7. Maintain firm tension on both ends of the gastrostomy tube. The patient may remove the grasping snare if desired. As the tip, covered with the gastrostomy tube is pushed through the abdominal wall, the internal dome will be folded and pushed against the abdominal wall. When the tip of the tube is approximately 2-3 cm from its distal tip, then retighten it. The tip of the tube should be in the stomach under direct endoscopic vision. If the grasping snare is unable to remove the internal dome, a hemostat may be used to enlarge the opening and reduce resistance. NOTE: If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. The guidewire now exits the body from the patient’s abdomen and mouth.

8. When the soft silicone portion of the gastrostomy tube is passed through the oropharynx and into the patient’s mouth, the guidewire is removed and the procedure is complete.

9. Reinsert the gastroscope to follow the tube as it passes through the fibrous tract to avoid potential separation of the stomach from the abdominal wall. If the grasping snare is unable to remove the internal dome, a hemostat may be used to enlarge the opening and reduce resistance.

10. Cleanse the gastrostomy tube and wound site.

11. Cut the gastrostomy tube approximately 12” from the skin level and if desired, place the incision on a loading forceps. The device may be removed or replaced in accordance with the instructions for device removal.

12. Cut the gastrostomy tube approximately 12” from the skin level and if desired, place the incision on a loading forceps. The device may be removed or replaced in accordance with the instructions for device removal.

**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 or replaced in accordance with the instructions for device removal.

**WARNING:** Do not attempt to remove in instances as a removal method may cause perforation of the esophagus. The user should refer to the Instruction Manual for removal procedure.

**WARNING:** Slowly rotate gastrostomy tube and gently push 1-2 cm into the stomach. Do not attempt to remove in instances as a removal method may cause perforation of the esophagus. The user should refer to the Instruction Manual for removal procedure.

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**Device Description**

The Gastrostomy Feeding Tube (GFT) is a soft, flexible tube designed to be passed through the abdominal wall and into the stomach to provide a feeding route for patients. It contains a dilating tip, an internal retention dome, and a flexible feeding tube assembly. The tube is packaged sterile and is meant for insertion under the guidance of a physician.

**Indications for Use**

- **Nutrition/Infusion:** For the delivery of enteric feeds and medications.
- **Biopsy:** For tissue sampling under direct endoscopic vision.

**Contraindications**

- **Absence of the abdominal wall, which may prevent the correct alignment or prevent the tube from entering the stomach.
- **Presence of a transmural stenosis, which may prevent the tube from entering the stomach.
- **Presence of a nasogastric tube in the stomach.

**Precautions**

- **Introduce gastroscope, insufflate stomach, inspect stomach interior and choose the correct location for placement of the gastrostomy tube.
- **Transilluminate abdominal wall with the light of the gastroscope to identify the correct location for the gastrostomy tube.
- **Pass the blue insertion wire loop through the dilating tip of the introducer sheath and into the stomach.
- **Apply water-soluble lubricant to gastrostomy tube assembly.
- **Pass the dome end of the gastrostomy feeding tube through the blue silicone dome.

**Section I: Instructions for Device Placement**

**Preparation**

1. Introduce gastroscope, insufflate stomach, inspect stomach interior and choose the correct location for the gastrostomy tube.
2. Transilluminate abdominal wall with the light of the gastroscope to identify the correct location for the gastrostomy tube.
3. Pass the blue insertion wire loop through the dilating tip of the introducer sheath and into the stomach.
4. Apply water-soluble lubricant to gastrostomy tube assembly.
5. Pass the dome end of the gastrostomy feeding tube through the blue silicone dome.

**Procedure**

1. Insertion of the gastrostomy tube should be avoided if it may result in discomfort or displacement of the upper gastrointestinal tract. If the stomach is not properly inflated, the procedure should be stopped.
2. The cannula should be placed into the stomach in such a way to avoid potential severe complications such as perforation, hemorrhage, or obstruction.
3. Be careful to keep the tip of the cannula as far down into the stomach as possible to avoid perforation or hemorrhage.

**Take Note**

- Do not continue procedure if transillumination cannot be identified.
- The stomach should be kept inflated throughout the procedure to ensure contact of the gastric and abdominal walls.
- Do not continue procedure if the cannula is not properly placed in the stomach.

**WARNING:** Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome.

**Precautions**

- Do not attempt to use the gastrostomy tube for suction or for any other purpose other than the intended use.
- Do not attempt to use traction as a removal method if the syringe is not locked.

**Labeling**

- The product is designed to be used in the skin area to drain fluids.
- The selection of the site should be free of major vessels, viscera, and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.
- 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.
- If the selected site 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.
- The tube should be positioned as close to the stomach as possible to avoid potential separation of the stomach from the abdominal wall.
- The tube should be positioned as close to the stomach as possible to avoid potential separation of the stomach from the abdominal wall.
- The sterility of the tube should be maintained throughout the procedure to avoid contamination.

