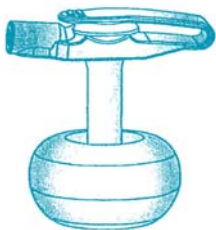


**MINI
ONE™**



BALLOON BUTTON

Mini ONE™ Balloon Button Caregiver's Reference Guide

Toll-free: 800-869-7382

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info@appliedmedical.net

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Notice: Peel off ID sticker from tray and store for future use in patient chart or other convenient location.



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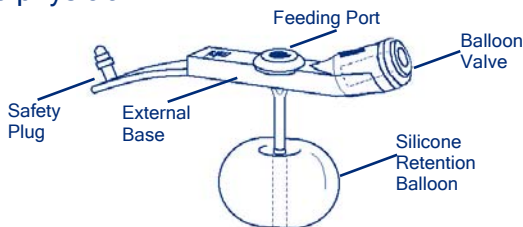
INTRODUCTION TO TUBE FEEDING

Proper nutrition is essential to maintaining our body's 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 & amount of water to most effectively feed each patient.

THE Mini ONE™ BALLOON BUTTON

The Mini ONE™ Balloon Button is a silicone device that is inserted into a gastrostomy to provide direct access to the stomach for feeding, decompression and medication. It has been designed as a low-profile (skin level) feeding device to offer the patient a higher level of comfort and mobility when compared to traditional P.E.G.'s or G-Tubes. The Mini ONE™ Balloon Button's low-profile design allows the patient to be more active and receive the nutrition necessary to maintain health.

To ensure proper use, always follow the instructions provided with the device and prescribed by the physician. Never administer diet formulas or medications through the Mini ONE™ Balloon Button that have not been prescribed by the physician.



External Base

The external base maintains tube position at the patient's skin level. A properly fitted device should not fit tightly against the skin. Instead, a $\frac{1}{8}$ 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

The Mini ONE™ Balloon Button feeding port allows access to the stomach for feeding, administering medications, monitoring stomach residuals and decompression. The feeding port should remain sealed by the safety plug when the device is not being used.

An anti-reflux valve is located in the bottom of the feeding port to prevent stomach contents from leaking out the tube. The valve is opened by the feeding set adapter. *Do NOT* attempt to insert any feeding set other than a Mini ONE™ Balloon Button feeding set into the feeding port.

Silicone Retention Balloon

The Mini ONE™ Balloon Button feeding tube has a balloon located at the end that is inflated inside the stomach to hold the tube in place. Once the Mini ONE™ Balloon Button is inserted, the physician or caregiver fills the balloon with the prescribed amount of distilled water or saline solution. It is recommended to check the balloon volume once a week.

Balloon Valve

The silicone retention balloon is inflated and deflated by inserting a luer tipped syringe into the balloon valve. It should only be used to check or adjust the balloon volume or when replacing the Mini ONE™ Balloon Button. *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.

THE Mini ONE™ BALLOON BUTTON KIT

The Mini ONE™ Balloon Button Kit contains both the Mini ONE™ Balloon Button and one 10ml luer tip syringe used to inflate the silicone balloon through the balloon valve and to administer medications through the med port of the Right Angle Feeding Set, and two 4" x 4" (10cm x 10cm) sterile gauze. The Mini ONE™ Balloon Button is the size and length prescribed by the physician.

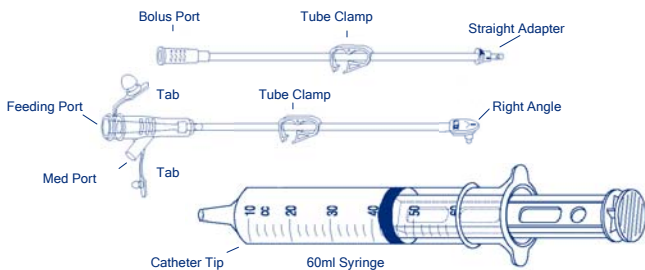
The Kit also includes:

One (1): Bolus Feeding Set with Single Port

One (1): Right Angle Feeding Set w/ Y-Port

One (1): 60ml Catheter Tip Syringe.

(See page 17 for reorder information.)

