Australian Patient Information Leaflet

MiniACE® Button

Antegrade Continence Enema

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: MiniACE® Button

Intended Purpose: The Bowel Management Device is intended to instill fluids through a stoma into the colon to promote evacuation of the contents of the lower bowel through the anus and is intended to be an aid in the management of fecal incontinence. The catheter is placed and maintained in a percutaneously prepared opening, such as a cecostomy or appendicostomy. The Bowel Management Device is intended to be used in children and adults.

Kind or patient on whom the device is intended to be used: Children and adults who suffer functional constipation, fecal incontinence, an anorectal malformation, Hirschsprung disease, spina bifida and are not able to maintain fecal incontinence.

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 every day. Use a cotton swab or terry cloth to clean the skin around the C-Tube with mild soap and water, or follow what your provider has advised you to do.
- Circulation: Turn/Rotate the **MiniACE® Button** every day, stopping at a different position each time. Rotating the external bolster of the **MiniACE®** Button promotes a healthy stoma by allowing air to get to the skin.
- Bath Time: Patients fitted with a C-Tube are allowed to bathe and swim. Be sure to close the safety plug before submerging the device in water. Bath time is a good opportunity for regular cleaning of the C-Tube and stoma site.
- After cleaning: Always allow the stoma site to air dry after cleaning.
- Always check the stoma site for redness, pain/soreness, swelling, or any drainage. If you notice any of these signs or symptoms, contact your healthcare provider.
- It is not necessary to use gauze or pads at the stoma site. If there is leaking, the **MiniACE® Button** may be too loose or too tight.

Any undesirable side effect that could be caused by the use of the device: Potential complications when using the **MiniACE® Button** include but are not limited to: Peristomal pain ● Abscess, wound infection and skin breakdown ● Pressure necrosis ● Hypergranulation tissue ● Intraperitoneal leakage ● Buried bumper syndrome ● Peristomal leakage ● Balloon failure or dislodgement ● Tube clog ● Colonic bleeding and/or ulcerations ● Bowel volvulus

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 cecostomy tract direction and length (colon wall thickness)

Replacement:

Lack of adherence of the cecum/appendix/colon to the abdominal wall ● Lack of a well-established cecostomy site ● Evidence of infection ● Uncertainty as to cecostomy tract direction and length (colon 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.
● The **MiniACE® Button** has been designed to provide irrigation access into the colon. Other applications are not advised

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

- If the irrigation set is not properly placed and locked leakage may occur. When twisting the connector hold the **MiniACE® Button** in place to avoid rotations while placing the irrigation set. Do not insert the irrigation set connector into the inflation port. This may cause the internal balloon to deflate or lead to balloon failure if improper contents are inserted into the balloon.
- Leakage can occur due to valve becoming stuck if syringe is inserted too hard into valve.

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 **MiniACE® Button** requires that a procedure is performed to affix the intestinal wall to the anterior abdominal wall. DO NOT use the retaining balloon of the device as an attachment/anchoring device. An Early balloon failure may prevent the intestinal wall from attaching to the anterior abdominal wall.
- Caution: It is recommended to perform a three point anchoring/securement in a triangle configuration to ensure attachment of the intestinal wall to the anterior abdominal wall.

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

- Caution: Selection of the correct size device is critical for safety and comfort of the patient. An inappropriately sized device can cause necrosis, buried bumper syndrome and/or Hypergranulation tissue. If patient size/weight has changed since the device was placed, fit is too tight or too loose, or it has been over six months since the device was last measured, it is

recommended that you speak to your healthcare professional to ensure that device size does not need to be changed.

Measure the stoma length:

- Caution: Selection of the correct size device is critical for safety and comfort of the patient. An inappropriately sized device can cause necrosis, buried bumper syndrome and/or Hypergranulation tissue.
- Warning: Under-sizing the device may cause embedding with erosion into the colon wall, tissue necrosis, infection, sepsis and 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.
- Caution: Do not attempt to replace the device or check for placement verification until first discussing the procedure with your healthcare professional.

