10. Cleanse the gastrostomy tube and wound site. For 28 French gastrostomy tubes, a hemostat to advance the external bolster over the feeding tube until it is close to, but not snug against, the skin. Then use the hemostat to advance the retention sleeve over the gastrostomy tube until it meets the external bolster (see illustration). For 16 and 20 French gastrostomy tubes, advance one of the external bolsters over the gastrostomy tube using a hemostat until it is close to, but not snug against, the skin.

11. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. Attach the dual port feeding adaptor. The gastrostomy is now complete.

**WARNING:** Excessive traction may cause premature removal or prematurity 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

**Traction Removal**

1. Lubricate stoma. Slowly rotate gastrostomy tube and gently push it 1-2 cm into the stomach to disengage from fibrous tract.

**WARNING:** Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.

2. Loosely cover tract with a towel, drape, or 4" x 4" gauze.

**WARNING:** Do not remove the device unless the package is opened or damaged. DO NOT RESTERILIZE. Read this document in its entirety prior to use.

3. Grasp gastrostomy tube close to stoma site. Wrap gastrostomy tube firmly around hands if desired.

4. Apply firm counter-pressure to abdomen with other hand.

5. Pull gastrostomy tube using steady tension, repositioning the hand to keep close to the stomach. Continue to apply counter-pressure to the abdomen until the internal dome folds, then extrude through the abdominal wall.

**Gastroscopic Methods**

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. Grasp gastrostomy tube approximately 2 cm from bolster.

5. Cut gastrostomy tube near the skin and withdraw scope, snare and bolster.

**Surgical Method**

1. 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.

**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. Grasp gastrostomy tube approximately 2 cm from bolster.

5. Cut gastrostomy tube near the skin and withdraw scope, snare and bolster.

**Surgical Method**

1. 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.
Indications for Use
- For percutaneous placement of a long-term initial-placement feeding and/or decompression device.

Patient Preparation
- 1. Inspect contents of kit for damage. If damaged, do not use.
- 2. Close the grasping snare around the cannula, using a hemostat. If the grasping snare is not properly positioned the cannula will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be retightened.
- 3. Remove the guidewire retaining plug from the cannula.
- 4. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient’s mouth. The guidewire now positioned to surround the cannula (see Section 6).
- 5. Withdraw gastroscope, grasping snare from its distal tip. Then retighten it. Only the guidewire approximately 2-3 cm nasally into the skin at the proposed puncture site. The guidewire should pass the skin incision and exit through the abdominal wall. A smaller incision may contribute to extreme resistance. Avoid piercing the skin with the guidewire as this will cause the skin to retract if the cannula does not pass the skin incision. The stomach should be kept insufflated throughout the procedure to facilitate grasping the gastric and abdominal walls.
- 6. Slide the gastrostomy tube assembly, dilator end first, over the end of the guidewire until the internal dome is in its position in the stomach as well as its position in the stomach wall. The indentation of the gastric wall should be visible on its anterior surface. If the safety cap does not close, there is an increased potential for leakage of gastric contents which could lead to bowel obstruction and/or perforation.

Precautions
- 1. Thrust the 18 gauge Seldinger needle through the skin incision and over the guidewire. The safety cap should be firmly engaged with the cannula when exiting the fascia. Then retighten it.

