

Reducing the risk of medical device tubing misconnections

Incompatibility by design—progress toward ISO 80369¹ standards for small-bore connectors

Small-bore connectors are important components of many medical devices and patient delivery systems.

The widespread use of traditional, flexible small-bore Luer connectors in diverse patient care applications created an environment that permitted connection between unrelated clinical therapeutic systems—e.g., vascular, enteral, respiratory, epidural, and limb cuff. This type of tubing misconnection has resulted in serious patient injury and death. (See examples from the U.S. Food and Drug Administration [FDA] on page 4.)

Changing standards for small-bore connectors

In the interest of patient safety and risk mitigation, the FDA, the international standards community, and the medical device industry are taking actions to reduce the likelihood of tubing misconnections.

Beginning in the early 2000s, this global collaboration has focused on developing standards for how mating halves of clinical therapeutic systems connect. The International Organization for Standardization (ISO) has been at the center of these changes and began publishing standards for ISO 80369 in 2010. (See a timeline of progress on page 3.) The original standards document (ISO 80369-1:2010) outlined general requirements for small-bore connectors for liquids and gases in health care applications, including design, material selection, and testing methods.

The committees assigned to each delivery system face unique challenges and each is progressing in stages. Their work is grounded in human-factors engineering and computer-aided design (CAD) analysis to reduce the likelihood of misconnections.

Inside, you will discover ...

- ➔ *ISO 80369 introduction and timeline*
- ➔ *Examples of device misconnections (FDA case studies)*
- ➔ *Importance of early compliance*
- ➔ *Implications for design and material selection*
- ➔ *Resources*

2016 is a critical year for ISO 80369.

After nearly 20 years of collaboration and 6 years of publications, the committees' work toward global release of the ISO 80369 series of standards has reached a point of critical mass, shifting from a development stage to an implementation stage.

In addition to recent committee action and approval of several system standards, California HB 1867 recently became law. Beginning January 11, 2016, HB 1867 prohibits general acute care, acute psychiatric, and specialty hospitals from using an epidural, intravenous, or enteral feeding connector that fits into a connection port other than the type for which it is intended.²

To date, there are no federal mandates for manufacturers or health care organizations to comply with ISO 80369. The ISO affiliate organization in the U.S.—the Association for the Advancement of Medical Instrumentation (AAMI)—expects that all medical device manufacturers and suppliers will comply with the new California law and develop modified products with compliant connectors.³

¹ <http://www.fda.gov/medicaldevices/safety/alertsandnotices/tubingandluermisconnections/ucm313322.htm>

² *Stay Connected—FAQs About Small-Bore Connectors and Tubing Misconnections, #14.* Available at http://www.ismp.org/newsletters/acutecare/articles/Stay_Connected_10152013.pdf. Accessed 20 Jan. 2016.

³ *ISO 80369 Standards for Small-Bore Connectors Move Closer to Implementation.* Medical Design Briefs.com, 01 May 2015. Available at <http://www.medicaldesignbriefs.com/component/content/article/1105-mdb/features/22072-iso-80369-standards-for-small-bore-connectors-move-closer-to-implementation?start=1>. Accessed 13 Jan. 2016.

Do your products comply with ISO 80369?

As adoption of all new standards for ISO 80369 draws closer, a medical device OEM should proactively determine:

- How well will my current materials comply with the new ISO 80369 standards?
- How will the change impact my business?
- How will we use the new standards in product designs and 510(k) submissions?
- How can we select materials to improve our opportunities for innovation?

How and when will ISO 80369 affect your medical devices?

ISO 80369 at a glance

ISO 80369 is a set of standards developed to reduce the risk of misconnections in critical patient systems. The different parts of the standards target specific needs of the systems shown in Figure 1—6 delivery systems as well as a general statement (ISO 80369-1) and common test methods for compliance (ISO 80369-20).

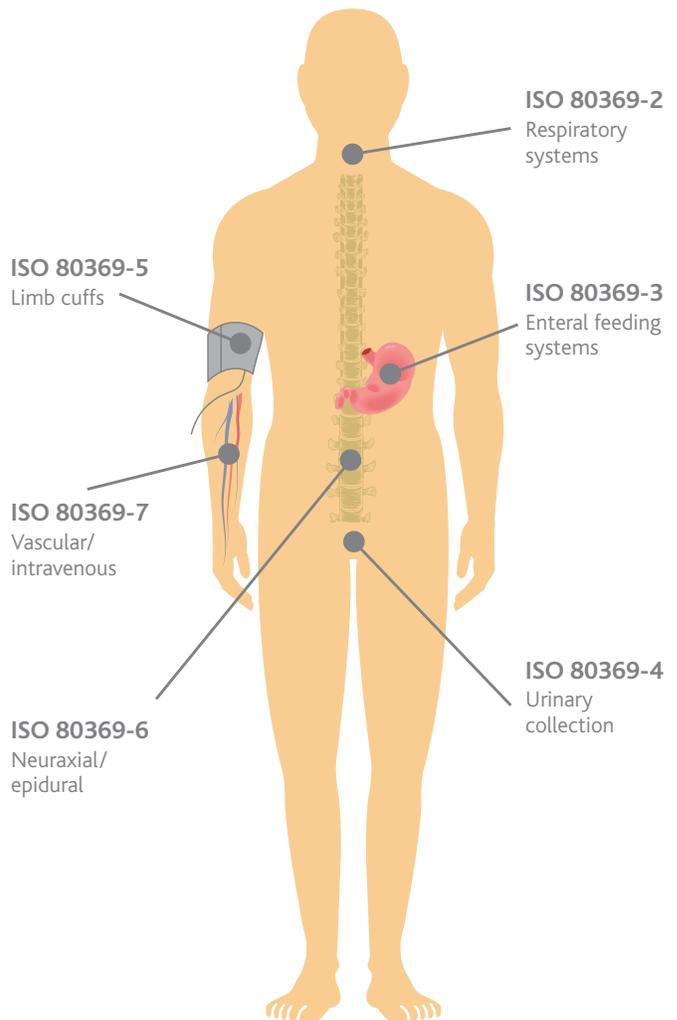
ISO 80369 is the result of a methodical process of coordinating and integrating data and testing from participant manufacturers, clinicians, and regulatory agencies around the world.

