

Patient Education Guide



Guidance and support to
help you manage enteral feeding

Balloon and Capsule Non-Balloon Mini ONE® Buttons



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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 is a specialist
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 is inserted to provide direct access to the stomach for feeding. A gastrostomy 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. Whether you use our Balloon or Non-Balloon design, we hope to provide the comfort and confidence you deserve.

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.



Balloon
Mini ONE[®]
Button



Customizable Balloons

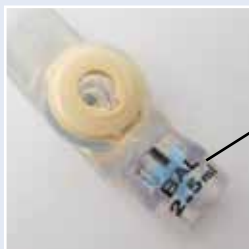
Balloon fill volume can be easily adjusted for a custom-fit, reducing leaks and improving patient comfort. Our durable silicone material permits fill variations to assure the proper fit.

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

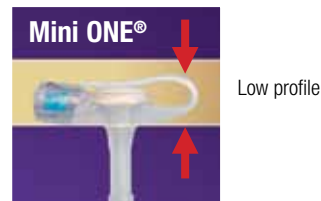


Recommended fill volume is printed on top of the fill valve.



Reduces Skin Irritation and Discomfort

- No hard, bulky external bolster means more patient comfort
- Low profile external bolster is easier to conceal under clothing and provides more comfort
- Flexible bolster is easy to clean around and less likely to create trauma to the stoma site



Components of the Balloon Mini ONE® Button



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.

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.

Recommended fill volume for 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.

Safety Plug

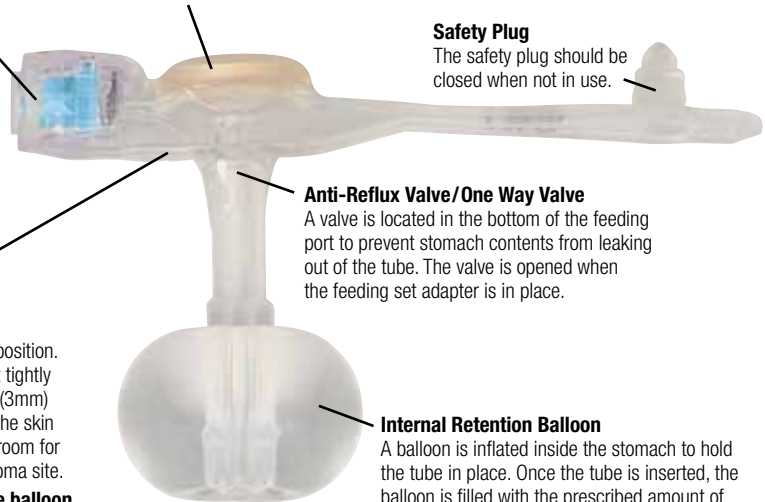
The safety plug should be closed when not in use.

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 distilled 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.



Your Balloon Button Kit



Balloon Mini One® Button is the size and length prescribed by the physician.



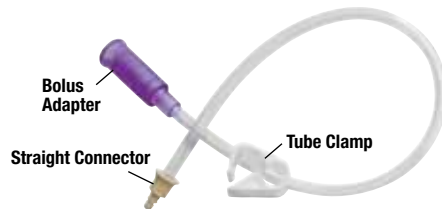
Two **4" x 4" (10 cm x 10 cm)** Sterile Gauze

Slip Tip Syringe to inflate the silicone balloon through the balloon valve and to administer medications directly into the feeding port.



Introducer/Stiffener makes placement of balloon button easier.

For re-ordering information see page 24.

