Australian Patient Information Leaflet

AMT Balloon G-Tube

Balloon G-Tube Replacement Gastrostomy Feeding Device

AMT has provided the following information as an educational resource tool. This is not intended as a substitute for professional medical care. Your FIRST source of information should be your healthcare provider.

Name/Model of the Device: AMT Balloon G-Tube

Intended Purpose: The AMT Balloon G-Tube is to be used as a percutaneous replacement gastrostomy tube for a patient with a well-established gastrostomy tract. This device will assist in providing nutrition directly into the stomach through an established stoma in a human patient who is unable to consume nutrition by conventional means. The AMT Balloon G-Tube can also deliver medication and allow for decompression of the stomach.

Kind of patient on whom the device is intended to be used: The Balloon G-Tube is intended to be used by elderly, adult, adolescent, child and infant patients.

Any special operating instructions for use of the device:

- Cleaning: The stoma site should be kept clean and dry at all times. It is important to clean the stoma site daily. Use a cotton swab or terry cloth to clean the skin around the G-tube with mild soap and water, or as directed by your doctor.
- Circulation: Turn the G-tube daily, stopping at different points each time to allow for air circulation.
- Bath Time: Patients fitted with a G-tube are allowed to bathe and swim (make sure the safety plug is in place). A good time for routine cleaning of the G-tube and stoma site is during a bath.
- After Cleaning: 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 your doctor.
- 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 stoma site remeasured. You may need a longer/shorter replacement device.

Any undesirable side effect that could be caused by the use of the device: Potential complications when using the AMT Balloon G-Tube include but are not limited to: Aspiration ● Abscess, wound infection and skin breakdown ● Hypergranulation tissue ● Buried bumper syndrome ● Pressure necrosis ● Gastrointestinal bleeding and/or ulcerations ● Ileus or gastroparesis ● Intraperitoneal leakage ● Bowel and gastric volvulus ● Peritonitis ● Gastrocolic fistula ●Sepsis ● Obstruction

Any residual risks that could arise due to any shortcomings of the protection measures:
Lack of adherence of the stomach to the abdominal wall, lack of a well established gastrostomy site, stoma irritation, evidence of infection, presence of multiple fistulous tracts, uncertainty as to gastrostomy tract direction, or evidence of tissue granulation. The product must NEVER be used in the vasculature.
Notice:
• Please contact a professional health care giver or physician for explanation of the warnings, care, and use of the device.
• This device has been designed to provide feeding/medication/decompression access into the stomach. Other applications not advised.

Warnings about risks that could arise from the interaction of the device with other equipment:

- Warning: This device has the potential to misconnect with small bore connectors of other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for not enteral applications.
- Warning: Ensure device is connected to an enteral port only and not to an IV set.
- Do not use excessive force to flush the tube. Excessive force can perforate the tube and can cause injury to the gastrointestinal tract. Use a 30 to 60 ml catheter tip syringe. Do not use smaller size syringes as this can increase pressure on the tube and potentially rupture smaller tubes

Precautions and other measures that, because of those risks, should be taken by the patient or a health professional.
The AMT Balloon G-Tube is designed for placement in a well-established gastrostomy site with no evidence of infection, fistulous tracts, or separation of the gastric wall from the fistulous tract. A thorough understanding of the technical principles, clinical applications, and risks associated with gastrostomy tube replacement is necessary before using this product. It is recommended that the AMT Balloon G-Tube French size selected be similar in size to the device being removed (unless otherwise indicated by a physician).
Device Placement:

- Note: The AMT Balloon G-Tube French size selected should be similar in size to the device being removed (unless otherwise indicated by a physician).
- Note: If the balloon is asymmetrical, gently roll it between your fingers or your hands until the balloon frees itself and is symmetrical
- The device is provided as sterile, for Single Patient Use. The patient or health care giver should be made aware of notes, warnings, precautions, care instructions, and information regarding this device. Inspect the package for any breach to ensure a sterile product. If the seal appears breached or there is apparent damage, do not use, and obtain another kit.

