INSTRUCTION FOR USE

BUTTON REPLACEMENT FEEDING TUBE

(RMS 81263810008)

Reprocessing Forbidden / Single Use / Sterile product

1- USE INDICATION

The purpose of this product is to provide medicine, nourishment, etc., through the catheter to patients unable to have oral food intake. Moreover, the product can be used for gastric decompression.

2- OPERATING PRINCIPLE

The Button replacement feeding tube is a Low Profile device to replace the Percutaneous Endoscopic Gastrostomy (PEG) or the gastrostomy tube. After catheter insertion and attachment in the gastric stoma, the balloon is placed and inflated. Nourishment is further injected in the proximal side, go through the internal lumen and are given to the stomach (Figure 1).

3- SPECIFICATIONS AND PACKAGE

The specifications indicated in the following table represent our standard model.

Reference	Ø Ext.	Actual Size	Balloon Volume
GPB-141010	14Fr 4.7mm	10mm	10 ml
GPB 141510		15mm	
GPB-142010		20mm	
GPB-142510		25mm	
GPB-143010		30mm	
GPB-143510		35mm	
GPB-144010		40mm	
GPB-144510		45mm	
GPB-161015	16Fr 5.3mm	10mm	15ml
GPB 161515		15mm	
GPB-162015		20mm	
GPB-162515		25mm	
GPB-163015		30mm	
GPB-163515		35mm	
GPB-164015		40mm	
GPB-164515		45mm	
GPB-182015	18Fr 6.0mm	20mm	15ml
GPB-182515		25mm	
GPB-183015		30mm	
GPB-183515		35mm	
GPB-184015		40mm	
GPB-184515		45mm	
GPB-202020	20Fr 6.7mm	20mm	20ml
GPB-202520		25mm	
GPB-203020		30mm	
GPB-203520		35mm	
GPB-204020		40mm	
GPB-204520		45mm	
GPB-242020	24Fr 8.0mm	20mm	20ml
GPB-242520		25mm	
GPB-243020		30mm	
GPB-243520		35mm	
GPB-244020		40mm	
GPB-244520		45mm	

Table 1

Components	Quantity	Specifications
Button	1 un.	Refer to the specifications in table 1.
Straight Extender Tube 300mm	1 un.	Bolus type administration
Angled Extender Tube 300mm	1 un	Continuous Bolus type administration
Gauze	1 un	Sterile compress
Luer slip syringe	1 un	10 ml - sterile
Luer catheter syringe	1 un	60 ml - sterile
Lubricating gel	1 un	2.7g – sterile sachet

Prior to using the product, inspect the package content to check that all components are present, that there is no damages/malfunction in the product and that it is within the validity period. If any irregularities are observed, do not use the product, and contact the distributor immediately.