**Trials**

- Do not use the gastrostomy tube for any other purpose other than the intended use.
- Do not use the gastrostomy tube for any other purpose other than the intended use.
...such as HBV (Hepatitis) or HIV (AIDS).

• 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.

• Removal of gastrostomy tubes using traction may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

3. Insertion wire looped end and pull the entire tube Site Selection

• It is recommended that feeding be initiated 24 hours following device placement. If the needle is not locked a needlestick injury could occur resulting in the transmission of serious diseases.

• 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.

5. Withdraw looped end of blue insertion wire, then retighten it.

6. After injection, activate the needle shield, away from yourself and any other person. Place the needle and syringe in the sharps container. Dispose of all sharps in an approved puncture-resistant container.

7. If the needle is not locked a needlestick injury could occur resulting in the transmission of serious diseases.

8. If the needle is not locked a needlestick injury could occur resulting in the transmission of serious diseases.

9. Retract the scalpel cover and discard in an approved puncture-resistant container. 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.

10. Reinsert the gastroscope to follow the tube as it enters the stomach.

Percutaneous gastrostomy

1. Insertion wire, needle, and scope are ready for placement of the gastrostomy tube. Ensure that the needle is locked prior to insertion. The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal walls.

2. Place patient in supine position. Prepare abdomen with antiseptic solution.

3. Pass the blue insertion wire loop through the dilating tip of the introducer sheath into the stomach.

4. Loosen the grasping snare and adjust it to surround only the blue insertion wire which is exiting the patient’s mouth: the grasping snare and scope simultaneously from patient’s mouth. The blue insertion wire now exits the body from the patient’s abdomen and mouth.

5. Insertion wire, needle, and scope are ready for placement of the gastrostomy tube. Ensure that the needle is locked prior to insertion. The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal walls.

6. It is recommended that approximately 24 inches (61 cm) of guidewire for withdrawal from the tissue prior to insertion. It is recommended that feeding tubes be installed 24 hours following device placement.

7. If the needle is not locked a needlestick injury could occur resulting in the transmission of serious diseases.

8. If the needle is not locked a needlestick injury could occur resulting in the transmission of serious diseases.

9. Retract the scalpel cover and discard in an approved puncture-resistant container. 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.

10. Gently separate the skin and underlying subcutaneous tissue with your thumb and forefinger and tighten the loops of the insertion wire looped end and pull the entire tube...
Instructions for Device Placement

**Section I: Instructions for Device Placement**

**Patient Preparation**

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

**Precautions**

- A newer device may contribute to colonoscopy discomfort. Use of a preprocedure protocol to ensure comfort of the patient and abdominal walls.
- It is recommended that approximately 24 inches (61 cm) of gasto-stomy tube be withdrawn from the hoop prior to insertion.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.
- Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for dome separation during traction removal. Visually confirm tube patency prior to traction removal.
- If the grasping snare is not positioned correctly, there is an increased risk of internal dome separation during traction removal. In this situation, the grasping snare should be positioned to surround the cannula.

**Adverse Reactions**

- Allergic reactions, infectious mononucleosis, immune rejection, infection, and perforation.
- Removal of gastrostomy tubes using traction may result in premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified in the instructions for device removal.
- Obstruction of the esophagus/airway which may prevent the introduction or removal of the feeding tube (i.e., tracheostomy, esophageal tumors, etc.).
- Obesity, extensive gastrointestinal surgery, ascites, etc.

**Contraindications**

- Multiple surgical procedures near the gastrostomy site.
- Conditions which would otherwise contraindicate endoscopy.

**Device Description**

The PEG Safety System is a soft, silicone gastrostomy feeding tube containing a soft, silicone dome designed to facilitate removal and safe passage of the gastrostomy tube through the abdominal wall. The dome is attached to the distal end of the tube. The device is packaged in a luer lock syringe designed to facilitate insertion of the device. The device is mounted on a luer lock syringe designed to facilitate insertion of the device. The device is mounted on a luer lock syringe designed to facilitate insertion of the device.

**Indications for Use**

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

**Warnings**

- Do not attempt to use traction as a removal method if the syringe is not locked a needle stick injury could occur.
- Prior to use of lidocaine ampule, please consult manufacturer’s product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.
- Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for dome separation during traction removal. Visually confirm tube patency prior to traction removal.
- If the grasping snare is not positioned correctly, there is an increased risk of internal dome separation during traction removal. In this situation, the grasping snare should be positioned to surround the cannula.

