PMDA
Medical Safety Information
Pharmaceuticals and Medical Devices Agency

No. 55 August 2018

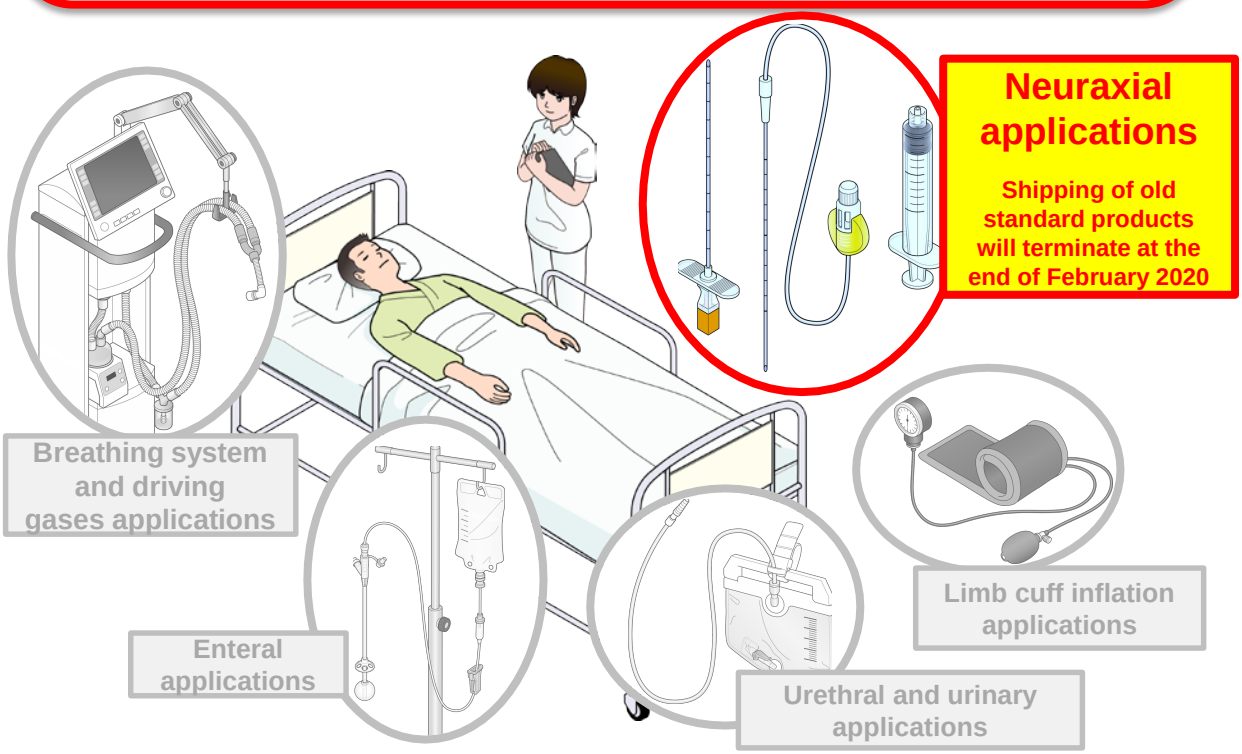
Introduction of Connectors to Prevent Misconnection (Neuraxial Anesthesia)

