Australian Patient Information Leaflet

MiniONE® Non-Balloon Button

Low Profile 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: MiniONE® Non-Balloon Button

Intended Purpose: The Low Profile Non-Balloon Feeding Device is indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma.

Kind or patient on whom the device is intended to be used: The AMT MiniONE® Non-Balloon Button is intended to be used by elderly, adult, adolescent, child and infant patients. The device aids patients with a wide array of medical conditions which cause inability to maintain an adequate nutritional state.

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 with mild soap and water or as directed by your physician. Use a cotton swab or terry cloth to clean the skin underneath the MiniONE® Non-Balloon Button as directed by your doctor.
- Circulation: Turn/Rotate the **MiniONE® Non-Balloon Button** daily, stopping at a different position each time to allow for air circulation.

- Bath Time: Patients fitted with the MiniONE® Non-Balloon Button are allowed to bathe and swim (make sure the safety plug is in place). A good time for routine cleaning of the MiniONE® Non-Balloon Button is during a bath.
- After cleaning: Always allow the stoma site to air dry after cleaning.
- Inspect: Always check the stoma site for redness, pain/soreness, swelling, or any drainage. If any of these signs or symptoms are observed, contact your doctor for advice.
- Gauze or pads are not necessary. If there is leakage, the G-Tube may be too loose or too tight and should be remeasured. Call your doctor to have the stoma site remeasured.

Any undesirable side effect that could be caused by the use of the device: Potential complications when using the **MiniONE® Non-Balloon Button** include but are not limited to: Nausea, vomiting, abdominal bleeding or diarrhea ● Aspiration ● Peristomal pain ● Abscess, wound infection and skin breakdown ● Pressure necrosis ● Hypergranulation tissue ● Intraperitoneal leakage ● Buried bumper syndrome ● Peristomal leakage ● Tube clog ● Gastrointestinal bleeding and/or ulcerations ● Ileus gastroparesis ● Bowel and gastric volvulus ● Peritonitis ● Gastrocolic fistula ● Sepsis

Any residual risks that could arise due to any shortcomings of the protection measures:
Initial Placement: Colonic interposition ● Ascites ● Portal hypertension ● Peritonitis ● Uncorrected coagulopathy ● Infection around stoma site ● Uncertainty as to gastrostomy tract direction and length (abdominal wall thickness)
Replacement: Lack of adherence of the stomach to the abdominal wall ● Lack of a well-established stoma site ● Evidence of infection ● Uncertainty as to gastrostomy tract direction and length (abdominal wall thickness) ● Presence of multiple stoma fistulous tracts.
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 are not advised

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

- If feeding set is not properly placed and locked, leakage may occur. When twisting the connector hold the button in place to avoid rotation while placing the feeding set.
- This device has the potential to misconnect with small-bore connectors of other healthcare applications. Only use this device to connect to enteral devices. Do not use for non-enteral applications.

Precautions and other measures that, because of those risks, should be taken by the patient or a health professional.
Placement by health professional:

- Warning: Initial placement of the **MiniONE® Button** requires that a gastropexy is performed to affix the stomach wall to the anterior abdominal wall. DO NOT use the internal dome of the device as a gastropexy device. An early device failure may prevent the stomach from attaching to the anterior abdominal wall.
- Caution: It is recommended to perform a three point gastropexy in a triangle configuration to ensure attachment of the gastric wall to the anterior abdominal wall.

- Warning: Allow adequate distance between the insertion site and gastropexy placement to prevent interference with the T-Fastener and internal dome.
- Caution: After the MiniONE® Button is place, do not remove the gastropexy sutures until the stoma site fully heals and the stomach is fully affixed to the anterior abdominal wall.

Replacement by professional or at home by the patient/caregiver:

Measure the stoma length:

- Caution: Selection of the correct size device is critical for safety and comfort of the patient. Measure the length of the patient's stoma with the AMT Balloon Stoma Measuring Device. The shaft length of the selected feeding device should be the same as the length of the stoma. An inappropriately sized feeding device can cause necrosis, buried bumper syndrome and/or Hypergranulation tissue.
- Warning: Under-sizing the device may cause embedding with erosion into the gastric wall, tissue necrosis, infection, sepsis, associated sequelae.

Device Placement:

- Caution: Prior to placement, please inspect all contents of the kit for damage. If the package is damaged or sterile barrier is breached, do not use the product.

Placement verification:

- Warning: Never inject air into the **MiniONE®Button**.

Removal of the **MiniONE®** Button:

- Warning: Spontaneous closure of stoma may occur within twenty-four (24) hours after removal. Insert a new device if enteral feeding by this route is still intended. If closure is desired, apply a dressing over the stoma site. Removal should not take place until the stoma is fully established, which may take two months or more. Removal is recommended to be performed by a qualified clinician.
- Warning: If the tube is resistant to removal, lubricate the stoma site with water-soluble lubricant. Rotate the tube gently and push it in about 2.5 cm. Carefully work the tube free. Never use force to remove the tube.
- Warning: Do not cut off the internal bolster (cut catheter section) to pass through the intestinal tract.

Feeding Set instructions for use:

- 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 non-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 an IV set.
- Warning: If the feeding set is not properly placed and locked, leakage may occur. When twisting the connector hold the button in place to avoid rotation while placing the feeding set.

