

Medical Safety Information

Pharmaceuticals and Medical Devices Agency

pmda No.70 December, 2024

Precautions for Handling Guidewires

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

Please also refer to "Medical Safety Information No. 217 of Project to Collect Medical Near-Miss/Adverse Event Information: Guidewire Fracture Due to Combined Use with a Metal Needle (December 2024)."

1 Precautions for Guidewire Coating Peeling

Case 1: When a polymer-coated guidewire was pulled out while a metal needle was left in place, the coating peeled off and remained in the body.

POINT Key points for safe use

- Do not pull a polymer-coated guidewire during the use of a metal needle or metal trocar. Also, do not advance a metal needle while the guidewire is still placed.



A guidewire with a peeled-off coating



Brand name: Radifocus Guide Wire M
Provided by Terumo Corporation

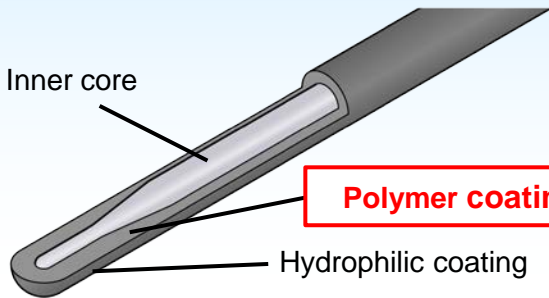


The coating has peeled off!

Mechanism of the Coating Peeling Off Due to the Combined Use with a Metal Needle, etc.

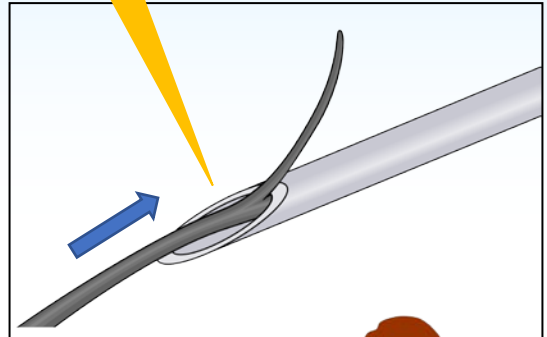
Types of Guidewires

Polymer-coated Guidewire



The structure consists of an inner core (metal wire) covered with polyurethane or PTFE polymer.

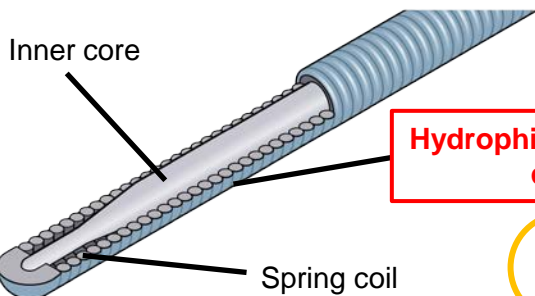
The edge (blade surface) of a metal needle, etc. cuts into the polymer coating on the guidewire's surface and peels off the coating.



If the coating peels off and remains in the body, it may cause serious health damage.



Spring Coil Guidewire



A structure in which a coil of platinum, gold, etc., is wound around an inner core (metal wire). Some products have a hydrophilic or hydrophobic coating applied to the coil.

Excessive contact with a metal needle, etc., may reduce the coating effect.

Precautions for Combined Use of Guidewires and Metal Needles, etc.

Package insert

CONTRAINDICATIONS

Precautions Concerning Directions for Use

IMPORTANT PRECAUTIONS

Guidewires are available in a variety of structures and properties. Please read the instructions for use of each product carefully, as some products are contraindicated for combined use with metal needles, etc., and some require special precautions for use.

