9. As the gastrostomy tube is pulled through the abdominal wall, the retention dome passes through the oropharynx and into the stomach.

10. Reinsert the gastroscope to follow the tube as it enters the stomach and the dome just meets the gastric mucosa to assure safe passage of the internal bumper. There should be no blanching of either the gastric mucosa or skin. The scope should remain inserted until the procedure is complete to confirm correct placement.

**WARNING:** Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

11. Lavage the gastrostomy tube and wound site. Advance one of the external bolsters over the gastrostomy tube using a hemostat until it is close to, but not snug against, the skin (Diagram 4).

12. Cut the gastrostomy tube approximately 1/2” from the skin level and attach the dual port feeding adaptor. The gastrostomy is now complete.

**WARNING:** Excessive traction may cause premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified under “Instructions for Device Removal.”

**SECTION II Instructions for Device Removal**

**Endoscopic Method**

1. Introduce gastroscope, insufflate stomach and inspect stomach interior.

2. Insert a grasping snare and position under the internal bolster.

3. Slowly rotate 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 scope, grasping snare and bolster.

**Surgical Method**

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

**WARNING:** The gastrostomy tube’s internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Tube Replacement**

Replacement should occur immediately following removal. Bard Access Systems offers a complete line of replacement devices. Please contact your Bard representative or Bard Customer Service at 1-800-545-0890 for additional information.

If the device will not be replaced, an occlusive dressing should be placed and the tract should close within 24 hours.

**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.

An issued or revision date and a revision number for these instructions are included for the user’s information on the first page directly beneath the telephone number of Bard Access Systems. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems to see if additional product information is available (Telephone Number: 1-800-545-0890).

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The Ponsky-Gauderer* Device Description

• Do not continue procedure if transillumination cannot be identified.

Warnings
• Conditions which would otherwise contraindicate endoscopic procedures.
• Multiple surgical procedures near the gastrostomy site
• Inability to identify transillumination (i.e., obesity, extensive abdominal surgery, ascites, etc.)

Contraindications
• Obstruction of the esophagus/gastric region which may prevent the introduction or removal of the feeding tube (i.e., tracheostomy, esophageal tumors, etc.)
• Inability to identify transillumination (i.e., excessive obesity, extensive gastrointestinal surgery, ascites, etc.)
• Multiple surgical procedures near the gastrostomy site
• Conditions which would otherwise contraindicate endoscopic procedures.

The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.
• Excessive traction may cause premature removal or premature fatigue of the device. In the event of premature failure the device may be removed as specified under “Instructions for Device Removal.”

Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

Instructions for Use

Section 1. Instructions for Device Placement

Patient Preparation
1. Inspect contents of kit for damage. If damaged, do not use.
2. Prep patient as required for upper endoscopy.
3. Prepare stomach with antisepsic solution and sterile drapes.

Tube Site Selection
1. Introduce gastroscope, insufflate stomach, inspect stomach interior and perform an EGD exam.
2. Transilluminate abdominal wall with the light of the gastroscope to choose the correct location for placement of the gastrostomy tube.

WARNING: Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.

1. Apply finger pressure at the point of clearest transillumination. A clear indentation of the gastric wall should be visible on its anterior surface.
2. Insert grasping snare through the scope channel and open over the dilating tip connection and may cause the feeding tube to separate from the dilator end.
3. It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

Adverse Reactions

• The gastrostomy tube’s internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.
• After opening the kit do not stretch or pull the feeding tube away from the dilator tip. This may unload force on the feeding tube and dilator tip connection causing separation of these components.
• A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
• The stomach should be kept insufflated throughout the procedure to Multiple surgical procedures near the gastrostomy site
• Conditions which would otherwise contraindicate endoscopic procedures.

1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned the grasping wire tip will pass through the open grasping wire loop. If it does not enter the loop, the grasping snare should be positioned around the cannula.
2. Gently separate the skin and underlying subcutaneous tissue.

Tub Placement
1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned the grasping wire tip will pass through the open grasping wire loop. If it does not enter the loop, the grasping snare should be positioned around the cannula.
2. Cross the grasping snare around the cannula, and then remove the inner stylet.
3. Pass the looped end of the blue insertion wire through the cannula into the stomach.
4. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then tighten it.
5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously from patient’s mouth. The blue insertion wire now exits the body from the patient’s abdomen and mouth.

