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Frequently Asked Questions

Stay Connected (ISO 80369-1)

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Frequently Asked Questions

Stay Connected (ISO 80369-1)

The following frequently asked questions are intended to be used for understanding the Stay Connected patient safety initiative, which involves safer medical connectors for small-bore tubing applications. The better this initiative is understood, the easier it will be for everyone involved to generate awareness, prepare for the transition, and adopt the safer standardized connectors.

1. What is the issue with tubing misconnections in healthcare?

A typical patient could be connected, via tubes or catheters, to several delivery systems to receive medication, nutrients, and fluids. Tubing misconnections, also called Luer misconnections, small-bore misconnections, or wrong route errors, refer to what happens when a medical device for one delivery system is connected to a system that serves a completely different function. For example, a feeding administration set being connected to a tracheostomy tube. Such errors have resulted in patient injury and deaths, and they are widely recognized as underreported. Misconnections are attributed to the universal design of Luer connectors, which are one of the most commonly used types of small-bore connectors in health care. The connectors are parts used to connect the tubing of one medical device to another. However, the simple design and ease of use of the Luer connector allows the tube of the device for one delivery system to be connected to an unrelated system (one that has a different intended use).

2. What is a small-bore connector?

A small-bore connector is a medical connector with an inner diameter of less than 8.5mm that is used to link or join medical devices, components, and accessories for the purposes of delivering fluids or gases. A Luer connector is a classic type of a small-bore connector used commonly in the healthcare setting. The current universal design of the Luer connector allows for medical misconnections between unrelated delivery systems that have different intended uses (e.g., vascular, enteral, respiratory, epidural, and intrathecal).

3. Why do we need design standards for small bore connectors?

Adoption of international standards for small-bore connectors will ensure compatibility and consistency while reducing the likelihood of misconnections. The ISO 80369 series of standards for clinical applications (enteral, neuraxial, respiratory, IV, limb cuff inflation) are being implemented globally. These connectors provide:

- Greater ability for different manufacturers' devices to integrate, while making it difficult, if not impossible, for unrelated delivery systems to be connected
- Standardized, application specific and dedicated, connections across all healthcare settings
- Less likelihood of therapy interruption due to connector incompatibility or unavailability

4. What are the risks associated with the use of small-bore connectors in healthcare?

The simple, universal design of the Luer connector allows unintended connections between unrelated delivery systems with different intended uses, including vascular, enteral, respiratory,

epidural, and intrathecal applications. As a result, clinicians may inadvertently connect incompatible systems, leading to the administration of fluids (such as medications or enteral nutrition) or gases (such as oxygen) via the wrong route. These misconnections can result in serious harm and, in some cases, fatal outcomes. To address this patient safety risk, ENFit® (ISO 80369-3) and NRFit® (ISO 80369-6) connectors are being adopted to improve patient safety by reducing the likelihood of cross-connection errors.

5. What are some examples of tubing misconnections?

Examples of dangerous misconnections include liquid formula or medication intended for delivery into the stomach via a feeding tube or nasogastric (NG) tube being mistakenly connected to an intravenous (IV) line, resulting in direct infusion into the bloodstream. In another scenario, a noninvasive blood pressure inflation tube is connected to an IV line, delivering pressurized air into the bloodstream and causing a potentially fatal air embolism. IV fluids have also been mistakenly connected to the inflation cuff of a tracheostomy or endotracheal tube, delivering large volumes of fluid into a device designed to be filled only with air, leading to airway obstruction. Additionally, a tube feeding has been inadvertently connected to a peritoneal dialysis catheter, delivering enteral formula intended for the stomach into the peritoneal cavity. Standardized connector designs, such as ENFit® and NRFit®, are specifically engineered to prevent these types of misconnections and improve patient safety.