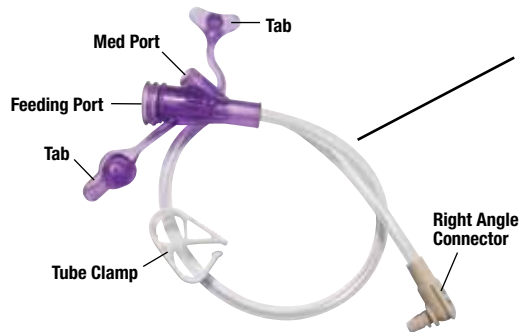


Bolus Adapter

Straight Connector

Tube Clamp

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

Attaching Feed Sets to the Balloon Mini ONE® Button

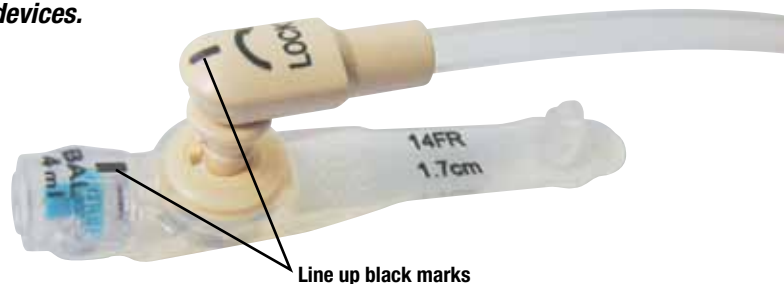
For full instructions and video go to: www.appliedmedical.net

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 no debris blocking the feeding port.

For information on feeding set maintenance, see page 11.

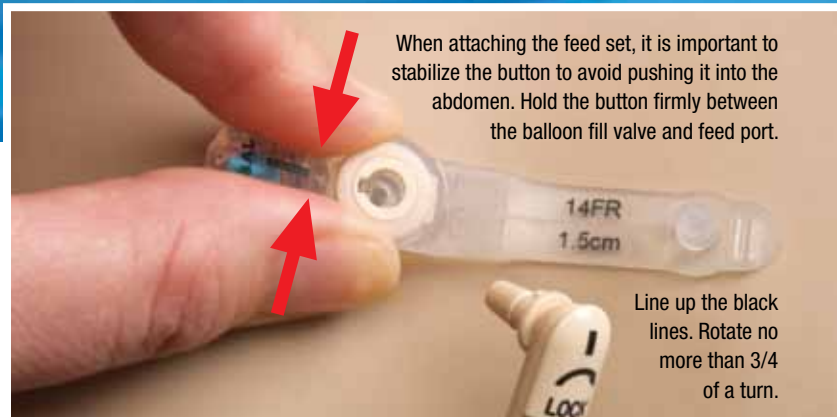


Mic-Key® Feed Set Compatible

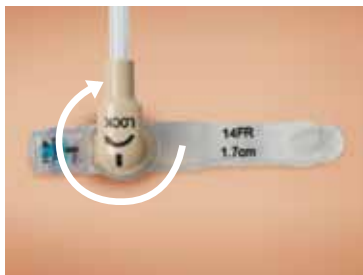
All Mini ONE® products accept either Mini ONE® or Mic-Key® feed sets.
See complete list of AMT feeding extension sets on page 24.



Here's the Best Way to Attach a Feed Set



- 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



Holding the device only by the balloon fill valve or only by the feed port will not allow proper stabilization of the button.



Feeding with Your Mini ONE® Feeding Tube



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.



After drawing 5 ml of water into a 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 kept with head elevated 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 prescribed amount of formula. Unclamp tube(s) and allow formula to fill tubes to purge the air. Re-clamp tubing.
3. Connect feeding set to Mini ONE Button feeding port.
4. Connect feeding bag tubing to the pump. Adjust pump rate according to the manufacturer's instructions or physician's recommendation. 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, clamp feeding set and disconnect syringe.
6. Rinse syringe and fill it with prescribed amount of water (5ml for children, 10-20ml for adults).
7. Reconnect syringe to feeding set, unclamp and flush feeding set and button with water.
8. 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. Flush feeding set and button with prescribed amount of water (5ml for children, 10-20ml for adults).
7. Disconnect feeding set and wash with warm soapy water.

