Patient Education Guide

Guidance and support to help you manage your gastrostomy tube (g-tube)

Balloon Mini ONE® Buttons

AMT
Applied Medical Technology, Inc.
The Leader in Enteral Device Innovation
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Introduction to Tube Feeding

Proper nutrition is essential to maintaining our bodies’ health, growth and ability to heal. Various medical conditions may make it difficult or impossible for a person to eat, and thus deny the body of essential nutrients. In such cases, a gastrostomy tube (g-tube) is inserted to provide direct access to the stomach for feeding. A g-tube is a convenient, comfortable and effective means for delivering nutritional formulas to the body. These nutritional formulas are either commercially available or homemade using a food processor. A physician will prescribe the proper feeding procedure, formula and amount of water to most effectively feed each patient.

Comfort and Confidence are Important, Too

As a caregiver or patient, we believe you have a right to the most comfortable and reliable gastrostomy tubes...that’s why we developed the Mini ONE® line of buttons. Reading and understanding this guide, along with using our products, will help provide the comfort and confidence you deserve.

George J. Picha, M.D., Ph.D., F.A.C.S.
Founder of AMT and Co-inventor of the first Button low profile feeding device.
AMT specializes in enteral devices, our core business.
How the **Balloon Mini ONE® Button** is Different

**Reduces Leaks**

**Unique “Apple” Shape**

The Balloon Mini ONE® Button is shaped like an apple to cover more surface area to create a better seal, and to minimize leaks at the gastrostomy site.

**Customizable Balloons**

Balloon fill volume can be easily adjusted for a custom-fit, reducing leaks and improving patient comfort. Our durable silicone material allows for different fill volumes and a better fit.

People don’t come in one size and neither should their balloons! Your physician can recommend the best fill volume for you. See page 11 for minimum, recommended and maximum fill volumes.
Longer Balloon Life

- Balloon is made from the highest grade medical silicone
- Stronger and more durable than other balloon buttons
- More compliant and better able to withstand stomach contractions

Reduces Skin Irritation and Discomfort

- No hard, bulky external bolster means more patient comfort
- Low profile and easier to hide under clothing and provides more comfort
- Flexible bolster is easy to clean around and less likely to irritate the skin
The Balloon Mini ONE® is a silicone device that is inserted into a gastrostomy to provide direct access to the stomach for feeding, decompression and medication. To ensure proper use, always follow the instructions provided with the device and prescribed by the physician.

**Components of the Balloon Mini ONE® Button**

- **Balloon Valve**: The balloon is inflated and deflated by inserting a slip tip syringe into the balloon valve. **Do NOT attempt to feed through the balloon valve.** The recess in the valve can trap foreign material, such as lint or spilled formula. The balloon valve must be kept clean to function properly.

- **External Bolster**: The external bolster maintains tube position. A properly fitted device should not fit tightly against the skin. Instead, a 1/8 inch (3mm) gap between the external base and the skin surface is recommended to provide room for air circulation and cleaning of the stoma site. The recommended amount of water to place into the balloon is printed on top of the fill valve.

- **Feeding Port**: Used for administering food and medication, and for decompression. The feeding port should remain sealed by the safety plug when the device is not being used.

- **Anti-Reflux Valve/One Way Valve**: A valve is located in the bottom of the feeding port to prevent stomach contents from leaking out of the tube. The valve is opened when the feeding set adapter is in place.

- **Internal Retention Balloon**: A balloon is inflated inside the stomach to hold the tube in place. Once the tube is inserted, the balloon is filled with the prescribed amount of water. It is recommended to check the balloon volume as directed by your physician. See page 11 for complete instructions on how to check fill volume.

- **Safety Plug**: The safety plug should be closed when not in use.

- **Lot Number**: The lot number is etched (laser engraved) on side of device.
The Bolus Feeding Set is intended for bolus feeding, administering medication, or flushing the Balloon Mini ONE® Button with water.

The Continuous Feeding Set is used for continuous/pump feeding.

The Catheter Tip Syringe fits into the bolus port of the Bolus Feeding Set and the feeding port of the Right Angle Feeding Set. It is intended for bolus feeding or flushing the Balloon Mini ONE® with water.

Feeding sets can be ordered in a variety of lengths and combinations to suit the needs of the patient.
Attaching Feed Sets to the Balloon Mini ONE® Button

For full instructions and video go to: www.appliedmedical.net

Always be sure to wash hands thoroughly before handling feeding devices.