Organizations that are expected to endorse the new standards include:

- The Joint Commission, the major accreditation agency for U.S. hospitals seeking Medicare and Medicaid reimbursement
- Novation and Premier, two major group purchasing organizations
- The Global Enteral Device Supplier Association (GEDSA), whose Stay Connected information programs and ENFit™ enteral connector standard are leading the way to understanding and adoption of ISO 80369-3 standards.

Figure 1—Therapeutic systems affected by ISO 80369

ISO 80369-1 provides general guidelines. Standards 2 through 7 apply to 6 specific systems (shown here). ISO# 80369-20 defines common test methods.



Tubing misconnections can result in life-altering injury and death.

Cases reported by the FDA include:

- Feeding tube connected to tracheal tube
- Epidural tubing connected to IV tubing
- Oxygen tubing connected to needleless IV port
- IV tubing connected to enteral feeding tube
- Foley catheter connected to NG tube
- Enteral feeding tube connected to ventilator in-line suction catheter

Additional information about each case can be found on the FDA website: <http://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM134873.pdf>.

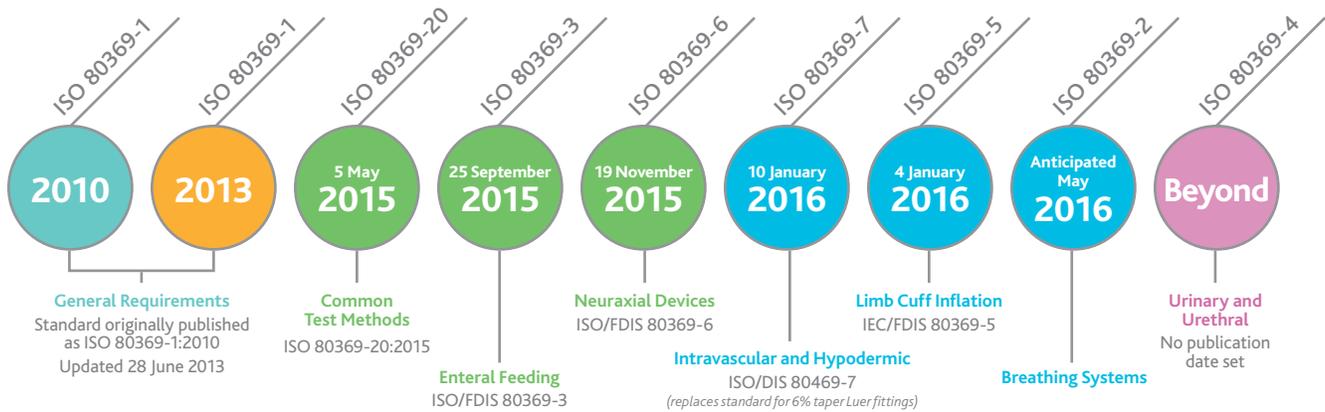
(Cases also have been reported by The Joint Commission, ISMP, and the ECRI Institute.)



Figure 2—An ISO 80369 timeline

The series of ISO 80369 standards will be adopted in stages, with allowances made for transitioning to the new standards. Figure 2 shows the progress, using information available today.

NOTE: To ensure the most current information on each section, see "Resources" on page 4.



Importance of early compliance with ISO 80369

Powerful market forces are encouraging compliance with the new standards as they are adopted.

- With Medicare and Medicaid now penalizing health care systems for poor outcomes and readmission rates, hospital customers are hypersensitive about performance.
- If product choices contribute to poorer outcomes, hospitals will switch to products perceived to be safer.
- Ultimately, systems that do not follow the new safety standards may suffer brand equity damage and lost sales.

Implications for design and material selection

The new small-bore connector standards are dimensionally driven—with connector material playing an important role.

- The proposed unique designs for the connectors must go through a rigorous process to ensure they connect only to the proper mating connector.
- The standards propose that materials used to make these connectors must be semirigid to rigid—having a modulus of elasticity, either in flexure or in tension, greater than 700 millipascals (mPa)—to prevent physically force-fitting mismatched connectors.

