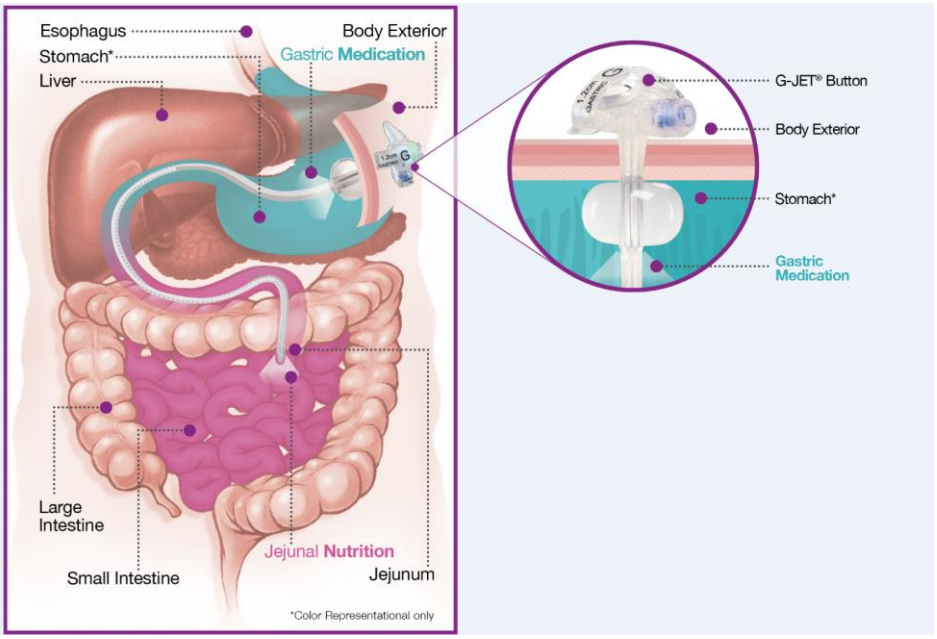
Australian Patient Information Leaflet

# AMT Traditional G-Jet®

## Traditional Length GJ 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 Traditional G-Jet®**

**Intended Purpose:** The Traditional Length GJ Feeding Device is indicated for use in adult, adolescent, child, and infant patients over 10kg who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy. The use of this tube is also clinically indicated when simultaneous gastric decompression and jejunal feeding are needed. This includes patients in whom malnutrition already exists, or may result, secondary to concurrent conditions

**Kind or patient on whom the device is intended to be used: The** AMT Transgastric-Jejunal feeding tube is indicated for use in adult, adolescent, child, and infant patients over 10kg who cannot absorb adequate nutrition through the stomach, who have intestinal motility problems, gastric outlet obstruction, severe gastroesophageal reflux, are at risk of aspiration, or in those who have had previous esophagectomy or gastrectomy.

**Any special operating instructions for use of the device:**

Clean the stoma site:

- Use warm water and mild soap
- Use a circular motion moving from the tube outwards. Clean sutures, external bolsters and any stabilizing devices using a cotton-tipped applicator.
- Rinse thoroughly and dry well

Assess the tube:

- Assess the tube for any abnormalities such as damage, clogging or abnormal discoloration.

Clean the feeding tube:

- Use warm water and mild soap being careful not to pull or manipulate the tube excessively.
- Rinse thoroughly, dry well.

Clean the jejunal, gastric and balloon ports:

- Use a cotton tip applicator or soft cloth to remove all residual formula or medication.

Do not rotate the external bolster:

- This will cause the tube to kink and possibly lose position.

Verify placement of the external bolster:

- Verify that the sliding external bolster rests 2-3mm above the skin.