**Precautions**

- A newer device may contribute to colonoscopy discomfort. Use of a preprocedure protocol to ensure comfort of the patient and abdominal walls.
- It is recommended that approximately 24 inches (61 cm) of gastrostomy tube be withdrawn from the hoop prior to insertion.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.
- Removal of gastrostomy tubes using traction may result in premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified in the instructions for device removal.

**Contraindications**

- Multiple surgical procedures near the gastrostomy site.
- Conditions which would otherwise contraindicate endoscopy.

**Device Description**

The PEG Safety System is a soft, silicone gastrostomy feeding tube containing a soft, silicone dome designed to facilitate removal and safe passage of the gastrostomy tube through the abdominal wall. The dome is attached to the distal end of the tube. The device is packaged in a luer lock syringe designed to facilitate insertion of the device. The device is mounted on a luer lock syringe designed to facilitate insertion of the device. The device is mounted on a luer lock syringe designed to facilitate insertion of the device.

**Indications for Use**

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

**Warnings**

- Do not attempt to use traction as a removal method if the syringe is not locked a needle stick injury could occur.
- Prior to use of lidocaine ampule, please consult manufacturer’s product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.
- Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for dome separation during traction removal. Visually confirm tube patency prior to traction removal.
- If the grasping snare is not positioned correctly, there is an increased risk of internal dome separation during traction removal. In this situation, the grasping snare should be positioned to surround the cannula.

**Precautions**

- A newer device may contribute to colonoscopy discomfort. Use of a preprocedure protocol to ensure comfort of the patient and abdominal walls.
Device Description
The Bard® GRST™ Device is a dual lumen, gastrostomy tube and internal retention dome, packaged sterile in a kit containing sharps protected procedural aids.

Indications for Use
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 identify transillumination for needle placement (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.).
3. Place patient in supine position.
4. Prepare abdomen with antiseptic solution and sterile drapes.
5. Withdraw looped end of blue insertion wire, then retighten it.
6. Attach the gastrostomy tube assembly to the dilator end, packaged sterile in a kit containing sharps protected procedural aids.
7. The gastrostomy tube's internal dome must be removed under "Instructions for Device Removal."• If the syringe is not locked a needlestick injury could occur resulting in the transmission of serious diseases.

Contraindications
- Saber of the grasping snare which may prevent the internal dome of the gastrostomy tube from exiting the fascia. After passing the device through the abdominal wall, the abdominal wall incision site is closed completely.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

Precautions
- A smaller incision may contribute to extreme resistance while exiting the abdominal wall, thus traumatizing the tract and associated complications. In the event of premature failure the device may be removed as specified under "Instructions for Device Removal.”
- Excessive traction may cause premature removal or premature leakage of the device. In the event of excessive traction the device should be removed as specified under "Instructions for Device Removal.”

Adverse Reactions
• Do not continue procedure if transillumination cannot be identified.
- Inability to identify transillumination for needle placement (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.).

SECTION I Instructions for Device Placement
Patient Preparation
1. Introduce gastroscope into stomach. If grasping snare is not available, proceed as follows:
2. Transilluminate abdominal wall with the light of the gastroscope to identify transillumination for needle placement (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.).

Tube Placement (Pull)
8. Make skin incision approximately 1 cm long at the selected site using the no. 11 safety scalpel.
9. As the gastrostomy tube is pulled through the abdominal wall, the soft dome just meets the gastric mucosa to assure safe passage of the internal bumper. There should be no blanching of the gastric mucosa or skin. The scope should remain inserted until the procedure is complete to confirm correct placement.
10. Reinsert the gastroscope to follow the tube as it enters the stomach under direct endoscopic vision. If the grasping snare is properly placed and the tube is within the stomach, the grasping snare should be able to secure the tube, 11. Cleanse the gastrostomy tube and wound site. Using a hemostat, advance the external dome to the skin. Using a hemostat, advance the external dome to the skin.

Tube Site Selection
• Do not continue procedure if transillumination cannot be identified.
- Inability to identify transillumination for needle placement (i.e., extreme obesity, extensive gastrointestinal surgery, ascites, etc.).

WARNING: Prior to use of lidocaine ampule, please consult manufacturer’s product labels and inserts for any indications, contraindications, hazards, warnings, cautions and instructions for use.

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.