6. What has been done to reduce the risk of misconnections?

Tubing misconnections have long been recognized as a serious patient safety risk, leading to alerts and guidance from numerous governmental, accreditation, professional, manufacturing, and healthcare organizations. These include The Joint Commission's Sentinel Event Alert, Issue 36: Tubing Misconnections—A Persistent and Potentially Deadly Occurrence; educational resources such as case studies, safety calendars, videos, and webinars from the U.S. Food and Drug Administration (FDA); clinical recommendations from the American Society for Parenteral and Enteral Nutrition (ASPEN); a letter from the Centers for Medicare & Medicaid Services (CMS) advising surveyors to review hospitals' misconnection prevention policies; and Making Healthcare Safer II from the Agency for Healthcare Research and Quality (AHRQ), which evaluates evidence-based patient safety practices.

In response, healthcare organizations have implemented educational programs and procedural safeguards, including tracing all tubing back to its point of origin before reconnection, physically separating tubes and catheters with different functions on opposite sides of the patient's body, and using visual cues to distinguish delivery routes. Some manufacturers have adopted color coding or developed proprietary connector designs intended to reduce the likelihood of misconnection. However, despite these efforts, tubing misconnections have continued to occur, demonstrating that education, labeling, and workarounds alone are not sufficient to eliminate the risk.

To more effectively address this issue, a fundamental design change supported by consensus standards was required to make misconnections between unrelated delivery systems—such as vascular, enteral, respiratory, epidural, and intrathecal—highly unlikely. This led to the development of the ISO 80369 series of small-bore connector standards. More recent efforts include updated FDA guidance, the widespread adoption of ENFit® (ISO 80369-3) and NRFit® (ISO 80369-6) connectors, and mandatory implementation in some regions. Today, many manufacturers produce non-Luer connectors that prevent misconnections by design, representing a significant

advancement in reducing wrong-route events and improving patient safety.

7. What changes are coming?

To reduce the frequency of tubing misconnection hazards, an international group of clinicians, manufacturers, and regulators (including the FDA) collaborated with the International Organization for Standardization (ISO) and the Association for the Advancement of Medical Instrumentation (AAMI) to develop the ISO 80369 series of standards. The first standard, ISO 80369-1, published in January 2011, provides general requirements for connectors used for liquids and gases in healthcare and establishes a framework to ensure non-interconnectability of unrelated delivery systems (e.g., vascular and enteral).

Other standards in the series are application-specific and focus on particular areas of therapy:

- ISO 80369-2 – Respiratory connectors
- ISO 80369-3 – Enteral feeding connectors (ENFit®)
- ISO 80369-4 – Urinary connectors
- ISO 80369-5 – Limb cuff connectors
- ISO 80369-6 – Neural connectors (NRFit®)
- ISO 80369-7 – IV/hypodermic connectors (Luer)

These connectors are designed to be incompatible with Luer connectors, preventing tubing misconnections between unrelated delivery systems. ENFit® and NRFit® connectors are already in use in many hospitals worldwide and additional, application-specific, connectors are being phased in as these standards are adopted.

A phase-in period is recommended to allow manufacturers, healthcare facilities, and regulators to implement these connectors safely, supported by FDA guidance and regional legislation. This approach ensures compatibility and safety while reducing the risk of wrong-route errors.

In summary, the ISO 80369 series provides a global standard for connector safety, replacing the universal Luer design in high-risk applications and significantly reducing the likelihood of tubing misconnections.

8. What products will be impacted by these ISO standards?

Connector designs have been developed for several device types, including respiratory systems and driving gases, limb cuff inflation applications, enteral feeding systems, and neuraxial applications. After implementation, the traditional Luer connector will be retained only for intravascular and hypodermic uses. All other delivery systems that previously relied on Luer connectors will be transitioned to non-Luer designs to ensure they cannot connect with intravascular Luer devices or with connectors intended for other clinical applications. ENFit® (ISO 80369-3) and NRFit® (ISO 80369-6) are already in global use, supporting safer device connections and significantly reducing the risk of cross-connection errors.

9. What are the implications of these ISO standards?

Unique, internationally standardized connector designs for each high-risk medical delivery system improve patient safety by ensuring that connectors for unrelated applications are physically

incompatible. Without a global industry design standardization, manufacturers would be forced to test their products against numerous proprietary connector designs to verify incompatibility, an impractical and incomplete approach. At the same time, healthcare organizations would be required to purchase and manage multiple systems across the continuum of care without a consistent, standardized method to evaluate or prevent potential misconnections. This lack of standardization could increase confusion and elevate the risk to patients.

