

AbbVie® NJ

NASO-JEJUNAL TUBE with STYLET

For enteral use only
Store at room temperature

REF

62903-001

Rx Only

STERILE EO



Catalog
number

Sterilized using
ethylene oxide

Do not
re-use

Do not use
if package is
damaged

DESCRIPTION

The AbbVie NJ is a 10 FR, 152 cm, naso-jejunal (NJ) tube made of white radiopaque polyurethane. The AbbVie NJ includes a silicone coated Stylet.

INTENDED USE

The AbbVie NJ is intended to provide short-term enteral access for administration of medication to the small intestine. The AbbVie NJ is indicated for the administration of the medication DUOPA® (carbidopa and levodopa enteral suspension) for patients with advanced Parkinson's disease.

CONTRAINDICATIONS

Use caution with patients who have anomalies or diseases of the nose, throat, esophagus, stomach or small bowel.

WARNINGS

- Device should only be inserted by a trained clinician.
- Do not use if package is open or damaged. Do not store at extreme temperatures. Do not use past use by date.
- This is a sterile, single-use device. Do not reuse. Reuse may result in contamination or product damage that could impact patient health.
- Do not re-insert a Stylet into an indwelling AbbVie NJ.
- During AbbVie NJ insertion do not detach the Stylet Hub or push the Stylet forwards or backwards. The Stylet could inadvertently be pushed through the tube outlets.

- Do not use petroleum based lubricants or products containing alcohol. Plant-based lubricants may contain allergens.
- If the AbbVie NJ becomes occluded, replace with new tube. Do not flush the lumen of the Tube using force or unblock using a wire. There is the risk of AbbVie NJ breakage or tube perforation.
- If there is any doubt about tube placement, x-ray confirmation should be performed.

As this medical device uses a small-bore connector design in Reverse Luer, there is a possibility that a misconnection can occur between this medical device and a medical device using a similar design, which can result in a hazardous situation causing harm to the patient. Special measures need to be taken by the user to mitigate these reasonable foreseeable risks.

- During connection, ensure both end connectors are compatible in the correct orientation to avoid misconnection of the tubing with other medical devices.
- During connection, ensure only to use other medical devices indicated for the administration of the medication DUOPA® (carbidopa and levodopa enteral suspension) for patients with advanced Parkinson's disease.

PRECAUTIONS

- The AbbVie NJ can stay *in situ* for up to 30 days.
- Stylet must be fully inserted and Stylet Hub connected to the AbbVie NJ Tube Fitting. Upon Stylet insertion the wire must not protrude out of any region of the Tube.
- If endoscopic placement/replacement is performed do not advance the forceps beyond the direct view of the endoscope.

- Consider looping external portion of the AbbVie NJ over the ear to reduce accidental dislodgement. Gently secure AbbVie NJ to nose, cheek and below ear using hypoallergenic tape. Avoid applying excessive pressure on the nose.

INSTRUCTIONS FOR USE

PREPARATION

1. Gather the following materials:

- AbbVie NJ
- Hypoallergenic tape (not included)
- Plant-based oil known to be hypoallergenic, such as medical-grade MCT (medium-chain triglyceride) oil to assist in Stylet removal and NJ tube placement (not included). Note: Water based lubricants are not effective to assist in Stylet removal.



Some plant-based oils may contain allergens (e.g. peanut, soy).

- Enteral Use Only tag (attach after the tube has been inserted)
- Luer Lock syringe (not included)
- Female to female Luer Lock adaptor (not included)

POSITIONING THE AbbVie NJ

2. Extend the tube and remove the Stylet wire completely from the tube.
3. Lubricate at least the last 20 cm at the distal end of the Stylet with enough oil obtained in Step 1 to cover the surface of the Stylet. The distal end of the Stylet is opposite the connector.

4. Insert the Stylet into the tube until the Stylet tip reaches the beginning of the coiled region (approximately 23 cm from the distal end of the tube).
5. Hold AbbVie NJ in a vertical hanging position. It may be helpful to have an assistant hold the distal (coiled) end straight. Advance the Stylet (wire) into the AbbVie NJ Tube 2 cm at a time, pausing in between to allow the distal end to uncoil.

Some resistance may be encountered.