6. After the final insertion of the assembly to the blue insertion wire which is exiting the patient’s mouth:
• Pass the blue insertion wire loop into the dilating tip of the gastrostomy tube (Diagram 1).
• Pass the dome end of the gastrostomy feeding tube through the blue insertion wire looped end and pull the entire gastrostomy feeding tube through it (Diagram 2).
• Grasp the dilating tip between the thumb and forefinger and tighten the loops together to form attachment (Diagram 3).
• Apply water-soluble lubricant to gastrostomy tube assembly.
• Grasp strands of the blue insertion wire and the final end of the blue insertion wire in one hand while it exits the abdominal incision site and begin to pull the gastrostomy tube into the mouth and out through the incision. NOTE: If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance.
**Device Description**

The Ponsky-Gauderer* Device Description

- Do not continue procedure if transillumination cannot be identified.
- 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.
- Presenting with improper PEG placement.
- This product is designed to properly function in vivo when used in conjunction with its accessories.

**Indications for Use**

- Sterile in a kit which also contains procedural aids.
- Excess tension on the gastrostomy tube may result in dislodgment or misalignment of the internal dome.

**Contraindications**

- Obstruction of the esophagus/airway which may prevent the introduction or removal of the feeding tube (i.e., tracheostomy, esophageal tumors, etc.)
- Inability to identify transillumination (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.)
- Multiple surgical procedures near the gastrostomy site.
- Conditions which would otherwise contraindicate endoscopic procedures.

**Precautions**

- 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.
- A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
- The stomach should be kept insufflated throughout the procedure for multiple procedures near the gastrostomy site.
- Do not tighten the grasping snare further after removal of the inner stylet as this may make passage of the blue insertion wire difficult.
- Do not grasp the gastrostomy insertion wire and pull the gastrostomy tube in a manner that may make passage of the gastrostomy tube through the abdomen and incision site.
- Excessive traction may cause premature removal or premature fatigue of the device. In the event of premature failure the device may be removed as specified under “Instructions for Device Removal.”
- Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

**Instructions for Use**

**SECTION I. Instructions for Device Placement**

**Patient Preparation**

1. Inspect contents of kit for damage. If damaged, do not use.
2. Prep patient as required for upper endoscopy.
3. Place patient in a supine position with antiseptic solution and sterile drapes.

**Tube Site Selection**

1. Introduce gastroscope, insufflate stomach, inspect stomach interior and perform an EGD exam.
2. Transilluminate abdominal wall with the light of the gastroscope to choose the correct location for placement of the gastrostomy tube.

**WARNING:** Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.

**Adverse Reactions**

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

**Tubal Placement**

1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned, the grasping snare will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be tightened and pulled through the cannula.
2. Cross the grasping snare around the cannula, and then remove the inner stylet.
3. Pass the looped end of the blue insertion wire through the cannula into the stomach.
4. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then tighten it.
5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously from patient’s mouth. The blue insertion wire now exits the body from the patient’s abdomen and mouth.
6. Adjust the grasping snare assembly to the blue insertion wire which is exiting this patient’s mouth:
   - Pass the blue insertion wire loop through the dilating tip of the gastrostomy tube (Diagram 1).
   - Pass the dome of the gastrosopic feeding tube through the blue insertion wire looped end and put the entire gastrosopic feeding tube through it (Diagram 2).
   - Carefully grasp the dilating tip between the thumb and forefinger and tighten the loops together to form attachment (Diagram 3).
7. Apply water-soluble lubricant to gastrosopic tube assembly.

- Grasp strands of the fenestrated end of the blue insertion wire in one hand while it exits the abdominal incision site and begin to pull the gastrosopic tube into the mouth and out through the incision. **NOTE:** If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance.
Silicone PEG is a 20 French soft, silicone gastrostomy tube with internal retention dome and dilating tip, packaged sterile in a kit which also contains procedural aids.

Indications for Use
For percutaneous placement of a long-term initial-placement feeding and/or decompression device.