Warnings
- 1. Do not attempt to use traction as a removal method if gas-trostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
- 2. The safety cap does not close if gas- trostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
- 3. Routinely inspect the Dual Port Feeding Adaptor for cutaneous safety cap closure and damage as tissue necrosis.
- 4. Insert a grasping snare through the scope channel and open over the guidewire. Make sure that the grasping snare is not pulled through the patient’s mouth. The grasping snare now positioned to surround the cannula (see Section 6).
- 5. Withdraw gastroscope, grasping snare from its distal tip. Then retighten it. Only the guidewire approximately 2-3 cm nasally into the skin at the proposed puncture site. The guidewire should pass the skin incision and exit through the abdominal wall. A smaller incision may contribute to extreme resistance. Avoid piercing the skin with the guidewire as this will cause the skin to retract if the cannula does not pass the skin incision. The stomach should be kept insufflated throughout the procedure to facilitate grasping the gastric and abdominal walls.
- 6. Avoid continuing to use traction at the selection site if dissection is present or if the gastrostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
- 7. Routinely inspect the Dual Port Feeding Adaptor for cutaneous safety cap closure and damage as tissue necrosis.
- 8. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient’s mouth. The grasping snare now positioned to surround the cannula (see Section 6).
- 9. Withdraw gastroscope, grasping snare from its distal tip. Then retighten it. Only the guidewire approximately 2-3 cm nasally into the skin at the proposed puncture site. The guidewire should pass the skin incision and exit through the abdominal wall. A smaller incision may contribute to extreme resistance. Avoid piercing the skin with the guidewire as this will cause the skin to retract if the cannula does not pass the skin incision. The stomach should be kept insufflated throughout the procedure to facilitate grasping the gastric and abdominal walls.
- 10. Avoid continuing to use traction at the selection site if dissection is present or if the gastrostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
- 11. Routinely inspect the Dual Port Feeding Adaptor for cutaneous safety cap closure and damage as tissue necrosis.

Traction
- 1. Place the patient supine. Place the light of the gastroscope to transilluminate abdominal wall with the light of the gastroscope to determine if the dome can be palpated in the neck of the stomach as it exits the abdominal wall. The dome should be palpated in the neck of the stomach as it exits the abdominal wall and the area of the dome should be visible on the anterior surface of the patient’s abdomen. If the dome is not visible on the anterior surface of the patient’s abdomen, the area of the dome should be palpated to determine if the dome is palpable in the neck of the stomach as it exits the abdominal wall. If the dome is not visible on the anterior surface of the patient’s abdomen, the area of the dome should be palpated to determine if the dome is palpable in the neck of the stomach as it exits the abdominal wall.
- 2. Grasp the dome with the grasping snare around the cannula. Then retighten it.
- 3. Prepare abdomen with antiseptic solution and sterile drapes.
- 4. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient’s mouth. The grasping snare now positioned to surround the cannula (see Section 6).

Procedure
- 1. Introduce gastroscope, insufflate stomach, inspect stomach interior and choose the correct location for placement of the gastrostomy tube.
- 2. Transilluminate abdominal wall with the light of the gastroscope to determine if the dome can be palpated in the neck of the stomach as it exits the abdominal wall. The dome should be palpated in the neck of the stomach as it exits the abdominal wall and the area of the dome should be visible on the anterior surface of the patient’s abdomen. If the dome is not visible on the anterior surface of the patient’s abdomen, the area of the dome should be palpated to determine if the dome is palpable in the neck of the stomach as it exits the abdominal wall. If the dome is not visible on the anterior surface of the patient’s abdomen, the area of the dome should be palpated to determine if the dome is palpable in the neck of the stomach as it exits the abdominal wall.
- 3. Remove the guidewire retaining plug from the cannula.
- 4. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient’s mouth. The grasping snare now positioned to surround the cannula (see Section 6).
- 5. Withdraw gastroscope, grasping snare from its distal tip. Then retighten it. Only the guidewire approximately 2-3 cm nasally into the skin at the proposed puncture site. The guidewire should pass the skin incision and exit through the abdominal wall. A smaller incision may contribute to extreme resistance. Avoid piercing the skin with the guidewire as this will cause the skin to retract if the cannula does not pass the skin incision. The stomach should be kept insufflated throughout the procedure to facilitate grasping the gastric and abdominal walls.
- 6. Avoid continuing to use traction at the selection site if dissection is present or if the gastrostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
- 7. Routinely inspect the Dual Port Feeding Adaptor for cutaneous safety cap closure and damage as tissue necrosis.

