



# **MEDORAH® Percutaneous Endoscopic Gastrostomy (PEG) KIT**

## **Instructions for Use**

**Medorah Meditek Pvt. Ltd.**

**[www.medorah.com](http://www.medorah.com)**

# **MEDORAH®**

## **Percutaneous Endoscopic Gastrostomy (PEG) KIT**

### **Intended Use / Indications for use**

**Intended use-** MEDORAH® Percutaneous Endoscopic Gastrostomy (PEG) Kit is intended for percutaneous endoscopic gastrostomy placement to provide enteral nutrition to patients requiring nutritional support.

**MEDORAH®** Percutaneous Endoscopic Gastrostomy (PEG) Kit is supplied sterile and is intended for single use only.

### **Device Description**

MEDORAH® Percutaneous Endoscopic Gastrostomy (PEG) Kit is used for patients needing long- term enteral support or hydration secondary to a primary condition relating to the head and/or neck. These conditions include stroke; cancer; head and neck tumors, injuries, or trauma; and neurological disorders resulting in a chewing or swallowing abnormality.

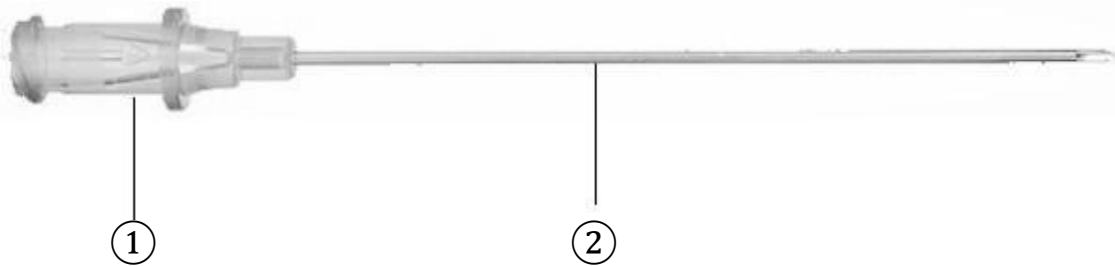
MEDORAH® Percutaneous Endoscopic Gastrostomy (PEG) Kit is designed to provide a safe and effective way to feed food, liquids and medications directly into the stomach. It is indicated to be used for a supply of nutrition when you have trouble eating.

This kit consists of various components as following:

- Traction removable pull PEG tube
- Feeding adaptor with luer lock
- Disposable scalpel (11 blade)
- Feeding adaptor
- Syringe (10ml)
- 19G Needle
- 25G Needle
- Retention ring
- Placement wire
- Fenestrated drape
- Tubing clamp
- 4 - Gauze sponges (10\*10)
- Introducer needle



①	Silicone tube
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①	Hub
②	Needle

### Contraindications

Contraindications associated with placement and use of a PEG tube include, but are not limited to:

- Sepsis
- Severe gastroesophageal reflux
- Ascites, Infectious
- Gastrointestinal obstruction

### Potential Complications

Potential complications associated with placement and use of a PEG tube include, but are not limited to:

- Bronchopulmonary aspiration
- Pneumonia
- Respiratory distress

- Peritonitis
- Septic shock
- Gastric dilatation
- Colocutaneous
- Gastrocolocutaneous
- sigmoid intra-abdominal herniation
- Volvulus
- Esophageal injury
- Necrotizing fasciitis
- Candida cellulitis
- Hemorrhage
- Tumor

### **Warnings**

The entire User's Manual must be read thoroughly before using the device. A detailed knowledge of the techniques, procedures, clinical applications and risks associated with the procedure is necessary before using the device.

1. Read all instructions prior to use. Inspect contents of PEG kit for damage. If damage is evident, do not use kit.
2. Overly pulling on the gastric feeding tube can lead to premature removal, fatigue, or malfunction of the device.
3. For single use only. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization 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.
4. PEG procedures should only be performed by persons having adequate training and familiarity with endoscopic techniques.
5. Maintain stomach insufflation until the external bolster is firmly positioned on the PEG tube.
6. If excessive resistance is met as the PEG dilating tip is exiting the abdominal wall, the incision and subcutaneous tissue may require expansion or enlargement.
7. After the completion of the PEG placement, wait 24 hours before feeding the patient.
8. Patients should be informed of the potential risks and complications. Traction removal may cause trauma or other complications, in some patients.

### **Precautions**

- Read the entire directions for use before using the MEDORAH® Percutaneous Endoscopic Gastrostomy (PEG) Kit.
- The benefit of a PEG tube to the patient must be weighed against the risks associated with any indwelling gastrostomy feeding tube.
- Care must be taken to prevent any cutting, crimping, or damaging on device components during placement and use.
- Do not change the PEG tube or adapters in any way.
- Any use for procedures, other than those indicated in these instructions, is not recommended.
- A thorough understanding of the technical principles, clinical applications and

risks associated with placement and/or removal of a PEG tube is necessary before using this device.

