All Silicone Gastrostomy Balloon Catheter

(Standard Type) (Flat Balloon Type)

Conforming to ISO 80369 -3

Do not reuse

[Warnings]

< Usage >

[1] The position of the stabilizer should be set appropriately to avoid excessive load of the gastric wall and abdominal wall during placement.
[Otherwise, pressure necrosis or catheter dislodgement due to balloon burst may occur.]

[2] In case the catheter adheres to the fistula at the catheter removal, do not pull out the catheter forcibly and remove it endoscopically.
[The damage of the mucosal tissue of fistula or catheter breakage may occur.]

[3] Before administration of nutrients, etc., make sure that the catheter tip is appropriately placed in the stomach. Special attention should be paid to catheter dislodgement due to accidental removal.
[Serious complication such as peritonitis etc. may occur due to the leakage of nutrients etc. into the abdominal cavity.]

[CONTRAINDICATIONS, PROHIBITIONS]

[[1] Do not reuse the product (single use for one case).
[The product is single use only and disposable, and its quality or performance after one use is not guaranteed. Further, reuse carries the possible risk of contamination (infection) to patients. Contamination of this product may lead to patient injury, illness or death.]

[2] Prohibition of reprocessing, re-sterilization.
[Reprocessing of the product may lead to defects. It may also cause patient injury, illness or death.]

< Target Patients >

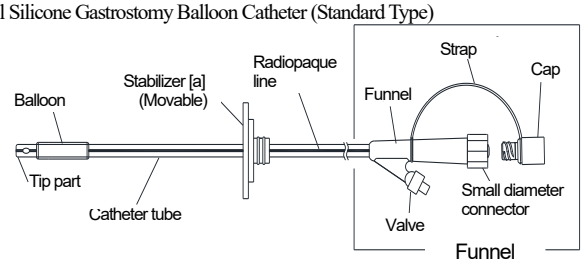
- Do not use the product if a fistula is not formed properly or there is a damage or abnormality in the fistula.
[If this product cannot be placed in the stomach, the nutrient, etc. may leak into the abdominal cavity and cause serious complications such as peritonitis.]
- Available to all ages, except for neonates.

[SHAPE, STRUCTURE AND PRINCIPLE]

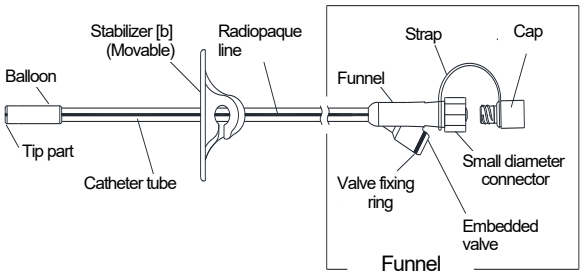
- This product has been sterilized with ethylene oxide gas.
- The connector of this product complies with ISO 80369-3.

< Shape >

- All Silicone Gastrostomy Balloon Catheter (Standard Type)

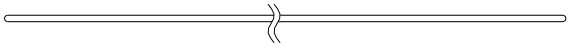


- All Silicone Gastrostomy Balloon Catheter (Flat Balloon Type)



*Catheter tube and funnel can be combined optionally.
*Catheter tube and fixation plate can be combined optionally.

- Exchange rod



- All Silicone Gastrostomy Balloon Catheter (Standard Type)

Size	Outer diameter	Valve color ※	Balloon capacity
12Fr	4.0mm	White	5mL
14Fr	4.7mm	Green	
16Fr	5.3mm	Orange	10mL
18Fr	6.0mm	Red	
20Fr	6.7mm	Yellow	
22Fr	7.3mm	Violet	
24Fr	8.0mm	Blue	

※1 : The embedded valve is out of the upper valve colors.

Total length	Depth mark	Tip	Side holes
225mm	Depth mark at 10 mm intervals between 20 mm and 100 mm from the balloon end.	Open tip	2 side holes

- Exchange rod:
All Silicone Gastrostomy Balloon Catheter (Standard Type)

Size of Standard type	Exchange rod outer diameter
12 to 14Fr	φ0.8mm
16 to 24Fr	φ1.4mm

- All Silicone Gastrostomy Balloon Catheter (Flat Balloon Type)

Size	Outer diameter	Valve color ※	Balloon capacity
12Fr	4.0mm	White	2mL or 3mL
14Fr	4.7mm	Green	3mL
16Fr	5.3mm	Orange	5mL
18Fr	6.0mm	Red	
20Fr	6.7mm	Yellow	
22Fr	7.3mm	Violet	
24Fr	8.0mm	Blue	

※1 : The embedded valve is out of the upper valve colors.

