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

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

WARNING: Excessive tension on the gastrostomy tube should be avoided as this may lead to dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

11. Cleanse the gastrostomy tube and wound site. 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 4). 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.

12. 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 Method

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: 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.

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 hand to keep applied counter-pressure to abdomen.

6. As tension is being applied to the gastrostomy tube, the internal dome will fold, then emerge through the abdominal wall.

Endoscopic Method

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

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

3. Slowly rotate tube and gently push 1-2 cm into the stomach.

4. Snare gastrostomy tube approximately 2 cm from bolster.

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

Surgical Method

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

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

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

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 on its own.

An issued or revision date and a revision number for these instructions are included for the user’s information on the first page directly beneath the telephone number of Bard Access Systems. In the event two years have elapsed between this date and product use, the user should contact Bard Access Systems to see if additional product information is available (Telephone Number: 1-800-545-0890 in the USA, or 801-595-0700). Bard and Ponsky are either a trademark or registered trademark of C. R. Bard, Inc, or an affiliate.

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PONSKY “Pull” PEG Kit with Soft Silicone Retention Dome

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.
**Device Description**

**Ponsky**

- This is a soft, silicone gastrostomy tube and retention dome with blue distal tip available in either a 16, 20 or 24 French size, packaged sterile in a kit containing procedural aids.

**Indications for Use**

- Tube placement is achieved by the dual port feeding adaptor (see Section II). The feeding tube extended through the fascia.

**Warnings**

- This product is designed to properly function in vivo when inserted through the stomach and retained within the abdominal wall.

**Contraindications**

- The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal wall.

**Precautions**

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

**Contraindications**

- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue.

**Contraindications**

- Do not tighten the grasping snare further after removal.

**Contraindications**

- Do not use if the stomach cannot be insufflated.

**Precautions**

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

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Tube Selection

- Choose a feed port and performance tube that best meets the needs of the patient. A soft silicone balloon, stomach, esophagus, stomach insert, insert balloon and perform an EGD exam.
- Tube placement: 8 to 30 French size, flexible gastrostomy tube, gastrostomy feeding tube.
- This product should be used in accordance with these directions for use. After using the kit do not stretch or pull the feeding tube away from the dilator tip. This may put undue force on opening the kit.

Precautions

- Do not attempt to use traction as a removal method if gas is present. The risk of gastric rupture is reduced if the stomach is kept deflated. Gas in the stomach may cause the feeding tube to adhere to the gastric wall, increasing the risk of injury to the wall. If the feeding tube is not properly removed, it may result in dislodgment or misalignment of the internal dome.
- Do not attempt to remove the feeding tube if the stomach appears to be insufflated. Gas in the stomach may cause the feeding tube to adhere to the gastric wall, increasing the risk of injury to the wall. If the feeding tube is not properly removed, it may result in dislodgment or misalignment of the internal dome.

Warnings

- Do not attempt to use traction as a removal method if gas is present. The risk of gastric rupture is reduced if the stomach is kept deflated. Gas in the stomach may cause the feeding tube to adhere to the gastric wall, increasing the risk of injury to the wall. If the feeding tube is not properly removed, it may result in dislodgment or misalignment of the internal dome.
- Do not attempt to remove the feeding tube if the stomach appears to be insufflated. Gas in the stomach may cause the feeding tube to adhere to the gastric wall, increasing the risk of injury to the wall. If the feeding tube is not properly removed, it may result in dislodgment or misalignment of the internal dome.


**Device Description**

*“Pull” PEG* is a soft, silicone gastrostomy tube and retention device with blue dilating tip available in a 16, 20 or 28 French size.

**Indications for Use**

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

**Contraindications**

- Gastrostomy tubes which have been in place for long periods of time, i.e., greater than three months, may have an increased potential for dome separation device. In the event of premature separation of the gastric and abdominal wall; gastrocolic fistula; small bowel obstruction and/or perforation; leakage of gastric contents; misalignment of the internal dome; tissue necrosis; dome separation; gastric ulceration; peritonitis and sepsis, all of which increase in likelihood with improper PEG placement.

**Precautions**

- Do not attempt to use traction as a removal method if gas- trostomy tube is not free-floating within the fibrous tract. The selected site should be free of tumors, etc.