Under the ISO 80369 series of standards, the Luer connector is retained exclusively for intravascular and hypodermic applications. All other small-bore delivery systems are transitioning to application-specific connector designs that are intentionally incompatible with the intravascular Luer connector and with one another. Adoption of these standards is ongoing worldwide to further reduce the risk of wrong-route connections and improve patient safety.

10. What product changes should be anticipated?

Manufacturers of breathing systems and driving gases, enteral feeding systems, limb cuff inflation devices, and neuraxial applications have redesigned (or are in the process of redesigning) their products to comply with the applicable ISO 80369 standard. Manufacturers are working to introduce the new connector designs with minimal disruption to product supply and routine clinical practice.

The transition began with the rollout of ENFit® (ISO 80369-3) in 2014 and have continued with additional applications, including NRFit® (ISO 80369-6). Manufacturers are expected to coordinate the introduction of these standardized connectors with structured transition plans to support customers as they convert from the legacy products currently in use.

11. How were the ISO connector designs tested to prove that they are safer than legacy connectors?

The goal was to develop unique, application-specific connectors for each medical delivery system so that their physical design makes it virtually impossible to connect unrelated systems. The ISO tubing connector designs were developed using human factors engineering principles and computer-aided design (CAD) analysis to reduce the likelihood of misconnections. Each connector design underwent a rigorous evaluation process to ensure it connected only with its intended mating connector.

Validation included hands-on usability testing to confirm that the connectors prevented connections between devices from different delivery systems while remaining intuitive for clinical use. In addition, design analysis and physical force and fit testing verified that connectors intended to mate did so securely, and that connectors from unrelated systems were physically incompatible. These validation processes were completed as part of the ISO 80369 standards development, and ongoing real-world use continues to confirm their effectiveness in improving patient safety.

12. What is the timeline for the changes?

The transition to the ISO standard connectors occurs in defined stages and varies by country, region, and clinical application, a process that continues today. Implementation is organized by delivery system, with manufacturers integrating the new connectors into their existing product portfolios where appropriate. By working closely with their suppliers, healthcare facilities and providers can plan conversions on timelines that best meet their operational needs and support

patient safety. ENFit® and NRFit® have already been adopted in many regions, with additional phases of global adoption continuing to progress.

13. What can I do to help my facility prepare for the adoption of these safer connectors?

Healthcare providers are strongly encouraged to follow a structured approach as standardized connectors, such as ENFit® and NRFit®, are introduced into clinical practice:

Aware

- Raise awareness of upcoming changes across the organization, ensuring all impacted clinicians, administrators, supply chain staff, health technology management personnel, and other support teams are informed.
- Designate a leader to stay current on transition plans and communicate updates regularly throughout the organization.

Prepare

- Form multidisciplinary teams to review existing systems, processes, and protocols, prioritizing areas at highest risk and those needing immediate conversion to the new connectors.
- Collaborate with supplier representatives and follow their product-specific transition plans.
- Train clinicians, materials management, and inventory staff on the impending changes.

Adopt

- Introduce the ISO connectors into clinical workflows to reduce tubing misconnections and enhance patient safety.
- Reinforce the long-term benefits of the transition, highlighting safety improvements over any short-term challenges.

Measure

- Track the organization's progress in adopting the new connectors.
- Use metrics and feedback loops to identify opportunities for improvement and to guide future phases of connector adoption.

For detailed information on implementation, transition plans, and timelines, healthcare providers should consult manufacturers and relevant industry groups as ISO connectors are adopted globally.

14. Are these standards mandatory for manufacturers and healthcare organizations?

As of 2025, there were no U.S. federal mandates requiring manufacturers or healthcare organizations to adopt standardized connectors. However, Section 1279.7 of California's Health and Safety Code prohibits general acute care, acute psychiatric, and specialty hospitals from using epidural, intravenous, or enteral feeding connectors that can attach to the wrong type of connection port. Medical device manufacturers and suppliers are expected to comply by offering products with the ISO connectors and phasing out devices with legacy connectors. Healthcare organizations must communicate these changes to clinicians and staff responsible for product transitions to ensure safe adoption.

