allwin® Medical Devices

SurgiPeg – Percutaneous Endoscopic Gastrostomy Tube

Description:
- SurgiPeg Percutaneous Endoscopic Gastrostomy Kit - Full
- SurgiPeg Percutaneous Endoscopic Gastrostomy Kit - Economic

Intended Use:
Used for percutaneous endoscopic placement to provide enteral access for the delivery of nutrition, medication, gastric drainage or decompression.

Contraindications:
- Conditions, which would otherwise contraindicate endoscopic procedures.
- Multiple surgical procedures near the gastrostomy site.
- Obstruction of the esophagus/airway, which may prevent the introduction or removal of the feeding tube.
- Extreme obesity, ascites, etc. which presents identifying transillumination.

Warnings:
- Do not use if package is opened or damaged.
- Only experience surgeons should place this device.
- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue.
- Keep the stomach insufflated until the external bolster has been finally positioned.
- If excessive resistance is met to the dilating tip while exiting the abdominal wall, the situation could require incision and subcutaneous tissue to be expanded with a hemostat.
- Wait 24 hours before feeding the patient after the procedure.
- Excess traction could cause PEG to be removed or dome to erode through stomach wall.
- Traction removal may cause trauma or other complications.
- Dispose in accordance with recognized medical practice and under observance of applicable law and regulation.
- For single use only.
- Attempt to resterilize a single use device may compromise its structural integrity and/or lead to device failure which may result in patient injury or illness.
- Storage temperature between 5ºC to 30ºC.

Adverse Reactions:
May include: minor wound infections at the stoma site; dislodgment or misalignment of the internal dome; tissue necrosis; dome separation; small bowel obstruction and/or perforation; leakage of gastric contents; premature separation of the gastric & abdominal wall; gastrocolic fistula; gastric ulceration; peritonitis and sepsis, all of which increases in likelihood with improper PEG placement.

Caution:
This product is designed to properly function in vivo when used in accordance with these directions for use. After opening the kit do not stretch or pull the feeding tube away from the dilator tip. This may put undue force on the feeding tube and dilator tip connection causing separation of these components.

Instruction for Use:
1. Prepare patient as required for upper endoscopy.
2. Prepare abdomen with antiseptic solution and sterile drapes.
3. Introduce gastroscope; insufflate stomach to ensure that abdominal and gastric walls are in contact.
4. Transilluminate the abdominal wall with the light of the gastroscope to choose the correct location for placement of the gastrostomy tube.
5. Apply finger pressure at the point of clearest transillumination. A clear indention of the gastric wall should be visible on its anterior surface.
6. Pass a snare through the scope channel to the anticipated exiting area of the introducer cannula.
7. Anesthetize locally the incision site and using # 11 scalpel make a 1cm incision. (A smaller incision could cause unwanted resistance to gastrostomy tube when exiting from the fascia).
8. Gently separate the skin & underlying subcutaneous tissue.
9. Thrust the 14-gauge needle/cannula through the skin incision & into the stomach under direct endoscopic vision.
10. Using the retrieval snare grasp around the cannula and then remove the inner needle. (Do not tighten the snare after removal of the needle as this may make passage of blue insertion wire difficult).
11. Pass the folded (bent) end of the blue insertion wire through the cannula into the stomach. Using the endoscopic vision, securely grasp the blue wire and extubate the scope / snare assembly with about 30cm blue wire extending from the oral cavity.
12. Attach the blue wire to the dilating tip wire using square knot by:
- Passing the blue wire through the loop of the dilating tip.
- Pull the dome end of the PEG through the blue wire.
- Tighten the square knot by gently pulling on both the sets of wires. Do not grasp the silicone tube as it may pull loose from the dilating tip.

13. Apply lubricant to the outside of PEG tube assembly.
14. Grasp the blue wire near the abdomen and gently pull the PEG until the blue dilating tip exits the abdominal incision. Remove the blue pull wire and introducer from the PEG assembly.
15. Carefully pull the dome safely through the oral pharynx and into the stomach cavity. Reintroduce the endoscope and observe the dome meeting the gastric mucosa. Excess tension should be avoided as undue pressure could cause blanching or unnecessary pressure.

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.

REF Catalogue Number | LOT Batch Code | Date of Manufacture | Use By | Do not re-use | Do not Re-Sterilize | Rx 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

EC REP
CMC Medical Devices & Drugs S. L.
C/Horacio Lengo N' 18, CP 29006, Malaga, Spain
Tel.: +34 951 214 054
E-mail : info@cmcmedicaldevices.com

CE 0123

Temperature Limit

allwin® Medical Devices
Allwin Medical Devices
Plot # 223, 230 & 221, Surat Special Economic Zone, Sachin, Surat - 394230 Gujarat. INDIA | Tel: +91 99870 84561
E-mail : info@allwinmedical.com | www.allwinmedical.com