Total length	Depth mark	Tip	Side holes
150mm	Depth mark at 10 mm intervals between 20 mm and 60 mm from the balloon end.	Open tip	no side hole
225mm	Depth mark at 10 mm intervals between 20 mm and 100 mm from the balloon end.		

- Exchange rod:
All Silicone Gastrostomy Balloon Catheter (Flat Balloon Type)

Size of Flat balloon Type	Exchange rod outer diameter
12 to 14Fr	φ0.8mm
16 to 18Fr	φ0.8mm or φ1.4mm
20 to 24Fr	φ1.4mm

< Raw Materials >

- Catheter: Silicone rubber, ABS resin
- Exchange rod: Polypropylene

< Principle >

Insert the catheter into the gastric fistula and fix and indwell by inflating the balloon. Inject nutrients from the proximal side. The nutrients etc. pass through the inner lumen and they are administered to the stomach. When exchanging the catheter, it is possible to reduce the possibility of catheter deviation into the abdominal cavity by using the exchanging rod.

[INTENDED USE]

This product is a catheter to be placed in the stomach for transluminal supplement of drug medicine such as nutrients etc. and food and drink through gastric fistula in patient who cannot take nutrients orally. Also, this product can be used for gastric decompression.
(except for neonates)

[EFFECT]

The nutrients can be administered from the fistula through the catheter.

[PERFORMANCE]

- Secure the sterility assurance level (SAL) 10^{-6}.
- Sterile residues: Shall conform to ISO10993-7.
- Shall not contain biological substance and conform to biological safety requirements.
- Shall be durable for 29 days continuous use.
- Shall maintain the stability and durability for 5 years.
- Tensile strength of the catheter is 15N or more.

[TARGET USER]

The user of the product is a physician. However, healthcare workers can be the users of the product for the administration of nutrients.

[OPERATING OR USING METHOD]

The general operational procedure is described below.

< Procedure for Catheter Replacement >

[1] Confirm that the fistula has been formed properly and in a state of not showing abnormality (a state without separation between the gastric and abdominal walls after completion of 3-week fistulation period following percutaneous endoscopic gastrostomy (PEG)).
[2] Apply lubricant agent to the inner lumen of the proximal side of the catheter placed in the fistula and insert the exchanging rod.
[3] Remove the catheter placed in the fistula according to its operating procedure, taking care not to draw out the exchanging rod.
[4] Apply lubricant agent to the fistula.
[5] Insert the replacement catheter along the exchanging rod from the distal end and advance the balloon part into the stomach.
[6] Inject the specified volume of sterile distilled water from the valve to inflate the balloon.
[7] Pull the replacement catheter gently to confirm the feeling that the balloon touches to the gastric wall lightly and then, remove the exchanging rod.
[8] Move the stabilizer to the side of the abdominal wall. At this time, set the stabilizer to the appropriate position not to contact to the skin. (Make some space about 1 to 2 cm from the skin surface)
[9] Confirm endoscopically or radiographically that the replacement catheter is inserted properly in the stomach.

< Procedure for Replacement Not Using Endoscope or X-Ray Fluoroscope as the First Choice to Check the Placement Site >

[1] Before removing the catheter already placed in the fistula, inject 20 to 30 mL of physiological saline (preferably stained with a food red) through the catheter.
[2] Replace the replacement catheter in accordance with [1] to [8] in the above < Procedure for Catheter Replacement > and aspirate the physiological saline injected into the stomach through the catheter with a syringe to make sure that the catheter is inserted properly into the stomach.
[3] If the catheter insertion into the stomach cannot be confirmed by this method, make sure to re-confirm endoscopically or radiographically.

