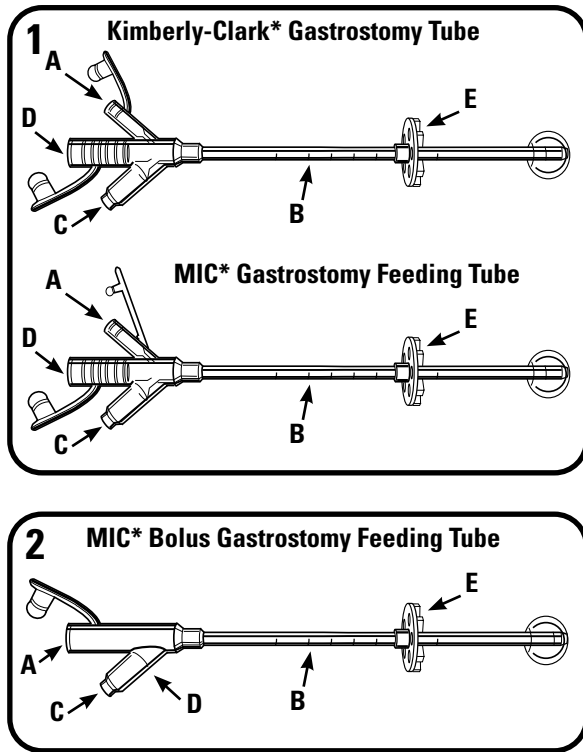


Kimberly-Clark*

MIC* Gastrostomy/Bolus Feeding Tube



Directions for Use

Description

The Kimberly-Clark* MIC* Gastrostomy (Fig 1) / Bolus Feeding Tube (Fig 2) allow for delivery of enteral nutrition and medication directly into the stomach and/or gastric decompression.

Indications For Use

The Kimberly-Clark* MIC* Gastrostomy / Bolus Feeding Tube are indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and / or medication delivery directly into the stomach.

Contraindications

Contraindications for placement of a gastrostomy feeding tube include, but are not limited to ascites, colonic interposition, portal hypertension, peritonitis and morbid obesity.

Complications

The following complications may be associated with any low-profile gastrostomy feeding tube:

- Skin Breakdown
- Infection
- Hypergranulation Tissue
- Stomach or Duodenal Ulcers
- Intraperitoneal Leakage
- Pressure Necrosis

Note: Verify package integrity. Do not use if package is damaged or sterile barrier compromised.

Placement

The Kimberly-Clark* MIC* Gastrostomy / Bolus feeding tubes may be placed surgically, percutaneously under fluoroscopic or endoscopic guidance or as a replacement to an existing device using an established stoma tract.

Caution: A gastrostomy must be performed to affix the stomach to the anterior abdominal wall, the feeding tube insertion site identified and stoma tract dilated prior to initial tube insertion to ensure patient safety and comfort.

Caution: Do not use the retention balloon of the feeding tube as a gastrostomy device. The balloon may burst and fail to attach the stomach to the anterior abdominal wall.

WARNING: THE INSERTION SITE FOR INFANTS AND CHILDREN SHOULD BE HIGH ON THE GREATER CURVATURE TO PREVENT OCCLUSION OF THE PYLORUS WHEN THE BALLOON IS INFLATED.

Tube Preparation

1. Select the appropriate gastrostomy feeding tube, remove from the package and inspect for damage.
2. Using a Luer slip syringe, inflate the balloon with sterile or distilled water through the balloon port (Fig 1C & 2C).
 - Inflate the balloon with 2-3 ml of sterile or distilled water for low volume tubes identified by LV following the REF code number.
 - Inflate the balloon with 7-10 ml sterile or distilled water for Standard tubes.
3. Remove the syringe and verify balloon integrity by gently squeezing the balloon to check for leaks. Visually inspect the balloon to verify symmetry. Symmetry may be achieved by gently rolling the balloon between the fingers. Reinsert the syringe and remove all the water from the balloon.
4. Lubricate the tip of the tube with a water soluble lubricant. Do not use mineral oil. Do not use petroleum jelly.