Indications for Use
1. Place patient in supine position. 2. Prepare abdomen with antiseptic solution and sterile drapes. 3. Place patient in supine position. 4. Prepare abdomen with antiseptic solution and sterile drapes. 5. Withdraw looped end of blue insertion wire, then retighten it. 6. Attach the gastrostomy tube assembly to the dilator end, packaged sterile in a kit containing sharps protected procedural aids.
7. If the needle cautery is not available, proceed as follows: 1. Place patient in supine position. 2. Prepare abdomen with antiseptic solution and sterile drapes. 3. Place patient in supine position. 4. Prepare abdomen with antiseptic solution and sterile drapes. 5. Withdraw looped end of blue insertion wire, then retighten it. 6. Attach the gastrostomy tube assembly to the dilator end, packaged sterile in a kit containing sharps protected procedural aids.
7. If the needle cautery is not available, proceed as follows: 1. Place patient in supine position. 2. Prepare abdomen with antiseptic solution and sterile drapes. 3. Place patient in supine position. 4. Prepare abdomen with antiseptic solution and sterile drapes. 5. Attach the gastrostomy tube assembly to the dilator end, packaged sterile in a kit containing sharps protected procedural aids.
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7. If the needle cautery is not available, proceed as follows: 1. Place patient in supine position. 2. Prepare abdomen with antiseptic solution and sterile drapes. 3. Place patient in supine position. 4. Prepare abdomen with antiseptic solution and sterile drapes. 5. Attach the gastrostomy tube assembly to the dilator end, packaged sterile in a kit containing sharps protected procedural aids.
7. If the needle cautery is not available, proceed as follows: 1. Place patient in supine position. 2. Prepare abdomen with antiseptic solution and sterile drapes. 3. Place patient in supine position. 4. Prepare abdomen with antiseptic solution and sterile drapes. 5. Attach the gastrostomy tube assembly to the dilator end, packaged sterile in a kit containing sharps protected procedural aids.
Device Description

The PEG Safety System - "Guidewire" is a soft, silicone gastrostomy tube (i.e., HBV (Hepatitis) or HIV (AIDS).

Indications for Use

For percutaneous placement of a long-term initial-placement feeding and/or removal of gastrostomy tubes using traction may result in trauma to the tract and associated complications.

Contraindications

• Multiple surgical procedures near the gastrostomy site.
• Conditions which would otherwise contraindicate endoscopy.

Adverse Reactions

- 2 - 3 - 4 - 5 - 6 -

Patient Preparation

Instructions for Use

1. Inspect contents of kit for damage. If damaged, do not use.

2. Place patient in supine position. 

3. Prep patient as required for upper endoscopy.

4. Prepare abdomen with antiseptic solution and sterile drapes.

5. Infiltrate local anesthetic subcutaneously into the skin at the proposed puncture site.

6. Attach the gastrostomy tube assembly to the blue insertion wire, then retighten it.

7. As the gastrostomy tube is pulled through the abdominal wall, the soft bolster over the feeding tube until it is close to, but not snug against the skin.

9. Retract the scalpel cover and discard in an approved puncture-resistant container.

10. Gently separate the skin and underlying subcutaneous tissue with your thumb and forefinger and tighten the loops together to form attachment (see "Instructions for Device Removal.")
**Device Description**

**PEG Safety System - “Guidewire”** is a soft, silicone gastrostomy decompression device.

- **Indications for Use**
  - For percutaneous placement of a long-term initial-placement feeding and/or decompression device.
  - May include: tracheostomy, esophageal tumors, etc.

- **Contraindications**
  - Previous gastrostomy site.
  - Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for dome separation during traction removal. Visually confirm tube patency prior to traction removal.
  - Multiple surgical procedures near the gastrostomy site.
  - Conditions which would otherwise contraindicate endoscopy.

- **Adverse Reactions**
  - Gastrostomy tubes may become dislodged or obstruct the esophagus/airway.

- **Warnings**
  - Do not attempt to use traction as a removal method if dislodgment or obstruction of the internal dome from its position in the stomach as well as tissue necrosis. If the syringe is not locked a needlestick injury could occur. In the event of premature failure the device may be removed as specified by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Precautions**

- A larger incision may contribute to extreme resistance to the internal dome and may result in incision-site trauma.

**Instructions for Use**

**Patient Preparation**

1. Insert the needle hub into the skin. If the syringe is not locked a needlestick injury could occur.
2. Place patient in supine position. Place patient in supine position.
3. Prep patient as required for upper endoscopy.
4. Prepare abdomen with antiseptic solution and sterile drapes.

**Procedure**

1. After injection, activate the needle shield, away from yourself and any other person, with a one handed technique by pressing forward on the hinge. Detach needle and discard in an approved puncture-resistant contamination waste container.
2. After use, this product may be a potential biohazard.
3. The stomach should be kept inflated throughout the procedure to ensure constant contact of the gastric wall.
4. The gastrostomy tube's internal dome must be removed to prevent small bowel obstruction and/or perforation.
5. The gastrostomy tube is not free-floating within the fibrous sheath, and may result in trauma to the tract and associated complications.
6. Use a smaller incision may contribute to extreme resistance to the internal dome and may result in incision-site trauma.
7. Devise methods to fixate the tube(s) at the skin surface using non-adhesives, and allow the tube to rest on the skin surface for a minimum of 10 minutes before continuing.
8. After the chosen site has been identified and prepared, the gastrostomy tube is inserted through the abdominal wall and incision site. If it does not enter the loop, the grasping snare should be positioned to surround the cannula.
9. If the needle shield is not activated then carefully twist the needle off and dispose of in a sharps container.