< Measures to Deal with Catheter Dropout, such as Accidental (Self) Removal >

[1] Confirm the absence of abnormality in the fistula and apply lubricant agent to the fistula and the exchanging rod.
[2] Insert the exchanging rod to the fistula.
[3] In accordance with [5] to [9] in the above <Procedure for Catheter Replacement >, confirm that the replacement catheter is inserted and placed properly into the stomach.
- Since the fistula with nothing inserted narrows in a short period of time, prevent the fistula narrowing by appropriate means and place the replacement catheter quickly.
- Forcible insertion may damage the fistula. If the fistula is already narrowing, stop the use and take appropriate measures.

< Combination devices >

[1] Use a nutrition line, etc. conforming to ISO 80369 -3.
[2] This product should be used in combination with the following devices.

Name	Specifications
Nutrition line	Conforming to ISO 80369 -3
Syringe (for balloon inflation)	▪ Slip type ▪ Capacity: 2 - 10 mL
Syringe (for flushing)	▪ Conforming to ISO 80369-3 ▪ Capacity: 5 - 10 mL
Syringe (to eliminate clogging)	▪ Conforming to ISO 80369-3 ▪ Capacity: Not less than 30 mL
Sterilized distilled water	-
Lukewarm water	-
Lubricant	Water-soluble lubricant
Nutrient	Enteral nutrient

< Procedure for Nutrient Administration >

[1] Pull this product lightly just before the nutrient administration and confirm the absence of dislocation or abnormality in the catheter.
[2] Remove the cap and perform flushing from the connector with 5 - 10 mL of lukewarm water. ("Flushing" in this document refers to the operation in which an appropriate amount of lukewarm water is taken into a syringe and injected rapidly.)
[3] Connect the nutrition line, etc. to the connector.
[4] Inject nutrients. In case of drug solution, dissolve it in the large volume of lukewarm water before injection.
[5] After the injection of nutrients etc., flush with 10 mL or more lukewarm water to wash the inner lumen of the catheter.
[6] Attach the cap to the connector.

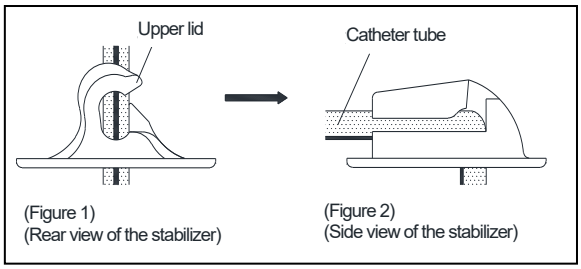
< Procedure for the Decompression in the Stomach >

[1] Remove the catheter cap from the connector to decompress the stomach. In the case of gastric emptying, discharge the contents into a container, etc., then flush with 10 mL or more of lukewarm water from the catheter connector to wash the catheter lumen.
[2] Attach the cap to the catheter connector.

< Operation Method of Stabilizer b >

The catheter tube can be fixed both horizontally and vertically (to the bottom surface of the stabilizer). Take care to avoid burdening the catheter tube by, for example, lifting the balloon with it.

- When fixing the catheter tube horizontally:
  Turn over the upper lid of the stabilizer (Figure 1) and turn the catheter tube horizontally to put it in the horizontal slit (Figure 2).
- When returning the catheter tube to the vertical position, hold the bottom of the stabilizer so that it will not be misaligned. Slowly remove the catheter tube from the horizontal slit of the stabilizer and bring it to the vertical slit.



(Figure 1)
(Rear view of the stabilizer)

(Figure 2)
(Side view of the stabilizer)

< Procedure for Catheter Removal >

[1] Remove the sterilize distilled water in the balloon with using a syringe.
[2] Remove the catheter gently from the fistula.