4- BUTTON REPLACEMENT FEEDING TUBE

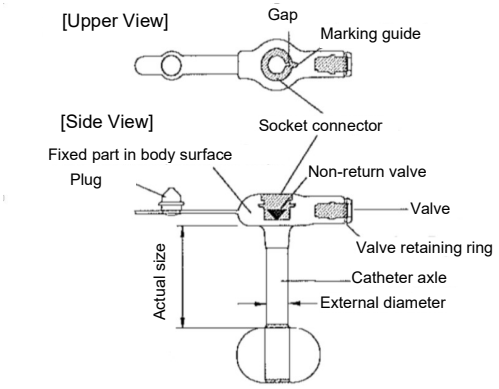

Figure 1

5- EXTENDER TUBES

- **Straight Extender Tube - *Bolus type administration***

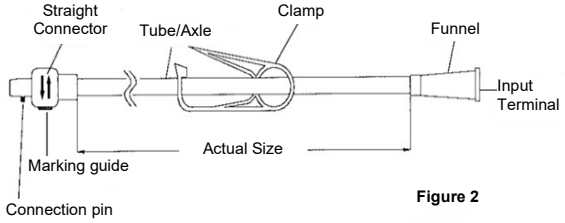

Figure 2

- **Angled Extender Tube - *Continuous Bolus type administration***

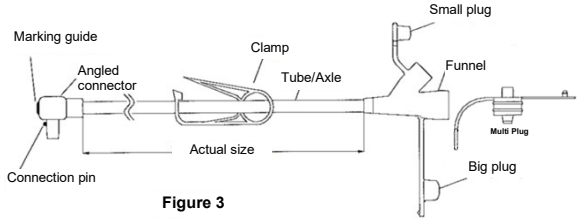

Figure 3

6- PRECAUTIONS FOR USE RELATED TO EFFICACY OR EFFECT

6.1. For this product stay, all the balloon distilled water must be replaced **once a week** according to the volume specified in the valve. This will keep the balloon inflated, near its nominal capacity, minimizing the volume reduction and preventing the catheter exteriorization.
6.2- As this product was not designed for long term use, its replacement is recommended within **29 days.**
6.3 - Product integrity and operation must be checked prior to the use, performing the **tests** below:

- Traction resistance

By slightly pulling both tube extremities, no rupture should occur.

- Air tension

After removing the tube from the envelope, connect the luer slip syringe to the tube valve and inject air (according to the volume indicated in Table 1). No extreme uneven inflation shall occur in the balloon. subsequently, immerse the balloon in the sterile water and observe it. No air leakage shall occur.

Once the test is finalized, completely empty the balloon and check that the balloon membrane is settled in the catheter.

7- OPERATIONAL PROCEDURE FOR CATHETER REPLACEMENT

7.1- Confirm if the stoma was correctly formed and does not show abnormality (without separation between the gastric wall and the abdominal wall) completed the ostomy period, of 3 weeks after the percutaneous endoscopic gastrostomy (PEG).
7.2- Apply the lubricant in the catheter proximal side placed in the stoma and remove it according to the operational procedure.
7.3- Apply the lubricating gel in the button tube catheter, insert it into the stoma and confirm endoscopically that the tube is properly inserted in the stomach.
7.4- Inject sterilized distilled water to inflate the balloon, according to the volume specified in the tube valve.
7.5 - Gently pull the tube to confirm the sensation that the balloon slightly touches the gastric wall.
7.6- The external part of the tube must be at around 1 to 2 mm away from the skin surface.

8- PROCEDURE FOR BUTTON REPLACEMENT FEEDING TUBE SUBSTITUTION

8.1 - Check if tube size is appropriate to the stoma diameter and previously perform the product check tests according to 6.3.

8.2- Check if the stoma was correctly formed and does not show abnormality (without separation between the gastric wall and the abdominal wall after the ostomy period completion of 3 weeks subsequent to the percutaneous endoscopic gastrostomy (PEG)).
8.3- Remove the tube placed in the stoma according to the operation method.
8.4- Connect the straight extender tube in the button replacement tube socket connector and turn to the right (around 180 degrees), to attach the connection and release the tube retention valve (Figure 4).
8.5 - Apply the sterile lubricant gel in the outer side of the tube catheter.
8.6- Insert the tube catheter through the stoma from the distal extremity, introducing the balloon into the stomach (Figure 5).
8.7- Inject the sterilized distilled water volume specified into the valve using a syringe and inflate the balloon (according to the specified in the product itself).
8.8- Gently pull the catheter to the point the balloon slightly touches the gastric wall to confirm that it is the proper tube stay position (Figure 6).

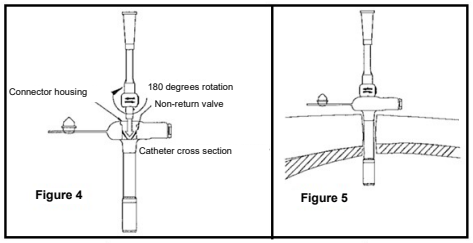

Figure 4

Figure 5

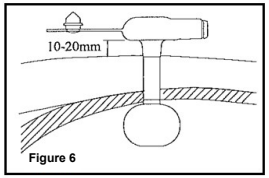

Figure 6

8.9- Turn the extender tube connector to the left to unlock and disconnect the tube tube.
8.10- Close the tube plug and confirm endoscopically or fluoroscopically that the catheter is properly placed in the stomach.

