

MiniONE[®]

EDUCATION GUIDE



Innovating. Educating. Changing Lives.™

Patient Information

Patient name: _____

In case of an emergency, dial 911 or call: _____

Device placement date: _____

Scheduled replacement date: _____

Device Information: MiniONE® Balloon Button

Device manufacturer:	Applied Medical Technology, Inc. (AMT)
Product number:	M1-5-
Lot number:	
French size:	
Stoma length (cm):	
Balloon fill volume (ml):	

MiniONE® Device Sticker
(Place Sticker Here)

Formula, Feed Instructions

Formula name: _____

Nutrition Type	Formula Per Day (ml, cc, kcal, etc.)	Additional Water Per Day (ml, cc, oz., cups)
Ready to use (pre-mixed):		
Powdered:		
Blended food diet:	Follow Physician's Instruction	

Medications: _____

Nutrition delivery method:	Bolus	Continuous	Other: _____	
	Syringe	Pump	Gravity bag	Other: _____

Pump settings (if applicable):	Flow rate (ml/hour): _____
	Volume of nutrition (ml): _____

Special instructions: _____



Healthcare Team + Other Resources

Healthcare provider (physician): _____
Phone number: _____

Nurse practitioner or physician assistant: _____
Phone number: _____

Nutrition team/dietitian: _____
Phone number: _____

Enteral supply company: _____
Phone number: _____

AMT’s team of Enteral Product Specialists are available to help:



CALL

TOLL FREE: 800-869-7382
LOCAL: 440-717-4000



EMAIL

USA: CS@AppliedMedical.net
INTERNATIONAL:
ICS@AppliedMedical.net

SUPPORT ORGANIZATIONS:

- www.oley.org The Oley Foundation is for people who feed by tube or IV at home.
- www.complexchild.com An online magazine for parents of kids with special healthcare needs.
- www.feedingmatters.org A unique support system focusing on pediatric feeding disorders.
- www.feedingtubeawareness.com A group of parents whose children use feeding tubes.
- www.foodfortubies.com An organization that helps people with feeding tubes use “real” food.
- www.lifeslittletreasures.org.au An Australian support group tailored for families of premature children.

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Introduction To Tube Feeding

Proper nutrition is essential to maintaining our bodies’ health, growth, and ability to heal. Sometimes, an illness and/or surgery may interfere with a person’s ability to eat. In these situations, nutrition must be supplied in a different way. One potential option is enteral nutrition, which is also known as tube feeding. An understanding of the digestive system will help you better appreciate enteral nutrition and why it is important.

The digestive system, also known as the gastrointestinal (GI) system, extends from the mouth to the anus. As food passes through the digestive system, it is broken down into absorbable nutrients. The digestive system includes the mouth, throat, esophagus, stomach, small intestine, large intestine, rectum, and anus. Digestion begins in the mouth, where food is chewed and broken down into small pieces. Swallowing allows the small pieces of food to travel down the esophagus and into the stomach. Once in the stomach, food is broken down into its main nutrients. The partially-digested food then moves into the small intestine where it is broken down even further. Most nutrients are absorbed in the small intestine. The remaining material passes into the large intestine where excess liquid is absorbed. Solid waste is expelled through the anus.

If a person cannot eat by mouth, but his/her stomach or small intestine is still working, one potential way to deliver nutrients is tube feeding (enteral nutrition). Tube feeding allows a person to bypass the mouth and esophagus and deliver nutrition directly to the stomach or small intestine. The feeding tube can be placed in the nose, the stomach, or the small intestine. A feeding tube that passes through the abdomen and into the stomach is called a gastrostomy tube, or G-Tube. AMT’s MiniONE® Balloon Button is one type of G-Tube.

If you or someone you care for cannot eat by mouth, your healthcare provider will help you choose the best option to get nutrition in a different way.



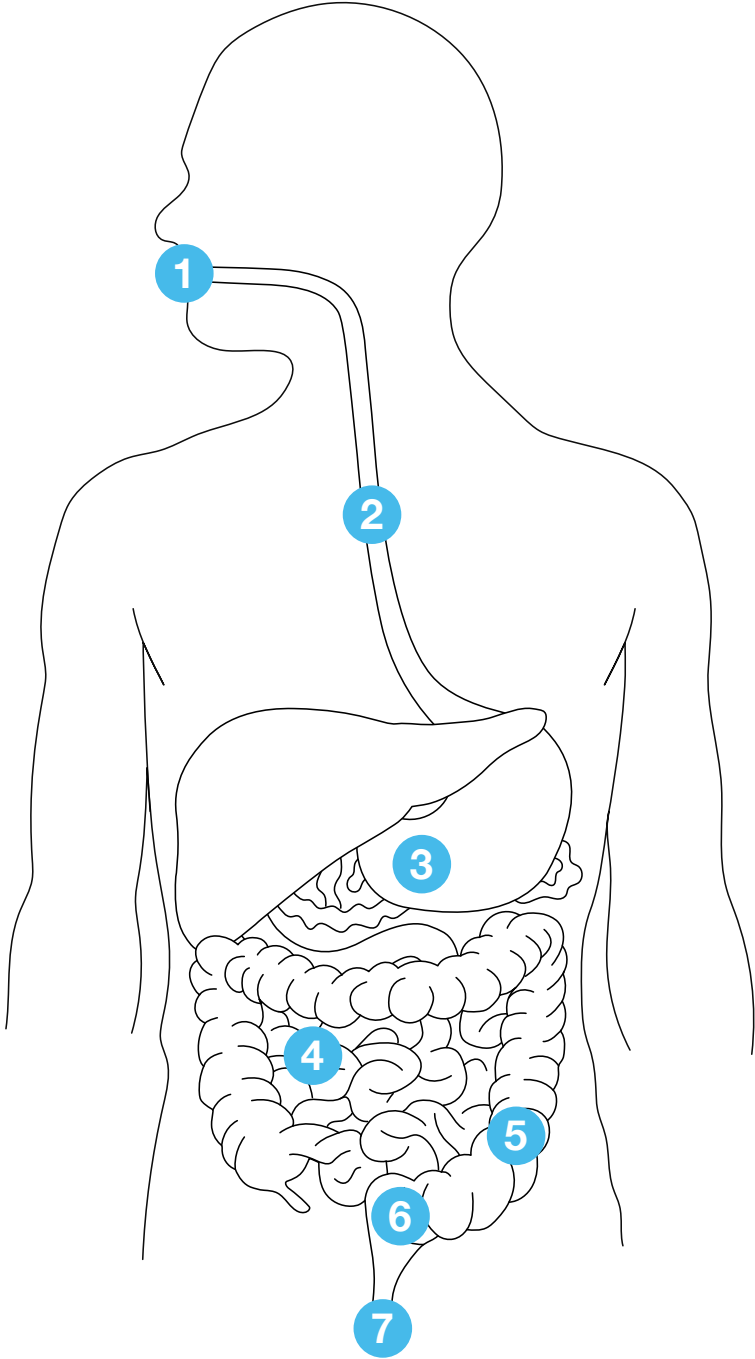
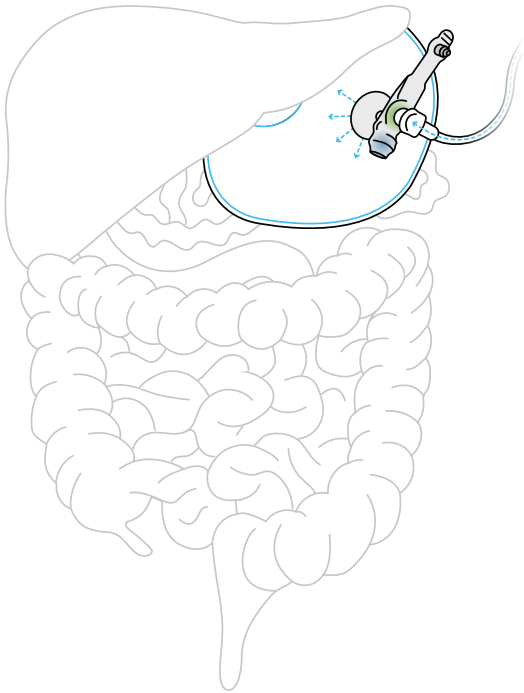
MiniONE® Button
Low Profile Balloon Gastrostomy Tube

The Basics Of Tube Feeding

Tube feeding (enteral nutrition) uses a special medical device, sometimes called a “feeding tube”, to create a direct pathway to deliver nutrition into either the stomach or the small intestine. Feeding tubes can be used to deliver formula, real food blends, medication, and water. Feeding tubes are named based on where they enter the body and where the nutrition is being delivered. For example, a tube that passes through the abdomen and into the stomach (also known as the gastric space) is called a gastrostomy tube, or G-Tube.

For some individuals, enteral nutrition (tube feeding) may be their only source of food; for others, enteral nutrition may be added to their daily food routine as a supplement.

Your healthcare team (doctors, nurses, dietitians, and pharmacists) will talk with you about the different types of feeding tubes and prescribe the proper feeding device for your medical and nutritional needs.



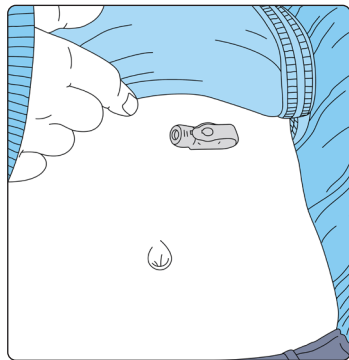
GASTROINTESTINAL SYSTEM DIAGRAM

- | | |
|--------------------|--------------------|
| 1. Mouth | 5. Large Intestine |
| 2. Esophagus | 6. Rectum |
| 3. Stomach | 7. Anus |
| 4. Small Intestine | |

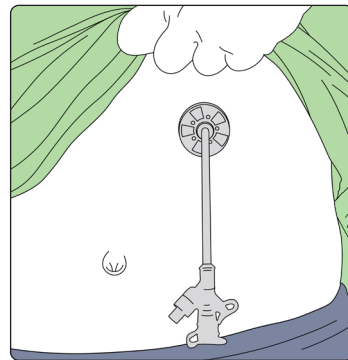
Types Of Gastrostomy Feeding Tubes

A **Gastrostomy Tube**, also known as a G-Tube, is used to deliver nutrition (food) directly into the stomach. The device is placed through the belly, or abdominal wall, and into the stomach. G-Tubes are available as “low profile” or “traditional length”.

