed with a physician or pharmacist. Don't administer medication with food without consulting the physician.
- Medication should never be given through the balloon lumen.
- Check to see whether the prescribed medication should be given on an empty or full stomach.
- Give liquid medication whenever possible to prevent clogging. Consult the physician about whether it should be diluted before use.
- If certain medication is available only in tablet form, consult the physician before crushing and mixing it with water.
- Do not use a **Gastrostomy Tube** to administer sublingual or buccal medicines, sustained-release tablets, or capsules. Never crush enteric-coated medication, which could result in improper drug administration.
- Medicines containing paraffin oil may swell the anti-reflex valve of the G-tube.

10. NOTE

Children require special care. A child's stomach cannot hold a large amount of food at one time. Therefore, you should perform feeding more frequently for children, using less food.

Ask your physician for guidelines. Always keep children hydrated especially if the weather is warm or the child has a fever.

CONSULT YOUR PHYSICIAN.

11. STORAGE

The **Gastrostomy Tube** should be stored in the original packaging at room temperature, and in a dry environment. Avoid direct sunlight and heat radiation.