To attach a feed set to the Balloon Mini ONE® Button:

- Holding the button as shown on page 7, line up the black mark on the Feeding Set Adapter with the black mark on the Balloon Mini ONE® Button.
- Make sure the feeding set adapter is pushed in completely and gently turn the adapter no more than 3/4 turn clockwise to lock the adapter in place. When fully locked, the adapter will stop.
- Do NOT attempt to rotate the adapter past 3/4 turn.
  If the adapter does not rotate freely when first inserted into the feeding port, make sure the adapter is pushed in all the way and that there is nothing blocking the feeding port.

For information on feeding set maintenance, see page 11.

Mic-Key® Feed Set Compatible
All Mini ONE® products accept either Mini ONE® or Mic-Key® feed sets. See complete list of AMT feeding extension sets on page 24.
Here’s the Best Way to Attach a Feed Set

When attaching the feed set, it is important to stabilize the button to avoid pushing it into the patient’s belly. Hold the button firmly between the balloon fill valve and feed port.

- Line up the black lines. Rotate no more than 3/4 of a turn.
- Holding the device only by the balloon fill valve or only by the feed port will not allow proper stabilization of the button.

• Line up black marks
• Insert feed set into button

Starting Position

Locked Position

• Turn clockwise up to 3/4 turn
• Process is same for continuous and bolus feeding set

Note: Remove the feeding set and close the safety plug when not feeding.
**Verify Proper Balloon Mini ONE® Button Placement & Functionality**

Before feeding through the Balloon Mini ONE® Button, it is important to verify proper placement inside the stomach as well as the functionality of the device.

1. Connect the extension set that will be used for feeding.
2. Draw 5 ml of water into syringe and attach it to the extension set.
3. Pull back on the plunger until stomach fluid (normally yellow or clear unless there is food in the stomach) is observed in the tube.
4. Flush the stomach contents from the device with the water in the syringe.

*Contact physician if trouble persists.*
For all feeding methods it is recommended that the patient be fed with head up above heart and kept head up for at least 30 minutes after feeding.

**Continuous Feeding**
1. Prime the tubing: Attach the feeding bag tubing to the right angle feeding set and clamp one or both tubes.
2. Fill bag with formula. Unclamp tube(s) and allow formula to fill tubes. Re-clamp tubing.
5. When feeding is complete, clamp both feeding set tubing and feeding bag tubing. Disconnect feeding bag.
6. Using catheter tip syringe, flush feeding set while it is connected to Mini ONE Button with prescribed amount of water (5ml for children, 10-20ml for adults).
7. Disconnect feeding set and wash with warm soapy water.

**Bolus Feeding using a catheter tip syringe:**
1. Prime the tubing: Attach a water filled catheter tip syringe to the bolus feeding set and fill with water. Clamp the feeding set.
2. Connect feeding set to Mini ONE Button feeding port.
3. Disconnect syringe from feeding set and remove syringe plunger. Reattach syringe without the plunger.
4. Slowly pour formula into syringe and unclamp feeding set. Keep syringe filled with formula to prevent air from entering the stomach. To adjust feeding flow rate, raise or lower the syringe.
5. When feeding is complete, use the catheter tip syringe to flush the feeding set and button with the prescribed amount of water (5ml for children, 10-20ml for adults).
6. After flushing, disconnect feeding set and wash with warm soapy water.
Stoma Site Care

• **The stoma site should be kept clean and dry at all times.** It is important to clean the stoma site daily with mild soap and warm water or as directed by your physician. Use a cotton swab or terry cloth to clean the skin underneath the Balloon Mini ONE® Button as directed by your physician.

• **Turn the Balloon Mini ONE® Button daily,** stopping at a different point each time to allow for air circulation.

• **Bath time.** Patients fitted with the Balloon Mini ONE® Button are allowed to bathe and swim (make sure the safety plug is in place). A good time for routine cleaning of the Balloon Mini ONE® Button/stoma site is during a bath. Always allow the stoma site to air dry after cleaning.

• **Always check the stoma site for redness, pain/soreness, swelling, or unusual drainage.** If any of these signs or symptoms are observed, contact a physician for advice.

• **Gauze or pads are not necessary.** If there is leakage, the g-tube may be too loose or too tight and should be remeasured. Call your doctor to have the g-tube remeasured.

For additional stoma site concerns, see page 22.
Balloon Button Maintenance

Routine maintenance is recommended for the Balloon Mini ONE® Button.

1. Remove all the water from the balloon by inserting a syringe into the balloon port and drawing back on the piston. Examine the amount.

2. Replace with the original prescribed amount of water or as prescribed by your physician. Check the balloon fill volume as recommended by your physician.

