Patient Education Guide

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

Capsule Non-Balloon Mini ONE® Buttons

The Leader in Enteral Device Innovation
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.
How the Capsule Non-Balloon Mini ONE® Button is Different

The capsule design of the Capsule Non-Balloon Mini ONE® Button offers advantages found nowhere else:

- No balloon to fail, so replacements occur less often
- Capsule design dramatically reduces pain during insertion
- Button shaft is as narrow as that of a balloon button, and the capsule is self-lubricating for easy insertion
- Easy to use pull-away tether releases capsule to deploy internal bolster
- For removal: Removal tool distends bolster to a smaller profile
- Ideal for people who don’t tolerate balloon buttons
- Internal bolster is smaller than a balloon (less likely to block the pylorus)
- Internal dome provides more holes/openings for better feeding and venting
- Feeding sets are interchangeable with Balloon Mini ONE® device
Easy to Insert (Like a balloon device) +
Long Life (Like a non-balloon device)

Once inserted, capsule material falls away, dissolves rapidly and passes - allowing for easy deployment of bolster.

Removal tool distends internal bolster for ease of removal.
The Capsule Non-Balloon Mini ONE® Button 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 Capsule Non-Balloon Mini ONE® Button

**Lot Number**
Lot number is etched (laser engraved) on side of device.

**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.

**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.

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

**Silicone Retention Bolster (deployed)**
A silicone bolster holds the device in place. Once the device is inserted, the bolster helps to prevent the button from being pulled out of the stomach.
Non-Balloon Mini One® is the size and length prescribed by the physician. The French size (F) refers to the diameter of the tube, while the centimeter size (cm) refers to tube length between the base of the external bolster and the top of the internal bolster.

The Bolus Feeding Set is intended for bolus feeding, administering medication, or flushing the Non-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 Non-Balloon Mini ONE® Button with water.

Feeding sets can be ordered in a variety of lengths and combination to suit the needs of the patient. See page 20.
For full instructions and video go to: www.amtbutton.com

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

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

• Holding the button as shown on page 7, line up the key on the Feeding Set Adapter with the key opening on the Non-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 (see photo for details). 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 nothing is blocking the feeding port.

For information on feeding set maintenance, see page 11.
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 by the feed port.

- Line up black marks
- Insert feed set into button
- 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.

Locked Position

- Holding the device only by the flange will not allow proper stabilization of the button.

Starting Position
Verify Proper Non-Balloon Mini ONE® Button Placement & Functionality

Before feeding through the Non-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.*

After drawing 5 ml of water into catheter tip syringe, pull plunger to withdraw stomach fluid. Flush after observing stomach fluid.
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. Flush feeding set 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, 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.

Bolus Feeding using a gravity drip bag:
1. Prime the tubing: Attach the gravity bag tubing to the bolus feeding set and clamp one or both tubes.
2. Fill bag with prescribed amount of formula. Unclamp tube(s) and allow formula to fill both tubes to purge the air. Re-clamp tubing.
3. Connect the feeding set to the Mini ONE Button feeding port.
4. Unclamp tube(s) to start feeding. Adjust the drip rate of the formula by adjusting the clamp pressure on the gravity bag tubing.
5. When feeding is complete, clamp both feeding set and gravity bag tubing. Disconnect gravity bag.
6. With a syringe, flush feeding set and button with prescribed amount of water (5ml for children, 10-20ml for adults).
7. 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 Non-Balloon Mini ONE® Button as directed by your physician.

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

• **Bath time.** Patients fitted with the Non-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 Non-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 18.
Non-Balloon Button Maintenance

Keep the Non-Balloon Mini ONE® Button clean and dry.

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.
It is recommended that the Non-Balloon Mini ONE® Button be replaced only by a qualified physician or care provider. Your physician will recommend when to replace the Non-Balloon Mini ONE® Button. Check the Information Card located on the inside back cover of this guide for the recommended replacement date.

**Warning:** The stoma site may begin to close within the first hour after a device has been removed. Consult a physician immediately in the event that an accidental device pull out occurs.

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

Also refer to the Capsule Non-Balloon Mini ONE® Button’s *Directions for Use* included in each Button kit.

*Don’t forget to remeasure!* To ensure proper fit, stoma sites should periodically be remeasured by your doctor using a stoma measuring device. Ask your doctor about this.
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.
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 18.
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.

The feeding set adapter will open the one way valve to vent stomach.
Device-Related Concerns

Stomach Contents Leak Around the Tube
Check stomach for residual. If excessive residual occurs often, the patient may be receiving too much formula at one time, 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 measured.

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 13 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 g-tube is removed. Refer to page 12.

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 Capsule Non-Balloon Mini ONE® Kits.

**FLUSH WITH WATER THOROUGHLY AFTER GIVING MEDICATION.**
## Mini ONE® Feeding Sets

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<tr>
<td>4-3000 AMT Clamp™ Device</td>
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* Included in each Mini ONE® Kit.

For ordering information call 800-869-7382

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

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 13.

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

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### 20 FRENCH

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<td>M1-2-2044</td>
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Each Kit Contains:

- Capsule Non-Balloon Mini One® Button
- Sterile Gauze
- Slip Tip Syringe
- Catheter Tip Syringe
- Removal Tool
- Bolus Feeding Set
- Continuous Feeding Set

*Kit includes removal tool

\[ F = \text{Diameter of Tube} \quad \text{cm} = \text{Stoma Length}\]

Example: 18F x 2.0cm = M1-2-1820
Information Card

Remove this page and carry it with patient.

Patient Information

Patient Name: ___________________________  Physician Name: ___________________________  Phone: ___________

Placement Date: ___________________________  Replacement Date: ___________________________

Capsule Non-Balloon Mini ONE® Button Information

Product No.: ___________________________  Lot No.: ___________________________

French Size: ___________________________

Length (cm): ___________________________

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): __________________________

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® Button
US Patent numbers 6,019,746 and D418,220 and additional patents pending

Capsule Products
US Patent number 6,896,665 and additional patents pending

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

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