Boston Scientific

EndoVive™ Safety PEG Kit
EndoVive Standard PEG Kit

PULL AND PUSH

Percutaneous Endoscopic Gastrostomy Kit

Directions for Use **2**

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EndoVive™ Safety PEG Kit
EndoVive Standard PEG Kit

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Percutaneous Endoscopic Gastrostomy Kit

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The EndoVive Percutaneous Endoscopic Gastrostomy (PEG) Kit consists of a gastrostomy tube and items used in the initial placement procedure of an enteral feeding device.

The PEG Kit is available with either a 20F or 24F gastrostomy tube to support either a push or pull placement technique.

The catheter is Magnetic Resonance (MR) Safe.

Contents

- High Grade Silicone PEG Tube
- Insertion Wire or Guidewire
- Fenestrated Drape
- Pre-cut Drainage Sponges
- Gauze Pads
- Surgical Scalpel or Safety Scalpel
- Retrieval Snare
- Scissors
- Curved Hemostat
- External Bolsters
- Y-Port
- C-Clamp
- Trocar Cannula and/or Seldinger Needle or Safety Trocar Cannula
- Three Pack Iodine Swabs (If Applicable)
- ChloraPrep™ One-Step (If Applicable)
- 5.0 g Lubrication Jelly (If Applicable)
- Local Anesthetic (If Applicable)
- Packet Antiseptic Ointment or Triple Antibiotic Ointment Packet
- 5.0 ml Syringe (If Applicable)
- 19 ga (1.1 mm) x 1.5 in (38.1 mm) Filter Needle (If Applicable)
- 22 ga (0.7 mm) x 1.5 in (38.1 mm) Injection Needle or Safety-Shielded Injection Needle 23 ga (0.6 mm) x 1.5 in (38.1 mm)

INTENDED USE/INDICATIONS FOR USE

The Initial Placement PEG is indicated for enteral nutrition directly into the stomach in both pediatric and adult patients who are unable to consume nutrition by conventional means.

Precaution: The Initial Placement PEG Kit should not be used on children under 15 kilos/33 pounds.

CONTRAINDICATIONS

- Patients on anticoagulants and/or with abnormal clotting parameters
- Obstruction of the esophagus which may prevent the introduction or removal of the feeding tube
- Inability to achieve transabdominal illumination or needle/cannula placement
- Patients with multiple surgical procedures near the gastrostomy site
- High medical risk patients

ADVERSE EVENTS

Possible complications include, but may not be limited to: fever, gastric distention, infection, blockage/occlusion, tissue necrosis, migration, peritonitis, sepsis, erosion/embedding into the gastric wall ("Buried Bumper Syndrome"), aspiration, bleeding, fistula, gastroparesis, GE reflux, pain, perforation, ulceration, tube clogging, malposition, leakage, kinking, inadvertent removal, small bowel obstruction, granulation tissue, and pneumoperitoneum.

OPERATIONAL USE

Caution: Carefully examine the unit to verify that the contents have not been damaged in shipment. DO NOT USE if damaged. Immediately return damaged product to Boston Scientific Corporation.

Precaution: Do not use without reading and understanding the complete instructions enclosed herein.

Caution: This device is intended to connect to enteral feeding device. Care should be taken to avoid the potential harm of misconnection with non-enteral feeding connectors.

1. **Patient Preparation**
   - Inspect kit for damage. If damaged, DO NOT use the product.
   - Prep patient as required for endoscopy per institution guidelines.
   - Prep abdomen in sterile manner with antiseptic solution.
2. **Tube site selection**
   - Introduce the endoscope and insufflate the stomach (Figure 1).
   - Transilluminate the abdominal wall with the endoscope light to select the site for placement of the PEG tube.
   - Apply finger pressure at the point where transillumination is most clear. The endoscopist should see an indentation of the gastric wall at this point.

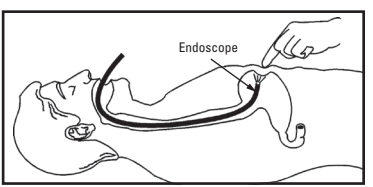

Figure 1

Standard Kit Method

3. **Incision Site Preparation**

Note: Select an appropriate local anesthetic and anesthetize per standard protocol.

