Medical Safety Information
Pharmaceuticals and Medical Devices Agency
http://www.pmda.go.jp/english/safety/info-services/safety-information/0001.html

No. 58 Revised May 2022
No. 58 July 2019

PMDA
Medical Safety Information
Pharmaceuticals and Medical Devices Agency

No. 58 Revised May 2022

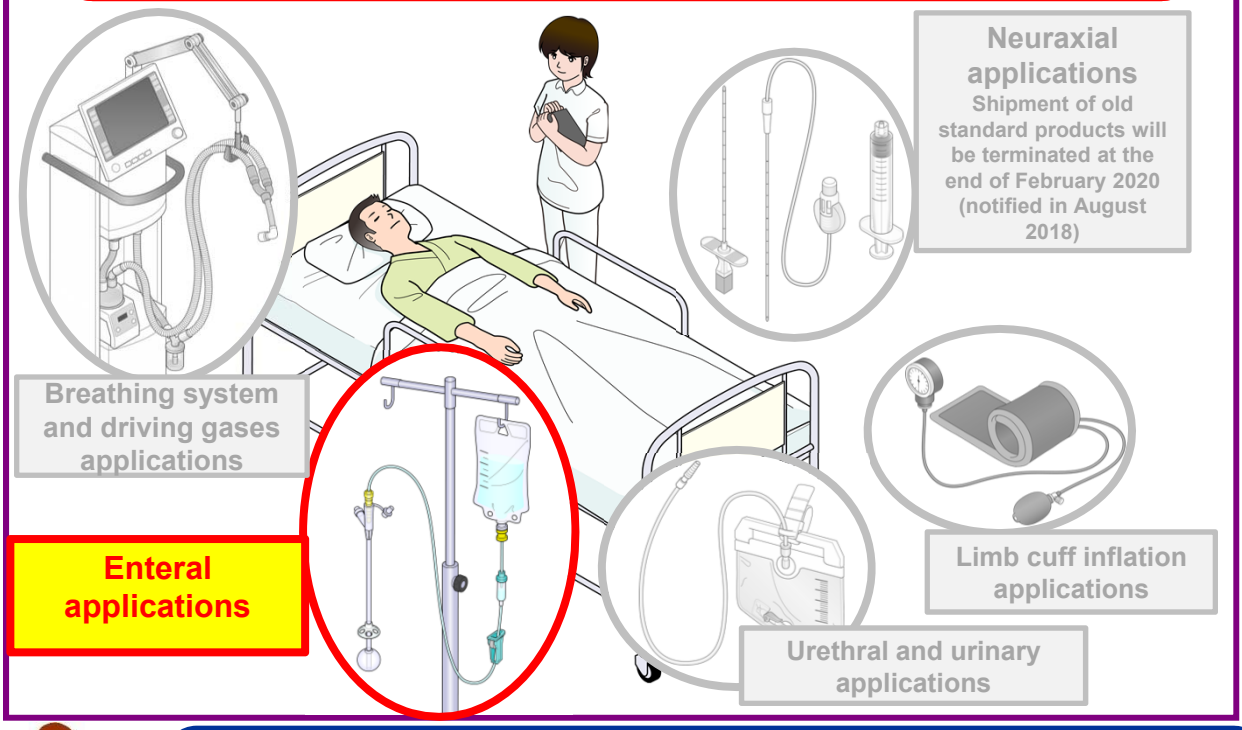
Introduction of Connectors to Prevent Misconnection (for Enteral Applications)