General Flushing Guidelines:

- Flush the feeding tube with water every 4-6 hours during continuous feeding, anytime feeding is interrupted, or at least every 8 hours if tube is not being used.
- Use a 30 to 60 ml syringe. Do not use smaller syringes as this can increase pressure on the tube and potentially rupture smaller tubes.
    - Use room temperature tap water for tube flushing. Sterile water may be appropriate where the quality of municipal water supplies is of concern. The amount of water will depend on the patient's needs, clinical condition, and type of tube, but the average volume ranges from 10 to 50 ml for adults and 3 to 10 ml for infants. Hydration status also influences the volume used for flushing feeding tubes. In many cases, increasing the flushing volume can avoid the need for supplemental intravenous fluid. However, individuals with renal failure and other fluid restrictions should receive the minimum flushing volume necessary to maintain patency.
- Flush the feeding tube before, after medication administration, and between medications. This will prevent the medication from interacting with formula and potentially causing the tube to clog.
    - Use liquid medication when possible and consult the pharmacist to determine if it is safe to crush solid medication and to mix with water. If safe, pulverize the solid medication into a fine powder form and dissolve the powder in warm water before administrating through the feed tube. Never crush enteric-coated medication or mix medication with formula.
    - Avoid using acidic irrigants such as cranberry juice or cola beverages to flush feeding tubes as the acidic quality when combined with formula proteins may actually contribute to tube clogging.
- Do not use excessive force to flush the tube. Excessive force can perforate the tube and can cause injury to the gastrointestinal tract.
- Document the time and amount of water used in the patient's record. This will enable all caregivers to monitor the patient's needs more accurately.

Tubing Blockage:

- Obstructions are usually caused by formula accumulation inside the tube. Body fluids and medications can also clog the tube. Prevent this by thoroughly flushing the tube EVERY SIX HOURS WITH A MINIMUM OF 30 ml WATER. If the flow is sluggish, gently inject the water, and

let it flow back out of the tube until the obstruction was cleared. When you feel too much resistance and cannot inject water at all, the tube may need to be repositioned or replaced because it may be kinked. High pressure can rupture the tube. Do not insert foreign objects into the tube. This may puncture the tube. If none of these measures work, call your specialist.
Tube occlusion is generally caused by:

- Poor flushing techniques
- Failure to flush after measurement of gastric residuals
- Inappropriate administration of medication
- Pill fragments
- Viscous medications
- Thick formulas, such as concentrated or enriched formulas that are generally thicker and more likely to obstruct tubes
- Formula contamination that leads to coagulation
- Reflux of gastric or intestinal contents up the tube

Feeding and decompression:

Jejunal feeding:

- Assemble the equipment: formula, feeding set, irrigating syringe, eternal feeding pump, water for flushing the tube and extension set.
- Wash your hands with soap and water. Rinse and dry them thoroughly.
- Shake the formula and wipe the container tops before opening. If you do not use all the formula, cover the open container, record the date and time, and store it in the refrigerator. Throw away formula more than 24 hours old. Do not mix new formula with old formula. There is always a chance of spoil.
- Pour the formula into the feeding bag
- Inject 30 ml water into the Traditional G-Jet® by using the 35ml irrigating syringe from your kit.
- Connect the feeding set tubing to the enteral feeding pump. Follow the manufacturer's directions to set the pump.
- If the feeding set has a clamp, open it.
- Start the feeding pump
- Flush the jejunal port EVERY SIX HOURS WITH AT LEAST 30 ml OF WATER. DO NOT USE FORCE

Note: if you are simultaneously decompressing the stomach while feeding and you see formula in the gastric drainage, stop the feeding and notify your specialist.

- When the feeding is complete, clamp the feeding set tubing and disconnect the feeding set tubing from the feeding tube
- Flush feeding tube thoroughly.

Gastric decompression:

Some specialists recommend decompressing the stomach (letting the air or fluid out) before or after feeding. FOLLOW YOUR SPECIALISTS INSTRUCTIONS. The gastric port may be left open for gravity drainage or connected to low intermittent suction. This allows stomach contents and/or gas to escape. Flush the gastric port EVERY SIX HOURS with at least 30 ml water. Do not use continuous or high intermittent suction. High pressure could collapse the tube or injure the stomach tissue and cause bleeding.

