

Critical Aspects of PEG-J Preparation Placement and Aftercare

Duodopa[®] (20mg/ml levodopa + 5mg/ml carbidopa intestinal gel)

For further information on Duodopa please refer to the Summary of Product Characteristics available at www.medicines.ie and www.hpra.ie

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRAs Pharmacovigilance, Earlsfort Terrace, IRL- Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

Duodopa: Important Additional Risk Minimisation Information for Healthcare Providers

- The information presented in these slides is provided as part of additional Risk Minimisation Program for Duodopa targeted to minimise:
 - Gastrointestinal (GI) events
 - Device-related risks
 - Procedure-related risks associated with the LCIG system
- The information does not include a complete list of all risks or safety information on GI or device related procedure events associated with Duodopa or PEG-J (Percutaneous Endoscopic Gastrostomy (PEG) and Jejunum Tube (J))
- Please carefully read your current and locally available Duodopa Prescribing and Patient Information for comprehensive safety information on Duodopa or Instructions for Use (IFU) for PEG-J

Outline

- Goals for additional Risk Minimisation Program
- Duodopa
 - Indication
 - Levodopa - Carbidopa Intestinal Gel (LCIG) System
 - Important Safety Information
- Critical aspects of PEG-J
- Procedure complications and actions to take

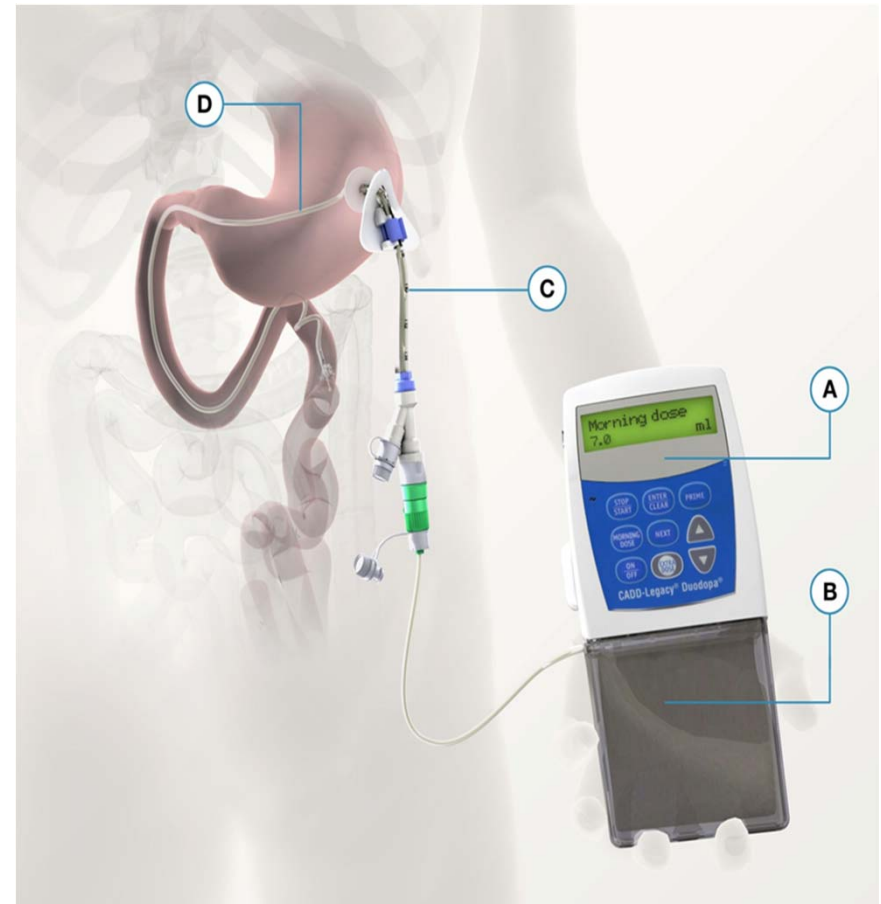
Goals: Additional Risk Minimisation Program

