

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

PMDA No.72 February, 2026

Precautions for Handling of Gastrostomy Catheters

Note: Gastrostomy catheters include button-type catheters and tube-type catheters.

PMDA 独立行政法人 医薬品医療機器総合機構
Pharmaceuticals and Medical Devices Agency

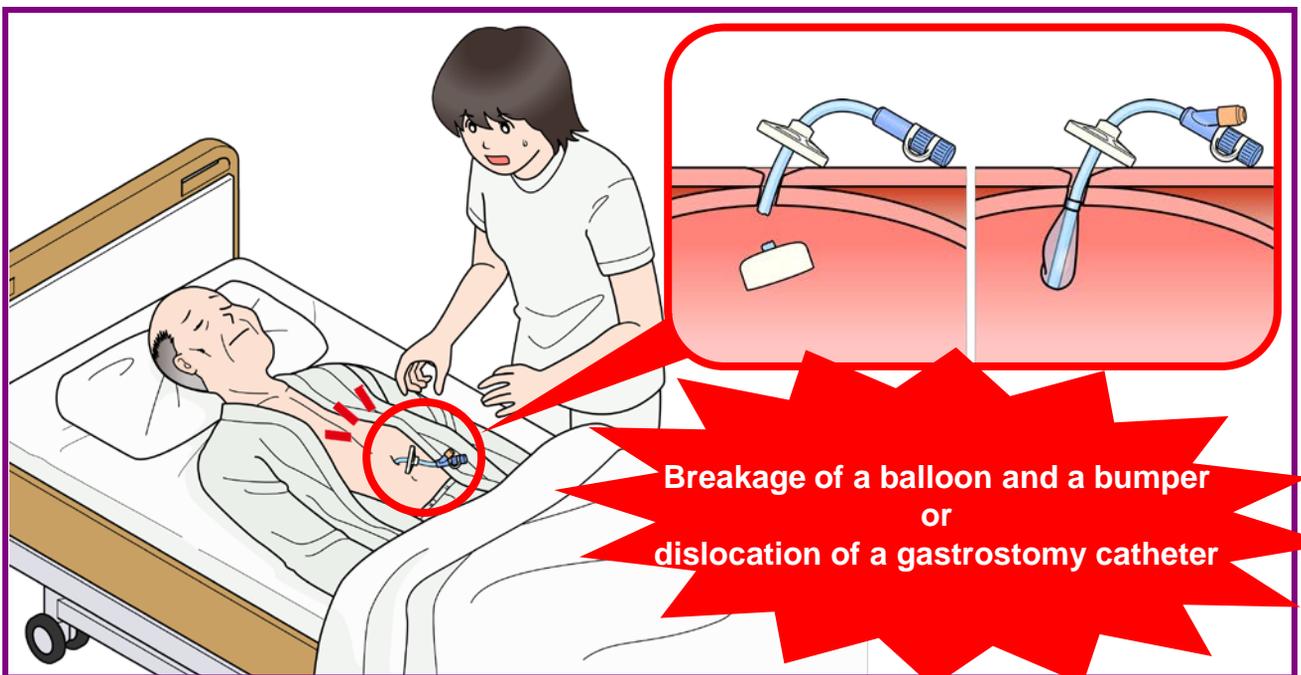
JQC 公益財団法人 日本医療機能評価機構
Japan Council for Quality Health Care

This is a joint project with the Project to Collect Medical Near-Miss/Adverse Event Information of the Japan Council for Quality Health Care.

Please also refer to "the Project to Collect Medical Near-Miss/Adverse Event Information - Medical Safety Information No. 231: Breakage of a Gastrostomy Catheter Used Beyond the Period of Use (February 2026)."

1 Breakage or Dislocation of a Gastrostomy Catheter Used Beyond the Period of Use

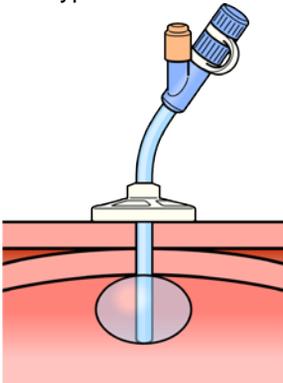
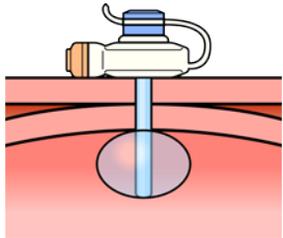
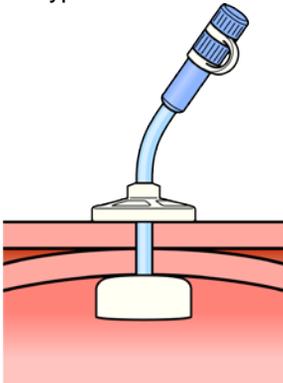
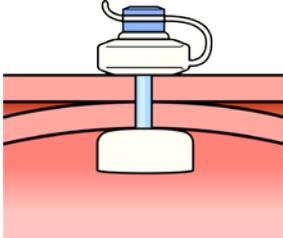
- (Case 1)** An inpatient in an orthopedic ward underwent a gastrostomy at the gastrointestinal surgery department. A gastrostomy catheter was found that the balloon was ruptured and the catheter was coming off during hygiene care at the orthopedic ward. The gastrostomy catheter, which should have been replaced within 30 days, had not been replaced for 4 months.
- (Case 2)** A patient visited to an emergency department with a complaint of "My gastrostomy tube came off." The gastrostomy catheter was coming off from the abdominal wall. The catheter, which should have been replaced every 4 months, had not been replaced for 3 years and 4 months. The bumper of the gastrostomy catheter was damaged and remained in the stomach.