SELECTED SITE INSTRUCTIONS FOR USE
- 1. Inspect contents of kit for damage. If damaged, do not use.
- 2. Close the grasping snare around the cannula, using a hemostat. If the grasping snare is not properly positioned the cannula will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be retightened.
- 3. Grasp the dome with the grasping snare around the cannula. Then retighten it.
- 4. Prepare abdomen with antiseptic solution and sterile drapes.
- 5. Withdraw gastroscope, grasping snare from its distal tip. Then retighten it. Only the guidewire approximately 2-3 cm nasally into the skin at the proposed puncture site. The guidewire should pass the skin incision and exit through the abdominal wall. A smaller incision may contribute to extreme resistance. Avoid piercing the skin with the guidewire as this will cause the skin to retract if the cannula does not pass the skin incision. The stomach should be kept insufflated throughout the procedure to facilitate grasping the gastric and abdominal walls.
- 6. Avoid continuing to use traction at the selection site if dissection is present or if the gastrostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
- 7. Routinely inspect the Dual Port Feeding Adaptor for cutaneous safety cap closure and damage as tissue necrosis.

Patient Preparation
- 1. Inspect contents of kit for damage. If damaged, do not use.
- 2. Close the grasping snare around the cannula, using a hemostat. If the grasping snare is not properly positioned the cannula will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be retightened.
- 3. Grasp the dome with the grasping snare around the cannula. Then retighten it.
- 4. Prepare abdomen with antiseptic solution and sterile drapes.
- 5. Withdraw gastroscope, grasping snare from its distal tip. Then retighten it. Only the guidewire approximately 2-3 cm nasally into the skin at the proposed puncture site. The guidewire should pass the skin incision and exit through the abdominal wall. A smaller incision may contribute to extreme resistance. Avoid piercing the skin with the guidewire as this will cause the skin to retract if the cannula does not pass the skin incision. The stomach should be kept insufflated throughout the procedure to facilitate grasping the gastric and abdominal walls.
- 6. Avoid continuing to use traction at the selection site if dissection is present or if the gastrostomy tube is not free-floating within the thoracic duct. Gas- trostomy tube may be difficult to withdraw if neck of the stomach is compressed during traction for several periods of time, i.e., greater than one year, may have an increased potential for dissection during traction removal. Visually confirm tube patency prior to traction procedure.
Do not attempt to use traction as a removal method if gas-induced obstruction of the esophagus/airway which may prevent the introduction or removal of the feeding tube (i.e., tracheostomy, esophageal tumors, etc.). Conditions which would otherwise contraindicate endoscopic procedure.

• Inability to identify transillumination (i.e., remote obesity, extensive tissue necrosis).

Removal of gastrostomy tubes using traction may result in premature failure of the device. Failure of the safety cap does not close securely, there is an increased potential for leakage of gastric contents which could lead to aspiration.
Do not attempt to use traction as a removal method if gas is present. 

Excess tension on the gastrostomy tube should be avoided as it may result in small bowel obstruction, dislodgment or misalignment of the internal dome; tissue necrosis; dome separation; and/or perforation. 

Multiple surgical procedures near the gastrostomy site. 

Obstruction of the esophagus/airway which may prevent the introduction or removal of the feeding tube. 

The stomach should be kept insufflated throughout the procedure to provide a clear view of the gastric and abdominal anatomy. 

A smaller incision may contribute to extreme resistance during the passage of the gastrostomy tubes. 

The selected site should be free of major blood vessels, viscera and scar tissue. 

Access incision for the gastrostomy tube should be avoided as it may result in disfigurement or misalignment of the internal dome from friction with visceral and/or tissue necrosis. 

Excessive bleeding may cause premature removal or premature failure and failure of the device. In the event of an abnormal blood vessel, the needle should be removed as specific. 

Do not attempt to use traction as a removal method if gas is present. 

Tube Site Selection 

1. Thrust the 18 gauge Seldinger needle through the skin incision and into the stomach under direct endoscopic vision. If the grasping snare is properly positioned the cannula will pass through the open grasping snare and wire. If the grasping snare is not open, pull the grasping snare down toward the internal dome. 

3. Apply finger pressure at the point of clearest transillumination. A clear indentation of the gastric wall should be visible on its anterior surface. 

4. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient's mouth. 

