HPB/GAD Notification No. 1227-1
PSEHB/PED Notification No. 1227-1
PSEHB/MDED Notification No. 1227-1
PSEHB/PSD Notification No. 1227-1
December 27, 2017

To: Commissioners of Prefectural/Cities with Established Health Centers/Special District Health Department (Bureau)

Director of General Affairs Division, Health Policy Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director of Pharmaceutical Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
(Official seal omitted)

Director of Medical Device Evaluation Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
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Director of Pharmaceutical Safety Division,
Pharmaceutical Safety and Environmental Health Bureau,
Ministry of Health, Labour and Welfare
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Switching of Small-bore Connectors for Neuraxial Anesthesia

The introduction of the international standards related to connectors for prevention of interconnection across product areas has been informed through Introduction of the International Standards (ISO [IEC] 80369 series) Related to Connectors for Prevention of Interconnection (HPB/GAD Notification No. 1004-1, PSEHB/PED Notification No. 1004-1, PSEHB/MDED Notification No.1004-1 and PSEHB/PSD Notification No. 1004-1 dated October 4, 2017, by the Director of General Affairs Division, Health Policy Bureau; Director of Pharmaceutical Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau;

Director of Medical Device Evaluation Division, Pharmaceutical Safety and Environmental Health Bureau; Director of Pharmaceutical Safety Division, Pharmaceutical Safety and Environmental Health Bureau; Ministry of Health, Labour and Welfare).

For the prevention of interconnection of small-bore connectors for neuraxial applications (products intended for spinal, epidural and subarachnoid administration used for anesthesia or nerve blockage[*1]), the approval and certification standards[*2] are to be revised to comply with the International Standard ISO 80369-6 (hereinafter referred to as the "new standard"), and products subject to the new standard (hereinafter referred to as the “new standard product(s)” including combination products corresponding to drugs) will be sequentially marketed. When products complying with the new standard and with the existing standard, e.g. ISO 594-1 and ISO 594-2 (hereinafter referred to as the “existing standards") coexist, non-compatibility between these products may occur (See Attachment). Thus, the switching period, etc. has been defined as stated below in order to prevent medical accidents in medical practice. Commissioners of the Health Department are requested to disseminate the information to business entities and medical institutions, etc., under their supervision, and also to the divisions (bureaus) in charge of long-term care insurance that hold jurisdiction over the long-term facilities, etc. in their organizations.

*1 Small-bore connectors for the neuraxial applications (ISO 80369-6) include sterilized anesthetic puncture needles and are shown in the Appendix. Injection needles for subcutaneous administration, etc. are not subject to the scope of neuraxial applications regardless of procedural site or procedure.

*2 The certification standard refers to the standards for medical devices as defined in the Medical Devices with Specific Standards Designated by the Minister of Health, Labour and Welfare based on Article 23-2-23 of the Law on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (Ministerial Notification No. 112 of the Ministry of Health, Labour and Welfare in 2005).

1. Period etc. for shipment of products subject to the existing standards (hereinafter referred to as the “existing standard product(s)”)

Marketing authorization holder of the existing standard products should promptly perform procedures (submission of application for approval [certification] of partial change to the approved (certified) items (hereinafter referred to as PCA) or minor change notification, etc.) required for the change from existing standard products as classified under generic names shown in the Appendix to the new standard products quoted in the approval or certification standards in the standard/remarks column of the Appendix (hereinafter referred to as approval standards etc.) on or after the date of revision to the Japanese Industrial Standards.

In view of prompt switching to the new standard products in medical practice, the period for shipment of existing standard products by marketing authorization holders shall be terminated by the end of the month 2 years from the date of revision to the standard for approval, etc. (i.e. end of February 2020).

2. Handling of PCA and minor change notification for existing standard products

The procedures for changing connectors subject to the existing standards as stated above to comply with ISO 80369-6 are as follows:

(1) Handling of medical devices

1) Scope of minor change notification

The scope of minor change notification is as shown below. When a change defined in iii alone is implemented, the changes in written description may be included in the first PCA or minor change notification submitted after conformity with the new standard is confirmed by the marketing authorization holder.

i. Change of the shape of connector from the existing standards to the new standard
ii. Change within the scope of minor change defined in the Procedures for Change in Raw Materials for Medical Devices (PFSB/ELD/OMDE Notification No. 0329-7, dated March 29, 2013)
iii. Change of the standard for connector defined in the column for standards related to performance and safety, etc. from the existing standards to the new standard

2) Scope of PCA

The scope of PCA is as follows. When the same change is to be made to more than one product, a PCA may be submitted for a selected representative product, followed by minor change notifications for the other products after the PCA for the representative item is approved or certified.