Difference between Short-Term Use and Long-Term Use of Gastrostomy Catheters

POINT Key points for safe use

- There are two types for gastrostomy catheters, short-term and long-term.
- Confirm the period of use for each product on its package insert, the patient handbook and the patient card.
- Use beyond the period of use increases the risk of breakage of a balloon and a bumper or dislocation of a gastrostomy catheter due to deterioration associated with the use. Adhere to the period of use.

Type	Short-term use	Long-term use
Japanese Medical Device Nomenclature	Enteral feeding kit for short-term use Gastrostomy feeding tube for short-term use Gastrostomy button for short-term use	Enteral feeding kit for long-term use Gastrostomy feeding tube for long-term use Gastrostomy button for long-term use
Period of use after placement	Within 30 days	Over 30 days Note: Check the package insert, etc. for the period of use of each product.
Structure	<p>Balloon-type (the balloon should be inflated with sterile or distilled water)</p> <p>Balloon-tube-type</p>  <p>Balloon-button-type</p> 	<p>Bumper-type</p> <p>Bumper-tube-type</p>  <p>Bumper-button-type</p> 



If gastrostomy and its management are performed at different departments, be sure to share the frequency and scheduled date of gastrostomy catheter replacement between the departments. Check the patient regularly during the use of a gastrostomy catheter to ensure that there is no dislocation or abnormality in the gastrostomy catheter.

Example of a Patient Card

Patient Card			
I have an indwelling gastrostomy catheter.			
Product Name:			
Name:	TEL:		
Name of Medical Facility:			
Name of Physician:	TEL:		
Date of Placement:	Day/	Month/	Year/
Scheduled Date of Next Replacement:	Day/	Month/	Year/

Share and confirm information about the scheduled date of next replacement by using a Patient Card in addition to medical charts and patient information forms!



2 Dislocation of a Balloon-Type Gastrostomy Catheter due to Failure to Check the Amount of Sterile Water or Distilled Water

(Case 3) The water for inflating the balloon was not checked for 10 days after the placement of a gastrostomy catheter, and nutrients leaked from the gastrostomy insertion site. The balloon deflated and the gastrostomy catheter was about to fall out.

A balloon-type gastrostomy catheter requires sterile water or distilled water for inflating the balloon. For proper management of the water, be aware of the following!

- Inject the volume of the water indicated on the package insert or product
- Replace the water regularly
- Refer to the package insert for the frequency of replacement of the water



Please access the link below for “Project to Collect Medical Near-Miss/Adverse Event Information - Medical Safety Information No. 231: Breakage of a Gastrostomy Catheter Used Beyond the Period of Use (February 2026)” published by the Japan Council for Quality Health Care.

https://www.med-safe.jp/pdf/med-safe_231.pdf

Refer to the following PMDA Medical Safety Information for further information.

- PMDA Medical Safety Information No.43 “Risks in Handling of Gastrostomy Tubes”

About this information

- * PMDA Medical Safety Information is issued by the Pharmaceuticals and Medical Devices Agency for the purpose of providing healthcare providers with clearer information from the perspective of promoting the safe use of pharmaceuticals and medical devices. The information presented here has been compiled, with the assistance of expert advice, from the following cases.
 - Cases collected in the Project to Collect Medical Near-Miss/Adverse Event Information and the Project to Collect and Analyze Pharmaceutical Near-Miss Events of the Japan Council for Quality Health Care
 - Cases collected in Adverse Drug Reaction and Malfunction Reports in accordance with the Law on Securing Quality, Efficacy and Safety of Pharmaceuticals and Medical Devices
- * We have tried to ensure the accuracy of this information at the time of its compilation but do not guarantee its accuracy in the future.
- * This information is not intended to impose constraints on the discretion of healthcare professionals or to impose obligations and responsibility on them, but it is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.

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