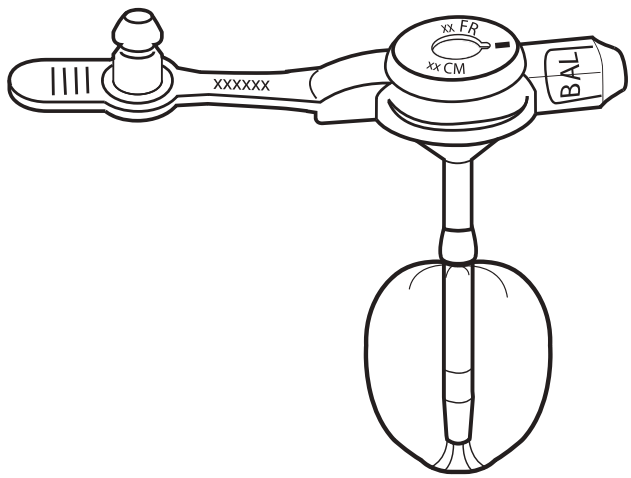
AVANOS*

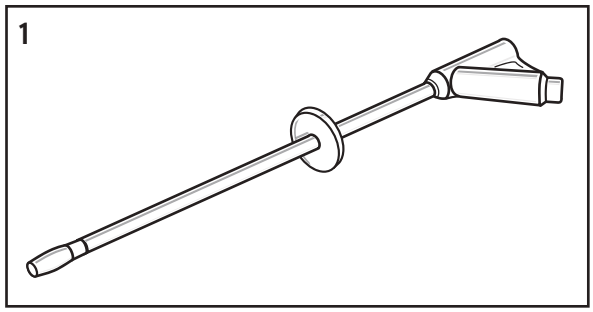
MIC-KEY* GASTROSTOMY FEEDING TUBE

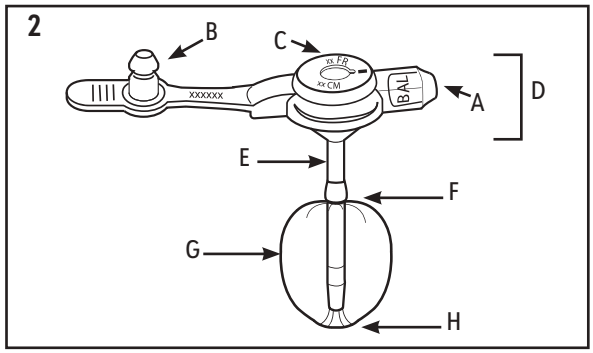
EXTENSION SETS WITH ENFit® CONNECTORS

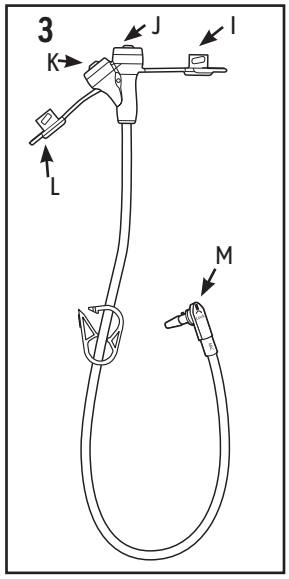
Low-Profile G-Tube

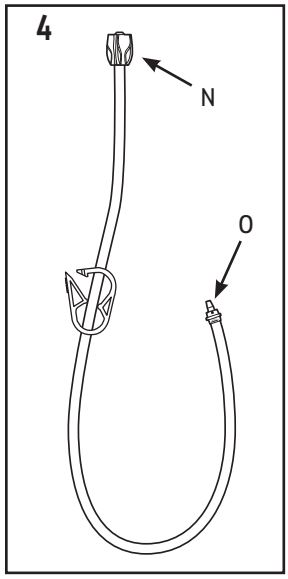
Instructions for Use











U.S. Patent Nos.: 6,808,521B; 7,534,224BB; 5,997,546A

Diameter / Length		Single Use Only	STERILE EO Sterilized Using Ethylene Oxide	Do not use if package is damaged	Do not resterilize
Not made with natural rubber latex		Product is NOT made with DEHP as a plasticizer	Rx Only	MR Conditional	Caution	Consult instructions for use

AVANOS* MIC-KEY* Low-Profile Gastrostomy Feeding Tube Extension Sets with ENFit® Connectors

Rx Only: Federal Law (USA) restricts this device to sale by or on the order of a physician.

