

Acute Care

ISMP Medication Safety Alert!®

Educating the Healthcare Community About Safe Medication Practices

NRFit: A global “fit” for neuraxial medication safety

Introduction



In an effort to prevent tubing misconnections that could result in harmful, sometimes fatal, wrong route errors, the International Organization for Standardization (ISO) developed the ISO 80369 engineering standards to specify the design of small-bore connectors for various clinical applications that are dissimilar.¹ The new ISO 80369 standards employ forcing functions to ensure that small-bore connectors and tubing used for a specific route of delivery will not fit into small-bore connectors used for different applications, including for intravenous (IV), enteral, and neuraxial medication administration, thus reducing the risk of misconnections. The transition to the new ISO 80369-compliant connectors can improve patient care by greatly minimizing the risk of adverse events.

Implementation of the new ISO standards began in 2016 with enteral connectors (ISO 80369-3), which the Global Enteral Device Supplier Association (GEDSA) named ENFit. More than 80% of California hospitals have transitioned to ENFit because its use is mandated in that state. However, fewer hospitals have adopted ENFit across the rest of the US. Many are in the planning stages, realizing that full adoption is a complex process that takes several months. According to GEDSA, approximately 25% of all US hospitals have adopted the ENFit system. GEDSA is a nonprofit trade association comprised of manufacturers, distributors, and suppliers worldwide, which was formed to help introduce the ISO standards in medical device connectors (<http://gedsa.org/>). ISMP joins GEDSA and other supporting organizations listed on its website, including ECRI, The Joint Commission, and the American Society for Parenteral and Enteral Nutrition, in strongly recommending widespread implementation of ENFit, the only ISO-compliant option for enteral administration.

The next phase of implementation of the ISO standards began last year with neuraxial connectors (ISO 80369-6), commonly referred to as NRFit. Does your organization have plans in place to transition to the new neuraxial connectors? The information that follows is intended to help you learn more about NRFit and how to adopt this life-saving strategy in your organization.

What is NRFit?

Medical device connectors for neuraxial applications are changing from Luer connectors to ISO 80369-6-compliant connectors, which are incompatible with the Luer system, thus preventing misconnections.² Similar to ENFit, NRFit is the name selected by GEDSA to use for these ISO-compliant neuraxial connectors. While the ISO 80369 standards only

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Figure 1. Most ISO 80369-6-compliant devices will incorporate the color yellow and include a NRFit logo.



Figure 2. Luer syringe (left) tip extends beyond the collar. NRFit syringe (right) tip is flush with the collar.



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address the shape and size of new connectors, there appears to be an industry trend to use yellow for NRFit devices. Thus, most neuraxial connectors compliant with ISO 80369-6 include yellow and a NRFit logo (**Figure 1**, page 1).²

The NRFit connector diameter is 20% smaller than the Luer connector diameter. NRFit syringes have a smaller collar and tip, although the inner diameter of the tip is the same as a Luer tip.² The NRFit tip is flush with the collar, while the Luer tip extends beyond the collar (**Figure 2**, page 1).² These design features make it unlikely that a medical device intended for neuraxial applications will fit together with medical device connectors used for other clinical applications, such as respiratory, enteral, urological, limb cuff, or IV routes of administration.

Why was NRFit developed?

ISO 80369-6 and NRFit connectors were developed because of numerous wrong-route errors (e.g., inappropriate medications, enteral feedings, or air being administered neuraxially), some with catastrophic outcomes, that have occurred around the world.³ ISMP alone has received dozens of reports of non-epidural medications (e.g., potassium chloride, antibiotics, vinca alkaloids) inadvertently administered into the epidural or intraspinal space, and of regional anesthetic solutions (e.g., fenta**NYL** and bupivacaine, ropivacaine) inadvertently administered by the IV route. While some of these wrong route errors produce few or short-lasting cardiac and neurological deficits, others can result in permanent cardiac and neurological deficits, including paraplegia and death.

