INSTRUCTION FOR USE

REPLACEMENT FEEDING TUBE

(RMS 81263810008)

Reprocessing Forbidden / Single Use / Sterile product

1- USE INDICATION

This product is a catheter to be placed into the stomach to supply medicines, nutrients, food, beverages, etc. or for decompression through gastric stoma, in patients unable to perform oral nourishment ingestion.

2- OPERATING PRINCIPLE

The replacement feeding tube is a device to replace the Percutaneous Endoscopic Gastrostomy (PEG) or Button replacement 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 administered to the stomach (Figure 1).

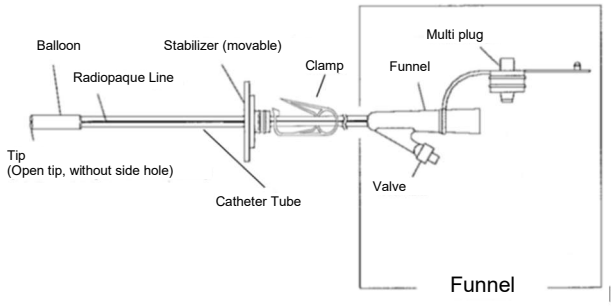


Figure 1

3- SPECIFICATIONS AND PACKAGE

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

Nominal Size	Volume	Specification Details:
12Fr	2ml	Total length: 22.5 cm. Depth marks in intervals of 1 cm, from 2 to 10 cm from the distal end of the balloon. Open tip, without side hole. Packed in sterilization envelope.
14Fr	3ml	
16Fr	5ml	
18Fr	5ml	
20Fr	5ml	
22Fr	5ml	
24Fr	5ml	

Table 1

Components	Quantity	Specifications
Replacement Tube	1 un	Refer to the specifications in table 1.
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- PRECAUTIONS FOR USE RELATED TO EFFICACY OR EFFECT

4.1. 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.
4.2- As this product was not designed for long term use, its replacement is recommended within **29 days.**
4.3 - 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.

5- OPERATIONAL PROCEDURE FOR CATHETER REPLACEMENT

5.1- 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).
5.2- Apply the lubricant in the catheter proximal side placed in the stoma and remove it according to the operational procedure.
5.3 - Apply lubrication gel in the replacement feeding tube catheter and insert it in the stoma. Confirm endoscopically if the replacement feeding tube is correctly inserted in the stomach.
5.4- Inject sterilized distilled water to inflate the balloon, according to the volume specified in the tube valve.
5.5 - Gently pull the replacement feeding tube to confirm the sensation that the balloon slightly touches the gastric wall.
5.6 - Move the fastener aside the abdominal wall, in the proper position, leaving a space of around 1 to 2 mm from the skin surface.

6- PROCEDURE FOR REPLACEMENT FEEDING TUBE SUBSTITUTION

6.1 - Check if the tube size is appropriate to the stoma diameter and previously perform the product check tests according to 4.3.

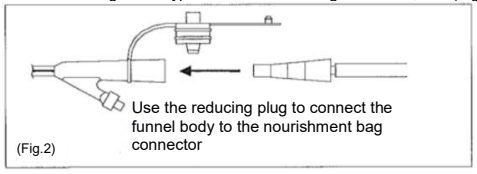
6.2 - Apply the sterile lubricant gel in the outer side of the replacement feeding tube catheter
6.3 - With the patient in supine position, carefully insert the tube through the stoma, keeping it perpendicular, until it is completely inside the stomach.
6.4 - After that, with the help of the syringe, inflate the tube balloon with sterile distilled water, according to the volume indicated in the valve.
6.5 - Once inflating is complete, slightly pull the catheter, until you feel the pressure of the balloon against the gastric wall.
6.6 - Place the fastener close to the abdominal wall, until it touches the body surface, taking care not to overcompress the stomach wall (keep 1 or 2 mm between the stoma and the fastener).
6.7 - Use the clamp to avoid food reflux, if necessary.

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

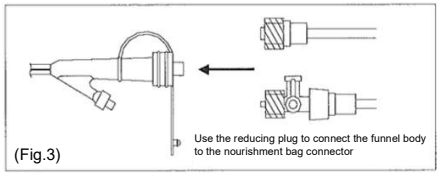
7.1 - Confirm the absence of stoma abnormalities and insert the replacement feeding tube according to [6.1] to [6.7] in the procedure above **<Procedure for replacement tube substitution>**
CAUTION: since the empty stoma narrows in a short period of time, quickly and carefully place the replacement feeding tube. Forced insertion could damage the stoma. If the stoma is already narrowing, stop the procedure and seek medical advice.

8- PROCEDURE FOR CONNECTING A PARENTERAL NOURISHMENT BAG ETC.

Select the connection according to the type of nourishment bag connector, etc. (Figure 2 and 3).



