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

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Ministry of Health, Labour and Welfare
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Director of Medical Device Evaluation Division,
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Introduction of the International Standards (ISO (IEC) 80369 series) Related to Connectors for Prevention of Interconnection

In Japan, based on Establishment etc. of Standards for Medical Devices to Prevent Medical Accidents (Standards for syringe-type manual infusion instruments, etc.) (PMSB Notification No. 888, by the Director of Pharmaceutical and Medical Safety Bureau dated August 31, 2000), measures have been taken to ensure that connectors of an administration line for internal medication and of an infusion line for intravascular administration of drug solution are physically non-interconnectable in terms of prevention of risk for infusion errors, etc. such as internal medication solution to be administered via an enteral nutrition line into the blood vessel by mistake.



In recent years, establishment of the international standards ^{Note)} (ISO [IEC] 80369 series. Hereinafter referred to as the "new standards") related to connectors for prevention of interconnection across product areas has been proceeded. For the promotion of measures to prevent medical accidents and stable supply of products in line with international harmonization, the measures and policies for introduction of the new standards have also been considered in Japan.

Products subject to the new standards (hereinafter referred to as the "new standard product(s)") will be sequentially marketed. However, non-compatibility between the new standard products and products subject to the existing standards (hereinafter referred to as the "existing standard product(s)", see Attachment) may occur depending on the product area, and there is concern over administrative effects related to medical safety in medical institutions. In consideration of this, commissioners of the health department are requested to disseminate the information to business entities and medical institutions involved, etc. under their supervision, and also to the divisions (bureaus) in charge of long-term care insurance that hold jurisdiction over the long-term care facilities, etc., in their organizations to draw attention to the following points when introducing the new standard products.

The period for switching from the existing standard products to the new standard products for each product area will be separately announced as appropriate.

1. Related marketing authorization holders (including distributors) should verify the risk of unavailability of devices due to non-compatibility between the new standard products and existing standard products in the market, sufficiently coordinate switching with medical institutions in advance, provide necessary information, and also provide necessary information regarding the timing of terminating the supply of their own existing standard products in a timely manner.
2. Medical institutions, etc. should ensure medical safety through measures such as appropriate inventory management in their own facilities based on sufficient information received from related marketing authorization holder, etc.
3. In terms of prevention of misconnections, connectors for connection between the existing standard products and the new standard products (hereinafter referred to as "conversion connectors") should not be used in principle.

Handling of conversion connectors in restricted use may be notified separately for each product area when necessary.

Note) For small-bore (the inner diameter of connector is ≤ 8.5 mm) luer connectors to be connected with a medical device (including the devices of combination products corresponding to drugs [e.g. prefilled syringe]), establishment of the new standards for connectors (ISO [IEC] 80369 series) is ongoing jointly by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) for the purpose of preventing misconnections by disabling interconnection between connectors used in different product areas. ISO 80369-1, the general requirement for the aforementioned standard, was established in December 2010, and ISO and IEC are currently promoting establishment of the new standards for the product groups related to the following 6 product areas.



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Standard No.	Product area
ISO 80369-2	Breathing system and driving gases applications
ISO 80369-3	Enteral applications
ISO 80369-4	Urethral and urinary applications
IEC 80369-5	Limb cuff inflation applications*
ISO 80369-6	Neuraxial applications ^{Note 3)} (spinal anesthesia, epidural anesthesia and nerve block)*
ISO 80369-7	Intravascular or hypodermic applications*

Note 1) Branch numbers are not in the order of establishment of standard.

Note 2) Standards with * have already been established.

Note 3) Some types of neurological anesthesia using an injection needle for subcutaneous administration, etc. are excluded.



Outline of the international standards related to connectors for prevention of interconnection (ISO [IEC] 80639 series)

The international standards ISO (IEC) 80639 series classifies possible connections at bedside into 6 areas of application as shown in the illustration below, and stipulates non-compatibility to prevent medical accidents.

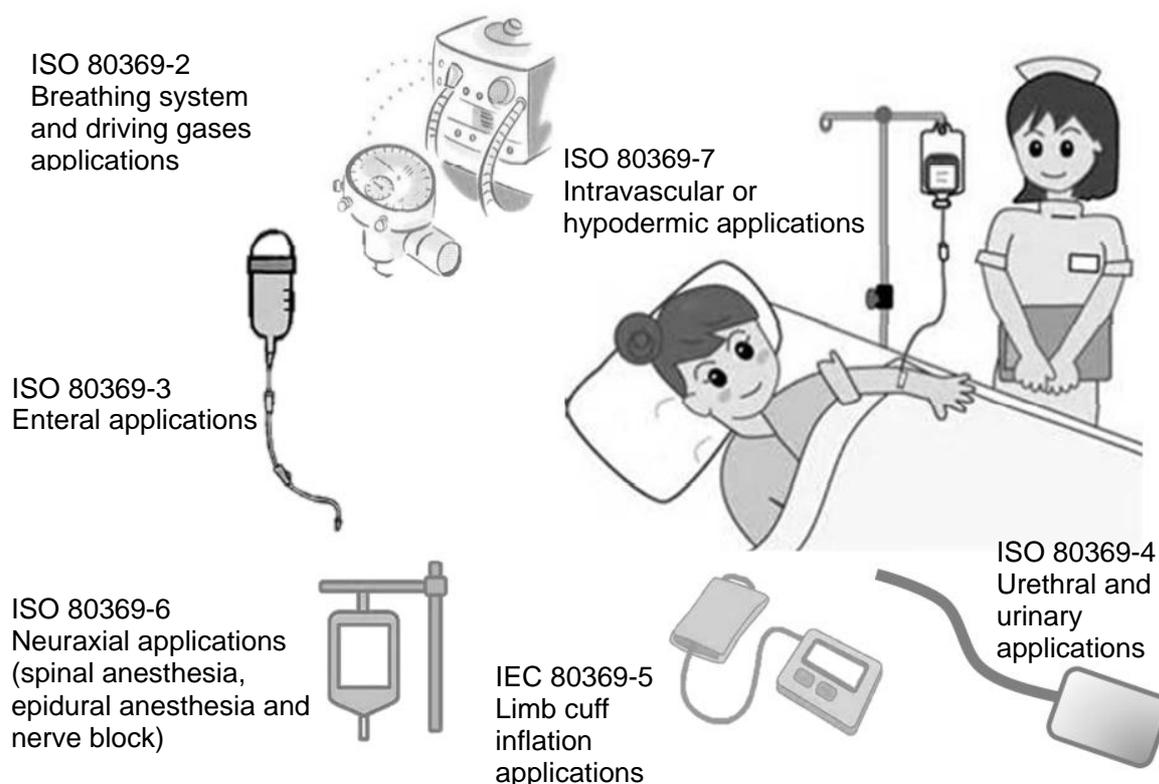


Figure courtesy of the Medical Technology Association of Japan

Although some ISO standards have not yet been established, products complying with ISO (IEC) 80369 series (the new standard products) may not be compatible with the existing standard products, and this may result in an inability to use both products together.

However, since the new standards originally started as the consideration of non-interconnectability, with the standards of the connectors for intravascular or hypodermic applications as the reference point, non-compatibility issues with the existing standard connectors will not arise for intravascular or hypodermic applications under the new standards.

The switching period and outlines of connectors for each product area will be sequentially informed from autumn 2017, starting with the area of neurological anesthesia.