INSTRUCTIONS FOR USE
Intended Use:
The Safety “Pull” Silicone PEG Tray (Traction Removal) is an initial placement percutaneous endoscopic gastrostomy tube kit designed for enteral feeding.

Warnings and Precautions:
- Inspect contents of PEG kit for damage. If damage is evident, do not use the kit.
- Gastrostomy procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques. Consult the medical literature relative to techniques, complications and hazards prior to the performance of any endoscopic procedure.
- Always keep the stomach insufflated until the external bolster has been positioned on the PEG.
- If excessive resistance is met as the PEG dilating tip is exiting the abdominal wall, the incision and subcutaneous tissue may require expansion or enlargement.
- Following the completion of the PEG placement, wait 24 hours before feeding the patient.
- Excess traction may cause the PEG tube’s dome to erode through the stomach wall, leading to medical complications or premature removal.
- Traction removal may cause trauma or other complications.
- US Endoscopy did not design this device to be reprocessed or reused, and therefore cannot verify that reprocessing can clean and/or sterilize or maintain the structural integrity of the device to ensure patient and/or user safety.

Contraindications:
- Esophageal obstruction will require a medical evaluation to determine if endoscopy and the passage or removal of the PEG are advisable.
- PEG placement should not be performed if abdominal transillumination is not achieved.

Direction for Use:
Following suggested medical techniques, prep the patient for PEG placement.
1. Prep the abdomen.
2. Perform endoscopy: insufflate the stomach to ensure that abdominal and gastric walls are in contact.
3. Transilluminate the abdominal wall to choose the correct location of the incision.
4. Apply finger pressure to the abdomen and endoscopically observe indentation.
5. Pass the snare through the scope channel to the anticipated exiting area of the Introducer Safety Needle. One method of retrieving the pull wire is to advance the opened snare loop under the target site to entrap the Introducer Safety Needle after it enters the stomach.
6. Draw Xylocaine into the 5cc Safety Syringe. To withdraw Xylocaine:
   i. Hold the ampule upright and open the ampule by twisting its top.
   ii. Attach the ampule directly to the syringe. Gently twist the syringe while applying pressure to the syringe piston and secure it to the ampule.
   iii. Invert the ampule. Without squeezing the ampule, withdraw the solution. Maintain downward pressure on the syringe piston after the solution has been withdrawn and remove the ampule.
7. Attach the 25 gauge x 1” needle and twist it tightly onto the filled syringe.
8. Remove the shield from the needle.
9. Locally anesthetize the incision site with Xylocaine.
10. After injection, unlock the inner syringe by gripping the flange and twisting. Pull the syringe back until the entire needle, including the tip, is closed in the barrel. The needle is locked when a click is heard and the red and green lines meet.
11. Discard the safety syringe in an approved Sharps waste container.
12. Activate the scalpel by pressing on the safety shield latch until a click is heard and the scalpel is exposed in a locked-out position.
13. Using the scalpel, make a 1cm incision at the anesthetized site. Performing a smaller incision may cause unwanted resistance as the PEG tube’s dilating tip exits the abdominal wall.
14. After making the incision, cover the exposed scalpel by pressing on the safety shield latch until a click is heard and the safety shield locks into place covering the scalpel.
15. Separate the incision site and subcutaneous tissue.
16. Remove the protective cover from the Introducer Safety Needle. Under endoscopic observation insert the Introducer Safety Needle through the abdominal incision, confirm desired position, and remove the needle stylet from the Introducer Safety Needle. Discard the needle stylet in an approved waste container.
17. Pass the folded (bent) end of the pull wire through the Introducer Safety Needle. Under endoscopic observation, use the retrieval snare to securely grasp the pull wire and extubate the scope/snare assembly. Leave approximately 30cm of pull wire extending from the oral cavity.

18. Attach the pull wire to the dilating tip wire on the end of the PEG tube using a square knot. Pass the pull wire through the loop of the dilating tip.

Pull the dome of the PEG tube through the pull wire.

Tighten the square knot by gently pulling on both sets of wires. Do not grasp the PEG tube because it may pull loose from the dilating tip.

19. Apply lubricating jelly to the outside of the PEG tube.
20. Grasp the pull wire near the abdomen and gently pull the PEG tube until the dilating tip exits the abdominal incision. Remove the pull wire and Introducer Safety Needle from the PEG tube.

21. Carefully pull the dome safely through the oral pharynx and into the stomach cavity. Reintubate the endoscope and observe the dome meeting the gastric mucosa. Excess tension should be avoided.
22. Wipe down the PEG tube and clean the wound site. If desired, apply Povidone-Iodine ointment to the abdominal incision.

23. External One Piece Bolster Placement: Use hemostat to dilate the hole in the bolster, slide the bolster onto the PEG tube until it meets the skin. Excess tension should be avoided as undue pressure may cause blanching or unnecessary pressure. Obstreperous patients may need the bolster sutured in place. If the bolster is not sutured, it can be frequently rotated for site cleaning. If sutured, site cleaning must be accomplished without bolster rotation.

24. Leave approximately 12 inches of the PEG tube extending from the abdomen and cut off the balance.

25. Place the dual feeding adaptor into the open end of the PEG tube and close both ports to prevent leakage.

PEG Removal Methods:
Consult the medical literature regarding PEG tube removal and the need for endoscopic observation.

Product Disposal:
Once the product has been determined to be of no further use, dispose of the product in compliance with hospital waste protocol.

Issued Date: August 2010

Warnings:
An issued or revision date for these instructions is included for the user’s information. In the event that two years have elapsed between this date and product use, the user should contact US Endoscopy to determine if additional information is available.

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**Explanation of symbols used on Labels and Instructions for Use**

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<thead>
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<th>Symbol</th>
<th>Description</th>
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**Federal law (U.S.A.) restricts this device to sale, distribution and use by or on the order of a physician.**

Rx Only (U.S.A.)