Kit Contents:

1 **MIC-KEY* Gastrostomy Feeding Tube (Low-Profile G-Tube) (Fig 2)**
- Balloon Valve **(Fig 2-A)**
- Extension Set Port Cover **(Fig 2-B)**
- Extension Set Port **(Fig 2-C)**
- External Base **(Fig 2-D)**
- Shaft **(Fig 2-E)**
- Balloon Cuff **(Fig 2-F)**
- Balloon **(Fig 2-G)**
- Balloon Tip **(Fig 2-H)**

1 **6 ml Luer Slip Syringe**

1 **35 ml Enteral Feeding Syringe with ENFit® Connector**

1 **MIC-KEY* Continuous Feed Extension Set with ENFit® Connectors, 12 in. (Fig 3)**
- Feeding/Medication Port Plugs **(Fig 3-I, 3-L)**
- Feeding/Medication Ports **(Fig 3-J, 3-K)**
- SECUR-LOK* Right Angle Connector **(Fig 3-M)**

1 **MIC-KEY* Bolus Feed Extension Set with ENFit® Connector, 12 in (Fig 4)**
- Feeding/Medication Port **(Fig 4-N)**
- SECUR-LOK* Straight Connector **(Fig 4-0)**

4 **Gauze Pads**

Not Included: Stoma Measuring Device **(Fig 1)**

⚠**Caution:** The MIC-KEY* Low-Profile Gastrostomy Feeding Tube is intended to connect to the MIC-KEY* Extension Sets with ENFit® Connectors. The MIC-KEY* Extension Sets with ENFit® Connectors are intended to connect to Enteral Feeding Syringes with ENFit® Connectors and Feed Administration Bags with ENFit® Connectors.

Description

The MIC-KEY* Low-Profile Gastrostomy Feeding Tube **(Fig 2)** allows for delivery of enteral nutrition and medication directly into the stomach and/or gastric decompression.

⚠**Warning: For enteral nutrition and/or medication only. Please use caution: breathing systems and driving gases, urethral/urinary, limb cuff inflation, neuroaxial, and intravascular/hypodermic connectors may have the potential for misconnection.**

Indications For Use

The MIC-KEY* Low-Profile Gastrostomy Feeding Tube is 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 low-profile gastrostomy feeding tube include but are not limited to ascites, colonic interposition, portal hypertension, peritonitis, and morbid obesity.

⚠Warning

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.

Complications

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

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

Placement

The MIC-KEY* Low-Profile Gastrostomy Feeding Tube may be placed percutaneously under fluoroscopic, laparoscopic, or endoscopic guidance or as a replacement to an existing device using an established stoma tract.

⚠**Warning: A gastropexy must be performed to affix the stomach to the anterior abdominal wall, the Feeding Tube insertion site identified, stoma tract dilated and measured prior to initial tube insertion to ensure patient safety and comfort.**

Do not use the retention balloon of the Feeding Tube as a gastropexy device. The balloon may burst and fail to attach the stomach to the anterior abdominal wall.

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.

An inappropriately sized MIC-KEY* can cause necrosis, buried bumper syndrome, and/or hypergranulation tissue.

Measuring the Stoma Length

⚠**Caution:** Selection of the correct size MIC-KEY* is critical for the safety and comfort of the patient. Measure the length of the patient's stoma with the Stoma Measuring Device **(Fig 1)**. The shaft length **(Fig 2-E)** of the MIC-KEY* selected should be the same as the length of the stoma. An inappropriately sized MIC-KEY* can cause necrosis, buried bumper syndrome, and/or hypergranulation tissue.

1. Lubricate the tip of the Stoma Measuring Device **(Fig 1)** with water-soluble lubricant.
   ⚠**Caution:** Do not use mineral oil. Do not use petroleum jelly.
2. Advance the Stoma Measuring Device over the guidewire, through the stoma, and into the stomach.
   ⚠**Caution:** Do not use force.
3. Fill the Luer slip syringe with 5 ml of water and attach to the balloon valve **(Fig 2-A)**. Depress the syringe plunger and inflate the balloon.
4. Gently pull the device toward the abdomen until the balloon rests against the inside of the stomach wall.
5. Slide the plastic disc down to the abdomen and record the measurement above the disc.
6. Add 4–5 mm to the recorded measurement to ensure the proper stoma length and fit in any position. Record the measurement.
7. Using a Luer slip syringe, remove the water in the balloon.
8. Remove the stoma measuring device.
9. Document the date, lot number, and measured centimeter shaft length **(Fig 2-E)**.