Neuraxial administration of IV medications and vice versa has been particularly concerning, but we have also heard about other types of neuraxial wrong-route errors. For example, an anesthetic agent intended for IV administration was administered into the cerebrospinal fluid via an external ventricular drain.³ There have also been numerous reports of antibiotics inappropriately administered into the cerebrospinal fluid. These wrong-route errors continue to occur despite repeated warnings about the risk as well as implementation of other strategies such as special packaging and application of auxiliary warning labels. The risk of unintentional cross-connections is high when using a universal Luer connector. The introduction of NRFit will help reduce the incidence of misconnections by creating unique non-Luer connectors for neuraxial applications.

Why adopt NRFit?

Implementation of the NRFit connector provides a way to reduce the risk of neuraxial misconnections, which can be devastating to patients, families, and healthcare practitioners. Simply put, patients expect healthcare practitioners to put their safety first, and transitioning to NRFit will clearly improve patient safety. Also, the legal system expects healthcare providers to take all reasonable steps to mitigate the risk of wrong-route errors. Non-adoption of NRFit may expose practitioners and organizations to legal challenges if wrong-route events take place that could have been prevented by NRFit.³

Is NRFit adoption mandatory?

A mandate to adopt ISO 80369-6 connectors (NRFit) varies by jurisdiction. Currently, California is the only US state to mandate its use.⁴ However, many accrediting and regulatory bodies strongly recommend transitioning to ISO-compliant connectors as they become available, and many manufacturers and suppliers have adopted, or plan to adopt, the same new global standard connector system.

When will NRFit devices be available?

Currently, B Braun and Smiths Medical offer an extensive line of NRFit devices in the US. This includes a variety of ISO-compliant NRFit epidural and spinal needles, filters and filter straws, catheter connectors, and syringes (loss-of-resistance [LOR], slip, and lock). There will be no adapters for the syringes since they are all supplied with the application-specific NRFit connectors. Smiths Medical also offers the CADD-Solis infusion

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pump (**Figure 3**) and the Portex regional anesthesia portfolio with NRFit connectors, as well as NRFit epidural administration sets (yellow lines, without injection ports), infusion pump accessories including extension sets, a spinal introducer, and syringe caps.

Additionally, BD is pursuing the development of a full portfolio of NRFit devices for neuraxial procedures for spinal and epidural anesthesia.⁵ Several other manufacturers are listed on the GEDSA *Stay Connected* NRFit Product and Supply Resources webpage (www.ismp.org/ext/513). However, some of these manufacturers may supply countries outside the US or offer limited devices with NRFit connectors. While each manufacturer may follow its own device and market launch timeline, the goal remains the same—to align to a common neuraxial connector across the globe to improve patient safety.⁶

Does NRFit work?

A study conducted in the United Kingdom in 2014 explored the clinical usability and cross connectivity of NRFit connectors.⁷ Specifically, the researchers tested whether the NRFit connectors functioned as well as Luer connectors, and whether they allowed clinically relevant cross connections with other small-bore connectors. Overall performance was found to be good, with connectors rated as easy or very easy to use. Leakage did not occur, and procedural times and number of attempts were generally similar between Luer and NRFit devices. Any concerns raised were usually device related, rather than connector related. The study also confirmed that clinically important cross connections do not exist between NRFit connectors and existing connectors. The study concluded that NRFit connectors were suitable for clinical use, were practical for implementation, and may provide an engineered solution to the problem of neuraxial—IV wrong-route errors.



Figure 3. CADD cassette with yellow NRFit (non-Luer) connector and cap for epidural use.

Will NRFit prevent all neuraxial misadministrations?

NRFit connectors will help prevent inadvertent neuraxial administration of non-neuraxial medications, solutions, enteral feedings, and air because Luer (or ENFit) connectors will not fit into the NRFit devices. Additionally, neuraxial medications prepared in NRFit syringes and/or administered via NRFit administration sets will not fit into Luer (or ENFit) connectors, helping to prevent intravascular administration of neuraxial medications. However, please keep in mind that wrong-route errors are still possible if the wrong medication is selected for preparation in a NRFit syringe, or if the wrong bag or bottle of medication or solution is spiked with a NRFit administration set. In these cases, the wrong medication or solution could still reach the patient via the neuraxial route because it has been prepared in, or administered through, a NRFit syringe or administration set. Similarly, a medication vial or bag intended for neuraxial administration can be selected or spiked with an IV administration set and administered via the wrong route. In addition to using NRFit, differentiation of these vials, bags, syringes, and administration sets via labeling, label color, and storage location remain key in your safety roll out.

