

Pharmaceuticals and Medical Devices Safety Information

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Executive Summary

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For full text version of Pharmaceuticals and Medical Devices Safety Information (PMDSI) No. 309, interested readers are advised to consult the PMDA website for upcoming information. The contents of this month's PMDSI are outlined below.

1. Precautions for Use of Puncture Site Closure Devices

Cases of serious malfunctions have been reported regarding puncture site closure devices that are used for hemostasis at the site of catheterization (site of femoral artery puncture) for percutaneous transluminal angioplasty or other procedures. This section provides information on the malfunctions reported in Japan, as well as precautions for patient care and other procedures during and after using closure devices.

2. List of Products Subject to Early Post-marketing Phase Vigilance (as of January 2014)

A list of products subject to Early Post-marketing Phase Vigilance as of January 1, 2014 will be provided in section 2 of the full text.

Reference: Drugs and Medical Devices Safety Information Reporting System

Healthcare professionals are encouraged to report to the MHLW about adverse reactions or device malfunctions of not only drugs and medical devices but also quasi-drugs and cosmetics.

This English version of PMDSI 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. The PMDA shall not be responsible for any consequence resulting from use of this English version.