

AbbVie™ PEG

PERCUTANEOUS ENDOSCOPIC GASTROSTOMY KIT 15 FR / 20 FR

For enteral use only

Store at room temperature

REF

62910-001
62912-001

Rx Only

STERILE EO



Catalog
number

Sterilized using
ethylene oxide

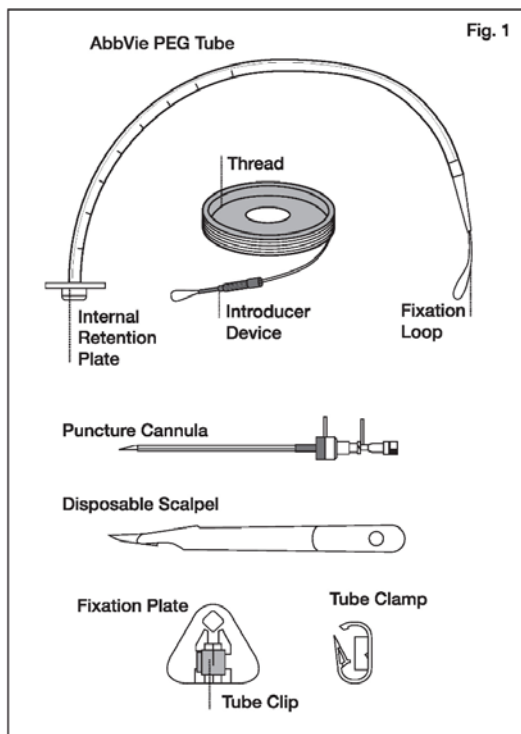
Do not
re-use

Do not use
if package is
damaged

DESCRIPTION

The AbbVie PEG is a percutaneous endoscopic gastrostomy (PEG, or gastric) tube, either 15 FR or 20 FR and 35 cm in length. The kit includes the following (Fig. 1):

- AbbVie PEG Tube (polyurethane)
- Reel of Thread with double thread and Introducer Device
- Puncture Cannula with safety (air) valve
- Disposable Scalpel
- Disposable Scalpel
- Silicone external Fixation Plate (radio-opaque) with integrated Tube Clip (blue for AbbVie PEG 15 FR, violet for AbbVie PEG 20 FR)
- Tube Clamp



INTENDED USE

The AbbVie PEG is intended to provide long-term enteral access for administration of medication to the small intestine when used in conjunction with the AbbVie J, intestinal tube. As needed, enteral nutrition may be administered directly to the stomach in parallel with medication delivery to the intestine. The AbbVie PEG is indicated for the administration of the medication DUOPA (carbidopa and levodopa enteral suspension).

CONTRAINDICATIONS

- Lack of transillumination and positive needle aspiration test are an absolute contraindication for AbbVie PEG insertion.
- Known or suspected intestinal obstruction
- Serious coagulation disorders
- Sepsis
- Active peritonitis
- Relative contraindications include ascites and neoplastic, inflammatory, and infiltrative diseases of the gastric and abdominal walls.

WARNINGS

- Enteral use only.
- Do not store at extreme temperatures. Do not use if package is open or damaged.
- This is a sterile single-use product. Do not reuse. Reuse may result in contamination or product damage that could impact patient health.
- Do not insert/place AbbVie PEG past expiration date on the label.
- The AbbVie PEG (15 FR or 20 FR) serves as a guide tube for the intestinal tube. The AbbVie PEG must be positioned according to the relevant instructions for use.

PRECAUTIONS

- Based on clinical experience, the tube can remain in place for many months without complications. In DUOPA clinical trials, 82.1% of patients retained their original tubing at 24 months¹.
- Do not use alcohol containing products with this tube as they may result in damage to the tube.
- If there is any doubt about tube placement, x-ray confirmation should be performed.
- Ointments should be used only if strictly indicated and only for limited periods. Products which contain the polyvidone/iodine complex should be avoided where possible to prevent material damage to the tube.

1. Lang AE, et al. Integrated safety of levodopa-carbidopa intestinal gel from prospective clinical trials. *Movement Disorders* 2016;31(4):538-46.