Suggested Radiologic Placement Procedure

1. Place the patient in the supine position.
2. Prep and sedate the patient according to clinical protocol.
3. Insure that the left lobe of the liver is not over the fundus or the body of the stomach.
4. Identify the medial edge of the liver by CT scan or ultrasound.
5. Glucagon 0.5 to 1.0 mg IV may be administered to diminish gastric peristalsis.

Caution: Consult Glucagon instructions for use for rate of IV injection and recommendations for use with insulin dependent patients.
6. Insufflate the stomach with air using a nasogastric catheter, usually 500 to 1,000 ml or until adequate distention is achieved. It is often necessary to continue air insufflation during the procedure, especially at the time of needle puncture and tract dilation, to keep the stomach distended so as to appose the gastric wall against the anterior abdominal wall.
7. Choose a catheter insertion site in the left sub-costal region, preferably over the lateral aspect or lateral to the rectus abdominis muscle (N.B. the superior epigastric artery courses along the medial aspect of the rectus) and directly over the body of the stomach toward the greater curvature. Using fluoroscopy, choose a location that allows as direct a vertical needle path as possible. Obtain a cross table lateral view prior to placement of gastrostomy when interposed colon or small bowel anterior to the stomach is suspected.

Note: PO/NG contrast may be administered the night prior or an enema administered prior to placement to opacify the transverse colon.
8. Prep and drape according to facility protocol.

Gastrostomy Placement

Caution: It is recommended to perform a three point gastrostomy in a triangle configuration to ensure attachment of the gastric wall to the anterior abdominal wall.

1. Place a skin mark at the tube insertion site. Define the gastrostomy pattern by placing three skin marks equidistant from the tube insertion site and in a triangle configuration.

WARNING: ALLOW ADEQUATE DISTANCE BETWEEN THE INSERTION SITE AND GASTROPEXY PLACEMENT TO PREVENT INTERFERENCE OF THE T-FASTENER AND INFLATED BALLOON.
2. Localize the puncture sites with 1% lidocaine and administer local anesthesia to the skin and peritoneum.
3. Place the first T-Fastener and confirm intragastric position. Repeat the procedure until all three T-Fasteners are inserted at the corners of the triangle.
4. Secure the stomach to the anterior abdominal wall and complete the procedure.

Create the Stoma Tract

1. Create the stoma tract with the stomach still insufflated and in apposition to the abdominal wall. Identify the puncture site at the center of the gastrostomy pattern. With fluoroscopic guidance confirm that the site overlies the distal body of the stomach below the costal margin and above the transverse colon.

Caution: Avoid the epigastric artery that courses at the junction of the medial two-thirds and lateral one-third of the rectus muscle.

WARNING: TAKE CARE NOT TO ADVANCE THE PUNCTURE NEEDLE TOO DEEPLY IN ORDER TO AVOID PUNCTURING THE POSTERIOR GASTRIC WALL, PANCREAS, LEFT KIDNEY, AORTA OR SPLEEN.

2. Anesthetize the puncture site with local injection of 1% lidocaine down to the peritoneal surface.
3. Insert a .038" compatible introducer needle at the center of the gastrostomy pattern into the gastric lumen.

Note: For gastrostomy tube placement, the best angle of insertion is a true right angle to the surface of the skin. The needle should be directed toward the pylorus if conversion to PEGJ tube is anticipated.

4. Use fluoroscopic visualization to verify correct needle placement. Additionally, to aid in verification, a water filled syringe may be attached to the needle hub and air aspirated from the gastric lumen.

Note: Contrast may be injected upon return of air to visualize gastric folds and confirm position.

5. Advance a J tip guidewire, up to .038", through the needle and into stomach. Confirm position.
6. Remove the introducer needle, keeping the J tip guidewire in place and dispose of according to facility protocol.

