# NRFit®

# Frequently Asked Questions

Neuraxial-Specific (ISO 80369-6)

GEDSA
ADVANCING PATIENT SAFETY

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# Frequently Asked Questions

## Neural-Specific (ISO 80369-6)

The following frequently asked questions are intended to be used for understanding the NRFit® patient safety initiative, which involves safer medical connectors for neural 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 new connectors.

**1. 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).

**2. What changes are coming to small-bore connectors?**

The ISO 80369 series replaces universal Luer connectors with application-specific connectors to prevent misconnections. The new connectors are incompatible with each other to reduce the risk of wrong-route administration or misconnection.

The 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)

**3. Why is industry adopting the new ISO neuraxial connector?**

The adoption of NRFit® is a proactive step toward improving patient safety. According to Viscusi et al. (2022), between 2008 and 2018, the FDA received 133 reports of neuraxial misconnections, including 56 involving intravenous tubing connected to neuraxial access and 5 deaths resulting from medication errors. These events often involved the accidental administration of intravenous medications into the spinal canal or intrathecal medications into the bloodstream. The NRFit® connector, developed under ISO 80369-6, is specifically designed to eliminate these risks by making such misconnections physically impossible.

Health systems are increasingly implementing NRFit® to align with international standards, reduce liability, and meet the safety expectations of regulatory and advisory organizations such as the FDA, ISMP, The Joint Commission, the NHS, and the Ministry of Health, Labour and Welfare of Japan, all of which have highlighted the dangers of tubing misconnections and support the adoption of safer connector systems

**4. What are the implications of these new standards?**

Unique connector designs promote patient safety and help ensure that connectors for unrelated applications are incompatible. This reduces the chances of wrong route injections and infusions and the harm and death associated with these incidents.

Syringes used for intravascular and hypodermic access will no longer be interchangeable with neuraxial syringes or connect to devices intended for neuraxial use. For manufacturers and suppliers this may cause temporary inconvenience as procedure packs may be more difficult to customize. Clinicians need to be aware of what extra items ('drop-ins' ) they use, as those will need to be ordered specifically (pulling those from intravenous supply stocks will no longer suffice).

Pharmacy departments preparing medicines for intrathecal and epidural use (for example, aseptic preparation of intrathecal chemotherapy preparations) will also have to ensure they have appropriate stocks of syringes, syringe caps, filling devices, filters and other equipment necessary to fill and dispense using the new connectors.

**5. Who developed the proposed new ISO 80369-6 connector design?**

The ISO 80369-6 connector was developed by the International Organization for Standardization (ISO) through a joint working group that included medical device manufacturers, clinicians, human factors experts, and regulatory bodies such as the U.S. Food and Drug Administration (FDA). The design was tested through mechanical simulations, laboratory assessments, and human factors evaluations to ensure safety, reliability, and usability across clinical environments.

**6. Why should we adopt the new 80369-6 connector?**

Adopting the NRFit® connector supports patient safety and aligns with global design standards intended to eliminate potentially fatal misconnections. Misuse of Luer connectors in neuraxial procedures has led to serious harm, including deaths, due to intravenous administration of spinal medications or vice versa. By transitioning to NRFit®, healthcare providers reduce the chance of such errors by creating a physically incompatible system for neuraxial use. Adoption also aligns with guidance from the FDA and other safety authorities and may reduce institutional liability in the event of a misconnection-related incident. As more institutions standardize their practices, NRFit® adoption also helps streamline procurement and improve clinical workflows across departments.

**7. What makes the new ISO 80369-6 connector different from the current Luer system?**

Although similar in general appearance, the NRFit® connector is approximately 20 percent smaller in diameter than a Luer connector and includes a collar on the male slip tip that visually and physically distinguishes it. These changes are specifically designed to prevent incompatible connections between neuraxial and other clinical systems, such as intravenous or enteral devices. In many syringe designs, NRFit® also reverses the gender orientation compared to Luer systems, further reinforcing incompatibility.

**8. Are NRFit® products available now?**

Yes. NRFit® compliant products are commercially available in the United States, Canada, Japan, throughout Europe, and many other countries. A growing number of manufacturers offer a wide range of NRFit® compatible devices, including syringes, needles, filters, and epidural or spinal kits. Several

health systems have already converted to NRFit®, and adoption is expected to accelerate as more hospitals seek to standardize around safer connector systems. At this time, adoption is not mandated in the U.S., but it is strongly encouraged by patient safety organizations.