9- INSTRUCTIONS FOR REPLACEMENT WITHOUT USE OF ENDOSCOPY OR RADIOGRAPHY AS FIRST TOOL OF CHOICE TO CONFIRM STAY SITE

9.1- Prior to removing the catheter present in the stoma, inject 20 to 30 ml isotonic sodium chloride solution (preferably stained with red food) through the catheter.
9.2- Replace the catheter according to the items “8.1” to “8.8” above.
9.3- Subsequently, aspire the isotonic sodium chloride solution injected in the stomach through the catheter with a luer catheter syringe, to ensure that the catheter is properly inserted in the stomach.
9.4- If the catheter insertion into the stomach cannot be confirmed by this method, confirm the insertion again through endoscopic or radiographic examination.

10- MEASURES TO DEAL WITH THE CATHETER DISPLACEMENT, SUCH AS ACCIDENTAL (AUTO) REMOVAL

10.1- Check stoma conditions and confirm the absence of abnormality.
10.2- Then, insert a new tube according to items [8.4] to [8.10].

ATTENTION: The stoma narrows in a short period of time when there is nothing inserted in it. Prevent the stoma narrowing by proper means and quickly place a replacement catheter.

Forced insertion could damage the stoma. If narrowing occurs, stop using the stoma and take proper measures.

11- PROCEDURE FOR NOURISHMENT OR MEDICINE ADMINISTRATION THROUGH BOLUS TYPE OR CONTINUOUS BOLUS TYPE

11.1- Select the extender tube to be used and gently pull the tube prior to the nourishment administration, medicine, etc. to confirm that there is no deviation / abnormality.
11.2- Open the tube plug and insert the connection pin until the extender tube marking guide matches to the tube. At this stage, the extender tube connection pin is fitted to the connector socket gap, named "connection / disconnection position") (Figure 7).

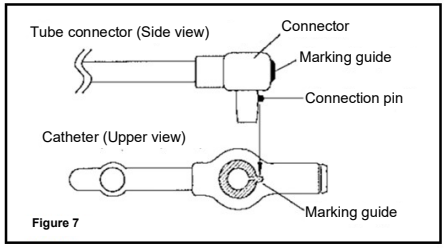

Figure 7

11.3- Subsequently, turn the extender tube connector around 180 degrees from the tube socket connector marking guide, so that the connectors marking guide are in opposite sides and so that is possible to feel the lock was fitted safely (Figure 8).

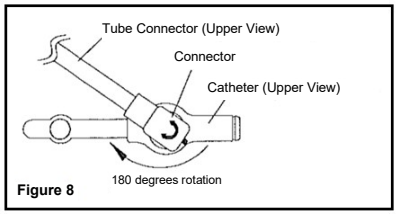

Figure 8

11.4- Administration of nourishment/medicine *continuous Bolus type*

11.4.1- Usually choose the angled extender tube for continuous (extended) nourishment administration.
11.4.2- In case of nourishment administration, close the multi plug coupled to the medicine injection input (Figure 9) and wash the nourishment injection input with 10ml to 15ml of warm water ("Washing" in this context means taking a proper volume of warm water in a syringe and perform a strong injection). Once this procedure is finalized, connect a nourishment line to the nourishment injection input and open the clamp, so that the nourishment administration to the patient can be performed.
11.4.3- In case of medicine administration, close the big plug and connect a syringe to the multi plug coupled to the medicine injection input. Inject 5ml to 10ml of warm water to wash it. (Figure 9). Subsequently, connect a luer slip syringe in the extender tube medicine injection input and open the clamp, for medicine administration.

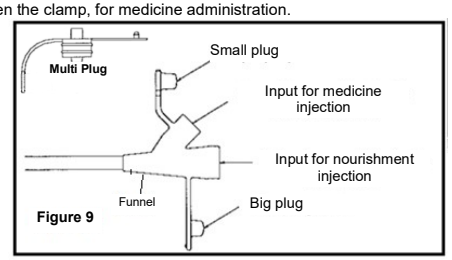

Figure 9

11.4.4 - After nourishment, medicine etc. injection, inject 10 ml of warm water or more to wash the tube catheter internal lumen.
11.4.5- Once the washing is finalized, close the clamp and turn the extender tube connector to the left, turning back to the "connection / disconnection position". Disconnect the extender tube connector from the tube connector socket and close the tube plug immediately.

11.5- Administration of nourishment/medicine *Bolus type*

11.5.1- Perform washing with 10 ml or more warm water from the funnel input terminal ("Washing" in this context means taking a proper volume of warm water in a syringe and perform a strong injection) (Figure 10).