Device Replacement:

- The AMT Traditional G-Jet® should be replaced periodically for optimal performance. Frequent performance checks are recommended. Clogging and/or reduced flow are indicators of diminished performance.
- The AMT Traditional G-Jet® should only be used by or under the supervision of personnel trained in percutaneous

**Any undesirable side effect that could be caused by the use of the device:** Potential complications when using the **AMT Traditional G-Jet®** include but are not limited to: Consult your healthcare practitioner if any of the following symptoms occur ● Abdominal pain ● Abdominal discomfort ● Abdominal tenderness ● Dizziness or fainting ● Unexplained fever ● Unusual amount of bleeding through or around the tube

**Any residual risks that could arise due to any shortcomings of the protection measures:**
Skin breakdown ● Infection ● Hypergranulation tissue ● Stomach or Duodenal ulcers ● Intraperitoneal leakage ● Pressure Necrosis ● Ascites ● Colonic interposition ● Portal Hypertension ● Peritonitis and morbid obesity

Granulation Tissue: A small amount of extra tissue around the stoma site is simply the body's attempt to heal the wound. This is normal. It is also normal for the extra tissue to secrete a small amount of mucus. If the tissue bleeds excessively, drains or interferes with the sliding external bolster, call your specialist.

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

- This device has the potential to misconnect with small-bore connections of other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for non-enteral applications
- Ensure device is connected to an enteral port only and not an IV set
- Never connect the jejunal port to suction. Do not measure residuals from the jejunal port.
- Do not use continuous or high intermittent suctions. High pressure could collapse the tube or injure the stomach tissue and cause bleeding.
- This device is intended to connect to compatible enteral device only. Do not use for non-enteral applications.
- When using a bolus style connector, this device has the potential to misconnect to intravenous, breathing system, limb cuff, and temperature connectors.

**Precautions and other measures that, because of those risks, should be taken by the patient or a health professional.**
Placement by health professional and at home by the patient/caregiver: Warnings and Risks
Prior to use:

- Components are supplied sterile for single use only. Do not reuse or re-sterilize.
- Verify package integrity. Do not use if package is damaged or sterile barrier compromised.

Device placement and replacement:

- Due to the presence of tubing support (spring) in the tubing, do not cut the device to custom length. Do not cut distal end of the tubing to create a customized jejunal length. Doing so will eliminate the soft, tapered tip of the device and expose the tubing support.
- The suture loop of the distal end of the device is most often utilized during endoscopic placements. If the suture loop of the device is not necessary for the anticipated method, it is recommended to cut and gently remove the suture loop prior to placement. DO NOT use excessive force to remove the suture loop as this can damage the tapered end of the tubing.
- A gastropexy must be performed to affix the stomach to the anterior abdominal wall. The feeding tube insertion site identified, stoma tract dilated and measured prior to initial tube insertion to ensure patient safety and comfort. The length of the tube should be sufficient to be placed beyond the ligament of treitz. Do not use the retention balloon of the feeding tube as a gastropexy device. The balloon may burst and fail. To attach the stomach to the anterior abdominal wall.
- 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.

General Use:

- Do not exceed the maximum rated balloon volume. Do not use air. Do not inject contrast into the balloon.
- Never connect the jejunal port to the suction. Do not measure residuals from the jejunal port. Do not use continuous or high intermittent suctions. High pressure could collapse the tube of injure the stomach tissue and cause bleeding.
- Do not administer medications through the jejunal feeding port. This will clog the tube. To help avoid clogging, use a feeding pump to deliver formula through the jejunal lumen. Never allow formula to stand in the tube.
- This device is intended to connect to compatible enteral devices only. Do not use non-enteral applications.
- Do not use excessive force or pressure when administered feed or medication to attempt to clear a clog in the tubing. This can cause the tubing to rupture or lead to damage of the tubing support structure. If clog cannot be cleared or tubing is clogging on a frequent basis, this may indicate that the device needs replaced. Failure to follow this warning may result in device failure and/or serious patient injury.
- 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 syringe. Do not use a smaller syringe as this can increase pressure on the tube and potentially rupture smaller tubes.
- When using a bolus style connector, this device has the potential to misconnect to intravenous, breathing system, limb cuff, and temperature connectors.

When using a transition adapter:

- This device has the potential to misconnect to small-bore connectors of other healthcare applications. Only use this device to connect to compatible enteral devices. Do not use for non-enteral applications.
- Tighten only by hand. Never us excessive force or a tool to tighten a rotating connector. Improper use can lead to cracking, leakage, or other failure
- Ensure device is connected to enteral port only and not an IV set.

