Frequently Asked Questions

Neuraxial Connectors (ISO 80369-6)

October 19, 2016 (v2)

Frequently Asked Questions

Neuraxial Connectors (ISO 80369-6)

---

1. **What is a small-bore connector?**
2. **What changes are coming to small-bore connectors?**
3. **Will new neuraxial medical connectors have distinct names?**
4. **Why is industry adopting the new ISO neuraxial connector?**
5. **What are the implications of these new standards?**
6. **What connectors are affected by the ISO 80369-6 (NRFit) connector standard?**
7. **Which devices are affected by the ISO 80369-6 standard?**
8. **Who developed the proposed new ISO 80369-6 connector design?**
9. **Why should we adopt the new 80369-6 connector?**
10. **What makes the new ISO 80369-6 connector different from the current Luer system?**
11. **When will the new ISO 80369-6 connector be available?**
12. **How will the new ISO 80369-6 connector be introduced into my healthcare organization?**
13. **If we use Neuraxial parts from another manufacturer's set, how will we know the products will work together?**
14. **Is it mandatory to transition to the new ISO 80369-6 connector?**
15. **When will the neuraxial devices with current connectors be discontinued?**
16. **Will there be new item numbers or SKUs for the new 80369-6 sets?**
17. **If applicable, when will the new item numbers be available and how will we know when to order the new item numbers (SKUs)?**
18. **Will there be a price increase?**
19. **Will there be a standard color for the 80369-6 connector?**
20. **What is the role of StayConnected?**
21. **Does this new system require that devices using the Luer connector become obsolete?**
22. **Will there be adapters for different kinds of syringes?**

1. What is a small-bore connector?

A small-bore connector is a connector with an inner diameter of less than 8.5mm used to connect medical devices, components and accessories for the purposes of delivering fluids or gases.

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

The International Organization for Standardization (ISO[1]) has developed a series of standards for small-bore connectors, known as ISO 80369 series. These standards will provide design and performance specifications for a range of connectors which can be used for different medical device applications (80369-3 enteral—"ENFit," 80369-6 neuraxial and major regional—"NRFit," 80369-7 intravascular and hypodermic—"Luer," etc.) and which will reduce the risks of misconnections between applications.

80369 section	Use	Common name
-2	Breathing systems and driving gases	
-3	Enteral applications	ENFit
-4	Urethral and urinary applications	
-5	Limb cuff inflation	
-6	Neuraxial applications and major regional anesthesia	NRFit
-7	intravascular or hypodermic applications	Luer

3. Will new neuraxial medical connectors have distinct names?

- Connector naming is not included in the ISO 80369 series of standards. Therefore, companies are free to name the new connectors as they choose.

- GEDSA and members of the ISO joint working group have proposed the use of the name "NRFit" (pronounced 'ner-fit') for the new connectors used for neuraxial and major regional applications. NRFit is a name that will be used to identify devices that comply with the ISO 80369-6 standard.

4. Why is industry adopting the new ISO neuraxial connector?

- The standard small-bore connector in the medical device field for many years has been the Luer connector. Because the Luer connector was such an effective and reliable design, it has been used in many different types of device applications, such as vascular, enteral, respiratory, epidural, and intrathecal. The consequence of this has been misconnection with devices that were not meant to connect, such as the delivery of toxic chemotherapy drugs into the spinal canal.

- As well as preventing the delivery of IV drugs into the neuraxial space, use of the ISO 80369-6 connectors will also prevent wrong-route delivery of neuraxial medicines (such as bupivacaine) intravenously.

1 ISO (International Organization for Standardization) is the world's largest developer of voluntary International Standards. It has published more than 19,500 International Standards covering

5. What are the implications of these new standards?

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

- Syringes used for intravascular and hypodermic access will no longer be interchangeable with neuraxial syringes. 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'[2]) they use, as those will need to be ordered specifically: pulling those from intravenous supplies stock 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.

6. What connectors are affected by the ISO 80369-6 (NRFit) connector standard?

80369-6 applications involve the use of medical devices to administer medications to and take samples from neuraxial sites (central nervous system including intracranial and spinal canal such as epidural and intrathecal), major peripheral nerve local anaesthetic blockade and continuous wound infiltration. This includes anaesthetic delivery, monitoring cerebro-spinal fluid (CSF) pressure, and removing CSF for therapeutic or diagnostic purposes.

7. Which devices are affected by the ISO 80369-6 standard?

Neuraxial devices and devices for major regional anesthesia that currently use Luer connectors will, over the next few years, incorporate the 80369-6 connectors.

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

- This new connector design was developed by ISO through the combined global effort of clinicians, regulators, test houses and industry.

- The ISO 80369-6 connector has undergone a rigorous validation process including computer aided design (CAD) misconnection tests, laboratory leak testing, human factors and usability assessment.

2 'Drop in' is a phrase used by industry for devices from other suppliers that are added by clinicians to procedure packs to make a complete kit.