POINT Key points for safe use

1 Precautions for products meeting new standards for neuraxial applications (1)

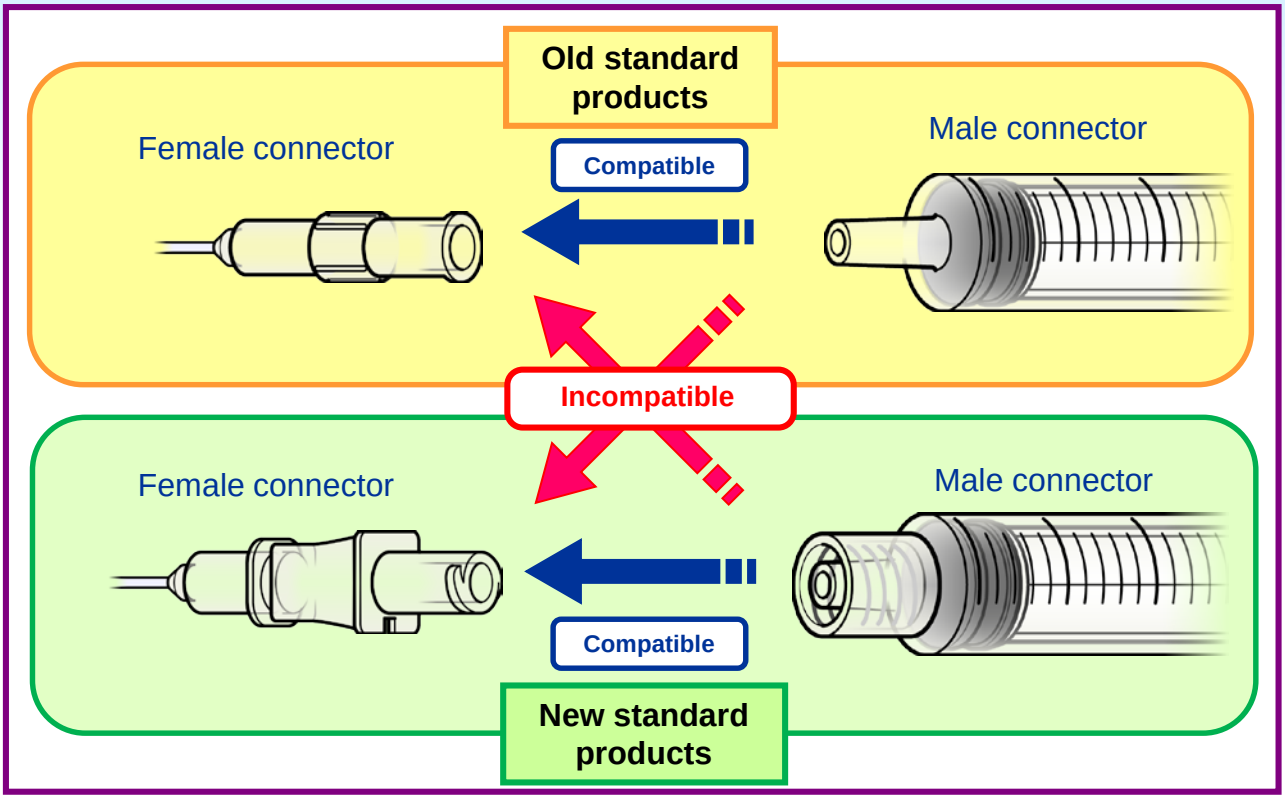
- **International standards (ISO [IEC] 80369 series) related to connectors for the prevention of interconnections across medical device product areas are being established. The new standards have now been introduced in the U.S. and Europe.**
- **Distribution of new standard products will begin as soon as these products are ready, and shipping of old standard products will be terminated at the end of February 2020.**

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



Please list products that are subject to switching, and check with marketing authorization holders, etc. regarding the schedule for starting distribution of new standard products. In order to prevent misconnections, **please implement all product switching simultaneously.**

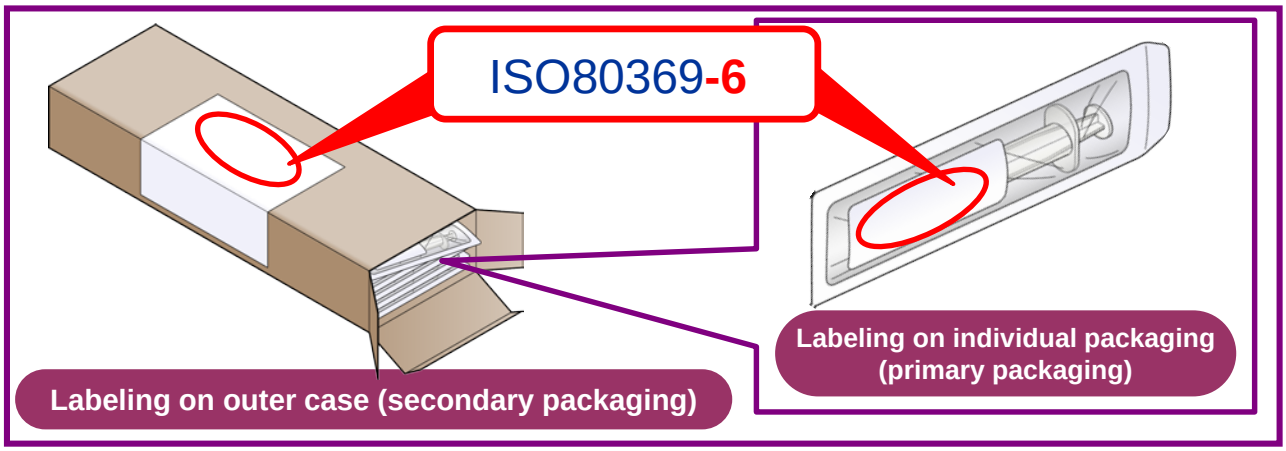
Connections of new and old standard products