Unclogging a device:

- Caution: Do not use excessive force or pressure to attempt to clear the clog. This can cause the tubing to rupture.

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

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
A tear has formed: Tears can occur due to contact with a sharp or abrasive object, excessive force, or excessive pressure. Due to the soft, comfortable nature of the material the device is made from, small tears can quickly lead to large tears or device failure. If a tear is noticed on the device, consider replacing device and check for any sources of tension, force, or sharpness that may be leading to the tears occurring.
Anti-reflux valve leakage or blockage: Leakage/blockage of the anti-reflux valve typically occurs due to residue (feed, medication, gastric contents, etc.) becoming stuck in the valve area, preventing the valve from closing. Make sure the device is flushed after each use. Leakage can also be caused due to excessive pressure in stomach. The valve can also become inverted in rare cases. Insert extension set into port to reset valve if this occurs. Avoid excessive pressure during administration through the device, as this can cause a tear in the valve over time.
Tubing has reduced flow or has become clogged: Tubing can become blocked due to not properly flushing after each use, use of thick or improperly crushed medication, use of thick feeds/formulas, gastric reflux, and/or fungus growth. If clogged: First make sure that the tubing is not kinked or clamped anywhere. If there is a visible clog in the tubing, attempt to message the device to break up the clog. Connect a catheter tip syringe to an extension set and attach into the interlock connector. Fill the syringe with warm water and gently push and pull the syringe plunger to free the clog. It may take several cycles of pushing/pulling the plunger to clear the clog. If clog cannot be removed, contact your healthcare professional, as the tube may need to be replaced.
Device fit is too tight or too loose: A device that is not correctly fitted for the stoma site can lead to leakage, embedding with erosion into the gastric wall, tissue necrosis, infection, sepsis and associated sequelae, or device dislodgement. If the device is not fitting properly, it is recommended that the stoma site is measure to ensure the correct device length is being used.
Device is becoming discolored: The device can become discolored over days to months of use. This is normal depending on the types of feeds and medications being used with the device.
Interlock failure or cracked: The interlock has been designed to withstand extreme forces without detaching or cracking. However, the strength of the bond and material can reduce over prolonged use depending on medications and feeds used through the device. Excessive forces over extended period of use can also reduce bond/material strength. The device should be replaced if interlock is found cracked, leaking, or separating from the device.
Foul smell coming from the device: Foul smells can occur due to not properly flushing the device after each use, infection, or other growth forming inside of the device. If a foul smell is noted coming from the device, device should be flushed and stoma site should be gently cleaned with soap and warm water. If foul smell does not go away, it is recommended that you contact your healthcare professional.

Device difficult to remove: Ensure that the correct removal tool length is being used for removal. If removal of the device is not possible using the preferred removal method, traction or endoscopic removal of the device may be necessary.
Device has pulled from stoma: The device may be undersized or excessive force was applied to the device during use. Avoid excessive force while using the device and secure extension set if it is a source of tension. If device length has not been checked recently, resizing the stoma length may be necessary. Device will need to be replaced by a medical professional promptly to avoid closure of the stoma site.
Plug will not stay closed: Ensure that the plug is being firmly and fully pressed into the interlock connector. If plug is not staying closed, check the plug and feed-port area for any excess residue build-up. Clean excess residue build-up with cloth and warm water.

The nature and frequency of regular or preventative examination, monitoring or maintenance of the device that should be undertaken. 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: Low-profile feeding devices are meant to be periodically replaced for optimal performance, functionality and cleanliness. 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 3-9 months. Some factors that can lead to reduced longevity include: gastric pH, diet of the patient, medications, trauma to the device, contact with sharp or abrasive objects, incorrect stoma length measurement, and overall tube care.

For optimal performance, it is recommended that **MiniONE® Non-Balloon Button** devices be changed every 6 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 un-needed 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:

- Skin around the stoma site is red or raw
- Drainage around the stoma site is white, yellow or green; and may smell bad
- Crusting is noted at the stoma site
- Repetitive leakage of food or stomach contents (gauze or pads should not be necessary)
- Leakage, the G-tube may be too loose or too tight and should be remeasured
- The G-Tube falls out and you are unable to replace it easily
- The patient experiences diarrhea or vomiting
- The patient develops a fever
- Pain at G-tube site
- Bleeding, pus or inflammation at the G-tube site

The materials and substances included in the device:
The materials of the **MiniONE® Non-Balloon Button** include the following: Medical-grade silicone, and medical-grade thermoplastic
The materials of the Feeding Set include the following: Medical-grade silicone, Medical-grade PVC (phthalate-free) and 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

The Non-Balloon Button is considered MR Safe once placed in the stoma site when none of the MR Unsafe components are attached.

Components:

The Non-Balloon Button, Placement T-Handle, feeding sets, syringes, and gauze are **MR Safe.**

The Snap Arm Assembly Tool and Removal T-Handle are **MR Unsafe**.

Notice that any serious incident that occurs in relation of the MiniONE® Non-Balloon Button 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

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

Applied Medical Technology, Inc.
8006 Katherine Boulevard
Brecksville, OH 44141
An ISO 13485 Registered Company

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