**Device Description**

**PEG Safety System - “Guidewire”** is a soft, silicone gastrostomy decompression device.

- **Indications for Use**
  - For percutaneous placement of a long-term initial-placement feeding and/or decompression device.
  - May include: tracheostomy, esophageal tumors, etc.

- **Contraindications**
  - Previous gastrostomy site.
  - Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for dome separation during traction removal. Visually confirm tube patency prior to traction removal.
  - Multiple surgical procedures near the gastrostomy site.
  - Conditions which would otherwise contraindicate endoscopy.

- **Adverse Reactions**
  - Gastrostomy tubes may become dislodged or obstruct the esophagus/airway.

- **Warnings**
  - Do not attempt to use traction as a removal method if dislodgment or obstruction of the internal dome from its position in the stomach as well as tissue necrosis. If the syringe is not locked a needlestick injury could occur. In the event of premature failure the device may be removed as specified by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Precautions**

- A larger incision may contribute to extreme resistance to the internal dome and may result in incision-site trauma.

**Instructions for Use**

**Patient Preparation**

1. Insert the needle hub into the skin. If the syringe is not locked a needlestick injury could occur.
2. Place patient in supine position. Place patient in supine position.
3. Prep patient as required for upper endoscopy.
4. Prepare abdomen with antiseptic solution and sterile drapes.

**Procedure**

1. After injection, activate the needle shield, away from yourself and any other person, with a one handed technique by pressing forward on the hinge. Detach needle and discard in an approved puncture-resistant contamination waste container.
2. After use, this product may be a potential biohazard.
3. The stomach should be kept inflated throughout the procedure to ensure constant contact of the gastric wall.
4. The gastrostomy tube's internal dome must be removed to prevent small bowel obstruction and/or perforation.
5. The gastrostomy tube is not free-floating within the fibrous sheath, and may result in trauma to the tract and associated complications.
6. Use a smaller incision may contribute to extreme resistance to the internal dome and may result in incision-site trauma.
7. Devise methods to fixate the tube(s) at the skin surface using non-adhesives, and allow the tube to rest on the skin surface for a minimum of 10 minutes before continuing.
8. After the chosen site has been identified and prepared, the gastrostomy tube is inserted through the abdominal wall and incision site. If it does not enter the loop, the grasping snare should be positioned to surround the cannula.
9. If the needle shield is not activated then carefully twist the needle off and dispose of in a sharps container.

**Device Description**

**PEG Safety System - “Guidewire”** is a soft, silicone gastrostomy decompression device.

- **Indications for Use**
  - For percutaneous placement of a long-term initial-placement feeding and/or decompression device.
  - May include: tracheostomy, esophageal tumors, etc.

- **Contraindications**
  - Previous gastrostomy site.
  - Gastrostomy tubes which have been in place for long periods of time, i.e., greater than one year, may have an increased potential for dome separation during traction removal. Visually confirm tube patency prior to traction removal.
  - Multiple surgical procedures near the gastrostomy site.
  - Conditions which would otherwise contraindicate endoscopy.

- **Adverse Reactions**
  - Gastrostomy tubes may become dislodged or obstruct the esophagus/airway.

- **Warnings**
  - Do not attempt to use traction as a removal method if dislodgment or obstruction of the internal dome from its position in the stomach as well as tissue necrosis. If the syringe is not locked a needlestick injury could occur. In the event of premature failure the device may be removed as specified by one of the methods listed in these instructions. Failure to remove the dome may result in small bowel obstruction and/or perforation.

**Precautions**

- A larger incision may contribute to extreme resistance to the internal dome and may result in incision-site trauma.

**Instructions for Use**

**Patient Preparation**

1. Insert the needle hub into the skin. If the syringe is not locked a needlestick injury could occur.
2. Place patient in supine position. Place patient in supine position.
3. Prep patient as required for upper endoscopy.
4. Prepare abdomen with antiseptic solution and sterile drapes.