**Warnings**

- Inability to identify transillumination (i.e., severe obesity, extensive tissue necrosis).

- May include: minor wound infections at the stoma site; dislodgment or misalignment of the internal dome; visceral injury or removal of the feeding tube (i.e., tracheostomy, esophageal dilation).

**Instructions for Use**

**SECTION 1  Instructions for Device Placement**

1. Introduce gastroscope, insufflate stomach, inspect stomach interior with proper positioning the cannula will pass through the open grasping wire, then retighten it.

2. Close the grasping snare around the cannula, and then remove the inner stylet.

3. Thrust the 14 gauge needle/cannula 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 wire, then retighten it.

4. Loosen the grasping snare and adjust it to surround only the blue inser-

5. Withdraw looped end of blue insertion wire, grasping snare and scope simultaneously into the mouth and reduce resistance. If excessive

6. Attach the gastrostomy tube assembly to the blue insertion wire which

7. Gently separate the skin and underlying subcutaneous tissue.

8. Grasp both strands of the proximal end of the insertion wire, then retighten it.

9. With the adhesive skin incision, insert and tug the gastrostomy tube into the mouth and reduce resistance. A hemostat may be used to enlarge the opening and reduce resistance.

10. The selected site should be free of tumors, etc.
Instructions for Use

Indications for Use

This device is a complete, packaged sterile device designed to properly function in vivo when used in accordance with these directions for use. After tube placement, consult the "Instructions for Device Removal." May include: minor wound infections at the stoma site; dislodgment or misalignment of the feeding tube and dilating tip connection causing separation of these components. Adverse Reactions

Precautions

The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal wall tissue, to minimize the risk of trauma to the tract and associated complications. Adverse Reaction

Tubal Site Selection

1. Inspect contents of kit for damage. If damaged, do not use. 2. Prepare abdomen with antiseptic solution and sterile drapes. 3. Pass the looped end of the blue insertion wire through the cannula into the mouth and exits the abdominal incision site and begin to pull the gastrostomy tube assembly. 4. With full force, grasp the gastrostomy tube assembly. 5. Place the loose end of the blue insertion wire into the cannula. 6. Loosen the grasping snare and adjust it to surround only the blue insertion wire, then retighten it. 7. Apply water-soluble lubricant to gastrostomy tube. 8. Grasp both strands of the proximal end of the insertion wire, then retighten it. 9. Pull the insertion wire, then loop it over the grasping snare. 10. Secure grasp and replace as necessary. If the safety cap does not close securely, there is an increased potential for leakage of gastric contents which could lead to skin irritation and/or infection. 11. Routinely inspect the Dual Port Feeding Adaptor for safety cap closure and replace as necessary. 12. If excessive resistance is met during grasping of the gastrostomy tube, advance the insertion wire difficult. The selected site should be free of major blood vessels, viscera and scar tissue. 13. The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal wall. 14. Handle and dispose of in accordance with accepted medical, state and federal laws and regulations.
Do not attempt to use traction as a removal method if gas- troscopy has been performed.

Gastrostomy tubes which have been in place for long periods of time, i.e., greater than three months, may have an increased potential for dome separation during traction removal. Visu- ally confirm tube pathology prior to traction removal. It is recommended that traction be utilized from the distal end to separate the dilator from the distal end.

It is recommended that feeding be initiated 24 hours fol- lowing gastrostomy tube placement. A single feeding can be given immediately after tube placement. However, because of the potential for leakage of gastric contents which could lead to aspiration, feed by one of the methods listed in these instructions.

NOTE:

- Do not attempt to use traction as a removal method if gas-
  troscopy has been performed.
- Gastrostomy tubes which have been in place for long periods of time, i.e., greater than three months, may have an increased potential for dome separation during traction removal. Visu-
  ally confirm tube pathology prior to traction removal. It is recommended that traction be utilized from the distal end to separate the dilator from the distal end.
- It is recommended that feeding be initiated 24 hours fol-
  lowing gastrostomy tube placement. A single feeding can be given immediately after tube placement. However, because of the potential for leakage of gastric contents which could lead to aspiration, feed by one of the methods listed in these instructions.

