INSTRUCTION FOR USE

Percutaneous Feeding Kit

(RMS:81263810006)

Reprocessing Forbidden / Single Use/ Sterile product

PROCEDURE GUIDELINES – PULL METHOD

INDICATION/ INTENDED USE

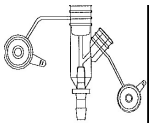
PULL method - PEG kit is used in parenteral nourishment, fluids and/or medicine supply, to patients who cannot receive oral nutrition. This product is also used for decompression.

FORM AND OPERATING PRINCIPLE

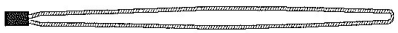
1 – PEG Catheter

2 - Fastener

3 - Clamp



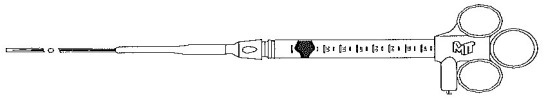
4 – Y-Connector



5 - Loop wire

6 - Scalpel

7 - Mandrel with needle



8 – Handle

9- Scissors 10- Kelly Tweezers 11- Lubricating Gel 12-Gauze 13- Fenestrated field 14- Nozzle

OPERATION OR USE INSTRUCTIONS

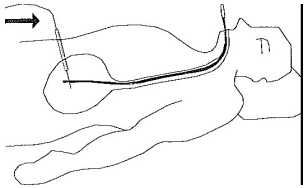
• Pre-surgery exam and procedure for patients

1. Inspect the kit content observing component preservation (searching for damages).
2. Administer the pre-surgery procedures required to the patient prior to the upper digestive endoscopy.
3. Place the bite block into the patient and position the patient in dorsal decubitus.
4. Inflate the stomach adequately during the endoscopic procedure.
5. Proceed with the abdominal wall transillumination using the endoscope light. (Inflate the balloon adequately, providing air, transilluminating the abdominal wall.)

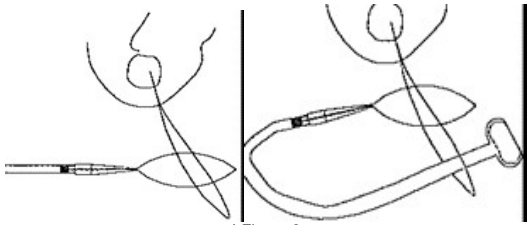
• Suggested Method for Catheter Placement

6. It is critical to properly select the gastrostomy insertion site. A gastrostomy place is usually built in the upper left quadrant, avoiding important blood vessels, organs and ligamentous tissues.
7. In order to select a safe insertion site, press the skin with the brighter endoscope light to confirm the gastric mucosa protrusion and apply pressure with the finger to the skin at the site the transillumination is stronger. The best place must be selected and flagged with a marker.
8. In order to prepare the selected insertion site, perform a wide skin disinfection in the area around the local and place a surgical field.
9. Administer local anesthesia, then make an incision of around 1cm in the skin, with a scalpel.
10. Using the endoscopic vision, insert the mandrel into the incision site in the skin and move it from the abdominal wall to the gastric wall.
11. Remove the needle when the mandrel tip reaches the stomach interior, keeping the mandrel.
12. Insert the loop wire into the stomach through the mandrel.
13. Insert the handle through the endoscope. (Figure 1).

* Figure 1



14. Hold the loop wire with the handle and remove it with the endoscope to the oral cavity exterior, with a sufficient length to the continued procedure (30cm approximately). Be careful that the introducer be gently taken when the loop wire is removed.
15. Disassemble the loop wire from the handle and connect it to the PEG catheter. Pass the loop wire through the catheter dilator loop and then pull the tapered catheter tip inwards the loop wire and remove the entire PEG catheter (Figure 2).