**Procedure**

1. After injection, activate the needle shield, away from yourself and any other person, with a one handed technique by pressing forward on the hinge. Detach needle and discard in an approved puncture-resistant contamination waste container.
2. After use, this product may be a potential biohazard.
3. The stomach should be kept inflated throughout the procedure to ensure constant contact of the gastric wall.
4. The gastrostomy tube's internal dome must be removed to prevent small bowel obstruction and/or perforation.
5. The gastrostomy tube is not free-floating within the fibrous sheath, and may result in trauma to the tract and associated complications.
6. Use a smaller incision may contribute to extreme resistance to the internal dome and may result in incision-site trauma.
7. Devise methods to fixate the tube(s) at the skin surface using non-adhesives, and allow the tube to rest on the skin surface for a minimum of 10 minutes before continuing.
8. After the chosen site has been identified and prepared, the gastrostomy tube is inserted through the abdominal wall and incision site. If it does not enter the loop, the grasping snare should be positioned to surround the cannula.
9. If the needle shield is not activated then carefully twist the needle off and dispose of in a sharps container.
7. Maintain firm tension on both ends of the gastrostomy tube. If the tube is looped, place the loop under tension in the abdominal wall. As the tube is pulled, the internal dome will fold and pass through the abdominal wall.

NOTE: If excessive tension is not maintained while the internal dome is in the stomach, the internal dome may not deploy properly.

WARNING: Excessive tension may cause premature dome separation. The procedure should be stopped immediately if the internal dome is not deployed properly.

8. After the internal dome has emerged from the abdominal wall, remove the guidewire by pulling it through the port. The guidewire should be removed to prevent injury to the patient or damage to the feeding tube.

NOTE: The guidewire should be removed if the internal dome is not deployed properly. The procedure should be stopped immediately if the internal dome is not deployed properly.

9. 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 (see Figure 6). The gastrostomy is now complete.

WARNING: Excessive tension may cause premature dome separation. The procedure should be stopped immediately if the internal dome is not deployed properly.

10. Place a sterile occlusive dressing over the tract and secure with tape. Remove the gown and gloves. Perform hand hygiene before and after the procedure.

NOTE: Sterile technique should be used when inserting or removing the gastrostomy tube to prevent infection. The tube should be changed according to institutional guidelines and recommendations.
WARNING: Excessive traction may cause premature fatigue and failure of the device. In fatal cases, it may result in small bowel obstruction and/or perforation.

1. Maintain firm tension on both ends of the gastrostomy tube assembly. As the tube is passed, the internal dome is pushed through the abdominal wall. The guidewire may be used to facilitate the disengagement of the fibrous tract to avoid potential separation of the stomach under direct endoscopic vision. If the grasping snare is not proximal to the internal dome, remove the guidewire by pulling it through the patient’s mouth and from the patient’s abdomen.

2. Thrust the introducer needle through the skin incision and into the abdominal wall, remove the guidewire retaining plug from the introducer sheath and grasp the guidewire approximately 2-3 cm from its distal tip. Then retighten it. Using a hemostat, advance the external bolster over the feeding tube until it is close to, but not snug against, the skin (see Tube Replacement). NOTE: Straighten out the dilator portion of the device prior to sliding it over the guidewire.

3. Grasp gastrostomy tube close to stoma site. Wrap gastrostomy tube near the skin line and withdraw scope, grasping snare and bolster. Apply firm counter-pressure to the abdomen with other hand.

4. Loosen the grasping snare. It should surround only the guidewire from the abdominal wall through the patient’s mouth. The guidewire now exits the body from the patient’s abdomen and mouth.

5. Withdraw gastroscope, grasping snare and guidewire simultaneously from patient’s mouth. The guidewire now exits the body from the patient’s abdomen and mouth.

6. Pull gastrostomy tube using steady force, suspending it by loop of endoscope close to the skin. The gastrostomy tube now exits the patient’s abdomen through the skin incision. When the grasping snare is closed, the internal dome will fold, then emerge through the abdominal wall.

7. Reinsert the gastroscope to follow the tube as it passes through the skin. The scope should remain inserted until the procedure is complete to confirm correct placement.

8. When the soft silicone portion of the gastrostomy tube is passed through the patient’s mouth, pull the grasping snare, and if desired, place the pinch clamp on the feeding tube. Attach the appropriate dual port feeding adaptor. The gastrostomy is now complete.

9. Strong traction is often needed to remove gastrostomy tube from the fibrous tract. The tube must be pulled as slowly as possible to avoid premature rupture of the fibrous tract. When the internal dome begins to emerge from the abdominal wall, the gastrostomy tube is in the position to be pulled to the skin as well as to three sources.

10. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. Pull the grasping snare, over the end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

11. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. Pull the grasping snare, over the end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

12. Cut the gastrostomy tube approximately 12” from the skin level and, if desired, place the pinch clamp on the feeding tube. Pull the grasping snare, over the end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

WARNING: Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract to avoid potential separation of the stomach from the abdominal wall.

WARNING: Excessive leverage may cause premature fatigue and failure of the device in fatal cases, it may result in small bowel obstruction and/or perforation.

WARNING: Excessive turn on both ends of the gastrostomy tube assembly. As the tube is passed, the internal dome is pushed through the abdominal wall. The guidewire may be used to facilitate the disengagement of the fibrous tract to avoid potential separation of the stomach under direct endoscopic vision. If the grasping snare is not proximal to the internal dome, remove the guidewire by pulling it through the patient’s mouth and from the patient’s abdomen.