Feeding Set Maintenance

- Feeding sets and syringes 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 feeding set should be cleaned at least once per day.
- To prevent clogging, always flush feeding sets after feeding and after administering medications.

Contact your insurance provider regarding the number of feeding extensions you are allowed per month.

Balloon Mini ONE® Button Fill Volume Table

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<tr>
<td>24F</td>
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The physician will recommend when to replace the Balloon Mini ONE® Button. Check the Information Card located on the inside back cover of this guide for the recommended replacement date.

Also refer to the Balloon Mini ONE® Button Directions for Use included in each Button kit.

The stoma site may begin to close within the first hour after a device has been removed.

Always be sure to have an extra Balloon Mini ONE® Button on hand for immediate replacement.

Don’t forget to remeasure! To ensure proper fit, stoma sites should periodically be remeasured by your doctor using a stoma measuring device. Ask you doctor about this.
Inspect the Balloon Mini ONE® Button Kit for damage. *Do not use if sterile seal is broken or if contents are damaged.*

Inflate the new Balloon Mini ONE® Button Retention Balloon to the recommended fill volume with water. See fill volume chart on page 11. *Note: Recommended fill volume is printed on fill valve.*

Inspect the balloon and port for signs of leakage. Deflate the balloon after inspection.

For full instructions and video go to: www.appliedmedical.net
Lubricate the patient’s stoma tract with a water soluble lubricant. Apply the lubricant to the site and then move the existing button up and down and rotate to help distribute lubricant. **DO NOT USE OILS OR PETROLEUM JELLY AS A LUBRICANT.**

Deflate the retention balloon by inserting a syringe into the balloon port and withdrawing the water.

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

Lubricate the tip of the new Balloon Mini ONE® Button with a water soluble lubricant. **DO NOT USE OILS OR PETROLEUM JELLY AS A LUBRICANT.**

Introducer/stiffener is optional, but makes placement easier. Place introducer through button. **Introducer must not extend past the end of the Button’s tubing.**

Lubricate the stoma. Gently guide the tube through the stoma into the stomach, stopping when the External Base reaches the patient’s skin. **Note: Not all stomas are straight and some buttons may need to be put in at an angle.**
Place the new device.  

4. Remove introducer.

5. Hold the Balloon Mini ONE® Button in place and inflate the balloon to the prescribed fill volume with water. *Do NOT inflate the balloon with air.* See fill volume chart on page 11. *Note: The recommended fill volume is printed on the fill valve.*

6. Gently pull up on the Balloon Mini ONE® Button to make sure the balloon is filled and positioned against the stomach wall. Stop when resistance is observed.

7. Clean the stoma site to remove any excess lubricant.

8. Ensure that the tube is positioned properly by attaching a feed set and withdrawing (pull back on syringe) until stomach contents are visible. (See pages 7 and 8 for step by step instructions.)

9. Check for leakage around the stoma site. If leakage is observed add an additional 0.5-1 ml of water until the leaking stops. *Do NOT exceed the balloon’s maximum fill volume.* (See page 11 for fill volume chart.)
Special Concerns for Children

Children require special care because of their developing bodies. A child’s stomach is very small and cannot hold a large amount of food at one time. Therefore, children may require feedings more often with less formula.

**Important:** Be sure to prime the tubing before feeding to reduce the placement of air into the patient’s stomach. To prime, simply pour the supplement into the feeding bag and let it flow through to the end of the feeding set (see page 9).

Although a child may receive food through a Mini ONE® Button, it is important to include the child in group meals at the table so the child learns about food and feels a part of the family.

Children are always growing! Be sure to ask your doctor to remeasure the stoma length periodically to ensure a proper fit.

For additional stoma site concerns, see page 22.
Decompression (venting the stomach/releasing gas)

“Venting” the stomach helps relieve pressure. Attach a feeding set to the g-tube and connect an open syringe or feeding bag to the feed set. Raise approximately 6” above the stomach so gas and stomach contents can pass freely up and down tube. Do this as directed by your physician.

Monitoring residuals and decompression can be done by using either the Bolus or Right Angle Feeding Set.
Leakage around the device:

- Make sure the balloon is filled. (Resistance should be felt when gently pulling on the tube.) Make sure the balloon is filled to the prescribed volume. See page 11 for instructions and fill volume chart. **Note: The recommended fill volume is printed on top of the fill valve.**

- Check that the g-tube corresponds to the prescribed French size and length. If the incorrect device is in place, call your doctor.

- The g-tube may be too tight or too loose. Call your doctor to have the stoma remeasured.