- To inform Healthcare Professionals (HCPs) and patients about the Gastrointestinal (GI), Gastrointestinal Device and Gastrointestinal Procedure-related risks associated with the LCIG system
- Educate HCPs on PEG-J and NJ (Naso-jejunal tube) insertion procedures
- Inform HCPs and patients about aftercare for long-term PEG-J placement in patients using the LCIG system

Duodopa (levodopa – carbidopa intestinal gel)

Indication: Treatment of advanced levodopa-responsive Parkinson's disease with severe motor fluctuations and hyper-/dyskinesia when available combinations of Parkinson medicinal products have not given satisfactory results

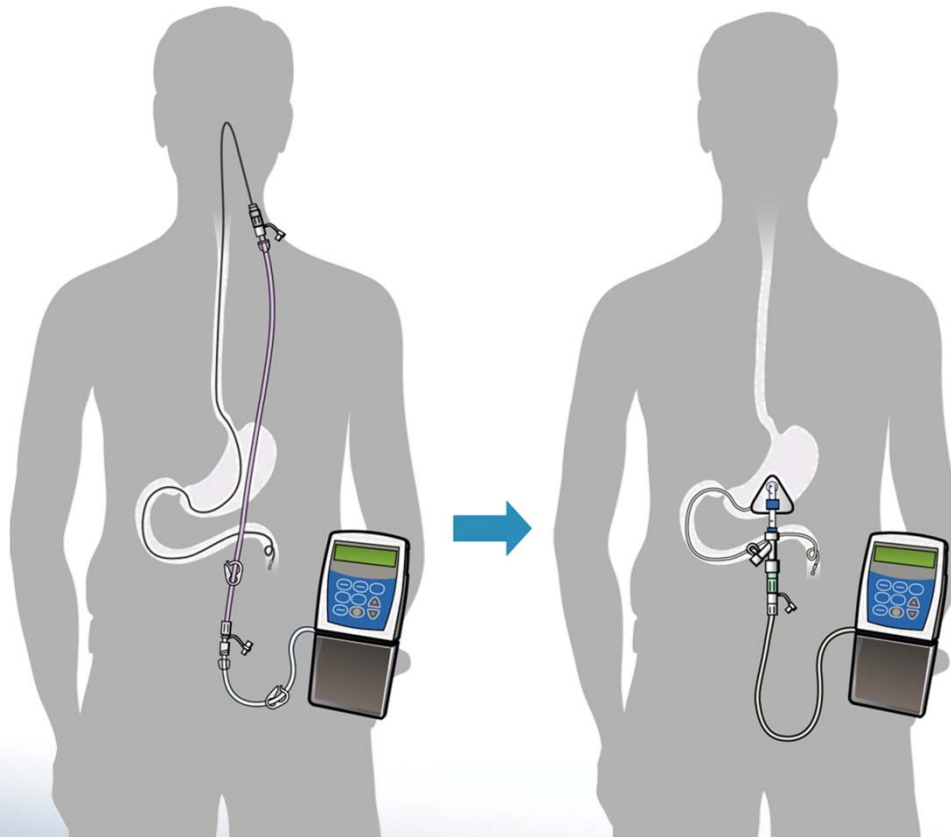
- A. Pump
- B. Duodopa cassette
- C. PEG
- D. Intestinal tube



Duodopa: Levodopa – Carbidopa Intestinal Gel System

NJ Tube

PEG-J Tube



Long-term administration of Duodopa uses the PEG-J delivery system.

A temporary NJ tube may be used to determine if the patient responds favorably before a permanent PEG-J is placed.