While NRFit is a high-leverage risk-reduction strategy in its own right, organizations should layer it with other strategies to reduce the risk of wrong-route errors. For example, whenever possible, bags or bottles of neuraxial medications (e.g., fenta**NYL** and bupivacaine) should be stored or dispensed with NRFit administration sets (attached by a rubber band to the bag, or spiked and primed if immediate administration is anticipated), along with an auxiliary label that notes, “Requires NRFit tubing.” For infusions, tubing should be traced from the source to the patient access site, and auxiliary labeling of the

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site (e.g., “epidural”) closest to the patient should be strongly considered. Some hospitals also require an independent double check before administering all epidural infusions or injections (outside the operating room). For neuraxial administration via syringe (or cerebral spinal fluid withdrawal), parenteral syringes with a Luer connector should never be used. Also ensure that IV lipid emulsion rescue is readily available wherever regional anesthetics are administered, and that standardized protocols and/or coupled order sets are in place that permit emergency administration in cases of inadvertent IV administration of regional anesthetics.

How do organizations adopt NRFit?

NRFit must be introduced in a healthcare organization in a planned and coordinated manner, starting with a small team of clinicians who are committed to transitioning from the Luer connector to NRFit for intrathecal and epidural procedures. While every organization will have a different process for implementing the change, all will require a well-informed, properly prepared cross-functional team composed of organizational leaders, anesthesia providers, other physicians who perform neuraxial procedures (e.g., spinal taps), nurses who assist with neuraxial procedures, and pharmacists who prepare neuraxial medications. The team should start by communicating with the organization’s supplier of neuraxial devices, requesting NRFit samples when available, familiarizing themselves with all the product-specific changes, practicing new connections with all the products affected by the NRFit connector, and developing an anticipated timeline and checklist for the organization-wide transition.

The next step for the team is to conduct a failure mode and effects analysis (FMEA) to identify before transition what could possibly go wrong. Risks may arise anywhere in the process due to staff unfamiliarity with the NRFit connector design changes, incorrect use, and supply chain issues. Potentially serious problems should be identified, anticipated, and addressed prior to transition.

Additionally, before transitioning to NRFit, all practitioners who will be involved in neuraxial procedures should receive hands-on education about the new NRFit connectors and the importance of this change. Organizations will also need to evaluate and update current procedures, related order sets, and pharmacy preparation and dispensing processes, adjusting them as needed to include the new NRFit devices. GEDSA offers a NRFit Connector Transition Checklist for Nurses and Clinicians (www.ismp.org/ext/514) to guide this process, offering recommended activities that support:

- S—Supplier Communication** to understand the timeline for NRFit availability
- T—Training** of clinicians regarding the importance of transitioning to NRFit
- E—Education** about how to use NRFit products
- P—Process** of updating current procedures, order sets, and pharmacy preparation
- S—Supply Management** of NRFit and legacy inventory

Please keep in mind that some devices, including long spinal needles, may be used in your facility for non-neuraxial applications, such as amniocentesis and joint injections.⁶ If this is the case in your organization, long needles with a Luer connector will still be required after transition to NRFit. Some manufacturers have expressed an interest in marketing such devices to meet clinical needs, so please contact your current suppliers to ask them about long needles with Luer connectors if you believe you will need them in the future after transition to NRFit.

It is also recommended that your organization’s transition team regularly visit the GEDSA *Stay Connected* website (<http://stayconnected.org/>) to remain apprised of any joint communication initiatives on behalf of the industry and to avoid any confusion as the new, safer connectors are introduced in the market.

References appear in the right column at the top ^