GASTROINTESTINAL AND GASTROINTESTINAL PROCEDURE-RELATED RISKS

Because DUOPA is administered using a PEG-J or naso-jejunal tube, gastrointestinal complications can occur.

These complications include abscess, bezoar, ileus, implant site erosion/ulcer, intestinal hemorrhage, intestinal ischemia, intestinal obstruction, intestinal perforation, intussusception, pancreatitis, peritonitis, pneumonia, pneumoperitoneum, post-operative wound infection, and sepsis. These complications may result in serious outcomes, such as the need for surgery or death.

Instruct patients to notify their healthcare provider immediately if they experience abdominal pain, prolonged constipation, nausea, vomiting, fever, or melanic stool.

INSTRUCTIONS FOR USE

PREPARATION

1. Prior to the procedure the patient should be:
 - Provided with oral hygiene
 - Given antibiotic prophylaxis per institutional protocol
 - Placed in a supine position for the procedure

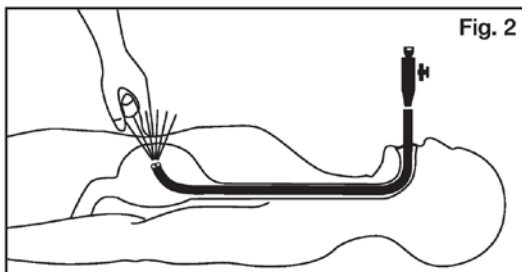
IDENTIFYING AN APPROPRIATE PUNCTURE SITE

2. After the endoscope has been passed into the stomach and the stomach sufficiently inflated with air, dim the lights and locate the appropriate puncture site by transillumination.



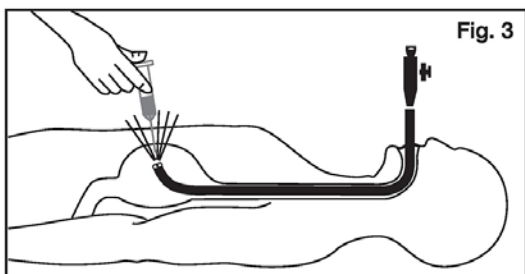
Lack of transillumination and positive needle aspiration test are an absolute contraindication for AbbVie PEG insertion.

3. Palpate the puncture site with the fingers at the point where transillumination is most clear. The gastric mucosa will bulge inwards and be detectable by endoscope (Fig. 2)



PUNCTURE OF THE STOMACH

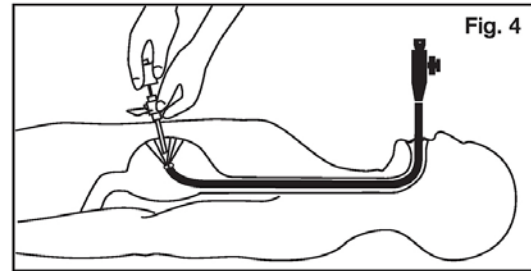
4. Disinfect the puncture site using aseptic technique.
5. Inject local anesthetic to all layers of the abdominal wall, slowly advancing the syringe into the gastric lumen (Fig. 3).



6. Make a careful dissection of subcutaneous tissue of approximately 4-5 mm (AbbVie PEG 15 FR) or 6-7 mm (AbbVie PEG 20

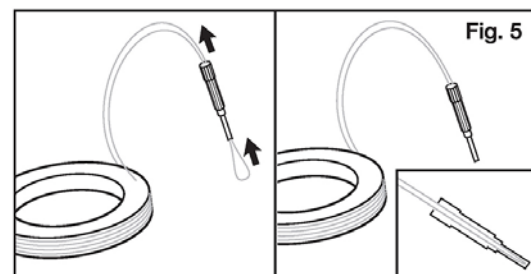
FR) in width level with the puncture site.

7. Advance the Puncture Cannula into the stomach under endoscopic control.
8. Remove the puncture needle from the Puncture Cannula (Fig. 4).