< Precautions for Use Related to the Operating Procedures >

[1] Do not use the exchanging rod for the replacement from other manufacturer's catheter.
[The specifications may not fit to other manufacturer's products.]
[2] Be careful not to touch the valve fixing ring.
[The fixing ring may come off and the valve may also come off.]
[3] Always check that the catheter tube is vertical to the bottom of the stabilizer before inflating or deflating the balloon or administering nutrients, etc.
[The horizontally fixed catheter tube cannot be passed through because its lumen is narrowed.] (for the stabilizer b)
[4] Do not use the exchanging rod other than that attached to this product.
[Selection of the exchange rod not fit to the catheter size may fail in the insertion or removal of the exchange rod.]
[5] Insert or remove the exchange rod with the catheter held straight.
[Operation of the exchange rod may be difficult.]
[6] Do not force to push the exchange rod in too much.
[Forced insertion of the exchange rod may cause damage (perforation, etc.) or bleeding.]
[7] Before using the product, confirm that the balloon is inflated and deflated properly.
[8] Please note the following when inflating and deflating the balloons.
1) Before using the product, confirm that the balloon is inflated and deflated properly.
2) Inflate the balloons slowly and carefully.
[The valve may slip off rarely or it may come off in some cases due to the pressure when injected rapidly.]
3) Use a general slip-type disposable syringe to inflate or deflate the balloons.
[Luer lock-type syringe cannot be inserted into the end of the valve firmly. And using a syringe with unfitted taper may cause breakage of the valve.]
4) Insert the tip of the syringe firmly to the end of the valve to inflate or deflate the balloon.
[If insertion of the tip of the syringe into the valve is insufficient, the valve may not operate properly to inflate or deflate the balloon.]

5) When it is difficult to remove the sterile distilled water from the valve or to inject the sterile distilled water into the balloon, make the catheter straight. Especially, do not perform the water injection or removal actions through the valve, under the condition that the catheter is fixed horizontally to the stabilizer.
[The valve may be damaged and the balloon inflation condition may be unable t be maintained and the catheter may be removed spontaneously.]
(for the stabilizer b)

6) Use only sterile distilled water to the balloon.
[When physiological saline or contrast medium etc. are used, the ingredients may coagulate and water may not be removed. In addition, in case of inflating the balloon with air, the balloon may deflate in a short period of time due to spontaneous leakage.]

7) Do not inject more than the regulated volume of sterile distilled water into the balloon.
[Excessive injection will overload the balloons and cause a burst]

8) When removing the syringe, make sure to press the valve and rotate the syringe to remove.
[In rare cases, the valve may be dislocated or come off.]

[9] When returning the catheter tube to the vertical position, hold the bottom of the stabilizer so that it will not be misaligned. Slowly remove the catheter tube from the horizontal slit of the stabilizer and bring it to the vertical slit.
(for the stabilizer b)

[10] Do not suture the stabilizer to the skin.

[11] When connecting the cap, nutrition line, etc. to the connector, connect the nutrition line, etc. straight along the connector. During use, check the connection for possible leakage or loosening as appropriate, and keep the product firmly connected.

[12] Take care not to apply any load such as pulling up of the balloon when attaching/detaching the nutrition line, etc.
[Balloon burst or catheter dislodgement may occur.]

[13] When administering the drug medicines, nutrients etc., refer to the instructions for use of the drug medicines, nutrients etc.

[14] At the catheter insertion and during indwelling, confirm if the catheter tip is reached to the correct position by multiple methods, such as X-ray radiography, aspiration of the gastric juice, endoscope, confirmation of the depth mark position etc.

[PRECAUTIONS FOR USE]

< Important Precautions >

[1] Use the catheter which fits to the fistula size.
[Too big catheter may not be placed or may damage the fistula during insertion.]

[2] Always flush the catheter with lukewarm water before and after the administration of nutrients etc.
[It is necessary to prevent the catheter clogging by the accumulation of the residue of nutrients etc.]

[3] When administering powdered medicines etc. (especially the medicines including binding agent etc. as additive) through the catheter, be careful about the catheter clogging.

[4] When administering the nutrients etc. or flushing by lukewarm water etc. with using an injection device, stop operating if some resistance during the injection is felt.
[There is a possibility that the inner lumen of the catheter may be clogged. In case continuing the operation without solving the clogging problem, inner pressure of the catheter is increased too much and the breakage or rupture of the catheter may occur.]

[5] When eliminating the catheter clogging, please note the following.
1. Use a big size injection device in volume (more than 30mL is recommended).
[In case using an injection device with smaller volume than 30mL, injection pressure becomes high and the possibility of the catheter breakage or rupture becomes high.]
2. Do not use stylet or guidewire.
3. In case the catheter clogging cannot be solved by the above operations, remove the catheter.

[6] During indwelling, monitor the balloon inflation condition by “light pulling of the catheter”, “under endoscopy” etc. In case of the balloon burst or spontaneous leakage, replace the catheter with a new one promptly or take measures to prevent spontaneous removal of the catheter until the replacement.
[Spontaneous removal of the catheter due to ignorance of the balloon burst or spontaneous leakage may result in the closure of gastric fistula.]

