

RGT - Replacement Gastrostomy Tube

Description:

The Replacement Gastrostomy Tube is a soft, silicone gastrostomy tube and internal retention dome with pre-attached external bolster and dual port feeding adaptor, packaged sterile with an obturator.

Intended Use:

RGT is used for replacement gastrostomy placement to provide enteral access for the delivery of nutrition, medication, gastric drainage or decompression.

Contraindications:

RGT placement is contraindicated for individuals who do not have a well-established gastrostomy tract. If any evidence of granulation tissue, infection or irritation is seen it must be addressed medically before insertion of the device.

Warnings / Precautions:

- RGT is intended for single use only. Do not resterilize. Do not re-use.
- Attempt to resterilizes a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Do not use if product or sterile packaging is damaged.
- Confirm the stoma patency before attempting the placement
- Before initiating feeding, proper location of the internal dome must be confirmed. If the device slips into the peritoneal cavity it will cause serious consequences such as peritonitis, sepsis or potentially death.
- Improper placement or excessive traction on the external portion of the RGT could cause dislodgement or misalignment of the internal dome.
- If gastrostomy tube is not free floating within the fibrous tract, do not use traction method to remove the device.
- Confirm tube patency before removal of device through traction method especially when the device is placed for a long period.
- Failure to remove the dome may result in small bowel obstruction and/or perforation.
- Removal of gastrostomy tube using traction may cause trauma to the tract and associated complications.
- Storage temperature between 5°C to 30°C
- Only experienced surgeons should place this device.

Direction for Use:

- The replacement gastrostomy tube is made for a well-established gastrostomy tract.
- Remove existing gastrostomy tube.
- Deform the replacement tube by using obturator.
- Insert the obturator in the dimple of the internal dome of the replacement tube and stretch to deform and narrow the dome.
- Lubricate the tubing, obturator, deformed internal dome and the stoma site.
- Insert the tip of the device carefully into the stoma and with slow and steady pressure advance through into the stomach.
- Withdraw the obturator, once the internal dome has been introduced into the stomach.
- Slowly rotate the tube and gently push the tube 1-2 cm into the stoma to confirm the placement. Minimal resistance should be encountered.

- Gently pull the replacement tube upwards until the inner dome just meets the gastric mucosa.
- Clean the catheter and wound site.
- With the use of hemostat, stretch the inner lumen tube of the external bolster and slide it over the feeding tube until it is close to the skin.
- Once placement and patency are established, feeding can start.

Directions for Removal: Traction Method:

1. Lubricate stoma. Slowly rotate gastrostomy tube and gently push it 1-2 cm into the stomach to disengage from fibrous tract.
2. Loosely cover tract with a towel, drape or 4" x 4" (10cm x 10cm) gauze.
3. Grasp gastrostomy tube close to stoma .Wrap gastrostomy tube firmly around hand if desired.
4. Apply firm counter-pressure to abdomen with other hand.
5. Pull gastrostomy tube using steady tension, repositioning hand to keep close to stoma. Continue to apply firm counter pressure to the abdomen.
6. As tension is being applied to the gastrostomy tube, the internal dome will fold then emerge through the abdominal wall.

Endoscopic Method:

1. Introduce gastroscope, insufflate stomach and inspect stomach interior.
2. Insert grasping snare and position under the internal bolster.
3. Slowly rotate gastrostomy tube and gently push 1-2 cm into the stomach.
4. Snare gastrostomy tube approximately 2 cm from bolster.
5. Cut gastrostomy tube near the skin line and withdraw gastroscope, grasping snare and bolster.

Surgical Method:

Surgically remove the dome from the stomach if unable to remove endoscopically.

Warning:

After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

Do not reuse, reprocess & resterilize:

Reuse, Reprocessing & resterilization may compromise the structural integrity, can also create risk of contamination & may not give desired result or create complications, infections which may result in injury, illness or death.

Limited Express Warranty:

The limited express warranty as set forth herein is exclusive and in lieu of all warranties of merchantability and fitness for use, remedies, obligations and liabilities for consequential damages. The products are being sold only for the purpose described herein and such limited express warranty runs only to the original user. In no event shall ALLWIN be liable for any breach of warranty in any amount exceeding the purchase price of the product. ALLWIN reserves the right to make design changes to products without liability to incorporate said changes in ALLWIN products previously designed or sold.

Catalogue Number
 Batch Code
 Date of Manufacture
 Use By
 Do not re-use
 Do not Re-Sterilize
 R_x only
 Caution: Federal Law restricts this device to sale by or on the order of a physician or a practitioner trained in its use.

Consult Instruction for use
 Do not use if Packing is damaged
 Caution
 Keep out of sunlight
 Keep Dry
 STERILE **EO**
 Sterilized using ethylene oxide

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