Warnings

- Conditions which would otherwise contraindicate endoscopic procedures.
- Obstruction of the esophagus/airway which may pre-
  vent the introduc-

Precautions

- After use, this product may be a potential biohazard.
- Handle and dispose of in accordance with accepted medi-
  cal practice and applicable local, state and federal laws
  and regulations.

Instructions for Use

SECTION 1  Instructions for Device Placement

1. Inspect contents of kit for damage. If damaged, do not use.
2. Pass the dome end of the gastrostomy feeding tube through the blue inser-

Tips 1 and 2

• Do not attempt to use traction as a removal method if gas-
  troscopy has been performed.

Gastrostomy tubes which have been in place for long periods of time, i.e., greater than three months, may have an increased potential for dome separation during traction removal. Visu-

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lowing gastrostomy tube placement. A single feeding can be given immediately after tube placement. However, because of the potential for leakage of gastric contents which could lead to aspiration, feed by one of the methods listed in these instructions.

In the event that the gastrostomy tube is not free-floating within the fibrous tract, one of the methods listed in these instructions may be used. After removing one of the grasping snare strands, pass the looped end of the blue insertion wire through the cannula 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 lumen, the grasping snare should be positioned to surround the cannula.

1. Inspect contents of kit for damage. If damaged, do not use.
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Tips 1 and 2

• Do not attempt to use traction as a removal method if gas-
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lowing gastrostomy tube placement. A single feeding can be given immediately after tube placement. However, because of the potential for leakage of gastric contents which could lead to aspiration, feed by one of the methods listed in these instructions.
9. As the gastrostomy tube is pulled through the abdominal wall, the soft silicone dome passes through the oropharynx and into the stomach.

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

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

11. 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 Method

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: 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.

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 hand to keep dome against abdominal wall.

6. As tension is being applied to the gastrostomy tube, the internal dome will fold, then emerge through the abdominal wall.

Endoscopic Method

1. Introduction: gastroscopy, visualize stomach and inspect stomach interior.

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

3. Slowly rotate tube and gently push 1-2 cm into the stomach.

4. Snare gastrostomy tube approximately 2 cm from bolster.

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

6. Surgery requires tube removal from the stomach. surgeons use a potentially biostable. handle and dispose of in accordance with accepted medical practices 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.

Introduction

PONSKY "Pull" PEG Kit with Soft Silicone Retention Dome Information for Use

As only

Single patient use

STERILE unless package opened or damaged.

DO NOT RENSTERILIZE

Read this document in its entirety prior to use.

Bard Access Systems, Inc.
Salt Lake City, UT 84116 USA
1-800-545-0890 (USA)
801-595-0700
www.bardaccess.com
0716564 Revised 11/2007

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

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

WARNING: Excess tension on the gastrostomy tube should be avoided as this may cause dislodgment of the internal dome or tissue necrosis.

11. 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 Image 4). 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.

12. 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.”

Surgical Method

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

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

Tube Replacement

Replacement should occur immediately following removal. Bard Access Systems offers a complete line of replacement devices. Please contact your Bard Representative or Bard Customer Service at 1-800-545-0890 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 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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WARNING: Excess tension on the gastrostomy tube should be avoided, as this may result in misalignment of the internal dome from its position in the stomach as well as tissue necrosis.

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SECTION II 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.

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: 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.

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 hand to keep the dome relatively still as it emerges through the abdominal wall.

Endoscopic Method

1. Introduction gastroscopy, insufflate stomach and inspect stomach interior.

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

3. Slowly rotate tube and gently push 1-2 cm into the stomach.

4. Snare gastrostomy tube approximately 2 cm from bolster.

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

Surgical Method

Surgically remove dome from the stomach (funnel) to remove endoscope.

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 Access Systems, Inc.
Salt Lake City, UT 84116 USA
1-800-545-0890 (USA)
801-595-0700
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SECTION II  Instructions for Device Removal

Traction Method

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:  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.  

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 hand to keep hand close to stoma.  

6. As tension is being applied to the gastrostomy tube, the internal dome will fold, then emerge through the abdominal wall.  

Endoscopic Method

1. Introduction gastroscopy, franchize stomach and inspect stomach interior.  

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

3. Slowly rotate stoma and gently push 1-2 cm into the stomach.  

4. Snare gastrostomy tube approximately 2 cm from bolster.  

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

Surgical Method

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

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

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

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 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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