Balloon Verification

1. Select the appropriate size MIC-KEY* Gastrostomy Feeding Tube, remove from the package, and inspect for damage.
2. Using the 6 ml Luer slip syringe contained in the kit, inflate the balloon with the appropriate amount of sterile or distilled water through the balloon valve **(Fig 2-A)**.
   ⚠**Caution:** Do not use air or saline.
   Refer to the following table for recommended inflation for the French size of the device.
   Table 1: Inflation Table

Size	Recommended Fill Volume	Maximum Fill Volume
12 Fr	3 ml	5 ml
14 Fr	5 ml	10 ml
16 Fr	5 ml	10 ml
18 Fr	5 ml	10 ml
20 Fr	5 ml	10 ml
24 Fr	5 ml	10 ml

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 balloon tip **(Fig 2-H)** with a water-soluble lubricant.
   ⚠**Caution:** Do not use mineral oil. Do not use petroleum jelly.

Initial MIC-KEY* Placement

1. Select the appropriate MIC-KEY* Low-Profile Gastrostomy Feeding Tube and prepare according to the instructions in the Balloon Verification section mentioned previously.
2. Advance the balloon tip **(Fig 2-H)** over the guidewire, through the stoma tract, and into the stomach.
3. Verify that the Feeding Tube is in the stomach, remove the endoscope if utilized, and remove the guidewire or peel-away sheath if utilized.
4. Ensure the external base **(Fig 2-D)** is flush with the skin.
5. Using the 6 ml Luer slip syringe, inflate the balloon with sterile or distilled water, per the Inflation Table **(Table 1)**.
   ⚠**Caution:** Do not exceed 5 ml total balloon volume inside the 12 Fr balloon. Do not inject contrast into the balloon. Do not use air or saline.
   ⚠**Caution:** Do not exceed 10 ml total balloon volume in 14 Fr or larger Feeding Tube balloons. Do not inject contrast into the balloon. Do not use air or saline.
6. Clean the residual fluid or lubricant from the Feeding Tube and stoma.

Bolus Feed and Continuous Feed Extension Set Assembly

1. Use either the MIC-KEY* Continuous Feed **(Fig 3)** or Bolus Feed **(Fig 4)** Extension Set with ENFit® Connectors for gastric feeding and gastric decompression.
2. Open the MIC-KEY* Feeding Tube Extension Set port cover **(Fig 2-B).**
3. Insert the MIC-KEY* Extension Set with ENFit® Connectors by aligning the black line on the SECUR-LOK* connector **(Fig 3-M or 4-0)** with the black line on the MIC-KEY* Extension Set port **(Fig 2-C)**.
4. Lock into place by pushing in and rotating the SECUR-LOK* connector **(Fig 3-M or 4-0)** CLOCKWISE until a slight resistance is felt (approximately ¼ of a turn).
   ⚠**Caution:** DO NOT rotate the connector past the stop point.
5. To remove the Extension Set, rotate it COUNTER CLOCKWISE until the black line on the Extension Set aligns with the black line on the MIC-KEY*. Remove the set and cap the extension set port with the attached port cover.

Verify MIC-KEY* Position and Patency

1. With either MIC-KEY* Extension Set with ENFit® Connectors connected **(Fig 3 or 4)**, attach an enteral feeding syringe with ENFit® Connector containing 10 ml of water to the extension set's feeding/medication port **(Fig 3-J or 4-N)**.
2. Aspirate gastric contents. The presence of gastric contents in the tubing confirms the correct Feeding Tube position within the stomach.
3. Flush stomach contents with the water in the syringe. Check for leakage around the stoma. If there is a leak, reconfirm proper balloon inflation. Also verify the French size, stoma length, and placement. Proper placement may be confirmed radiographically. The MIC-KEY* has a Radiopaque stripe on the Feeding Tube.
   ⚠**Caution:** Do not use contrast inside the balloon.
4. Begin feeding only after confirmation of proper patency and placement, according to physician instructions.