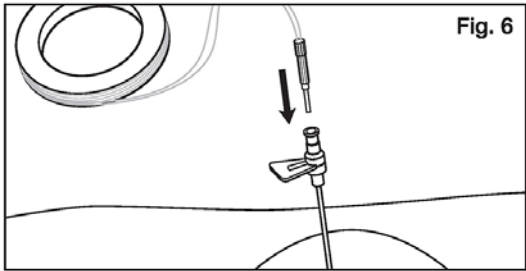


INSERTING THE THREAD

9. Advance the Introducer Device by means of the Thread until the loop only protrudes approximately 1 mm out of the narrowed area (Fig. 5).



10. Attach the Introducer Device to the Puncture Cannula and guide the Thread through the Puncture Cannula into the stomach (Fig. 6).

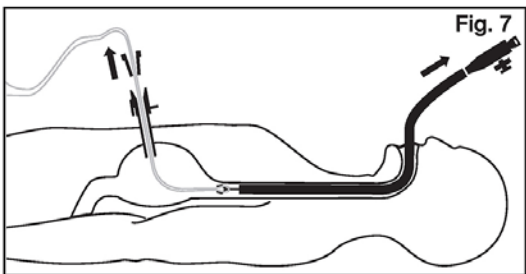
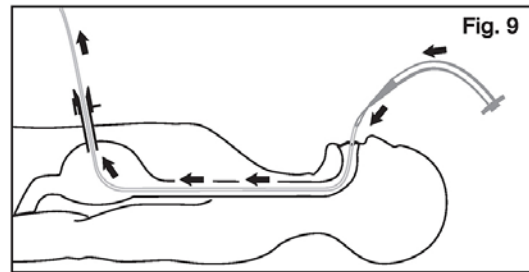


distal end of the Thread (Fig. 9). Pass Thread and Tube with the hand.

Press down the tongue sideways with a finger to prevent a cut on the tongue by the Thread.

A slight resistance will be felt when the tip of the AbbVie PEG Tube enters the Puncture Cannula.

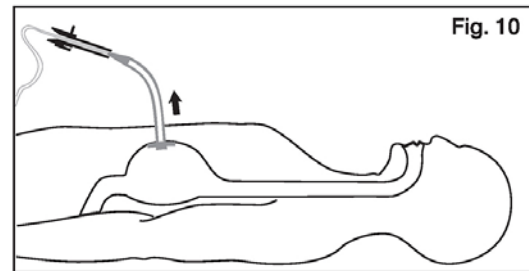
- As soon as the Thread is visible in the stomach, grip it with biopsy forceps and withdraw the Introducer Device on the Thread, which automatically closes the safety air valve of the Puncture Cannula (Fig. 7).



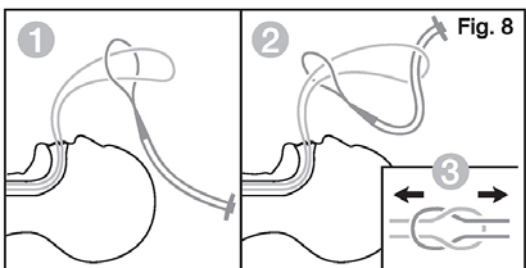
- Pull the AbbVie PEG Tube together with the Puncture Cannula out through the abdominal wall until the Internal Retention Plate is in direct apposition to the inner gastric wall (Fig. 10).

- Draw the Thread out through the mouth with the endoscope (Fig. 7).

PLACING THE AbbVie PEG TUBE



- Fix the loop of the Thread at the Fixation Loop of the AbbVie PEG (Fig 8).



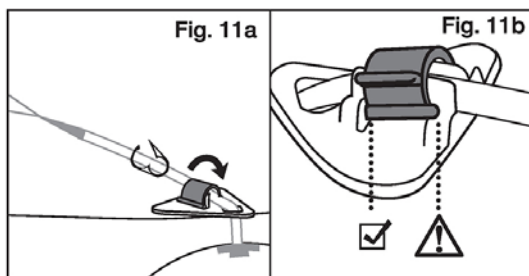
- Position the AbbVie PEG Tube in the stomach by slowly pulling on the

FIXING THE AbbVie J TUBE TO THE AbbVie PEG TUBE

16. Cut off the Thread of the Tube close to the cone.

SECURING THE AbbVie PEG TUBE

17. Thread the AbbVie PEG Tube through the hole in the Fixation Plate.
18. Slide the Tube Clamp onto the AbbVie PEG Tube.
19. Pull on the AbbVie PEG Tube until elastic resistance is felt and keep under tension.
20. Clean and dry puncture site, Fixation Plate and AbbVie PEG Tube thoroughly to ensure secure attachment.
21. Apply appropriate dressings to stoma site per institutional protocol.
22. Slot the AbbVie PEG Tube into the Fixation Plate guide. Close the Tube Clip to ensure a secure connection (Fig. 11a). Ensure that the Tube Clip is fully closed (Fig. 11b).



