COOK® MEDICAL

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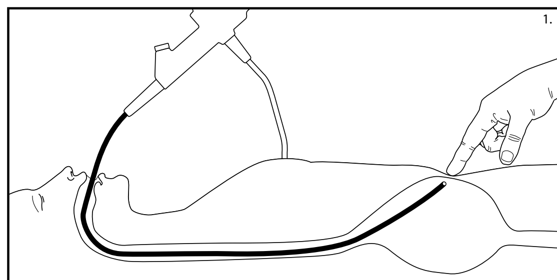
Percutaneous Endoscopic Gastrostomy Sets - FLOW / PEG Push Technique - Safety Sharps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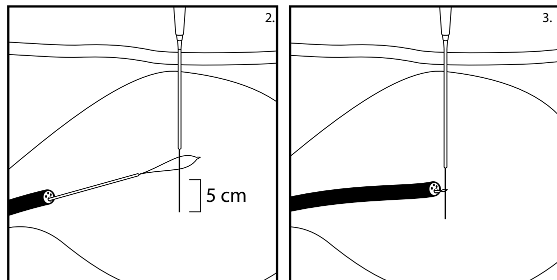

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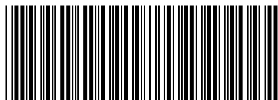

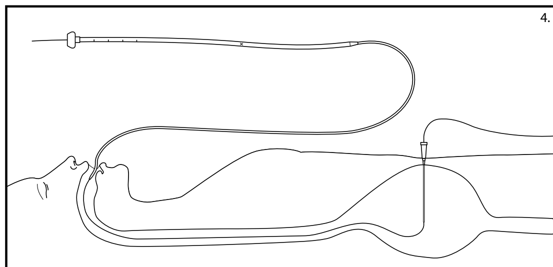
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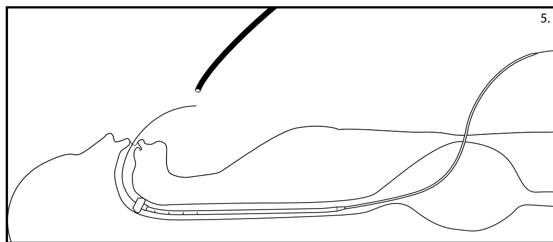
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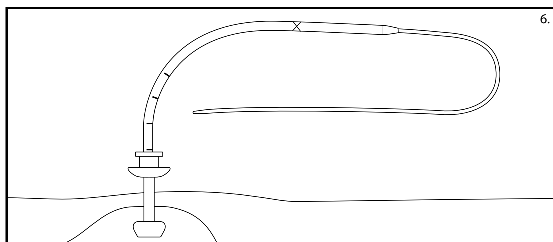
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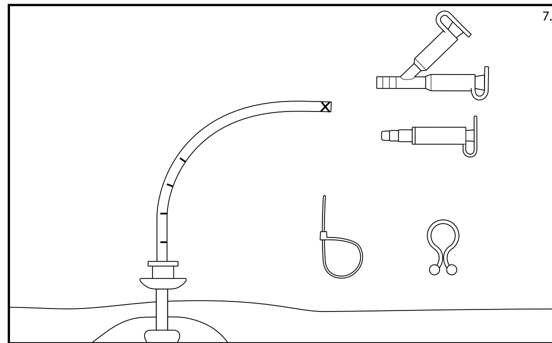
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INTENDED USE

Used for percutaneous endoscopic placement to provide enteral nutrition to patients requiring nutritional support.

GASTROSTOMY SET CONTENTS

- 1 Silicone Feeding Tube
- 1 Prep Tray
- 5 Gauze Pads
- 1 Instruction Manual
- 1 Cold Snare
- 1 Wire Guide
- 1 Bolster Kit
- 1 Drape
- 1 Patient Care Manual

PREP TRAY CONTENTS

- 1 Syringe
- 1 Needle Cannula
- 1 22 gauge 1 1/2" Needle
- 1 #11 Scalpel
- 1 Pk. Antiseptic Swabsticks with Instruction
- 1 Pk. Antiseptic Ointment
- 2 Pks. Water Soluble Lubricant

BOLSTER KIT CONTENTS

- 1 Bolster
- 1 Cable Tie
- 1 Universal Adapter
- Hemostats
- 1 Twist Lock
- 1 Pr. Scissors
- 1 Bolus Adapter
- Tubing Clamp

NOTES

Do not use this device for any purpose other than the stated intended use.