Dilation

1. Use a #11 scalpel blade to create a small skin incision that extends alongside the guidewire, downward through the subcutaneous tissue and fascia of the abdominal musculature.
2. Advance a dilator over the guidewire and dilate the stoma tract to the desired size.
3. Remove the dilator over the guidewire, leaving the guidewire in place.

Tube Placement

Note: A peel-away sheath may be used to facilitate advancement of the tube through the stoma tract.

1. Select the appropriate gastrostomy feeding tube and prepare according to the directions in the Tube Preparation section.
2. Advance the distal end of the tube over the guidewire, through the stoma tract and into the stomach.
3. Verify that the tube is in the stomach, remove the guidewire or peel-away sheath if utilized and inflate the balloon.

4. Using the Luer slip syringe, inflate the balloon.

- Inflate the LV balloon with 2-3 ml of sterile or distilled water.

- Inflate the standard balloon with 7-10 ml of sterile or distilled water.

Caution: Do not exceed 5 ml total balloon volume inside the LV balloon. Do not use air. Do not inject contrast into the balloon.

Caution: Do not exceed 20 ml total balloon volume in the Standard balloon. Do not use air. Do not inject contrast into the balloon.

5. Gently pull the tube up and away from the abdomen until the balloon contacts the inner stomach wall.
6. Clean the residual fluid or lubricant from the tube and stoma.
7. Gently slide the SECUR-LOK® ring to approximately 1-2 mm (approximately 1/8 inch) above the skin.

Verify Tube Position and Patency

1. Attach a catheter tip syringe with 10 ml water to the feeding port. Aspirate gastric contents. When air or gastric contents are observed, flush the tube.
2. Check for moisture around the stoma. If there are signs of gastric leakage, check the tube position and SECUR-LOK® ring placement. Add fluid as needed in 1-2 ml increments. Do not exceed balloon capacity as indicated previously.
3. Begin feeding only after confirmation of proper patency, placement and according to physician instructions.

Suggested Endoscopic Placement Procedure

1. Perform routine esophagogastroduodenoscopy (EGD). Once the procedure is complete and no abnormalities are identified that could pose a contraindication to placement of the tube, place the patient in the supine position and insufflate the stomach with air.
2. Transilluminate through the anterior abdominal wall to select a gastrostomy site that is free of major vessels, viscera and scar tissue. The site is usually one third the distance from the umbilicus to the left costal margin at the midclavicular line.
3. Depress the intended insertion site with a finger. The endoscopist should clearly see the resulting depression on the anterior surface of the gastric wall.
4. Prep and drape the skin at the selected insertion site.

Gastrostomy Placement

Caution: It is recommended to perform a three point gastrostomy in a triangle configuration to ensure attachment of the gastric wall to the anterior abdominal wall.

1. Place a skin mark at the tube insertion site. Define the gastrostomy pattern by placing three skin marks equidistant from the tube insertion site and in a triangle configuration.

WARNING: ALLOW ADEQUATE DISTANCE BETWEEN THE INSERTION SITE AND GASTROPEXY PLACEMENT TO PREVENT INTERFERENCE OF THE T-FASTENER AND INFLATED BALLOON.

2. Localize the puncture sites with 1% lidocaine and administer local anesthesia to the skin and peritoneum.
3. Place the first T-Fastener and confirm Intra-gastric position. Repeat the procedure until all three T-Fasteners are inserted at the corners of the triangle.
4. Secure the stomach to the anterior abdominal wall and complete the procedure.

Create the Stoma Tract

1. Create the stoma tract with the stomach still insufflated and in apposition to the abdominal wall. Identify the puncture site at the center of the gastrostomy pattern. With endoscopic guidance confirm that the site overlies the distal body of the stomach below the costal margin and above the transverse colon.

Caution: Avoid the epigastric artery that courses at the junction of the medial two-thirds and lateral one-third of the rectus muscle.