In this case, the reason for the selection of the representative product, a list of products to be included in the subsequent minor change notifications (brand names, generic names, approval [certification] numbers) and the product summary (package insert, etc.) should be attached to the form of the PCA of the representative item. For the selection of a representative product, one with the highest classification must be selected in principle, and Simple consultation of the Pharmaceuticals and Medical Devices Agency should be utilized as appropriate.

i. Change in the standard column for performance and safety (change other than those defined in 1) iii)
ii. Change in the materials of a connector (change other than those defined in 1) ii)

(2) Handling of combination products corresponding to drugs

In principle, change in the connectors as the device of combination products corresponding to drugs shall be subject to PCA. However, for a change in the shape of a connector alone with no change in the material which comes in contact with the drug solution and the contact area between the drug solution and the container, a minor change notification may be submitted. When a PCA is submitted, the required procedure should be facilitated through measures such as utilization of Pre-, or Simple consultation with the Pharmaceuticals and Medical Devices Agency.

3. Identification labeling of the new standard products

In order to prevent confusion between the new standard and the existing standard products, the new standard products should be identified as such with a labeling, for example, of "ISO 80369-6"on the secondary package of each product.

Identification labeling is also preferable on the medical device itself and the primary package in terms of prevention of mix-up.

4. Use of connectors for connection between the existing standard and the new standard products, etc.

In terms of prevention of misconnections, connectors for connection between the existing standard and the new standard products (hereinafter referred to as "conversion connectors") should not be used in principle.

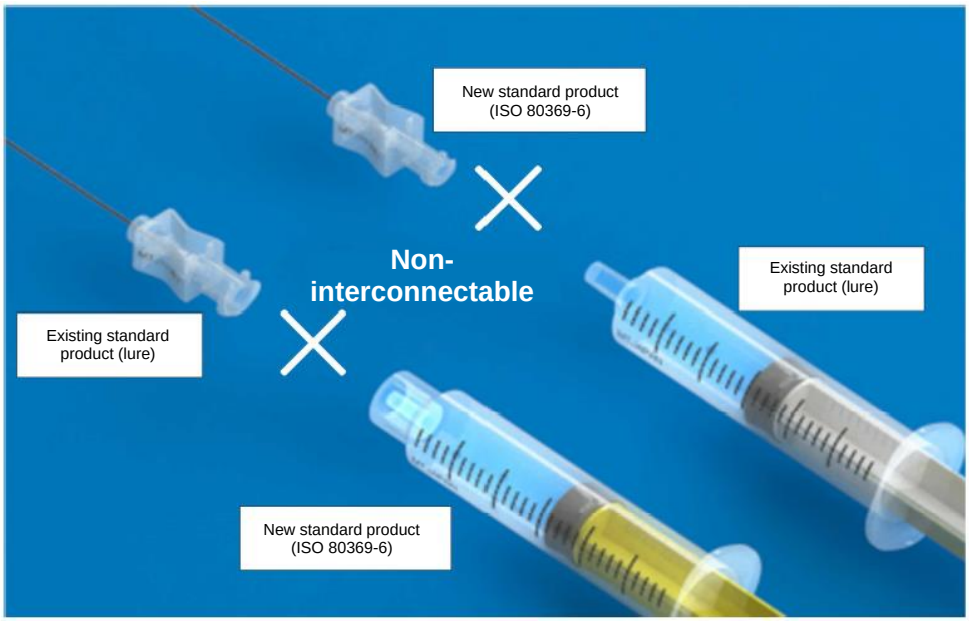
However, a minimum necessary number of conversion connectors may be supplied only when requested by a medical institution to avoid the risk that the treatment, etc. in medical practice is interfered with due to non-compatible connection between the existing standard and the new standard products.

The period for shipment of conversion connectors from marketing authorization holders and distributers shall be terminated corresponding to the termination of shipment of existing standard products.

Attachment

Main Product groups for neuraxial applications and changes in the shape of connector

The new standard products (products complying with ISO 80369-6) are non-compatible with the existing standard products.



[Examples of the new standard products] (Including products used in connection (combination) with the new standard products.)

Spinal needles, epidural needles, epidural anesthesia catheters, epidural/spinal anesthetic needles, nerve block needles (mainly for epidural and spinal/subarachnoid administration), epidural anesthetic filters, loss of resistance syringes, syringes (for neuraxial applications), Elastomeric infusion system (for neuraxial applications), extension tubes (for neuraxial applications), three-way stopcocks (for neuraxial applications), liquid sampling needle (for neuraxial applications)

Note) Kits/sets containing the above are also to be subject to the new standard.