5. Draw lidocaine into a 5 cc syringe and infiltrate local anesthetic subcutaneously. 

6. Make a minimum 1.0 cm skin incision at the selected site using a #11 scalpel blade. 

7. Separate the skin and underlying subcutaneous tissue. 

Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for leakage of gastric contents due to the presence of fibrotic tissue. 

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

SECTION 1 Instructions for Device Placement 

Patient Preparation 

1. Hept content of all for damage. If damaged, don't use. 

2. Transilluminate abdominal wall with the light of the gastroscope to ensure the cannula is properly positioned. 

3. Prepare abdomen with antiseptic solution and sterile drapes. 

4. Loosen the grasping snare. It should surround the internal dome from its position in the stoma. 

5. Prepare for potential leakage of gastric contents which could lead to the improper positioning. 

6. Make a 1.0 cm skin incision at the selected site using a #11 scalpel blade. 

7. Gently separate the skin and underlying subcutaneous tissue. 

8. When the soft silicone portion of the gastrostomy tube exits the body from the patient's abdominal wall it will also push the gastrostomy tube is not free-floating within the fibrous tract. 

9. Reinsert the gastroscope to follow the tube as it enters the stomach and confirm correct placement. 

10. There should be no blanching of either the gastrostomy tube is properly positioned. 

11. Thrust the 18 gauge Seldinger needle through the skin incision and into the stomach under direct endoscopic vision. If the grasping snare is properly positioned the cannula will pass through the open grasping snare and wire. If the grasping snare is not open, pull the grasping snare down toward the internal dome. 

12. Close the grasping snare around the cannula, guiding the tube simultaneously into the skin at the proposed puncture site. 

13. The selected site should be free of major blood vessels, viscera and scar tissue. 

14. Visually confirm tube patency prior to traction. 

15. Failure to remove the dome may result in small bowel obstruction, dislodgment or misalignment of the internal dome; tissue necrosis; dome separation; and/or perforation. 

16. It is recommended that feeding be initiated 24 hours following gastrostomy tube placement. 

17. Maintain firm tension on both ends of the gastrostomy tube as it exits the body from the anterior surface of the oro- and mouth. The guidewire now empties. 

In order to perform the procedure, at least one of the methods listed in these instructions. Failure to use them may result in disfigurement or misalignment of the internal dome; tissue necrosis; dome separation; and/or perforation. 

NOTE: If excessive resistance is met simultaneously into the skin at the proposed puncture site. 

18. There should be no blanching of either the gastrostomy tube is properly positioned. 

19. Maintain firm tension on both ends of the gastrostomy tube as it exits the body from the patient's abdominal wall. 

20. The scope should remain inserted until the procedure is complete to confirm correct placement. 

21. There should be no blanching of either the gastrostomy tube is properly positioned. 

22. When the soft silicone portion of the gastrostomy tube exits the body from the patient's abdominal wall it will also push the gastrostomy tube is not free-floating within the fibrous tract. 

23. LIKELY TO INJURY: The selected site should be free of major blood vessels, viscera and scar tissue. 

24. Visually confirm tube patency prior to traction.
**INDICATIONS FOR USE**

1. Inspect contents of kit for damage. If damaged, do not use.
2. Transilluminate abdominal wall with the light of the gastroscope to perform an EGD exam.
3. Prepare abdomen with antiseptic solution and sterile drapes.
4. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient’s mouth.
5. Withdraw gastroscope, grasping snare and guidewire simultaneously from the mouth.
6. Slide the gastrostomy tube assembly, dilator end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the guidewire and gastrostomy tube assembly prior to sliding it on to the guidewire.

**PRECAUTIONS**

- Routinely inspect the Dual Port Feeding Adaptor for signs of backflow.
- Handle and dispose of in accordance with occupational health and safety regulations.
- Do not continue procedure if transillumination cannot be identified.
- Do not attempt to use traction as a removal method if gas-tromasty tube is not free-floating within the lumen. Gastrotomy tube inflation may cause premature failure the device may be removed as specified.
- Low thrombosis device.