WARNING: TAKE CARE NOT TO ADVANCE THE PUNCTURE NEEDLE TOO DEEPLY IN ORDER TO AVOID PUNCTURING THE POSTERIOR GASTRIC WALL, PANCREAS, LEFT KIDNEY, AORTA OR SPLEEN.

2. Anesthetize the puncture site with local injection of 1% lidocaine down to the peritoneal surface.
3. Insert a .038" compatible introducer needle at the center of the gastrostomy pattern into the gastric lumen.

Note: For gastrostomy tube placement, the best angle of insertion is a true right angle to the surface of the skin. The needle should be directed toward the pylorus if conversion to PEGJ tube is anticipated.

4. Use endoscopic visualization to verify correct needle placement. Additionally, to aid in verification, a water filled syringe may be attached to the needle hub and air aspirated from the gastric lumen.

5. Advance a J tip guidewire, up to .038", through the needle and into stomach. Confirm position.
6. Remove the introducer needle, keeping the J tip guidewire in place and dispose of according to facility protocol.

Dilation

1. Use a #11 scalpel blade to create a small skin incision that extends alongside the guidewire, downward through the subcutaneous tissue and fascia of the abdominal musculature. After the incision is made, dispose of according to facility protocol.
2. Advance a dilator over the guidewire and dilate the stoma tract to the desired size.
3. Remove the dilator over the guidewire, leaving the guidewire in place.

Tube Placement

Note: A peel-away sheath may be used to facilitate advancement of the tube through the stoma tract.

1. Select the appropriate gastrostomy feeding tube and prepare according to the directions in the Tube Preparation section.
2. Advance the distal end of the tube over the guidewire, through the stoma tract and into the stomach.

3. Verify that the tube is in the stomach, remove the endoscope, remove the guidewire or peel-away sheath if utilized and inflate the balloon.
4. Using the Luer slip syringe, inflate the balloon.

- Inflate the LV balloon with 2-3 ml of sterile or distilled water.

- Inflate the Standard balloon with 7-10 ml of sterile or distilled water.

Caution: Do not exceed 5 ml total balloon volume inside the LV balloon. Do not use air. Do not inject contrast into the balloon.

Caution: Do not exceed 20 ml total balloon volume in the Standard balloon. Do not use air. Do not inject contrast into the balloon.

5. Gently pull the tube up and away from the abdomen until the balloon contacts the inner stomach wall.
6. Clean the residual fluid or lubricant from the tube and stoma.
7. Gently slide the SECUR-LOK® ring to approximately 1-2 mm (approximately 1/8 inch) above the skin.

Verify Tube Position and Patency

1. Attach a catheter tip syringe with 10 ml of water to the feeding port. Aspirate gastric contents. When air or gastric contents are observed, flush the tube.
2. Check for moisture around the stoma. If there are signs of gastric leakage, check the tube position and SECUR-LOK® ring placement. Add fluid as needed in 1-2 ml increments. Do not exceed balloon capacity as indicated previously.
3. Begin feeding only after confirmation of proper patency, placement and according to physician instructions.

Tube Removal

1. First, make sure that this type of tube can be replaced at the bedside.
2. Assemble all equipment and supplies, cleanse hands using aseptic technique and apply clean, powder-free gloves.
3. Rotate the tube 360 degrees to ensure the tube moves freely and easily.
4. Firmly insert the catheter tip syringe into the balloon port and withdraw all the fluid from the balloon.
5. Apply counter pressure to the abdomen and remove the tube with gentle, but firm traction.

Note: If resistance is encountered, lubricate the tube and stoma with water soluble lubricant. Simultaneously push and rotate the tube. Gently manipulate the tube free. If the tube will not come out, refill the balloon with the prescribed amount of water and notify the physician. Never use excessive force to remove a tube.

WARNING: NEVER ATTEMPT TO CHANGE THE TUBE UNLESS TRAINED BY THE PHYSICIAN OR OTHER HEALTH CARE PROVIDER.

