Please consult package insert for more detailed safety information and instructions for use.

BPV/FEED/0616/0012

BARD

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Enteral
Feeding Tube

Wide Range of Choices to Meet Patient Needs

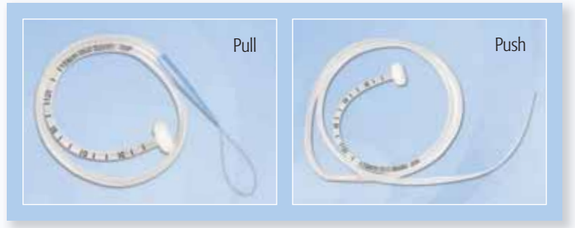



BARD

Percutaneous Endoscopic Gastrostomy (PEG)

BARD® PEG feeding devices offer physicians a wide range of choices to meet specific patient needs

- Soft and compressible internal dome designed to minimize trauma at insertion
- Identification of tube obstructions enhanced with translucent tubing
- Designed for enhanced patient comfort with soft silicone external bolster and tubing



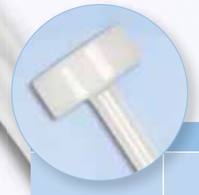
WIDE RANGE OF choices

PONSKY® PEG Feeding Devices

Radiopaque Dome allows X-ray confirmation

	Product Codes						
	Tube		Dual Port Adaptor	Safety†		Non-Safety	
	Outer Diameter	Inner Diameter	Inner Diameter	Pull	Push††	Pull	Push††
Deluxe Kits (Snare & Scissors included)	20F	13.8F	10.9F	003029	003030	000792	000793
	28F	19F	13F	003027	–	–	–
Standard Kits (Snare & Scissors NOT included)	20F	13.8F	10.9F	–	–	000330	000331

The design of these enteral feeding products do not restrict their use to enteral feeding devices only. Please check local laws for any applicable usage restrictions.



PONSKY-GAUDERER® PEG Feeding Devices

Radiopaque Dome allows X-ray confirmation

Requires Endoscopic Removal

	Product Codes						
	Tube		Dual Port Adaptor	Safety†		Non-Safety	
	Outer Diameter	Inner Diameter	Inner Diameter	Pull	Push††	Pull	Push††
Standard Kits (Snare & Scissors NOT included)	20F	13.8F	10.9F	–	–	000329	000328

The design of these enteral feeding products do not restrict their use to enteral feeding devices only. Please check local laws for any applicable usage restrictions.

*This product and packaging is not made with natural rubber latex. DEHP-Free.

†Safety kits include safety engineered sharp devices ††Push=Guidewire

Replacement Devices

Low-Profile Replacement Devices

Non-Balloon

BARD® Button Gastrostomy Tube and Accessories

- Cosmetically appealing low profile design
- Designed with simple, easy to connect tubing sets
- Obturator facilitates button placement
- Anti-reflux valve helps to provide safer feeding
- Kits include a continuous and bolus feeding tube

	Product Codes				
F	Stoma Length (cm)	BARD® Button Gastrostomy Tube Kit	Decompression Tube	BARD® Button Continuous Feeding Tube (90° adaptor)	BARD® Button Bolus Feeding Tube (straight adaptor)
18F	1.2	000292	000361	000256	000257
	1.7	000282	000350		
	2.4	000283	000351		
	3.4	000284	000352		
24F	1.2	000293	000362	000258	000259
	1.7	000285	000353		
	2.4	000286	000354		
	3.4	000287	000355		
	4.4	000296	000356		
28F	1.5	000261	000357	000268	000269
	2.7	000262	000358		
	4.3	000263	000359		

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Replacement Devices

Product Codes		
F	5cc Balloon	20cc Balloon
12F	000712	–
14F	000714	–
16F	–	000716
18F	–	000718
20F	–	000720
22F	–	000722
24F	–	000724

The design of these enteral feeding products do not restrict their use to enteral feeding devices only. Please check local laws for any applicable usage restrictions.