One clear polymer that provides this rigidity is Eastman Tritan™ copolyester. In addition to helping you meet the new ISO 80369 standards, Tritan provides many other advantages, including:

- Excellent chemical resistance to oncology drugs, drug carrier solvents, hospital disinfectants, plasticizers, and lipids
- Excellent solvent bonding to PVC or TPU tubing
- Excellent toughness and clarity
- Color stability after e-beam or gamma sterilization
- Free of BPA, BPS, halogens, and phthalate plasticizers

Tritan has been tested for chemical resistance and durability against polycarbonate (PC), PMMA, tABS, TPE, and TPU. To see test results and learn more about the technical design and molding expertise available from Eastman Chemical Company, contact an Eastman medical polymer specialist.

Connect with innovation.

The sections of ISO 80369, as well as parallel standards from the AAMI and recommendations from the FDA, will continue to be updated and approved in advance of mandatory regulations.

Resources

Use these resources for an ongoing flow of information about patient safety and ISO 80369 and related AAMI standards for small-bore connectors. If you have questions, visit eastman.com/medical.

Association for the Advancement of Medical Instrumentation (AAMI)
<http://www.aami.org/>

For the latest publications, visit the AAMI store: <http://my.aami.org/store/SearchResults.aspx?searchterm=small%20bore&searchoption=ALL>.

Global Enteral Device Supplier Association (GEDSA)
<http://gedsa.org>

Stay Connected information at <http://www.stayconnected.org>

ENFit™ press release at <https://www.ismp.org/newsletters/acutecare/showarticle.aspx?id=105>

ENFit information also available at manufacturers, including Medela, Nordson, Colder Products, Nestlé, Nutricia

Institute for Safe Medical Practices (ISMP)
www.ismp.org

U.S. Food and Drug Administration (FDA)

- <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections>
- <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/ucm313275.htm>
- <http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/TubingandLuerMisconnections/ucm313320.htm>
- <http://www.fda.gov/MedicalDevices/Safety/MedSunMedicalProductSafetyNetwork/ucm127745.htm> (pre-ISO 80369)
- <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM313385.pdf>

Novation (health care group purchasing organization)
<http://www.healthcaregpoii.com/signatorycompanies/novation.html>

Premier (health care group purchasing organization)
<https://www.premierinc.com/events/advisor-live-new-standards-medical-tubing-connectors-ready>

Current ISO 80369 standards

ISO General Standards (ISO 80369-1:2010): http://www.iso.org/iso/catalogue_detail.htm?csnumber=45976

Committee updated 28 June 2013: http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=45976&commid=54892

ISO/FDIS 80369-3 (25 Sept. 2015): http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?ics1=11&ics2=040&ics3=25&csnumber=50731

IEC/FDIS 80369-5 (4 Jan. 2016): http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?ics1=11&ics2=040&ics3=25&csnumber=50733

ISO/FDIS 80369-6 (19 Nov. 2015): http://www.iso.org/iso/catalogue_detail.htm?csnumber=50734

ISO/DIS 80369-7 (10 Jan. 2016): http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=58011

ISO 80369-20:2015 (15 May 2015): http://www.iso.org/iso/home/store/catalogue_ics/catalogue_detail_ics.htm?ics1=11&ics2=040&ics3=25&csnumber=63837 (also available at http://www.iso.org/iso/catalogue_detail.htm?csnumber=63837)

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It is the responsibility of the medical device manufacturer ("Manufacturer") to determine the suitability of all component parts and raw materials, including any Eastman product, used in its final product to ensure safety and compliance with requirements of the United States Food and Drug Administration (FDA) or other international regulatory agencies.

Eastman products have not been designed for nor are they promoted for end uses that would be categorized either by the United States FDA or by the International Standards Organization (ISO) as implant devices. Eastman products are not intended for use in the following applications: (1) in any bodily implant applications for greater than 30 days, based on FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" tests (including any cosmetic, reconstructive, or reproductive implant applications); (2) in any cardiac prosthetic device application, regardless of the length of time involved, including, without limitation, pacemaker leads and devices, artificial hearts, heart valves, intra-aortic balloons and control systems, and ventricular bypass assisted devices; or (3) as any critical component in any medical device that supports or sustains human life.

For manufacturers of medical devices, biological evaluation of medical devices is performed to determine the potential toxicity resulting from contact of the component materials of the device with the body. The ranges of tests under FDA-Modified ISO-10993, Part 1, "Biological Evaluation of Medical Devices" include cytotoxicity, sensitization, irritation or intracutaneous reactivity, systemic toxicity (acute), subchronic toxicity (subacute), implantation, and hemocompatibility. For Eastman products offered for the medical market, limited testing information is available on request. The Manufacturer of the medical device is responsible for the biological evaluation of the finished medical device.

The suitability of an Eastman product in a given end-use environment is dependent on various conditions including, without limitation, chemical compatibility, temperature, part design, sterilization method, residual stresses, and external loads. It is the responsibility of the Manufacturer to evaluate its final product under actual end-use requirements and to adequately advise and warn purchasers and users thereof.

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