LOW PROFILE



TRADITIONAL



Low Profile refers to the external portion of the device, often called the bolster, being very flat or flush against the skin. The flat/flush design means that low profile devices are easily hidden under clothing. Low profile tubes are often called “buttons”. AMT offers low profile G-Tubes for both children and adults. The MiniONE® Family includes Balloon, Non-Balloon, and Capsule Non-Balloon devices:

- The MiniONE® Balloon Button has an internal retention balloon with an exclusive apple shape that keeps the device in place. For insertion and removal, the balloon can be inflated and deflated in either a clinical setting or a home-care setting. The balloon fill valve on 12-14F MiniONE® Balloon devices is compatible with both Luer (slip tip) and Luer Lock syringes; the balloon fill valve on 16-24F devices is compatible with a slip tip syringe.
- The MiniONE® Non-Balloon and MiniONE® Capsule Non-Balloon buttons have a mushroom-shaped internal retention bolster that keeps the device in place. *Placement/Removal is to be performed by a qualified clinician.*



MiniONE® Button
Low Profile Balloon G-Tube



MiniONE® Button
Low Profile Non-Balloon G-Tube



MiniONE® Button
Low Profile Capsule Non-Balloon G-Tube

Traditional Length means that the external portion of the device is long and extends from the body. These tubes are sometimes called “long tubes”, “adjustable length tubes”, “standard length tubes”, and even “danglers”. Traditional length devices have a round disc, or retention ring, for the external bolster. The disk can be moved up and down the tube to accommodate stoma lengths up to 10 cm. AMT offers a few different kinds of traditional length G-Tubes for both children and adults. For more information about our Traditional Length family of devices, visit our website: <https://www.AppliedMedical.net/Enteral/G-Tubes/>

G-Tubes are easy to use and they work very well to deliver essential nutrition and/or medicine into the body. There are many types of nutritional formulas: powdered, “ready to use” (pre-mixed), and homemade (using a food processor). A healthcare provider will prescribe the appropriate type of feeding device, the best formula for you, and the amount of extra water you need to stay healthy.

Tube Feeding Methods

Your healthcare provider will determine a feeding schedule that best fits your specific dietary needs. There are two main types of feeding routines: Bolus and Continuous.

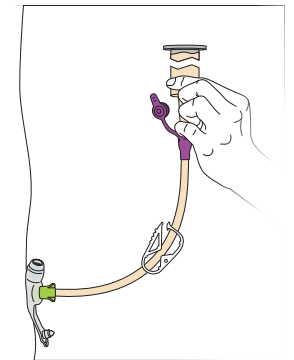
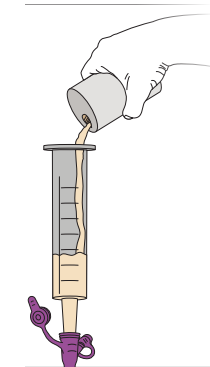
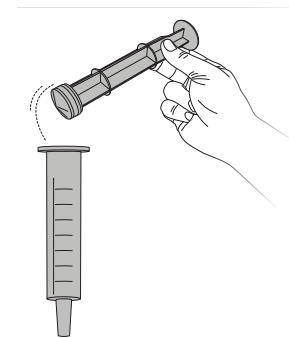


BOLUS FEED SET

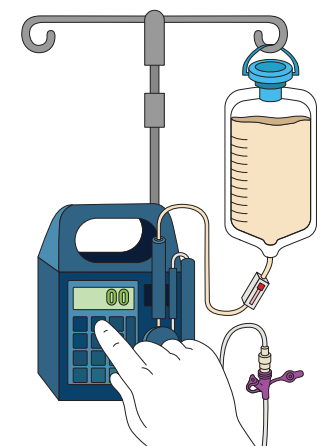
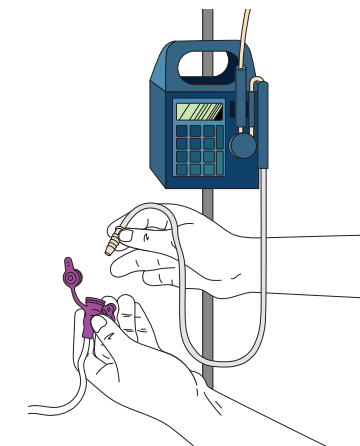
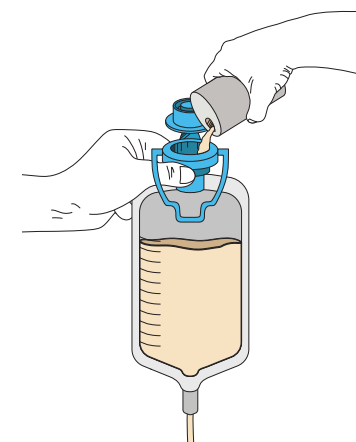


CONTINUOUS FEED SET

The **Bolus** method (also referred to as intermittent feeding) is a type of feeding where nutrition is delivered at a relatively fast rate over a relatively short time period, typically 30-60 minutes. This style of feeding may be performed several times a day in order to fulfill daily caloric needs. Bolus feeding is typically performed by attaching a large syringe (30-60 ml) to a Bolus Feed Set.



The **Continuous** method is a type of feeding where nutrition is delivered at a relatively slow rate over a relatively long time period, typically 24 hours per day. This style of feeding is typically performed by attaching a feeding pump or a gravity bag to a Continuous Feed Set with a y-port adapter.



MiniONE® Balloon Button Kit Contents

MiniONE® Balloon Button

Feed Sets

- Legacy feed sets:◦8-1211 (12” straight connector with bolus adapter)
◦8-1255 (12” right angle connector with y-port adapter)
- ENFit® feed sets:◦8-1211-ISOSAF (12” straight connector with ENFit® single-port adapter)
◦8-1255-ISOSAF (12” right angle connector with ENFit® y-port adapter)

5 ml slip tip syringe (included in 12F - 14F devices only)

- To inflate and deflate the internal retention balloon

10 ml slip tip syringe (included in 16F – 24F devices only)

- To inflate and deflate the internal retention balloon

35 ml catheter tip syringe

- To prime and flush the feed set

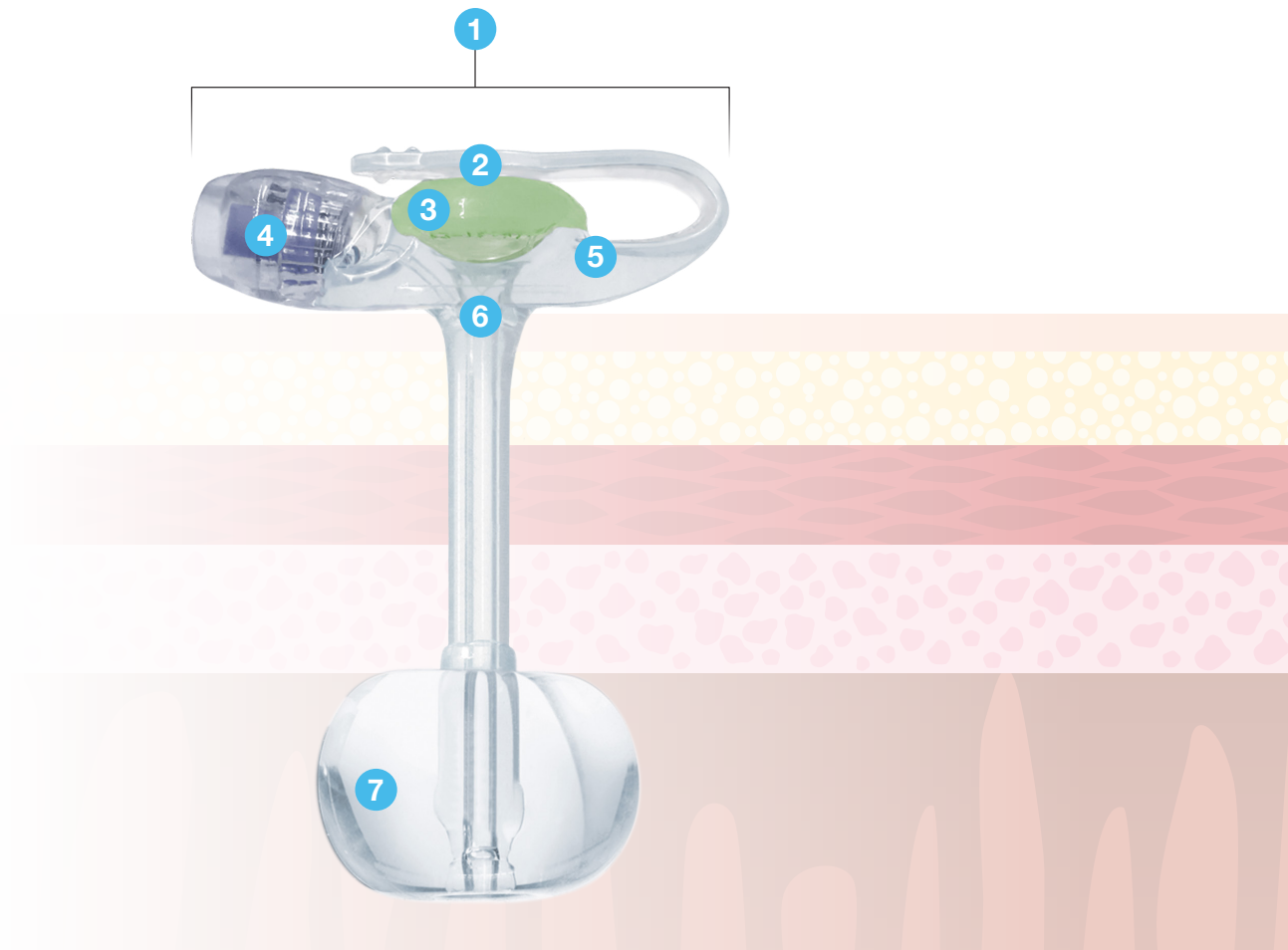
Introducer/Stiffener (only available in 12F – 18F devices)

Lubricant



*KITS CONTAIN EITHER LEGACY FEED SETS OR ENFIT® FEED SETS, NOT BOTH.