**9. How will the new ISO 80369-6 connector be introduced into my healthcare organization?**

This will vary depending on where you are based. In some countries, it will be under the direction of regulatory authorities and practice experts. In other countries the decision of when to deploy ISO 80369-6 compliant devices may be up to local healthcare organizations or governments. No matter who is driving the process, healthcare facilities and providers will be able to call upon industry to help them with a careful transition plan to replace Luer devices with the new ISO 80369-6 connector. Although each company may follow their own device and market launch timeline, it is expected that there will be substantial efforts to coordinate the availability of devices in a way that minimizes confusion and logistical problems. To that end, the global industry group has agreed to:

- Develop and execute a coordinated communications initiative
- Use a common brand name for the ISO-80369-6 connector – NRFit®.
- Use the same time frame to introduce neuraxial devices with the new connector

**10. If we use Neuraxial parts from another manufacturer's set, how will we know the products will work together?**

As long as all connectors comply with the ISO 80369-6 standard, devices from different manufacturers are expected to connect effectively and safely. Major neuraxial device manufacturers adhere to this standard to ensure compatibility across products. Many compliant devices will be marked with the NRFit® label or the ISO 80369-6 designation for easy identification. For user convenience, some components, such as syringe plungers, may be color-coded (often yellow), but color is not a safety requirement.

**11. Is it mandatory to transition to the new ISO 80369-6 connector?**

Mandates vary by region. Globally, many healthcare systems and manufacturers are moving toward adopting ISO 80369-6 connectors to standardize neuraxial access and improve patient safety. Some jurisdictions, such as California, have set specific deadlines for transition. For example, California required NRFit® connectors for epidural use beginning January 1, 2017. The UK's National Health Service (NHS) also mandated the adoption of NRFit® connectors, issuing implementation guidance in 2021 and requiring full transition in the UK by January 31, 2025, as part of its national patient safety initiative. In other markets, including Europe, timelines differ, but the overarching goal remains global alignment on a single neuraxial connector standard. Regulatory requirements continue to evolve, so healthcare providers should stay informed through their local regulatory bodies and suppliers.

**12. When will the neuraxial devices with the current Luer connectors be discontinued?**

Discontinuation timelines are determined by manufacturers and may vary widely by product and region. Luer connectors for neuraxial applications will be phased out over time. Healthcare providers should consult their suppliers for detailed information about product discontinuations and continue to assess clinical requirements, especially for devices requiring long needles with Luer connectors.

**13. Will there be new item numbers or SKUs for the new 80369-6 sets?**

The introduction of new items and corresponding item numbers or SKUs is at the discretion of individual manufacturers. It is recommended to consult supplier representatives for details on product coding. In some cases, new item numbers are used to help clearly differentiate NRFit® compliant products from Luer-based ones, which is important to prevent clinical confusion. Countries with existing proprietary non-Luer connectors may already use distinct codes, so vigilance is necessary during the transition.

**14. If applicable, when will the new item numbers be available and how will we know when to order the new item numbers (SKUs)?**

Introduction of new items and related issues, such as new item numbers, are at the sole discretion of manufacturers. For precise answers relative to new item introductions, contact your supplier representative.

**15. Will there be a price increase?**

Pricing is at the sole discretion of device manufacturers.

**16. Will there be a standard color for the 80369-6 connector?**

The ISO 80369 standards specify the physical dimensions and design requirements of connectors but do not mandate color coding. However, many manufacturers have adopted yellow as a de facto color for neuraxial connectors and devices to help clinicians visually identify NRFit® components. It is important to note that color serves as a convenience aid rather than a safety control, as the physical incompatibility of connectors is the primary safety feature.

**17. What is the role of GEDSA?**

The Global Engineered Device Supplier Association (GEDSA) is a non-profit trade association composed of leading medical device manufacturers and distributors. GEDSA's mission is to support the introduction and adoption of ISO 80369 series connectors, including NRFit®, by providing consistent communication, educational resources, and implementation support to the healthcare community. GEDSA serves as a unified industry voice, engaging with government agencies, professional societies, healthcare organizations, and suppliers to help ensure a smooth and coordinated transition to safer connector standards.

**18. Does this new system require that devices using the Luer connector become obsolete?**

The Luer connector remains the standard for intravascular and hypodermic access and is governed by its own standard, ISO 80369-7. However, neuraxial devices with Luer connectors are expected to decline rapidly as NRFit® adoption increases, due to the significant patient safety benefits of physically incompatible connectors that prevent misconnections. Eliminating cross-compatibility between neuraxial and intravascular systems is a critical safety advancement. Thus, while Luer connectors will continue for IV use, their neuraxial applications will be phased out.

**19. Will there be adapters for different kinds of syringes?**

Adapters are not part of the planned NRFit® transition process. To maintain the safety benefits of the ISO 80369 series, particularly the goal of preventing misconnections, connectors that bridge incompatible systems, such as Luer to NRFit®, are not intended for production or distribution. Instead,

syringes and other devices are designed with application-specific connectors to help reduce the risk of wrong-route administration.

**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.