Administration of Duodopa

SHORT-TERM TEMPORARY THERAPY

(Prior to PEG-J tube placement)

- Treatment may be initiated by a Naso-jejunal (NJ) tube with observation of the patient's clinical response

LONG-TERM THERAPY

(Requires placement of a PEG trans-abdominal tube and inner jejunal tube by percutaneous endoscopic gastrostomy or radiological gastrojejunostomy if necessary)

- Duodopa is dispensed from medication cassette specifically designed to be connected to only a CADD-Legacy® 1400 pump
- PEG-J insertion and placement should be performed by a gastroenterologist or other healthcare professional experienced in this procedure

Contraindications: Duodopa

Hypersensitivity to levodopa, carbidopa or to any of the excipients

Narrow-angle glaucoma

Severe heart failure

Severe cardiac arrhythmia

Acute stroke

Non-selective MAO inhibitors and selective MAO type A inhibitors

Conditions in which adrenergics are contraindicated (e.g., pheochromocytoma, hyperthyroidism and Cushing's syndrome)

Suspicious undiagnosed skin lesions or a history of melanoma

Contraindications:* PEG Insertion

Lack of trans-illumination and positive needle aspiration test are an absolute contraindication for PEG insertion

Known or suspected intestinal obstruction

Serious coagulation disorders: ESPEN guideline⁺⁺: (INR > 1.5, PTT > 50 s, platelets < 50,000/mm³)

Sepsis

Active peritonitis

Relative contraindication includes ascites, and neoplastic, inflammatory, and infiltrative diseases of the gastric and abdominal walls

Interposed organs (e.g., liver, colon), marked peritoneal carcinomatosis, severe ascites, anorexia nervosa, severe psychosis and a clearly limited life expectancy⁺⁺

* Instruction for Use, AbbVie™ Percutaneous Endoscopic Gastrostomy Kit 15 FR / 20 FR

⁺⁺ Löser C, Aschl G, Hebutérne, et al. ESPEN guidelines on artificial enteral nutrition – Percutaneous endoscopic gastrostomy (PEG). *Clinical Nutrition* 2005;24:848-861.

Device: Special Warnings and Precautions for Use

<p>Previous Surgery in Upper Abdomen</p>	<p>May lead to difficulty in performing gastrostomy or jejunostomy</p>
<p>Reduced Ability to Handle the System* Can Lead to Complications</p> <p>*Pump, tube connections</p>	<p>In such patients a caregiver (e.g., nurse, assistant nurse, or close relative) should assist the patient</p>
<p>Sudden or Gradual Worsening of Bradykinesia</p>	<p>May indicate an obstruction or other issue with the device and needs to be evaluated</p>

Device: Special Warnings and Precautions for Use (cont.)

Reported Complications

Bezoar, ileus, implant site erosion/ulcer, intestinal haemorrhage, intestinal ischaemia, intestinal obstruction, intestinal perforation, intussusception, pancreatitis, peritonitis, pneumoperitoneum and post-operative wound infection

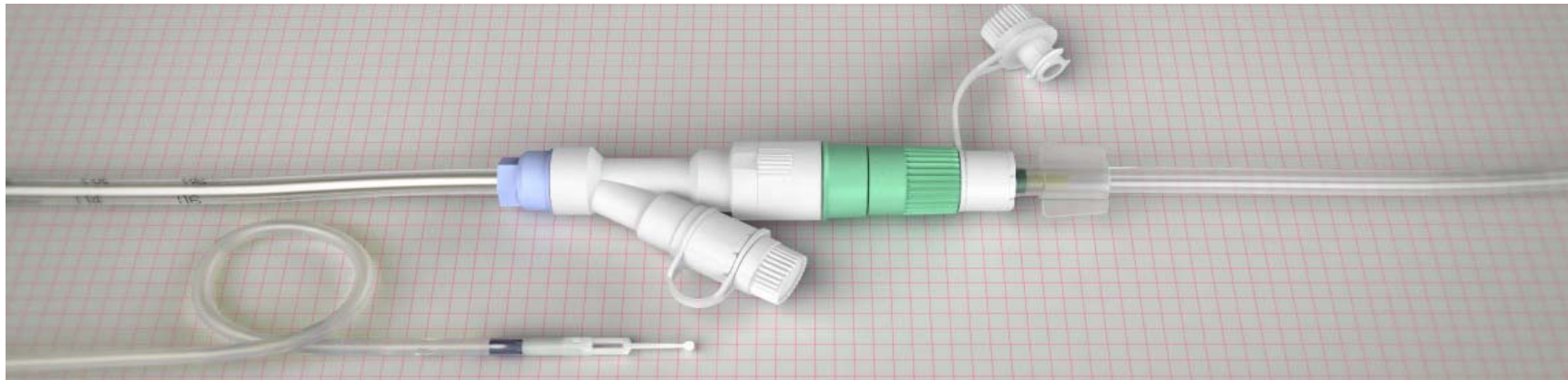
- A bezoar around the tip of the jejunal tube may function as a lead point for intestinal obstruction or the formation of intussusception
- Abdominal pain may be a symptom of the above listed complications
- Potential serious outcomes, such as surgery and/or death may occur with these complications