Replacement Procedure

1. Cleanse the skin around the stoma site and allow the area to air dry.
 2. Select the appropriate size Gastrostomy feeding tube and prepare according to the directions in the Tube Preparation section.
 3. Lubricate the distal end of the tube with water soluble lubricant and gently insert the Gastrostomy through the stoma into the stomach.
 4. Using the Luer slip syringe, inflate the balloon.
 - Inflate the LV balloon with 1-3 ml of sterile or distilled water.
 - Inflate the Standard balloon with 7-10 ml of sterile or distilled water.
- Caution: Do not exceed 5 ml total balloon volume inside the LV balloon. Do not use air. Do not inject contrast into the balloon.**
- Caution: Do not exceed 20 ml total balloon volume in the Standard balloon. Do not use air. Do not inject contrast into the balloon.**
5. Gently pull the tube up and away from the abdomen until the balloon contacts the inner stomach wall.
 6. Clean the residual fluid or lubricant from the tube and stoma.
 7. Gently slide the SECUR-LOK® ring to approximately 1-2 mm (approximately 1/8 inch) above the skin.
 8. Verify proper tube position according to the direction in the Verify Tube Position section above.

Medication Administration

Use liquid medication when possible and consult the pharmacist to determine if it is safe to crush solid medication and mix with water. If safe, pulverize the solid medication into a fine powder form and dissolve the powder in water before administering through the feeding tube. Never crush enteric coated medication or mix medication with formula.

Using a catheter tip syringe flush the tube with the prescribed amount of water. 14-64-128-0-00

Tube Patency Guidelines

Proper tube flushing is the best way to avoid clogging and maintain tube patency. The following are guidelines to avoid clogging and maintain tube patency.

- Flush the feeding tube with water every 4-6 hours during continuous feeding, anytime the feeding is interrupted, before and after every intermittent feeding, or at least every 8 hours if the tube is not being used.
- Flush the feeding tube before and after medication administration and between medications. This will prevent the medication from interacting with formula and potentially causing the tube to clog.
- Use liquid medication when possible and consult the pharmacist to determine if it is safe to crush solid medication and to mix with water. If safe, pulverize the solid medication into a fine powder form and dissolve the powder in warm water before administering through the feeding tube. Never crush enteric-coated medication or mix medication with formula.
- Avoid using acidic irrigants such as cranberry juice and cola beverages to flush feeding tubes as the acidic quality when combined with formula proteins may actually contribute to tube clogging.

General Flushing Guidelines

- Use a 30 to 60 cc catheter tip syringe. Do not use smaller size syringes as this can increase pressure on the tube and potentially rupture smaller tubes.
- Use room temperature tap water for tube flushing. Sterile water may be appropriate where the quality of municipal water supplies is of concern. The amount of water will depend on the patient's needs, clinical condition, and type of tube, but the average volume ranges from 10 to 50 mls for adults, and 3 to 10 mls for infants. Hydration status also influences the volume used for flushing feeding tubes. In many cases, increasing the flushing volume can avoid the need for supplemental intravenous fluid. However, individuals with renal failure and other fluid restrictions should receive the minimum flushing volume necessary to maintain patency.
- Do not use excessive force to flush the tube. Excessive force can perforate the tube and can cause injury to the gastrointestinal tract.
- Document the time and amount of water used in the patient's record. This will enable all caregivers to monitor the patient's needs more accurately.

Daily Care & Maintenance Checklist

Assess the patient

Assess the patient for any signs of pain, pressure or discomfort.

Assess the stoma site

Assess the patient for any signs of infection, such as redness, irritation, edema, swelling, tenderness, warmth, rashes, purulent or gastrointestinal drainage. Assess the patient for any signs of pressure necrosis, skin breakdown or hypergranulation tissue.

Clean the stoma site

Use warm water and mild soap.

Use a circular motion moving from the tube outwards.

Clean sutures, external bolsters and any stabilizing devices using a cotton-tipped applicator.