[Details of non-compatibility]

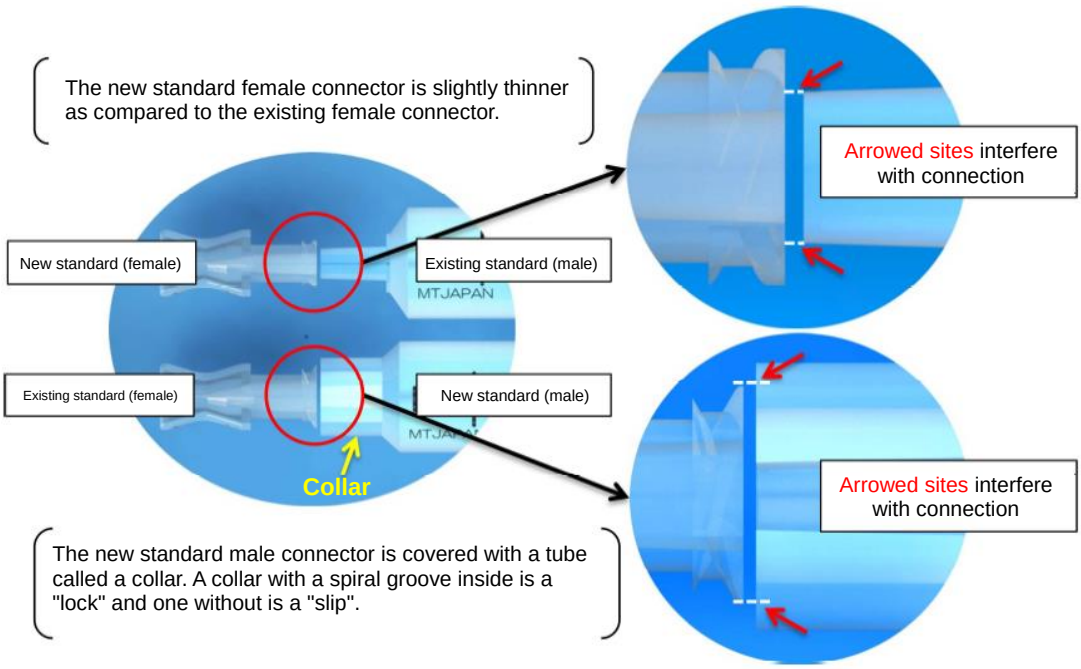


Figure courtesy of the Medical Technology Association of Japan

Appendix

A list of products for neuraxial applications (ISO 80369-6)

Products with approval standards within the scope of ISO 80369-6

Generic name	Class*	Standards/Remarks
Needle, anesthesia, sterile	III	Approval standards for needle, anaesthesia, sterile
Needle, anaesthesia, spinal	III	Approval standards for needle, anaesthesia, spinal
Needle, anaesthesia, epidural	III	Approval standards for needle, anaesthesia, epidural
Needle, anaesthesia, spinal/epidural	III	Approval standards for needle, anaesthesia, spinal/epidural
Catheter, anaesthetic conduction	III	Approval standards for catheter, anaesthetic conduction

Products with certification standards within the scope of ISO 80369-6

Generic name	Class	Standards/Remarks
Needle, puncture, anesthesia, temporary use	II	Certification standards for needle, puncture, anesthesia, temporary use
Filter, anaesthetic	II	Certification standards for filter, anaesthetic
Syringe, anaesthesia	II	Certification standards for syringe, anaesthesia

Products without approval or certification standards within the scope of ISO 80369-6

Generic name	Class	Standards/Remarks
Catheter epidural	III	
Anesthetic infusion set	III	
Portable continuous anesthesia kit	III	
Spinal-epidural anesthesia kit	III	
Spinal anesthesia kit	III	
Loss of resistance syringe for epidural space localization	II	
Obstetric anesthesia kit	II	
Caudal anesthesia kit	II	
Brachial plexus anesthesia kit	II	
Epidural anesthesia kit	II	
Loss of resistance syringe without needle for epidural space localization	I	
Reusable lumbar puncture needle	I	
Anesthetic syringe	I	
Reusable lumbar puncture kit	I	

Products to be used also in other areas within the scope of ISO 80369-6

Generic name	Class	Standard/Remarks
Injector, medication, pressurized (including connection-type PCA device)	III	Approval standards for injector, medication, pressurized
Single-use Class III procedure kit	III	
Stopcock, infusion pump	II	Certification standards for stopcock, infusion pump, etc.
Tube, extension, infusion pump	II	Certification standards for tube, extension, blood transfusion/catheter, etc.
Intravenous line extension kit	II	
Extension tube	II	
Needle, lumbar puncture	II	Certification standards for needle, biopsy, single-use, etc.
Lumbar puncture kit	II	Certification standards for needle, biopsy, single-use, etc.
Single-use Class II procedure kit	II	
Syringe for prefilled drug with needle	II	Certification standards for syringe for prefilled drug with needle
Glass syringe	I	
Extension tube for infusion	I	
Stopcock	I	
Liquid sampling needle	I	
Instruments for adjustment of drug solution	I	
Catheter connector	I	
Syringe cap	I	
Syringe/needle adapter	I	
Single-use Class I procedure kit	I	
Infusion accessory set	I	
Universal stopcock valve	I	
Prefill syringe	I	

* Classification of medical devices based on Attachment 1 of "Revision to Rules of Classification Related to Specially Controlled Medical Devices, Controlled Medical Devices and General Medical Devices" (PFSB Notification No. 0510-8, by the Director of Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, dated May 10, 2013)