6. Fully thread the Stylet Hub onto the Tube Fitting.



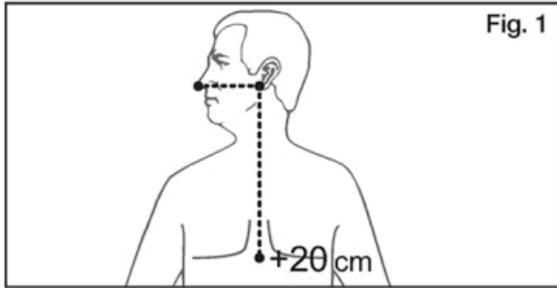
Ensure that the Stylet does not protrude from the Tube outlets.

7. Lubricate the outside of the distal coiled end of the NJ tube with oil described in Step 1.

INSERTING INTO THE STOMACH

8. Advise the patient of the placement procedures.
9. Place the patient in a comfortable sitting or semi-erect position.
10. Estimate distance for placement into the stomach (Fig. 1) using centimeter markings on the Tube. Measure from:
 - tip of patient's nose to earlobe
 - then earlobe to xiphoid process
 - then add 20 cm to account for the coil that will form once the Stylet is removed

OR use standard procedure and add 20 cm.



11. Record the total distance for later use.
12. Using the patient's more patent nostril, gently pass the AbbVie NJ posteriorly and inferiorly through the nostril. If possible, when the AbbVie NJ reaches the pharynx, have the patient sip water through a straw (Fig. 2).



13. Continue to gently pass the AbbVie NJ into the stomach until the previously recorded total distance (Step 11) is reached.

INSERTING INTO THE SMALL INTESTINE

14. Place the AbbVie NJ into the small intestine by following one of the three placement procedures:
 - Stomach Motility
 - Fluoroscopic Guidance
 - Endoscope

PLACING USING STOMACH MOTILITY

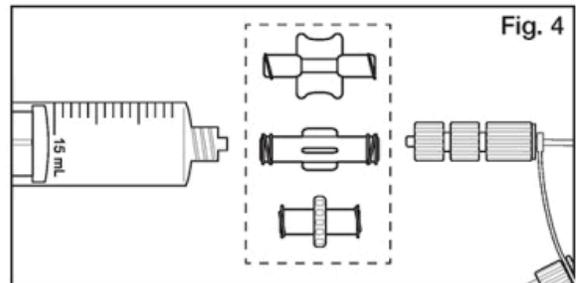
- a. Place the AbbVie NJ in the stomach until the previously

recorded total distance is reached per steps 1-13 above.

- b. Confirm the position of the AbbVie NJ by using a variety of bedside techniques to assess Tube placement (e.g., aspiration, pH, auscultation, x-ray, etc.) per institution policy or per physician orders (Fig. 3 shows auscultation).

If necessary, use a female to female Luer Lock adaptor (not included, examples shown in Fig. 4) to connect the syringe to the AbbVie NJ.

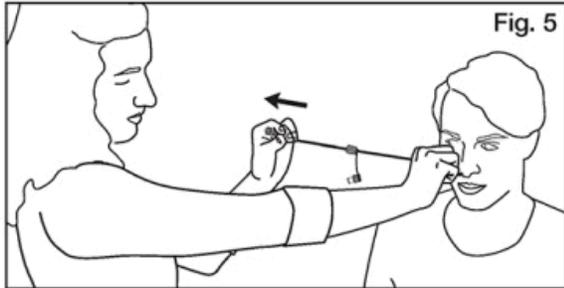
 Remove adaptor from the AbbVie NJ tube when procedure is completed.



- c. Partially withdraw the Stylet (approximately 25 cm) while holding the AbbVie NJ taut by holding the tube as close to the nose as possible as shown in Figure 5. **IMPORTANT: Do NOT inject any water into the tube lumen.**

 Do not fully remove the Stylet.

Some resistance may be encountered. If significant buckling of the AbbVie NJ or resistance is observed reduce pulling force and allow Stylet to withdraw slowly.

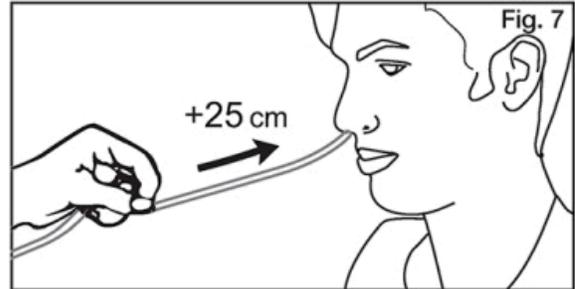


- d. Insert the AbbVie NJ an additional 25 cm to allow for passage into the small intestine.
- e. Gently pull the remainder of the Stylet entirely out of the AbbVie NJ.
- f. Loop external AbbVie NJ over the ear to reduce accidental dislodgement. Gently secure to the nose, cheek and below ear using hypoallergenic tape (Fig. 6).