Earlier, in July 2010, the U.S. Food and Drug Administration (FDA) issued guidance to manufacturers, healthcare professionals, and hospital purchasing departments outlining steps to

reduce the risk of tubing misconnections. The FDA also noted its involvement in the development of international standards designed to prevent misconnections through functional design and usability testing. Since then, the FDA has formally recognized the ISO 80369 series of standards, and many healthcare systems worldwide have voluntarily implemented ENFit® (ISO 80369-3), NRFit® (ISO 80369-6), and other small-bore connectors in alignment with global best practices.

15. What areas in a healthcare organization might be impacted by the changes and when?

Personnel across healthcare facilities involved in product supply, administration, or direct patient care will be affected by the introduction of the ISO connectors. Staff responsible for procurement, materials management, and pharmacy should be engaged to understand the implications and actions required to prepare for small-bore connector implementation. Clinicians (physicians, nurses, nurse practitioners, infusion therapists, and dietitians) should receive timely information and training well in advance to prevent any disruption to therapy. Additional stakeholders to consider include healthcare technology management, patient safety, and quality assurance personnel, all of whom play a critical role in a smooth and safe transition.

16. What kind of financial impact will the ISO standards have on healthcare organizations?

Depending on the therapeutic area, implementing the ISO connectors may increase the cost of producing certain medical devices. Pricing decisions are determined solely by the device manufacturers. Healthcare organizations are encouraged to consult with their suppliers to understand any potential financial impact and plan accordingly.

17. Should healthcare facilities or providers change even if they have not had a tubing misconnection incident?

Many healthcare organizations may believe they have never experienced a tubing misconnection, but this is often not the case. Many misconnections are detected before harm occurs and, as a result, are rarely reported. Every organization is only one human error away from a potentially harmful event. To enhance patient and clinician safety, it is essential to use devices designed according to human factors engineering principles, which help prevent misconnections and reduce the risk of error in the care environment.

18. Will guidance be provided to healthcare organizations to help them understand the implications of the ISO standards?

A coordinated, collaborative approach is underway to transition from legacy connectors to the ISO standardized designs. Suppliers will provide advance notice to help healthcare organizations prepare for these changes. Information on the ISO design standards, transition timelines, and educational resources are available at www.StayConnected.org, which remains the primary source for the latest updates on connector changes by therapeutic group. For details on specific suppliers and the introduction of their products, please visit the suppliers' individual websites.

19. What are suppliers doing to make sure connections are possible between the old legacy connectors and ISO connectors from different vendors?

To avoid confusion and promote the widespread adoption of ISO standardized connections, a global industry group representing manufacturers, suppliers, and distributors of medical devices is

coordinating an ongoing and synchronized introduction of the ISO connectors. This coordinated effort includes guiding healthcare providers through structured transition plans, implementing a joint communications strategy, and assigning a common name to each unique connector to be used consistently by all suppliers within each delivery system. The goal of this effort is to prevent any interruption in therapy while allowing suppliers and healthcare providers to work through existing inventory. Where appropriate, bridging devices, such as transition sets and adapters, are available to facilitate the delivery of fluids using ISO connectors alongside current or legacy systems during the transition period. For details regarding specific products or plans, healthcare providers are encouraged to contact their suppliers directly.

20. What should be done with existing inventory when implementing a transition to devices with ISO connectors?

Healthcare providers should ensure that all personnel involved in their organization's supply chain are fully informed and prepared for connector changes. Extra attention should be given to managing inventory levels of products affected by the transition. The primary goal should be to prevent any interruption in therapy while allowing suppliers and providers to work through existing inventory. Bridging devices, such as transition sets and adapters, are available to maintain compatibility between ISO and legacy connectors during the transition period. For details on specific products or plans, providers should contact their suppliers directly.