PEG-J: Preparation, Placement and Aftercare

Educate HCPs on PEG-J and NJ tube insertion procedures through “Critical Aspects of PEG-J”:

- Materials to be used
- Preparation of the patient
- Placement
- Aftercare

Material to be Used: AbbVie PEG-J System – Assembled



References:

Instruction for Use, AbbVie™ Percutaneous Endoscopic Gastrostomy Kit 15 FR / 20 FR

Instruction for Use, AbbVie™ J Intestinal Tube 9 FR for PEG 15 and 20 FR

Material to be Used: AbbVie PEG-J System – Components



A. Intestinal tube

B. Internal retention plate

C. External retention plate

D. PEG tube

E. Fixation screw

F. Y-connector

G. Click connector

H. Luer Lock connector

Reference: Instruction for Use, AbbVie™ J Intestinal Tube 9 FR for PEG 15 and 20 FR

Materials to be Used: AbbVie PEG 15 FR – Kit Contents

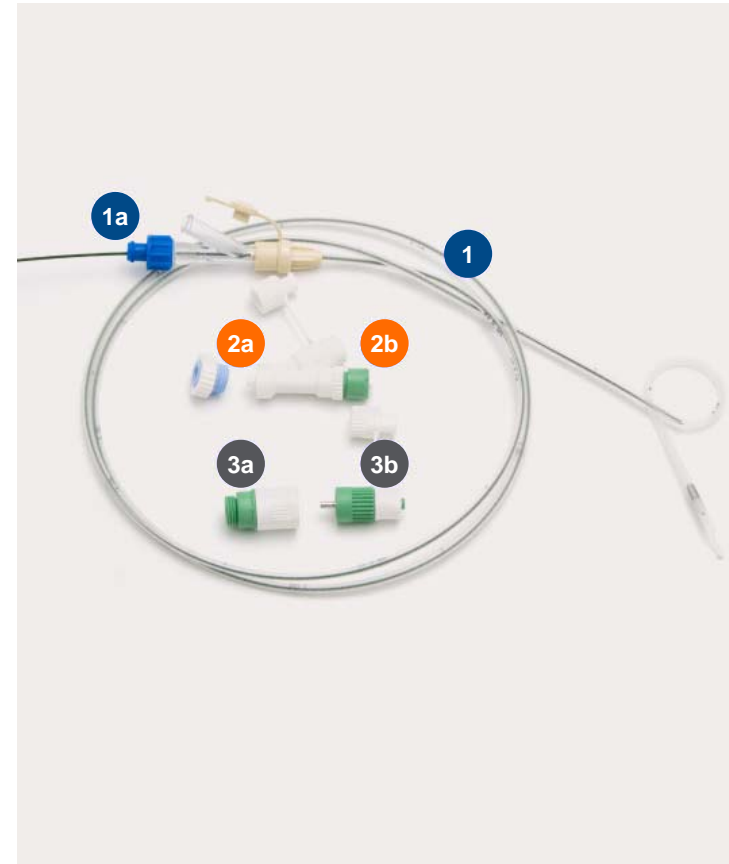
- 1 PEG tube, polyurethane, 15 FR
- 2 Puncture cannula with safety (air) valve
- 3 Disposable scalpel
- 4 Reel of thread with double thread and 4.1 introducer device
- 5 Universal funnel adapter for Luer and catheter tip syringe
- 6 Tube clamp
- 7a Fixing screw for the Luer lock connector
- 7b Luer lock connector
- 8 Silicone external fixation plate, radio-opaque