Contraindications
May include:
- Obstruction of the esophagus/gastrointestinal tract which may prevent the introduction or removal of the feeding tube (i.e., thoracicostomy, esophageal tumors, etc.)
- Inability to identify transillumination (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.)
- Multiple surgical procedures near the gastrostomy site
- Inability to identify transillumination (i.e., obesity, extensive scar tissue)

Conditions which would otherwise contraindicate endoscopic procedures.

Warnings
- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.
- Excessive traction may cause premature removal or premature fatigue of the device. In the event of premature failure of the device may be removed as specified under “Instructions for Device Removal.”
- Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.
- The stomach should be kept insufflated throughout the procedure.
- The stomach's internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.
- After opening the kit do not stretch or pull the feeding tube away from the dilator tip. This may create undue force on the feeding tube and dilator tip connection and may cause the feeding tube to separate from the dilator tip.
- Do not tighten the grasping snare further after removal of the inner stylet as this may make passage of the blue insertion wire difficult.
- Do not grasp the gastrostomy insertion wire and stylet as a means of tightening attachment. This may put undue force on the tube and dilating tip connection which may cause the feeding tube to separate from the dilator tip.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

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

Protocol Description
The Ponsky-Gauderer* silicone PEG is a 20 French soft, silicone gastrostomy tube with internal retention dome and dilating tip, packaged sterile in a kit which contains procedural aids.

Indications for Use
For percutaneous placement of a long-term initial-placement feeding and/or decompression device.

Contraindications
May include:
- Obstruction of the esophagus/gastrointestinal tract which may prevent the introduction or removal of the feeding tube (i.e., thoracicostomy, esophageal tumors, etc.)
- Inability to identify transillumination (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.)
- Multiple surgical procedures near the gastrostomy site
- Inability to identify transillumination (i.e., obesity, extensive scar tissue)

Conditions which would otherwise contraindicate endoscopic procedures.

Warnings
- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.
- Excessive traction may cause premature removal or premature fatigue of the device. In the event of premature failure of the device may be removed as specified under “Instructions for Device Removal.”
- Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.
- The stomach should be kept insufflated throughout the procedure.
- The stomach's internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.
- After opening the kit do not stretch or pull the feeding tube away from the dilator tip. This may create undue force on the feeding tube and dilator tip connection and may cause the feeding tube to separate from the dilator tip.
- Do not tighten the grasping snare further after removal of the inner stylet as this may make passage of the blue insertion wire difficult.
- Do not grasp the gastrostomy insertion wire and stylet as a means of tightening attachment. This may put undue force on the tube and dilating tip connection which may cause the feeding tube to separate from the dilator tip.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

Tubal Placement
1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned the grasping snare will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be pulled further through the cannula.
2. Cross the grasping snare around the cannula, and then remove the inner styllet.
3. Pass the looped end of the blue insertion wire through the cannula into the stomach.
4. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then tighten it.
5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously from patient’s mouth. The blue insertion wire now exits the body from the patient’s abdomen.
6. Ask an assistant to make an assembly to the blue insertion wire which is exiting this patient’s mouth:
   - Pass the blue insertion wire loop through the dilating tip of the gastrostomy tube (Diagram 1).
   - Pass the dome of the gastrostomy feeding tube through the blue insertion wire looped end and push the entire gastrostomy feeding tube through it (Diagram 2).
   - Carefully grasp the dilating tip between the thumb and forefinger and tighten the loops together to form attachment (Diagram 3).
7. Apply water-soluble lubricant to gastrostomy tube assembly.
   - Grasp the ends of the blue insertion wire at the end of the blue insertion wire in one hand while it exits the abdominal incision site and begin to pull the gastrostomy tube into the mouth and out through the incision. NOTE: If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance.

Section 1: Instructions for Device Placement

Patient Preparation
1. Inspect contents of kit for damage. If damaged, do not use.
2. Prepare patient as required for upper endoscopy.
3. Perform dry run with antisepsic solution and sterile drapes.

Tube Site Selection
1. Introduce gastrostomy, insufflate stomach, inspect stomach interior and perform an EGD exam.
2. Transilluminate abdominal wall with the light of the gastrostoscope to choose the correct location for placement of the gastrostomy tube.