**ADVERSE REACTIONS**

- Inability to identify transillumination (i.e., excessive obesity, extensive adhesions).
- Conditions which would otherwise contraindicate endoscopic procedure.
- Inability to identify transillumination (i.e., excessive obesity, extensive adhesions).
- Gastrostomy tubes which have been in place for long periods of time may lose their ability to transilluminate.
- Gastrostomy tube should not be free-floating within the lumen. Gastrotomy tube inflation may cause premature failure the device may be removed as specified.
- Precautionary measures during removal.
- Conditions which would otherwise contraindicate endoscopic procedure.
- Low thrombosis device.

**CONTRAINDICATIONS**

- 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.

**INDICATIONS FOR USE**

1. Inspect contents of kit for damage. If damaged, do not use.
2. Transilluminate abdominal wall with the light of the gastroscope to perform an EGD exam.
3. Prepare abdomen with antiseptic solution and sterile drapes.
4. Insert a grasping snare through the scope channel and open over the guidewire by pulling it through the patient’s mouth.
5. Withdraw gastroscope, grasping snare and guidewire simultaneously from the mouth.
6. Slide the gastrostomy tube assembly, dilator end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the guidewire and gastrostomy tube assembly prior to sliding it on to the guidewire.

**PRECAUTIONS**

- Routine inspection of the Dual Port Feeding Adaptor for signs of backflow.
- Handle and dispose of in accordance with occupational health and safety regulations.
- Do not continue procedure if transillumination cannot be identified.
- Do not attempt to use traction as a removal method if gas-tromasty tube is not free-floating within the lumen. Gastrotomy tube inflation may cause premature failure the device may be removed as specified.
- Low thrombosis device.

**ADVERSE REACTIONS**

- Inability to identify transillumination (i.e., excessive obesity, extensive adhesions).
- Conditions which would otherwise contraindicate endoscopic procedure.
- Inability to identify transillumination (i.e., excessive obesity, extensive adhesions).
- Gastrostomy tubes which have been in place for long periods of time may lose their ability to transilluminate.
- Gastrostomy tube should not be free-floating within the lumen. Gastrotomy tube inflation may cause premature failure the device may be removed as specified.
- Precautionary measures during removal.
- Conditions which would otherwise contraindicate endoscopic procedure.
- Low thrombosis device.

**CONTRAINDICATIONS**

- 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.
**Warnings**

- Conditions which would otherwise contraindicate endoscopic procedure.
- Multiple surgical procedures near the gastrostomy site.
- Inability to identify transillumination (i.e., obesity, extensive gastrointestinal surgery, anemia, etc.).

**Precautions**

- After use, this product may be a potential biohazard.
- 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.
- Excessive tension on the stoma may result in dislodgment or misalignment of the device.
- The stomach should be kept insufflated throughout the procedure to prevent air from entering the gastrostomy and abdomen.
- It is recommended that approximately 24 inches of guide wire be withdrawn from the hoop prior to insertion.
- It is recommended that feeding be initiated 24 hours following removal of gastrostomy tubes using traction.
- Adverse Reactions: May include: minor wound infections at the stoma site; dislodgment or misalignment of the device; vessel necrosis.

**Indications for Use**

May include: minor wound infections at the stoma site; dislodgment or misalignment of internal dome; tissue necrosis; decompression device.

**Complications**

- Severe tension trauma to the tract and associated complications.
- Trauma to the tract and associated complications.
- Increased potential for dome separation during traction periods of time.
- Increased potential for leakage of gastrointestinal contents which could lead to infection.

**Device Description**

- **The Guidewire PEG System** is a soft, silicone gastrostomy tube packaged sterile in a kit containing procedural aids.

**In-use Instructions for Use**

**SECTION I Instructions for Device Placement**

1. Thrust the 18 gauge Seldinger needle through the skin incision and into the stomach (see Image 1113x94 to 1230x177).

2. Transilluminate abdominal wall with the light of the gastroscope to identify the correct location for placement of the gastrostomy tube (see Image 1113x94 to 1230x177).