- Draw up and administer anesthetic using appropriate technique.

Warning: DO NOT proceed to inject with the filter needle. If the filter traps glass shards, injection of shards into the patient may result.

- Anesthetize in a four-quadrant pattern around the proposed incision site.

4. **Gain Access**
   - Using the scalpel provided, make a 1 to 1.5 cm incision at the selected incision site.

Note: Too small an incision may contribute to excessive resistance on the PEG tube when exiting the skin.

Caution: The stomach should be kept insufflated throughout the procedure to insure contact between the gastric wall and the abdominal wall.

   - Insert the retrieval snare through the scope and open it over the proposed puncture site.
   - Advance the Trocar Cannula or Seldinger needle through the incision and into the stomach under direct visualization.
   - Close the snare firmly but not too tightly around the Trocar Cannula/ Seldinger needle.
   - Remove the needle from the cannula.

Safety Kit Method

3. **Incision Site Preparation**

Note: Select an appropriate local anesthetic and anesthetize per institutional protocol.

- Without removing the plastic shield, twist off the Safety Shielded Injection Needle from the syringe.
- Draw up anesthetic into the syringe using appropriate technique. Reattach the Safety Shielded injection needle to syringe.
- When ready to administer the injection, remove the plastic shield from the injection needle.

Note: When removing the plastic shield from the injection needle, pull the shield straight off. DO NOT pull the shield off at an angle, as this may result in needle damage.

- Anesthetize in a four-quadrant pattern around the proposed incision site.
- After completing the anesthetic injection, DO NOT recap or remove the injection needle from the syringe. Use a single finger to push the lever arm forward to advance the shielding mechanism over the needle tip. A click will be heard as the shield passes over the needle tip. Needle coverage should then be visually confirmed (Figure 2).

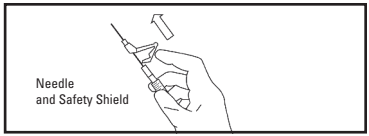

Figure 2

Note: Once safety shielding mechanism has been fully deployed, the needle can no longer be used.

- After confirming needle coverage, discard the needle and syringe into an approved sharps container.

4. Gain Access

- To uncover the safety scalpel blade, place thumb on scalpel and push forward until the blade locks (Figure 3).

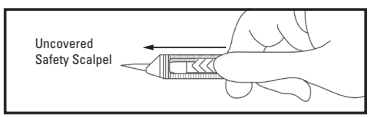

Figure 3

- Using the exposed blade of the safety scalpel provided, make a 1 to 1.5 cm incision at the selected incision site.
- To retract the safety scalpel blade, place thumb on scalpel handle as shown below and apply pressure until the scalpel blade retracts (Figure 4).
- The safety scalpel is now ready for passing or disposal.

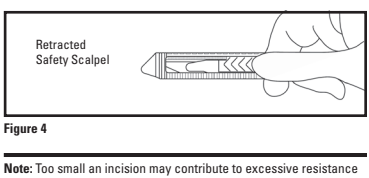

Figure 4

Note: Too small an incision may contribute to excessive resistance on the PEG tube when exiting the skin.

Caution: The stomach should be kept insufflated throughout the procedure to ensure contact between the gastric wall and the abdominal wall.

- Insert the retrieval snare through the scope and open it over the proposed puncture site.
- Advance the Safety Trocar Cannula through the incision and into the stomach under direct visualization.
- Close the snare firmly but not too tightly around the Safety Trocar Cannula.
- Remove the needle from the cannula.

Note: When the needle is removed from the cannula a protective sheath automatically engages to protect the distal tip. However, if the needle is required again during the procedure, the stylet can be carefully placed back in the cannula and the protective sheath will retract to return the Safety Trocar Cannula to its original functionality.

Pull Method

5. Wire Placement

- Pass the looped end of the insertion wire through the cannula into the stomach (Figure 5).

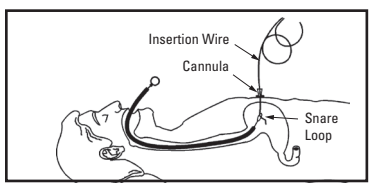

Figure 5

Caution: The metal (crimped) end of the insertion wire should never enter the patient's body.