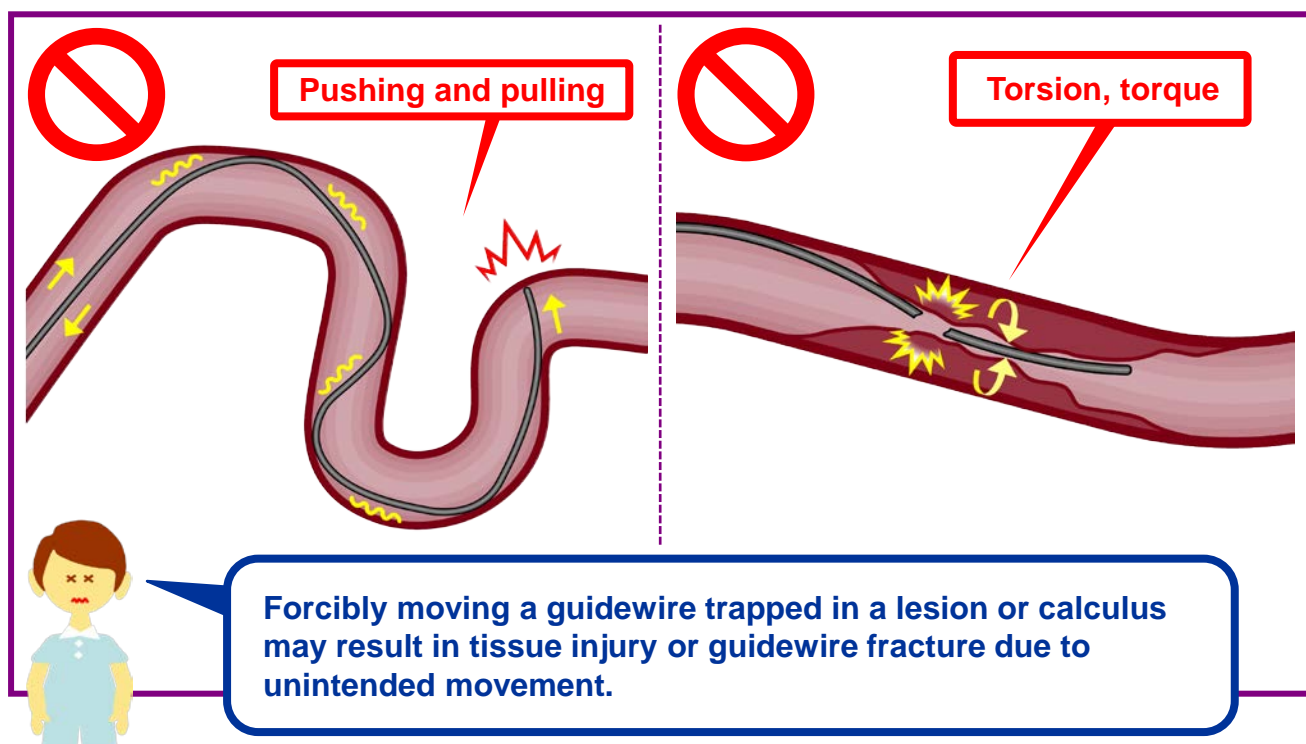
2 Precautions for Fracture, Tissue Injury, etc., Caused by Guidewire Operation

Case 2: While advancing a guidewire through a stenotic area, the operator felt a slight resistance but forced it through, resulting in vessel perforation.

Case 3: During pancreatic lithotomy, the tip of a guidewire broke when it was pulled out.

POINT Key points for safe use

- If resistance is felt or the tip of the product gets stuck, check the position and condition under X-ray fluoroscopy.
- After removing the guidewire, check if there are any abnormalities, such as flaking or fraying.
- If any abnormality is found in the removed guidewire, check for any remnants, etc., under X-ray fluoroscopy.



Please access the link below for “Medical Safety Information No. 217 of Project to Collect Medical Near-Miss/Adverse Event Information: Guidewire Fracture Due to Combined Use with a Metal Needle (December 2024)”, issued by Japan Council for Quality Health Care.

https://www.med-safe.jp/pdf/med-safe_217.pdf

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

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