- g. Wait approximately 24-48 hours for spontaneous transpyloric passage.
While waiting, consider:
 - Placing patient in semi-Fowler's position with rotation to the right side to expedite migration.
 - Giving something to eat or drink (if possible) to stimulate migration.

- Insert AbbVie NJ an additional 25 cm upon migration into the intestine (often after 24-48 hours) (Fig. 7).



- h. Gently secure AbbVie NJ according to Fig. 6.
- i. Before administration of the medication, confirm the AbbVie NJ is positioned correctly through appropriate imaging techniques.

PLACING USING FLUOROSCOPIC GUIDANCE

- a. Place the AbbVie NJ in the stomach until the previously recorded total distance is reached per steps 1-13 above.
- b. When the AbbVie NJ is in the stomach, carefully direct the distal end of the Tube toward and through the pylorus.
- c. After passage through the pylorus advance the tip to just beyond the ligament of Treitz. AbbVie NJ distal tip may retract (approximately 10 cm to 20 cm) as coil forms upon Stylet removal. Advance tip accordingly prior to Stylet removal.
- d. Confirm tip location.
- e. Slowly withdraw the Stylet while holding AbbVie NJ taut by holding the tube as close to the nose as possible as shown in Figure 5.

IMPORTANT: Do **NOT** inject any water into the tube lumen.

Some resistance may be encountered. If significant buckling of the AbbVie NJ or resistance is observed reduce pulling force and allow Stylet to withdraw slowly.

- f. Loop external AbbVie NJ over the ear to reduce accidental dislodgement. Gently secure to the nose, cheek and below ear using hypoallergenic tape (Fig. 6).
- g. Before administration of the medication, confirm the AbbVie NJ is positioned correctly through appropriate imaging techniques.

PLACING USING ENDOSCOPE

- a. Place the AbbVie NJ in stomach until the previously recorded total distance is reached per steps 1-13 above.
- b. Insert the gastroscope into the insufflated stomach.
- c. Grasp the AbbVie NJ's distal tip with the endoscope forceps and with help of the endoscope, guide the Tube through the pylorus. The AbbVie NJ distal tip should be positioned as far down the small intestine as possible, preferably near the ligament of Treitz. AbbVie NJ distal tip may retract (approximately 10 cm to 20 cm) as coil forms upon Stylet removal. Advance AbbVie NJ distal tip accordingly prior to Stylet removal.
- d. Keep the AbbVie NJ distal tip in place with the forceps while withdrawing the endoscope back to the stomach.

- e. Gently ungrasp the AbbVie NJ and withdraw the forceps back to the endoscope.
- f. Partially withdraw the Stylet (approximately 25 cm) while holding the AbbVie NJ taut by holding the tube as close to the nose as possible as shown in Figure 5. **IMPORTANT:** Do **NOT** inject any water into the tube lumen.



Do not fully remove the Stylet.

Some resistance may be encountered. If significant buckling of the AbbVie NJ or resistance is observed reduce pulling force and allow Stylet to withdraw slowly.

- g. Withdraw the endoscope confirming that AbbVie NJ is kept in place with the aid of the marks on the Tube.
- h. When the endoscope is entirely withdrawn, carefully withdraw the entire Stylet.
- i. Loop external AbbVie NJ over the ear to reduce accidental dislodgement. Gently secure to the nose, cheek and below ear using hypoallergenic tape (Fig. 6).
- j. Before administration of the medication, confirm the AbbVie NJ is positioned correctly through appropriate imaging techniques.

Remove an in-position AbbVie NJ in a slow and controlled manner.

SAFE DISPOSAL

Dispose according to Hospital procedure for potentially biohazardous waste.

EXPLANATION OF SYMBOLS
(per ISO 15223-1):

	Catalog number
	Batch code
	Do not re-use
	Manufacturer
	Use-by-date
	Tube Length
	Do not use if package is damaged
	Sterilized using ethylene oxide
	Units per package
	Consult <i>instructions for use</i> or consult <i>electronic instructions for use</i>
	Caution
	Medical Device



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