

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

Contents



Capsule Non-Balloon Mini ONE® Button

- 2** How the Capsule Non-Balloon Mini ONE® Button is Different
- 4** Kit Contents of the Capsule Non-Balloon Mini ONE® Button
- 6** Attaching Feed Sets
- 8** Feeding with Your Non-Balloon Button
- 10** Stoma Site Care / Button Maintenance
- 12** Replacing the Non-Balloon Mini ONE® Button
- 14** Special Concerns for Children
- 15** Decompression (Venting the Stomach / Releasing Gas)
- 16** G-Tube Related Concerns
- 18** Stoma Site Related Concerns
- 19** Administering Medications
- 20** Feeding Sets and Accessories
- 21** Re-Ordering Information



Introduction to Tube Feeding



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.

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**



**Capsule
Non-Balloon
Mini ONE® Button**

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.

Components of the Capsule Non-Balloon Mini ONE® Button

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.



Removal tool

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-Reflex Valve/One Way Valve

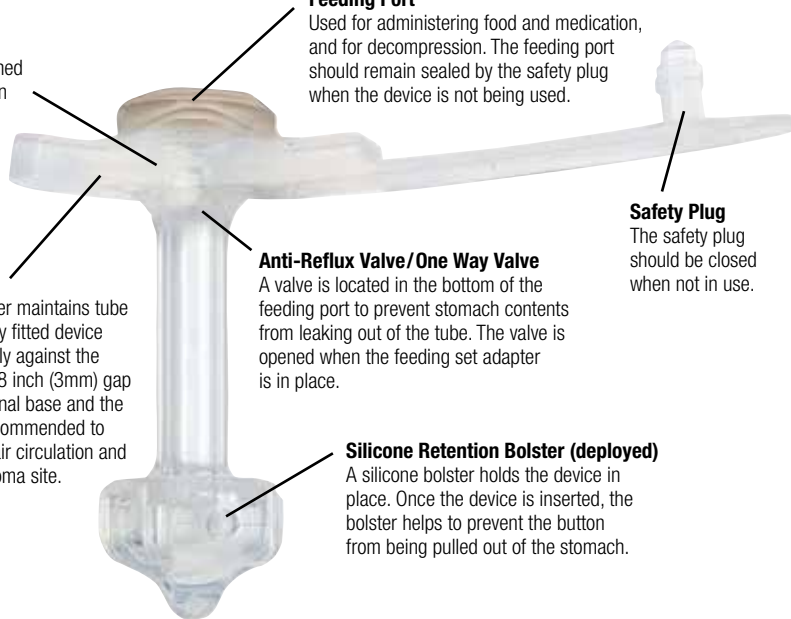
A valve is located in the bottom of the feeding port to prevent stomach contents from leaking out of the tube. The valve is opened when the feeding set adapter is in place.

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.

Safety Plug

The safety plug should be closed when not in use.



Your Non-Balloon Button Kit



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.

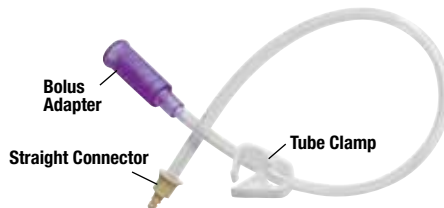


4" x 4" (10 cm x 10 cm) Sterile Gauze

Slip Tip Syringe to administer medications directly into the feeding port.



Removal Tool distends internal bolster for easy removal.

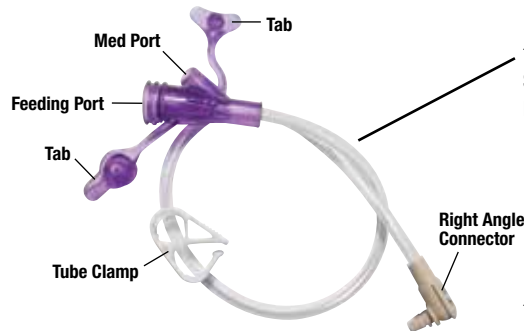


Bolus Adapter

Straight Connector

Tube Clamp

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



Med Port

Tab

Feeding Port

Tab

Tube Clamp

Right Angle Connector

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



Catheter Tip Syringe

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.