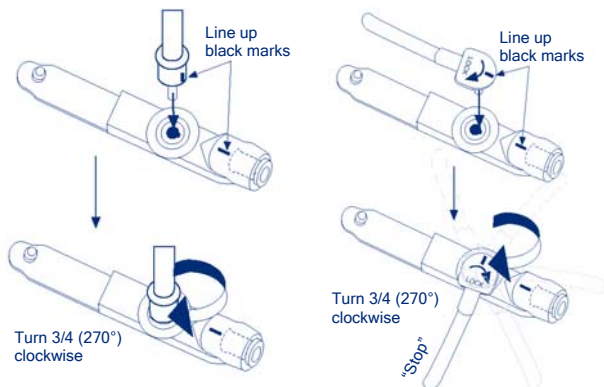


The Bolus Feeding Set is intended for bolus feeding, administering medication, or flushing the Mini ONE™ Balloon Button with warm water. The Right Angle Feeding Set with Y-Port is used for continuous feeding. The 60ml Syringe fits into the bolus port of the Bolus Feeding Set and the feeding port of the Right Angle Feeding Set. It is intended for bolus feeding, administering medications, or flushing the Mini ONE™ Balloon Button with warm water.

FEEDING

Attaching Feed Sets to the Mini ONE™ Balloon Button
Always be sure to wash hands thoroughly before handling feeding devices. To attach a feed set to the Mini ONE™ Balloon Button, line up the black mark on the Feeding Set Adapter with the black

mark on the Mini ONE™ Balloon Button. Make sure the feeding set adapter is pushed in completely and gently turn the adapter $\frac{3}{4}$ turn clockwise to lock the adapter in place. When fully locked, the adapter will stop. *Do NOT* attempt to rotate the adapter past $\frac{3}{4}$ 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.



Proper Mini ONE™ Balloon Button Placement & Functionality

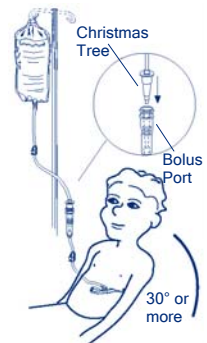
Before feeding through the Mini ONE™ Balloon Button, it is important to verify proper placement inside the stomach as well as the functionality of the device. First, connect the extension set that will be used for feeding. Draw 10ml of water into the catheter tip syringe and attach it to the extension set. Pull back on the plunger until stomach fluid (normally yellow or clear unless there is food in the stomach) is observed in the tube. Flush the stomach contents from the device with the water in the syringe. If stomach contents are not observed or if contents cannot be extracted from or injected into the stomach, reposition the patient and try again. Contact the physician if trouble persists.

Bolus Feeding

Bolus feeding can be done using either the 60ml

catheter tip syringe or a gravity drip bag. Both methods are outlined below.

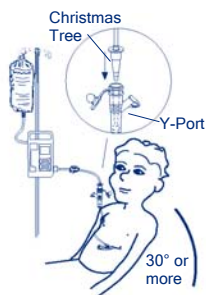
1. Attach a 60ml water filled catheter tip syringe to the Bolus Port. Unclamp the tube and flush with water to prime it. Re-clamp the tube after priming.
2. Remove the Safety Plug from the Mini ONE™ Balloon Button Feeding Port and attach the Bolus Feeding Set as described above.
3. Disconnect the syringe and remove the syringe plunger. Reconnect the syringe once the syringe plunger has been removed.
4. Slowly pour the formula into the syringe and unclamp the feeding tube. Keep the syringe filled until all the formula has been poured out to prevent air from entering the stomach.
5. When the syringe is nearly empty, add the prescribed amount of water.
6. Once the formula and water have been administered, clamp the feeding tube and disconnect the syringe. Reinsert the syringe plunger and fill the syringe with 5ml warm water (10-20ml for adults).
7. Reconnect the syringe and unclamp the feeding tube. Flush the tube with water until it is clear of formula. Proceed to Step 14.
8. To bolus feed with a gravity bag, slip the Christmas tree adapter of the gravity bag into the bolus port of the feed set.
9. Fill the bag with the prescribed amount of formula and purge the air from the tubes by opening the Bolus Feeding Set clamp and allowing formula to flow. If the gravity bag tube has a clamp make sure it is open as well. Close the Bolus Feeding Set clamp when the formula reaches the straight feeding adapter.



10. Attach the Bolus Feeding Set to the Mini ONE™ Balloon Button feeding port as described in *Attaching Feeding Sets to the Mini ONE™ Balloon Button*.
11. Open the clamp & adjust the drip rate of the formula by adjusting the clamp pressure.
12. When the gravity bag is nearly empty, add the prescribed amount of water to the bag.
13. Once the formula and water have been administered, clamp the feeding tube and disconnect the gravity bag. Fill the catheter tip syringe with 5ml warm water (10-20ml for adults). Connect the syringe to the Bolus Port, unclamp the tube, and flush with water until it is clear.
14. Disconnect the Bolus Feeding Set by rotating the adapter *Counter-Clockwise*. Insert the Mini ONE™ Balloon Button safety plug into the feeding port. Wash the feeding set with warm water and soap. Clean the Mini ONE™ Balloon Button and surrounding area if spillage occurred.
15. It is recommended that the patient be kept with head elevated for at least 30 minutes after feeding.