The AbbVie PEG Tube should remain under moderate tension for 24-72 hours to promote good adherence of the stomach wall to the inner abdominal wall.

After 24-72 hours, the Tube Clip should be opened and the Fixation Plate loosened. For long term maintenance, leave 5-10mm free play between the outer stomach wall and the Fixation Plate.

Do not pull the AbbVie PEG Tube too hard on the outside, otherwise pressure necroses form.

23. To complete the intended use of the AbbVie PEG, proceed to the AbbVie J (J for 15 FR PEG: List Number 62918-001 and J for 20 FR PEG: List Number AV062-001) package insert.

PUNCTURE SITE CARE POST PLACEMENT

- Keep the AbbVie PEG Tube under moderate tension for 24-72 hours post-placement to promote good adherence to the stomach wall, then loosen.
- Avoid in/out movement of the AbbVie PEG Tube within 72 hours post-placement.
- No petroleum based ointments should be used as they may cause the Fixation Plate to slip.
- The puncture site should be checked regularly within the first week post-placement.
- Keep the puncture site, AbbVie PEG Tube, and the underside of the Fixation Plate clean and dry using aseptic technique or per institutional protocol. Dressings should be changed per institutional protocol.
- Careful follow-up observation is required in the case of patients with severe cachexia, multiple diseases, poor general condition and long-standing diabetes, as there is an

increased risk of infection (e.g. local infection, peritonitis).

- In the case of healing disorders, and if food and secretion escape from the stoma, a healthcare professional must always perform an examination.

STOMA AND TUBE CARE

- The stoma site should be cleansed daily and kept dry at all times.
- Once the stoma site is healed, the AbbVie PEG Tube should be mobilized.

Push the AbbVie PEG Tube carefully 3-4 cm into the stoma and move the Tube in a bi-directional motion (back and forth) every time the dressing is changed. **When doing so the tube should not be turned or rotated under any circumstances to prevent the formation of loops and dislocation of the AbbVie J tube.** It is important for the Tube to move freely in the stoma to prevent the Internal Retention Plate from becoming embedded (“buried bumper syndrome”).

Then pull the AbbVie PEG Tube gently until resistance is felt, place the Fixation Plate back and fix in position with 0.5-1 cm of room.

- Flush the AbbVie PEG Tube (via white, blue, or violet “g” port) with at least 20 mL room temperature tap or drinking water daily and after it has been used for feeding. Failure to adequately flush the AbbVie PEG Tube may result in occlusion or blockage.

TUBE REMOVAL



The AbbVie PEG Tube should not be removed any sooner than 10-14 days after it has been positioned, otherwise there is a risk of peritonitis.

AbbVie PEG Tubes are removed endoscopically as follows:

1. Remove the Tube Clamp, open the Tube Clip, and remove the Fixation Plate.
2. Insert the gastroscope into the stomach.
3. Advance the AbbVie PEG Tube slightly in the direction of the stomach.
4. Cut off AbbVie PEG Tube level with the abdominal wall.
5. Pull out the AbbVie PEG Tube using the gastroscope.
6. Apply an adhesive dressing.

It is recommended that the patient is kept under a healthcare professional's supervision until the stoma has closed completely.

EXPLANATION OF SYMBOLS



Catalog number



Batch code



Do not re-use



Manufacturer



Date of Manufacture



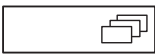
Use-by date



Do not use if package
is damaged



Sterilized using
ethylene oxide



Units per package



Consult Instructions
for Use



Caution



Manufactured for:

AbbVie Inc.

1 North Waukegan Road

North Chicago, IL 60064 USA

Product of Poland