# ISO 80369 Standards on Small-Bore Tubing Connectors

## Inch Forward Toward Release

Some sections of the standard could be adopted as early as fourth quarter 2014. Manufacturers are committed to launching the new connectors with minimal disruption to supply and clinical practice and to working through existing inventory. A phase-in period for product development and implementation will be guided by the U.S. Food and Drug Administration (FDA) and state legislation.

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The Luer connector has, for decades, been one of the most common types of small-bore (less than 8.5mm) connectors used in hospitals and other healthcare facilities to link or join medical devices, components, and accessories for the purpose of delivering fluids or gases. A typical patient can be connected via tubes/catheters and Luers to several delivery systems – vascular, enteral, respiratory, epidural, or intrathecal – to receive medication, nutrients, fluids, and gases. Connectors are also made to provide limb cuff attachments or wound pressure treatment, or for draining of the body's fluids. But just as the Luer's simple and universal design has allowed for ease of use in diverse patient-care applications, permitting connection between unrelated patient delivery systems that have different intended uses, so too has it made possible the inadvertent connection of wrong systems by healthcare providers, with detrimental and fatal consequences to patients. The problem is well documented. The U.S. Food and Drug Administration, The Joint Commission, the Institute for Safe Medication Practices, the United States Pharmacopeia, and the ECRI Institute have all received reports of misconnection errors.

The effort to minimize these system misconnections, also called Luer misconnections or wrong-route errors, has been approached in the past by some manufacturers using color coding with their connectors. Others have developed proprietary alternative connectors and product designs that are incompatible with Luer connectors, such as for intravenous delivery systems, which are frequently involved in misconnections. Proprietary connectors are also widely found in blood pressure systems where the safety concern of delivering air through an IV or an enteral port is present. These efforts have not proven successful in eliminating the problem. What was needed was a design change and correlating standards, which would make misconnections between unrelated delivery systems, medical devices, and accessories highly unlikely.

### Initiating a Universal Standard

In 2009, an international group of manufacturers, clinicians, and regulators, including the FDA, collaborated with the International Organization for Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to reduce the frequency of small-bore connector hazards. To this end, the group initiated the development of a new standard known as ISO 80369.

The AAMI was charged with organizing technical committees and working groups to produce the ISO 80369 standards, and recommend practices and technical information reports for medical device compliance to these standards.

ISO 80369 is divided into seven sections.

**Plastic diaphragm check valves excel at removing air bubbles from their downstream flow path.**

The first section (Part 1) identifies the general requirements for small-bore connectors, and the following six identify specific requirements for connectors falling into one of the following general application areas: Part 2) breathing and driving gases; Part 3) enteral (feeding tube) applications; Part 4) urethra and urinary; Part 5) limb cuff inflation or non-invasive blood pressure; Part 6) neuraxial applications; and Part 7) intravascular or hypodermic applications. Other standards may be added later, if warranted by patient safety risk and clinical need.

The first of these standards, 80369-1, was published in January 2011. It provides general requirements for small-bore connectors for liquids and gases in healthcare applications. It also establishes a framework for testing connectors to ensure non-interconnectability of unrelated delivery systems. International standards for non-Luer-compatible, delivery system-specific connections have since been under development. Each additional standard in the series focuses on connectors for each of the remaining six specific clinical applications, which will be released as they are completed.

The adoption of ISO 80369 as an international standard for small-bore connectors will ensure compatibility and consistency that influences several patient-care factors: a) Standardized connections across the healthcare delivery systems; b) Greater ability for manufacturers' devices to integrate, while making it difficult, if not impossible, for unrelated delivery systems to be connected; and c) Less likelihood of therapy interruption due to connector incompatibility or unavailability.



## Design Methodology

The system required to approve the ISO 80369 standards is a methodical and tedious process of coordinating and integrating data and testing from participant manufacturers, clinicians, and regulators. The procedure involves participation in repetitive committees, including the following actions: a) Post-committee completion of a CD, then sending out for review and feedback; b) Addressing and incorporating feedback, in committee, then conducting usability testing with actual molded connectors; c) Sending out another revision as a DIS (Draft International Standard) for final review and vote; d) if approved, submitting the standard to the members as an FDIS (Final Draft International Standard); and e) Sending the standard to ISO for review and approval. Each of these steps takes considerable time for review, comment, and incorporation into the final standard. This procedure is necessary to ensure that connectors for unrelated patient delivery systems are incompatible.

The new small-bore tubing connector designs are dimensionally driven. The design methodology is based on human-factors engineering and computer-aided design (CAD) analysis to reduce the likelihood of misconnections. The proposed unique designs for the connectors go through a rigorous process to ensure they connect only to the proper mating connector. It was proposed that the materials used to make these connectors have a minimum hardness value to prevent interconnectability when force fitted. Proposed designs are validated through hands-on usability testing to confirm that they meet their intended purpose of preventing the connection of a medical device from one delivery system to a device of another delivery system. Analysis of design drawings and physical force-fit testing are used to verify that connectors that are supposed to connect do so securely, while connectors that should not join are physically prevented from doing so.