MiniONE® Balloon Button Device Anatomy



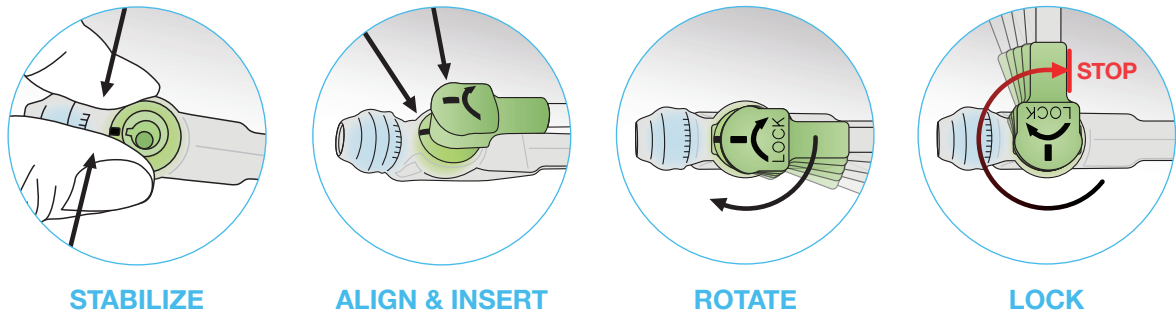
MINIONE® BALLOON BUTTON DEVICE ANATOMY

1. External Bolster
2. Safety Plug
The safety plug should be closed when the device is not in use.
3. Feeding Port
4. Balloon Fill Port
The recommended balloon fill volume is printed on top of the balloon fill port.
5. Lot Number
6. Anti-Reflux Valve / One-Way Valve
The Anti-Reflux Valve prevents stomach contents from leaking out of the device. Attaching a feed set opens the valve and allows nutrition to flow into the device.
7. AMT Exclusive Balloon
AMT’s exclusive apple-shaped balloon provides a superior gastric seal.¹

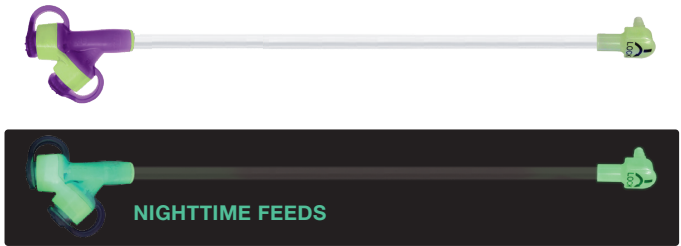
Attaching A Feed Set To The MiniONE® Balloon Button

Always wash your hands with soap and water. Rinse and dry them well.
Refer to the MiniONE® Balloon Button Directions for Use for full instructions.

To attach a feed set to MiniONE® Balloon Button, line up the black line on the feed set connector with the black line on the button's feeding port. Press the feed set connector into the feeding port. Turn 3/4 to the right (clockwise) to lock the feeding set in place.



Nighttime feeds are simplified with the MiniONE® Button. The AMT MiniONE® Button, and its corresponding feed sets, feature our patented Glow Green™ Technology. Glow Green™ Technology facilitates easier nighttime connections by illuminating the feed port and the feed set connector.

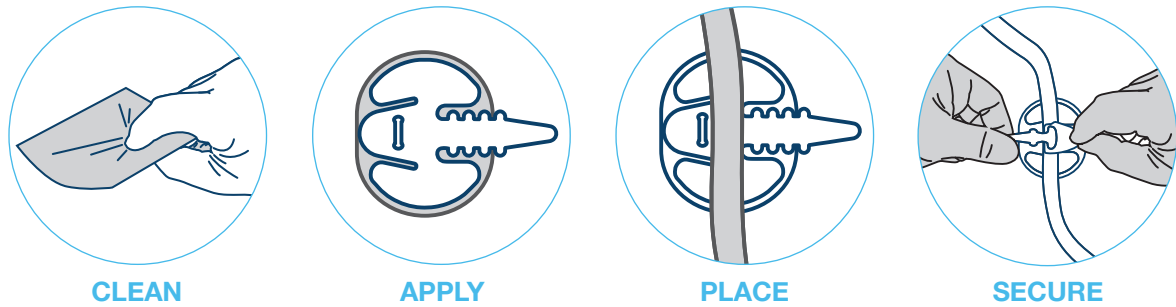


Routine maintenance is recommended for MiniONE® feed sets.

- The feed set should be removed when not in use.
- The feed set should be cleansed with mild soap and warm water after each use.
 - Be sure to rinse thoroughly to remove any formula or soap residual.
- For continuous feeding, the feed set should be cleaned at least once per day.
- To help prevent clogging: flush the feed set after feeding, flush the feed set after administering medication(s), and follow proper flushing guidelines as recommended in the MiniONE® Balloon Button Directions for Use (DFU).

CINCH® Tube Securement Device

While feeding, you can secure the feed set to the belly with an AMT CINCH®. This will help keep the feed set in place and prevent excessive movement and tension on the MiniONE® Balloon Button and around the stoma site.



www.AppliedMedical.net/Enteral/CINCH/

Feeding With The MiniONE® Balloon Button

Feed in an upright position and remain upright for at least 30 minutes after feeding is complete.
Refer to the MiniONE® Balloon Button Directions for Use for full instructions.

1. Gather the following supplies:
 - Nutrition:** Formula (ready to use/pre-mixed or powdered) or blended food
 - Delivery Method:** Feeding pump, syringe, or gravity bag
 - Water** (for flushing the tube)
 - Support Products/Accessories:** A place to hang/ mount your feeding bag (such as an IV pole)

The equipment that you need will vary depending on the feeding method prescribed by your health care provider.

2. Wash your hands with soap and water. Rinse and dry them well.
3. Prepare nutrition for delivery. Do not use formula that is more than 24 hours old. Make sure to write the date and time on the feeding container.

READY TO USE (PRE-MIXED) FORMULA:

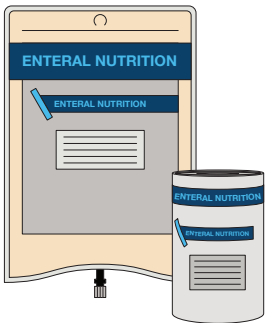
Make sure the formula is room temperature prior to feeding. Shake the formula and wipe the top of the container with a clean, damp towel before opening. If you do not use all of the formula, cover the open container, record the date and time, and store in the refrigerator. Throw away formula that is more than 24 hours old. Do not mix new formula with old formula. There is always a chance it will spoil.

POWDER FORMULA:

Measure out the appropriate amount of powder or concentrate and water. Mix powder or concentrate formula with water following the product label instructions.

BLENDED FOOD:

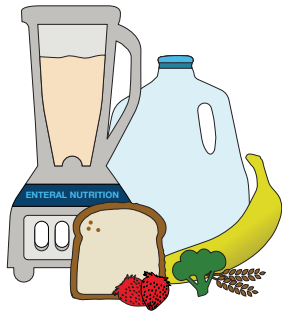
Follow your physician's instructions.



READY TO USE



POWDER FORMULA

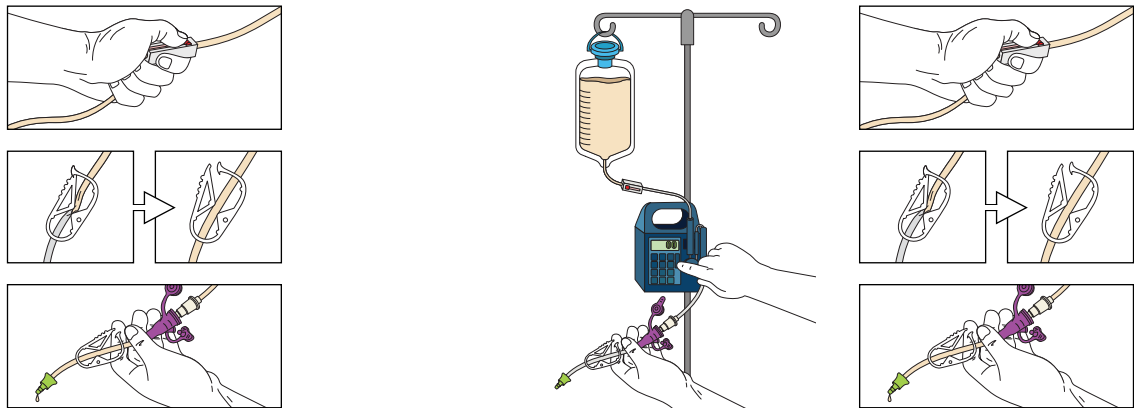


BLENDED FOOD

4. Prime the tubing: Priming the feeding sets removes air from the tubing and prevents it from being pumped into the stomach.

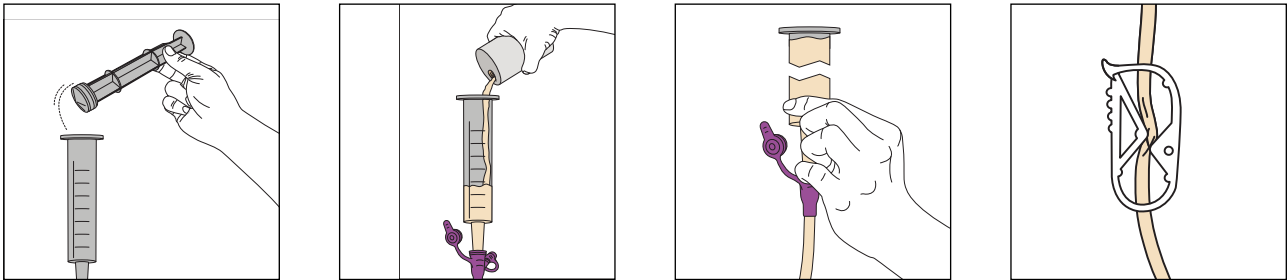
Pump Feeding: Attach the feeding bag tubing to the feed set and clamp one or both tubes. Pour the prescribed amount of formula into the feeding bag, carefully squeeze the air out of the bag and close it. To prime the tubing, you can either:

1. Unclamp the tubing and allow the formula / liquid to flow through to the end of the tubing,
- or
2. Attach the feeding bag tubing to the feeding pump and follow the manufacturer's directions. Be sure to close the pinch clamp when priming is complete.

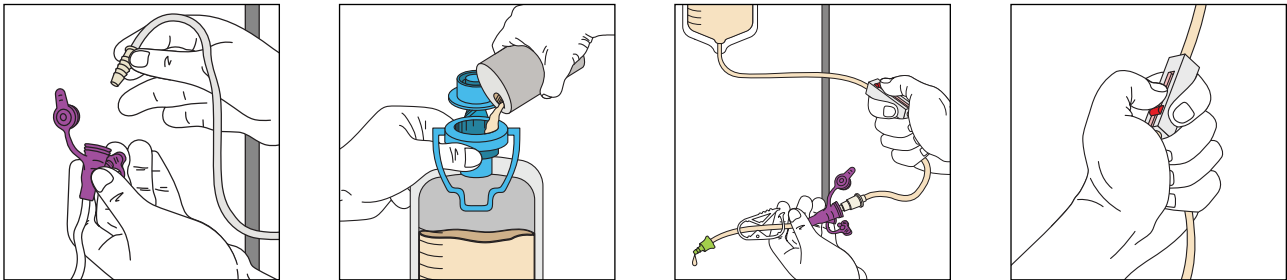


If you chose to prime the tubing using **Option 1**, you will need to attach the feeding bag tubing to the feeding pump at this time.

Syringe Bolus: Clamp the feed set. Remove the plunger from the large syringe and attach the syringe to the feed set. Pour 10-15 ml of formula or water into the syringe, unclamp the feed set, and allow the formula to flow through the feed set until it reaches the end. Then, clamp the feed set and disconnect the syringe.



Gravity Drip Bag: Attach the gravity bag tubing to the feed set and clamp one or both tubes. Pour the prescribed amount of formula into the feeding bag, carefully squeeze the air out of the bag and close it. Hang the gravity feeding bag in a secure location, such as on an IV pole. To prime the tubing, unclamp the feed set and slowly open the roller clamp on the gravity bag tubing. Allow the formula to flow until it reaches the end of the feed set. Close the pinch clamp when priming is complete.