* Figure 2

16. Pass the loop wire through the snare loop in the PEG catheter tip and pass the PEG catheter through the loop wire, and then remove the entire PEG catheter.
17. Tighten the loop snare, holding the PEG catheter inner support with a thumb and a forefinger, to create a connection.
18. Apply water-soluble lubricant to the PEG catheter.
19. Slowly pull the loop wire coming out of the incision site in the abdomen, holding it with the hand to pull the PEG catheter tip into the patient oral cavity. Then, simultaneously pull the catheter and the dilator outside the patient's body through the incision site.
20. As the PEG catheter is pulled outside the patient's body, the bumper passes from the oral cavity to the stomach through the esophagus.
21. Insert the endoscope again.
22. Slowly pull the PEG catheter, slightly rolling it to the right, until the bumper gently tap the gastric wall.

* Do not pull the PEG catheter with excessive force. The stoma could be injured and / or the catheter could be damaged. The PEG catheter has a useful scale to understand how much of the tube is removed from the patient.

23. Cut the PEG catheter in the proper body surface place.
24. Advance the fastener to the incision local until it touches the body surface, being careful not to excessively compress the stomach wall.
26. Confirm by endoscopic vision that the bumper was correctly placed.
25. Attach the clamp, as necessary.
26. Connect the Y-connector to the catheter incision local. (Figure 3).

• Safely connect an enteral nutrition set to the Y-connector.

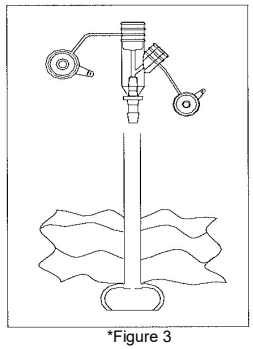


*Figure 3

PROCEDURE TO PERFORM STOMACH DECOMPRESSION

1 - After opening the plug from the Y-connector, perform the stomach decompression. In case of gastric content getting out, drain it into a container and wash the catheter internal lumen with warm water.
2- Once the procedure is finalized, close the Y-connector plug.

CATHETER REMOVAL

The PEG catheter kit from PULL Method must be replaced by a new one, due to stains, clogging, etc., moreover due to the bumper (dome) that can be detached due to an accidental removal, etc. (so the catheter must be periodically checked). Besides, some nutrients could harden the silicon rubber, which is the catheter material.
The catheter must be removed only when the physician considers that the gastrostomy local is strong enough to withstand a catheter replacement.
As this product was not designed for long term use, its replacement is recommended within **29 days.**

ENDOSCOPIC REMOVAL

1. Insert an endoscope into the stomach and inflate it for observation.
2. Insert the handle. Then, release the fastener from the body surface.
3. Slowly turn the PEG catheter and gently pull it at 2 cm into the stomach.
4. Hold the catheter between the bumper (dome) and the stomach wall with the handle wire loop snare.
5. Cut the PEG catheter in the body surface at the proper local and remove the bumper with the endoscope, holding the catheter with the handle. Dispose the removed catheter in a proper container.

PRECAUTIONS RELATED TO THE USE INSTRUCTIONS

1.The user must study this manual closely prior to the first product use, since previous understanding of operation and handling is vital.
2. Do not bend or pull the PEG catheter part towards the dilator when the individual components of this product are removed from its package. The presence of bends in the catheter makes its operation difficult or impossible. Also, excessive force applied when connecting the catheter to the dilator could detach the connection.
3. Care must be taken since the fascia could produce substantial resistance when the catheter is pulled (pushed) outside the patient's body through the incision site in the skin during the PEG catheter placement.
4. The stomach must be sufficiently inflated during the procedure to ensure the contact between the stomach wall and the abdominal wall.
5. The silicon portion in the PEG catheter must not be strongly pulled to firmly attach the connection between the handle and the PEG catheter. Excessive force applied to the connection of the catheter to the dilator could lead to the parts detachment.
6. All needle stick devices used in the PEG catheter placement (for example, puncture needle, scalpel, scissors, etc) must be immediately disposed in a proper container.
7. In order to connect a nourishment bag to the Y-connector coupled to the catheter, select one that fits perfectly. Forced insertion of the bag into the Y-connector could damage the catheter internal lumen, due to the nourishment bag connector tip, leading to the connector cracking or breaking.
8 - During nourishment bag use, confirm that there is no leaking or loosening in the connection with the Y-connector, and use it only in a completely connected condition.