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 Balloon Mini ONE[®] Button as directed by your physician.
- **Rotate 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 (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.



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 distilled water or as prescribed by your physician. **Check the balloon fill volume as recommended by your physician.**



Feeding Set Maintenance

- Feeding sets and accessories 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

French Size	Minimum	Recommended	Maximum
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

Replacing the Balloon Mini ONE® Button

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 a replacement Balloon Mini ONE® Button on hand for immediate replacement.





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

Directions for Placement / Replacement



Inspect the new device.

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 distilled 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.

Replacing the Balloon Mini ONE® Button

(continued)

Remove the existing device.



1 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.



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



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

Place the new device.



1 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.**



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



3 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 slight angulation of the device may be necessary.**



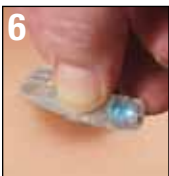
Place the new device. *continued*



4 Remove introducer.



5 Hold the Balloon Mini ONE® Button in place and inflate the balloon to the prescribed fill volume with distilled 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 aspirating stomach contents with a syringe. (See pages 7 and 8 for step by step instructions.)



9 Monitor for leakage around the stoma site. If leakage is observed add an additional 0.5 - 1 ml of distilled 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 minimize 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.

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.

**For additional stoma site concerns,
see page 22.**





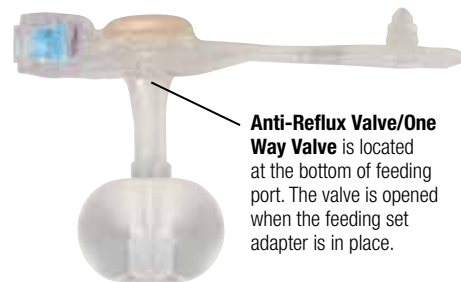
Decompression (venting the tube)

"Venting" the stomach helps relieve pressure. Attach an open blunt tip syringe to the end of a feeding set port. 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

For Balloon Buttons

Leakage around the device:

- Make sure the balloon is filled: Resistance should be observed 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 device corresponds to the prescribed French size and length. If the incorrect device is in place, consult a physician.

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.



Balloon Failure

A balloon may leak or burst over time due to medications, balloon inflation volume, gastric pH, device care, or natural wear. Always keep a replacement device on hand in case of incident. ***Do NOT remove device 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 or fill lumen. Insert a slip tip syringe, push and twist one-quarter turn. If the balloon still will not deflate, depress the valve with a paperclip to release the water. If the problem persists consult a physician.

**For additional stoma site concerns,
see page 22.**

Device-Related Concerns

For Balloon Buttons

Stomach Contents Leak Around the Tube

Check stomach for residual. If stomach often contains excess residual the patient may be receiving too much formula at one time or the stomach may not be emptying normally, consult a physician.

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 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 device.** This will damage the device causing it to become nonfunctional. Make sure the device is in the correct location within the stomach.

Device is Too Tight Against the Patient's Skin

The device should be able to rotate freely without resistance from the patient's skin. If device does not rotate freely or redness/bleeding occurs at the stoma or the area directly underneath the device consult a physician. The patient may need to be re-measured for a longer device.



Device is Pulled Out of the Patient

Although the device is designed to minimize the occurrence of pull out, a device may become accidentally dislodged. Replace the device immediately or consult a physician 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 device 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.**

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.** Avoidance of soap in the formula is important as well. Consult a physician if condition persists.

Constipation

May occur due to insufficient amounts of water in addition to formula, inactivity, change in formula or medication, or change in feeding routine. Consult a physician if condition persists.

Upset Stomach

May occur if too much formula is administered or if the formula is delivered too quickly. Consult a physician if condition persists.

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 leakage of food or stomach contents.
- 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.