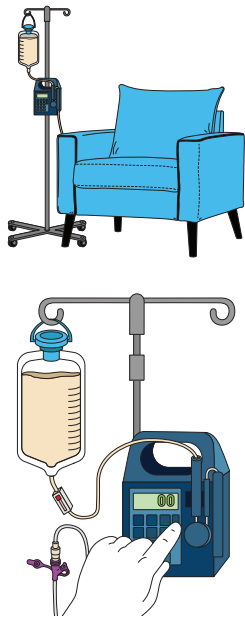
5. Once the feeding bag tubing/feed set is primed, connect the AMT feed set to the Glow Green™ feeding port on the MiniONE®. Refer to the section “Attaching a Feed Set to the MiniONE® Balloon Button” for detailed instructions.

6. Begin feeding:

Pump Feeding

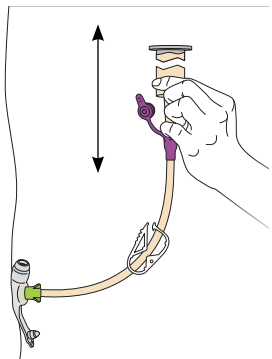
Be sure the feeding bag is mounted in a safe location (such as on an IV pole). Follow the manufacturer's directions to set the pump rate, unclamp the feed/feeding set, and then begin feeding. Be sure to place your feeding pump in a location that is easy for you to access and allows for proper delivery of the enteral nutrition. Food/nutrition should be administered as prescribed by your healthcare team.

- There are several different ways in which food can be delivered using an enteral feeding pump. Two common methods are continuous feeding (consistent delivery of nutrition over a 24-hour period) and intermittent feeding (nutrition is delivered every 4-6 hours).
- You can adjust the settings on your enteral feeding pump to accommodate the feeding schedule your healthcare team has prescribed.

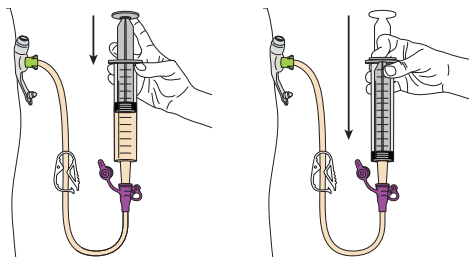


Syringe Bolus

• **Gravity Method:** With the plunger still removed from the syringe, attach the syringe to the feed set. Then, slowly pour the prescribed amount of formula into the syringe. Unclamp the feed set and allow the formula to slowly flow into the stomach. Keep the syringe filled with formula to prevent air from entering the stomach, which could cause discomfort. To adjust the flow rate, raise or lower the syringe in relation to the stomach.

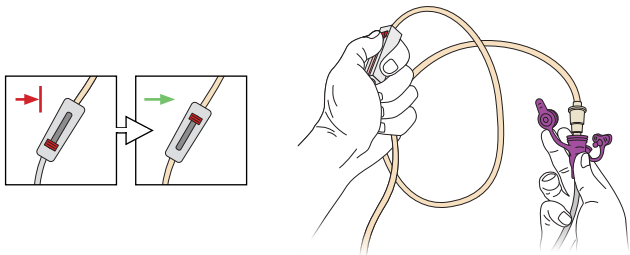


• **Push Method:** Fill a large syringe with formula by pulling back on the plunger to draw the formula into the syringe. Attach the syringe to the primed feed set. Unclamp the feed set and slowly push the formula into the stomach until you empty the syringe. Clamp the feed set and disconnect the syringe. Repeat these steps until you give the prescribed amount of formula for one feeding.

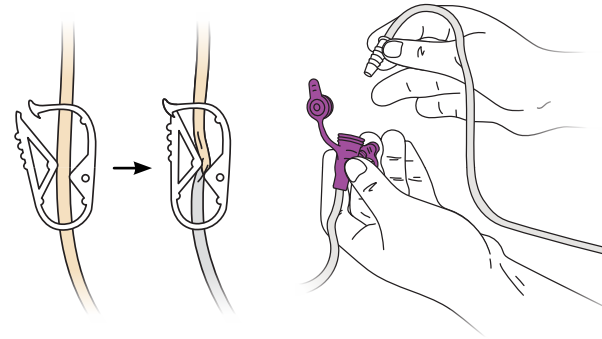


Gravity Drip Bag

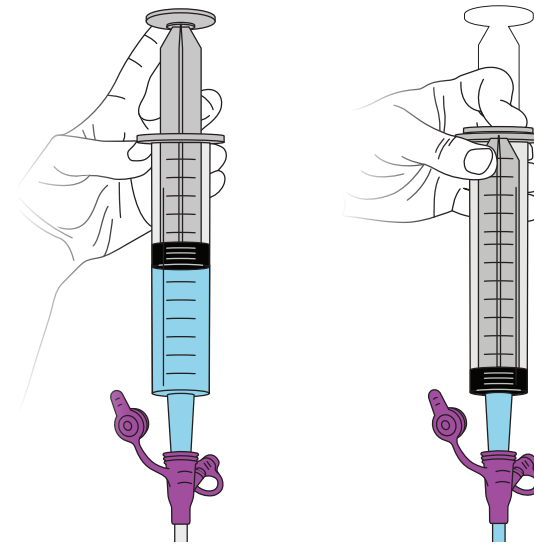
Unclamp the feed set and allow the formula to slowly flow into the stomach. You can control the feeding rate by adjusting the roller clamp. Open the roller clamp to increase the rate of feeding; close the roller clamp to decrease/slow the rate of feeding.



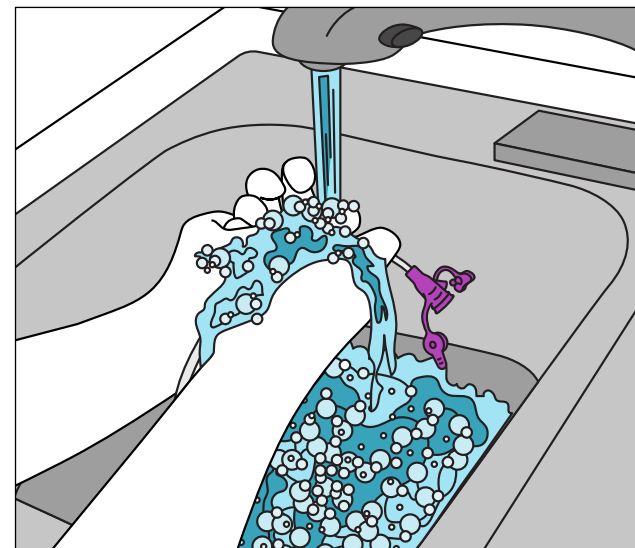
7. When feeding is complete, clamp off all extension tubing. Disconnect the feed set from the feeding bag tubing. Do not disconnect the feed set from your MiniONE®.



8. With the feed set still attached to the MiniONE®, use a syringe to flush water through the feed set and the device (3-10 ml for children, 10-50 ml for adults, or amount recommended by your healthcare provider). Close the clamp on the feed set (to prevent leaking) and disconnect the feed set from the MiniONE®. Refer to the section “Attaching a Feed Set to the MiniONE® Balloon Button” for detailed instructions.



9. Wash the feed set with soap and water; be sure to rinse it well. Hang the feed set so that both ends are down; for example, over the side of a dish rack. Once the feed set is completely dry, it can be stored in a clean, air-tight container. Never use a dishwasher to clean the feed set.



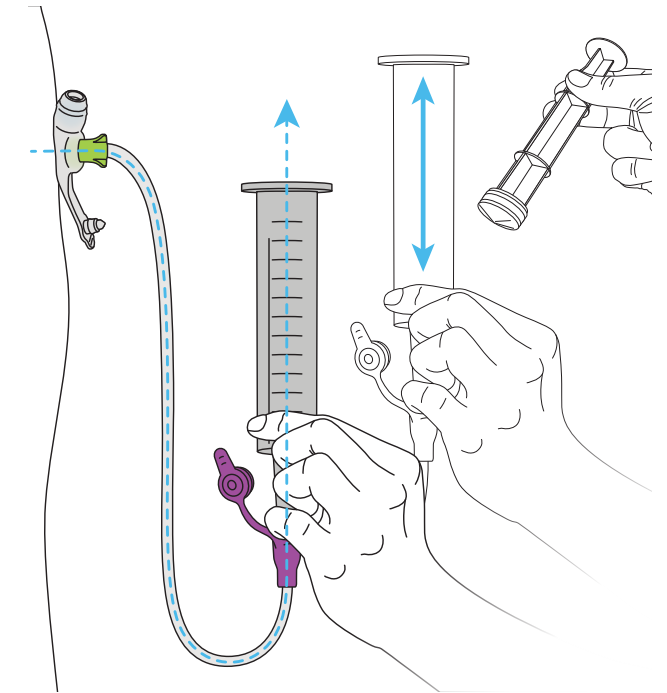
Decompressing/Venting With The MiniONE® Balloon Button

Your healthcare provider may recommend decompressing or “venting” the stomach (letting the air or liquid out) before or after feeding to help reduce pressure inside the stomach.

Refer to the MiniONE® Balloon Button Directions for Use for full instructions.

1. Close the pinch clamp on the feed set and attach the feed set to the MiniONE® Button. Be sure to line up the black line on the feed set with the black line on the feeding port. Refer to the section “Attaching a Feed Set to the MiniONE® Balloon Button” for detailed instructions.
2. There are several ways to vent/decompress the stomach. The end of the feed set may be left open for gravity drainage or attached to a syringe. Once the feed set is locked into place and any necessary equipment is properly attached, unclamp the pinch clamp to allow venting.
 - When using a syringe to vent the stomach, raise the syringe approximately 6 inches (15 cm) above the stomach so gas and stomach contents can pass freely up and down the tube.
 - Venting/decompression should be performed as directed by a healthcare provider.
3. After venting is complete, use a syringe to flush water through the feed set and the device. Disconnect the feed set from the MiniONE®.

You should discuss decompression and venting procedures with a healthcare professional.



Giving Medicine Into The MiniONE® Balloon Button

Always check and see if you have received the correct form of medication. Medications can be given through the MiniONE® Balloon Button in liquid form. If a prescribed medication is only available as a tablet or capsule, check with a pharmacist or doctor to see if it is safe to crush the medicine. If safe, medication should be crushed as fine as possible (into powder form) and dissolved in water before administering through the device.

Warning: NEVER crush enteric coated medications and NEVER mix medications with feeding formula, unless directed by your physician.

Medications should be given through the med-port of your y-port extension set (if you are unsure which port is the med-port, please note that the med-port is smaller than the feed port and labeled as “MED”). Flush with water after giving medications (3-10 ml for children, 10-50 ml for adults, or with an amount recommended by your healthcare provider).