[7] During the use, manage the position of the stabilizer based on the depth mark.
[In rare case, the catheter may be dragged into the intestinal tract and the stabilizer position may be changed. Especially, the influence of peristalsis may be stronger around the antrum of stomach.]

[8] Once a week, remove all the sterile distilled water from the balloon and inject the sterile distilled water of the regulated volume again.
[The catheter may be pulled out due to the decrease of the sterile distilled water]

[9] Do not grip this product strongly with forceps, etc.
[The Tube may be damaged. In addition, the tube may be cut, the lumen may be occluded, and the balloon may be broken.]

[10] Keep the connection between the catheter and nutrition line clean.
[Adherence of dirt/oil, etc. to the connection may cause leakage of nutrients, etc., detachment of the nutrient line, poor fitting, and removal of the cap during suspension of administration.]
[If nutrients, etc. adhere to the inside of the connector and when it is connected as it is, the nutrition line or cap may adhere and become difficult to be detached.]

[11] Metal is used in the valve of the product. So, when performing MRI examination, be careful that artifact may occur on the image or local high-frequency heating may occur.

[12] Before using this product, check whether there is any abnormality in each part.

[13] Do not insert forcibly. If insertion is difficult, discontinue the use and take appropriate measures.
[Forcible insertion of the gastrostomy catheter may damage the fistula. The fistula with nothing inserted due to accidental (self) removal narrows in a short period of time.]
[Forcible insertion of the exchange rod may cause damage (perforation, etc.). If the inner lumen of the catheter is clogged due to the adhesion of nutrients or stomach contents, it may interfere with the insertion of the exchange rod.]

[14] Do not insert or remove forcibly, and operate with great care.
[The product may be damaged.]

[15] Observe the condition of the indwelled product and if abnormality is detected, stop using the product promptly and take appropriate measures.

[16] Confirm the patient's condition and indwelling condition of the product regularly.

[17] Do not modify the product.
[If a side hole, etc. is added, the catheter may be cut.]

[18] Do not use the product if the packaging is damaged or if any abnormality such as damage is found in the product.

[19] Use immediately after opening and dispose in a safe manner for each country after use.

[20] If drug solution is injected into the patient’s body by using this product, select the appropriate drug solution under the responsibility of the physician.

[21] During placement, keep the product under full control to prevent its handling by an untrained person.

[22] Medical devices used concomitantly with the product should be handled according to the package insert and the instructions for use of the concomitant product.

[23]  printed on the label means that the product should not be used if the package is damaged or opened.

[24]  printed on the label means that the product does not contain phthalic acid in the contact part of the body fluid/drug solution.

[25] Any serious incident that has occurred in relation to the product should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

[26] MRI Safety Information
 printed on the label indicates that this product is "MR Conditional." A patient with the device may be safely scanned under the following conditions. Failure to follow these conditions may result in injury to the patient.

▪ Without the embedded valve

Parameter	Condition of Use / information
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Static Magnetic Field (B0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient	87 T/m
Magnetically-induced torque	The device is not produced magnetically induced torque using 3T MR system.
RF Polarization	Circularly Polarized
RF Transmit Coil	Body Coil
MR System Operating Modes or Constrains	Whole Body Averaged SAR 1.5T : 2.8 W/kg 3.0T : 3.0 W/kg B_{1+RMS} 1.5T : 4.13 μT 3.0T : －
Scan Duration and Wait Time	In non-clinical testing, the device does not produce temperature rises during MR image performed for 15 minutes in the above conditions.
MR Image Artifact	The presence of the device may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.

Additional information of safety using the device in MR environment.	－

▪ With the embedded valve

Parameter	Condition of Use / information
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Static Magnetic Field (B0) Orientation	Horizontal, Cylindrical Bore
Maximum Spatial Field Gradient	35 T/m
Magnetically-induced torque	The device is not produced magnetically induced torque using 3T MR system. However, you should confirm additional information since the valve has metal material.
RF Polarization	Circularly Polarized
RF Transmit Coil	Body Coil
MR System Operating Modes or Constrains	Whole Body Averaged SAR 1.5T：2.8 W/kg 3.0T：3.0 W/kg B_{1+RMS} 1.5T：4.13 μT 3.0T：－
Scan Duration and Wait Time	In non-clinical testing, the device does not produce temperature rises during MR image performed for 15 minutes in the above conditions.
MR Image Artifact	The presence of the device may produce an MR image artifact. Imaging protocol modifications may be necessary to compensate for the MR image artifact.
Additional information of safety using the device in MR environment.	The valve is fixed away from the area of interest and is covered with gauze.