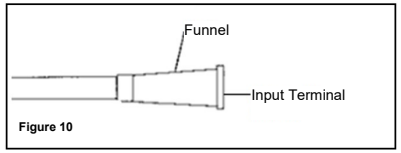

Figure 10

11.5.2- Subsequently, connect a nourishment line or a luer catheter syringe to the funnel input terminal and open the clamp, for nourishment or medicine administration to the patient.
11.5.3- After administration, remove the nourishment line or the extender tube syringe and perform the rinsing with 10ml or more of warm water to wash the extender tube internal lumen and the button catheter.
11.5.4- Once the washing is finalized, close the clamp and turn the extender tube connector to the left, turning back to the "connection / disconnection position". Disconnect the extender tube connector from the button connector socket and close the button plug immediately.

12- PROCEDURE TO PERFORM GASTRIC DECOMPRESSION

12.1- Gently pull the extender tube to confirm that there are no deviations / abnormalities.
12.2- Close the clamp and connect the extender tube to be used to the button connector socket, according to [11.2] and [11.3].
12.3- For ***bolus type*** administration, open the clamp and drain the gastric content through the input terminal to a container.
12.4- For **continuous bolus type** administration, close the small plug and open the clamp to drain the gastric content to a container, from the nourishment injection input.
12.5- In case of continuous or intentional drainage, it must be performed with low pressure.
12.6- After decompression, perform washing with 10ml or more of warm water through the input terminal (bolus type) or through the nourishment injection input (continuous bolus type) and make sure the extender internal lumen is clean.
12.7- Once the washing is finalized, close the clamp and turn the extender tube connector to the left, turning back to the "connection / disconnection position". Disconnect the extender tube connector from the button connector socket and close the button plug immediately.

13- PROCEDURE FOR BUTTON REPLACEMENT FEEDING TUBE REMOVAL

13.1 - Apply the sterile lubricant gel in the stoma portion next to the button catheter.
13.2- Pull and push the catheter to feed the lubricant into the stoma.
13.3- Connect a disposable luer slip syringe to the button valve and remove all the sterilized distilled water from the balloon.
13.4- Carefully remove the catheter from the stoma, while holding firmly the attached part in the body surface.

14- PRECAUTIONS FOR USE RELATED TO OPERATIONAL PROCEDURES

14.1 - Choose a tube of appropriate size, because changes in the patient body influence the stoma size. During the stay, confirm regularly if the product diameter is suitable and check the condition of the external part attached to the body surface.
- If the catheter diameter is smaller than the stoma, the button could be loose and the gastric content could leak out.
- If the catheter diameter is bigger than the stoma, the gastric wall or skin could be damaged and, in some cases, a necrosis due to pressure or button removal could occur.
-If the effective catheter length is too long regarding the stoma depth, although rare, the catheter can be attracted to the intestinal tract, especially around the stomach antrum, which is easily influenced by peristaltism.
-If the effective catheter length is lower than the stoma depth, it could excessively compress both gastric and abdominal walls and lead to necrosis due to tissue pressure or catheter deviation / removal due to balloon rupture, etc.
14.2- Confirm that the balloon is properly inflating and deflating prior to using this product.
14.3- Insert the syringe tip safely up to the end of the valve to inflate or deflate the balloon. In case the insertion of the syringe into the valve is insufficient, the valve may not operate properly to inflate or deflate the balloon.
14.4- To remove the syringe, turn it while holding the valve. In rare occasions, the valve may move from its position or come out.
14.5 - Inject sterile distilled water slowly and carefully to inflate the balloon, because fast injection (in rare occasions) could result in valve displacement or closing due to the pressure.
14.6 - Inject sterile distilled water slowly and carefully to inflate the balloon, because fast injection (in rare occasions) could result in valve displacement or closing due to the pressure. Moreover, if the inflating procedure is quickly performed, it can cause the balloon fold or overlap or burst it.
14.7- If the balloon is not inflated up to the catheter tip correctly, deflate the balloon once and then confirm it, inflating again while organizing the balloon shape with your hand.
14.8- If the balloon is pronounced or overlaid, it is possible to solve by inflating or deflating with a small quantity (3ml or more) of sterilized distilled water.
14.9- Use a disposable luer slip syringe to perform balloon inflation and emptying, because luer lock tip syringe cannot connect firmly to the valve. Moreover, the use of a syringe not adapted to the connector may result in damages to the valve.
14.10 - When attaching the multi plug, always confirm its condition and attach it after cleansing the "moisture" caused by nourishment or water etc. from each attaching part. In case the attaching part is wet, or the attachment is not performed correctly, the multi plug is naturally released and the gastric content could leak out.
14.11 - Do not suture the product to the skin.
14.12 - In order to connect a nourishment line, etc. to the button, select the connector that fits perfectly. During use, confirm (once in a while) that there is no leaking or loosening in the connection and use it only in a completely connected condition.
14.13- Gently and carefully place or remove a nourishment line tube, etc, taking care so as not to force the balloon (such as, for example, not pulling up), because the balloon may burst or the catheter may come out.
14.14- The medicine to be administered through tube must be proper and selected by the physician and the instructions for use must be previously consulted.
14.15- Clean the extender tube with neutral detergent, whenever is used for nourishment administration or decompression. If the disinfection is performed prior to the use, select a proper disinfectant and under the physician responsibility.
14.16- Replace the product by a new one in proper intervals, at a physician discretion, to ensure its performance. Clogging or contamination can occur, depending on the method or duration of the use.