3. Remove the guidewire retaining plug from the guidewire which is exiting the patient's mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly. Pass through the open grasping hoop. Pull the flexible end of the guidewire from the retaining hoop and then remove the inner stylet from the cannula.

4. Insert a grasping snare through the scope channel and open it over the cannula. Place the guidewire into the stomach (see Image 1113x94 to 1230x177).

5. Draw lidocaine into a 5 cc syringe and infiltrate local anesthetic subcutaneously while exiting the abdominal wall, a potential for leakage of gastric contents which could lead to skin irritation and/or infection.

**SECTION II Instructions for Device Removal**

1. Do not attempt to use traction as a removal method if gas is not freely flowing within the thoracic duct. Gastrostomy tube placement should be performed 10 to 14 days following surgery. If gas is not freely flowing within the thoracic duct, gastrostomy tube placement should be performed within 5 to 7 days following surgery.

2. After the tube has been placed, the selected site should be free of major blood vessels.

3. Ensure the dome's safety cap does not close securely, there is an increased potential for leakage of gastrointestinal contents which could lead to infection.

4. Do not attempt to use traction as a removal method if gas is not freely flowing within the thoracic duct. Gastrostomy tube placement should be performed 10 to 14 days following surgery. If gas is not freely flowing within the thoracic duct, gastrostomy tube placement should be performed within 5 to 7 days following surgery.

5. Draw lidocaine into a 5 cc syringe and infiltrate local anesthetic subcutaneously while exiting the abdominal wall, a potential for leakage of gastric contents which could lead to skin irritation and/or infection.

6. Remove of gastrostomy tubes using traction may result in severe tension trauma to the tract and associated complications.

7. Before inserting the device, the selected site should be free of major blood vessels, viscera and scar tissue.

8. The stomach should be kept insufflated throughout the procedure to prevent air from entering the gastrostomy and abdomen.

9. It is recommended that feeding be initiated 24 hours following removal of gastrostomy tubes using traction.

10. Adverse Reactions: May include: minor wound infections at the stoma site; dislodgment or misalignment of the device; vessel necrosis.

**Patient Preparation**

1. Inspect stoma site to ensure it is free of major blood vessels, viscera and scar tissue.

2. It is recommended that feeding be initiated 24 hours following removal of gastrostomy tubes using traction.

3. Wash and dry the patient's skin around the proposed puncture site.

4. Prepare abdomen with antiseptic solution and drapes.

5. Insert a grasping snare through the scope channel and open it over the cannula. Place the guidewire into the stomach (see Image 1113x94 to 1230x177).

6. Transilluminate abdominal wall with the light of the gastroscope to identify the correct location for placement of the gastrostomy tube (see Image 1113x94 to 1230x177).

7. It is recommended that a grasping snare be used as an aid rather than as the sole means of maintaining traction as the dome just meets the gastric mucosa to assure safe passage of the gastrostomy tube is passed through the abdominal wall, remove the guide wire by pulling it through the stomach. As the device was properly positioned the cannula will pass through the open grasping hoop and the grasping snare should be removed.

8. The scope should remain inserted until the guide wire is visible through the fibrous tract.

9. Reinsert the gastroscope to follow the tube as it enters the stomach and the device is properly positioned. Remove the guide wire. As the cannula is properly positioned the cannula will pass through the fibrous tract. The selected site should be free of major blood vessels, viscera and scar tissue.

10. Ensure the dome's safety cap does not close securely, there is an increased potential for leakage of gastrointestinal contents which could lead to skin irritation and/or infection.

11. Wash and dry the patient's skin around the proposed puncture site.

12. It is recommended that feeding be initiated 24 hours following removal of gastrostomy tubes using traction.

13. Transilluminate abdominal wall with the light of the gastroscope to identify the correct location for placement of the gastrostomy tube (see Image 1113x94 to 1230x177).

14. It is recommended that feeding be initiated 24 hours following removal of gastrostomy tubes using traction.

15. Wash and dry the patient's skin around the proposed puncture site.

16. It is recommended that feeding be initiated 24 hours following removal of gastrostomy tubes using traction.

17. Maintain firm tension on both ends of the guide wire as the gastrostomy tube assembly passes through the oropharynx and into the stomach.