To more easily administer medications, AMT offers a 2” bolus medication set with straight connector (order# 8-0211) as well as a 2” y-port medication set with straight connector (order# 8-0212).

Medicine may also be administered directly into the MiniONE® Glow Green™ feeding port (interlock) using the slip tip syringe that comes in the G-Tube kit.

- Mix the medicine with a little water and draw back the mixture into the slip tip syringe (only do this if your doctor/pharmacist has told you it is safe to mix the medicine with water).
- Put the syringe directly into the MiniONE® Glow Green™ feeding port (interlock).
- When you are done giving the medication, flush the port with water (3-10 ml for children, 10-50 ml for adults, or amount recommended by your healthcare provider).

MiniONE® Balloon Button Maintenance:

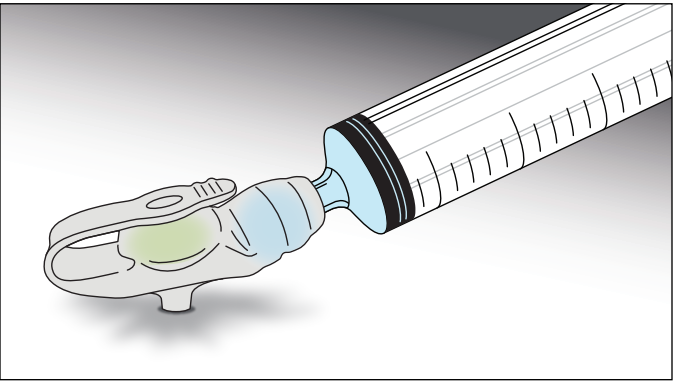
Routine maintenance includes tasks such as checking the balloon volume, stoma site care, device replacement, and more!

Checking the Balloon Volume

Check the balloon fill volume as recommended by your physician.

Remove all water from the balloon by inserting a small syringe into the balloon fill port and drawing back on the plunger (5 ml syringe for 12F-14F devices, 10 ml syringe for 16F-24F devices). The balloon fill port on 12-14F MiniONE® Balloon Buttons is compatible with both Luer (slip tip) and Luer lock syringes; the balloon fill port on 16-24F devices is compatible with a slip tip syringe.

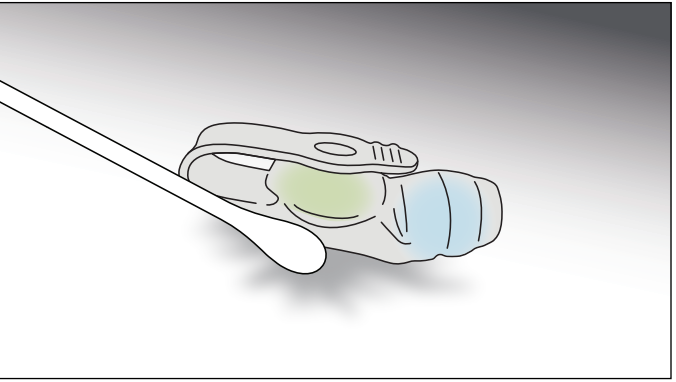
- If the water volume is at the prescribed amount: push the plunger to return the water into the balloon; disconnect the syringe.
- If the water volume is less than the prescribed amount or if the water appears dirty: discard the water that was removed from the device. Draw the prescribed amount of water into the syringe from a container of fresh water. Reconnect the syringe to the balloon fill port and push the plunger to refill the balloon with water.



MiniONE® Balloon Button Fill Volume Table			
Fr.	Min.	Rec.	Max
12F	2 ml	2.5 ml	3 ml
14F	3 ml	4 ml	5 ml
16F	4 ml	6 ml	8 ml
18F	6 ml	8 ml	10 ml
20F	7 ml	10 ml	15 ml
24F	7 ml	10 ml	15 ml

Stoma Site, General Care

Cleaning: The stoma site should be kept clean and dry at all times. It is important to clean the stoma site every day. A cotton swab or terry cloth can be used to clean the skin around the G-Tube with mild soap and water. Clean the stoma as directed by a healthcare provider.



- After Cleaning: allow the stoma site to air dry.
- Always check the stoma site for redness, pain/soreness, swelling, or any drainage. If these symptoms are observed, contact a healthcare provider.
- It is not necessary to use gauze or pads at the stoma site. If there is leaking, the G-Tube may be too loose or too tight.

Circulation: Once the stoma site is fully healed, turn/rotate the MiniONE® every day, stopping at a different position each time. Rotating the external bolster of the MiniONE® promotes a healthy stoma by allowing air to get to the skin.

Bath Time: Patients fitted with a G-Tube are allowed to bathe and swim. Be sure to close the safety plug before submerging the device in water. Bath time is a good opportunity for regular cleaning of the G-Tube and stoma site.

WHEN TO CALL A HEALTHCARE PROFESSIONAL

Call your physician if any of the following are observed:

- Fever, vomiting, or diarrhea
- Skin around the stoma site is red, discolored, or raw
- Drainage around the stoma site is white, yellow, or green
- Drainage around the stoma site is discolored and has an unpleasant odor
- Crusting at the stoma site
- Large amount of tissue build up, such as granulation tissue
- Swollen skin or tissue at the stoma site
- Repetitive leakage of food, or gastric contents
- Leakage, the device may be too loose or too tight (stoma length may need to be re-measured)
- Possible tube migration:
 - Low profile device: External bolster is no longer flush against the skin. Look for either a distinct indentation at the stoma site or a distinct gap between the device and skin.
- The G-tube falls out and you are unable to replace it easily
- Pain at the stoma site
- Bleeding, pus, or inflammation at the stoma site
- Distended stomach, a possible indication of gastric or intestinal blockage

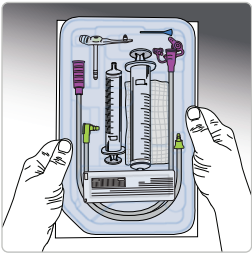
Replacing The MiniONE® Balloon Button

The MiniONE® Balloon Button should be changed at least every 3 months, or as often as suggested by your healthcare provider. Proactively changing the tube every 3 months will help prevent unexpected problems. Each tube will last a different amount of time depending on the patient. The typical longevity of a MiniONE® Button is about 1-9 months.

Refer to the MiniONE® Balloon Button Directions for Use for full instructions.

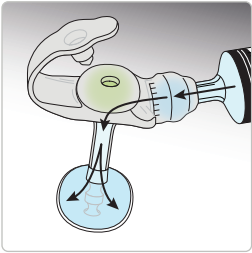
Place The New Device:

CAUTION: BEFORE CHANGING THE G-TUBE, PLEASE CHECK EVERYTHING IN THE KIT. IF THE PACKAGE LOOKS LIKE IT IS BROKEN OR OPEN, DO NOT USE THE G-TUBE.



Be sure you have the correct MiniONE® Button size. Verify that the French size and stoma length of the replacement device match what is prescribed by your physician.

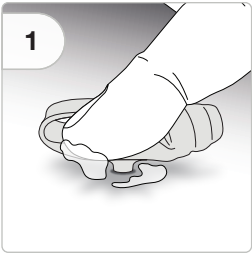
NOTE: It is important to have the stoma site re-measured on a regular basis. For optimal device performance, the stoma site should be measured every 6-12 months or after any significant change to weight/height that impacts how the device fits.



Prior to placing the new MiniONE® Button, inflate the balloon to the recommended fill volume using distilled or sterile water. (See MiniONE® Balloon Button Fill Volume Table on page 16).

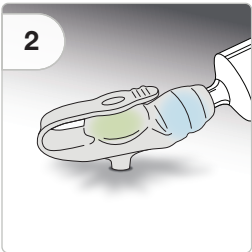
Verify that there are no signs of leakage from the balloon and that the balloon is symmetrical in shape. A balloon can be gently massaged with fingers into a symmetrical shape if it is not excessively misshaped. Deflate the balloon once inspection is complete.

REMOVE THE EXISTING DEVICE:



Lubricate the stoma tract with a water soluble lubricant. To distribute the lubricant, rotate the existing button and move the button up and down.

DO NOT USE OILS OR PETROLEUM JELLY AS A LUBRICANT.

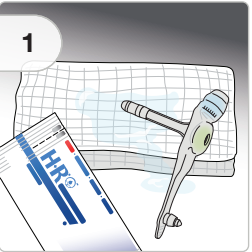


Deflate the retention balloon by inserting a syringe into the balloon fill port and withdrawing the water. The balloon fill port on 12-14F MiniONE® Balloon Buttons is compatible with both Luer (slip tip) and Luer lock syringes; the balloon fill port on 16-24F devices is compatible with a slip tip syringe.



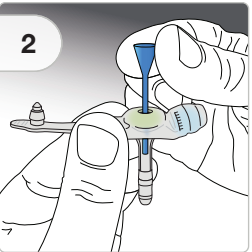
Pull up and gently remove the device from the stoma site with slow, steady pressure.

Place The New Device:

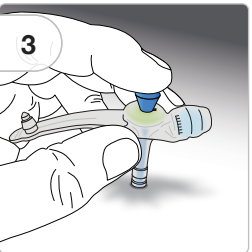


Apply a water soluble lubricant to the tip of the MiniONE® device (a packet of lubricant is included in the MiniONE® device kit).

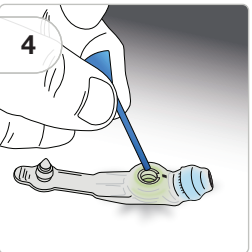
DO NOT USE MINERAL OIL OR ANY CREAMS WITH PETROLEUM JELLY.



NOTE: The blue stiffener is included with 12F-18F MiniONE® Balloon Button. The blue stiffener is NOT included with 20F-24F MiniONE® Balloon Button.



Gently press the tip of the MiniONE® through the stoma and into the stomach until the outside of the tube is flat against the skin.



Remove the blue stiffener (if used in step 2-3).



Fill a syringe with the correct volume of water. The balloon fill port on 12-14F MiniONE® Balloon Buttons is compatible with both Luer (slip tip) and Luer lock syringes; the balloon fill port on 16-24F devices is compatible with a slip tip syringe. Insert the syringe into the balloon fill port of the MiniONE® and inflate the balloon to the recommended fill volume listed in the MiniONE® Balloon Button Fill Volume Table. The recommended fill volume is printed on the balloon fill port of the MiniONE®.



Gently pull on the G-Tube and check for signs of gastric leaking.



MiniONE® Balloon Button Problem Solving / FAQs

There is leaking around the MiniONE® Balloon Button; what should I do?

There are many reasons why the MiniONE® might leak. Some of the most common reasons include:

Low Water Level in the Balloon.

Make sure the balloon is filled with the right amount of water (resistance should be felt when gently pulling on the tube). The recommended amount of water for the balloon is printed on top of the balloon fill port.

