Introduction of Connectors to Prevent Misconnection (for Enteral Applications)

**Key points for safe use**

1. **Termination of the shipment 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) will begin in December 2019 as soon as these products are ready, and the shipment of old standard products will be terminated at the end of November 2021.

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

   - **Breathing system and driving gases applications**
   - **Enteral applications**
     - Shipment of old standard products will be terminated at the end of November 2021.
   - **Neuraxial applications**
     - Shipment of old standard products will be terminated at the end of February 2020 (notified in August 2018)
   - **Limb cuff inflation applications**
   - **Urethral and urinary applications**

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.

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)

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.
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.