

This is a joint project with the Pharmaceuticals and Medical Devices Agency (PMDA).

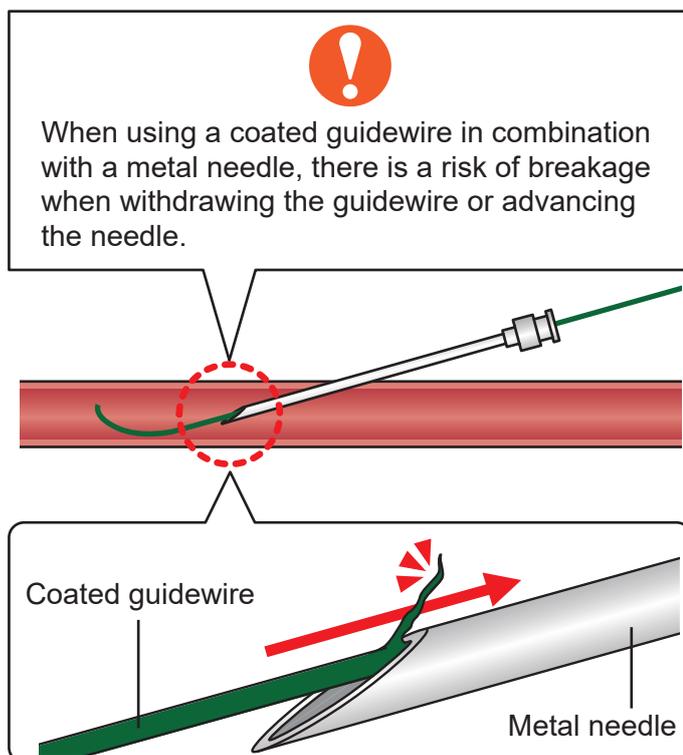
Please also refer to PMDA Medical Safety Information No. 70 December 2024 “Precautions for Handling Guidewires.”

Guidewire Breakage Due to Combined Use with a Metal Needle

Cases have been reported in which, while using a metal needle, a guidewire suffered a breakage and was left in the body when a coated guidewire was withdrawn or the needle was advanced.

Fifteen such cases were reported between January 1, 2019 and October 31, 2024. This information was compiled on the basis of the content featured in the Analysis Themes section of the 54th Quarterly Report.

Image of case



Situations Involving Combined Use with a Metal Needle	Number of Cases
Nephrostomy	5
Central venous catheter (including PICC) insertion	4
Pacemaker implantation	1
Pericardiocentesis	1
ECMO venous line replacement	1
Transcatheter arterial embolization (TAE)	1
Percutaneous transhepatic gallbladder drainage (PTGBD)	1
Ureteral stent insertion	1

Item Left in Body	Number of Cases
Peeled-off coating material	11
Guidewire tip	4

- ◆ The package insert for some coated guidewires states, “Do not use a metal needle or metal trocar when inserting or removing a guidewire” in the [Contraindications] section, or “Do not carry out insertion, removal, or other operations when using in combination with a metal cannula or needle” in the “Important Precautions” of the [Precautions Concerning Directions for Use] section.

Guidewire Breakage Due to Combined Use with a Metal Needle

Case 1

During a nephrostomy procedure, the guidewire that was part of the kit being used became bent. The physician had the nurse unwrap a new coated guidewire that was not part of a kit. The physician inserted the guidewire via a metal needle, but while advancing and withdrawing it, the coating peeled off and was left in the patient's body. The individually packaged guidewire used was contraindicated for combined use with metal needles.

Case 2

When inserting peripherally inserted central catheter (PICC), the physician usually used individually packaged coated guidewires, rather than using guidewires that came as part of a kit. When inserting the guidewire after using a metal needle for the puncture, the physician felt resistance and withdrew the guidewire while leaving the metal needle inserted. The guidewire tip broke off and was left in the blood vessel. The individually packaged guidewire used was contraindicated for combined use with metal needles.

Preventive measures taken at the medical institutions in which the events occurred

- Medical staff will be informed that some coated guidewires are contraindicated for combined use with metal needles, and that, when used with a metal needle, there is a risk of guidewires breaking when withdrawn or when advancing the needle.
- When using an individually packaged guidewire, medical staff will check the package insert to ensure that the item is not contraindicated for combined use with metal needles or that there are no precautions concerning combined use.

The measures above are examples. Please consider initiatives suitable for your own facility.

Please refer to PMDA Medical Safety Information No. 70 December 2024 "Precautions for Handling Guidewires."

<https://www.pmda.go.jp/files/000272465.pdf>

* As part of the Project to Collect Medical Near-Miss/Adverse Event Information (a Ministry of Health, Labour and Welfare grant project), this medical safety information was prepared based on the cases collected in the Project as well as on opinions of the "Comprehensive Evaluation Panel" to prevent the occurrence and recurrence of medical adverse events. See the Project website for details.

<https://www.med-safe.jp/>

* Accuracy of information was ensured at the time of preparation but cannot be guaranteed in the future.

* This information is intended neither to limit the discretion of healthcare providers nor to impose certain obligations or responsibilities on them.