(Fig.2)



(Fig.3)

9- PROCEDURE FOR NOURISHMENT ADMINISTRATION

9.1 - Slightly pull the catheter prior to nourishment administration and confirm that there is no displacement or abnormality in the catheter.
9.2 - Wash with 10 ml of warm water or more. ("Washing" in this case relates to the strong injection of an appropriate volume of warm water using a syringe).
9.3 - Connect a nourishment bag, etc. to the catheter funnel.
9.4 - Inject the nourishment. In case of drug solution, dissolve it in a high volume of warm water prior to the injection.
9.5 - After nourishment injection, etc., inject 10 ml of warm water or more to wash the catheter internal lumen of the replacement feeding tube.

10- PROCEDURE TO PERFORM STOMACH DECOMPRESSION

10.1 - After removing the reducing plug from the tube funnel, perform the stomach decompression. In case of gastric content getting out, drain it into a container and wash the catheter internal lumen with 10ml of warm water or more.
10.2 - Attach the reducing plug to the funnel again and keep it closed.

11- PROCEDURE FOR TUBE REMOVAL

11.1 - Remove the sterile water from the balloon using a syringe.
11.2 - Gently remove the tube, keeping it perpendicular to the stoma.

12- PRECAUTIONS FOR USE RELATED TO OPERATIONAL PROCEDURES

12.1 - Choose a tube of appropriate size, because changes in the patient body influence the stoma size. During the product stay, confirm regularly if the diameter is suitable and check the condition of the part attached to the body surface.

- If the catheter diameter is smaller than the stoma, the tube 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 caused by pressure or catheter removal could occur.

12.2 - When inserting or removing the replacement feeding tube, ensure the reducing plug is open.
12.3- Confirm that the balloon is properly inflating and deflating prior to using this product.
12.4 - 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.
12.5- 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.
12.6- To remove the syringe, turn it while holding the valve. In rare occasions, the valve may move from its position or come out.
12.7 - 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.
12.8- 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.
12.9 - Do not suture the fastener to the skin.
12.10 - When attaching the reducing 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 reducing plug is naturally released and the gastric content could leak out.
12.11 - In order to connect a nourishment line, etc. to the replacement tube, 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.
12.12- 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.
12.13- 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.
12.14- The medicine to be administered through tube must be proper and selected by the physician and the instructions for use must be previously consulted.
12.15- 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.

12.16 - 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.

13- IMPORTANT PRECAUTIONS DURING USE

13.1 In order to connect a nourishment bag, etc, to the tube, insert its connector directly into the funnel internal lumen, without forcing. In case the connection happens forcibly, the funnel internal lumen could be damaged by the nourishment bag connector tip, etc., which could lead to the funnel cracking or breaking.
13.2 - Do not load the funnel by bending, twisting or pinching, while attaching the nourishment bag connector etc. The tip of the nourishment bag connector, etc, could damage the funnel internal lumen, which could lead to the funnel cracking or breaking.
13.3- 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.
13.4 - Always wash the catheter with warm water before and after nourishment administration, etc, in order to avoid the catheter clogging due to the accumulation of nourishment residues etc.
13.5 - When administering powdered medicine, etc. through the tube (especially medicine including binders, etc., as additive), be careful with catheter clogging.
13.6- 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.
13.7- do not expose the product to medicine classified as strong acids or strong alkalis and organic solvents.
13.8 - Monitor tube internal lumen during its stay in the patient and confirm that the injection can be performed safely.
13.9 - When administering nourishment, medicine, etc, 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 tube internal lumen is clogged and if the procedure continues without solving the clogging, the tube internal pressure is excessively raised leading to its breaking or cracking.
13.10 - In order to eliminate the tube catheter clogging, 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 breaking or rupture.
13-11 - 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.
13.12 - During the tube stay, 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).
13.13 - 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.
13.14 - Do not forcibly insert this product. Stop the procedure if its insertion is difficult and take proper measures not to damage the stoma.
13.15 - During the insertion, stay and removal due to replacement, do not forcibly pull or bend the catheter and operate this product carefully and gently. Replacement tube breakage or rupture could occur.
13.16 - Confirm patient and tube stay conditions regularly.
13.17- Do not alter this product. Changes such as the addition of side holes could lead to tube breakage.
13.18 - Do not tighten this product with very strong tweezers, otherwise it could damage the tube. Furthermore, it could break the tube, lumen clogging or damage to the balloon.
13.19 - Clean the connection part between this product and the nourishment line regularly. The nourishment line or plug displacement could occur during non-administration due to dirt in the connection part or oil adherence etc.
13.20 - The operation of this product, nourishment administration etc., or handling after placement must be properly done, under the physician responsibility.
13.21 - For medical devices handling, etc. to be used in addition to this product, refer to the instructions for medical devices use.