Continuous Feeding

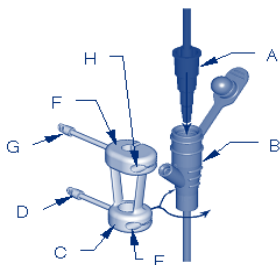
1. Fill the feeding bag with the prescribed amount of formula.
2. Slip the Christmas tree adapter of the feeding bag tube into the feeding port of the Right Angle Feeding Set. To prevent accidental disconnects install the AMT Clamp (see next section). Purge the air from the tubes by opening the Right Angle Feeding Set clamp and allowing formula to flow. If the feeding bag tube has a clamp make sure it is open. Close the Right Angle Feeding Set clamp



- when the formula reaches the right angle adapter.
3. Remove the safety plug from the feeding port and attach the Right Angle Feeding Set as described in *Attaching Feeding Sets to the Mini ONE™ Balloon Button*.
 4. Adjust the pump rate according to the manufacturer's instructions. Unclamp the Right Angle Feeding Tube & begin feeding.
 5. When the feeding bag is nearly empty, add the prescribed amount of water to the feeding bag.
 6. Once the formula and water have been administered, stop the pump, clamp the feeding tube and disconnect the feeding bag. Fill the catheter tip syringe with 5ml warm water (10-20ml for adults). Connect the syringe to the feeding port, unclamp the tube, and flush with water until it is clear.
 7. Disconnect the Right Angle Feeding Set by rotating the adapter *Counter-Clockwise*. Insert the Mini ONE™ Balloon Button safety plug into the feeding port. Wash the feeding set & feeding bag thoroughly with warm water and soap. Clean the Mini ONE™ Balloon Button and surrounding area if spillage occurred.
 8. It is recommended that the patient be kept with head elevated for at least 30 minutes after feeding.

Using the AMT Clamp for Continuous Feeding

The AMT Clamp is a silicone device used to prevent disconnects between Christmas tree adapters and feeding devices during continuous feeding. Disconnects prevent the patient from receiving essential nutrients and require the caregiver to clean up lost formula. The AMT Clamp can eliminate these problems.



To place the AMT Clamp:

1. Make sure the Christmas tree adapter (A) and the feeding set / G-tube (B) are connected securely per original manufacturer's directions.
2. Place the small bottom ring of the AMT Clamp (C) around the base of the feeding set / G-tube (B) just *below* the side port.
3. Secure the wrap-strap (D) around the bottom ring of the AMT Clamp by tucking the strap into the slot and placing the tab into pocket (E).
4. Stretch the main straps so the large top ring (F) is above the Christmas tree adapter (A) and snap the top ring around the tubing.
5. Secure the wrap-strap (G) around the top ring of the AMT Clamp by tucking the strap into the slot and placing the tab into pocket (H).
6. Ensure your feed set connection and AMT Clamp is not bent and all parts appear to be in their proper places before you begin enteral feeding.

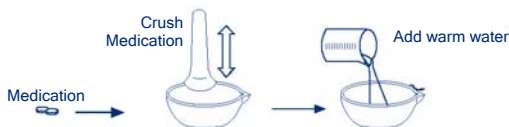


The AMT Clamp part number is 4-3000. For ordering information please call 800.869.7382

Administering Medications

Medications can be administered through the Mini ONE™ Balloon Button in liquid form. Diluting thick liquid medications, when possible, helps prevent the Mini ONE™ Balloon 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, Applied Medical Technology offers a 2" (5 cm) Bolus Medication Set with Straight Port (8-0211) as well as a 2" (5 cm) Bolus Medication Set with Y-Port (8-0212). Medication may also be administered into the interlock with the luer slip syringe provided in the Mini ONE™ Balloon Kit. Flush with water thoroughly after administration.

Monitoring Residuals and Decompression

The Mini ONE™ Balloon Button does not require special decompression tubes for monitoring residuals and decompression. Instead, monitoring residuals and decompression can be easily performed using either the Bolus or Right Angle Feeding Set. Attach either feeding set to the Mini ONE™ Balloon Button feeding port and the catheter tip syringe to either the bolus port or feeding port depending on the feeding set used. Draw back on the syringe to monitor the residual or to decompress the stomach. When monitoring residual, return the residual to the stomach to ensure that the patient receives the proper nutrients.