Standard Profile Replacement Devices
Balloon

BARD® Tri-Funnel Replacement Gastrostomy Tube

- Inflatable internal retention balloon
- Radiopaque stripe for X-ray placement verification
- Easy to identify obstructions with translucent silicone tubing
- Meets patient sizing needs with adjustable external bolster
- Separate medication port

Product Code			
Tube		Dual Port Adaptor	
Outer Diameter	Inner Diameter	Inner Diameter	PONSKY® Non-Balloon Replacement Tube
20F	13.8F	10.9F	000700

The design of these enteral feeding products do not restrict their use to enteral feeding devices only. Please check local laws for any applicable usage restrictions.

Standard Profile Replacement Devices
Non-Balloon

PONSKY® Non-Balloon Replacement Gastrostomy Tube

- Allows X-ray placement confirmation with radiopaque dome
- Bold centimeter markings for easy identification
- Easy to identify obstructions with translucent silicone tubing
- Obturator facilitates tube placement
- Meets patient sizing needs with adjustable external bolster
- Separate medication port

*This product and packaging is not made with natural rubber latex. DEHP-Free.

Accessories

PONSKY® Dual Port Feeding Adaptor*

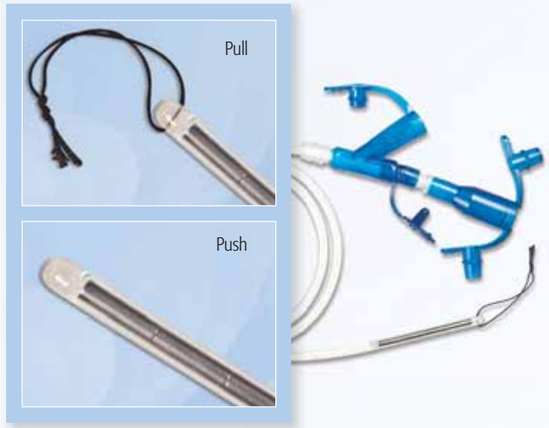
- Available for 20F and 28F PONSKY® devices
- Made of silicone

Product Codes		
PONSKY® PEG	28F	000318
PONSKY-GAUDERER® PEG	20F	000333
PONSKY® PEG	20F	000333

The design of these enteral feeding products do not restrict their use to enteral feeding devices only. Please check local laws for any applicable usage restrictions.

Jejunal Feeding/Gastric Decompression Tube

- Designed for easy insertion with Hydromer™ coating
- Simultaneous feeding and decompression facilitated by two port design



Product Codes			
J-Tube Outer Diameter	Compatible Bard PEG Size	Pull 27 Inch	Push 35 Inch
12F	28F	000733	000734
9F	20F	000319	000732

The design of these enteral feeding products do not restrict their use to enteral feeding devices only. Please check local laws for any applicable usage restrictions.

*This product and packaging is not made with natural rubber latex. DEHP-Free.

BARD® PEG Cleaning Brush

- Excellent tube cleaning with nylon brush
- Optimized flushing with cleaning solutions provided through utilization of Luer hub
- Silicone tip helps to protect stomach

Product Code
000396

Stoma Measuring Device*

- Expandable/collapsible retention dome facilitates stoma length measurement
- Ease of insertion with consistent tubing diameter

Product Codes	
Used with Button 18F/24F	000842
Used with Button 28F	000843

General Product Information:

- **Rx Only: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.**
- **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.**
- **Intended for Single Use. DO NOT REUSE. Reuse and/or repackaging may create a risk of patient or user infection, compromise the structural integrity and/or essential material and design characteristics of the device, which may lead to device failure, and/or lead to injury, illness or death of the patient.**

Bard® Button Device Bolus Feeding Tube with Straight Adaptor

Indications for Use:

To deliver enteral feeding and/or medication into the Bard® Button replacement gastrostomy device in patients requiring long-term nutritional support.

Contraindications:

Include use of this device with any product other than the Bard® Button replacement gastrostomy device; or for indications other than delivering feeding nutrients and/or medication.

Precautions:

Too much pressure may cause the Button device to be pushed into the stomach or to be prematurely pulled out of the stomach.

