

AbbVie™ J

INTESTINAL TUBE 9 FR for PEG 15 and 20 FR

For enteral use only
Store at room temperature

REF

62918-001
AV062-001

Rx Only

STERILE | EO



Catalog
number

Sterilized using
ethylene oxide

Do not
re-use

Do not use
if package is
damaged

DESCRIPTION

The AbbVie J is a 9 FR intestinal (J) tube, 120 cm in length.

AbbVie J Tube for 15 FR PEG kit (List Number 62918-001)

AbbVie J Tube for 20 FR PEG kit (List Number AV062-001)

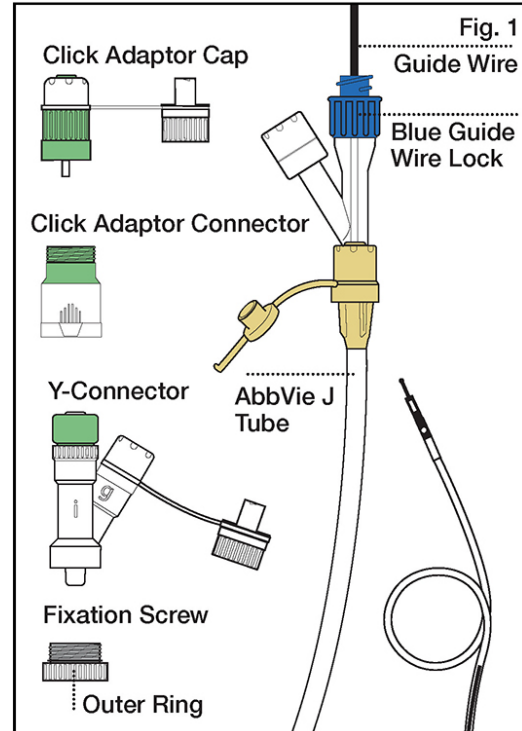
The kit includes (Fig. 1):

- AbbVie J Tube (polyurethane) with Teflon™-coated Guide Wire and Blue Guide Wire Lock
- Y-Connector for the 15 FR PEG or 20 FR PEG:

Y-Connector Size	Design	Gastric ("g") Port Color	Intestinal ("i") Port Color
15 FR	Original	White	Green
	New	Blue	
20 FR	Original	White	
	New	Violet	

Note: The original design of the Y-Connector is represented in the Figures throughout the instructions for use.

- Fixation Screw (blue: 15 FR or violet: 20 FR) with Outer Ring
- Click Adaptor consisting of:
 - Click Adaptor Cap
 - Click Adaptor Connector



INTENDED USE

The AbbVie J is intended to provide long-term enteral access for administration of medication to the small intestine. The AbbVie J is indicated for the administration of the medication DUOPA (carbidopa and levodopa enteral suspension).

CONTRAINDICATIONS

- Known or suspected intestinal obstruction
- 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 J past expiration date on the label.
- The AbbVie PEG (15 FR or 20 FR) serves as a guide tube for the AbbVie J. The AbbVie J must be positioned according to the relevant instructions for use.
- Do not use petroleum based lubricants as they result in the AbbVie J Tube becoming loose.
- Ensure that the metal pin of the Click Adaptor Cap and the external end of the AbbVie J Tube are clean, dry, and free of grease.
- An AbbVie J Tube should be inserted through the gastric lumen into the small intestine; it should be slack and straight – without loops. Any loops remaining in the stomach increase the risk of the tube becoming dislocated.
- Do not rotate the AbbVie J Tube as kinking or knotting may occur.
- During insertion do not release the Blue Guide Wire Lock or push the Guide Wire forwards or backwards. The Guide Wire could inadvertently be pushed through the tube outlets.
- To prevent the Click Adaptor from being opened inadvertently, the screwed connection cannot be undone without

destroying the Click Adaptor. If the screwed connection is undone, a new Click Adaptor, List Number 62922-001 must be used

- Do not flush the lumen of the AbbVie J Tube using force or unblock using a wire. There is the risk of AbbVie J Tube disconnection or tube perforation. Check for patency of the Tube. If the Tube becomes occluded, replace with new Tube.

PRECAUTIONS

- Based on clinical experience, the AbbVie J can remain in place for many months without complications. In DUOPA clinical trials, 48.5% of patients retained their original tubing at 24 months¹.
- Endoscopic placement/replacement of the AbbVie J should be with direct visualization of the tip of the Tube as it is advanced. Blind advancement of the Tube by pushing with the grasping forceps is to be absolutely avoided.
- If endoscopic placement/replacement is performed do not advance the forceps beyond the direct view of the endoscope.
- **Do not use alcohol containing products with the AbbVie J as they may result in damage to the Tube.**
- If there is any doubt about AbbVie J placement, x-ray confirmation should be performed.