PATIENT CARE INSTRUCTIONS and Mini ONE™ BALLOON 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. Use a cotton swab or terry cloth to clean the skin underneath the Mini ONE™ Balloon Button (wait at least two weeks for initial placements). Rotate the Mini ONE™ Balloon Button daily stopping at a different point each time to allow for air circulation.



Patients fitted with the Mini ONE™ Balloon Button are allowed to bathe (make sure the safety plug is in place). A good time for routine cleaning of the Mini ONE™ Balloon 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.

Mini ONE™ Balloon Button Maintenance

Routine maintenance is recommended for the Mini ONE™ Balloon Button. Aspirate all the water or saline solution from the balloon by inserting the 10ml luer tip syringe into the balloon port and drawing back on the piston, and replace with the

original prescribed amount of distilled water or saline solution as often as recommended by the physician. Check the balloon fill volume weekly and adjust according to

**Mini ONE™ Balloon Button
Fill Volume Table**

French Size	Min.	Rec.	Max.
12Fr.	2.5ml	3ml	4ml
14Fr.	4ml	6ml	8ml
16Fr.	4ml	6ml	10ml
18Fr.	6ml	8ml	10ml
20-24 Fr.	7ml	10ml	15ml

the prescribed amount as necessary. Frequent refilling of the balloon is an indication of diminished device performance and should be replaced.

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.

REPLACING THE Mini ONE™ BALLOON BUTTON

The physician will recommend when to replace the Mini ONE™ Balloon Button (unless failure occurs). Check the Information Card located on the inside back cover of this guide for the recommended replacement date.

The stoma site may begin to close within the first hour after a device has been removed. Always be sure to have a replacement Mini ONE™ Balloon Button on hand for immediate replacement.

Mini ONE™ Balloon Button Replacement

1. Inspect the Mini ONE™ Balloon Button Kit for damage. Do not use if sterile seal is broken or if contents are damaged.
2. Inflate the new Mini ONE™ Balloon Button Retention Balloon to the recommended fill volume with distilled water or saline solution.
3. Remove the syringe from the balloon port and inspect the balloon and port for signs of leakage. *Do NOT* squeeze the inflated balloon. Deflate the balloon after inspection.
4. Lubricate the patient's stoma tract with a water soluble lubricant. Apply the lubricant to the site and then move the Mini ONE™ Balloon Button up and down and rotate.
5. Deflate the retention balloon by inserting the luer tip syringe into the balloon port and withdrawing the water or saline solution.
6. Gently remove the device from the stoma site with slow, steady pressure.
7. Lubricate the tip of the replacement Mini ONE™ Balloon Button with a water soluble lubricant. **DO NOT USE OILS OR PETROLEUM JELLY AS A LUBRICANT.**
8. Gently guide the tube through the stoma to the stomach, stopping when the External Base reaches the patient's skin.
9. Hold the Mini ONE™ Balloon Button in place and inflate the balloon to the prescribed fill volume with distilled water or saline solution. *Do NOT inflate the balloon with air.*
10. Gently pull up on the Mini ONE™ Balloon Button to make sure the balloon is filled and to position the balloon against the stomach wall. Stop when resistance is observed.
11. Clean the stoma site to remove any excess lubricant.

12. Ensure that the tube is positioned properly by attaching a feed set and listening for air or aspirating stomach contents with the catheter tip syringe.
13. Monitor for leakage around the stoma site. If leakage is observed add an additional 1ml of distilled water or saline solution until the leaking stops. *Do NOT* exceed the balloon's maximum fill volume.

DEVICE-RELATED CONCERNS

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. For continuous feeding, decrease the rate of flow.

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 by inserting a luer tip syringe in the balloon port and withdrawing the fluid from the balloon. Take care not to pull the device from the patient's stoma while the balloon is deflated. Note the volume in the syringe and compare it to the prescribed volume. If the actual volume is less than the prescribed volume, re-inflate the balloon with water to the prescribed volume and repeat the test after 10 to 20 minutes. If the balloon remains inflated, gradually inflate the balloon by 1ml increments until stoma leakage stops. Do not inflate the balloon past its maximum fill volume. The device should rotate freely to avoid erosion of the gastric wall.

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 and firm up around the tube. If leaking persists contact your health-care provider.

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.

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.

Preventing Tube Blockage

Flush tube with 5ml (10-20ml 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.

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 luer 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.