Placement verification:

- Warning: Never inject air into the **MiniACE® Button**.
- Warning: Never connect the irrigation set to the balloon inflation port.

Removal of the **MiniACE®** Button:

- Warning: Do not cut off the internal bolster or tubing, or allow to pass through the intestinal tract.

Irrigation 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 irrigation devices.
- 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 irrigation port only and not an IV set.
- Warning: If the irrigation set is not properly placed and locked, leakage may occur. When twisting the connector hold the **MiniACE® Button** in place to avoid rotation while placing the irrigation set. Do not insert irrigation set connector into the balloon inflation port. This may cause the internal balloon to deflate or lead to balloon failure if improper contents are inserted into the balloon.
- Warning: In case of fever, abdominal distention, infection, blockage, or tissue necrosis, patients should see their physician immediately.
- Warning: Do not place any foreign objects into the irrigation port.
- Warning: If using a transition connector, ensure that it is not connected to an IV set prior to use.
- Warning: When using a bolus style irrigation set, this device had the potential to misconnect to breathing system, limb cuff, and neuraxial connectors.

Unclogging a device:

- 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:

Low-profile balloon cecostomy devices are meant to be periodically replaced for optimal performance and functionality. 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 1-6 months. Some factors that can lead to reduced longevity include: intestinal pH, diet of the patient, medications, balloon fill volume, 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 **MiniACE® Button** devices be changed 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 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.

Symptoms that could indicate that the device is malfunctioning:
Peristomal pain ● Abscess, wound infection and skin breakdown ● Pressure necrosis ● Hypergranulation tissue ● Intraperitoneal leakage ● Buried bumper syndrome ● Peristomal leakage ● Balloon failure or dislodgement ● Tube clog ● Colonic bleeding and/or ulcerations ● Bowel volvulus

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.
Leaking of balloon volume: If balloon is deflating, remove balloon from stoma and inflate balloon with recommended fill-volume. Check balloon for leakage by gently messaging tubing and balloon. If no leakage is noted, reinsert balloon back into stoma and re-inflate the balloon to desired fill-volume. Do not exceed maximum fill volume. Only access the balloon inflation port for balloon inflation and deflation. Other uses can result in balloon leakage or device failure.
Note: The balloon is made of semi-permeable material and can lose a small amount of fill-volume over time depending on environment and usage conditions.
Anti-reflux valve leakage or blockage: Leakage/blockage of the anti-reflux valve typically occurs due to residue (irrigation solution, intestinal contents, etc.) becoming stuck in the valve area, preventing the valve from closing. Make sure the device is flushed after each use. The valve can also become inverted in rare cases. Insert extension set into port to reset valve if this occurs.
Tubing has reduced flow or has become clogged: Tubing can become blocked due to not properly flushing after each use, use of thick irrigation solutions, and/or fungus growth. If clogged: First check to make sure that the tube is not kinked or clamped anywhere. If there is a visible clog in the tubing, attempt to massage the device to break up the clog. Connect a catheter tip syringe to an irrigation 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: Balloon fit can be adjusted by adjusting the balloon inflation with the balloon inflation range:

French Size	Min	Rec.	Max	
10F	1 ml	1.5 ml	2 ml	
12F	2 ml	2.5 ml	3 ml	
14F	3 ml	4 ml	5 ml	

Recommended water fill volume is clearly printed on the balloon fill valve of each MiniACE® Button. Consult your healthcare provider before adjusting fill volumes.

If balloon is too loose, increase the balloon fill-valve above recommended but not above the max fill-volume. If balloon is too tight, decrease the fill-volume below recommended but not below the min fill-volume. If device does not properly fit with the fill-volume range, a new device length will be needed.