21. Will there be a universal color code system with each device type assigned a unique color?

Color coding is not part of the ISO 80369 series of standards, which focus exclusively on connector shape and size. Engineering controls, known as forcing functions, are designed to make it highly unlikely for incompatible connectors to be joined, offering a more reliable safety mechanism than relying on color coding. While suppliers may choose to apply color coding for brand recognition or product identification, it is neither standardized nor required by the ISO 80369 series.

22. What should healthcare providers keep in mind as they plan their transition to the safer ISO connectors?

While manufacturers are working to communicate connector changes and support an orderly supply chain transition, they cannot manage the process on behalf of healthcare providers. Healthcare providers should develop a multidisciplinary plan to minimize disruption and reduce the risk of unintended consequences. Active engagement of supply chain personnel, clinical leadership, and frontline staff is essential to ensure readiness for the transition and maintain uninterrupted patient care.

Non-Traditional Use of Patient Access Devices

GEDSA advises against and cannot comment on or address any off-label use. All products and product designs are the responsibility of each specific legal manufacturer, distributor or supplier. Products with these design features may be pending regulatory clearance or may not be available in a specific geography. Consult your supplier representative for product-specific use, availability, indications, contraindications, precautions, and warnings.

Additional Resources

1. ANSI/AAMI/ISO 80369-1:2010: *Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements*. AAMI, Arlington, VA, 2010.

2. Section 1279.7 of California's Health and Safety Code https://leginfo.legislature.ca.gov/faces/codes_displaySection.xhtml?lawCode=HSC&sectionNum=1279.7

3. Guenter, P., Hicks, R., Simmons, D., Crowley, J., Croteau, R., Gosnell, C., Vanderveen, T. Enteral Feeding Misconnections: A Consortium Position Statement. *The Joint Commission Journal on Quality and Patient Safety.* https://pubmed.ncbi.nlm.nih.gov/18491692/

4. Making healthcare safer II: An updated critical analysis of the evidence for patient safety practices, pp.487-492, AHRQ. https://www.ahrq.gov/research/findings/evidence-based-reports/ptsafetyuptp.html Published March 2013.

5. Examples of Medical Device Misconnections https://www.fda.gov/medical-devices/medical-device-connectors/examples-medical-device-misconnections

6. Memorandum to manufacturers, healthcare professionals and hospital purchasing departments about Luer misconnections. FDA Website. https://www.fda.gov/media/78921/download Published July 9, 2010.

7. Memorandum: Luer Misconnection Adverse Events. CMS Website. https://www.cms.gov/medicare/provider-enrollment-and-certification/surveycertificationgeninfo/policy-and-memos-to-states-and-regions-items/survey-and-cert-letter-13-14 Published March 2013.

8. Sentinel Event Alert: Tubing misconnections: A persistent and potentially deadly occurrence. The Joint Commission Website. https://www.jointcommissionjournal.com/article/S1553-7250(06)32054-5/abstract Published April 2006.

9. Simmons, D., Phillips, M., Grissinger, M., Becker, S. Error-Avoidance Recommendations for Tubing Misconnections When Using Luer-Tip Connectors: A Statement by the USP Safe Medication Use Expert Committee. *The Joint Commission Journal on Quality and Patient Safety*. https://pubmed.ncbi.nlm.nih.gov/18491693/ Published May 2008.

10. Simmons, D., Symes, L., Guenter, P., Graves, K. Tubing Misconnections: Normalization of Deviance. *Nutrition in Clinical Practice.* https://pubmed.ncbi.nlm.nih.gov/21586413/ Published June 2011.

11. FDA Guidance document Safety Considerations to Mitigate Risks of Misconnections with Small bore Connectors Intended for Enteral Applications February 11, 2015 https://www.fda.gov/files/medical%20devices/published/Safety-Considerations-to-Mitigate-the-Risks-of-Misconnections-with-Small-bore-Connectors-Intended-for-Enteral-Applications---Guidance-for-Industry-and-Food-and-Drug-Administration-Staff.pdf

12. Joint Commission Sentinel Event Alert Issue 53 Managing risk during transition to new ISO tubing connector standards August 20, 2014 https://www.jointcommission.org/en-us/knowledge-library/newsletters/sentinel-event-alert/issue-53