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White Paper

Actionable Steps to Eliminate Small-Bore Connector Misconnection

Adopting ISO 80369

Abstract

The Japanese principle of "poka-yoke", or passive mistake-proofing, is a key principle of product design in many industries. The goal is simply to remove product defects by preventing human errors on the front end of a process, correcting them during the process, or drawing attention to them after a process is completed, to reduce the chance of part failure, insufficient performance, or most importantly user/operator safety. It is in this spirit that the ISO 80369 standard was written.

The standard incorporates design modifications, improvements and/or clarifies validation steps needed to take human error out of stressful medical facility situations. This study, focused on three medical device applications of ISO 80369, provides practical insight into the challenges and solutions that device designers can implement to ensure their products are standard-compliant.

For ISO 80369-3 (connectors for enteral applications), this paper lists the modulus of elasticity in two force directions, and it addresses a critical counterpoint regarding flow rate with the smaller nozzle aperture. For ISO 80369-6 (connectors for neuraxial device applications), this white paper describes geometric differences of the new fitting, and it addresses how end users can ensure that joining connectors from different manufacturers will interface properly. ISO 80369-7 (connectors for intravascular or hypodermic applications) describes nuances of the section of the standard specific to some of the most commonly misconnected device types, and designates what steps are needed for new or existing products to confirm or achieve compliance.

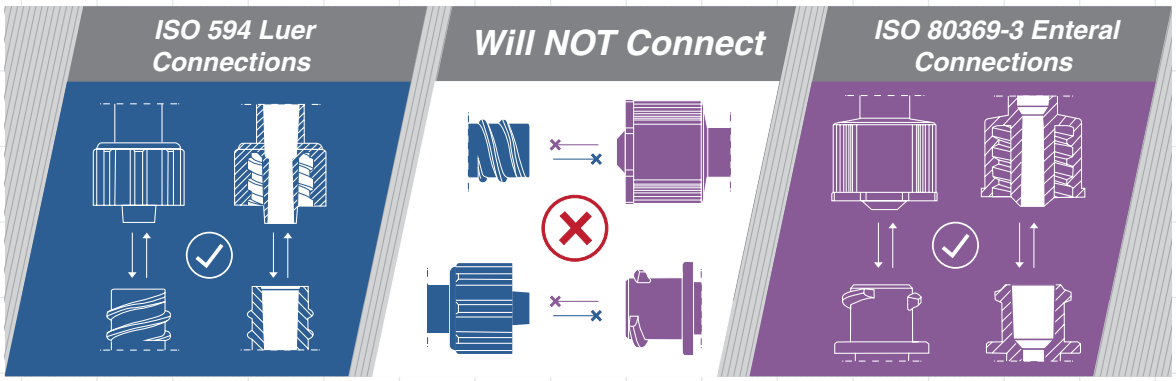
Problem Statement

During the stress of a high-intensity event in an emergency room or intensive care unit, there are many high-risk factors in play. Doctors, nurses, assistants and technicians are all working as rapidly as possible to help their patient. This critical work carries an inherent level of risk on its own, due to the complexity of potential ailments, diagnosis timing and the sheer amount of split-second decisions that have to be made. Due to the level of disruption to existing products and manufacturing processes, coupled with potential tooling investment, medical device suppliers and hospitals have been resistant to implementing the standard. In addition to all of that, the risk of medical device misconnection is also at its highest during those moments.

Due to variabilities in historic connection types, the industry adopted a standard geometry to mitigate the added time, cost and confusion of matching up incompatible male/female connectors. The decision-makers assumed commonizing the connection geometry would save time, affording the specialists more time for the critical aspects of their work.

With a boom of additional innovation in the medical industry as a whole, ERs, ICUs and operating rooms began to include increasingly higher amounts of equipment. What the device supply base did not plan on then, was the increasing likelihood of two standard-connection components (that were not meant to connect) now being errantly attached in the heat of the moment. This realization gave rise to ISO 80369, a standard meant to design out the misconnection failure mode of small-bore luer fittings used with liquids and gases. Luer slip connectors, originally intended to connect an intravenous cannula with a hypodermic syringe, became the standard for patient connections due to its simple design, size and ease of use. Images of the connection types are shown in Figure 1.