WARNING: Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, visceral and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.

3. Apply finger pressure at the point of closest transillumination. A clear indentation of the gastric wall should be visible on its anterior surface.
4. Insert grasping snare through the scope channel and open over the proposed puncture site.
5. Drive dilating tip through a 6 cc syringe and infiltrate local anesthetic subcutaneously into the skin at the proposed puncture site.
6. Make a minimum 1.0 cm skin incision at the selected site using a #11 scalpel blade.
7. Gently separate the skin and underlying subcutaneous tissue.

Instructions for Use

1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned the grasping snare will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be pulled further through the cannula.
2. Cross the grasping snare around the cannula, and then remove the inner styllet.
3. Pass the looped end of the blue insertion wire through the cannula into the stomach.
4. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then tighten it.
5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously from patient’s mouth. The blue insertion wire now exits the body from the patient’s abdomen and mouth.
6. Ask an assistant to make an assembly to the blue insertion wire which is exiting this patient’s mouth:
   - Pass the blue insertion wire loop through the dilating tip of the gastrostomy tube (Diagram 1).
   - Pass the dome of the gastrostomy feeding tube through the blue insertion wire looped end and push the entire gastrostomy feeding tube through it (Diagram 2).
   - Carefully grasp the dilating tip between the thumb and forefinger and tighten the loops together to form attachment (Diagram 3).
7. Apply water-soluble lubricant to gastrostomy tube assembly.
   - Grasp the ends of the blue insertion wire at the end of the blue insertion wire in one hand while it exits the abdominal incision site and begin to pull the gastrostomy tube into the mouth and out through the incision. NOTE: If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance.

1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned the grasping snare will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be pulled further through the cannula.
2. Cross the grasping snare around the cannula, and then remove the inner styllet.
3. Pass the looped end of the blue insertion wire through the cannula into the stomach.
4. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then tighten it.
5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously from patient’s mouth. The blue insertion wire now exits the body from the patient’s abdomen and mouth.
6. Ask an assistant to make an assembly to the blue insertion wire which is exiting this patient’s mouth:
   - Pass the blue insertion wire loop through the dilating tip of the gastrostomy tube (Diagram 1).
   - Pass the dome of the gastrostomy feeding tube through the blue insertion wire looped end and push the entire gastrostomy feeding tube through it (Diagram 2).
   - Carefully grasp the dilating tip between the thumb and forefinger and tighten the loops together to form attachment (Diagram 3).
7. Apply water-soluble lubricant to gastrostomy tube assembly.
   - Grasp the ends of the blue insertion wire at the end of the blue insertion wire in one hand while it exits the abdominal incision site and begin to pull the gastrostomy tube into the mouth and out through the incision. NOTE: If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance.
**Instructions for Use**

**SECTION 1. Instructions for Device Placement**

**Patient Preparation**

1. Inspect contents of kit for damage. If damaged, do not use.
2. Prep patient as required for upper endoscopy.
3. Prepare abdomen with antiseptic solution and sterile drapes.
4. The stomach should be kept insufflated throughout the procedure to keep the stomach open. Multiple puncture procedures near the gastrostomy site can cause tissue necrosis; dome separation; and dilator tip connection and may cause the feeding tube to separate from the dilator end.
5. After feeding tube is inserted, the stomach must be inflated to the level of the anterior axillary line or higher.
6. Attach the gastrostomy tube assembly to the blue insertion wire which is exiting the patient's mouth:
   - Pass the blue wire through the dilator tip connection and may cause the feeding tube to separate from the dilator end.
   - It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

**Tubing Placement**

1. Thrust the 14 gauge needle/cannula through the skin incision and into the stomach under direct endoscopic vision. If a grasping snare is properly positioned, the inner stylet may pass through the grasping snare loop. If it does not enter the loop, the grasping snare should be repositioned through the gastrostomy tube and tightened to the correct location for placement of the gastrostomy tube.

