PMDA
Medical Safety Information
Pharmaceuticals and Medical Devices Agency

No. 53 March 2018

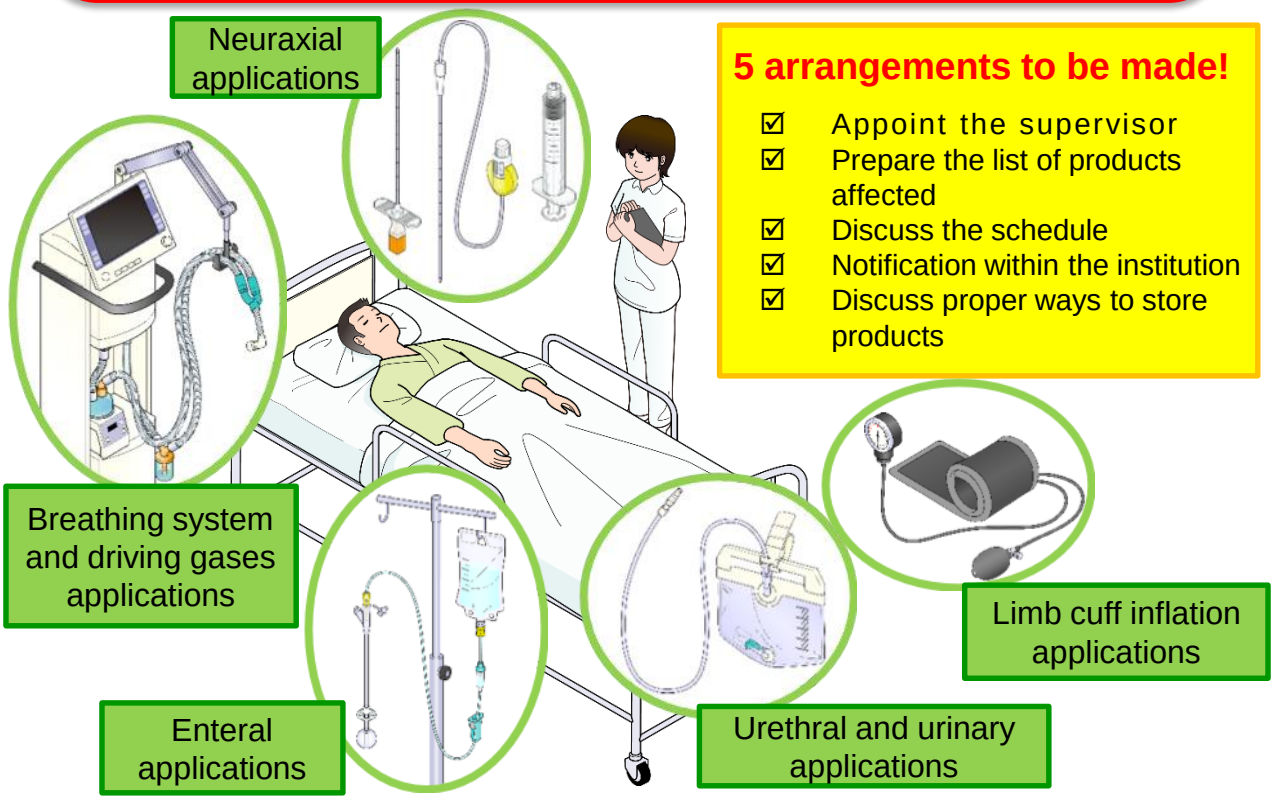
Introduction of Connectors that Prevent Misconnection

POINT Key points for safe use

1 Introduction of connectors that prevent misconnection

- **Revision of standards (connector geometry) has been underway internationally in order to prevent misconnections across different product areas.**
- **New standard products of each product area will be marketed in sequence as soon as required arrangements are made.**

New and old standard products will not connect with each other!



5 arrangements to be made!

- ☑ Appoint the supervisor
- ☑ Prepare the list of products affected
- ☑ Discuss the schedule
- ☑ Notification within the institution
- ☑ Discuss proper ways to store products

※Please confirm **the details of the five arrangements** in the subsequent page!※

2 General precautions for switching to connectors that prevent misconnection

- **Proper inventory management and information sharing among the facility staff are important in order to avoid confusion associated with the introduction of new standard products. For that purpose, the following measures should be discussed at each facility.**

☑ To unify information, please appoint the division and the supervisor (the medical devices safety management supervisor, etc.) responsible for coordinating with distributors.
☑ To ensure steady and complete product switching, please prepare the lists of products in each product area subjected to the switching.
☑ Please check with the distributors, etc. when they start the switching and terminate the supply, and discuss the switching method within the facility as well as its schedule.
☑ Hold a briefing session, etc. by the distributors or the responsible division (supervisor) to sufficiently inform the facility staff.
☑ Please discuss proper ways to store products to prevent the mix up of products non-connectable with each other.

The featured page was established.
(Japanese language only)

<Contents >
・Outline of the International Standards
・Precautions on the launch of new standard products
・A list of contacts of industry groups for inquiries
・Other updates on new standard products

* Please contact marketing authorization holders for information on product details.
(https://www.pmda.go.jp/safety/info-services/medical-safety-info/0185.html)

The Ministry of Health, Labour and Welfare (MHLW) issued notification related to PMDA Medical Safety Information No. 53.
●HPB/GAD Notification No. 1004-1, PSEHB/PED Notification No. 1004-1, PSEHB/MDED No. 1004-1, PSEHB/PSD Notification No. 1004-1 dated on October 4, 2017
Introduction of the International Standards (ISO (IEC) 80369 series) Related to Connectors for Prevention of Interconnection

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 available via PMDA medi-navi.

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