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, occasionally a disoriented patient may pull the device out from the stoma. Consult a physician in the occurrence of device pull out.

PATIENT-RELATED CONCERNS

Vomiting

Aspiration (inhalation of food or stomach contents into the patient's 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.

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 require feedings more often with less formula. Always keep a child hydrated; especially in warm weather or if the child has a fever.

Although a child may receive food through the Mini ONE™ Balloon Button, it is important to include the child in group meals at the table so the child learns about food. Encourage the child to experience the food by tasting and feeling it.

Mini ONE™ BALLOON BUTTON ACCESSORIES For ordering information call 800-869-7382

Part #	Description
8-0211	2" (5 cm) Bolus Medication Set with Straight Port
8-0212	2" (5 cm) Bolus Medication Set with Y-Port
8-1211	12" (30 cm) Bolus Feeding Set with Straight Port
8-2411	24" (60 cm) Bolus Feeding Set with Straight Port
8-1212	12" (30 cm) Bolus Feeding Set with Y-Port
8-1221	12" (30 cm) Right Angle Feeding Set w/ Strt Port
8-2421	24" (60 cm) Right Angle Feeding Set w/ Strt Port
8-1222	12" (30 cm) Right Angle Feeding Set with Y-Port
8-2422	24" (60 cm) Right Angle Feeding Set with Y-Port
8-1223	12" (30 cm) Right Angle Feeding Set w/ Luer Lock
8-2423	24" (60 cm) Right Angle Feeding Set w/ Luer Lock
4-3000	AMT Clamp
1704	Balloon Stoma Measuring Device

GLOSSARY

ASPIRATION: Accidentally inhaling liquid into the windpipe and/or lungs.

BOLUS FEEDING: Large amounts of formula delivered through the tube during a relatively short amount of time.

CONSTIPATION: Bowel movements (stools) sometimes painful, and difficult to pass.

CONTINUOUS FEEDING: Small amounts of formula delivered constantly throughout the day (or night) without interruption.

DIARRHEA: Frequent, loose, watery bowel movements.

ESOPHAGUS: The passage in the throat through which food passes from the mouth into the stomach.

FEEDING PUMP: A small machine, plug-in or battery powered, that automatically controls the amount of formula being delivered through the feeding tube.

FEEDING SET: Tubing that connects the feeding container to the feeding tube. Both Continuous and Bolus Extension Sets are feeding sets.

FEEDING TUBE: Tube through which formula flows into the stomach or intestine. Gastrostomy or jejunostomy tubes.

G-TUBE: Gastrostomy tube. A tube that passes through the skin into the stomach.

GASTRO ESOPHAGEAL REFLUX: Backing up of formula or gastric juice from the stomach into the esophagus.

GASTROINTESTINAL DECOMPRESSION: The removal of gas or fluid from the stomach. Also called venting.

GASTROSTOMY: A surgical opening (stoma) through the skin into the stomach.

GRANULATION TISSUE: Fleishy projections formed on the surface of the stoma that will later form fibrous scar tissue.

GRAVITY DRIP: Formula flows into the feeding set and stomach by gravity.

INTERMITTENT FEEDING: Feeding smaller amounts of formula frequently during the day or night. Intermittent feeding supplements nighttime continuous feeding.

NUTRIENTS: Food or any substance that nourishes the body; protein, carbohydrates, fat, vitamins, minerals, and water.

P.E.G.: Percutaneous Endoscopic Gastrostomy

STOMA: Surgical opening through which feeding tube can enter the body.

STOMACH RESIDUAL: Contents of the last feeding remaining in the stomach just before the next feeding is to be given.

INFORMATION CARD

Patient Information:

Patient Name: _____

Physician Name: _____

Placement Date: _____

Replacement Date: _____

Mini ONE™ Balloon Button Information:

French Size: _____ Length (cm): _____

Balloon Fill Volume (ml): _____

Product No.: _____ Lot No.: _____

Formula:

Type of Formula: _____

Additional Ingredients: _____

Feeding Schedule: _____

Amount per Feeding: _____

Type of Feeding:

Bolus: Y / N

Water to prime tube before feeding (ml): _____

Length of Feeding (minutes): _____

Additional Water (ml): _____

Continuous: Y / N

Flow Rate (formula/hour): _____

Additional Water (ml): _____

Special Instructions:

Contact Information:

Physician: _____ Phone: _____

HCP: _____ Phone: _____

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Email: info@appliedmedical.net Web: www.appliedmedical.net
Patent Nos. - 6,019,746 & 418,220 + other patents pending



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