MIC-KEY* Removal

1. Make sure that this type of Feeding Tube can be replaced at the bedside.
2. Assemble all equipment and supplies, cleanse hands using aseptic technique, and put on clean, powder-free gloves.
3. Rotate the Feeding Tube 360 degrees to ensure the tube moves freely and easily.
4. Firmly insert the Luer slip syringe into the balloon valve **(Fig 2-A)** and withdraw all the fluid from the balloon.
5. Apply counter pressure to the abdomen and remove the Feeding Tube with gentle but firm traction.
   Note: *If resistance is encountered, lubricate the Feeding Tube and stoma with water-soluble lubricant. Simultaneously push and rotate the Feeding Tube. Gently manipulate the Feeding Tube free. If the Feeding Tube will not come out, refill the balloon with the prescribed amount of water and notify the physician.*
   ⚠**Caution:** Never use excessive force to remove a Feeding Tube.
   ⚠**Warning: Never attempt to change the Feeding Tube unless trained by the physician or other health care provider.**

Replacement Procedure

Notice: Device replacement and after care (e.g. feeding/medication administration, decompression) can be performed by the healthcare professional or at home by the patient/caregiver after receiving instructions from the healthcare professional (active decompression must be performed by the healthcare professional while passive decompression can be performed by either party, as described under "Decompression").

Do not attempt to replace device until first discussing with your healthcare professional.

Notice: Please contact a professional health care provider or physician for explanation of the warnings, care, and use of the device.

1. Cleanse the skin around the stoma site and allow the area to air dry.
2. Measure the stoma length with the AVANOS* Stoma Measuring Device **(Fig 1)**.
3. Select the appropriate size MIC-KEY* Gastrostomy Feeding Tube and prepare according to the instructions in the Balloon Verification section.
4. Lubricate the balloon tip **(Fig 2-H)** with water-soluble lubricant and gently insert the MIC-KEY* through the stoma into the stomach.
5. Ensure the external base **(Fig 2-D)** is flush with the skin.
6. Using the 6 ml Luer slip syringe, inflate the balloon with sterile or distilled water per the Inflation Table **(Table 1)**.
   ⚠**Caution:** Do not exceed 5 ml total balloon volume inside the 12 Fr balloon. Do not inject contrast into the balloon. Do not use air or saline.
   ⚠**Caution:** Do not exceed 10 ml total balloon volume in 14 Fr or larger feeding tube balloons. Do not inject contrast into the balloon. Do not use air or saline.
7. Clean the residual fluid or lubricant from the Feeding Tube and stoma.
8. Verify proper Feeding Tube position according to the instructions in the Verify MIC-KEY* Position and Patency section above.

Feeding Administration

1. Flush the system with water prior to feeding.
2. If feeding with a syringe, connect an enteral feeding syringe with ENFit® Connector to the Bolus Feed Extension Set feeding/medication port **(Fig 4-N)**. Twist to secure the connection.
3. If using a feeding bag, purge the air from the bag and tubing. Connect the tubing to the Continuous Feed Extension Set feeding/medication port **(Fig 3-J)**. Twist to secure the connection.
4. Adjust the formula flow rate and administer the feeding.
5. Upon completion, flush the MIC-KEY* Extension Set and Feeding Tube with water until the tubing is clear, or per physician's instructions.
6. Disconnect the MIC-KEY* Extension Set and replace the MIC-KEY* Extension Set port cover **(Fig 2-B)**.
7. Wash the MIC-KEY* Extension Set and the enteral feeding syringe or feeding bag with warm soapy water, rinse, and dry thoroughly.
8. If feeding continuously with a pump, flush the MIC-KEY* with water every 4–6 hours, any time feeding is interrupted, or per physician's instructions.

Decompression

1. Passive and active decompression may be done with either the MIC-KEY* Continuous Feed **(Fig 3)** or Bolus Feed **(Fig 4)** Extension Set with ENFit® Connectors. Passive decompression/ venting can be performed by the healthcare professional or at home by the patient/caregiver after receiving instructions from the healthcare professional. Active decompression should be performed by a healthcare professional.
2. For passive decompression/venting, attach extension set **(Fig 3 or Fig 4)** to the MIC-KEY* **(Fig 2)** and open port plug **(Fig 3-I)** to allow decompression.
3. For active decompression/gastric residual collection, healthcare professional should perform the procedure according to their decompression protocol.
4. After decompression, flush the MIC-KEY* Extension Set and Feeding Tube with water.
5. Disconnect the MIC-KEY* Extension Set and replace the MIC-KEY* G-Tube Extension Set port cover **(Fig 2-B)**.

Medication Administration

⚠**Caution:** Consult physician prior to administering medication through the tube.

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.

⚠**Caution:** Never crush enteric-coated medication or mix medication with formula.

Using an Extension Set **(Fig 3 or Fig 4)** and an enteral feeding syringe, flush the Feeding Tube with the prescribed amount of water.

⚠**Warning: Do not fill balloon with medication.**

MIC-KEY* Patency Guidelines

Follow these guidelines for proper flushing, which is the best way to avoid clogging and to maintain Feeding Tube patency.