2. Close the grasping snare around the cannula, and then remove the inner stylet.
3. Pass the looped end of the blue insertion wire through the cannula into the stomach.
4. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then tighten it.
5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously from patient's mouth. The blue insertion wire now exits the body from the patient's abdomen and mouth.
6. After removing the grasping snare, perform an EGD exam.
7. Gently separate the skin and underlying subcutaneous tissue.
8. Grasp both strands of the proximal end of the blue insertion wire in one hand while the other hand is exiting the abdominal wall.
9. Insert grasping snare through the scope channel and open over the proposed puncture site.
10. Use a scalpel blade to create a 5 cm incision and infiltrate local anesthetic subcutaneously into the skin at the proposed puncture site.
11. Make a minimum 1.0 cm skin incision at the selected site using a #11 scalpel blade.
12. Gently separate the skin and underlying subcutaneous tissue.

**Adverse Reactions**

May include: minor wound infections at the stoma site; disharmonization 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 and abdominal wall; fistulous fistula; gastric ulceration; peritonitis and sepsis, all of which increase in likelihood with improper PEG placement.

**Contraindications**

- Obstruction of the esophagus/airway which may prevent the introduction or removal of the feeding tube (i.e., tracheostomy, esophageal tumors, etc.)
- Inability to identify transillumination (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.)
- Fatigue and failure of the device.
- Premature failure of the device.
- Excessive tension on the gastrostomy tube may result in dislodgment or misalignment of the internal dome.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.
- The stomach under direct endoscopic vision.
- If a grasping snare is properly positioned, the inner stylet may pass through the grasping snare loop.
- If it does not enter the loop, the grasping snare should be repositioned through the gastrostomy tube and tightened to the correct location for placement of the gastrostomy tube.
- Failure to remove the device may result in small bowel obstruction and/or perforation.
- The stomach should be kept insufflated throughout the procedure to keep the stomach open.
- Multiple puncture procedures near the gastrostomy site can cause tissue necrosis; dome separation; and dilator tip connection and may cause the feeding tube to separate from the dilator end.
- Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.
9. As the gastrostomy tube is pulled through the abdominal wall, the retention dome passes through the oropharynx and into the stomach.

10. Reinsert the gastroscope to follow the tube as it enters the stomach and the dome just meets the gastric mucosa to assure safe passage of the internal bumper. There should be no blanching of either the gastric mucosa or skin. The scope should remain inserted until the procedure is complete to confirm correct placement.

**WARNING:** Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

11. Lavage the gastrostomy tube and wound site. Advance one of the external bolsters over the gastrostomy tube using a hemostat until it is close to, but not snug against, the skin (Diagram 4).

12. Cut the gastrostomy tube approximately 12" from the skin level and attach the dual port feeding adaptor. The gastrostomy is now complete.

**WARNING:** Excessive traction may cause premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified under “Instructions for Device Removal.”

**SECTION II  Instructions for Device Removal**

**Endoscopic Method**

1. Introduce gastroscope, insufflate stomach and inspect stomach interior.

2. Insert a grasping snare and position under the internal bolster.

3. Slowly rotate 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 scope, grasping snare and bolster.

**Surgical Method**

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

**WARNING:** The gastrostomy tube’s internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Tube Replacement**

Replacement should occur immediately following removal. Bard Access Systems offers a complete line of replacement devices. Please contact your Bard representative or Bard Customer Service at 1-800-545-0890 for additional information.

If the device will not be replaced, an occlusive dressing should be placed and the tract should close within 24 hours.

**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.

**Section II  Instructions for Device Removal**

**Endoscopic Method**

1. Introduce gastroscope, insufflate stomach and inspect stomach interior.

2. Insert a grasping snare and position under the internal bolster.

3. Slowly rotate 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 scope, grasping snare and bolster.

**Surgical Method**

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

**WARNING:** The gastrostomy tube’s internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Tube Replacement**

Replacement should occur immediately following removal. Bard Access Systems offers a complete line of replacement devices. Please contact your Bard representative or Bard Customer Service at 1-800-545-0890 for additional information.

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An issued or revision date and a revision number for these instructions are included for the user’s information on the first page directly beneath the telephone number of Bard Access Systems. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems to see if additional product information is available (Telephone Number: 1-800-545-0890).