NOTE: Traction method is not used on Bard* PEG Safety System – “Guidewire” Surgical Method

SECTION II Instructions for Device Removal

Technical and Clinical Support 1-866-893-2691 (USA).

Telephone Number: 1-800-545-0890 in the USA, or 801-595-0700.

Email: medical.services@crbard.com

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Information for Use

Read this insert before using the Bard* PEG Safety System – “Guidewire” Bard Access Systems, Inc.

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**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.”

**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.”

---

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

2. Close the grasping snare around the introducer sheath and pull the sheath out from the abdominal wall.

3. Remove the guide wire using a hemostat. As the tube is passed, the internal dome will fold, then emerge through the abdominal wall.

**NOTE:** If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance. As the tube is pushed through the anterior abdominal wall, it will also push the introducer sheath out (see information for use).

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

5. Pull gastrostomy tube using steady tension, repositioning hand to keep tension applied to the internal dome.

---

1. Thrust the introducer needle through the skin incision and into the stomach. As the firm, tapered end of the gastrostomy tube is pushed through the skin, the dome just meets the gastric mucosa to assure safe passage of the internal bumper (see information for use).

2. Close the grasping snare around the introducer sheath and pull the sheath into the stomach (see information for use).

3. Insert the grasping snare and position under the internal bolster. Using a hemostat, advance the external bolster over the feeding tube until it is close to, but not snug against, the skin (see information for use).

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

5. Pull gastrostomy tube using steady tension, repositioning hand to keep tension applied to the internal dome.

---

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

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

3. Grasp gastrostomy tube at the end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

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

5. Pull gastrostomy tube using steady tension, repositioning hand to keep tension applied to the internal dome. Do not allow gastroscope to enter the stomach before the gastrostomy tube assembly is fully advanced past the internal dome.

---

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

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

3. Grasp gastrostomy tube at the end first, over the end of the guidewire which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

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

5. Pull gastrostomy tube using steady tension, repositioning hand to keep tension applied to the internal dome. Do not allow gastroscope to enter the stomach before the gastrostomy tube assembly is fully advanced past the internal dome.
7. Maintain firm tension on both ends of the gastrostomy tube. By doing so, premature failure of the device may be avoided.

WARNING: Excessive tension 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 I Tube Placement

1. Loosen the retaining hoop approximately 2 cm from its distal tip. Then retighten it.
2. Attach the appropriate dual port feeding adaptor. The gastrostomy is now complete.

WARNING: Excessive tension 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.”

Method

Guidewire Method

1. Insert the guidewire through the oropharynx and into the stomach. As the firm, tapered end of the gastrostomy tube is pushed through the anterior abdominal wall it will also push the introducer sheath out (see Image 302x244 to 339x330).
2. Close the grasping snare around the introducer sheath and guidewire simultaneously from patient’s mouth. The guidewire now exits the body from the patient’s abdomen and mouth.
3. Remove the guidewire retaining plug from the retaining hoop and pass through the introducer sheath into the stomach (see Image 302x244 to 339x330).
4. Apply firm counter-pressure to abdomen with other hand. As tension is being applied to the gastrostomy tube the internal dome will fold, then emerge through the abdominal wall.
5. The scope should remain inserted until the procedure is complete to confirm correct placement.

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.”

Traction Method

1. Firmly grasp the tube at both ends. After loosening the grasping snare, the device may be removed as specified under “Instructions for Device Removal.”
2. Then retighten it.

NOTE: 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.”

WARNING: Excessive tension 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.”

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1-800-545-0890 in the USA, or 801-595-0700.

NOTE: If excessive resistance is met while exiting the abdominal wall, a hemostat may be used to enlarge the opening and reduce resistance.

5. Loosely cover tract with a towel, drape, or 4" x 4" (10 cm x 10 cm) gauze.

WARNING: Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fissions tract to avoid potential separation of the stomach from the abdominal wall.

Surgical Method

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

NOTE: A biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal laws and regulations.

In the event of premature failure, the device may be removed as specified under “Instructions for Device Removal.”

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.”

E-mail: medical.services@crbard.com
11. Lubricate stoma. Slowly rotate gastrostomy tube and gently push it 1-2 cm into the stomach. If the grasping snare is properly positioned, the cannula will pass through the open grasping snare loop. If it does not enter the loop, the grasping snare should be positioned to surround the cannula. (see Section III for details). There should be no blanching of either the gastric mucosa or skin under direct endoscopic vision. If the grasping snare is not opened during advancement, the cannula will not properly engage the grasping snare. If the cannula is not properly engaged, it will not pass through the abdominal wall.