- NOTE:** The balloon is made of a semi-permeable material and may lose a small amount of fill volume over time depending on environment and usage conditions. It is important to periodically check the balloon volume of your MiniONE® Balloon Button (as recommended by your healthcare team).

Incorrectly Sized Device.

If the MiniONE® feels too tight or too loose, make sure that the French size and stoma length match what is prescribed by your healthcare provider. If the wrong device is in place, contact your provider.

- For helpful recommendations on adjusting the fit of the MiniONE® Balloon Button, refer to the section “The MiniONE® Button Balloon Button feels loose/tight against the skin; what should I do?”
- It is important to have the stoma site re-measured on a regular basis. For optimal device performance, the stoma site should be measured every 6-12 months or after any significant change to weight/height that impacts how the device fits.

Newly Placed G-Tube.

For new placements, it may take time for the stoma tract to naturally heal and firm up around the tube and the balloon. If leakage continues, contact your healthcare provider.

Stomach Residuals and/or Gas.

Your healthcare provider may recommend decompressing or venting the stomach (letting the liquid or air out) before or after feeding to help reduce pressure inside the stomach. Too much pressure in the stomach can lead to bloating and discomfort.

I think the balloon broke; what should I do?

A balloon may leak or lose water over time due to medicines, stomach acid, G-Tube care, or natural wear. If you think the balloon on the MiniONE® is broken, fully deflate the balloon and remove the MiniONE® from the stoma. Once removed, inflate the balloon with water to the recommended fill volume that is printed on the balloon fill port. Check the balloon for leakage by gently massaging the tubing and the balloon.

- If no leakage is observed: Deflate the balloon, re-insert the MiniONE® into the stoma, and inflate the balloon with the desired volume of water.
- If leakage is observed: Insert a spare G-Tube or stoma plug into the stoma. Please contact our Customer Service Team by calling us at 800-869-7382.

ALWAYS have a stoma plug or a spare G-Tube available in case the balloon on the MiniONE® breaks. The back-up device should match the French size and stoma length of the current MiniONE® device. By inserting a spare stoma plug/G-Tube into the stoma, you will help to keep the stoma tract from closing. Follow the Directions for Use, and the training provided by your healthcare team, to properly place the G-Tube in the stoma.

- Do not insert a device that is too long or too short into the stoma site.

The balloon will not deflate; what should I do?

Clean the balloon port with a cotton swab to remove any substances (e.g., ointment, lotion, formula, medication, etc.) that may be blocking the balloon fill port. Insert a slip tip syringe into the balloon fill port, push and twist one-quarter turn. If the balloon still will not deflate, please contact our Customer Service Team by calling 800-869-7382. If the problem continues, call your healthcare provider.

The MiniONE® Balloon Button feels loose /tight against the skin; what should I do?

If the MiniONE® feels too loose or too tight, one option is to adjust the volume of water in the balloon (always consult a healthcare professional before adjusting the volume of water in the balloon). The MiniONE®Balloon Button Fill Volume Table shows the minimum, recommended, and maximum volume of water for each French size of the MiniONE®.

Be sure to check the current balloon volume before making any adjustments. To do this, insert an empty syringe into the MiniONE® balloon fill port and pull back on the plunger. The balloon fill port on 12-14F MiniONE® Balloon Buttons is compatible with both Luer (slip tip) and Luer Lock syringes; the balloon fill port on 16-24F devices is compatible with a slip tip syringe. Be sure to keep one hand on the device so it stays in place. Use the volume indicators on the syringe to determine how much water you just removed from the balloon. Compare the amount of water you removed from the MiniONE® to the MiniONE® Balloon Button Fill Volume Table. If the MiniONE® fit is too loose, increase the amount of water in the balloon, but stay within the recommended range. One option is to add an additional 0.5 ml of water to the balloon and see if that improves the fit. For example,

you can fill the balloon with 3.0 ml of water instead of 2.5 ml of water. If the MiniONE® fit is too tight, decrease the amount of water in the balloon, but stay within the recommended range. One option is to reduce the water volume by 0.5 ml and see if that helps. For example, you could fill the balloon with 2.0 ml of water instead of 2.5 ml.

If the MiniONE® does not properly fit, even though you increased or decreased the volume of water in the balloon, the stoma may need to be re-measured for a longer or shorter MiniONE® G-Tube.

- The MiniONE® should be able to turn easily without rubbing the surrounding skin. If the MiniONE® does not turn easily or if the MiniONE® cannot move side-to-side without excessive force, call your healthcare provider. The stoma may need to be re-measured for a longer MiniONE®.
- It is important to have the stoma site re-measured on a regular basis. For optimal device performance, the stoma site should be measured every 6-12 months or after any significant change to weight/height that impacts how the device fits.

The MiniONE® Balloon Button dislodged (came out); what should I do?

Although the MiniONE® is designed to reduce the risk of a pull out, the device may accidentally be dislodged (pulled out) from the stoma.

If the MiniONE® has become dislodged, visually inspect the device for any damage. One potential cause for accidental dislodgement is reduced balloon volume. A balloon may leak or lose water over time due to medicines, stomach acid, G-Tube care, or natural wear. To inspect the balloon for leakage, inflate the balloon with water to the recommended fill volume that is printed on the balloon fill port. Gently massage the tubing and the balloon and look for signs of leakage.

- NOTE:** The balloon is made of a semi-permeable material and can lose a small amount of fill volume over time depending on environment and usage conditions. It is important to periodically check the balloon volume of your MiniONE® Balloon Button (as recommended by your healthcare team).
 - If no leakage is observed: Deflate the balloon, re-insert the MiniONE® into the stoma, and inflate the balloon to the desired volume. If you are not able to re-insert the MiniONE®, call your healthcare provider (the stoma may begin to close within the first hour that the G-Tube is out).
 - If leakage is observed: Insert a spare G-Tube or stoma plug into the stoma. Please contact our Customer Service Team by calling us at 800-869-7382.

ALWAYS have a stoma plug or a spare G-Tube available in case the balloon on the MiniONE® breaks. The back-up device should match the French size and stoma length of the current MiniONE® device. By inserting a spare stoma plug/G-Tube into the stoma, you will help to keep the stoma tract from closing. Follow the Directions for Use, and the training provided by your healthcare team, to properly place the G-Tube in the stoma.

- Do not insert a device that is too long or too short into the stoma site.

MiniONE® Balloon Button Fill Volume Table			
Fr.	Min.	Rec.	Max
12F	2 ml	2.5 ml	3 ml
14F	3 ml	4 ml	5 ml
16F	4 ml	6 ml	8 ml
18F	6 ml	8 ml	10 ml
20F	7 ml	10 ml	15 ml
24F	7 ml	10 ml	15 ml

MiniONE® Balloon Button Problem Solving / FAQs

I think the MiniONE® Balloon Button has a clog; what should I do?

- 1. Make sure that the feeding tube is not kinked or clamped off.
- 2. Fill a catheter tip syringe with warm water (always use a 30 ml – 60 ml syringe). Insert the tip of the syringe into the purple adapter of the feed set. Gently push warm water through the feed set until all of the air is removed from the tubing. Close the pinch clamp on the feed set and then attach the connector to the MiniONE® device.

CAUTION: Do not use a syringe less than 30 ml to administer a flush. Smaller syringes (such as 10 ml) can generate high pressure and may negatively impact the device.

- 3. Release the pinch clamp and gently push and pull on the syringe plunger to free the clog. It may take several cycles of pushing/pulling the plunger to clear the clog.
- 4. If you are unable to remove the clog, repeat steps #1-3 with a new solution of warm water. Pushing and pulling on the syringe plunger will likely break up the clog.
- 5. If the clog cannot be removed, contact your healthcare professional; the MiniONE® may need to be replaced.

DO NOT use cranberry juice, cola drinks, meat tenderizer or any other medicines as they can actually cause clogs or make things worse in some patients.

DO NOT place any objects except the feed set or the blue stiffener into the feeding port of the MiniONE® Balloon Button. Inserting foreign objects into the feeding port could damage the MiniONE® Balloon Button and negatively impact device performance.

How can I prevent blockages/clogs in the MiniONE® Balloon Button?

Clogs are most commonly formed when formula remains within the device after feeding (not following recommended flushing procedures) and when medicines are not properly dissolved before being delivered through the tube. Always be sure to follow recommendations for proper flushing. You can help prevent clogs by following these recommended flushing procedures:

- 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.
- Always flush the feeding tube before and after giving food and medication (3-10 ml for children, 10-50 ml for adults, or an amount recommended by your healthcare provider).

CAUTION: Do not use a syringe less than 30 ml to administer a flush. Smaller syringes (such as 10 ml) can generate high pressure and may negatively impact the device.

Another way to help prevent clogs is to avoid delivering medicine and formula at the same time. Do NOT mix medicines with formula while feeding. Always give medicines one at a time and clean the feed set immediately after use with proper flushing.

Try to obtain your medicine as a liquid, instead of as a tablet or capsule, when possible. If a prescribed medication is only available as a tablet or capsule, check with a pharmacist or doctor to see if it is safe to crush the medicine. If safe, medication should be crushed as fine as possible (into powder form) and dissolved into water before administering through the device.

Do NOT place any objects except the feed set or the blue stiffener into the feeding port of the MiniONE® Balloon Button. Inserting foreign objects into the feeding port could damage the MiniONE® Balloon Button and negatively impact device performance.

What type of dental care and oral hygiene should I do if I'm not eating by mouth?

General recommendations for oral care include:

- Gently brush the teeth and gums with a soft toothbrush at least twice per day.
- If possible, rinse with a mouthwash or warm salt water to help maintain fresh breath and to help prevent dry mouth. Rinsing with warm salt water may also help a sore throat.
- If taking in liquids by mouth is allowed, sucking on ice chips can also help prevent dry mouth.
- Use a lip balm regularly to help prevent dry or cracked lips.

Good dental care and oral hygiene are important to maintaining healthy teeth, gums and tongue. Consult with your healthcare team for specific recommendations on oral care.

Will I be able to eat by mouth?

Your healthcare provider will talk with you about the possibility of both receiving nutrition through your feeding tube and also eating by mouth. The decision to eat by mouth will depend on several factors including your medical condition and ability to swallow.

MiniONE® Balloon Button + Feed Set Ordering Information

A prescription is required to purchase any AMT device directly.

Placing An Order:

Healthcare Professionals can order with established NET 30 terms or prepayment/credit card.

Patients can order directly, via prepayment/credit card, with a prescription. However, please note that AMT does not process medical billing claims.

- US Direct Customers: We will need a copy of your US prescription.
- Canadian Direct Customers: We will need a copy of your Canadian prescription.
- All Other International Direct Customers: We will need a copy of your prescription from a US doctor and can only ship to countries we are registered in. Contact your local rep or AMT's Internal Customer Service team to learn about how you can set up an account and order AMT products.