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 melanotic stool.

INSTRUCTIONS FOR USE

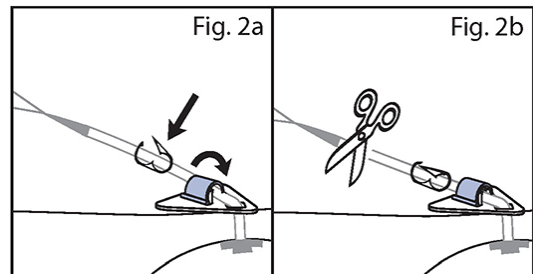


Before insertion of the AbbVie J the AbbVie PEG (15 FR or 20 FR) must be positioned according to the relevant instructions for use. It is important to ensure that the appropriate Y-Connector (15 FR has white or blue “g” port; 20 FR has white or violet “g” port) is used according to the PEG tube (15 FR or 20 FR).

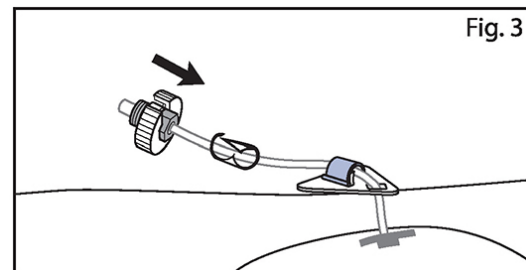
FIXING THE Y-CONNECTOR TO THE AbbVie PEG TUBE

1. Ensure that the Tube Clamp and Tube Clip are both closed (Fig. 2a).
2. Cut off the proximal cone and Fixation Loop of the AbbVie PEG Tube (15 FR or 20 FR) (Fig. 2b). Ensure that the cut is perpendicular (90 degree angle) to the tube and not on a diagonal as this ensures

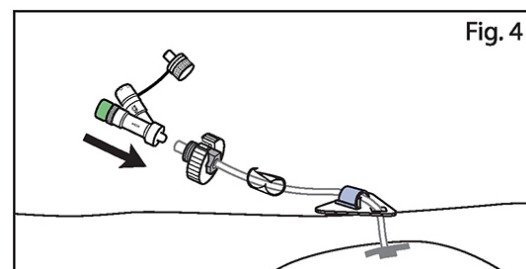
proper seating of the tube when engaged into the pin of the Y-Connector fitting.



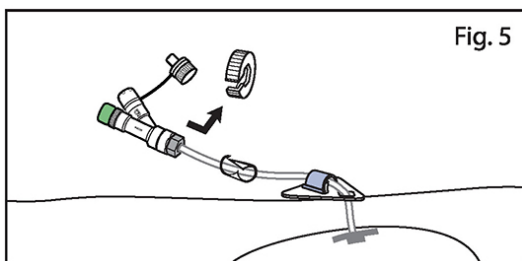
3. Slide the colored Fixation Screw (including the outer ring) over the AbbVie PEG Tube (Fig. 3):
 - For 15 FR, use the blue/white screw
 - For 20 FR, use the violet/white screw



4. Grasp near the end of the PEG tube, push the PEG tube fully onto the Y-Connector pin prior to fastening the Fixation Screw. **Visually verify the tubing has been pushed all the way onto the pin of the Y-Connector (Fig. 4).**

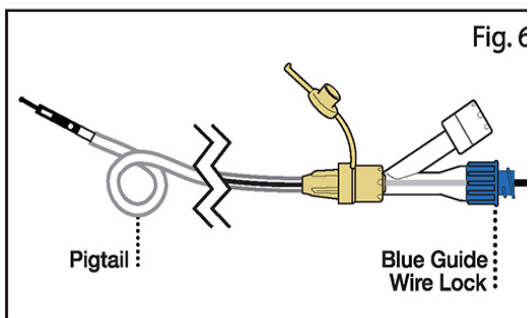


5. Tighten the colored Fixation Screw onto the Y-Connector using the outer ring and ensure connection is complete. It is important to ensure that the appropriate Y-Connector is used according to the PEG tube (15 FR or 20 FR). **Confirm there is no space between the Fixation Screw and the Y-Connector.**
6. Remove the Fixation Screw's Outer Ring by pulling downward (Fig. 5).




