

# PMDA Medical Safety Information

Pharmaceuticals and Medical Devices Agency



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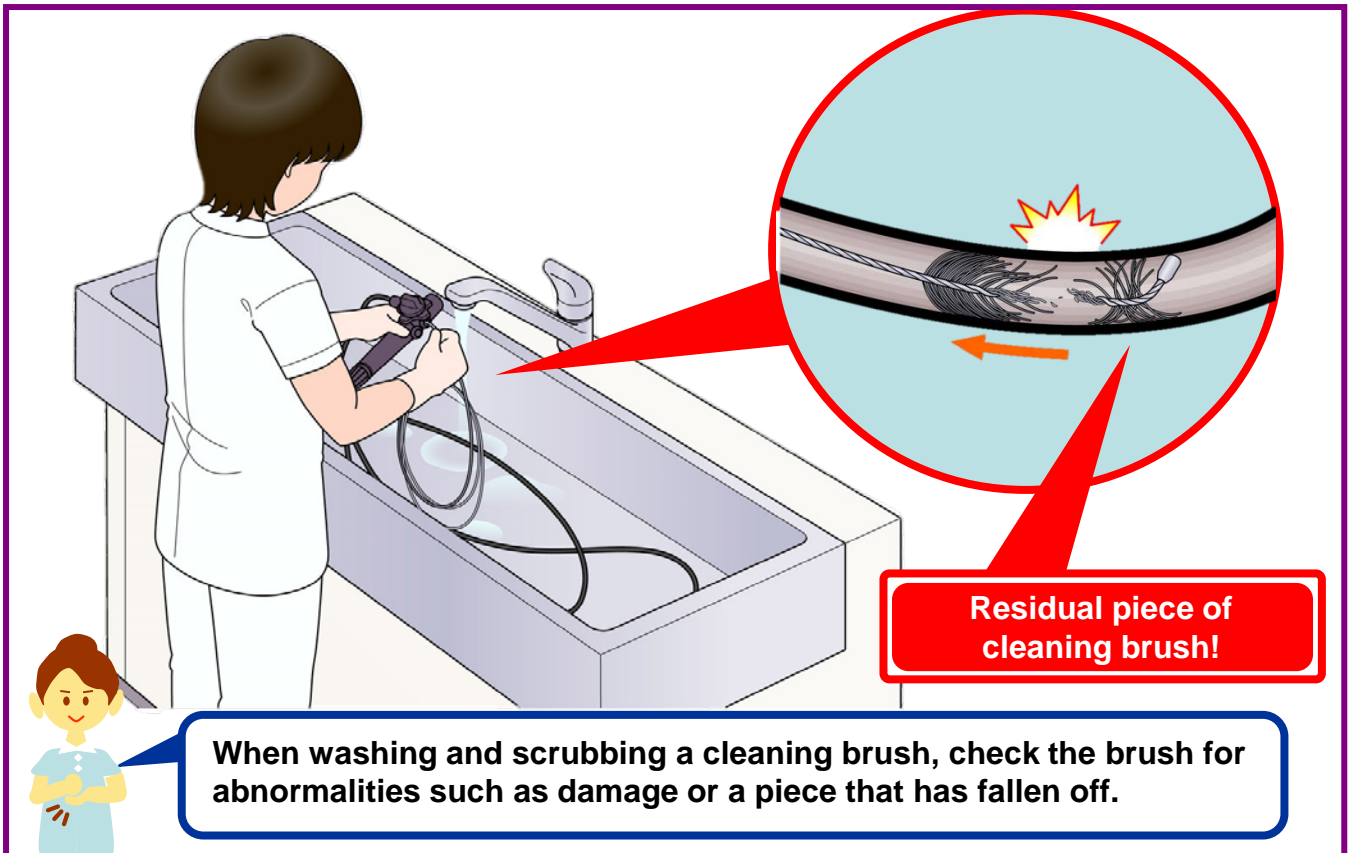
## Precautions for Cleaning and Disinfection of Gastrointestinal Endoscopes