Customer Service:

- PHONE | 800-869-7382
- FAX | 440-717-4200
- EMAIL | CS@AppliedMedical.net
- INTERNATIONAL | ICS@AppliedMedical.net

Success Stories





MiniONE® Balloon Button + Feed Set Ordering Information

Length cm	12F		14F		16F		18F		20F		24F	
	Legacy	ENFit®	Legacy	ENFit®	Legacy	ENFit®	Legacy	ENFit®	Legacy	ENFit®	Legacy	ENFit®
0.8	M1-5-1208	M1-5-1208-I	M1-5-1408	M1-5-1408-I								
1.0	M1-5-1210	M1-5-1210-I	M1-5-1410	M1-5-1410-I	M1-5-1610	M1-5-1610-I	M1-5-1810	M1-5-1810-I	M1-5-2010	M1-5-2010-I		
1.2	M1-5-1212	M1-5-1212-I	M1-5-1412	M1-5-1412-I	M1-5-1612	M1-5-1612-I	M1-5-1812	M1-5-1812-I	M1-5-2012	M1-5-2012-I		
1.5	M1-5-1215	M1-5-1215-I	M1-5-1415	M1-5-1415-I	M1-5-1615	M1-5-1615-I	M1-5-1815	M1-5-1815-I	M1-5-2015	M1-5-2015-I	M1-5-2415	M1-5-2415-I
1.7	M1-5-1217	M1-5-1217-I	M1-5-1417	M1-5-1417-I	M1-5-1617	M1-5-1617-I	M1-5-1817	M1-5-1817-I	M1-5-2017	M1-5-2017-I	M1-5-2417	M1-5-2417-I
2.0	M1-5-1220	M1-5-1220-I	M1-5-1420	M1-5-1420-I	M1-5-1620	M1-5-1620-I	M1-5-1820	M1-5-1820-I	M1-5-2020	M1-5-2020-I	M1-5-2420	M1-5-2420-I
2.3	M1-5-1223	M1-5-1223-I	M1-5-1423	M1-5-1423-I	M1-5-1623	M1-5-1623-I	M1-5-1823	M1-5-1823-I	M1-5-2023	M1-5-2023-I	M1-5-2423	M1-5-2423-I
2.5	M1-5-1225	M1-5-1225-I	M1-5-1425	M1-5-1425-I	M1-5-1625	M1-5-1625-I	M1-5-1825	M1-5-1825-I	M1-5-2025	M1-5-2025-I	M1-5-2425	M1-5-2425-I
2.7	M1-5-1227	M1-5-1227-I	M1-5-1427	M1-5-1427-I	M1-5-1627	M1-5-1627-I	M1-5-1827	M1-5-1827-I	M1-5-2027	M1-5-2027-I	M1-5-2427	M1-5-2427-I
3.0	M1-5-1230	M1-5-1230-I	M1-5-1430	M1-5-1430-I	M1-5-1630	M1-5-1630-I	M1-5-1830	M1-5-1830-I	M1-5-2030	M1-5-2030-I	M1-5-2430	M1-5-2430-I
3.5	M1-5-1235	M1-5-1235-I	M1-5-1435	M1-5-1435-I	M1-5-1635	M1-5-1635-I	M1-5-1835	M1-5-1835-I	M1-5-2035	M1-5-2035-I	M1-5-2435	M1-5-2435-I
4.0	M1-5-1240	M1-5-1240-I	M1-5-1440	M1-5-1440-I	M1-5-1640	M1-5-1640-I	M1-5-1840	M1-5-1840-I	M1-5-2040	M1-5-2040-I	M1-5-2440	M1-5-2440-I
4.4			M1-5-1444	M1-5-1444-I	M1-5-1644	M1-5-1644-I	M1-5-1844	M1-5-1844-I	M1-5-2044	M1-5-2044-I	M1-5-2444	M1-5-2444-I
5.0			M1-5-1450	M1-5-1450-I	M1-5-1650	M1-5-1650-I	M1-5-1850	M1-5-1850-I	M1-5-2050	M1-5-2050-I	M1-5-2450	M1-5-2450-I
5.5			M1-5-1455	M1-5-1455-I	M1-5-1655	M1-5-1655-I	M1-5-1855	M1-5-1855-I	M1-5-2055	M1-5-2055-I	M1-5-2455	M1-5-2455-I
6.0			M1-5-1460	M1-5-1460-I	M1-5-1660	M1-5-1660-I	M1-5-1860	M1-5-1860-I	M1-5-2060	M1-5-2060-I	M1-5-2460	M1-5-2460-I
6.5			M1-5-1465	M1-5-1465-I								
7.0			M1-5-1470	M1-5-1470-I								
8.0			M1-5-1480	M1-5-1480-I								
9.0			M1-5-1490	M1-5-1490-I								
10.0			M1-5-14100	M1-5-14100-I								

1x

Feed Sets Included In Kit



Feed Sets

	2"	12"	24"	2"	12"	24"
		8-1221	8-2421	8-0211	LEGACY KIT 8-1211	8-2411
	8-0222	8-1222	8-2422	8-0212	8-1212	
		8-1257G LEGACY KIT 8-1255	8-2455			
		8-1221-ISOSAF 8-1223-ISOSAF 8-1226-ISOSAF	8-2421-ISOSAF 8-2423-ISOSAF	8-0211-ISOSAF	ENFit® KIT 8-1211-ISOSAF	8-2411-ISOSAF
	8-0222-ISOSAF	8-1222-ISOSAF ENFit® KIT 8-1255-ISOSAF	8-2422-ISOSAF 8-2455-ISOSAF	8-0212-ISOSAF	8-1212-ISOSAF	

10x

Does not contain PVC : 8-1255-ISOSAF-NP | 8-2455-ISOSAF-NP | 8-1211-ISOSAF-NP

AMT Accessories

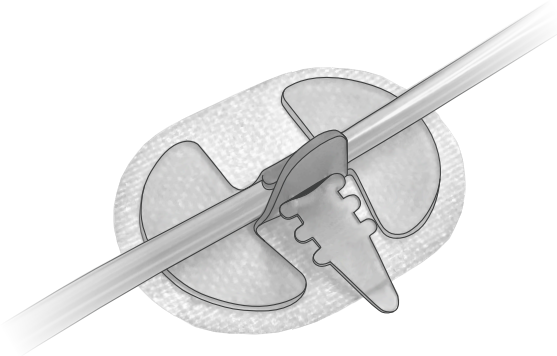
AMT CLAMP™



The AMT Clamp™ device can reduce disconnects between a “Christmas Tree”/stepped adapter and a feed set. Using the AMT Clamp™ ensures delivery of essential nutrients while avoiding the mess of lost formula.

Item# 4-3000 (Box 10)

AMT CINCH®



AMT CINCH® Tube Securement Device is designed to secure any type of medical tubing ranging in size from 4F to 30F.

Small CINCH®: 4F-10F
Item# CINCH410S-10 (Box 10)
Item# CINCH410S-50 (Box 50)

Medium CINCH®: 4F-17F
Item# CINCH417M-10 (Box 10)
Item# CINCH417M-50 (Box 50)

Large CINCH®: 9F-30F
Item# CINCH930L-10 (Box 10)
Item# CINCH930L-50 (Box 50)

AMT ONE SOURCE® APP



AMT ONE Source® provides parents, caregivers, and patients with quick and easy access to our educational materials! The app offers up-to-date product information and fun activities for the enteral nutrition and bowel management communities.

AMT ONE Source® can be found in the App Store or in the Google Play Store. Scan QR code to download.



App Store
DOWNLOAD



Google Play
DOWNLOAD

Glossary

Bolus Feeding (also referred to as intermittent feeding) A type of feeding where nutrition is delivered at a relatively fast rate over a relatively short time period, typically 30-60 minutes. This style of feeding is usually performed by attaching a large syringe (30-60 ml) to a Bolus Feed set.

Continuous Feeding A type of feeding where nutrition is delivered at a relatively slow rate over a relatively long time period, typically 24 hours per day. This style of feeding is usually administered with a feeding pump or a gravity drip bag.

Enteral Pertaining to or by means of the intestine.

Enteral Nutrition Nutrition delivered to the body through the gastrointestinal (GI) tract.

Esophagus A muscular tube that connects the throat (pharynx) with the stomach.

Feeding Pump A pump used for the administration of enteral nutrition. The pump can be programmed to administer formula at specific rate (ml per hour).

Feeding Tube A tube used to provide nutrition to patients who cannot obtain nutrition orally, are unable to swallow safely or need nutritional supplementation.

Flushing The process of pouring water through the tube to help prevent potential clogs.

French Size A measuring system used to define the diameter of a feeding tube. The larger the number, the bigger the diameter.

Gastric Decompression Removing the contents of the stomach, such as air/gas and liquid/residual, which have accumulated in excessive amounts. Gastric decompression can be performed with a gastrostomy tube.

Gastroesophageal Reflux Disease (GERD) A condition in which the stomach contents leak backwards from the stomach into the esophagus causing heartburn and other symptoms.

Gastroparesis Delayed gastric emptying due to nerve or muscle damage to the stomach.

Gastrostomy Tube (G-Tube) A tube (feeding device) that is inserted through the abdomen and delivers nutrition directly to the stomach.

Granulation Tissue Beefy red, friable, inflamed tissue surrounding the gastrostomy tube. Caused by leakage of gastric juices around the button.

Gravity Drip Method of enteral feeding that does not use a pump. Formula flows on its own using gravity from a bag or container.

Intermittent (Bolos) Feeding Formula delivered via a feeding container or bag over 30-45 minutes with or without an enteral feeding pump.

Low Profile Gastrostomy Tube (Button) The external portion of the G-Tube, often called the bolster, is very flat or flush against the skin.

Percutaneous Endoscopic Gastrostomy (PEG) A procedure in which a flexible feeding tube is placed through the abdominal wall and into the stomach.

Prime the Tubing Remove air from the feed set tubing prior to feeding; prevents air from being pumped into the stomach.

Stoma An artificial opening between one hollow organ (such as the stomach) and the outside of the body. A stoma is constructed to allow the passage of nutrition, fluids, or waste products. It can be permanent or temporary.

Traditional Length Gastrostomy Tube The external portion of the G-Tube is long and extends from the body. These tubes are sometimes called “*long tubes*”, “*adjustable length tubes*”, “*standard length tubes*”, and even “*danglers*”.