< Defects >

Other Defects

[1] Balloon burst.

[Burst due to the following causes.]

- Damage caused by handling during insertion (Damage caused by tweezers, forceps, scissors, scalpel, or other instruments).
- Excessive injection volume (injection of more than the regulated volume).
- Injection of the wrong substance for balloon inflation (substance that is likely to cause coagulation of components such as physiological saline and contrast medium).
- Sudden load on the product due to self (accidental) removal, etc.
- Other complex causes due to factors such as the above events.

[2] Occlusion of catheter and connector.

[The catheter lumen and connector lumen may be occluded by adhesion of drugs, nutrients, etc. or gastric contents, etc.]

[3] Impossibility of catheter removal

[Adhesion of nutrients in the catheter lumen due to insufficient flushing may deform the tube and result in clogging of the balloon lumen and interference of water removal. Use of physiological saline or contrast medium for balloon inflation may clog the balloon lumen due to coagulation of ingredients and interfere with the removal of water.]

[4] Catheter cut.

[Cut due to the following causes.]

- Damage caused by tweezers, forceps, scissors, scalpels, or other apparatuses.
- Sudden load on the product due to self (accidental) removal, etc.
- Other complex causes due to factors such as the above events.

[5] Valve breakage or leakage. （With the embedded valve）

[Valve breakage or leakage may occur due to local high-frequency heating.]

[6] Poor fitting of the cap.

[Adhesion of nutrients, drugs, etc. may cause leakage of gastric contents, inability to connect to the connector, or inability to remove due to adhesion.]

[7] Poor connection of the nutrition line, etc.

[Adhesion of nutrients, drugs, etc. may cause leakage of nutrients, disconnection or connection failure of nutrition line, etc.]

[8] Cut of the exchange rod.

[Cut due to the following causes.]

- Damage caused by tweezers, forceps, scissors, scalpels, or other apparatuses.
- Operations such as forcible insertion, removal, etc.

< Adverse events >

Serious Adverse Events

[1] Pressure necrosis due to excessive pressure between the gastric and abdominal walls.

[2] Peritonitis caused by the nutrients leakage into the abdominal cavity due to catheter false insertion or fistula damage.

Other Adverse Events

[1] Following adverse events may be developed by the product.

- The catheter dropout and associated fistula closure due to balloon burst and accidental (self) removal.
- Damage of the fistula and associated wound infections due to insertion/removal.
- Occurrence of ulcers due to contact irritation of the catheter tip on the posterior gastric wall
- Skin troubles (granuloma formation, redness, skin ulcer, pressure necrosis) around the fistula due to contact and leakage of the stomach contents to the skin.
- Dilation of the fistula due to catheterization
- Digestive tract obstruction and difficulty in gastric juice drainage, gastric dilation, vomiting etc.

  [In case the balloon part is drawn into the intestinal tract by the gastric peristalsis etc., digestive tract obstruction may occur.]
- Burns due to local high-frequency heating. （With the embedded valve）

[2] Following adverse events may be developed by the exchange rod.

- Damage (perforation, etc.).
- Bleeding.

< Use During Pregnancy, Delivery or Lactation and Pediatric Use >

Be careful when using X-ray to the patient who is pregnant or has some possibility of pregnancy.

[The influence of X-ray to the fetus is concerned.]

[STORAGE METHOD AND DURATION OF USE]

< Storage Method >

Store the product cleanly. Avoid wetting, direct sunlight, high temperature and humidity, and ultraviolet rays such as germicidal lamp, etc.

< Duration of Use >

The product has been developed for “use within 29 days”.

[Based on self-certification (our company data).]

< Expiration Date >

When the proper storage method has been maintained, refer to the expiration date on the individual package.

[Based on self-certification (our company data).]

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