Adverse Reactions:

May include: minor wound infection or pressure necrosis at stoma site; leakage of gastric contents; gastrocolic fistula; and gastric separation leading to peritonitis, sepsis and death. All of these potential complications increase in likelihood with improper placement. If the stoma measuring device is pulled too tightly against the stomach wall an improperly sized, i.e., too short, replacement device may be selected.

Bard® Button Device Continuous Feeding Tube with 90° Adaptor

Indications for Use:

To provide enteral feeding in patients requiring long-term nutritional support.

Contraindications:

Include use of this device with any product other than the Bard® Button replacement gastrostomy device; or for indications other than delivering feeding nutrients.

Precautions:

Too much pressure may cause the Button device to be pushed into the stomach or to be prematurely pulled out of the stomach.

Adverse Reactions:

May include: minor wound infection or pressure necrosis at stoma site; leakage of gastric contents; gastrocolic fistula; and gastric separation leading to peritonitis, sepsis and death. All of these potential complications increase in likelihood with improper placement. If the stoma measuring device is pulled too tightly against the stomach wall an improperly sized, i.e., too short, replacement device may be selected.

Bard® Button Device Decompression Tube

Indications for Use:

To provide gastric decompression in patients requiring long-term nutritional support or who are otherwise unable to expel gas or gastric contents.

Contraindications:

Include use of this device with any product other than the Bard® Button replacement gastrostomy device; or for indications other than gastric decompression.

Warnings:

- Do not connect the feeding/gastric decompression tube feeding adaptor with any device component other than the Bard® Button Device.
- Do not use excessive force when inserting the feeding/gastric decompression male adaptor into the plug.

Precautions:

- Too much tension may cause the entire Button device to be pushed into the stomach.
- Too much tension may cause the entire Button device to be prematurely pulled out of the stomach.

Bard® Button Replacement Gastrostomy Device

Indications for Use:

The Button replacement gastrostomy device is indicated for percutaneous placement of a low-profile, long-term gastrostomy feeding and decompression device through an established stoma. The stoma measuring device is used for measurement of a well-established gastrostomy stoma tract for selection of an appropriate length Button device.

Contraindications:

- Placement of this device is contraindicated in individuals who do not have a well-established stoma tract or whose stomach has not been approximated to the stomach wall. In addition, any evidence of granulation tissue, infection or irritation should be addressed medically prior to insertion of this device.
- Placement of this device is also contraindicated in individuals with stoma tracts measured to be longer than 4.4 cm.

Warnings:

- Proper location of the internal dome must be confirmed prior to initiating feeding. Placement or slippage of the device into the peritoneal cavity will result in serious consequences including peritonitis, sepsis, and potentially death.
- Improper placement or excessive traction on the external portion of the device, whether intentional or unintentional, could result in dislodgement or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.
- If device is not free-floating within the tract, do not attempt to use traction as a method of removal as tract damage could occur.

Precautions:

- Excess tension should be avoided as it may result in selection of an improperly sized, i.e., too short, replacement device and complications such as pressure necrosis.
- If the stoma length falls between two markings, the one which is external to the stoma tract should be selected.
- Care should be taken to orient the device along the path of the stoma during insertion.
- Too much pressure may cause the entire Button device to be pushed into the stomach.
- Too much pressure may cause the entire Button device to be prematurely pulled out of the stomach.

Adverse Reactions:

May include: minor wound infection or pressure necrosis at stoma site; leakage of gastric contents; gastrocolic fistula; and gastric separation leading to peritonitis, sepsis and death. All of these potential complications increase in likelihood with improper placement. If the stoma measuring device is pulled too tightly against the stomach wall an improperly sized, i.e., too short, replacement device may be selected.

Bard® Guidewire PEG System with Soft Silicone Retention Dome

Indications for Use:

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

Contraindications:

May include:

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

Warnings:

- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue.
- 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.
- 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."
- Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.
- 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.
- 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.

Precautions:

- A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
- The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal walls.
- It is recommended that approximately 24 inches of guidewire 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 trauma to the tract and associated complications.
- Routinely inspect the Dual Port Feeding Adaptor for secure safety cap closure 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.