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

- Be sure to rotate the g-tube daily

Causes for leakage:

- Incorrect size
- Weight change
- Amount of water in balloon may be too much or too little
- Tension at stoma site (from extension sets)
- Stomach may need to be decompressed
Balloon Failure
A balloon may leak or burst over time due to medications, balloon inflation volume, stomach acid, g-tube care, or natural wear. Always keep an extra g-tube on hand in case of incident. Do NOT remove g-tube until a replacement is available in order to prevent the stoma from closing.

Balloon Will Not Deflate
Clean the balloon port with a cotton swab to make sure formula/medication or other contaminants are not blocking the balloon port. Insert a slip tip syringe, push and twist one-quarter turn. If the balloon still will not deflate, push the valve with a paperclip to release the water. If the problem persists call your doctor.

For additional stoma site concerns, see page 22.
Device-Related Concerns

Stomach Contents Leak Around the Tube
Check stomach for residual. If excessive residual occurs often, the stomach may not be emptying normally, or the g-tube may be too loose or too tight. Call your doctor to have the stoma remeasured.

Feeding Tube Becomes Disconnected
Stop the feeding pump and estimate the amount of formula lost. Wipe tube connections thoroughly with soap & water. Clean the inside of the extension set feeding port with a cotton swab and soap and water. Dry connectors and reconnect tubes. Resume feeding, adding additional formula for the estimated loss. If disconnects persist, ask for an AMT Clamp™ device to eliminate disconnects. See page 26 for more details.

Preventing Tube Blockage
Flush g-tube with 5 ml (10-20 ml for adults) warm water before and after administering food or medication, every 3-4 hours of continuous feeding, and after checking for stomach content residual. Do NOT place foreign objects down the center of the g-tube. This will damage the g-tube causing it to become nonfunctional. Make sure the g-tube is in the correct location within the stomach.

G-tube is Too Tight Against the Patient’s Skin
The g-tube should be able to turn easily without resistance from the patient’s skin. If g-tube does not turn easily or redness/bleeding occurs at the stoma or the area directly underneath the g-tube, call your doctor. The patient may need to be remeasured for a longer g-tube.
G-tube is Pulled Out of the Patient
Although the g-tube is designed to decrease the number of pull outs, a g-tube may become accidentally dislodged. Replace the device immediately or call your doctor as the stoma may begin to close within the first hour a device is removed. Refer to pages 12-15 and/or the Directions for Use.
Always be sure to have a replacement g-tube on hand for immediate replacement.

Vomiting
Aspiration (inhalation of food or stomach contents into the lungs) may occur while vomiting, causing difficulty in breathing or other serious medical conditions. Stop feeding and decompress the stomach immediately if incidence occurs. Contact emergency care immediately if difficulty in breathing occurs or aspiration is suspected. Do not feed while the patient is laying flat.

Diarrhea
May occur if formula is spoiled or delivered too quickly. Mix new formula before each feeding. Deliver formula at a slower rate. Cleanliness is also very important. All caregivers should wash their hands thoroughly prior to preparing the formula and handling the feeding sets. Make sure the feeding sets are rinsed thoroughly to avoid soap in the formula. Call your doctor if diarrhea continues.

Constipation
May occur due to insufficient amounts of water in addition to formula, inactivity, change in formula or medication, or change in feeding routine. Call your doctor if this continues.

Upset Stomach
May occur if too much formula is administered or if the formula is delivered too quickly. Call your doctor if this continues.
Stoma Site Related Concerns

Call your physician if any of the following is observed:

- If the skin around the site is red or raw.
- If there is drainage around the site that is white, yellow or green and may smell bad.
- If crusting is noted at the site.
- If there is repetitive leakage of food or stomach contents. (Gauze or pads should not be necessary.) If there is leakage, the g-tube may be too loose or too tight and should be remeasured. Call your doctor to have the g-tube remeasured.
- If the tube falls out and you are unable to replace it easily.
- If the patient experiences diarrhea or vomiting.
- If the patient develops a fever.
- Pain at the g-tube site.
- Bleeding, puss or inflammation at the g-tube site.
Medications can be administered through the Mini ONE® Buttons in liquid form. Diluting thick liquid medications, when possible, helps prevent the Mini ONE® Button tube from clogging. If a prescribed medication is only available as a tablet or capsule, check with a pharmacist or physician to make sure it can be crushed and dissolved in warm water. Never mix medications with feeding formula unless prescribed by the physician.