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

- The ISO 80369-6 connector provides a simple way to reduce the risk of neuraxial misconnections and improve patient safety.
- The new connector reduces the chance of an unintentional cross-connection with any other connector intended for non-neuraxial routes.
- In some countries, the legal systems expect clinical staff to take all reasonable steps to mitigate the risk of cross-connection incidents, and therefore may expect clinical staff to use devices that use these application specific connectors.
- Non-adoption of the new connectors may expose clinical staff and organizations to legal challenges if further wrong-route incidents take place which could have been prevented by use of ISO 80369-6 compliant devices.

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

The new ISO 80369-6 connector looks like a Luer connector, but is about 20% smaller and has a unique design that reduces the risk of cross connection with other connectors developed under the same series of standards, especially with Luer connectors. There is one visible difference: slip males will have a collar surrounding the connector.

11. When will the new ISO 80369-6 connector be available?

Neuraxial devices with the ISO 80369-6 connector are expected to be available starting in the U.S., Canada and other markets in 2017. The ISO 80369-6 connector should be introduced into use with minimal disruption. Timing is subject to change pending regulatory agency clearance and each manufacturer's readiness. Check with your supplier representative for precise timing and device-specific details.

12. 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

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

As long as the connectors have been produced in compliance with the ISO standard, then it is expected that the devices will connect together effectively and safely. All major neuraxial device manufacturers are expected to comply with the proposed new ISO standards to help ensure neuraxial components fit together as a system. Many compatible devices will be marked with the NRFit label or with the standard number (ISO 80369-6). For clinician convenience, some items, such as syringe plungers, may be colored yellow.

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

- This varies by jurisdiction. For example, in California all epidural use must be transitioned by January 1, 2017.
- In the UK, the National Health Service (NHS) has already started planning for the introduction of 80369-6 connectors within 6 months of the California deadline.
- In Europe and other markets throughout the world, many manufacturers and suppliers are following the subject closely, and plan to adopt the same new global standard connector system.
- The deployment of devices with the 80369-6 connector may be on different timelines in different global markets, but the goal remains the same—to align to a common neuraxial connector across the globe to improve patient safety.

15. When will the neuraxial devices with current connectors be discontinued?

- Discontinuation of items is at the sole discretion of manufacturers. For precise timing of item discontinuation, contact your supplier representative. The Luer connector for neuraxial devices will be phased out of hospitals on varying timelines.
- It is important to understand that some devices, such as spinal needles, are presently used for non-neuraxial applications, such as amniocentesis and joint injections. The use of long needles with a Luer connector will still be required after the change to 80369-6 connectors, and some manufacturers have declared their intent to market such devices to meet clinical needs. You should start contacting the suppliers of the needles you presently use and ask them what plans they have for long needles with Luer connectors in the future. If this does not happen, then there is a risk that many common clinical procedures will find themselves in difficulty after the withdrawal of Luer-based spinal needles from the healthcare setting.

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

- 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.
- In the UK, clinical incidents have already arisen over confusion between proprietary neuraxial connector devices and standard Luer devices, resulting in delays to treatments. It is anticipated that many manufacturers will use product codes that allow individuals to distinguish easily between Luer and ISO 80369-6 devices to avoid such incidents. In countries where proprietary non-Luer connectors are already in use the codes will also be different, but there will be need for additional vigilance in these settings.

17. 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.

18. Will there be a price increase?

Pricing is at the sole discretion of device manufacturers.

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

Color-coding is not included in the ISO 80369 series of standards. The standards will only address the shape and size of the new connectors. These engineering controls make it unlikely that two unintended connectors will fit together. While you might see a consistent color used for devices with neuraxial connectors, it is not a requirement. There is, however, a trend in parts of the world to use the color yellow to indicate neuraxial routes. This feature would be provided for convenience, not safety.

20. What is the role of StayConnected?

- StayConnected is the implementation branch of the Global Enteral Device Supplier Association (GEDSA) which is a federally tax exempt non-profit trade association StayConnected was established in part to help introduce the new ISO standard connectors and facilitate adoption of the new 80369-6 connectors with the healthcare community. GEDSA, which is composed of leading manufacturers and distributors of medical devices, is united by a shared desire to increase patient safety and optimal delivery of neuraxial treatments and procedures. GEDSA speaks with a unified voice to communicate with government agencies, professional associations, healthcare institutions and member suppliers regarding issues that face device manufacturers, suppliers and distributors.

- GEDSA will lead StayConnected, a joint communication initiative on behalf of the industry to ensure consistency and avoid any confusion as new, safer connectors are introduced in market.

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

- The Luer connector will still be used for intravascular and hypodermic access and now has its own standard in the ISO 80369 series – ISO 80369-7.

- It is, however, expected that availability of neuraxial devices using Luer connectors will decline rapidly because of the significant patient safety benefits associated with a connector which will not cross-connect with Luer. One of the most effective ways to comprehensively reduce the risk of misconnections and enhance patient safety is to ensure that connectors of different delivery systems (i.e., neuraxial and intravascular) are not compatible.

22. Will there be adapters for different kinds of syringes?

There will be no adapters for ISO 80369-6 syringes. Syringes will be supplied with the application specific connector.

692 N. High St. Suite 304
Columbus, OH 43215 USA

gedsa.org

Prepared by GEDSA