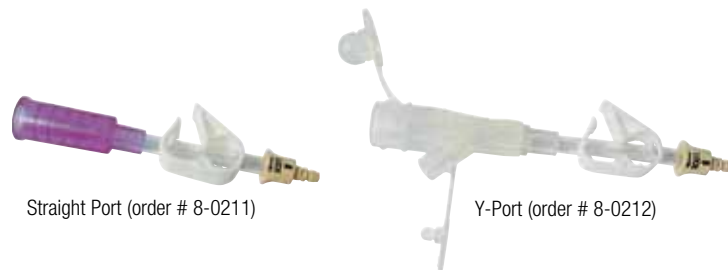
Administering Medications



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 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 ADMINISTRATION.



Straight Port (order # 8-0211)

Y-Port (order # 8-0212)

**See ordering information
on page 24.**

Feeding Sets and Accessories

Mini ONE® Feeding Sets (Mic-Key® Equivalents)

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



Bolus Adapter



Right Angle Connector



Y-Port Adapter (purple)



AMT Clamp™ Device

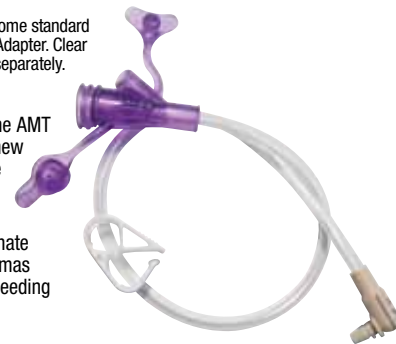


Y-Port Adapter (clear)

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 26.

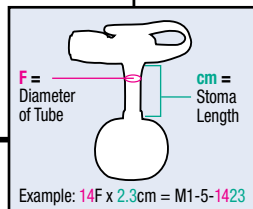


Re-Ordering Information



Balloon Mini ONE® Button Kits

12 FRENCH		14 FRENCH		16 FRENCH		18 FRENCH		20 FRENCH		24 FRENCH	
Stoma Length (cm)	Order Number	Stoma Length (cm)	Order Number	Stoma Length (cm)	Order Number	Stoma Length (cm)	Order Number	Stoma Length (cm)	Order Number	Stoma Length (cm)	Order Number
—	0.8	M1-5-1208	—	0.8	M1-5-1408	—	1.0	M1-5-1610	—	1.0	M1-5-1810
—	1.0	M1-5-1210	—	1.0	M1-5-1410	—	1.2	M1-5-1612	—	1.2	M1-5-1812
—	1.2	M1-5-1212	—	1.2	M1-5-1412	—	1.5	M1-5-1615	—	1.5	M1-5-1815
—	1.5	M1-5-1215	—	1.5	M1-5-1415	—	1.7	M1-5-1617	—	1.7	M1-5-1817
—	1.7	M1-5-1217	—	1.7	M1-5-1417	—	2.0	M1-5-1620	—	2.0	M1-5-1820
—	2.0	M1-5-1220	—	2.0	M1-5-1420	—	2.3	M1-5-1623	—	2.3	M1-5-1823
—	2.3	M1-5-1223	—	2.3	M1-5-1423	—	2.5	M1-5-1625	—	2.5	M1-5-1825
—	2.5	M1-5-1225	—	2.5	M1-5-1425	—	2.7	M1-5-1627	—	2.7	M1-5-1827
—	2.7	M1-5-1227	—	2.7	M1-5-1427	—	3.0	M1-5-1630	—	3.0	M1-5-1830
—	3.0	M1-5-1230	—	3.0	M1-5-1430	—	3.5	M1-5-1635	—	3.5	M1-5-1835
—	3.5	M1-5-1235	—	3.5	M1-5-1435	—	4.0	M1-5-1640	—	4.0	M1-5-1840
—	4.0	M1-5-1240	—	4.0	M1-5-1440	—	4.4	M1-5-1644	—	4.4	M1-5-1844
—	—	—	—	4.4	M1-5-1444	—	—	—	—	5.0	M1-5-1850
—	—	—	—	5.0	M1-5-1450	—	—	—	—	6.0	M1-5-1860
—	—	—	—	5.5	M1-5-1455	—	—	—	—	—	—
—	—	—	—	6.0	M1-5-1460	—	—	—	—	—	—
—	—	—	—	6.5	M1-5-1465	—	—	—	—	—	—