Figure 1: Luer Lock and Luer Slip fittings



Background Information

ISO 594, first published in 1986, governs the connection geometry of conical fittings with a 6% (luer) taper for syringes, among other types of medical devices. The general requirements standard, ISO 594-1, specifies characteristics to mitigate risks of the slip connectors from leaking, stress cracking, gauging and separation at low pressures. The standard also lists validation test methods for the performance requirements. ISO 594-2 added specification for the luer lock and used higher-pressure applications that must seal. The additional specifications govern the screw-lock that creates the seal in terms of the following: over-tightening, torque requirements and higher maximum force limits.

Upon mass implementation, misconnections became an increasingly prevalent issue. The FDA cites multiple case studies that led to the movement to design out medical device misconnection. Of the nine high harm-potential cases cited, six (67%) led to patient fatality. Some examples of the case studies are:

1. An anesthetist and a midwife mistakenly connected an epidural set to the patient's IV tubing. The epidural medicine was mistakenly delivered to the patient's IV, resulting in fatality.
2. A child was in a pediatric intensive care unit, and had both an IV line and a trach tube. The IV tube was mistakenly connected to the trach cuff port, causing the IV fluid to stretch and break the trach cuff, flooding the child's lungs with IV fluids. This again resulted in patient fatality.
3. An IV tube inadvertently connected to a nebulizer instead of the patient's oxygen tube, which had fallen off. The IV fluid aspirated into the patient's lungs upon inhaling. A respiratory therapist identified the misconnection, and the patient survived.
4. A similar misconnection occurred when an oxygen tube was disconnected from a nebulizer. The oxygen tube was accidentally attached to the patient's IV tubing Y-site by a staff member at the end of a double shift. The improper connection was broken quickly, but the patient died from an air embolism as a result of the error.
5. A patient's blood pressure cuff tubing was disconnected before a trip to the bathroom. When she returned, her spouse mistakenly connected the BP cuff tube to the IV catheter, delivering 15 mL of air to the IV catheter. The patient died from a fatal air embolus.

The cases cited all share a common theme: human error, usually due to fatigue, poor training, inefficient supply chain or misdiagnosis after a tube inadvertently came loose. All of these factors present the opportunity for misconnection. The frequency of misconnection events, coupled with the increasing amount of connections in a given room, motivated the drafting of ISO 80369 to reduce or remove the amount of human error associated with connecting medical devices. The FDA also issued a letter on September 7, 2018, in support of adopting the ISO 80369-3 application of the standard. This application is specific to enteral devices.

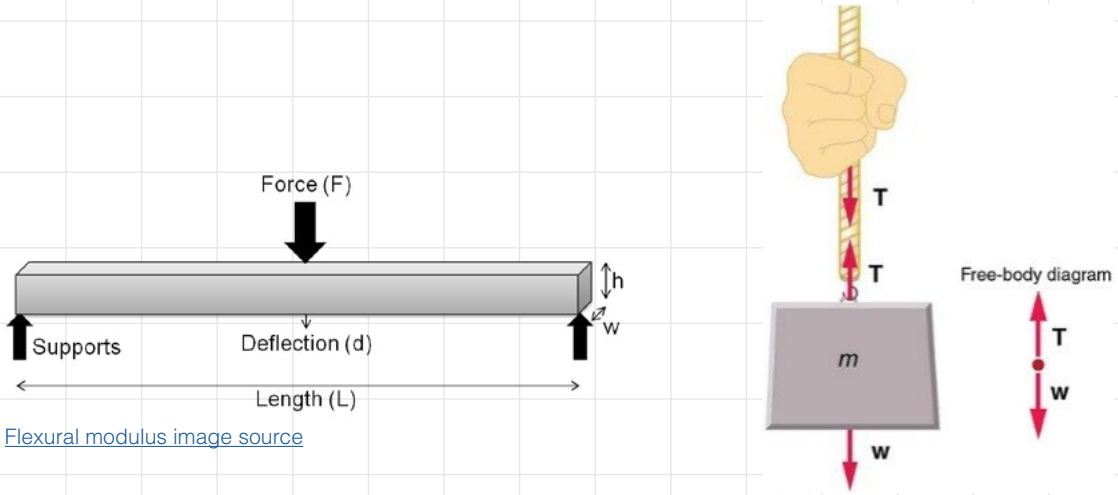
The potential for and severity of misconnection is clear; the principal goal is to save lives, and the standard challenges the industry to push to reduce human error. The question, then, becomes HOW manufacturers adopt the new standard for the range of applications it addresses. This white paper discusses practical steps medical device companies can take to adapt to the new ISO requirements for the published applications ISO 80269-3, -6, and -7, in addition to addressing the common concerns, challenges and proposed solutions when switching to the new connector geometry.