Adverse Reactions:

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

Bard® Jejunal Feeding/Gastric Decompression Tube

Indications for Use:

For enteral nutritional support and decompression where feeding via the upper gastrointestinal tract is contraindicated. This includes, but is not limited to, post-upper gastrointestinal tract surgery, radiation therapy, chemotherapy, reflux and other conditions associated with nausea, vomiting and possible aspiration.

Contraindications:

Crohn's disease, extensive adhesions, radiation enteritis, ascites, profound immunosuppression and coagulopathy.

Warnings:

- Do not reinsert the stylet once the tube has been placed as this may cause the stylet to exit through the distal eyeholes, potentially causing patient injury. Do not use stylet to dislodge clogs or manipulate obstructed tubes as this could potentially cause damage to the device or injury to the patient.
- Do not commence feeding unless J-tube has been determined to be properly placed to ensure nutritional support is administered within the jejunum.
- To avoid excessive pressure and the possibility of tube rupture, syringes smaller than 50 ml in size must not be used and infusion pumps must not exceed 40 psi.

Precautions:

- Instillation of crushed or ground medication through the J-tube may cause blockage.
- Use only with the Bard® gastrostomy feeding devices listed above.

Adverse Reactions:

Include, but are not limited to, inadvertent removal or dislodgment, leakage of contents into peritoneum, clogging of the tube, volvulus and diarrhea.

Bard® PEG Cleaning Brush

Indications for Use:

For the prophylactic cleaning and maintenance of Bard® gastrostomy feeding tubes. If properly sized to match internal lumen diameter, the Bard® PEG cleaning brush can be used to clean any manufacturer's gastrostomy tube lumen.

Contraindications:

- Do not use to clean clogged or severely encrusted gastrostomy tubes; such tubes should be replaced rather than cleaned.
- Do not use in gastrostomy tubes smaller than 18 French (6.0 mm).
- May also be contraindicated in some patients with gastrostomy tube-associated skin erosion or stoma irritation.

Warnings:

Do not force the brush through a clogged channel as the device could become entrapped or break as well as result in irritation to the stomach lining. If significant resistance to the brush's movement is felt, the gastrostomy tube may need to be changed.

Precautions:

- Wait fourteen days after gastrostomy tube placement before using the Bard® PEG cleaning brush to minimize the potential for tube dislodgement.
- If the gastrostomy tube end falls between marker bands, it is always safest to select the lower marker band.
- If the gastrostomy tube has been cut to a length which is shorter than the marker bands on the cleaning brush, the safe penetration level should be either carefully visually monitored with clear gastrostomy tubes, or marked with a piece of tape.

Adverse Reactions:

- Irritation of the stomach lining resulting from excessive penetration of the cleaning device and contact with the contralateral stomach wall.
- If used in contraindicated conditions, the cleaning device could become entrapped or break.

Bard® Stoma Measuring Device

Indications for Use:

For measurement of a well established gastrostomy stoma tract for selection of an appropriate length Bard® Button Gastrostomy Device.

Contraindications:

Use of this device is contraindicated in individuals who do not have a well established stoma tract.

Precautions:

- If the Bard® Stoma Measuring Device is pulled too tightly against the stomach wall, an improperly sized, i.e. , too short, replacement device may be selected.
- If the stoma length falls between two markings, the one which is external to the stoma tract should be selected.

Bard® Tri-Funnel Replacement Gastrostomy Tube

Indications for Use:

For percutaneous placement of a replacement gastrostomy feeding and/or decompression device into an established, appropriately sized stoma.

Contraindications:

Placement of this device is contraindicated in individuals who do not have a well established gastrostomy site. In addition, any evidence of granulation tissue, infection or irritation should be addressed medically prior to insertion of this device.