Medication Administration:

- Use liquid medication when possible and consult the pharmacist to determine if it is safe to crush solid medication and mix with water. If safe, pulverize the solid medication into a find powder form and dissolve in water before administering through the feeding tube. Never crush enteric-coated medication or mix medication with formula. Using a syringe, flush the tube with the prescribed amount of water.

Balloon Maintenance:

It is recommended that balloon volume is checked at least every two weeks, or as recommended by your healthcare professional.

Note: Refill the balloon using sterile or distilled water, not air or saline. Saline can crystalize and clog the balloon valve or lumen, and air may seep out and cause the balloon to collapse. Be sure to use the recommended amount of water as over-inflation can obstruct the lumen or decrease balloon life and under inflation will not secure the tube properly

Health Care Professionals: Insert a Luer slip syringe into the balloon inflation port and withdraw the fluid while holding the tube in place. Compare the amount of water in the syringe to the amount recommended or the amount initially prescribed and documented in the patient record. If the amount is less than recommended or prescribed, refill the balloon with the water initially removed, then draw up and add the amount needed to bring the balloon volume up to the recommended and prescribed amount of water. Be aware as you deflate the balloon there may be some gastric contents that can leak from around the tube. Document the fluid volume, the amount of volume to be replaced (if any) the date and time.

Wait 10-20 minutes and repeat the procedure. The balloon is leaking if it has lost fluid and the tube should be replaced. A deflated or ruptured balloon could cause the tube to dislodge or be displaced. If the balloon ruptured, it will need to be replaced. Secure the tube into position using tape, then follow facility protocol and/or call the physician for instructions.

End User: It is recommended that balloon volume is checked at least every two weeks, or as recommended by your healthcare professional. While holding the external bolster in place, insert a luer slip syringe into the balloon inflation port. Withdraw the water from the balloon. The amount of water you withdraw should be equal to the prescribed amount, replace the amount recommended by your specialist. Never add water before you withdraw all of the water from the balloon. Note: the use of a luer-lock syringe may make this more difficult. A luer-slip syringe is recommended.

Stoma Care:

- Clean the site with normal saline three times daily to remove the small amount of mucus that normally accumulates around the stoma. If the mucus dries, it may irritate the skin. Applying a small amount of water may loosen the dried material. After the stoma heals, a thorough cleansing with soap and water is best. A dressing is not necessary, and contributes to skin maceration and infection. Unless recommended by your specialist, avoid medicated ointments or powders. DO NOT use oil or petroleum based products. DO NOT ROTATE THE TUBE. Jejunal tubes must not be rotated because they will kink. Should the tube become kinked, call your health care professional.

**Symptoms that could indicate that the device is malfunctioning:**
Consult your healthcare practitioner if any of the following symptoms occur ● Abdominal pain ● Abdominal discomfort ● Abdominal tenderness ● Dizziness or fainting ● Unexplained fever ● Unusual amount of bleeding through or around the tube

**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.
Gastric Leakage: Gastric leakage may occur if the sliding external bolster is not properly adjusted or if the balloon is not against the stomach wall. Adjust the external bolster so that it sits 1-2mm from the skin. Once the bolster is adjusted, check the water volume in the balloon. Do not add more water to the balloon before first withdrawing all of the water from the balloon. Fill the balloon according to the balloon inflation range in table below.

Inflate the balloon with sterile or distilled water within the fill-volume range below:

**Table 1**

| FR Size | Min Volume | Recommended Volume | Max Volume |
|---|---|---|---|
| 14 FR & 16 FR | 3 ML | 4 ML | 5 ML |
| 18 FR | 7 ML | 8 ML | 9 ML |

- 14Fr and 16Fr sized tubes: Inflate the balloon with 3-5 ml of sterile or distilled water.

**CAUTION: DO NOT EXCEED 5 ML TOTAL BALLOON VOLUME. DO NOT USE AIR. DO NOT INJECT CONTRAST INTO THE BALLOON.**

- 18Fr sized tubes: Inflate the balloon with 7-9 ml of sterile or distilled water.