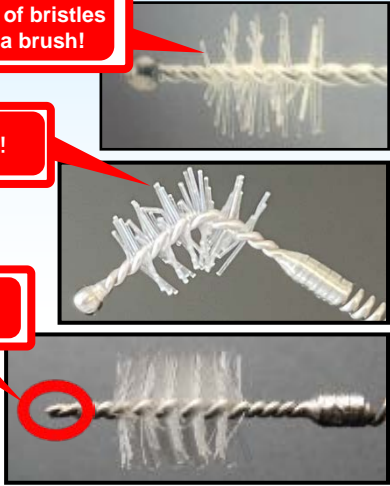
### POINT Points to be noted for safe use

#### 1 Precautions for use of cleaning brush

- (Case 1)** When a cleaning brush was inserted at the time of cleaning the endoscope, it was difficult to insert. When checked, a piece of another broken cleaning brush remained in the channel of the endoscope.
- (Case 2)** During surgery, the tip of the cleaning brush fell out of the endoscope channel into the patient's body. This occurred because the cleaning brush was broken during endoscope cleaning and left in the channel without being noticed by a cleaning operator.

- Confirm that there are no abnormalities before and after use of the cleaning brush
- After every brushing, confirm that there are no cleaning brush abnormalities.

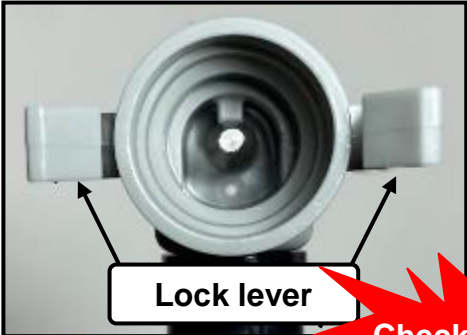





<p>✓</p> <p>Normal cleaning brush</p>  <p>Check for abnormalities before and after use!</p>	<p>✗</p> <p>Examples of abnormal cleaning brush</p> <p>Loss of bristles on a brush!</p> <p>Bending of a brush !</p> <p>Detachment of the tip!</p> 
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## 2 Precautions when using the automated endoscope reprocessor

**(Case 3)** The connector of the washing tube was found to be damaged. The solution could not be sent to the channel of the endoscope sufficiently resulting in insufficient cleaning and disinfection.

- Check if there are no abnormalities in each connector and washing tube before use

<p>✓</p> <p>Normal connector</p>  <p>Lock lever</p>	<p>✗</p> <p>Examples of abnormal connector</p>  <p>Lock lever is chipped!</p>
<p>✗</p> <p>Examples of abnormal washing tube</p> 	<p>✗</p> <p>Connecting part is damaged!</p> 

### 3 Precautions when using disinfectants

**(Case 4)** When cleaning and disinfecting endoscope with the automated endoscope reprocessor, the concentration of disinfectant solution used was below the effective concentration, and the endoscope was used in patients. The concentration check according to the package insert was not carried out.

When using disinfectant in an automated endoscope reprocessor, pay attention to the following points:

- Before preparing a disinfectant, check its effective concentration, pH, expiration date, etc.
- Follow each instruction for use, storage temperature, etc. of prepared disinfectant.
- For the range of appropriate concentration and confirmation method, check the electronic package insert and instruction manual, etc.

#### Example of confirmation of disinfectant



Expired!

Serial No. PXXXX

Expiration date

30/09/2018

Sufficient disinfection effect may not be obtained, if disinfection with an **appropriate concentration** of disinfectant is not performed for an **appropriate immersion time**. It may cause inadequate disinfection of the endoscope and result in cross infection, etc.



**For cleaning and disinfection of endoscopes, check the electronic package insert of each product, instruction manual, and guidelines for cleaning of gastrointestinal endoscopes issued by related academic societies!**

Notifications related to this medical safety information have been issued by the Ministry of Health, Labour and Welfare.

- PFBSB/SD Notification No. 0320-1 and PFBSB/SD Notification No. 0320-2 dated March 20, 2015  
"Adherence to Methods for Cleaning and Sterilization/Disinfection of Duodenoscope Devices"
- HPB/RMCPD Notification No. 0320-3 and PFBSB/SD Notification No. 0320-4 dated March 20, 2015  
"Transmission of Multidrug-Resistant Bacteria by Duodenoscopy"

#### 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 cases collected as Medical Accident Information Reports by the Japan Council for Quality Health Care, and collected as 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 is provided as a support to promote the safe use of pharmaceuticals and medical devices by healthcare professionals.
- This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.

Access to the most up-to-date safety information is provided via the PMDA Medi-navi service.