Warnings:

- Be certain that the balloon has passed through the fistulous tract and is completely in the stomach prior to inflation of the balloon. Placement or slippage of the device into the peritoneal cavity will result in serious consequences including peritonitis, sepsis and potentially death.
- Never use air to fill balloon as this can result in incorrect balloon inflation size and device retention and could potentially lead to inadvertent device removal by the patient. Do not exceed the maximum recommended inflation volume as this may cause excessive pressure on the gastric mucosa and migration of the internal balloon into the peritoneal cavity which can result in serious consequences including peritonitis, sepsis and potentially death.
- Excess tension should be avoided as this may cause tissue necrosis.
- Do not administer feeding or medication into the color-coded balloon inflation lumen as this lumen does not provide access for nutritional support to the patient's GI tract and could potentially damage the balloon and cause blockage of the balloon inflation lumen. If placement and patency cannot be confirmed do not begin feeding. Placement or slippage of the device into the peritoneal cavity will result in serious consequences including peritonitis, sepsis and potentially death.

Adverse Reactions:

Minor wound infections at stoma site, leakage of gastric contents, gastrocolic fistula and sepsis.

Bard® Wire-Guided Jejunal Feeding/Gastric Decompression Tube

Indications for Use:

For enteral nutritional support and decompression where feeding via the upper gastrointestinal tract is contraindicated. This includes, but is not limited to, post-upper gastrointestinal tract surgery, radiation therapy, chemotherapy, reflux and other conditions associated with nausea, vomiting and possible aspiration.

Contraindications:

Crohn's disease, extensive adhesions, radiation enteritis, ascites, profound immunosuppression and coagulopathy.

Warnings:

- Do not commence feeding unless J-tube has been determined to be properly placed to ensure nutritional support is administered within the jejunum.
- To avoid excessive pressure and the possibility of tube rupture, syringes smaller than 50 ml in size must not be used and infusion pumps must not exceed 40 psi.

Precautions:

- Instillation of crushed or ground medication through the J-tube may cause blockage.
- Use only with the Bard gastrostomy feeding devices listed above.

Adverse Reactions:

Include, but are not limited to, inadvertent removal or dislodgment, leakage of contents into peritoneum, clogging of the tube, volvulus and diarrhea.

Dual Port Feeding Adaptor

Indications for Use:

For attachment to the proximal end of Bard® silicone PEG tubes for administration of bolus and/or continuous feedings and delivery of medications.

Contraindications:

None known.

Warnings:

This device is designed for use with Bard® silicone PEG tubes only.

Precautions:

Routinely inspect the Dual Port Feeding Adaptor for secure safety cap closure 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.

Adverse Reactions:

To avoid complications, it is recommended that a pharmacist be consulted prior to medication administration.

May include: Gastrostomy tube clogging if certain medications are administered simultaneously with feedings; Impaired absorption of feeding and/or medication if they are not administered at recommended intervals.

Ponsky-Gauderer® Silicone PEG Kit

Indications for Use:

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

Contraindications:

May include:

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

Warnings:

- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.
- Excessive traction may cause premature removal or premature fatigue and failure of the device. In the event of premature failure the device may be removed as specified under "Instructions for Device Removal."
- Excess tension on the gastrostomy tube should be avoided as it may result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.
- 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.

Precautions:

- This product is designed to properly function in vivo when used in accordance with these directions for use. After opening the kit do not stretch or pull the feeding tube away from the dilator tip. This may put undue force on the feeding tube and dilator tip connection causing separation of these components.
- A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
- The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal walls.
- Do not tighten the grasping snare further after removal of the inner stylet as this may make passage of the blue insertion wire difficult.
- Do not grasp the gastrostomy feeding tube as a means of tightening attachment. This may put undue force on the tube and dilating tip connection and may cause the feeding tube to separate from the dilator end.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

Adverse Reactions:

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

Ponsky® Non-Balloon Replacement Gastrostomy Tube

Indications for Use:

For percutaneous placement of a long-term replacement gastrostomy feeding and/or decompression device into an established stoma.

Contraindications:

Placement of this device is contraindicated for individuals who do not have a well established gastrostomy tract, including patients whose stomach wall is not approximated to the abdominal wall. In addition, any evidence of granulation tissue, infection or irritation should be addressed medically prior to insertion of this device.