- Remove the AMT Balloon G-Tube from the package and inspect for any visible defects. If defects are observed, do not use device. Obtain another package.
- Warning: Do not use oil or petroleum based lubricant.
- Warning: When guiding into the tract, if any resistance is experienced, do not use excessive force to avoid damaging the tract or gastric wall.
- Warning: Never use air to fill balloon.
- Note: It may be necessary to adjust the balloon volume to prevent leakage of gastric contents based on the individual patient needs.
- Warning: Creating too snug a fit may cause embedding with erosion into the gastric wall, resulting in tissue necrosis, infection, peritonitis, sepsis and associated sequelae. The external bolster should not be sutured into place.
- Warning: Do not exceed maximum balloon fill volume.

Fill Volumes		
French Size	Recommended Fill	Maximum Fill
12F	2-2.5 ml	3 ml
14F	3-4 ml	5 ml
16F	4-6 ml	8 ml
18F	6-8 ml	10 ml
20-24F	7-10 ml	15 ml

Placement verification:

1. Aspirate though the Feeding Port for gastric contents. Return of gastric contents should occur. If gastric contents are not present, attach a large catheter tip syringe (attach a transition adapter or ENFit® syringe for certain configurations) to the AMT G-Tube Feeding Port and irrigate with 10 ml of water. Aspirate for gastric contents.
2. Radiographic examination (X-Ray) may be performed to evaluate for location of the internal bolster (balloon).
3. A flexible guidewire may be temporarily placed in the center of the device to further facilitate radiographic examination.
4. Fiber optic exam may be performed through the Feeding Port using a 3 mm Endoscope.
5. After air and/or gastric contents are observed, flush with water.

WARNING: NEVER INJECT AIR INTO THE AMT BALLOON G-TUBE FEEDING PORT OR BALLOON FILL-VALVE.
When placement is confirmed, gastric decompression or feeding administration can begin through the Feeding Port. Refer to the
manufacturer's Directions For Use for the feeding and/or medication attachments used.

Removal of the **AMT Balloon G-Tube**:

- Note: Removal should only be completed by a healthcare professional or if you have been trained by a professional to remove the device.
- WARNING: After removal, the device may be a potential biohazard. The removed device should be handled and disposed of according to your local, state, and federal laws and regulations. Your healthcare professional may be able to advise the most acceptable method of disposal.

- NOTE: Spontaneous closure of the stoma may occur as early as twenty-four (24) hours after removal. Insert a new AMT Balloon G-Tube if feeding by this route is still intended as prescribed.
- WARNING: Do NOT cut off the internal bolster or tubing, or allow to pass through the intestinal tract.

Tube Care Instructions

- CAUTION: Tubing should be monitored for possible inward migration or unintentional extubation.
- Warning: never inject air into the G-Tube.
- Warning: Tube migration could result in the following: obstruction, inability to feed, peritonitis, infection and associated sequelae.
- Warning: In case of fever, gastric distention, infection, blockage, or tissue necrosis, patients should see their physician immediately.

Medication/Nutrition Administration:

- Warning: this device has the potential to misconnect with small bore connectors or other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for not enteral applications.
- Warning: Only tighten by hand. Never use excessive force or a tool to tighten a rotating connector. Improper use can lead to cracking, leakage, or other failure.
- Warning: Ensure device is connected to an enteral port only and not to an IV Set.
- Caution: Medication should be administered separately from feeding, one dose at a time.
- Using a catheter tip or ENFit® syringe flush the tube with the prescribed amount of water

Unclogging a device:

- Do not use excessive force to flush the tube. Excessive force can perforate the tube and can cause injury to the gastrointestinal tract. Use a 30 to 60 ml catheter tip syringe. Do not use smaller size syringes as this can increase pressure on the tube and potentially rupture smaller tubes
- CAUTION: Do not use excessive force or pressure to attempt to clear the clog. This can cause the tubing to rupture.

The nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken:

Exact device longevity cannot be predicted. Device performance and functionality can degrade over time depending on usage and environmental conditions. Typical device longevity will vary for each patient depending on a number of factors, with typical device longevity ranging from 1-9 months. Some factors that can lead to reduced longevity include: gastric pH, diet of the patient, medications, balloon fill volume, trauma to the device, contact with sharp or abrasive objects, and overall tube care.

For optimal performance, it is recommended that AMT Balloon G-Tube device be changed at least every 3 months or as often as indicated by your healthcare professional. Proactive replacement of the device will help ensure optimal functionality and will help prevent unexpected device failure. If devices are failing or performance is degrading earlier than the typical range for device longevity, it is recommended that you speak with your healthcare professional regarding eliminating common factors that can lead to early device degradation.

NOTE: To help prevent unneeded hospital visits, it is recommended that a spare device is kept on hand at all times for replacement in case device failure occurs prior to scheduled replacement.

Symptoms that could indicate that the device is malfunctioning:
Aspiration ● Abscess, wound infection and skin breakdown ● Hypergranulation tissue ● Buried bumper syndrome ● Pressure necrosis ● Gastrointestinal bleeding and/or ulcerations ● Ileus or gastroparesis ● Intraperitoneal leakage ● Bowel and gastric volvulus ● Peritonitis ● Gastrocolic fistula ●Sepsis ● Obstruction

Precautions and other measures that should be taken by the patient if the performance of the device change or the patient experiences any of the symptoms mentioned above

Leakage around the device:

• Make sure the balloon is filled to the prescribed volume. Resistance should be felt when gently pulling on the tube.
• Check that the G-tube corresponds to the prescribed French (F) size and stoma length (cm). If the incorrect device is in place, call your doctor.
• The G-tube may be too tight or too loose. Call your doctor to have the stoma remeasured.
• For new placements, it may take time for the stoma tract to naturally heal, firm up around the tube, and conform to the balloon. If leaking persists contact your healthcare provider.

Causes for Leakage:

• Incorrect size
• Weight change (increase or decrease)
• Volume of water in balloon (high or low)
• Tension at the stoma site (from extension or feeding sets)
• Stomach may need to be decompressed

Balloon Failure:

A balloon may leak or burst over time due to medications, balloon inflation volume, stomach acid, G-tube care, or natural wear. Always keep an extra G-tube on hand in case of an incident.
Prior to any device change, consult your doctor first. Do NOT remove the G-tube until a replacement device 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 balloon port. Insert a slip tip syringe, push and twist one-quarter turn, and pull back on the plunger. If the problem persists call your doctor.

Stomach Contents Leak Around the Tube:

Check stomach for residual (the gastric fluid and formula left within the stomach cavity between feeds). If excessive residual occurs often it may be caused by:

• The patient may be receiving too much formula at a time
• The stomach may not be emptying normally
• The G-tube may be too loose or too tight, call your doctor to have the stoma remeasured

Feeding Tube Becomes Disconnected:

Stop the feeding pump and, if possible, estimate the amount of formula lost. Wipe tube connections thoroughly with soap and water. Clean the inside of the feed port with a cotton swab, soap, and water. Dry the connectors and then reconnect feed set to the G-tube. Add the estimated lost formula and resume feeding.

Preventing Tube Blockage:
Flush the G-tube with 5 ml (10-20 ml for adults) warm water before and after administering food or medicine, after 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; doing so may cause damage or malfunction.
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 the G-tube does not turn easily, or redness or bleeding occurs, 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 internal balloon or bolster is designed to decrease the number of pullouts, G-tubes can accidentally become dislodged. If this happens, replace the device immediately or call your doctor. STOMA SITES MAY BEGIN TO CLOSE WITHIN THE FIRST HOUR AFTER A DEVICE IS REMOVED. Refer to the device Directions for Use and always be sure to have a replacement G-tube on hand for immediate replacement.
Vomiting:
Aspiration (inhalation of food or stomach contents into the lungs) may occur while vomiting, causing difficulty in breathing or other serious medical conditions. Stop feeding and decompress the stomach immediately if this occurs.
Diarrhea:
Diarrhea may occur if formula is spoiled or delivered too quickly. Mix new formula before each feeding. Deliver formula at a slower rate. All caregivers should wash their hands thoroughly prior to preparing the formula and handling the feeding sets. After washing, ensure the feeding sets are rinsed thoroughly to avoid soap in the formula. Call your doctor if diarrhea continues.
Constipation or Upset Stomach:
Constipation or upset stomach may occur due to insufficient amounts of water in addition to: formula, inactivity, a change in formula or medication, or a change in feeding routine. Upset stomach may occur if too much formula is administered or if the formula is delivered too quickly. Call your doctor if constipation or upset stomach continues.