Reference: Instruction for Use, AbbVie™ Percutaneous Endoscopic Gastrostomy Kit 15 FR / 20 FR

Materials to be Used: AbbVie Intestinal Tube 9 FR for PEG 15 FR Kit Components

- 1 Intestinal tube, polyurethane, 9 FR, 120 cm
 - 1a Integrated Teflon-coated guide wire with fitted Y-piece and blue transparent fixation screw
- 2 AbbVie Y-connector for PEG 15 FR for simultaneous gastric and intestinal access consisting of:
 - 2a Fixation screw (blue-white)
 - 2b Y-connector with two positive Luer lock access points
- 3 AbbVie Click adaptor 9 FR consisting of:
 - 3a AbbVie click connector
 - 3b Luer lock connector (with metal pin)



Reference: Instruction for use, AbbVie™ Intestinal Tube 9 FR for PEG 15 and 20 FR.

Preparation of the Patient: PEG-J Placement

Prior to the procedure the patient should be:

- Fasting overnight, at least 8 hours or longer in cases in which there is evidence of impairment of gastric motility
- Provided with oral hygiene
- Given antibiotic prophylaxis per institutional protocol
- Current coagulation status per local guideline. ESP advised:
 - ESPEN guideline⁺⁺: INR < 1.5, PTT < 50 s, platelets > 50,000/mm³⁺⁺
- Placed in a supine position for the procedure
- Placement of tube system under sterile surgical conditions
- On the morning of the procedure the patient should take their oral Parkinson's disease medications to prevent stiffness during the procedure

WARNING: Lack of trans-illumination and positive needle aspiration tests are an absolute contraindication for AbbVie™ PEG insertion.

*Reference: Instruction for Use, AbbVie™ Intestinal Tube 9 FR for PEG 15 and 20 FR.
Instruction for Use, AbbVie™ Percutaneous Endoscopic Gastrostomy Kit 15 FR / 20 FR
++ Löser C, Aschl G, Hebutérne, et al. ESPEN guidelines on artificial enteral nutrition – Percutaneous endoscopic gastrostomy (PEG). Clinical Nutrition 2005;24:848-861.*

PEG Placement: Important Highlights

The PEG tube should be placed according to standard procedure as published in the ESPEN-Guidelines and recommended by the tube manufacturer.

Reserve at least 40 minutes for the PEG-J procedure; it is essential to reserve enough time for the whole procedure.

The standard PEG pull-through method takes approx. 12 minutes; intestinal tube insertion generally requires 10 to 30 minutes.

The skin incision at the puncture site should be slightly larger than the PEG tube.

Parkinson's patients tend to be thin. Be careful not to make skin incisions too deeply into their skin.

Angle the PEG toward the pylorus to enable direct access of the inner intestinal tube to pylorus.

PEG length: 20 cm
After placement of the PEG, make a straight cut 20 cm outside of the body.

Before connector assembly, ensure parts are dry and connectors are engaged.

Reference: Löser C, Aschl G, Hebutérne, et al. ESPEN guidelines on artificial enteral nutrition – Percutaneous endoscopic gastrostomy (PEG). Clinical Nutrition 2005;24:848-861.

Intestinal Tube Placement; Endoscopic Insertion

The intestinal tube can in general be placed in two different ways: endoscopic insertion or interventional radiology using standard equipment.