**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.

8. When the soft silicone portion of the gastrostomy tube is passed through the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall.

9. 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 (see Section III for details).

10. Cleanse the gastrostomy tube and wound site.

**SECTION II Instructions for Device Removal**

1. Thrust the introducer needle through the skin incision and into the abdominal cavity. The fascial tract may have become fibrous and needs to be incised to allow passage of the introducer needle. Using a hemostat, advance the external bolster over the feeding tube until it is close to, but not snug against, the skin (see Section II for details). The aperture is designed to allow passage of the introducer needle; the aperture is not an orifice for gastrostomy access.

2. Place the introducer needle over the feeding tube and withdraw the introducer needle and feeding tube from the abdominal cavity. The enteric dome of the tube must be removed before securing the feeding tube to the skin at the desired site. It is recommended to place the pinch clamp on the feeding tube. Attach the appropriate dual port feeding adaptor. The gastrostomy is now complete.

3. Grasp gastrostomy tube close to stoma site. Wrap gastrostomy tube firmly around bolster. Men. As tension is being applied to the gastrostomy tube the internal dome will fold, then emerge through the abdominal wall.

4. Grasp gastrostomy tube approximately 2 cm from bolster. It is recommended to place pinch clamp on feeding tube. Attach appropriate dual port feeding adaptor. The gastrostomy is now complete.

5. Pull gastrostomy tube using steady tension, repositioning hand to keep gastrostomy tube in line with the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

6. Slide the gastrostomy tube assembly, dilator and guidewire simultaneously from patient’s mouth to the abdominal cavity. The gastroscope should be passed through the introducer sheath into the stomach (see Section III for details). There should be no blanching of either the gastric mucosa or skin under direct endoscopic vision. This includes areas where the abdominal wall has been incised. The ostomy area should be examined for any lift off of the abdominal wall. It is recommended to place the pinch clamp on the feeding tube. Attach the appropriate dual port feeding adaptor. The gastrostomy is now complete.

7. If resistance is encountered, apply a water soluble lubricant to the gastrostomy feeding tube assembly and reposition the feeding tube. Reapply steady tension to advance the feeding tube into the stomach.

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

9. When the soft silicone portion of the gastrostomy tube is passed through the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall.

10. Cleanse the gastrostomy tube and wound site.

**Method**

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

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

3. Grasp gastrostomy tube approximately 2 cm from bolster.

4. Insert grasping snare over the end flange which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

5. Apply the internal dome into the abdomen with other hand.

6. Pull gastrostomy tube using steady tension, repositioning hand to keep gastrostomy tube in line with the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

**Withdrawal Method**

1. Lubricate stoma. Slowly rotate gastrostomy tube and gently push 1-2 cm into the stomach.

2. Grasp gastrostomy tube close to stoma site. Wrap gastrostomy tube firmly around bolster. It is recommended to place pinch clamp on feeding tube. Attach appropriate dual port feeding adaptor. The gastrostomy is now complete.

3. Strong rotation gastrostomy tube and gently push 1-2 cm into the stomach.

4. Grasp gastrostomy tube approximately 2 cm from bolster.

5. Insert grasping snare over the end flange which is exiting the patient’s mouth. Apply a water soluble lubricant to the gastrostomy feeding tube assembly.

6. Apply the internal dome into the abdomen with other hand.

7. Pull gastrostomy tube using steady tension, repositioning hand to keep gastrostomy tube in line with the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

8. Cleanse the gastrostomy tube and wound site.

**WARNING:** Excessive tension may cause premature removal or premature fatigue and failure of the device. In the event of premature failure, the device may be removed as outlined in Section II. If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

**WARNING:** Excessive tension may cause premature removal or premature fatigue and failure of the device. In the event of premature failure, the device may be removed as outlined in Section II. If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

**WARNING:** Excessive tension may cause premature removal or premature fatigue and failure of the device. In the event of premature failure, the device may be removed as outlined in Section II. If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

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**WARNING:** Excessive tension may cause premature removal or premature fatigue and failure of the device. In the event of premature failure, the device may be removed as outlined in Section II. If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

**WARNING:** Excessive tension may cause premature removal or premature fatigue and failure of the device. In the event of premature failure, the device may be removed as outlined in Section II. If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.

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**WARNING:** Excessive tension may cause premature removal or premature fatigue and failure of the device. In the event of premature failure, the device may be removed as outlined in Section II. If excessive resistance is met while exiting the abdominal wall, remove the guidewire by pulling it through the patient’s mouth. It is not necessary to cut the external guidewire; simply pull it through the patient’s mouth. You may encounter some resistance as the tube exits the abdominal wall. If the gastrostomy tube does not move, it is not necessarily obstructed. It may be necessary to rotate the gastrostomy tube gently once it enters the stomach.