14- WARNINGS

14.1 - Do not use the replacement tube if the stoma is not properly formed or if there is damage or abnormality in the stoma.
14.2- Choosing a replacement tube not adjusted to the catheter size may cause insertion or removal failures in the tube to be replaced.
14.3 - Do not anchor gastric and abdominal walls through balloon traction. Excessive traction could cause adverse events, such as necrosis by gastric wall pressure and cause much stress to the balloon, leading to its rupture.
14.4 - 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, confirmation of depth mark position etc.
14.5- Prior to the nourishment administration, etc., confirm that the tube tip is properly settled into the stomach. Take special care of tube deviation due to accidental (auto) removal, because serious complications could occur due to nourishment leakage, etc. into the abdominal cavity.
14.6 - 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.
14.7 - Strictly check the balloon distilled water weekly, because the catheter could be removed due to water volume reduction.
14.8 - Use only sterile distilled water to inflate the balloon and to inject the volume specified in the valve. Excessive injection may burst the balloon.
14.9 - The balloon could expand due to stomach environmental changes, balloon deterioration or gastric content adherence, etc.
14.10 - Do not use this product if the package is damaged, open or wet, or the expiration date is due. Moreover, use this product immediately after opening the package.

15- ADVERSE EVENTS

The following adverse events could develop by using the replacement tube:
15.1- Damages to the stoma and associated wound infections, due to catheter insertion / removal.
15.2- Peritonitis caused by nourishment leakage, etc., into the abdominal cavity, from catheter false/improper insertion or stoma injury.
15.3 - Catheter displacement and associated stoma closure due to balloon rupture and accidental (auto) removal.
15.4- Occurrence of ulcers due to contact rash of the catheter tip in the posterior gastric wall.
15.5 - Skin problems around the stoma (formation of granulomas, redness, skin ulcer, necrosis by pressure), due to contact and stomach content leaking to the skin.
15.6- Stoma dilation due to catheterism.
The replacement tube could also cause damages (perforation, etc) and bleeding.

16- 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

17- CLEANING AND STERILIZATION

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

18- 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.

19- 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.

20- 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.

21- REPAIR AND CLAIMS

In order to protect our employees' health, only disinfected and/or sterilized products 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.

22- LEGAL BASIS

The Brazilian law shall be applied.

23- PRODUCT SUPPORT

In case of doubts or difficulties related to our products, 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).

24- 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's Possible Cause
1 - Equipment connection easily disconnecting	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.
	1.2 - 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.
	1.3 - Fast nourishment / medicine introduction, etc.	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.
	1.4 - 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.
	1.5 - Product time of use exceeded regarding 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 - Improper cleansing after use	After nourishment / medicine administration, a cleansing 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.
	1.7 – Defective connection	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.
2 – Replacement feeding tube color change	2.1 - Improper cleansing after use.	After nourishment / medicine administration, the cleansing must be performed in the tubes and connectors. An inadequate cleaning plus the incidence of natural or artificial light will result in the replacement tube color change.
	2.2 - Product time of use exceeded regarding 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.

3 - Gastric juice leakage	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.
	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.
	3.3 - Fast nourishment, medication introduction, etc	A fast nourishment and medicine introduction produces a considerable 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.
	3.4 - Balloon volume well below the specified	Weekly balloon volume checking and maintenance are very important to ensure the product integrity and stay, in order to avoid the tube and gastric juice exteriorization.
	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.
4- Tube exteriorization	4.1 - Very strong unintentional traction mechanical strength	If an unintentional traction force is applied, the tube could exteriorize.
	4.2 - Balloon volume well below the recommended by the manufacturer	Weekly balloon volume checking and maintenance are very important to ensure the product integrity and stay, in order to avoid the tube and gastric juice exteriorization.
5 - Ruptured balloon	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.
	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.
	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.
	5.4 - Product time of use exceeded regarding 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.
	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.
	5.6 - Unintentional traction mechanical strength very strong	If an unintentional traction force is applied (auto removal), the tube could exteriorize after balloon rupture.
	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.
	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.

6 - Leaking plug	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.
	6.2 - Product time of use exceeded regarding 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.
	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. The tube has a clamp to block the leaking.
	6.4 - Improper cleansing after use	After nourishment / medicine administration, the cleansing must be performed in the connector. The inadequate cleaning may cause the attrition reduction between the tube plug and the tube, leading to leakage.
	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.
	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.
7 - Leaking Balloon	7.1 - Non-return valve leaking	The non-return valve is defective.
	7.2 - Balloon punctured	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.
	7.3 - Product time of use exceeded regarding 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.
	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.
8 - Damage to the tube catheter	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.
	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.
9-Impossibility of tube removal	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.
	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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