- **Endoscopic insertion:**

- **Long enough endoscope;** the Intestinal tube is placed by using an endoscope long enough to reach the ligament of Treitz
- **Avoid intestinal perforation;** make sure to lock the guide wire inside the intestinal tube before insertion

✓ **Confirm with X-ray that the distal end of the intestinal tube is located beyond ligament of Treitz**

Reference: Löser C, Aschl G, Hebutérne, et al. ESPEN guidelines on artificial enteral nutrition – Percutaneous endoscopic gastrostomy (PEG). Clinical Nutrition 2005;24:848-861.

Intestinal Tube Placement; Endoscopic Insertion

- Endoscopic instruments to be used; grip the distal end of the intestinal tube using one of the following instruments:
 - The foreign body forceps, 2:1 teeth
 - The two-arm gripper or
 - The three-arm polyp gripper
- Distal end of intestinal tube beyond ligament of Treitz:
 - Advance the endoscope and the distal end of the intestinal tube under observation until it has safely passed the ligament of Treitz to reduce risk of dislocation of the tube back into the gastric lumen

Reference: Löser C, Aschl G, Hebutérne, et al. ESPEN guidelines on artificial enteral nutrition – Percutaneous endoscopic gastrostomy (PEG). Clinical Nutrition 2005;24:848-861.

Aftercare: Day of Placement, Day of Surgery (< 24 Hours After PEG-J Placement)

- The Duodopa treatment can normally be initiated directly following an uncomplicated PEG-J placement, after consultation with the gastroenterologist
- Oral feeding might be possible after 2 hours but it is preferred to wait until the next morning
- Do not change the dressing during the first 24 hours unless necessary
- Observe for signs of complications such as pain and bleeding
- Prior to discharge from hospital, the patient should have his/her stoma site examined by a member of the treating team to ensure there are no signs of infection

Aftercare: Day 1–10 (After PEG-J Placement)



Healthy PEG-J Stoma:
No redness, swelling, drainage,
or crust at stoma site

The stoma site should be cleansed daily and kept dry at all times

- Wound dressing should be performed under good aseptic conditions once a day, for the first 7–10 days
- Disinfect hands and put on disposable gloves. Remove the dressing, open the retention plate and release the tube from the plate.
- Dispose the gloves, disinfect hands and put on new gloves
- Inspect the wound area (bleeding, erythema, secretion, induration, allergic skin reaction)
- Clean, disinfect, dry completely and redress the wound
- If there are any signs of complications, inform a physician

Aftercare: After Initial Wound Healing

After initial wound healing (24–72 hours, after initial PEG-J insertion), this procedure should be performed every 2–3 days to prevent **buried bumper syndrome**

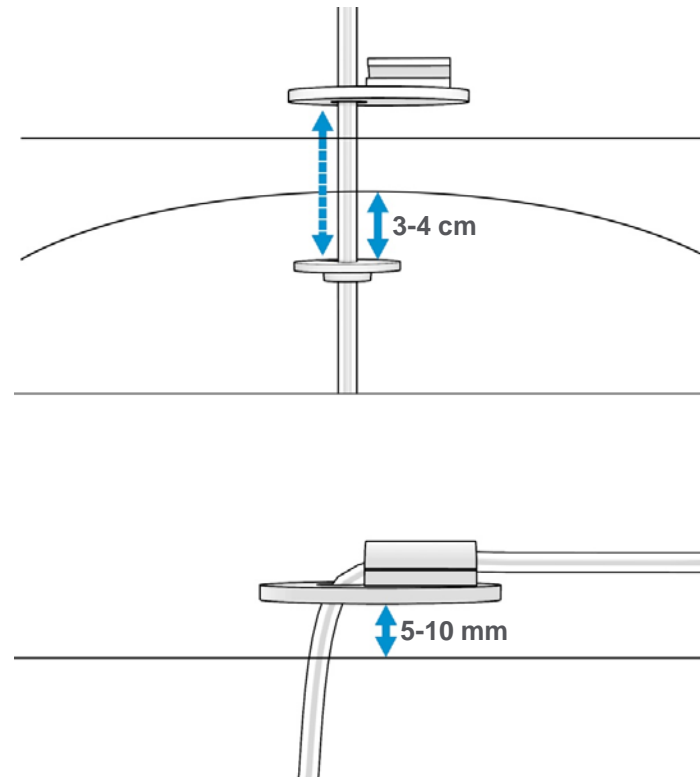
Remove the dressing and release the external retention plate to allow free movement of the PEG-J tube.