- Loosen the snare and allow it to surround only the insertion wire. Retighten the snare.
- Withdraw the insertion wire, snare and endoscope from the mouth. The insertion wire will now exit the body from the abdomen and the patient's mouth.

Caution: Use caution when handling the insertion wire to avoid undue trauma to the incision site.

6. Tube Placement

- Attach the PEG tube assembly to the insertion wire exiting the patient's mouth.
- Pass the insertion wire loop through the wire loop on the PEG tube (Figure 6).

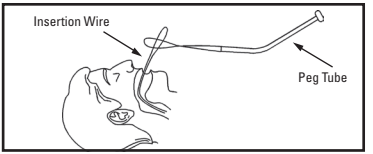

Figure 6

- Pass the dome end of the PEG tube through the insertion wire loop end and pull the entire PEG tube through (Figure 7).

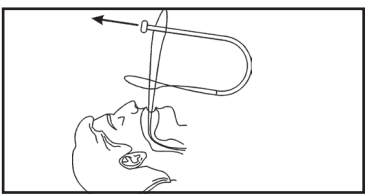

Figure 7

- By grasping the dilating tip between the thumb and forefinger, tighten the loop together to form the attachment (Figure 8).

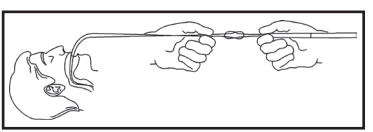

Figure 8

Caution: The PEG tube should not be grasped as a means of tightening the attachment. Avoid stretching or pulling of the PEG tube away from the dilator as undue force may cause the PEG tube to separate from the dilator.

- Apply the water-soluble lubricant to the PEG tube assembly.
- While grasping both strands of the proximal end of the insertion wire, pull the PEG tube through the incision site (Figure 9).

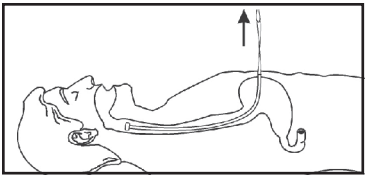

Figure 9

Push Method

5. Wire Placement

- Pass the tip of the guidewire through the cannula and into the stomach (Figure 10).
- Loosen the snare and allow it to surround only the guidewire. Retighten the snare.

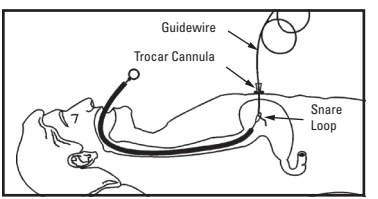

Figure 10

Caution: Firmly grasp and retrieve the guidewire. Excessive force on the snare could damage the guidewire.

- Withdraw the guidewire, snare and endoscope from the mouth. The guidewire will now exit the body from the abdomen and the patient's mouth.
- Once the guidewire has been placed, the cannula can be removed from the incision site.

Caution: Use caution when handling the guidewire to avoid undue trauma to the incision site.

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6. Tube Placement

Note: Straighten the dilator end of the PEG tube prior to sliding over the guidewire.

Caution: DO NOT stretch or pull the PEG tube away from the dilator. Undue force may cause the PEG tube to separate from the dilator.

- Apply water-soluble lubricant to the PEG tube assembly.
- Slide the dilator end of the PEG tube assembly over the guidewire exiting the patient's mouth.
- Firm tension is required at both ends of the guidewire to allow for passage of the PEG tube into the oropharynx and into the stomach (Figure 11).

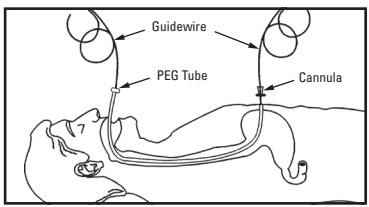

Figure 11

- Continue to push until the dilator tip exits the abdominal wall.
- Grasp the tip (with a hemostat if necessary) and pull until the soft catheter portion exits the abdominal wall.
- When the soft catheter portion of the PEG tube is pulled through the abdominal wall, the guidewire is then removed and the PEG tube pulled through.