The connectors of new and old standard products are not compatible with each other due to differences in the connectors' size and geometry.
Please also check all labeling on packages, as it may be difficult to distinguish between new and old standard products in some cases.

2 Precautions for products meeting the new standards for neuraxial applications (2)

- **The code "ISO80369-6" is indicated on the packaging of new standard products for neuraxial applications.**



The above image is an example of new standard product presentation.
Please check each product as the locations of codes, etc. may differ.

3 Precautions for products meeting the new standards for neuraxial applications (3)

- **Please refer to the below for names (general names) of products subject to switching.**

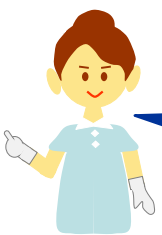
- ☑ **Spinal needles**
- ☑ **Epidural needles**
- ☑ **Epidural anesthesia catheters**
- ☑ **Epidural/spinal anesthetic needles**
- ☑ **Nerve block needles**
- ☑ **Epidural anesthetic filters**
- ☑ **Loss of resistance syringes**
- ☑ **Prefilled syringes**
- ☑ **Syringes (for neuraxial applications)**
- ☑ **Elastomeric infusion systems (for neuraxial applications)**
- ☑ **Extension tubes (for neuraxial applications)**
- ☑ **Three-way stopcocks (for neuraxial applications)**
- ☑ **Liquid sampling needles (for neuraxial applications)**

etc.

Confirmed product names are available on the websites of related Associations!

・**Prefilled syringes**
URL: http://www.fpmaj.gr.jp/documents/ISO80369-6.pdf (only in Japanese)

・**Other medical devices**
URL: http://www.mtjapan.or.jp/jp/mtj/smallbore/index.php (only in Japanese)



Please check with marketing authorization holders, etc. to confirm whether any products you use are subject to switching, as it is possible that some products may require switching despite not being listed on the websites of related Associations!

Please also check with marketing authorization holders, etc. to confirm whether the nonproprietary names of products you use are included in the nonproprietary names list at the below URL, as product names (general names) and nonproprietary names may differ!
URL: http://www.pmda.go.jp/files/000223210.pdf (only in Japanese)

4 Precautions for products meeting the new standards for neuraxial applications (4)

- **Use of conversion adapters for interfacing between old and new standard products may result in misconnections. In principle, conversion adapters should not be used and old standard products should be switched to new standard products simultaneously.**

Please confirm with marketing authorization holders, etc. about proper product handling when medical practice is anticipated to be impeded by incompatibility between old and new standard products.

5 Precautions for products meeting the new standards for neuraxial applications (5)

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

☑ To ensure the consistency of information disseminated, please appoint a division and supervisor (e.g., a medical device safety management supervisor, etc.) responsible for coordinating with distributors.

☑ To ensure steady and complete product switching, please prepare lists of products in each product area that will be subject to switching.

☑ Check with distributors, etc. when switching is initiated and the supply is terminated, and discuss the switching method within the facility as well as the switching schedule.

☑ Arrange a briefing session, etc. by the distributors or the responsible division (supervisor) to sufficiently inform staff at each facility.

☑ Discuss appropriate methods for storing products to prevent mix-ups involving incompatible products.

Examples of checklists necessary for implementing product switching are available at the webpage featured below!

The webpage displayed to the right was created.
(only in Japanese)

<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, etc. for detailed product information.
(http://www.pmda.go.jp/safety/info-services/medical-safety-info/0185.html)

The Ministry of Health, Labour and Welfare (MHLW) issued the following Notifications related to PMDA Medical Safety Information No. 55:

- HPB/GAD Notification No. 1227-1, PSEHB/PED Notification No. 1227-1, PSEHB/MDED No. 1227-1, and PSEHB/PSD Notification No. 1227-1, dated December 27, 2017, Switching of Small-bore Connectors for Neuraxial Anesthesia Applications

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.