ISO 80369 Challenges and Solutions

ISO 80369-3: Connectors for Enteral Applications

A common point of resistance from hospitals considering adoption of ISO 80369-3 is the feeding time delta associated with the new fitting geometry. Enteral tubes introduce or remove fluid (respectively) directly to and from the gastrointestinal tract. Extending the time required for the fluid transfer due to the smaller nozzle is an understandable concern. While the somewhat newly named ENFit® connector will likely have a smaller hole than the catheter-type syringe, the hole will still be larger than the patient access end. As long as the patient hole remains the smallest in the circuit, the flow rate is not expected to change appreciably from the current geometry.

Another area of consideration is the material requirement. The FDA recommendation is rigid or semi-rigid materials (as described in ISO 80369-1), with a modulus of elasticity (in either flexure or tension) of 700 MPa. ASTM D790 provides testing guidelines for the modulus test. These forces are illustrated in Figure 2.



Flexural modulus image source

Tension image source

Figure 2: Flexural and tension force diagrams for elasticity modulus measurement

Partnering with a device distributor with intimate knowledge of the new geometric specifications and validation methods is critical, and the distributors can remove a lot of the burden from manufacturer design engineers by acting as consultants on the new standard.

ISO 80369-6: Connectors for neuraxial device applications

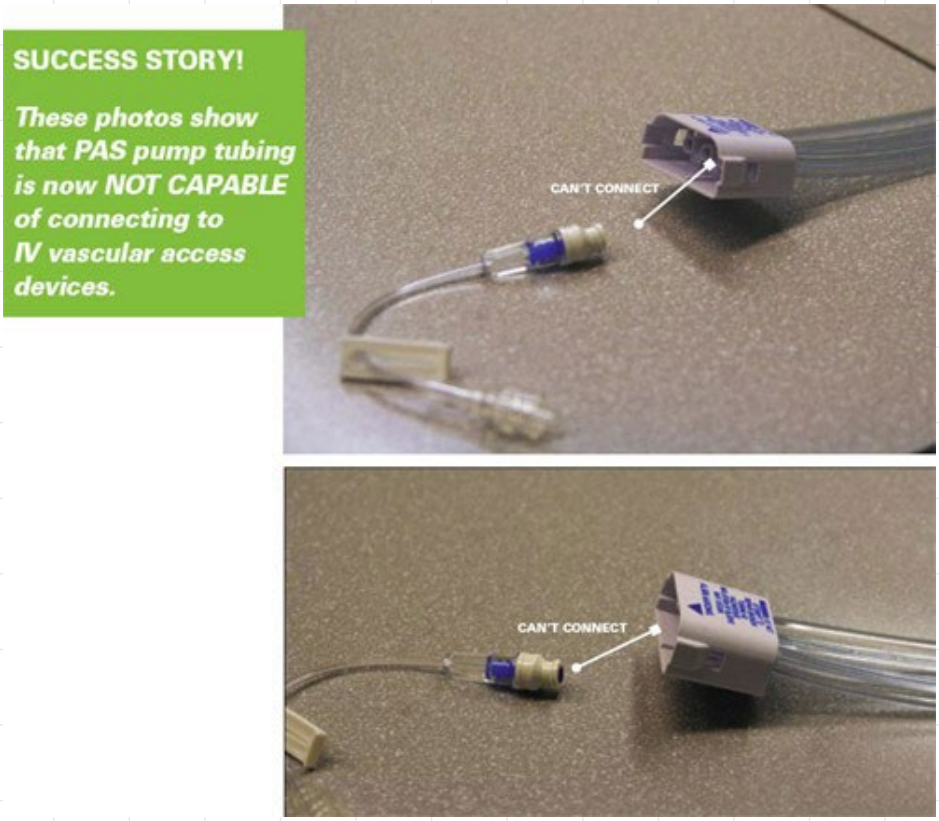
This portion of the standard addresses neuraxial device applications. These include the spine, intrathecal space, cerebral ventricles, and epi-, extra- or peri-dural regime. Neuraxial anesthetics can be administered locally while still influencing large regions of the body. Implementing this standard will prevent IV drugs from entering into the neuraxial space. The ISO 80369 solution to the standard luer connector in this application is that the neuraxial fitting is about 20% smaller and has a collar surrounding the connector. A brand of these connectors is NRFit™, developed by GEDSA. As the industry slowly adopts the standard, additional manufacturers have entered the market making the connectors. As long as the fittings are standard-compliant, they should interface together regardless of manufacturer. Partnering with a reputable components distributor like Qosina can ensure the connector designs will integrate into the existing product inventory at a given hospital or medical facility.