Balloon is misshaped: Be sure to inflate and inspect balloon prior to placement to check balloon symmetry. Balloons becoming misshaped typically occur due to excessive force or tension on the device (pulling device out of stoma while balloon is inflated). Balloons can be gently messaged with fingers back into symmetry if not excessively misshaped. Devices should be replaced if balloon is found excessively misshaped.

Device is becoming discolored: The device and become discolored over days to months of use. This is normal depending on the types of solutions being used with the device.

Balloon inflation valve leakage: Leakage from the valve typically occurs due to residue in the fill-valve. Always use a clean syringe when inflating the balloon and only inflate water through the valve. Leakage can also occur due to valve becoming suck if syringe is inserted too hard into valve. Insert the syringe into the balloon inflation port if leakage is occurring to attempt reset valve. Several attempts may be necessary before valve resets.

Balloon will not inflate or deflate: Inflation and deflation problems typically occur due to residue blocking the fill-lumen. Always use a clean syringe when inflating the balloon. In some rare occurrences, fungus can grow inside of the tubing and block the fill-lumen. Fungus growth can occur depending on patient environment and irrigation fluid being administered though the device. If balloon will not deflate, contact your healthcare professional for removal. If deflation problem is the result of fungal growth, eliminating source of fungal growth or anti-fungal medication may be required.

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 solutions used through the device. 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.

Balloon Failure: Early balloon failure can occur due to a number of patient or environment factors, including but not limited to: intestinal pH, diet, certain medications, improper balloon fill volume, placement of the device, improperly administering irrigation into the balloon port, trauma, contact with a sharp or abrasive material, incorrect stoma length measurement, and overall care of the device.

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 irrigation-port area for any excess residue build-up with cloth and warm water.

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 balloon cecostomy devices are meant to be periodically replaced for optimal performance and functionality. 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 1-6 months. Some factors that can lead to reduced longevity include: intestinal pH, diet of the patient, medications, balloon fill volume, 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 **MiniACE® Button** devices be changed 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. Also reference the TROUBLESHOOTING section of the instructions for use for additional information regarding device performance issues.
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:

- Fever or vomiting
- Skin around the stoma site is red, discolored or raw
- Drainage around the stoma site is white, yellow or green; drainage may have an unpleasant odor
- Crusting is noted at the stoma site
- Large amount of tissue build up, such as granulation tissue
- Swollen skin or tissue at the stoma site
- Repetitive leakage of stool
- **MiniACE® Button** falls out and you are unable to replace it easily
- Pain at the stoma site
- Bleeding, pus of inflammation at the stoma site
- Distended stomach, a possible indication for an intestinal blockage

The materials and substances included in the device:
The materials of the **MiniACE® Button** include the following: Medical-grade silicone, medical-grade thermoplastic, and stainless steel.
The materials of the Irrigation Set include the following: Medical-grade silicone, medical-grade thermoplastic and DEHP-free PVC

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

Non-clinical testing demonstrated that the MiniACE® Button is MR Conditional. A patient with this device can be scanned safely in an MR system under the following conditions:

- Static magnetic field of 1.5-Tesla and 3-Tesla, only
- Maximum spatial gradient magnetic field of 1,000-gauss/cm (10-T/m)

- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2-W/kg for 15 minutes of scanning (i.e., per pulse sequence) in the Normal Operating Mode

Under the scan conditions defined, the MiniACE® Button is expected to produce a maximum temperature rise of 1.6°C after 15 minutes of continuous scanning (i.e., per pulse sequence).
In non-clinical testing, the image artifact caused by the MiniACE® Button extends approximately 20-mm from this device when imaged using a gradient echo pulse sequence and a 3-Tesla MR system.

Notice that any serious incident that occurs in relation of the MiniACE® Button should be reported to Applied Medical Technology, Inc. and The Therapeutic Goods Administration (TGA):

Applied Medical Technology, Inc.
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Call: +1 800 869 7382
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Therapeutic Goods Administration (TGA)
https://www.tga.gov.au

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