Challenges are an inherent factor in the process. There is a chance that connectors defined by different subcommittees may mate with one another, and analysis and testing will need to be done to avoid this, along with usability testing for each system.

The procedure of developing any ISO standard is a very deliberate and time-consuming process, and ISO 80369 is no different. Once a standard is established, then implementation will take additional time.

### Federal and State Mandates

As of February 2014, there were no federal mandates regarding small-bore connectors for manufacturers or healthcare organizations.

Effective January 11, 2016, a California law (HB 1867) will prohibit general acute care, acute psychiatric, and special hospitals from using an epidural, intravenous, or enteral feeding connector that fits into a connection port other than the type for which it was intended. The AAMI expects that all medical device manufacturers and suppliers will comply with the new California law, and develop modified products that incorporate the new connectors, while phasing out products with old connectors.

The FDA has announced that it is considering recognizing the ISO 80369 standards. If the FDA does recognize them, it will provide guidance to manufacturers regarding the timeline for devices currently on the market to come into compliance (typically three to five years).

The European Union (EU) and other international regulatory bodies have their own requirements for acceptance of the standards. Foreign medical device manufacturers wishing to sell product into U.S. markets, however, would need to comply with the ISO 80369 standards.

### Transition

The ISO 80369 committees are all engaged in varying amounts of progress. Most have significant work to be done to finalize connectors for their specific market.

Once the standards are approved, there will be a transition period marked by stages. That approach is under development and will be communicated by manufacturers with advanced warning so that all parties can prepare for the changes in the market.

The changes for the new standard connectors will roll out by delivery system. Manufacturers will incorporate the new connectors into their existing offerings where applicable. The introduction will include developing and executing a coordinated joint communications plan, identifying each unique connector with a common name to be used by all suppliers of devices for each respective delivery system.

Beginning in 2014, manufacturers of breathing systems and driving gases, enteral, limb cuff inflation, and neuraxial and urethral devices will need to redesign their products to accept the new small-bore connector standards as they are approved. Enteral feeding devices (ISO 80369-3), intravascular or hypodermic (ISO 80369-7), and limb cuff inflation (ISO 80369-5) are the ones likely to be among the first to be released, expected as early as fourth quarter 2014. The enteral devices that will be impacted include feeding tubes, administration sets, and syringes.

Manufacturers are prepared to launch new connectors with minimal disruption to supply and clinical practice. There will be a phase-in period for product development and implementation guided by the FDA, and existing state legislation (i.e., California). The standard generally allows three years to manufacturers for new product adoption of the new connector standards, and five years for adoption into existing devices. However, these timelines are

influenced by state legislation.

ISO 80369-7 states that the existing Luer connector will be maintained only for vascular access in the form of intravascular and hypodermic applications.

### Progress

The AAMI/ISO working group for small bore connectors for liquids and gases in healthcare applications (ISO 80369) met at the DIN office in Berlin, Germany between March 17 and March 21, 2014. The agenda of this meeting included reviewing the recent ballot results and arriving at a resolution of the following committee drafts: ISO/CD 80369-1 general requirements, ISO 80369-20 common test methods, ISO 80369-3 enteral feeding, and ISO 80369-7 intravascular. Updates were also provided by the task groups leading ISO 80369-5 limb cuff inflation, ISO 80369-6 neuraxial, and ISO 80369-2 respiratory.

Highlights from the Berlin working group include:

- ISO 80369-1 General Requirements – The current version is already released and available to the general public. A new version is being worked on by the committee and is expected to be released in 2016.
- ISO 80369-2 Connectors for Breathing Systems and Driving Gases Applications – The committee facilitated the creation of a task (sub) group that will be trusted with building tools, molding connectors, and completing the functional tests as per ISO 80369-20. The standard is expected to be released in 2015.
- ISO 80369-3 Connectors for Enteral Applications – The committee decided that the proposed E1 connector design is applicable for both adult and pediatric applications.
- ISO 80369-5 Connectors for Limb-Cuff Applications – Functional testing of parts conforming to the CAD designs are scheduled to start now. This standard is expected to be released in late 2014 or early 2015.
- ISO 80369-6 Connectors for Neuraxial Applications – Functional testing of parts conforming to the CAD designs is in progress. It was discovered that in certain situations, the parts could misconnect with luers. The CAD committee offered options during the meeting session, such as modified thread designs and revised specifications, to mitigate these misconnections. This standard is expected to be released between late 2014 and early 2015.
- ISO 80369-7 Connectors with 6% (Luer) Taper for Intravascular or Hypodermic Applications – The committee is now preparing a Final Draft International Standard (FDIS) draft. This standard is expected to be published late in 2014.
- ISO 80369-20 Common Test Methods – This standard is now expected to be released in late 2014.

### Patient Safety

The unique driving force about the ISO 80369 standard that is pushing the unilateral participation and collaboration by so many different manufacturers, healthcare providers, organizations, and regulatory bodies is patient safety. These medical devices, and the small-bore connectors that facilitate their application, are used to interface directly with patients in hospitals and healthcare facilities.

From the device manufacturer to the healthcare provider to the patient, it is a win-win situation of improved and safer medical care. **MDT**

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