9. The connection site between PEG catheter and the Y-connector must be periodically cleansed. Also, while the PEG catheter is not in use, the connector plug must be periodically checked to see if it is closed. If stains, oil, etc. are attached to the Y-connector coupling part, the detachment of Y-connector coupling during the administration would become more probable. Those substances also increase the likelihood of adapter plug detaching, resulting in higher chances of gastric content leakage and associated necrosis and skin infections.

PRECAUTIONS:

1. This product is not suitable for purposes other than those described herein, and must be used by skilled and qualified professionals.
2. This product may only be used by or under the direct supervision of a physician thoroughly trained in endoscopy therapy, as well as in gastrostomy.
3. This product was sterilized. The package, content and expiration date must be checked prior to the use. This product must not be used in case any abnormality is noted.
4. This product must be used as soon as the package is opened. After use, it must be securely disposed, considering the prevention of infections.
5. The catheter must be washed with warm water, prior and after nourishment administration. It is necessary to avoid the catheter clogging due to the residual nutrients' accumulation, etc.
6. If there is resistance during nourishment administration, etc. or catheter washing with warm water; these procedures must be discontinued. The catheter lumen may be clogged and if the procedures are continued without solving the catheter lumen clogging, the pressure in the catheter will raise excessively, possibly resulting in damages or catheter rupture.
7. If a procedure is performed to solve the catheter clogging, pay attention to:

• Use high capacity injectors (syringes) of 30 ml or more. (Using a lower capacity syringe below 30 ml will raise the injection pressure, resulting in risk of damages or rupture in the PEG catheter).
• Do not use stylet, etc.
• If the catheter clogging cannot be solved through the procedure above, the catheter must be replaced.

DEFECTS

The following defects / adverse effects can occur associated to the use of this product:

• Bumper separation. If the bumper (dome) is separated, it must be promptly recovered under endoscopic vision. (Could develop the ileus if not removed).
• Catheter obstruction
• Catheter breakage and deformation
• Catheter position moved (fastener detached)
It must be confirmed periodically that the length of the catheter exposed outside the body is not shorter than usual, if the catheter was taken to the bowel, that could cause ileus).
• Leakage or disconnection of a connection

ADVERSE EVENTS

• Peritonitis and sepsis
• Gastric bleeding
• Wrong perforation in another organ
• Wound infection
• Buried bumper entombment (dome) syndrome
• Unintentional catheter removal
• Pyloric stenosis
• Gastroesophageal reflux
• Obstruction of the small bowel (ileus) or perforation of the small bowel
• Early separation between the stomach wall and the abdominal wall
• Diarrhea, anorexia
• Gastric ulcer
• Skin problems (redness, skin ulcer, necrosis caused by pressure, granulation)
• Nourishment leakage, etc., in the stoma circumference

WARNINGS

- **Use strict aseptic technique to handle and implant the product.**
- **Prior to a puncture with needle in the abdominal wall, if the light transmitted by the endoscope cannot be seen, the procedure should not continue. Moreover, the puncture site must be selected, avoiding big blood vessels, other organs and ligamentous tissues.**
- **The excessive percutaneous endoscopic gastrostomy (PEG) catheter pressure and / or in this product's bumper must be prevented. This can cause not only necrosis pressure of the involved tissue, but also the bumper entombment or misalignment from its proper position in the stomach, or intentional catheter removal.**
- **The stoma circumference must be checked in a daily basis. Specifically, if the PEG tube is moved by displacement, while the stoma is not completed after the surgery. Contents and gastric nutrients could leak into the peritoneum, possibly causing peritonitis.**
- **The PEG catheter must not be forcibly pulled. This could injure the stoma and/or damage the catheter.**
- **After the incision, it should be confirmed that the extraction of the PEG catheter excess compresses the gastric mucosa and/or the skin. Buried bumper syndrome may occur.**
- **Prior to the nourishment administration, the proper bumper placement must be confirmed through the use of more than one confirmation method as listed below. Special attention must be given if there is the suspicion of catheter misalignment. If its placement or improper displacement cause nourishment leakage, and/or others into the abdominal cavity, this may cause severe complications, such as peritonitis, which could be fatal.**

Confirmation Procedure

a. Gastric content aspiration (gastric juice).
b. Aspiration after infusion of isotonic saline solution.
c. Confirmation by x-ray fluoroscopy.
d. Confirmation by endoscopy, etc.