AMT 1-800-869-7382

Attaching Feed Sets to the Non-Balloon Mini ONE[®] Button

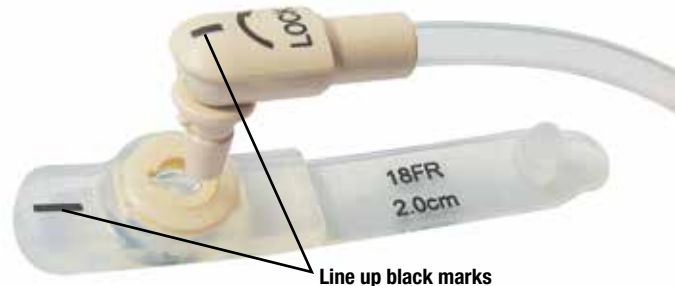
For full instructions and video go to: www.amtbutton.com

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.

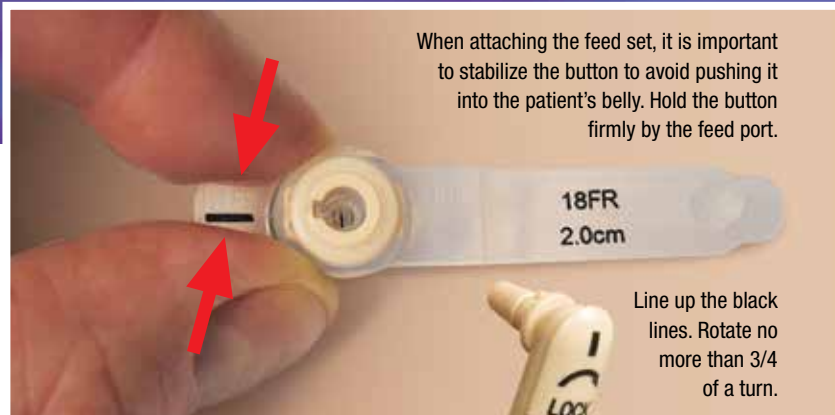
For information on feeding set maintenance, see page 11.



See complete list of AMT feeding extension sets on page 20.



Here's the Best Way to Attach a Feed Set



- 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.



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



Feeding

with Your **Non-Balloon Button**

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.

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.
3. Connect feeding set to Mini ONE Button feeding port.
4. Connect feeding bag tubing to the pump. Set flow rate. Unclamp tubes and begin feeding.
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.

Continuous/
Overnight
Feeding



Bolus
Feeding



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.

Non-Balloon Mini ONE[®] Button Maintenance

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.

Replacing the Non-Balloon Mini ONE® Button

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.

Eliminate Pullouts with the AMT Clamp™ Device for Continuous Feeding



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.



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 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.



Anti-Reflux Valve (One Way Valve) is located at the bottom of feeding port. The valve is opened when the feeding set adapter is in place.

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 you 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.

Administering Medications

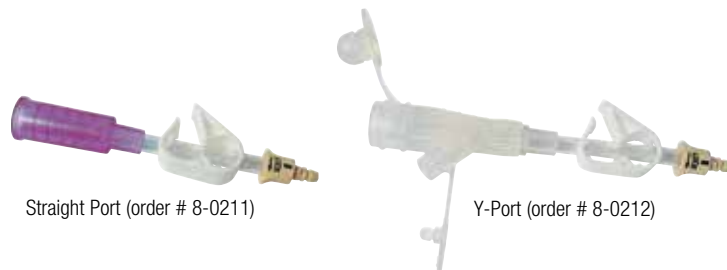


Medications can be administered through the Mini ONE® Buttons in liquid form. Diluting thick liquid medications, when possible, helps prevent the Mini ONE® Button tube from clogging. If a prescribed medication is only available as a tablet or capsule, check with a pharmacist or physician to make sure 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.

See ordering information
on page 20.