POINT Key points for safe use

1 Handling of old standard products

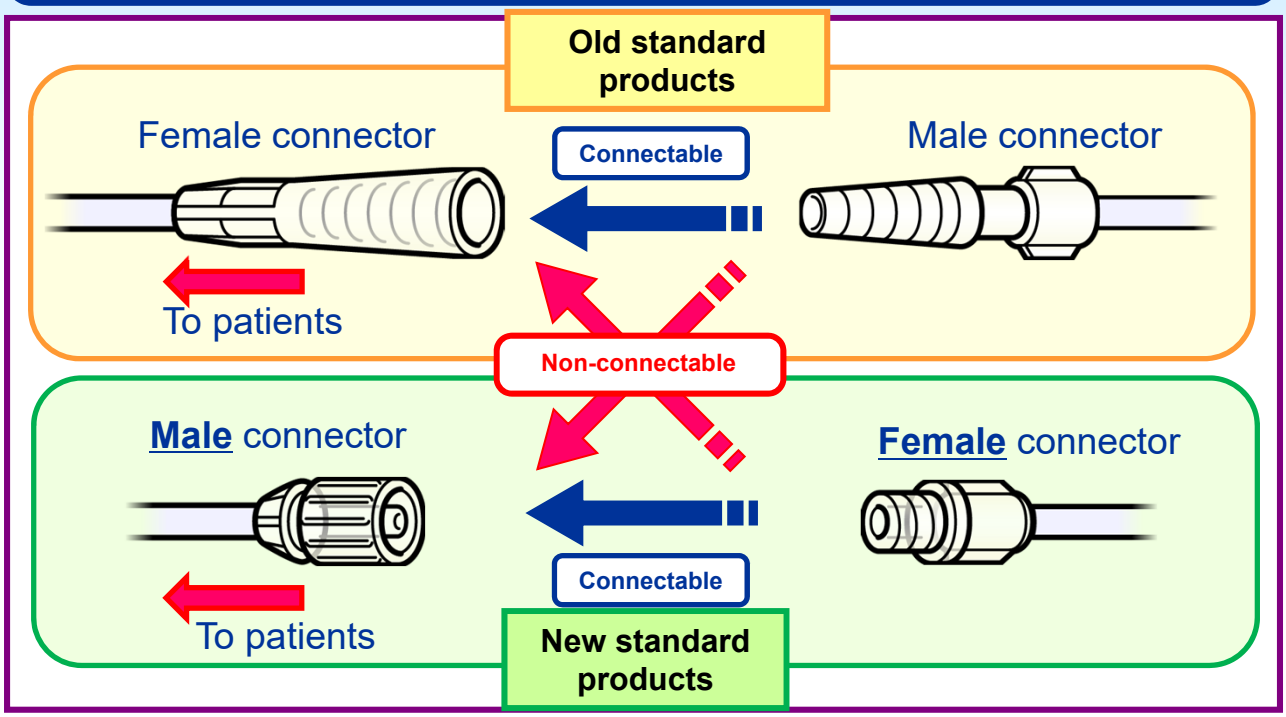
- International standards (ISO [IEC] 80369 series) related to connectors for the prevention of interconnection across product areas of medical devices etc. are being established. The new standards have now been introduced in the U.S. and Europe.
- The distribution of new standard products (ISO80369-3) has been phased in starting from December 2019. (For your information, expiration date for the shipment of old-standard products will not be set for the time being.)

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



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

Connections of new and old standard products



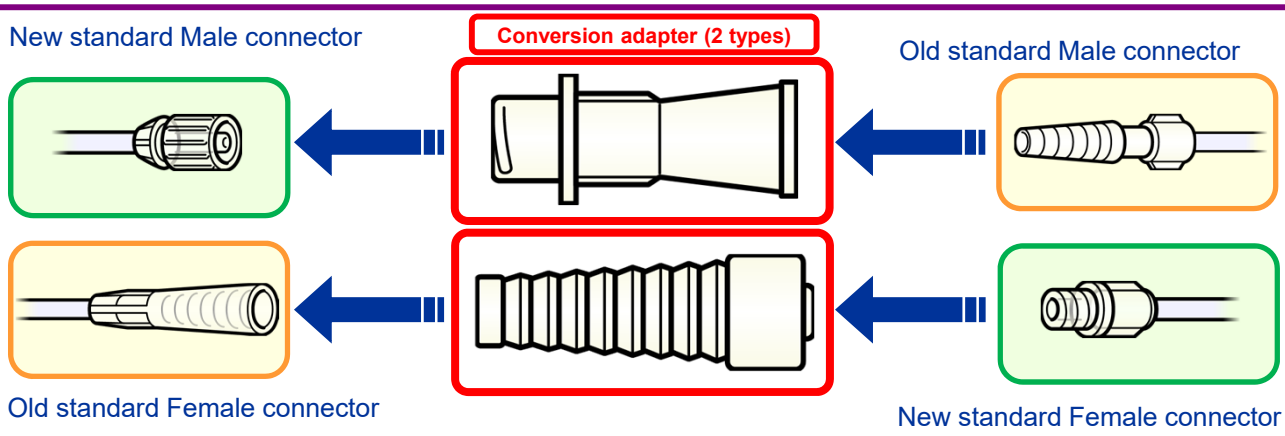
The connectors of new and old standard products are not compatible with each other due to differences in the connectors' size and geometry.

In addition, connection of new standard connector products are in reverse female to male orientation.

Please also check all labeling on packages as it may be difficult to distinguish between new and old standard products in some cases.

2 Conversion adapters should be available

- **Although simultaneous switching is basically important, medical facilities will have to be prepared to take proper care of patients moving between facilities. For example, adapters to connect new and old standard products (conversion adapters) should be available.**



A certain period of time will be required to complete switching to new standard products in all medical facilities. During such transition period, patients using a long-term indwelling device may move between facilities. Therefore, conversion adapters should be available at medical facilities.