14.17- Firmly close the tube plug, after cleansing and removing any nourishment or water from the plug site. The plug may open if it is humid, resulting in gastric content leakage.
14.18 - Be careful not to touch the valve attachment ring, except when the balloon is inflated / emptied with a disposable luer slip syringe, otherwise the valve attachment ring could loosen, causing the valve to drop.

15- IMPORTANT PRECAUTIONS FOR USE

15.1 In order to connect a nourishment bag, etc, to the tube, insert its connector directly into the extender tube internal lumen, without forcing. In case the connection happens forcibly, the extensor tube internal lumen could be damaged by the nourishment bag connector tip, etc., which could lead to the funnel cracking or breaking.
15.2- Keep track of the balloon inflating condition during the tube stay, since the balloon deflation may occur due to spontaneous emptying, when compared to other latex balloons.
15.3 - Do not forcibly insert the button. Stop the procedure if the insertion is difficult and take the proper measures, because the forced button insertion may damage the stoma.
15.4- Regularly clean the extender connector and the button connector. The nourishment line or tube plug displacement could occur during non-administration due to dirt in the connection areas or oil adherence etc.
15.5- Do not clean the part attached to the body surface with alcohol, because the printing in the connector plug may disappear. Moreover, a crack or a breakage may occur in the tube connector socket.
15.6 - Always wash the extender and the tube catheter with warm water before and after nourishment, medicine, etc. administration, in order to avoid clogging due to the accumulation of nourishment residues.
15.7 - When administering powdered medicine through the tube (especially medicine including binders, etc., as additive), be careful with extender tube and tube catheter clogging.
15.8- Care should be taken for the possible di(2-ethylhexyl) phthalate elution, which is a polyvinyl chloride plasticizer, when lipophilic drugs or drug solutions are used. Check any lipophilic drug or medicine solution information leaflet to be used for possible di(2-ethylhexyl) phthalate elution prior to the use, thus preventing the occurrence of damages to the product.
15.9- Do not expose the product to medicine classified as strong acids or strong alkalis and organic solvents.
15.10 - When administering nourishment/ medicine or injecting warm water with the help of a syringe, stop the operation if any resistance is felt during the injection. In this case, there is the possibility that the extender tube lumen or the tube catheter are clogged and if the procedure continues without solving the clogging, the tube and/or catheter internal pressure is excessively raised leading to its breaking or cracking.
15.11 - In order to eliminate the tube catheter clogging and/or extender tube, use a high-volume injection device (above 30ml recommended). If a device with size below 30ml is used, the pressure becomes higher, increasing the likelihood of catheter/tube breaking or rupture.
15.12 - Do not use stylet, guide wire or sharp objects to solve the clogging. If it is not possible to resolve it through the solutions above, remove the tube and/or extender tube.
15.13 - Confirm patient and tube presence conditions regularly.
15.14- While the tube is present, monitor the balloon inflating condition by slightly pulling the tube. If the balloon bursts, immediately replace the tube by a new one or take measures to prevent the spontaneous tube removal until its replacement (spontaneous catheter removal due to unawareness of balloon rupture may result in the closing of the gastric stoma).
15.15- Do not use contrast agent, sodium chloride solution, etc. or air to inflate the balloon. Substances such as contrast medium or sodium chloride solution, etc. are susceptible to constituents clogging, hindering the balloon deflating. If air is being used, the balloon may deflate due to the quick deaeration.
15.16 - Do not tighten this product with very strong tweezers, otherwise the tube or extender tubes could be damaged. Furthermore, it could break the tubes, lumen clogging or damage to the balloon.
15.17 - During the tube insertion and stay, do not forcibly pull or bend the connector tubes and operate this product carefully and gently. Connector tubes breakage or rupture could occur.
15.18 - The operation of this product, nourishment administration etc., or handling after placement must be properly done, under the physician responsibility.
15.19- During stay, keep this product totally under control to prevent operation by untrained person.
15.20 - For medical devices handling, etc. to be used in addition to this product, refer to the instructions for medical devices use.