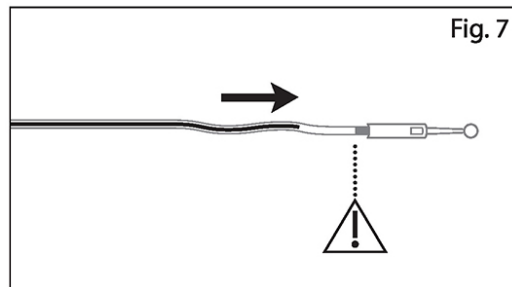
POSITIONING THE AbbVie J TUBE

7. Take the AbbVie J Tube from the kit. Confirm by identifying the pigtail and Blue Guide Wire Lock (Fig. 6).




8. Loosen the Blue Guide Wire Lock on the AbbVie J Tube.
9. Advance the Guide Wire to just before the metal insert at the distal end of the tube so that the pigtail bend is stretched.

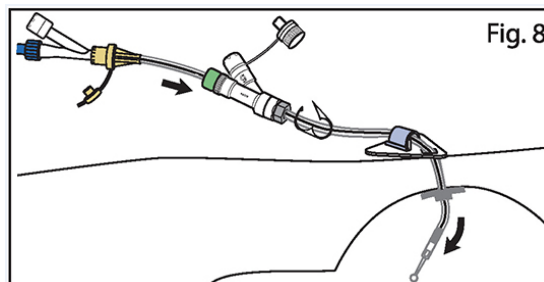
 Do not advance the Guide Wire beyond the metal band of the AbbVie J Tube (Fig. 7).




10. Lock the Guide Wire in position by tightening the Blue Guide Wire Lock.

 Ensure that the Blue Guide Wire Lock is fully tightened (no visible screw threads and the Guide Wire does not move).

11. Open the Tube Clamp on the AbbVie PEG Tube.
12. Moisten the tip of the AbbVie J Tube with sterile water or water soluble lubricant, if desired, to facilitate insertion.
13. Insert the AbbVie J Tube carefully through the straight limb (green, labeled "I") of the Y-Connector (Fig. 8).



 A long-term intestinal tube should be inserted through the gastric lumen into the small intestine; it

should be slack and straight – without loops. Any loops remaining in the stomach increase the risk of the tube becoming dislocated.



During insertion do not release the attachment of the Guide Wire or push the Guide Wire forwards or backwards. The Guide Wire could inadvertently be pushed through the tube outlets.

- The AbbVie J can be advanced under endoscopic, x-ray, or image sensor control as applicable.

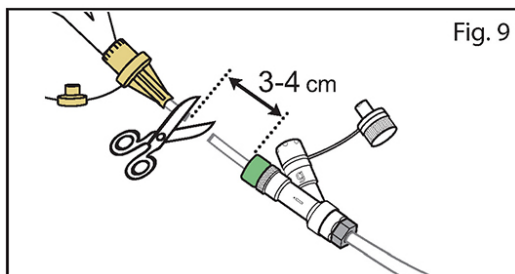
In case of endoscopic control:

- The distal end needs to be visualized and be placed beyond the ligament of Treitz.
- When withdrawing the endoscope from the small bowel, the AbbVie J Tube should be maintained in position using the forceps or the gripper.

- Once the required position is reached, remove the Guide Wire.

FIXING THE AbbVie J TUBE TO THE AbbVie PEG TUBE

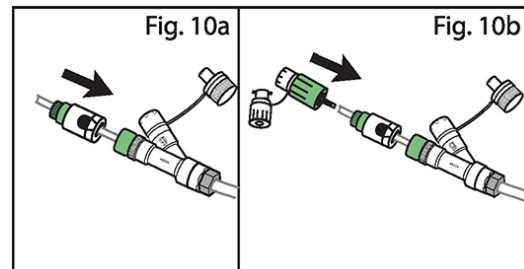
- Close the Tube Clamp to secure AbbVie PEG and AbbVie J Tube positions.
- Cut off the AbbVie J Tube approximately 3-4 cm from the green top of the Y-Connector (Fig. 9).



- Gather the Click Adaptor components: the Click Adaptor Connector and Click Adaptor Cap.
- With the white end first, slide the Click Adaptor Connector onto the AbbVie J Tube (Fig. 10a).



Do not fully connect the Click Adaptor Connector yet.