- Carefully push the tube 3-4 cm into the stomach and gently pull back until you feel resistance of the internal retention plate into the stoma and move the tube in a bi-directional motion (in and out) every time the dressing is changed
- The PEG tube should remain under moderate tension for 24 to 72 hours to promote good adherence of the stomach wall to the inner abdominal wall
- Avoid in/out movement of the PEG tube within 72 hours post placement,

Do not twist or rotate the PEG tube. It is important for the tube to move freely in the stoma to prevent the inner retention plate becoming embedded (“buried bumper syndrome”).

Replace the retention plate allowing free movement of 5–10 mm. Apply sterile Y-compress under the tube.

- A plaster fixation is recommended for agitated patients



Aftercare: Tube Care

- Flush the AbbVie™ PEG tube daily with room temperature tap or drinking water (via the Flush Port)
- Flush the AbbVie™ J-tube and PEG daily with room temperature tap or drinking water
- Failure to adequately flush the PEG tube may result in occlusion or blockage
- The stoma area should be cleansed using an aseptic technique or refer to facility procedures for stoma care
- The gastric PEG tube should be carefully moved in and out slightly in the stoma every 2–3 days once the site has healed
- The stoma site should be clean and dry at all times

PEG-J: Precautions

Disinfectants such as **Povidone-Iodine** (PVP-I; e.g., Iso-Betadine[®], Braunol[®]) and **Octenidindihydrochlorid-Phenoxyethanol** (e.g., Octanosept[®]) **should not be used**; it might negatively affect the physical/mechanical properties of the tube.

NOTE: Washing or showering with regular soap and water is possible two weeks after insertion of PEG. Always leave the area clean and dry.

Bathing and swimming (after complete initial wound healing) is possible. Fix tube securely with transparent adhesive dressing. Always leave the area clean and dry.

Aftercare: Some Complications and Action to Take

General:

- Circular erythema < 5 mm around the outer stoma canal is frequent and not a sign of wound infection
 - Carefully observe the reddening of the wound during initial wound dressing
 - **Never apply an ointment** on a PEG stoma nor an inflamed PEG wound
- Encrusted dressing → remove with 0.9% saline solution
- Signs of inflammation → twice daily sterile change of dressing with regular wound inspection, swab if prescribed by a doctor
 - Severe cases: systemic antibiotic treatment

Aftercare: Some Complications and Action to Take

- Severe discharge → keep the wound as dry as possible, change the dressing several times daily and place multiple Y- sterile compresses
- Over granulation tissue → remove granulation tissue only if there are complications (either by surgery or cauterization: Silver Nitrate)
- Residual tape → remove with disinfection spray (in special cases with surgical spirit – on intact skin only)
- Although rare serious abdominal complications have been reported with the AbbVie PEG-J system
 - All PEG-J patients and their caregivers should be informed to immediately contact their HCPs if they develop abdominal pain, abdominal bleeding, or signs of abdominal obstruction

In Summary

- The neurologist should work with a gastroenterologist who is experienced in PEG-J placement
- The gastroenterologist should examine patient for GI-related complications following PEG-J insertion procedure, long-term use of the PEG-J and associated tubing
- Follow proper PEG-J aftercare procedures to promote appropriate fistula tract formation for the PEG-J and to avoid potential complications, including peritonitis and postoperative wound infections
- Local care of the stoma site following PEG-J placement is important; carefully examine the stoma site at each visit and at any time the patient or caregiver is concerned about the site
- For more information on specific recommendations for PEG-J procedure and stoma care, please refer to aftercare materials