- Placement and removal of the PEG tube should only be performed by, or under the supervision of, physicians thoroughly trained in the procedure.
- When placing a PEG tube, observe all institutional guidelines regarding gastroscopy, including removal of dentures.
- PEG replacement is recommended every three months or at the discretion of the physician.

### **Procedure**

- Visually inspect the device and its components upon unpacking paying close attention to any kinks, bends or breaks in the feeding tube assembly. If any abnormalities are found that could affect the proper functioning, do not use the device.
- After introducing the gastroscope, insufflate the stomach and examine if the mucosa is free of ulcerations or bleeding before proceeding.
- Align the tip of the gastroscope and illuminate the left anterior wall of the stomach.
- Adjust the gastroscope tip to illuminate the desired PEG position and lightly press the area externally (with finger) to ensure clear visualization of the depression. Confirm healthy mucosa by observing the depression with the scope before proceeding with the procedure.
- Drape the area using the enclosed fenestrated drape and inject local anesthetic into the PEG region and make a 1 cm long incision through the skin using enclosed scalpel.
- While maintaining stomach insufflation, insert the introducer needle and cannula unit through the skin incision and into the stomach. Leave the cannula in place to maintain access to the stomach while removing the inner needle.
- Pass the looped placement wire through the introducer needle cannula and into the stomach.
- Place snare or non-spiked biopsy forceps through the channel of the gastroscope and grasp the looped end of the wire.
- Secure the snare or biopsy forceps around the looped placement wire, then withdraw both the gastroscope and the wire from the patient's mouth, leaving the wire protruding from both the mouth and the incision site.
- Pass the placement wire loop through the looped wire on the dilator end of the feeding tube and place internal bumper of the feeding tube through the extended placement wire loop.
- Gently pull the feeding tube through the placement wire loop and form a knotless connection by applying simultaneous gentle traction on both wire loops.
- Lubricate the dilator and the entire external length of the tube including the internal bumper.
- Pull on the wire from the abdominal incision to advance the dilator tip through the patient's mouth. Depressing the tongue can aid in the initial feeding tube introduction. Apply gentle pressure around the incision to avoid excessive pulling.
- Once the internal bumper of the Pull PEG tube enters the mouth, insert the gastroscope again. Observe the tip as it moves down the esophagus into the stomach. Continuously monitor the patient for any signs of respiratory distress as you navigate the internal bumper through the esophagus.

- While observing centimeter increments, gradually withdraw the tube from the abdominal incision. Ensure the internal bumper makes contact with the stomach wall, avoiding any undue tension. Apply gentle pressure to the portion of the feeding tube that is exiting.
- Slide the tubing clamp over the dilation catheter loop and onto the tube.
- Position the tubing clamp onto the tube.
- Cut the Pull PEG tube from the Distal end of the tube using sterile scissors.
- Connect the adapter of your preference (with or without luer lock) and securely close the caps.
- The PEG tube has been designed for removal using the external/traction method. If this method of removal is not possible, another method such as endoscopic or surgical should be utilized.

### Change of performance

If the device's performance is changed or the intended purpose is lost, further actions shall be taken according to the medical specialist's decision considering the clinical condition of patients.












### Disposal of a used device

After use, this product may be a potential biohazard. It must be disposed of according to hospital, local and country regulations. Disposal is the responsibility of user.

### Storage

The product should be stored in a cool, dry, clean, well-ventilated, non-corrosive gas environment. Do not expose the package to organic solvent, ionizing radiation or ultraviolet radiation.

### Explanation of Symbols

	Date of Manufacture		Use-By Date
	Catalogue Number		Single Use
	Read instruction before Use		Caution
	Keep away from sunlight		Batch Code
	Do Not Re-sterilize		Keep dry
	Sterilized using Ethylene Oxide		

## **Warranty**

Medorah Meditek Pvt. Ltd. warrants that this product has been manufactured by following appropriate procedures and reasonable care has been applied in designing and manufacturing of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed 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 device as well as other factors relating to patient, diagnosis, treatment, surgical procedures, and other matters beyond Medorah Meditek Pvt. Ltd.'s control directly affect the device and the results obtained from its use. Medorah Meditek Pvt. Ltd.'s obligation under this warranty is limited to the repair or replacement of this device and Medorah Meditek Pvt. Ltd. shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. Medorah Meditek Pvt. Ltd. neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device. Medorah Meditek Pvt. Ltd. assumes no liability with respect to devices reused, reprocessed or re-sterilized and makes no warranties, expressed or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such devices.



Mfd. By: Medorah Meditek Pvt. Ltd.

353, Udyog Vihar, Phase-IV, Gurugram, Haryana-122015 (INDIA)

Phone: 0124-4712471 | E-mail: [info@medorah.com](mailto:info@medorah.com)

[www.medorah.com](http://www.medorah.com)

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