ISO 80369-7: Connectors for intravascular or hypodermic applications

The IV portion of the new ISO standard is slightly different than the other application-specific classes, in that the size of the connector does not change. The benefit in maintaining the size is that the connectors might not need to be retooled at the various manufacturers. The specifics of connector geometry are simply better defined, compelling the supply chain to ensure their connectors are compliant. Re-validating

the connectors may be required, in the event the stricter requirements cause a manufacturer's existing design to now be out of specification. Additionally, the standard might drive a re-tooling or tooling modification step for manufacturers, but only in the event that the connector fails in the re-validation process. Medical device distributors with more in-depth expertise into the standard may coordinate the revalidation procedure, to enable smoother adoption of the connector types and alleviate this burden from the product designers. An example of a connection now made incompatible by the ISO 80369 standard is shown below in Figure 3.

Figure 3: PAS pump tubing is now incompatible with IV access devices



Conclusion

The possibility of misconnection has proven to be a significant risk to patient safety due to the increased number of connections, devices and applications in close proximity within a confined area. Misconnections occur due to:

- Lack of training in an emergency
- Connectors coming loose due to insufficient designs to handle the forces on the fluid lines

- Human error when trying to connect with similar connection geometries
- Poor supply chain
- Hospitals being reluctant to adopt the new small-bore connection standard

Medical device product designers that have begun making compliant fitting connectors have encountered unplanned resistance when trying to supply hospitals with their products. The hospitals' familiarity with prior connector types and brands, coupled with reluctance to any assumed disruption from procuring different designs and manufacturers' connectors, creates strong loyalty to the existing type, size and brand that is difficult to overcome. It is important for the device manufacturers to educate the hospital decision-makers that changes from adopting the standard would eliminate the risk of misconnection, often with significantly less disruption than they assume. Full adoption of ISO 80369 would, in turn, improve the level of care, increase the efficiency of patient care and reduce the liability on the hospital by removing a common (and broad) source of human error from high-stress scenarios. Manufacturers that commit to adopting the standard across the board will show to be proactive, making the hospital talent's jobs easier while prioritizing the primary goal of patient safety.

Neither device labeling, color-coding, nor even training are fool-proof ways to eliminate the misconnection hazard from the hospital environment. All of the above, while part of ISO 80369 aimed at further decreasing risk, accompany the active measure of mistake-proofing the device connections by improving the design and/or validation methods.

While the complex new series of standards are still being released, the best way to ensure a new fitting design will be compliant is to rely on a supply chain partner who is knowledgeable on the standard. Connector product designers, distributors and validation houses have to work together to ensure that the spirit and result of the standard is realized for hospitals. Forming a reliable team that can teach each other will ensure that the inherent risk of small-bore misconnection is a thing of the past.

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How Does Qosina Help You Comply with ISO 80369?

Qosina stocks an extensive line of components that are ISO 80369-3, -6 and -7 compliant. We closely monitor developments to the ISO 80369 standard and add new products on a regular basis. For ISO 80369-7, if you find a Qosina part that you need and it is not ISO 80369-7 compliant, please contact us to find out if we are able to test and/or modify the component. Additional fees may be required based on volume.

About Qosina

Qosina is a leading global supplier of OEM single-use components to the medical and pharmaceutical industries. Our philosophy is to address our customers' need to reduce time to market by providing thousands of stock components. We offer free samples of most items, low minimum order requirements, just-in-time delivery, modification of existing molds, and new product design and development. Qosina is ISO 9001, ISO 13485 and ISO 14001 certified, and operates in a 95,000 square-foot facility with an ISO Class 8 Clean Room. Visit qosina.com to learn about our full component offering.

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