Each Kit Contains:



Balloon Mini One® Button



Sterile Gauze



Slip Tip Syringe



Introducer/Stiffener



Bolus Feeding Set



Continuous Feeding Set



Catheter Tip Syringe

Eliminate Pullouts with the AMT Clamp™ Device for Continuous Feeding

Our new Y-Port is made from a special elastomer that helps secure the stepped connector with a “sticky” friction fit.

The new purple color signifies “enteral feeding” to avoid misconnections, and the translucent material aids visualization 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



“We can finally give
Jacob his tummy time”

– Jacob’s mommy



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



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



Capsule Non-Balloon Mini ONE[®] Button

Ideal for patients who don't tolerate balloon buttons.

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® and Mic-Key® balloon device



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

Easy to Insert (Like a balloon device)
+
Long Life (Like a non-balloon device)

Non-deployed bolster for ease of insertion

Deployed bolster

Internal bolster that distends to a smaller profile during placement and removal



Removal tool

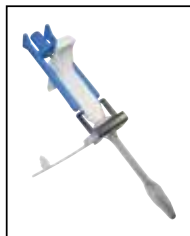
Components of the Capsule Non-Balloon Mini ONE® Button

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.



Non-deployed



Removal tool

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

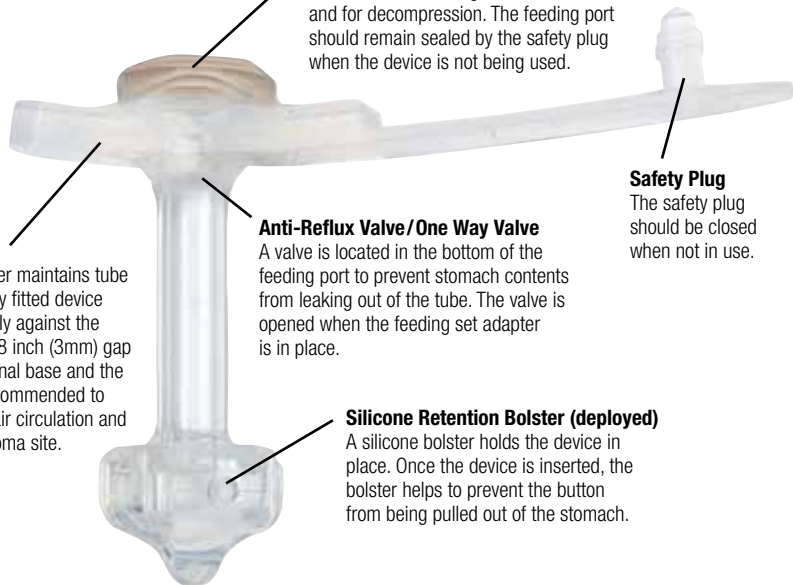
A valve is located in the bottom of the feeding port to prevent stomach contents from leaking out of the tube. The valve is opened when the feeding set adapter is in place.

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.

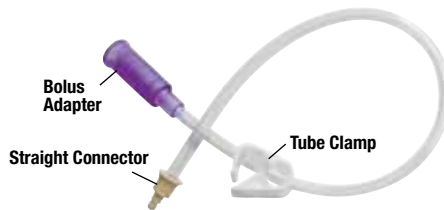


4" x 4" (10 cm x 10 cm) Sterile Gauze

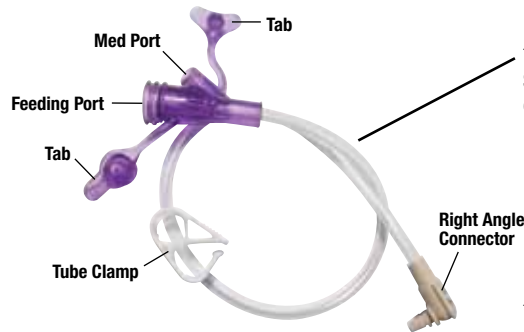
Slip Tip Syringe to administer medications directly into the feeding port.