16- WARNINGS

16.1 - Do not use the button replacement feeding tube if the stoma is not properly formed or if there is damage or abnormality in the stoma.
16.2- Choosing a replacement feeding tube not adjusted to the catheter size may cause insertion or removal failures in the tube to be replaced.
16.3- If the tube catheter adheres to the stoma during removal, do not force to withdraw and remove it endoscopically, to prevent damages to the stoma mucosa or catheter breakage.
16.4 - When inserting the tube and during its stay, confirm that the tip of the catheter is reached at the correct position through several methods, such as X-ray, gastric juice aspiration, listening of air bubbles sound, endoscope, etc.
16.5- Prior to the nourishment administration, etc., confirm that the tube tip is properly settled into the stomach. Take special care with tube deviation due to accidental (auto) removal, because serious complications, such as peritonitis, etc. could occur due to nourishment leakage into the abdominal cavity.
16.6 - The spontaneous tube removal due to accidental (auto) removal, could cause the closing of the gastric stoma, because when there is nothing inserted, it reduces in a short period of time.
16.7 - Strictly check the balloon distilled water weekly, because the catheter could be removed due to water volume reduction.
16.8- Do not inject more sterilized distilled water than the volume specified in the balloon. Excessive injection may burst the balloon.
16.9 - The balloon could expand due to stomach environmental changes, balloon deterioration or gastric content adherence, etc.
16.10 - Do not anchor gastric/ abdominal wall by pulling the balloon. Excessive pressure could cause adverse events, such as necrosis due to pressure in the gastric wall and also cause much stress to the balloon, leading to its rupture.
16.11- Do not use this product if the package is damaged, the expiration date is due, the package is already open or wet. Moreover, use this product immediately after opening the package.
16.12- Do not resterilize or boil the product for disinfection, because such processes may damage the product.

17- ADVERSE EVENTS

The following adverse events could develop by using the button:
17.1- Tissue pressure necrosis due to excessive gastric and abdominal walls pressure
17.2- Peritonitis caused by nourishment leakage, etc., into the abdominal cavity, from catheter false insertion/improper or stoma injury.
17.3 - Skin problems around the stoma (formation of granulomas, redness, skin ulcer, necrosis due to pressure), due to contact and stomach content leaking to the skin.
17.4- Damages to the stoma and associated wound infections, due to catheter insertion/removal
17.5 - Catheter displacement and associated stoma closure due to balloon rupture and accidental (auto) removal.
17.6- Occurrence of ulcers due to contact rash of the catheter tip in the posterior gastric wall.
17.7- Stoma dilation due to catheterism.
17.8- Looseness due to local high frequency heating
17.9- A bowel obstruction may occur if the tube internal balloon is attracted to the bowel due to gastric peristaltism, causing the difficulties in gastric liquid drainage, gastric dilation, in addition to vomits, etc.

18- STORAGE

Do not place any object over the product or its package!
Do not place the product near aggressive chemicals!

Do not expose the product 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 product was improperly stored.

It is recommended that inspections be performed at regular intervals to ensure the product use prior to validity date expiration

19- CLEANING AND STERILIZATION

This product was designed and guaranteed for single use!
Re-use and reprocessing are prohibited.