- **The connections could come loose during use. Attention to tube leakage and detachment and proper measures, such as tighten and retighten the connection, must be taken.**
- **When the bumper catheter is pulled and removed through percutaneous intervention, it must be raised alongside the stoma. If the catheter is pulled in an oblique or crossed direction, a more than expected force is applied, resulting in bumper breakage or detachment.**
- **If the bumper is detached, it should not be left, but instead be promptly recovered under endoscope observation. If the bumper is left, it could cause gastrointestinal obstruction (ileus) or gastrointestinal perforation.**
- **When the bumper is transcendentally recovered under endoscopic observation, the endoscope must be slowly removed along with the bumper, taking care not to injure the gastric wall and the esophagus. If the endoscope is forcibly or quickly removed, it could cause injuries or esophageal perforation.**

CONTRAINDICATIONS AND PROHIBITIONS

- The re-use of this product is prohibited. This is a single-use and disposable product. Its quality after the use cannot be guaranteed. Moreover, the re-use of this product could be associated to a risk of patient contamination (infection). Contamination of this product may result in patient injury, disease, or death.
- Reprocessing or re-use of this product are prohibited. Reprocessing of this product can lead to defect(s). Moreover, it could result in patient injury, disease, or death.
- This product must not be applied if:
  - the patient has sepsis;
  - presents difficulty in endoscope progression due to esophageal or airways stenosis (these conditions can hinder the catheter placing and removal procedures);
  - presents surgical scars around the gastrostomy site.

PACKING

1 PEG catheter	1 Gauze	1 Clamp
1 Scalpel	1 Fenestrated field	1 Fastener
1 Kelly Tweezers	1 Bactericide lubricant gel	1 Mandrel with needle
1 Scissors	1 Handle	1 Loop wire
1 Nozzle	1 Y-Connector	

Storage

Do not place any object over the instrument or its package!

Do not place the instruments near aggressive chemicals!

Do not expose the instruments to direct or indirect sunlight or other ultraviolet rays!

Keep it in a dry place, at room temperature and free of contamination.

The product must remain in its original package provided by G-Flex Latin America and must be stored horizontally.

Complaints will not be accepted if the instruments were improperly stored.

Cleaning and sterilization

This device is designed and guaranteed for single use!

Risk in case of re-use

These devices are intended for single use only. G-Flex disclaims any liability in case of re-use. The re-use of a single use device could represent risks for the user safety, equipment, or patient, due to possible uncontrolled contamination and/or lack of reliability in the device performance.

Disposal

Product disposal must be performed in medical waste or according to local laws. In case of expired shelf life product or non-intact package, such product may be disposed as appropriate.

User

G-FLEX product users must be experts in their areas. A proper and specific training is mandatory regarding product preparation, care, and maintenance.

Repair and claims

In order to protect their employees' health, only disinfected or sterilized instruments will be accepted for analysis or repairs. Disinfection or sterilization date and validity must always be indicated in the package exterior. If this requirement is not met, the instruments will be sent back to the sender without analysis or repair.

Legal basis

The Brazilian law shall be applied.

Product support

In case of doubts or difficulties related to our instruments, please contact your local distributor or contact G-FLEX directly during business hours.
Available time schedule: Monday to Friday, 08:00 AM to 05:48 PM (Brasília time).

REF	Catalog number	STERILE EO	Sterilized with ethylene oxide
	Refer to instructions of use		Do not re-use
LOT	Batch		Keep away from sunlight
	Manufacturing date		Keep it dry
	Use before		Quantity per box
	Attention		Do not use if the package is damaged

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