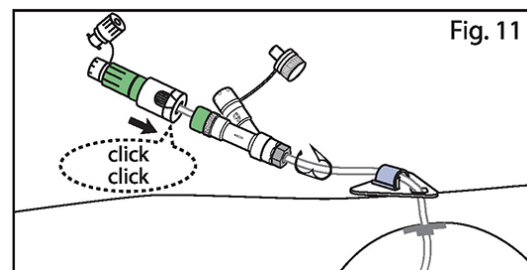


- Push the metal pin of the Click Adaptor Cap onto the AbbVie J Tube (Fig. 10b).
- Screw the Click Adaptor Connector onto the Click Adaptor Cap until it stops.



Only rotate the Click Adaptor Connector. Do not rotate the AbbVie J Tube or Click Adaptor Cap as kinking or knotting may occur.

- Open the Tube Clamp again.
- Slide the excess AbbVie J Tube and connected Click Adaptor as a completed unit over the Y-Connector until you hear two clicks (Fig. 11).



24. Ensure that the Tube Clamp and Tube Clip are both locked.
25. Attach Enteral Use Only tag to white, blue, or violet “g” port of the Y-Connector.

NOTES ON THE FEEDING REGIMEN

- When the AbbVie PEG Tube is simultaneously inserted with the AbbVie J Tube and if feed is being administered intragastrically, it is recommended that a fasting period of approximately 1-2 hours is observed.
- Feed should be introduced slowly at first and increased gradually. A syringe or standard enteral feeding pump should be used for feed administration.

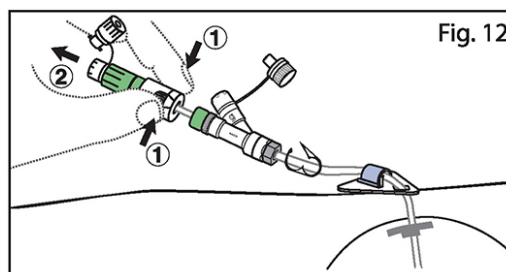
NOTES ON TUBE CARE

- 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.
- Flush the AbbVie J Tube (via green “i” port) with at least 20 mL room temperature tap or drinking water daily. Failure to adequately flush the AbbVie J may result in occlusion or blockage.
- The AbbVie PEG Tube should be carefully moved in and out slightly in the stoma every day once the site has healed. When doing so the AbbVie PEG Tube should not be turned or rotated under any circumstances to prevent the formation of loops and dislocation of

the AbbVie J Tube. Free movement of the AbbVie PEG Tube in the stoma is important to ensure that the Internal Retention Plate does not become ingrown (“buried bumper syndrome”).

NOTES ON REMOVAL AND CHANGING OF THE AbbVie J TUBE

- To remove/change the AbbVie J Tube, squeeze the contoured surfaces of the Click Adaptor firmly between two fingers and pull off (Fig 12). After that, carefully pull out the AbbVie J Tube and replace with a new AbbVie J if required.



To prevent the Click Adaptor from being opened inadvertently, the screwed connection cannot be undone without destroying the Click Adaptor. If the screwed connection is undone, a new Click Adaptor, List Number 62922-001 must be used.

MRI Safety Information



MR Conditional

Non-Clinical testing has demonstrated that the AbbVie J is MR Conditional. Refer to the

MR Conditional Letter for full details
regarding MR conditions.

EXPLANATION OF SYMBOLS



Catalog number



Batch code



Do not re-use



Manufacturer



Date of Manufacture



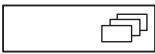
Use-by date



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

MRI Safety Information



The AbbVie J (Intestinal Tube 9 FR for PEG 15 and 20 FR / 62918-001, AV062-001) contains a small piece of metal in the tube tip for x-ray visibility of the tube.

Non-clinical testing has demonstrated that the AbbVie J is MR Conditional. A patient with this device can be safely scanned in an MRI system meeting the following conditions:

- Static magnetic field of 1.5 Tesla and 3.0 Tesla only
- Maximum spatial gradient magnetic field of 1900 gauss/cm (19 T/m)
- Maximum MRI system reported, whole body averaged specific absorption rate (SAR) of 4.0 W/kg (First Level Controlled Mode).

Under the scan conditions defined above, the AbbVie J Intestinal Tube is expected to produce a maximum temperature rise of 1.0°C after 15 minutes of continuous scanning.

MR Artifact

In non-clinical testing, the image artifact caused by the device extends approximately 42 mm from the tip of the AbbVie J Intestinal Tube when imaged with a spin echo pulse sequence and a 3.0 Tesla MRI system. Similarly, the image artifact caused by the device extends approximately 37 mm from the tip of the AbbVie J Intestinal Tube when imaged with a spin echo pulse sequence and a 1.5 Tesla MRI system.