



Patient Safety Alert

Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks

Alert reference number: NHS/PSA/RE/2017/004

Resource Alert

The universal Luer connector has been used for decades in devices for intravenous infusions, needles and syringes, and also for equipment used for neuraxial (that is, intrathecal and epidural) procedures and for delivery of regional blocks. There has been a drive to introduce non-Luer connectors for devices used for neuraxial procedures and regional blocks^{1, 2, 3, 4} to avoid the accidental, but potentially fatal, connection of an intravenous infusion or injection.

As an international standard for these connectors was expected to take several years to develop, one manufacturer developed an interim safety connector known as Surety® and this has been adopted by some but not all NHS organisations. The new international standard (ISO 80369)⁵ for these connectors is now available and includes a dedicated connector for neuraxial devices known as NRFit™ (ISO 80369-6)^{6, 7} that is not compatible with Luer connectors. The non-ISO compliant Surety® devices will cease to be manufactured or imported into the UK from December 2017.

From this month (August 2017) an initial range of NRFit™ devices sufficient for the most common intrathecal procedures will be available to the NHS. We anticipate that NRFit™ devices for all intrathecal procedures, epidurals and regional blocks will be available to the NHS by April 2018, but precise timescales will be driven by industry, and suppliers may bring these products to the market at different times.

The withdrawal of Surety® devices before a full range of NRFit™ devices is available, the staggered introduction of the NRFit™ range, and the potential need to source devices from a range of suppliers creates risks that organisations need to recognise and manage as safely as possible.

This Resource Alert asks all organisations undertaking neuraxial procedures and regional blocks to review their transition plans to NRFit™ devices and directs them to sources of support in this transition period. This includes a dedicated web page <https://improvement.nhs.uk/resources/small-bore-connectors-safety-introduction/> that includes links to this Alert's supporting information, and supplier user guides and implementation guidelines on the Barema website.

NHS Improvement, the Department of Health, the NHS Supply Chain and MHRA are working together with industry to support organisations in their transition to ISO-compliant neuraxial connectors (NRFit™).

Explanation of terminology:

- Neuraxial comprises intrathecal and epidural procedures
- Intrathecal procedures include spinal anaesthesia, lumbar puncture and other intrathecal drug delivery
- Regional block is an abridged term for peripheral nerve anaesthesia block. While this does not fall within the definition of a neuraxial procedure, NRFit™ devices are also used for regional blocks

Actions

Who: All providers of NHS-funded care where intrathecal, epidural or regional block procedures are undertaken. Not all organisations undertake intrathecal chemotherapy but all acute hospital services will undertake epidural procedures and regional blocks.

When: To begin as soon as possible and be completed by 11 December 2017

- 1** Bring this Alert to the attention of those holding leadership roles for the safe transition to NRFit™ connectors.
- 2** Review the resources signposted in this Alert and identify which of the three groups in the supporting information best reflects current use of neuraxial devices in your organisation.
- 3** Review current implementation plans for ISO-compliant devices or develop new implementation plans to reflect the advice provided in the resources.
- 4** Once you have agreed your implementation plan, ensure that all relevant clinical staff and staff involved in training, purchasing and distribution of neuraxial devices are aware of it and of any linked resources relevant to their practice.

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Alert stage: Two - Resources

Link to resources

All relevant resources including this Alert's supporting information and links to other resources including the Barema website can be found on the *Small bore connectors: an introduction to safe use* web page <https://improvement.nhs.uk/resources/small-bore-connectors-safety-introduction/>

References

1. NPSA Patient Safety Alert NPSA/2009/PSA004A/B. Safer spinal (intrathecal), epidural and regional devices. 29 November 2009 <https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=101302>
2. NPSA Patient Safety Alert NPSA/2011/PSA001. Safer spinal (intrathecal), epidural and regional devices. 31 January 2011 <https://www.cas.dh.gov.uk/ViewandAcknowledgment/ViewAlert.aspx?AlertID=101535>
3. NHS England Patient Safety Alert NHS/PSA/D/2014/002 Non-Luer spinal (intrathecal) devices for chemotherapy. 20 February 2014 <https://improvement.nhs.uk/news-alerts/patient-safety-alert-non-luer-spinal-intrathecal-devices-chemotherapy/>
4. NHS England Patient Safety Alert NHS/PSA/W/2015/004. Stage One: Warning. Managing risks during the transition period to new ISO connectors for medical devices. 27 March 2015 <https://improvement.nhs.uk/news-alerts/managing-risks-during-transition-period-new-iso-connectors-medical-devices/>
5. ISO 80369 ISO 80369-1:2010. Small-bore connectors for liquids and gases in healthcare applications -- Part 1: General requirements. <https://www.iso.org/standard/45976.html>
6. GEDSA (The Global Enteral Device Supplier Association) proposed the name and have trademarked 'NRFit™' for the new connectors used for neuraxial and major regional applications. This name will be used to identify devices that comply with the ISO 80369-6 standard. GEDSA is a Non-Profit Trade Association www.gedsa.org
7. ISO 80369-6:2016. Small-bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications. <https://www.iso.org/standard/50734.html>

Stakeholder engagement

- Barema - the Association for Anaesthetic and Respiratory Device Suppliers
- Department of Health Supplies and Resilience
- NHS Supply Chain
- National Patient Safety Response Advisory Panel (for a list of members and organisations represented on the panel, see improvement.nhs.uk/resources/patient-safety-alerts/)

Sharing resources and examples of work

If there are any resources or examples of work developed in relation to this alert you think would be useful to others, please share them with us by emailing patientsafety.enquiries@nhs.net

Advice for Central Alerting System officers and risk managers

This alert asks for a systematic approach to transferring to ISO 80369-6 compliant neuraxial connectors (NRFit™). Therefore implementation needs to be co-ordinated across the organisation rather than in the hands of individual teams or departments. You should not disseminate this Alert widely before an organisational position and plan have been agreed. If you are unsure who leads this work for your organisation, colleagues such as clinical nurse specialists in a pain or chemotherapy team will be able to identify the key individuals in anaesthetic, oncology, pharmacy and medical devices services needed to review or develop the local organisation-wide action plan.