Notes

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Notes

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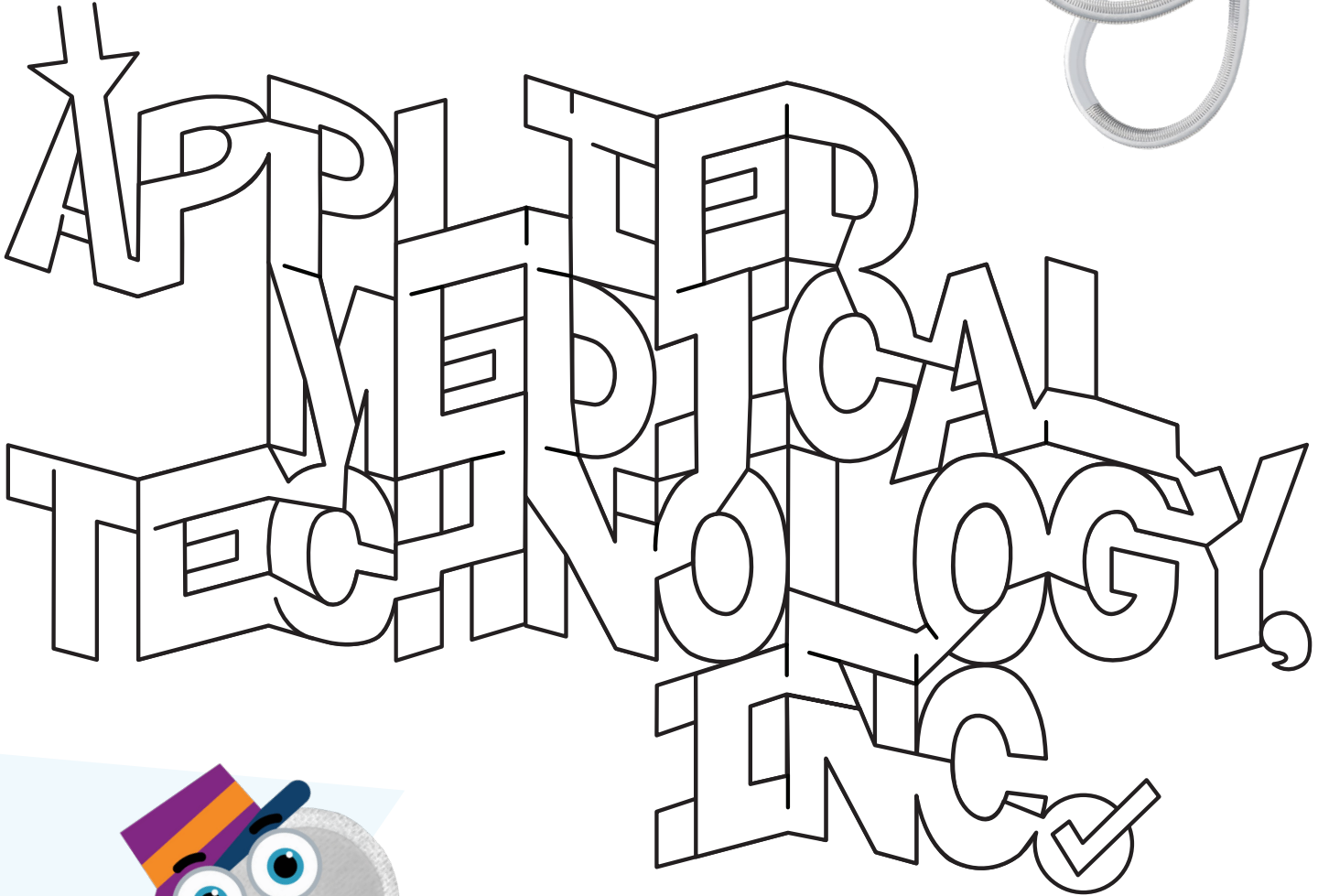


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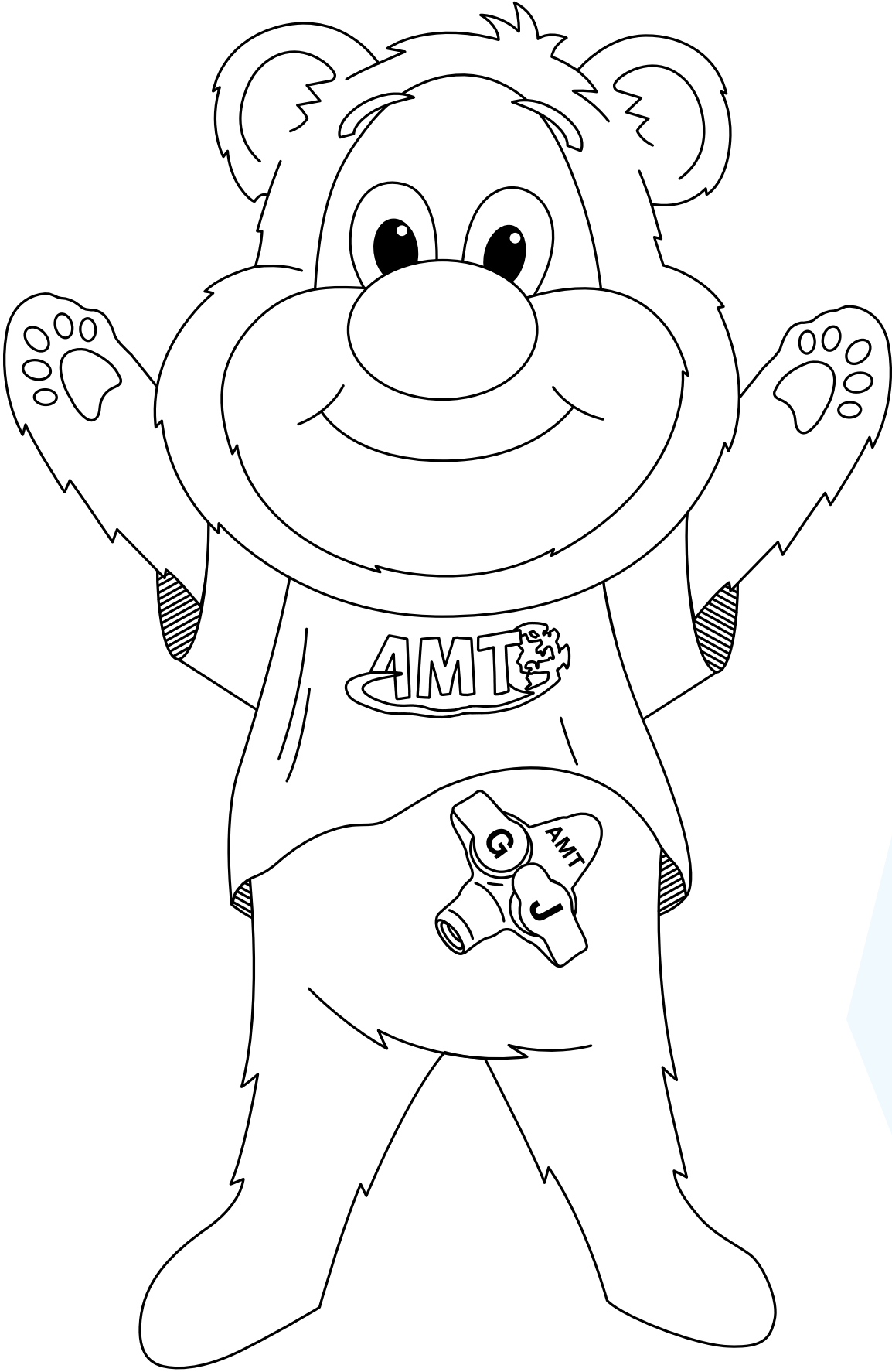
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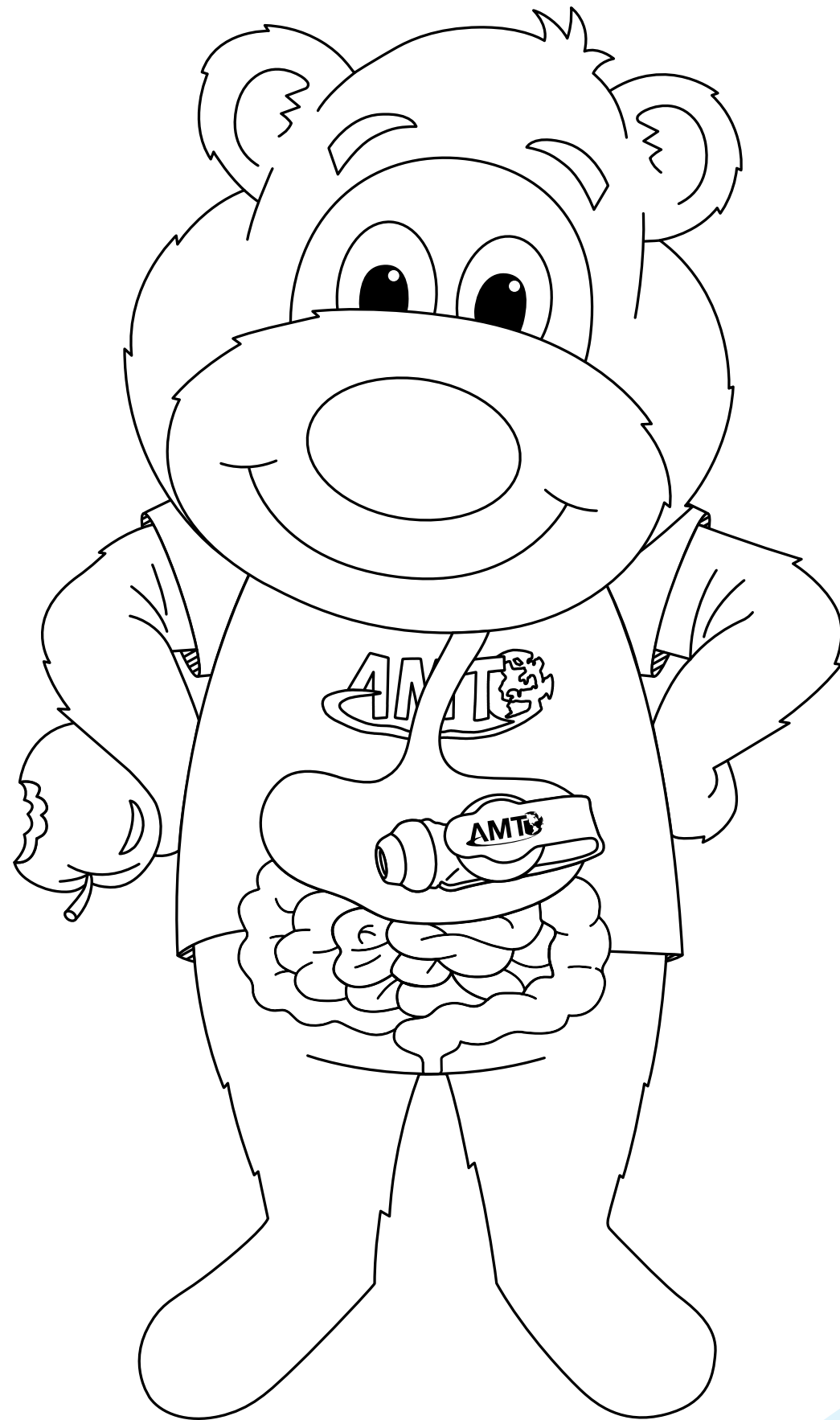




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