Removal Tool distends internal bolster for easy removal.



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/overnight 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 46.

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

- Holding the button as shown on page 33, 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 there is no debris blocking the feeding port.

For information on feeding set maintenance, see page 37.

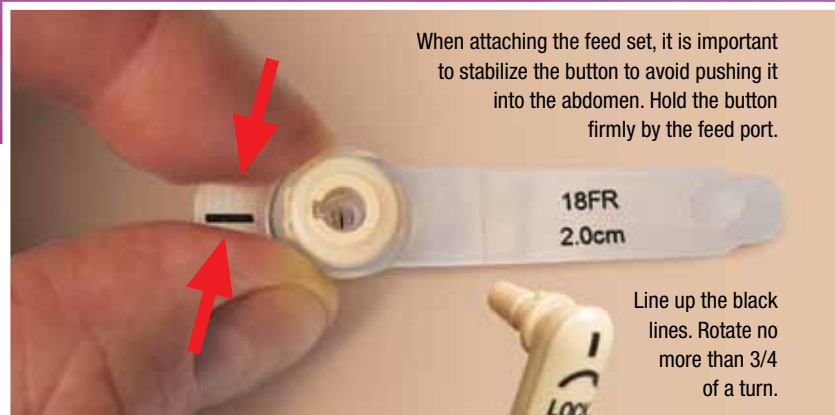


Mic-Key® Feed Set Compatible

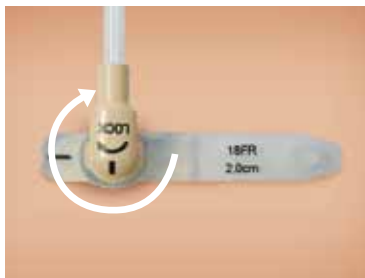
All Mini ONE® products accept either Mini ONE® or Mic-Key® feed sets. See complete list of AMT feeding extension sets on page 46.



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



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 kept with head elevated 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 prescribed amount of formula. Unclamp tube(s) and allow formula to fill tubes to purge the air. Re-clamp tubing.
3. Connect feeding set to Mini ONE Button feeding port.
4. Connect feeding bag tubing to the pump. Adjust pump rate according to the manufacturer's instructions or physician's recommendation. 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, clamp feeding set and disconnect syringe.
6. Rinse syringe and fill it with prescribed amount of water (5ml for children, 10-20ml for adults).
7. Reconnect syringe to feeding set, unclamp and flush feeding set and button with water.
8. 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. Flush feeding set and button with prescribed amount of water (5ml for children, 10-20ml for adults).
7. 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.

- **Rotate 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 (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.



For additional stoma site concerns, see page 44.



Non-Balloon Button Maintenance

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

Feeding Set Maintenance

- Feeding sets and accessories 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 a replacement 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.



Eliminate Pullouts with the AMT Clamp™ Device for Continuous Feeding



Our new Y-Port is made from a special elastomer that helps secure the stepped connector with a “sticky” friction fit.

The new purple color signifies “enteral feeding” to avoid misconnections, and the translucent material aids visualization 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 minimize 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.

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.

**For additional stoma site concerns,
see page 44.**





Decompression (venting the tube)

“Venting” the stomach helps relieve pressure. Attach an open blunt tip syringe to the end of a feeding set port. 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.



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.



The feeding set adapter will open the one way valve to vent stomach.