Inventory rotation of sterile products is essential. Verify the expiration date on the package label prior to using the product. If the expiration date has lapsed, do not use or resterilize this device.

If the product package is open or damaged when received, do not use the device.

Cook devices must be stored in a dry location, away from temperature extremes.

CONTRAINDICATIONS

Contraindications associated with placement and use of a PEG tube include, but are not limited to: sepsis, severe gastroesophageal reflux, ascites, or diffuse inflammatory, infectious, or neoplastic disease involving the walls of the abdomen or anterior stomach, gastrointestinal obstruction or proximal small bowel fistulae.

POTENTIAL COMPLICATIONS

Potential complications associated with placement and use of a PEG tube include, but are not limited to: bronchopulmonary aspiration and pneumonia, respiratory distress or airway obstruction, peritonitis or septic shock, colocutaneous, gastrocolocutaneous or small bowel fistula, gastric dilatation, sigmoid intra-abdominal herniation and volvulus, persistent fistula following PEG removal, esophageal injury, necrotizing fasciitis, candida cellulitis, improper placement or inability to place PEG tube, tube dislodgment or migration, hemorrhage, and tumor metastasis.

Additional complications include, but are not limited to: pneumoperitoneum, peristomal wound infection and purulent drainage, stomal leakage, bowel obstruction, gastroesophageal reflux (GERD), and blockage or deterioration of the PEG tube. **Note:** Patients with cirrhosis have an increased risk of developing ascites which is a contraindication to PEG placement.

PRECAUTIONS

The benefit of a PEG tube to the patient must be weighed against the risks associated with any indwelling gastrostomy feeding tube.

During placement and use, care must be taken to avoid cutting, crimping, or damaging components.

Do not modify the PEG tube or adapters in any way.

Follow the instructions and the Patient Care Manual supplied with each kit. It is essential for the Patient Care Manual to accompany the patient and be explained to all people responsible for the care of the patient.

The PEG system is radiopaque. Proper location and integrity of any internal component can be visualized by x-ray.

Manufacturer guidelines are not intended to replace physician's recommendations.

A thorough understanding of the technical principles, clinical applications and risks associated with placement and/or removal of a PEG tube is necessary before using this device. Placement and/or removal of the PEG tube should only be performed by, or under the supervision of, physicians thoroughly trained in the procedure.

When placing a PEG tube in obese patients, all anatomical structures must be identified prior to placement.

When placing a PEG tube, observe all institutional guidelines regarding gastroscopy, including removal of dentures.

PEG replacement is recommended every **three** months or at the discretion of the physician.

WARNING

Excessive traction on the gastric feeding tube may cause premature removal, fatigue or failure of the device.