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**Section II  Instructions for Device Removal**

**Endoscopic Method**

1. Introduce gastroscope, insufflate stomach and inspect stomach interior.

2. Insert a grasping snare and position under the internal bolster.

3. Slowly rotate 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 scope, grasping snare and bolster.

**Surgical Method**

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

**WARNING:** The gastrostomy tube’s internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Tube Replacement**

Replacement should occur immediately following removal. Bard Access Systems offers a complete line of replacement devices. Please contact your Bard representative or Bard Customer Service at 1-800-545-0890 for additional information.

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**Section II  Instructions for Device Removal**

**Endoscopic Method**

1. Introduce gastroscope, insufflate stomach and inspect stomach interior.

2. Insert a grasping snare and position under the internal bolster.

3. Slowly rotate 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 scope, grasping snare and bolster.

**Surgical Method**

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

**WARNING:** The gastrostomy tube’s internal dome must be removed by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Tube Replacement**

Replacement should occur immediately following removal. Bard Access Systems offers a complete line of replacement devices. Please contact your Bard representative or Bard Customer Service at 1-800-545-0890 for additional information.

If the device will not be replaced, an occlusive dressing should be placed and the tract should close within 24 hours.

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9. As the gastrostomy tube is pulled through the abdominal wall, the retention dome passes through the oropharynx and into the stomach.

10. Reinsert the gastroscope to follow the tube as it enters the stomach and the dome just meets the gastric mucosa to assure safe passage of the internal bumper. There should be no blanching of either the gastric mucosa or skin. The scope should remain inserted until the procedure is complete to confirm correct placement.

WARNING: Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

11. Cleanse the gastrostomy tube and wound site. Advanced one of the external bolsters over the gastrostomy tube using a hemostat until it is close to, but not snug against, the skin (Diagram 4).

12. Cut the gastrostomy tube approximately 12" from the skin level and attach the dual port feeding adaptor. The gastrostomy is now complete.

WARNING: Excessive traction may cause premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified under "Instructions for Device Removal."

SECTION II Instructions for Device Removal

Endoscopic Method
1. Introduce gastroscope, insufflate stomach and inspect stomach interior.
2. Insert a grasping snare and position under the internal bolster.
3. Slowly rotate tube and gently push 1-2 cm into the stomach.
4. Snare gastrostomy tube approximately 2 cm from bolster.

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

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AN ISSUED OR REVISION DATE AND A REVISION NUMBER FOR THESE INSTRUCTIONS ARE INCLUDED FOR THE USER’S INFORMATION ON THE FIRST PAGE DIRECTLY BENEATH THE TELEPHONE NUMBER OF BARD ACCESS SYSTEMS. IN THE EVENT TWO YEARS HAVE ELAPSED BETWEEN THIS DATE AND PRODUCT USE, THE USER SHOULD CONTACT BARD ACCESS SYSTEMS TO SEE IF ADDITIONAL PRODUCT INFORMATION IS AVAILABLE (TELEPHONE NUMBER: 1-800-545-0890).

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PONSKY-GAUDE RER* Silicone PEG Kit

Information for Use
Rx only
For One Time Use Only
STERILE unless package opened or damaged.
DO NOT RERESTERILIZE

Read this document in its entirety prior to use.

Bard Access Systems, Inc.
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9. As the gastrostomy tube is pulled through the abdominal wall, the retention dome passes through the oropharynx and into the stomach.
10. Reinsert the gastroscope to follow the tube as it enters the stomach and the dome just meets the gastric mucosa to assure safe passage of the internal bumper. There should be no blanching of either the gastric mucosa or skin. The scope should remain inserted until the procedure is complete to confirm correct placement.

WARNING: Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

11. Lavage the gastrostomy tube and wound site. Advance one of the external bolsters over the gastrostomy tube using a hemostat until it is close to, but not snug against, the skin (Diagram 4).

12. Cut the gastrostomy tube approximately 1/2” from the skin level and attach the dual port feeding adaptor. The gastrostomy is now complete.

WARNING: Excessive traction may cause premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified under “Instructions for Device Removal.”

SECTION II Instructions for Device Removal

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