Straight Port (order # 8-0211)

Y-Port (order # 8-0212)

Feeding Sets and Accessories

Mini ONE® Feeding Sets

| Catalog No. | Description | Qty/Box |
|---|--|---------|
| Re-Order Numbers for PURPLE ADAPTERS | | |
| * 8-1255 | 12" Right Angle Connector w/ Y-Port Adapter (purple) | 10 |
| 8-2455 | 24" Right Angle Connector w/ Y-Port Adapter (purple) | 10 |
| 8-1221 | 12" Right Angle Connector w/ Bolus Adapter (purple) | 10 |
| 8-2421 | 24" Right Angle Connector w/ Bolus Adapter (purple) | 10 |
| * 8-1211 | 12" Straight Connector w/ Bolus Adapter (purple) | 10 |
| 8-2411 | 24" Straight Connector w/ Bolus Adapter (purple) | 10 |
| 8-0211 | 2" Straight Connector w/ Bolus Adapter (purple) | 10 |

Re-Order Numbers for CLEAR ADAPTERS

| | | |
|--------|---|----|
| 8-1222 | 12" Right Angle Connector w/ Y-Port Adapter (clear) | 10 |
| 8-2422 | 24" Right Angle Connector w/ Y-Port Adapter (clear) | 10 |
| 8-1212 | 12" Straight Connector w/ Y-Port Adapter (clear) | 10 |
| 8-0212 | 2" Straight Connector w/ Y-Port Adapter (clear) | 10 |
| 4-3000 | AMT Clamp™ Device | |

* 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



Straight Connector



Right Angle Connector



AMT Clamp™ Device



Bolus Adapter (purple)



Y-Port Adapter (purple)



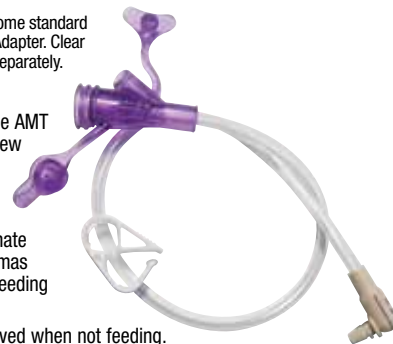
Y-Port Adapter (clear)

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.



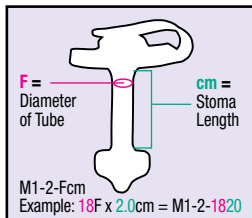
Re-Ordering Information



Capsule Non-Balloon Mini ONE® Button Kits

| 14 FRENCH | | | 18 FRENCH | | |
|-------------------|--------------|--|-------------------|--------------|--|
| Stoma Length (cm) | Order Number | | Stoma Length (cm) | Order Number | |
| ___ 1.0 | M1-2-1410 | | ___ 1.2 | M1-2-1812 | |
| ___ 1.2 | M1-2-1412 | | ___ 1.5 | M1-2-1815 | |
| ___ 1.5 | M1-2-1415 | | ___ 1.7 | M1-2-1817 | |
| ___ 1.7 | M1-2-1417 | | ___ 2.0 | M1-2-1820 | |
| ___ 2.0 | M1-2-1420 | | ___ 2.4 | M1-2-1824 | |
| ___ 2.5 | M1-2-1425 | | ___ 3.0 | M1-2-1830 | |
| ___ 3.0 | M1-2-1430 | | ___ 3.4 | M1-2-1834 | |
| | | | ___ 4.4 | M1-2-1844 | |

| 20 FRENCH | | | 24 FRENCH | | |
|-------------------|--------------|--|-------------------|--------------|--|
| Stoma Length (cm) | Order Number | | Stoma Length (cm) | Order Number | |
| ___ 1.7 | M1-2-2017 | | ___ 1.7 | M1-2-2417 | |
| ___ 2.4 | M1-2-2024 | | ___ 2.4 | M1-2-2424 | |
| ___ 3.4 | M1-2-2034 | | ___ 3.4 | M1-2-2434 | |
| ___ 4.4 | M1-2-2044 | | ___ 4.4 | M1-2-2444 | |



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

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): _____

PLACE STICKER HERE

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): _____

Additional Water (ml): _____

Special Instructions

Contact Information

Physician: _____

Phone: _____

HCP: _____

Phone: _____

Notes



Patient Education Guide

Non-Balloon Mini ONE® Buttons



See the
AMT website
for details

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



C-4399-C

Made in USA

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



The Leader in Enteral Device Innovation

An ISO 13485 Registered Company 

8006 Katherine Boulevard
Brecksville, OH 44141

Toll-Free: 800-869-7382

E-mail: cs@appliedmedical.net

www.appliedmedical.net