Rinse thoroughly and dry well.

Assess the tube

Assess the tube for any abnormalities such as damage, clogging or abnormal discoloration.

Clean the feeding tube

Use warm water and mild soap being careful not to pull or manipulate the tube excessively.

Rinse thoroughly, dry well.

Clean the gastric and balloon ports

Use a cotton tip applicator or soft cloth to remove all residual formula and medication.

Rotate the tube

Rotate the tube 360 degrees plus a quarter turn daily.

Verify placement of the external bolster

Verify that the external bolster rests 2-3mm above the skin.

Flush the feeding tube

Flush the feeding tube with water using a catheter tip or slip tip syringe every 4-6 hours during continuous feeding, anytime the feeding is interrupted, or at least every 8 hours if the tube is not being used. Flush the feeding tube after checking gastric residuals. Flush the feeding tube before and after medication administration. Avoid using acidic irrigants such as cranberry juice and cola beverages to flush feeding tubes.

Balloon Maintenance

Check the water volume in the balloon once a week.

- Insert a Luer slip syringe into the balloon inflation port and withdraw the fluid while holding the tube in place. Compare the amount of water in the syringe to the amount recommended or the amount initially prescribed and documented in the patient record. If the amount is less than recommended or prescribed, refill the balloon with the water initially removed, then draw up and add the amount needed to bring the balloon volume up to the recommended and prescribed amount of water. Be aware as you deflate the balloon there may be some gastric contents that can leak from around the tube. Document the fluid volume, the amount of volume to be replaced (if any), the date and time.
- Wait 10-20 minutes and repeat the procedure. The balloon is leaking if it has lost fluid, and the tube should be replaced. A deflated or ruptured balloon could cause the tube to dislodge or be displaced. If the balloon is ruptured, it will need to be replaced. Secure the tube into position using tape, then follow facility protocol and/or call the physician for instructions.

Note: Refill the balloon using sterile or distilled water, not air or saline. Saline can crystallize and clog the balloon valve or lumen, and air may seep out and cause the balloon to collapse. Be sure to use the recommended amount of water as over-inflation can obstruct the lumen or decrease balloon life and under-inflation will not secure the tube properly.

Tube Occlusion

Tube occlusion is generally caused by:

- Poor flushing techniques
- Failure to flush after measurement of gastric residuals
- Inappropriate administration of medication
- Pill fragments
- Viscous medications
- Thick formulas, such as concentrated or enriched formulas that are generally thicker and more likely to obstruct tubes
- Formula contamination that leads to coagulation
- Reflux of gastric or intestinal contents up the tube

To Unclog A Tube

1. Make sure that the feeding tube is not kinked or clamped off.
2. If the clog is visible above the skin surface, gently massage or milk the tube between fingers to break up the clog.
3. Next, place a catheter tip syringe filled with warm water into the appropriate adaptor or lumen of the tube and gently pull back on then depress the plunger to dislodge the clog.
4. If the clog remains, repeat step #3. Gentle suction alternating with syringe pressure will relieve most obstructions.
5. If this fails, consult with the physician. Do not use cranberry juice, cola drinks, meat tenderizer or chymotrypsin, as they can actually cause clogs or create adverse reactions in some patients. If the clog is stubborn and cannot be removed, the tube will have to be replaced.

Balloon Longevity

Precise balloon life cannot be predicted. Silicone balloons generally last 1-8 months, but the life span of the balloon varies according to several factors. These factors may include medications, volume of water used to inflate the balloon, gastric pH and tube care.

WARNING: FOR ENTERAL NUTRITION AND/OR MEDICATION ONLY.

For more information, please call 1-800-KCHELPS in the United States, or visit our web site at www.kchealthcare.com.

Educational Booklets: "A Guide to Proper Care" and "A Stoma Site and Enteral Feeding Tube Troubleshooting Guide" is available upon request. Please contact your local representative or contact Customer Care.



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