Australian Patient Information Leaflet

Capsule Monarch® / Capsule Dome

Pre-loaded Replacement Gastrostomy Tube

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: Capsule Monarch® and Capsule Dome

Intended Purpose: The Monarch® / Dome G-Tube (Pre-Loaded Replacement G-Tube – with Capsule) 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 patient who is unable to consume nutrition by conventional means. The Monarch® / Dome G-Tube can also deliver medication and allow for decompression of the stomach. The Capsule Monarch® and Capsule Dome aid in the delivery of nutrients, fluids, and medications, directly into the stomach bypassing the mouth and esophagus.

Kind of patient on whom the device is intended to be used: The Capsule Monarch® and Capsule Dome G-Tubes are intended to be used by elderly, adult, adolescent, child and infant patients. Ideal for patients who do not tolerate balloon buttons due to anatomy or differences in gastric environment.

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 Capsule Monarch®/Dome 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 gastrostomy tract direction, or evidence of tissue granulation. The product must NEVER be used in the vasculature.

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.
Placement by health professional:
The Capsule Monarch® or Capsule Dome G-Tube should only be used by or under the supervision of the personnel trained in percutaneous gastrostomy tube replacement. A thorough understanding of the technical principles, clinical applications, and risks associated with percutaneous gastrostomy tube placement is recommended prior to using this device.
Device Placement:
- The Monarch® / Dome G-Tube is supplied sterile. If the package is opened or damaged, do not use or re-sterilize the device.
- Warning: Keep the Monarch® / Dome G-Tube away from all moisture until it is ready to be placed in patient.
- Warning: The Monarch®/ Dome G-Tube must be placed immediately after lubrication to prevent the capsule from dissolving prematurely.

- Warning: Do not use oil or petroleum based lubricant.
- Note: If steady force is applied to the suture removal tab and the bolster will not deploy, ensure that the encapsulated dome is fully inserted into the stomach. The device can be held within the stomach for a moment to allow the capsule to soften, making for easier deployment of the inner dome.
- Warning: When guiding into the tract, if any resistance is experienced, discontinue insertion. Do not use excessive force to avoid damaging the tract or gastric wall.
- NOTE: The capsule will remain in the stomach, where it will dissolve within the gastro-intestinal tract.
- 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.

Placement verification:

1. Aspirate for gastric contents. Spontaneous return of gastric contents should occur. If gastric contents are not present, attach the 60 ml catheter tip syringe to the Monarch® / Dome G-Tube and irrigate with approximately 10 ml of water. Aspirate again for gastric contents, spontaneous return of gastric contents should occur. This indicated that proper placement has been achieved. When placement is confirmed, gastric decompression, medication, or feeding administration may begin.
Caution: Medication should be administered separately from feeding, one dose at a time.
2. Radiographic examination (X-Ray) may be performed to evaluate for location of the internal bolster.
3. A flexible guidewire may be temporarily placed in the center of the device to further facilitate radiographic examination.
4. Fiberoptic exam may be performed through the lumen of the Monarch® / Dome G-Tube using a 3 mm Endoscope.
5. After air and/or gastric contents are observed, flush with water.

Removal of the **Capsule Monarch® and Capsule Dome**:

- Warning: Removal is recommended to be performed by a qualified clinician. Spontaneous closure of stoma may occur as early as 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.
- Warning: If the tube is resistant to removal, the clinician is recommended to lubricate the stoma site with a water-soluble lubricant. Rotate the tube gently and push it in about an inch. Never use force to remove the tube. Sedation may be required to complete the procedure.
- Warning: Do not allow the internal bolster (cut catheter section) to pass through the intestinal tract.
- Caution: AMT recommends that a balloon style device is kept on hand as a spare in case the monarch device becomes pulled from the stoma or other failure occurs. Temporary placement of a spare device would prevent the stoma site from closing while scheduling a device replacement.
- 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.
  Any use of this device, other than those indicated in these instructions, is not recommended.

Patient Care Instructions:

The Monarch® / Dome G-tube Device should be replaced periodically for optimal performance. Frequent performance checks are recommended. Clogging and/or reduced flow are indicators of diminished performance.

• Be sure the internal bolster is within the stomach, and the Monarch® / Dome G-Tube rotates freely, and has approximately 1 cm of play (in-out), before feedings begin.

• The stoma area should be cleansed daily with a mild soap and water. The stoma site should be clean and dry at all times.

• To avoid clogging of the tube, flush the Monarch® / Dome G-Tube Device with at least 10 ml of water to rinse the feeding passage of any particulate after each feeding.

Warning: Never inject air into the pre-loaded replacement G-Tube device.

• Tubing should be monitored for possible inward migration or unintentional extubation.

Warning: Tube migration could result in the following: inability to feed, obstruction, 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 of 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.

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 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, and overall tube care.

For optimal performance, it is recommended that the Capsule Monarch® or Capsule Dome G-Tube device be changed every 6 months or as often as indicated by your healthcare professional. Proactive replacement of the device will help ensure optimal functionaltiy 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
The Capsule Monarch® or Capsule Dome G-Tube should only be used by or under the supervision of the personnel trained in percutaneous gastrostomy tube replacement. A thorough understanding of the technical principles, clinical applications, and risks associated with percutaneous gastrostomy tube placement is recommended prior to using this device.

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 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, and overall tube care.
For optimal performance, it is recommended that the Capsule Monarch® or Capsule Dome G-Tube device be changed every 6 months or as often as indicated by your healthcare professional. Proactive replacement of the device will help ensure optimal functionaltiy 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

The materials and substances included in the device: The materials of the **Capsule Monarch® and Capsule Dome** include the following: Medical-grade silicone, Medical-grade thermoplastic, Medical-grade suture, Medical-grade adhesive, Medical-grade cellulose.
The materials of the Y-Port feeding 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 Capsule Monarch® / Capsule Dome 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

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