ISO 80369: A New Standard to Avoid Medical Device Misconnections

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Today's hospitals and health care facilities are normally places of healing and restitution, technically advanced healing centers where people go to get well, improve their bodies, and learn how to live stronger and more productive lives. Sometimes, though, the hospital environment poses risks we cannot see, ranging from contagious, hospital-acquired infections to medical personnel inadvertently miscalculating a patient's treatment. Improper use of medical device equipment and a patient's often-complex "connection" process also fall into this realm. With patient lives at stake, the healthcare industry considers it a top priority to reduce the number of misconnections with patients, and to that end has upgraded to a new standard known as ISO 80369.

In a hospital environment, patients often have multiple medical devices and lines connected to them to receive medicine and nutrients. Numerous devices and systems use universal connectors to deliver medicine, food and fluids to the patient. A healthcare worker or patient could mistakenly connect one device used for one application, such as enteral therapy, to another device used for another application, such as intravenous therapy. This situation can bring dire—and even fatal—consequences to the patient.

What Are Misconnections?

A medical device misconnection is often defined as "a connection between devices that is not intended to connect, unintentionally delivering medication, oxygen or fluid to the wrong place." To mitigate this problem, the U.S. Food and Drug Administration (FDA), the International Organization for Standardization (ISO) and the medical device industry have taken actions to reduce the likelihood of misconnections by creating a new industry standard: ISO 80369. This standard has been developed to prevent misconnections between small-bore connectors used in different applications, defined as connectors with internal diameters of less than 8.5 mm.

ISO 80369 consists of six parts:

- Part 1 (ISO 80369-1) describes the general specifications for small-bore connectors.
- Part 2 (ISO 80369-20) describes the test methods to assess the compliance of a small-bore connector to the standard.
- The remaining four parts describe in detail the design specification for connectors depending on their application: Enteral (ISO 80369-3), Limb Cuff Inflation (ISO 80369-5), Neuraxial (ISO 80369-6) and Intravascular Applications (ISO 80369-7).

ISO 80369-7 cancels and replaces the first edition of ISO 594-1:1986 and the second edition of ISO 594-2:1998, clauses, subclauses, tables, figures and annexes of which have been consolidated and technically revised. The change was implemented in 2016 so needle and syringe 6% Luer taper connectors could be included under the small-bore connector collection of ISO 80369 specifications. This standard will be mandatory as of January 2020, with the FDA still receiving applications that comply with the old standard until December 2019.

Small-bore connectors are used in various applications and therefore exposed to different substances: aggressive drugs, lipids, carrier solvents and various gases. Such substances may result in chemical attack of small-bore connectors, which can prevent devices from properly doing their job and cause them to fail prematurely under stress, putting patients and medical personnel at risk. When selecting the material for small-bore connectors, it is important to comply with the new ISO 80369 standard, but also to understand the forces and substances with which the connectors will be in contact.

For example, for medical devices used in oncology or nutrition therapies, materials should comply with oncology drugs, have lipid and chemical resistance, and be durable, clear and able to withstand different sterilization methods. The most common materials for small-connectors can range from PC/ABS and

PVC compounds to materials with better chemical resistance like copolyesters, nylons and acrylics. Which material to use will depend on the characteristics of the application and the substance and forces to which the small-bore connectors will be exposed.

Reducing Risk and Improving Outcomes

With so much at stake for patients and the healthcare providers who care for them, the new ISO 80369 standard for small-bore connectors offers the industry an important way to eliminate mistakes while improving patients' outcomes. Adopting the new standard will be crucial for companies that seek to remain competitive in the medical market as a consolidated player. Medical device manufacturers and small-bore connector producers will be able to reduce issues generated by medical device misconnections by carefully adhering to each part of the ISO80369 standard.

References:

"ISO 80369-3:2016," International Organization for Standardization, https://www.iso.org/standard/50731.html, (July 2016)

"ISO 80369-7:2016," International Organization for Standardization, https://www.iso.org/standard/58011.html, (October 2016)

"ISO 80369-6:2016," International Organization for Standardization, https://www.iso.org/standard/50734.html, (March 2016)

"ISO 80369-5:2016," International Organization for Standardization, https://www.iso.org/standard/50733.html, (March 2016)

"ISO 80369-20:2015," International Organization for Standardization, https://www.iso.org/standard/63837.html, (May 2015)

"ISO 80369-1:2010," International Organization for Standardization, https://www.iso.org/standard/45976.html, (December 2010)

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