- ⚠**Caution:** Always flush through the Extension Set. Using a syringe in the extension set port can damage the anti-reflux valve and cause leaking.
- 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 Feeding 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 Extension Set.
- ⚠**Caution:** Never crush enteric-coated medication or mix medication with formula. Avoid using acidic irrigants such as cranberry juice and carbonated soft drinks to flush through the Extension Sets as the acidity when combined with formula proteins may actually contribute to clogging.

General Flushing Guidelines

- 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 5 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, infants and individuals with renal failure and other fluid restrictions should receive the minimum flushing volume necessary to maintain patency.
- To minimize the amount of air that enters the stomach during feeding, prime the extension set by filling it with water prior to connecting it to the Feeding Tube and flushing the system.
- ⚠**Caution:** Do not use excessive force to flush the Feeding Tube. Excessive force can perforate the Feeding 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 Check List

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, or 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 Feeding Tube outwards. Clean sutures, external base **(Fig 2-D)**, and any stabilizing devices using a cotton-tipped applicator. Rinse thoroughly and dry well.
Assess the MIC-KEY*	Assess the Feeding Tube for any abnormalities such as damage, clogging, or abnormal discoloration.
Clean the MIC-KEY*	Use warm water and mild soap, being careful not to pull or manipulate the Feeding Tube excessively. Rinse thoroughly, dry well.
Verify placement of the external base	Verify that the external base **(Fig 2-D)** rests 2–3mm above the skin.
Flush the Feeding Tube	Flush the Feeding Tube with water 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 carbonated soft drinks to flush Feeding Tubes.

Balloon Maintenance

Check the water volume in the balloon once a week.

- Insert a Luer slip syringe into the balloon valve **(Fig 2-A)** and withdraw the fluid while holding the Feeding 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 Feeding 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 Feeding Tube should be replaced. A deflated or ruptured balloon could cause the Feeding Tube to dislodge or be displaced. If the balloon is ruptured, it will need to be replaced. Secure the Feeding Tube into position using tape, then follow facility protocol and/or call the physician for instructions.

  ⚠**Caution:** Refill the balloon using sterile or distilled water, not air or saline. Saline can crystallize and clog the balloon valve and air may seep out and cause the balloon to collapse. Be sure to use the recommended amount of water as overinflation can decrease balloon life and underinflation will not secure the Feeding Tube properly.

Feeding Tube Occlusion

Feeding 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 feeding tubes
- Formula contamination that leads to coagulation
- Reflux of gastric or intestinal contents up the feeding tube
- Overinflation of the balloon

To Unclog A Feeding Tube

1. Place an enteral feeding syringe filled with warm water into the appropriate Extension Set and gently pull back on then depress the plunger to dislodge the clog.
2. If the clog remains, repeat step #1. Gentle suction alternating with syringe pressure will clear most obstructions.
3. If this fails, consult with the physician.
   ⚠**Caution:** Do not use cranberry juice, carbonated soft drinks, meat tenderizer or chymotrypsin as they can actually cause clogs or create adverse reactions in some patients. If the clog cannot be removed, the Feeding Tube will have to be replaced.
   ⚠**Caution:** Do not insert foreign objects through the tube.

Closing The Extension Set Port Cover

If the Extension Set port cover **(Fig 2-B)** becomes difficult to close or does not stay in place:

1. Verify that the Extension Set port is free of formula build up.
2. Lubricate the tip of the Extension Set port cover with water. This will ease the insertion of the Extension Set port cover into the Extension Set port **(Fig 2-C)**.

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 feeding tube care.

MRI Safety Information

Non-clinical testing has demonstrated the Low-Profile (MIC-KEY*) Enteral Feeding Tube System 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 or 3 Tesla;
- Maximum spatial field gradient of 1,960 G/cm (19.6 T/m) or less.
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of < 2 W/kg (Normal Operating Mode).

MRI-related heating: Under the scan conditions defined above, the Low-Profile (MIC-KEY) Tube System is expected to produce a maximum temperature rise of less than 1.3 °C after 15 minutes of continuous scanning.

Artifact Information

In non-clinical testing, the image artifact caused by the device extends less than 45 mm from the Low-Profile (MIC-KEY*) Enteral Feeding Tube System when imaged with a gradient echo pulse sequence and a 3 T MRI system.

For more information, please call 1-844-4AVANOS (1-844-428-2667) in the United States, or visit our web site at www.avanos.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.