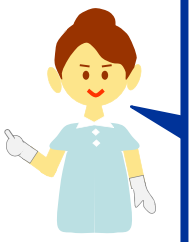
As shown in the upper figure, two different types of conversion adapters exist and caution should be taken. Please check with the MAH, etc. for the handling of conversion adapters.

3 List of product subject to switching

● **Please refer to the below for names (common name) of products subjected to switching.**

- ☑ **Transesophageal enteral feeding tube**
- ☑ **Set for nutrition infusion**
- ☑ **Enteral nutrition pump extension tube**
- ☑ **Enteral nutrition infusion stopcock**
- ☑ **Gastrostomy feeding tube (PEG tube/button)**
- ☑ **Injector (nutrition)**

and others



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

● **Liquid foods**
URL：http://www.ryudoshoku.org/info1 (only in Japanese)

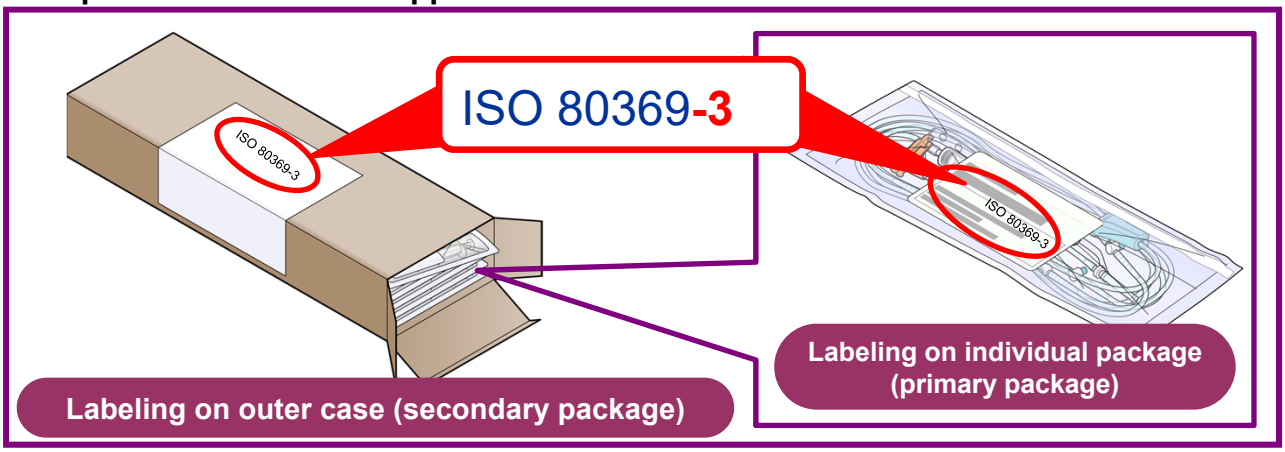
● **Other medical devices**
URL: http://www.mtjapan.or.jp/jp/mtj/smallbore/index.php (only in Japanese)

Please check with MAHs, etc. 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 MAHs, etc. if the nonproprietary names of products you use are in the nonproprietary names list from the URL below, since product names (common names) and nonproprietary names are different!
URL：http://www.pmda.go.jp/files/000225222.pdf (only in Japanese)

4 Labeling of new standard products

● **The code "ISO 80369-3" is indicated on the packages of new standard products for enteral applications.**



The image above is an example of the label. Please check each product since the location of the label etc. may be different.

5 Precautions upon switching

- **Proper inventory management and information sharing among the 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 detailed procedures needed for the switching is available from the featured page 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 MAHs for information on product details.

URL: 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. 58.
- ●HPB/GAD/MSPO Notification No. 0316-1, PSEHB/PED Notification No. 0316-1, PSEHB/MDED No. 0316-1, PSEHB/PSD Notification No. 0316-1 dated on March 16, 2018
  Switching of Small-bore Connectors for Enteral applications
- ●HPB/GAD/MSPO Notification No. 0216-5, PSEHB/PED Notification No. 0216-1, PSEHB/MDED No. 0216-1, PSEHB/PSD Notification No. 0216-1 dated on February 16, 2021
  Extension of Shipment of Old Standard Products related to Small-bore Connectors for Enteral Applications
- ●HPB/GAD/MSPO Notification No. 0520-1, PSEHB/PED Notification No. 0520-7, PSEHB/MDED No. 0520-1, PSEHB/PSD Notification No. 0520-1 dated May 20, 2022
  Partial Revision of Policies on Switching of Small-bore Connectors for Enteral 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 available via the PMDA medi-navi.