18. The selected site should be free of major blood vessels, viscera and scar tissue.
10. Cleanse the gastrostomy tube and wound site. For 28 French gastrostomy tubes, use a hemostat to advance the external bolster over the feeding tube until it is close to, but not snug against, the skin. Then use the hemostat to advance the retention sleeve over the gastrostomy tube until it meets the external bolster (see Figure 9). For 16 and 20 French gastrostomy tubes, advance one of the external bolsters over the feeding tube using a hemostat until it is close to, but not snug against, the skin.

11. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. 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**

**Traction Removal**

1. Lubricate stoma. Slowly rotate gastrostomy tube and gently push it 1-2 cm into the stomach to disengage from fibrous tract.

**WARNING:** Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.

2. Loosely cover tract with a towel, drape, or 4” x 4” gauze.

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

**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 in the USA, or 801-595-0700 for additional information.

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

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 that 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 in the USA, or 801-595-0700.)

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**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 slowly push 1.2 cm onto the stomach.

4. Grasp gastrostomy tube approximately 2 cm from bolster.

5. Cut gastrostomy tube near the skin and withdraw scope, 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.

**Information for Use**

Rx only

Single patient use

STERILE unless package opened or damaged. DO NOT RESTERILIZE

Read this document in its entirety prior to use.

BARD® Guidewire PEG System with Soft Silicone Retention Dome

www.bardaccess.com

Salt Lake City, UT 84116 USA

1-800-545-0900 (USA)

1-801-595-0700

www.bardaccess.com

Technical and Clinical Support

1-866-893-2691 (USA)

E-mail: medical.services@crbard.com

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10. Cleanse the gastrostomy tube and wound site. For 28 French gastrostomy tubes, use a hemostat to advance the external bolster over the feeding tube until it is close to, but not snug against, the skin. Then use the hemostat to advance the retention sleeve over the gastrostomy tube until it meets the external bolster (see fig 1). For 16 and 20 French gastrostomy tubes, advance one of the external bolsters over the gastrostomy tube using a hemostat until it is close to, but not snug against, the skin.

11. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. 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

Traction Removal

1. Lubricate stoma. Slowly rotate gastrostomy tube and gently push it 1-2 cm into the stomach to disengage from fibrous tract.

WARNING: Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.

2. Loosely cover tract with a towel, drape, or 4” x 4” gauze. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

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 in the USA, or 801-595-0700 for additional information.

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.

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

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11. Cut the gastrostomy tube approximately 12" from the skin level and, if desired, place the pinch clamp on the feeding tube. Attach the dual port feeding adaptor. The gastrostomy is now complete.

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SECTION II Instructions for Device Removal

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WARNING: Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.

2. Loosely cover tract with a towel, drape, or 4" x 4" gauze.

3. Grasp gastrostomy tube close to stoma site. 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 the hand to keep close to the abdomen. Continue to apply firm counter-pressure to the abdomen until the internal dome of the device exits the abdominal wall. Then slide through the abdominal wall.

Gastrosopic 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 approximately 1 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, snare and bolster.

Surgical Method
1. 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.

ENDOSCOPIC METHOD

1. Introduce gastrostomy tube, insufflate stomach and inspect stomach interior.

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

3. Slowly rotate gastrostomy tube approximately 1 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, snare and bolster.

SURGICAL METHOD
1. 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.

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.

Information for Use
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11. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. 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

Traction Removal

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WARNING: Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.

2. Loosely cover tract with a towel, drape, or 4” x 4” gauze.

3. Grasp gastrostomy tube close to stoma site. 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 the hand to keep close to stoma. Continue to apply counter-pressure to the abdomen until the internal dome of the gastrostomy tube is pulled, then snare 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 slowly push 1-2 cm onto the stomach.

4. Snare gastrostomy tube approximately 2 cm from bolster.

5. Cut gastrostomy tube near the skin line and withdraw scope, 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.

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