20- RISKS IN CASE OF RE-USE AND REPROCESSING

These products are intended for single use only. G-Flex disclaims any liability in case of re-use and reprocessing.

The re-use and/or reprocessing of a single use product could represent risks for the user, product, or patient safety, due to possible uncontrolled contamination and/or lack of reliability in the product quality and performance. Contamination of this product may result in patient injury, disease, or death.

21- 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.

22- USER

G-FLEX product users must be experts in their areas. 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.

23- REPAIR AND CLAIMS

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

24- LEGAL BASIS

The Brazilian law shall be applied.

25- PRODUCT SUPPORT

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

26- IDENTIFICATION AND PROBLEMS/ DEFECTS SOLUTION

Below are described the possible replacement feeding tube defects and the main problems that may occur during use, and its causes as well, thereby assisting in its solution and prevention.

Problem Description	Possible Diagnostic	Problem Cause
1.1 - Equipment connection easily disconnecting	1.1.1 - High frequency of use	If the frequency of use is high, the connector form features may suffer small changes, easily allowing for the occurrence of disconnections.
	1.1.2 - Connection mismatch with the equipment	Tube connector has a conical shape allowing for the connection of a greater equipment range. However, some equipment may not be within this range, in a way that the disconnection occurs easily.
	1.1.3 - Fast nourishment, medicine etc. introduction	A fast nourishment, medicine etc. introduction produces a considerable pressure increase throughout the circuit, which goes from the stomach all the way to the nourishment / medicine source. This pressure increase could lead to an easy disconnection.
	1.1.4 - Diet rich in fats	As the connection is made by pressure, diets rich in fats may reduce the friction between the equipment and the connector, leading to an easy disconnection.
	1.1.5 - Product time of use exceeded regarding to manufacturer determination	This product is designed and guaranteed so its safety and efficacy be met as long as the time of use filed by the manufacturer be respected.
	1.1.6 - Improper cleansing after use	After nourishment / medicine administration, a cleansing with neutral detergent must be performed in the tubes and connectors. An inadequate cleaning may cause the attrition reduction between the tube connection and the equipment, leading to an easy disconnection.