Contact emergency care immediately if difficulty in breathing occurs or aspiration is suspected. Do not feed the stomach while the patient is laying flat.

The expected device lifetime, anything that could shorten or lengthen the device lifetime, precautions and other measures that should be taken at, or near, the end of the expected device lifetime:
Exact device longevity cannot be predicted. Device performance and functionality can degrade over time depending on usage and environmental conditions. Typical device longevity will vary for each patient depending on a number of factors, with typical device longevity ranging from 1-9 months. Some factors that can lead to reduced longevity include: gastric pH, diet of the patient, medications, balloon fill volume, trauma to the device, contact with sharp or abrasive objects, and overall tube care.
For optimal performance, it is recommended that AMT Balloon G-Tube device be changed at least every 3 months or as often as indicated by your healthcare professional. Proactive replacement of the device will help ensure optimal functionality and will help prevent unexpected device failure. If devices are failing or performance is degrading earlier than the typical range for device longevity, it is recommended

that you speak with your healthcare professional regarding eliminating common factors that can lead to early device degradation.
NOTE: To help prevent unneeded hospital visits, it is recommended that a spare device is kept on hand at all times for replacement in case device failure occurs prior to scheduled replacement.

Other circumstances in which the patient should contact a health professional in relation to the operation of this device:
Nausea, vomiting, abdominal bloating, or diarrhea ● Pain, bleeding, and/or inflammation at the G-tube site ● Crusting at the stoma site ● Skin around the stoma site that is red, discolored, or raw ● Stoma site drainage and/or puss that is white, yellow, or green and may smell bad ● Repetitive leakage of food or stomach contents ● Distended stomach ● Fever ● Tube clog ● Migration of the tubing resulting in the device extending longer or shorter from the stoma ● Extubation resulting in the device becoming removed from the stoma and unable to be replaced easily ● Distinct indentation at the G-tube site or a distinct gap between the device and skin ● Large amount of tissue build up, such as granulation tissue ● Swollen skin or tissue at the stoma site ●Leakage, the G-tube may be too loose or too tight and should be remeasured

- Warning: In case of fever, gastric distention, infection, blockage, or tissue necrosis, patients should see their physician immediately.

The materials and substances included in the device:
The materials of the **AMT Balloon G-Tube** include the following: Medical-grade silicone, medical-grade thermoplastic.
The materials of the ENFit® Adapter include the following: Medical-grade thermoplastic.

Any manufacturing residuals that could pose a risk to the patient: There are no manufacturing residuals used that could pose a risk to the patient.

MRI Safety Information
MR Safe

Notice that any serious incident that occurs in relation of the AMT Balloon G-Tube should be reported to Applied Medical Technology, Inc. and The Therapeutic Goods Administration (TGA):

Applied Medical Technology, Inc.
8006 Katherine Blvd | Brecksville, OH 44141
Call: +1 800 869 7382
Fax: +1 440 717 4200
Email International: ICS@AppliedMedical.Net

Therapeutic Goods Administration (TGA)
https://www.tga.gov.au/reporting-problems

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AMT Family

800 869 7382 | CS@AppliedMedical.net | ICS@AppliedMedical.net
www.AppliedMedical.net

Applied Medical Technology, Inc.
8006 Katherine Boulevard
Brecksville, OH 44141
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