INSTRUCTIONS FOR USE

Tube Placement

1. Upon removing the device and its components from the package, visually inspect with particular attention to kinks, bends or breaks in the feeding tube assembly. If an abnormality is detected that would prohibit proper working condition, do not use. Please notify Cook for return authorization.
2. After introducing the gastroscope, insufflate the stomach and examine the mucosa. Determine if the mucosa is free of ulcerations or bleeding before proceeding.
3. Position the tip of the gastroscope and illuminate the left anterior wall of the stomach. **Note:** It may be necessary to dim the lights in the procedure room to better visualize the light through the abdominal wall. **Important:** Ideally, placement of the PEG should be low in the body of the stomach or high in the antrum towards the pylorus to allow for easier insertion of the PEG-J (jejunal) feeding tube into the PEG, if indicated as an option.
4. Manipulate the gastroscope tip until the light trans-illuminates the desired PEG position. *(See fig. 1)*
5. Lightly depress the illuminated area with a finger while viewing the site with the gastroscope. The depression of this area should be clearly visualized with the scope. After determining that the mucosa is healthy, proceed with this procedure.
6. Prepare the site following surgical guidelines as determined by your institution. Drape the area using the enclosed surgical drape. Inject local anesthetic (not included) into the PEG site.
7. Using the enclosed scalpel, make a 1 cm long incision through the skin, subcutaneous tissue. **Caution:** A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
8. Endoscopically observe the site.
9. While maintaining stomach insufflation, insert the needle and cannula unit through the skin incision and into the stomach. Leave the cannula in place to maintain access to the stomach while removing the inner needle.
10. Place the floppy tip of the wire guide through the needle cannula and into the stomach.
11. Maintain stomach insufflation to obtain close proximity of the stomach and abdominal walls. Place a snare or non-spiked biopsy forceps through the channel of the gastroscope and grasp the end of the wire guide. **Caution:** Do not tighten the snare around the needle cannula after removal of the inner stylet as this may interfere with passage of the wire guide. **Note:** For wire guide removal, grasp the wire with a snare or non-spiked biopsy forceps at least 5 cm from the tip of the wire guide *(See fig. 2)*. Pull the wire guide to the tip of the endoscope, not into the endoscope channel. *(See fig. 3)*
12. While maintaining the snare or non-spiked biopsy forceps securely around the wire guide, remove the gastroscope and wire from the patient's mouth. The wire guide will now be protruding from both the patient's mouth and incision site.
13. Using **water-soluble lubricant** and gauze, **thoroughly lubricate** the dilator and entire external length of the tube including the internal bumper.
14. Advance the dilator tip over the wire guide and through the patient's mouth. *(See fig. 4)* **Note:** Firm tension on both ends of the wire guide will ease passage through the oropharynx.
15. When the end of the dilator meets the cannula in the stomach, push the dilator through the abdominal wall. **Note:** Maintaining wire guide tension will aid this process.
16. After the tapered end of the dilator passes through the abdominal wall, release the wire guide and gently pull the tube and wire guide through the abdominal wall.
17. When the internal bumper of the PEG tube enters the mouth, reintroduce the gastroscope and view the tip as it advances through the esophagus and into the stomach. Monitor the patient for respiratory distress as you advance the internal bumper through the esophagus. *(See fig. 5)*
18. While observing centimeter increments, slowly pull the dilating portion of the tube through the abdominal incision.
19. Bring the internal bumper in contact with the abdominal wall, carefully avoiding excess tension.
20. Apply gentle pressure to the exiting portion of the feeding tube and remove the wire guide. **Caution:** Blanching of the site indicates excessive pressure on the mucosa and should be avoided.
21. Slide the bolster onto the tube and toward the skin surface. *(See fig. 6)* The hemostats provided with the kit may be used to facilitate placement of the bolster over the PEG tube. **Note:** Antiseptic ointment may be applied to the surrounding tissue prior to sliding the bolster into position. **Warning:** The bolster should sit close to the skin but not tight against the skin. Excessive traction on the tube may cause premature removal, fatigue or failure of the device.
22. Cut the tube at the X mark.
23. Secure the twist lock or cable tie around the bolster collar, being careful not to crimp it. **Important:** Use the twist lock or cable tie to secure the bolster to the tube. This will help prevent future migration of the tube and reduce the need to constantly reposition or pull on the tube.
24. Cut off the excess length of the cable tie (if applicable) using the scissors provided.
25. If desired, slide the tubing clamp onto the tube leaving a gap between bolster and tubing clamp.
26. Plug in the adapter of choice (universal or bolus) and close the caps. *(See fig. 7)* **Note:** The adapter may be secured to the tube with a cable tie.
27. Note the centimeter marking on the tube that is closest to the bolster and record it on the patient's chart and on the patient information sheet in the Patient Care Manual. **Note:** The Patient Care Manual enclosed in the kit is intended as a reference for caregivers of the patient. It is essential for the Patient Care Manual to accompany the patient and be explained to all people responsible for the care of the patient.
28. Dispose of residual kit materials per institutional guidelines for biohazardous medical waste.
29. Record physician's instructions for feeding and administration of prescribed medications in the Patient Care Manual.
30. The patient should remain NPO for 24 hours unless otherwise directed by a physician.

TUBE REMOVAL

The PEG tube has been designed for removal using the external/traction method shown below. If this method of removal is not possible, another method such as endoscopic or surgical should be utilized.

Caution: If a replacement tube is desired, it must be placed immediately after removal. External tube removal may result in minimal trauma or bleeding that may require treatment.

External/Traction Method

The feeding tube may be removed without the need for endoscopy in the following manner:

1. Grasp the gastric feeding tube near the stoma site. While slowly rotating the tube, gently push 1-2 cm of the tube into the stomach to separate the tube from the stoma tract. **Warning:** If the tube does not rotate freely within the tract, do not attempt to use traction as a method of removal.
2. Hold the gastric tube near the stoma site and apply counter pressure by placing the fingers of the other hand around the base of the tube.
3. Loosely cover the stoma site with either a towel or a drape.
4. Holding the gastric feeding tube straight, apply steady traction to the tube until the internal dome emerges through the abdominal wall. **Caution:** The tube must be pulled straight out of the stoma tract.
5. Dispose of the feeding tube per institutional guidelines for biohazardous medical waste. The stoma tract should heal and close within 24 hours.

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