	1.1.7 – Connection of a tube with a manufacturing defect	Prior to the use, inspect the product and the package, observing the components preservation. If damages are observed or in case of doubts or difficulties related to our instruments, please contact your local distributor or directly with G-FLEX during business hours.
1.2 – Button Replacement tube color change	1.2.1 - Improper cleansing after use.	After nourishment / medicine administration, the cleansing with neutral detergent must be performed in the tubes and connectors. An inadequate cleaning plus the incidence of natural or artificial light will result in the button replacement tube color change.
	1.2.2 - Product time of use exceeded regarding to manufacturer determination	This product is designed and guaranteed so its safety and efficacy be met as long as the time of use filed by the manufacturer be respected.
1.3 - Gastric Juice Leakage	1.3.1 - Improper tube diameter (smaller)	The gastric juice may exteriorize with the gastric pressure if the tube diameter is much smaller than the stoma.
	1.3.2 - Looseness between the balloon and stomach wall	The gastric juice may exteriorize if the support adjustment is much loose, in addition to the gastric pressure.
	1.3.3 - Quick nourishment and medicine introduction	A fast nourishment, medicine etc. introduction produces a considerable pressure increase throughout the circuit, which goes from the stomach all the way to the nourishment / medicine source. This pressure increase may cause gastric juice exteriorization.
	1.3.4 - Balloon volume well below the specified	Weekly balloon volume checking and maintenance are very important to ensure the product integrity and permanence, in order to avoid the tube and gastric juice exteriorization.
	1.3.5 – Strong gastric pressure	Some patients may, at some point, feel a strong gastric pressure, causing a gastric juice leakage even if the tube and the stoma are in perfect condition.
1.4- Tube exteriorization	1.4.1 - Very strong unintentional traction mechanical strength	If an unintentional traction force is applied, the tube could exteriorize.
	1.4.2 - Balloon volume well below the recommended by the manufacturer	Weekly balloon volume checking and maintenance are very important to ensur the product integrity and stay, in order to avoid the tube and gastric juice exteriorization.
1.5 - Ruptured balloon	1.5.1 - Strong pressure of the balloon against the gastric wall	If the tube length adjustment excessively compresses the balloon, this constant force may lead to the balloon rupture.
	1.5.2 - Medicine / nourishment introduction into the balloon inflating part	If medicine / nourishment are introduced in the balloon inflation connection, the volume will considerably increase, causing the balloon rupture.
	1.5.3 - Water volume well above the indicated	Even if the balloon has a capacity higher than the nominal volume indicated, if the volume filled with water is bigger than the nominal measure, the balloon rupture or even the reduction of product service life may occur.
	1.5.4 - Product time of use exceeded regarding to manufacturer determination	This product is designed and guaranteed so its safety and efficacy be met as long as the time of use filed by the manufacturer be respected.
	1.5.5 - Environmental conditions	Although the balloon is made of silicone, a noble material for medical area, such could have its initial features weakened due to contact with medicine / nourishment that lead to silicone membrane dryness, or even with the gastric juice.
	1.5.6 - Very strong unintentional traction mechanical strength	If an unintentional traction force is applied (auto removal), the tube could exteriorize after balloon rupture.
	1.5.7 - Balloon inflating with solution not indicated by the manufacturer	The use of any liquid other than the indicated by the manufacturer (sterilized distilled water) may result in reduction of product service life, balloon rupture and even risk of injuries to the patient.
	1.5.8 - Damage caused by handling during insertion	If forceps, scissors, knives, or other instruments are used to insert the tube, that may cause damages to the balloon, causing its rupture.
1.6 - Leaking plug	1.6.1 - High frequency of use	If the frequency of use is high, the connector form features may suffer small changes, easily allowing for the occurrence of disconnections.
	1.6.2 - Product time of use exceeded regarding to manufacturer determination	This product is designed and guaranteed so its safety and efficacy be met as long as the time of use filed by the manufacturer be respected.
	1.6.3 - Diet rich in fats	Since the plug closure is made by pressure, diets rich in fats may reduce the attrition between the plug and the tube, allowing for leakage.
1.6 - Leaking plug	1.6.4 – Improper cleansing after use	After nourishment / medicine administration, the cleansing with neutral detergent must be performed in the tubes and connectors. The inadequate cleaning may cause the attrition reduction between the tube plug and the tube, leading to leakage.
	1.6.5 - Strong gastric pressure	Some patients may, at some point, feel a strong gastric pressure, causing gastric juice leakage even if the tube and the stoma are in perfect condition.
	1.6.6 – Plug not performing correct sealing due to deviation from quality	Prior to the use, inspect the product and the package, observing the components preservation. If damages are observed or in case of doubts or difficulties related to our products, please contact your local distributor or contact G-FLEX directly during business hours.
1.7 - Leaking Balloon	1.7.1 - Non-return valve leaking	The non-return valve is defective.
	1.7.2 – Punctured balloon	The balloon has a small puncture allowing its deflating. Such condition can be noticed by checking the air tension, when the balloon is immersed in water after inflating with the syringe. This checking must be performed prior to the tube introduction into the patient, using sterile water.
	1.7.3 - Product time of use exceeded regarding to manufacturer determination	This product is designed and guaranteed so its safety and efficacy be met as long as the time of use filed by the manufacturer be respected.
	1.7.4 - Water volume well above the indicated	Even if the balloon has a capacity higher than the nominal volume indicated, if the volume filled is bigger than the nominal measure, may cause the balloon rupture or even the reduction of product service life.
1.8– Damages to tube catheter	1.8.1 - Improper product use	If the tube is forcibly inserted or removed, an excessive torque operation is performed or if the catheter is used while twisted, the catheter may brake, fold or be cut.
	1.8.2 - Damage caused by handling during insertion	Instruments such as forceps, scissors, knives or other must not be used to insert the tube, because they could damage the catheter and prevent the product use.
1.9-Impossibility of tube removal	1.9.1 - Nourishment, medicine, etc. or gastric juice adherence	The residue accumulation due to insufficient washing may distort the tube, resulting in catheter and/or balloon lumen occlusion, preventing the water removal.
	1.9.2 - Balloon inflating with solution not indicated by the manufacturer	The use of any liquid other than the indicated by the manufacturer (sterilized distilled water) may result in reduction of product service life, balloon rupture and even risk of injuries to the patient.

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
	Expiration date		Quantity per box
	Do not use if the package is damaged		Caution

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