For Pull & Push Methods

- Pull the PEG tube until the internal bolster sits snugly against the gastric mucosa. Confirm placement endoscopically. Avoid excess tension (Figure 12).

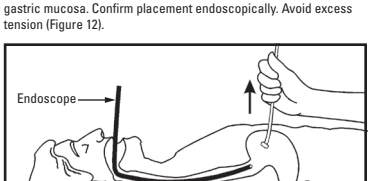

Figure 12

Caution: Excessive force or lack of care in gradually advancing the catheter through fascia tissue could result in pulling the entire device through the abdominal wall.

- Cut the catheter approximately 12 in (30.5 cm) away from skin level.

Note: If a Through-the-PEG J-tube is being used, follow the Directions for Use for that device.

- Slide external bolster close to but not tight to the skin in order to facilitate healing.

Note: A hemostat can be used to dilate the external bolster to facilitate placement on the PEG tube.

- Position the C-Clamp and Y-Port on the PEG tube (Figure 13).
- Clean insertion point. Apply antibiotic or antiseptic ointment and dress wound appropriately.

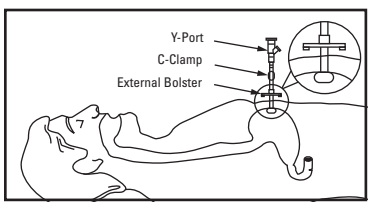

Figure 13

Warning: Wait 24 hours before initial feeding to assure that the tube is in the correct location.

Warning: Avoid excessive pulling on the PEG tube as this may cause the internal bolster to embed against the gastric mucosa. The result can be tissue necrosis, tube migration, infection and associated sequelae.

- Monitor the tube for possible migration. Tube migration could result in the following: inability to feed, peritonitis, infection and associated sequelae.
- Prior to discharge, instruct the patient on device monitoring and medication administration (when applicable). Ensure that the patient is provided with a Patient Care guide for additional device monitoring instructions.

7. Tube Care

Note: Cleanse stoma site and external portion of gastrostomy tube with soap and water. The bolster should be rotated daily for site hygiene. The stoma site should be clean and dry at all times.

- A Y-port has been included for bolus, pump or gravity feeding.

Note: When feeding, make certain the Y-port is pushed into the PEG tube fully.

- Always flush the Y-port and PEG tube with water after it has been used.

Warning: NEVER use air to flush the PEG tube. Air flush could result in air embolus if the tube has migrated from indicated location.

- Once the feeding has been completed, flush the tube with 10 ml of water to rinse any remaining particulate.
- Close the C-clamp to prevent reflux of any fluids.
- The PEG tube has been designed to be a feeding access into the stomach. Other applications are not advised.

Precaution: In the case of fever, abdominal distention, infection, blockage or tissue necrosis, patients should see their physician immediately.

8. Tube Removal

- Using traction and counter traction, the PEG tube may be removed by grasping the tube near the skin line and placing the other hand around the stoma site then pulling upward on the PEG tube (Figure 14).

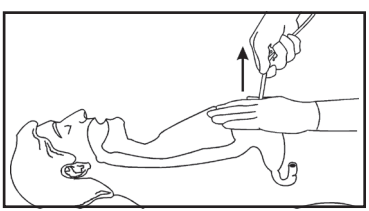

Figure 14

- If traction removal provides too much stress to the patient, the feeding tube can be cut at skin level and removed endoscopically.

Warning: DO NOT allow the internal section of tube to be passed through the intestinal tract.

Note: The silicone feeding tubes should remain in place until the stoma is mature. The healthcare provider should decide when a replacement device is necessary, as precise device life cannot be predicted due to several factors. These factors may include medications, nutrition, gastric pH and tube care. Clinical literature suggests that silicone PEG implant replacement be evaluated approximately one year after implantation.

HOW SUPPLIED

Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

Store between 20-25°C.

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose**. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments**.

ChloraPrep is a trademark of CareFusion 2200, Inc.

Catalog Number

Consult instructions for use.

Contents

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Lot

Recyclable Package

Use By

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Argentina Local Contact

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Ballybrit Business Park
Galway
IRELAND

AUS **Australian Sponsor Address**

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PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

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Boston Scientific Corporation
300 Boston Scientific Way
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