Warnings:

- Any evidence of granulation tissue, infection or irritation should be addressed medically prior to insertion of this device.
- Prior to attempting placement, stoma patency must be confirmed.
- Prior to initiating feeding, proper location of the internal dome must be confirmed, as per institutional protocol. Slippage of the device into the peritoneal cavity will result in serious consequences including peritonitis, sepsis and potential death.
- Improper placement or excessive traction on the external portion of the device, whether intentional or unintentional, could result in dislodgment or misalignment of the internal dome from its position in the stomach as well as tissue necrosis.
- Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.
- Visually confirm tube patency prior to traction removal.
- Do not grasp the catheter with any instrument that might damage the catheter.
- During the traction removal procedure, pull the catheter parallel to the stoma tract. Do not pull catheter laterally at an acute angle to the stoma tract. Doing so will apply a force greater than intended for the design and may result in damage to or separation of the dome.
- 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.

Precautions:

- Care should be taken to orient the device along the path of the stoma tract during insertion.
- Removal of gastrostomy tubes using traction may result in trauma to the tract and associated complications.
- Since this device may be contaminated or occluded with the passage of time, it should be replaced with a new catheter per institutional protocol or on the advise of a physician. If this device will not be replaced, an occlusive dressing should be placed and the tract should close within 24 hours.

Adverse Events:

May include: minor wound infections at stoma site; peritonitis, sepsis and potential death; gastric hemorrage; damage to the stomach lining; trauma to tract; pyrolic obstruction; dome separation or damage; early separation of stomach and abdominal wall; dislodgement or misalignment of the internal dome; small bowel obstruction, ileus obstruction and/or perforation; leakage of gastric contents; gastrocolic fistula; gastroesophageal reflux; peristomal leakage of nutrients; tissue necrosis; diarrhea, weight loss; buried bumper syndrome.

Ponsky® PEG Safety System - "Pull" / Bard® PEG Safety System "Guidewire"

Indications for Use:

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

Contraindications:

May include:

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

Warnings:

- This product is designed to properly function in vivo when used in accordance with these instructions for use. After opening kit do not stretch or pull the feeding tube away from the dilator tip. This may put undue force on the feeding tube and dilator tip connection causing separation of these components.
- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue to ensure safe passage of the gastrostomy tube through the abdomen and incision site.
- If the syringe is not locked a needlestick injury could occur resulting in the transmission of serious diseases 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.
- 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."
- Do not attempt to use traction as a removal method if gastrostomy tube is not free-fl oating within the fibrous tract to avoid potential separation of the stomach from the abdominal wall.
- 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.
- 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.

Precautions:

- A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
- The stomach should be kept insuffl ated throughout the procedure to ensure contact of the gastric and abdominal walls.
- It is recommended that approximately 24 inches (61 cm) of guidewire 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 trauma to the tract and associated complications.
- Dispose of all sharps in an approved puncture-resistant contamination waste container. Do not resterilize after use.
- Routinely inspect the Dual Port Feeding Adaptor for secure safety cap closure 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.

Adverse Reactions:

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

Ponsky® "Pull" PEG Kit with Soft Silicone Retention Dome

Indications for Use:

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

Contraindications:

May include:

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

Warnings:

- Do not continue procedure if transillumination cannot be identified. The selected site should be free of major blood vessels, viscera and scar tissue.
- 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.
- 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."
- Do not attempt to use traction as a removal method if gastrostomy tube is not free-floating within the fibrous tract.
- 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.
- 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.

Precautions:

- This product is designed to properly function in vivo when used in accordance with these directions for use. After opening the kit do not stretch or pull the feeding tube away from the dilator tip. This may put undue force on the feeding tube and dilating tip connection causing separation of these components.
- A smaller incision may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
- The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal walls.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.
- Routinely inspect the Dual Port Feeding Adaptor for secure safety cap closure 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.

Adverse Reactions:

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

Silicone PEG Guidewire System

Indications for Use:

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

Contraindications:

May include:

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

Warnings:

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

Precautions:

- A skin incision smaller than 1.0 cm may contribute to extreme resistance of the gastrostomy feeding tube when exiting the fascia.
- The stomach should be kept insufflated throughout the procedure to ensure contact of the gastric and abdominal walls.
- It is recommended that approximately 24 inches of guidewire be withdrawn from the hoop prior to insertion.
- It is recommended that feeding be initiated 24 hours following gastrostomy tube placement.

Adverse Reactions:

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