To more easily administer medications, AMT offers a 2" Bolus Medication Set with Straight Port (order # 8-0211) as well as a 2" Bolus Medication Set with Y-Port (order # 8-0212). Medication may also be administered into the interlock with the slip tip syringe provided in the Balloon Mini ONE® Kits.

**Flush with water thoroughly after giving medication.**

See ordering information on page 24.
Mini ONE® Feeding Sets (Mic-Key® Equivalents)

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* Included in each Mini ONE® Kit. For ordering information call 800-869-7382

Note: All Mini ONE® Button kits come standard with a translucent purple Y-Port Adapter. Clear Y-Port Adapters can be ordered separately. All feeding sets are DEHP free.

Pull-outs are reduced with the AMT Purple Y-Port, made with a new “sticky” elastomer to provide a more secure friction fit.

If pull-outs persist, try the AMT Clamp™ device to eliminate disconnects between “Christmas tree”/stepped adapters and feeding sets. See page 26.

Feeding sets should be removed when not feeding.

New Glow in the Dark Connector and Improved Medication Port
- Optional Glow Green Connector makes nighttime connections easier.
- Call Customer Service to order.
- Med port has higher plug retention to reduce chance of “feeding the bed.”

Contact your insurance provider regarding the number of feeding extension sets you are allowed per month

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* Included in each Mini ONE® Kit. For ordering information call 800-869-7382

Feeding sets should be removed when not feeding.
### Balloon Mini ONE® Button Kits

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### Each Kit Contains:
- Balloon Mini One® Button
- Sterile Gauze
- Slip Tip Syringe
- Introducer/Stiffener
- Bolus Feeding Set
- Continuous Feeding Set
- Catheter Tip Syringe

**Example:** $14F \times 2.3\text{cm} = M1-5-1423$
Our new Y-Port is made from a special elastomer that connects with a “sticky” friction fit.

The new purple color means “g-tube feeding” to avoid misconnections, and the see-through material helps so you can see the flow through the Y-Port walls.

If pullouts persist, ask for an AMT Clamp™ device to totally eliminate disconnects.

The AMT Clamp Device part number is 4-3000.
What People Are Saying About the AMT Balloon Mini ONE® Button

“Cayleigh’s had three different brands of g-button and by far we love the AMT Mini ONE balloon the best!” – Cayleigh’s Mom

“We can finally give Jacob his tummy time” – Jacob’s mommy

“Our girl’s stoma site is amazing. The days of massive leaking and granulation tissue are far behind us!” – Emily’s Daddy

AMT 1-800-869-7382
Patient Information

Patient Name: ___________________________  Physician Name: ___________________  Phone: ________________

Placement Date: _________________________  Replacement Date: _______________________

Balloon Mini ONE® Button Information

Product No.: ________________  Lot No.: ________________

French Size: ________________  Length (cm): ________________

Balloon Fill Volume (ml): ________________

Fill in the above information or peel off die-cut sticker from tray.

Formula

Type of Formula: ____________________________

Medications: __________________________________________

Homecare Company Name: ____________________________________  Phone: ________________

Toll-Free: 800-869-7382  www.appliedmedical.net
**Type of Feeding**

Bolus: Y / N ________________________________  Continuous: Y / N ________________________________

Water to prime tube before feeding (ml): ____________________________

Flow Rate (formula/hour): ____________________________

Length of Feeding (minutes): ____________________________

Additional Water (ml): ____________________________

**Special Instructions**

________________________________________________________________________

________________________________________________________________________

________________________________________________________________________

**Contact Information**

Physician: ____________________________  Phone: ____________________________

HCP: ____________________________  Phone: ____________________________
Support is available. In addition to your physician, there are many resources available to help you with enteral feeding:

- **www.oley.org** — The Oley Foundation is for people who feed by tube or IV at home
- **www.parent-2-parent.com** — A unique support system for parents of children with developmental disabilities
- **www.feedingtubeawareness.com** — Group of parents of children with feeding tubes
- **www.foodfortubies.com** — Organization that helps people with feeding tubes use “real” food

**Introducing a Better G-J Button**
- Less clogging
- Increased safety
- Improved comfort

**Balloon Mini ONE® Buttons**
- US Patent numbers 6,019,746 and D418,220
- Additional patents pending

**AMT Clamp™ Product**
- US Patent number 6,375,231

**The Leader in Enteral Device Innovation**
An ISO 13485 Registered Company

**AMT**
8006 Katherine Boulevard
Brecksville, OH 44141
**Toll-Free:** 800-869-7382
**E-mail:** cs@appliedmedical.net
**www.appliedmedical.net**