**CAUTION: DO NOT EXCEED 9 ML TOTAL BALLOON VOLUME. DO NOT USE AIR. DO NOT INJECT CONTRAST INTO THE BALLOON.**

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 medications, use of thick feeds/formulas, gastric reflux, and/or fungus growth. If clogged:

1. First make sure that the tubing is not kinked or clamped off.
2. If clog is visible above the skin surface, gently message or milk the tube between the fingers to break up the clog.
3. Next place a 30-60 ml syringe filled with warm water into the appropriate adapter of lumen of the tube and gently pull back on, and then depress the plunger to dislodge the clog.
4. If clog remains, repeat step #3. Gentle suction alternating with syringe pressure will relieve most obstructions.
5. If this fails, consult with the physician. Do not use cranberry juice, cola drinks, meat tenderizer or chymotrypsin, as they can actually cause clogs or create adverse reactions in some patients. If the clog is stubborn and cannot be removed, the tube will have to be replaced.

Device had become 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.
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.
Leaking of balloon volume: If balloon is deflating, fully deflate the balloon. Compare the amount of water in the syringe to the amount recommended or the amount initially prescribed and documented in the patient record. Inflate the balloon with the recommended fill-volume. Do not exceed maximum fill

volume. Wait 10-20 minutes and repeat the procedure. The balloon is leaking if it has lost fluid, and the tube should be replaced. 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.

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 feeding/medications 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.

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). This can occur if the device is too short for the patient's stoma site. Additionally, a device that is placed too close to the pylorus can result in a misshaped balloon and blockage of the pylorus. Balloons can be gently messaged with fingers back into symmetry if not excessively misshaped. Devices should be replaced if balloon is found excessively misshaped.

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 food/medication 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 feed-port area for any excess residue build-up. Clean excess residue build-up with cloth and warm water.

Diarrhea

- The flow rate may be too fast. Decrease the rate, then increase it slowly until you reach the prescribed flow rate. Diluting formula with water may help slow the diarrhea, but check with your specialist first.
- Prepare fresh formula for each feeding. Discard unused formula after 24 hours.
- Keep your equipment clean. Prepare only enough formula for eight hours. Wash, rinse and dry the equipment after each use.
- If the diarrhea continues for more than three days despite your efforts, call your specialist.
- Never attempt to bolus feed through the jejunal lumen.

**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:** Balloon-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 1-9 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 **AMT Traditional G-Jet®** device 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.

**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)
- The patient experiences diarrhea or vomiting
- The patient develops a fever

**The materials and substances included in the device:**

The materials of the **AMT Traditional G-Jet ®** include the following: Medical-grade silicone, Medical-grade stainless steel, Medical-grade silicone pad print ink, braided suture (non-resorbable) and medical-grade thermoplastic

The materials of the Feeding Set include the following: Medical-grade thermoplastic and Medical-grade PVC (phthalate-free)

**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 AMT Traditional G-Jet® is MR Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 1.5-Tesla (1.5T) or 3.0 –Tesla (3.0T).
- Spatial gradient magnetic field up to:
  - 9,570 G/cm (95.70 T/m) for 1.5T systems
  - 5,720 G/cm (57.20 T/m) for 3.0T systems
- Maximum whole body averaged specific absorption rate (SAR) of:
  - 4.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 1.5 T
  - 4.0 W/kg for 15 minutes of scanning in Normal Operating Mode at 3.0 T


MR Conditional

1.5 RF Heating

In non-clinical testing with body coil excitation, the G-Jet® feeding tube produced a temperature rise of less that 1.0°C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 1.5T Siemens Espree (MRC30732) MR Scanner with SYNGO MR B17 Software.

3.0 RF Heating

In non-clinical testing with body coil excitation, the G-Jet® feeding tube produced a temperature rise of less that 1.0°C at a maximum whole body averaged specific absorption rate (SAR) of 4.0 W/kg, as assessed by calorimetry for 15 minutes of scanning in a 3.0T Siemens Trio (MRC20587) MR Scanner with SYNGO MR A30 4VA30A Software.

3.0T MR Artifact

In testing using a 3.0T system with gradient-echo sequencing, the shape of the image artifact follows the approximate contour of the device and extends radially up to the 2.0 cm from the implant.

Note: A magnetic resonance environment safety card has been approved in the AMT G-Jet® Kit. Please keep the card with your records. This card can be given to your radiologist when undergoing MRI Scan.

**Notice that any serious incident that occurs in relation of the AMT Traditional G-Jet® 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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