Device-Related Concerns

For Non-Balloon Buttons

Stomach Contents Leak Around the Tube

Check stomach for residual. If stomach often contains excess residual the patient may be receiving too much formula at one time or the stomach may not be emptying normally, consult a physician.

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 39 for more details.

Preventing Tube Blockage

Flush 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 device.** This will damage the device causing it to become nonfunctional. Make sure the device is in the correct location within the stomach.

Device is Too Tight Against the Patient's Skin

The device should be able to rotate freely without resistance from the patient's skin. If device does not rotate freely or redness/bleeding occurs at the stoma or the area directly underneath the device consult a physician. The patient may need to be re-measured for a longer device.



Device is Pulled Out of the Patient

Although the device is designed to minimize the occurrence of pull out, a device may become accidentally dislodged. Replace the device immediately or consult a physician as the stoma may begin to close within the first hour a device is removed. Refer to page 38.

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.**

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.** Avoidance of soap in the formula is important as well. Consult a physician if condition persists.

Constipation

May occur due to insufficient amounts of water in addition to formula, inactivity, change in formula or medication, or change in feeding routine. Consult a physician if condition persists.

Upset Stomach

May occur if too much formula is administered or if the formula is delivered too quickly. Consult a physician if condition persists.

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 leakage of food or stomach contents.
- 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.

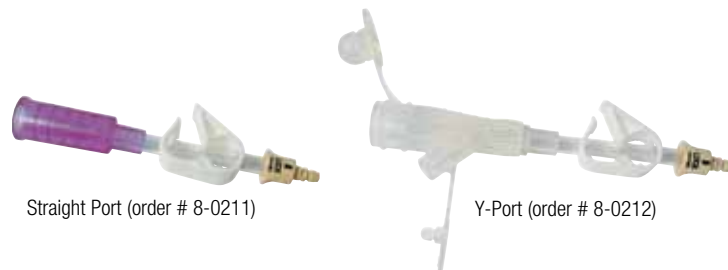
Administering Medications



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 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 ADMINISTRATION.



Straight Port (order # 8-0211)

Y-Port (order # 8-0212)

**See ordering information
on page 46.**

Feeding Sets and Accessories

Mini ONE® Feeding Sets (Mic-Key® Equivalents)

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



Bolus Adapter



Right Angle Connector



Y-Port Adapter (purple)



AMT Clamp™ Device

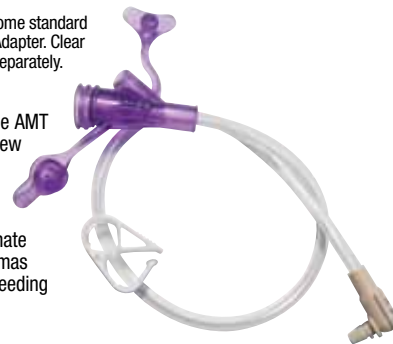


Y-Port Adapter (clear)

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 39.



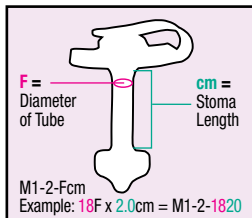
Re-Ordering Information



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:



Balloon Mini One® Button



Sterile Gauze



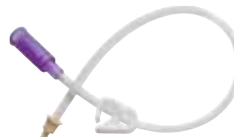
Slip Tip Syringe



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: _____



Balloon Mini ONE® Button Information

Product No.: _____ Lot No.: _____

French Size: _____ Length (cm): _____

Balloon Fill Volume (ml): _____

PLACE STICKER HERE



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: _____

Patient Education Guide

Balloon and Non-Balloon Mini ONE® Buttons

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 — Children with feeding tubes

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-3974-G Made in USA



An ISO 13485 Registered Company 

8000 Katherine Boulevard
Brecksville, OH 44141

Toll-Free: 800-869-7382

E-mail: info@appliedmedical.net

www.appliedmedical.net

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