

Supporting information for Patient Safety Alert:

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

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Issued by: NHS Improvement working with partners in MHRA, Department of Health (DH), NHS Supply Chain, and industry and clinical professionals

1. Background: Development of a new connector for neuraxial procedures

The universal Luer connector has been used with a wide range of medical devices in the NHS for decades. This includes intravenous, neuraxial (that is, intrathecal and epidural) and regional block devices such as needles, syringes and intrathecal and epidural catheters. Patient safety incidents are occurring due to the accidental wrong route administration of medication intended for intravenous use via a neuraxial device and vice versa. In some cases this has been fatal.

In 2010 a new international standard for small bore connectors (ISO 80369) was developed.¹ This now includes a dedicated connector for neuraxial and regional block devices – NRFit™ (ISO 80369-6:2016) – which is **not** compatible with Luer connectors.^{2,3} Industry has now adopted this new ISO standard for use throughout the UK and NRFit™ is becoming available as the dedicated connector for neuraxial devices.

This new ISO standard took several years to develop and in the interim one manufacturer developed a connector (Surety®) that cannot be connected to Luer devices. This addressed some of the risks of accidental connections of neuraxial devices but does not comply with the new ISO standard.



In 2011, the National Patient Safety Agency (NPSA) issued a Patient Safety Alert ([NPSA/2011/PSA001](#)), *Safer spinal (intrathecal), epidural and regional devices*,⁴ and asked organisations to introduce safer devices into practice without undue delay, once the range of new devices and test information had been evaluated locally and actions taken to minimise any potential risks arising from their use.

These devices have taken longer than expected to become available and further clarification and advice was issued in a Patient Safety Alert ([NHS/PSA/D/2014/002](#)) in 2014, *Non-Luer spinal (intrathecal) devices for chemotherapy*.⁵

Yet further guidance on the introduction of NRFit™ connectors was provided in a Patient Safety Alert ([NHS/PSA/W/2015/004](#)) in 2015, *Managing risks during the transition period to new ISO connectors for medical devices*.⁶

2. Current position on availability of Surety® and Luer devices

Withdrawal of Surety® devices from the UK market

We have been informed by GBUK Healthcare Ltd (the Surety® brand owner) that the manufacture and supply of its range of Surety® devices will cease in December 2017. Other manufacturers of products that utilise the Surety® connector may continue to supply them after this date, but GBUK is the sole supplier of a large proportion of Surety® devices (eg syringes).

GBUK is unable to estimate how long residual stock of Surety® devices will remain available after December 2017 as this will depend on how quickly current users adopt the new NRFit™ devices.

Luer devices

There is currently no indication that Luer devices for neuraxial use will be withdrawn from the UK healthcare market.

3. Implications for transition

Planned UK introduction of the ISO 80369-6 neuraxial connector (NRFit™)

The full range of NRFit™ devices for neuraxial procedures produced by GBUK to replace its Surety® range will be available for purchase by the NHS from August 2017, with the exception of the Ommaya reservoir which is not expected to be available until September 2017. Other suppliers are working to a variety of timescales and it is anticipated that by April 2018 all will be marketing NRFit™ devices for neuraxial procedures. In the interim devices will appear on the market in a phased manner rather than collectively as originally anticipated in the [position statement](#) issued by the NHS England Small Bore Connector Advisory Group in 2015.

Organisations need to review their transition plans for the use of NRFit™ devices to reflect this information, guided by:

- manufacturers' NRFit™ device updates, supplier product information and ISO 80369-6 implementation guidance developed to help organisations with their transition planning; these can be accessed via the Barema (Association of Anaesthetic & Respiratory Equipment Suppliers) website (<http://www.barema.org.uk/content/barema-neuraxial-sig-portal>)
- further supporting information on the NHS Improvement Patient Safety website (<https://improvement.nhs.uk/resources/small-bore-connectors-safety-introduction/>).

The actions individual organisations now need to take will depend on their current situation as described below:

Current situation	Considerations
<p>Group one Organisations that adopted Surety® devices for selected procedures only (eg bolus intrathecal chemotherapy)</p>	<p>The impending withdrawal of the GBUK's Surety® devices makes planning for transition to NRFit™ devices for these procedures a priority.</p> <p>For other neuraxial procedures and regional blocks transition plans need to consider when supply of the full range of NRFit™ devices for individual procedures can be assured. They need to weigh the benefits of adopting NRFit™ for all remaining procedures simultaneously (to reduce the risk inherent in having further different devices in simultaneous use) compared to prioritising those procedures associated with the known risk of error from administration of medication through the wrong route.</p>
<p>Group two Organisations that have continued to use Luer devices for all neuraxial procedures and regional blocks.</p>	<p>Transition plans should consider when supply of the full range of NRFit™ devices for all neuraxial procedures and regional blocks can be assured.</p> <p>They need to weigh the benefits of adopting the new devices for all procedures simultaneously (to reduce the risk inherent in having different devices in simultaneous use) compared to prioritising those procedures associated with the known risk of error from administration of medication through the wrong route, eg intrathecal bolus administration.</p>
<p>Group three Organisations that have implemented a complete range of Surety® devices for all relevant procedures.</p>	<p>There may be an interim phase after December 2017 when a range of Surety® devices is no longer available and the NRFit™ equivalent devices are not yet on the market, although NHS Supply Chain, DH and the manufacturers are aiming to divert remaining stocks of Surety® devices to this group of organisations.</p> <p>Transition plans should consider moving to NRFit™ for intrathecal procedures (spinal anaesthesia, lumbar puncture</p>

and drug administration). It is recognised that stocks for any remaining procedures may subsequently run out and it will then be necessary to revert back to Luer devices for individual procedures on a piecemeal basis. The option of reverting to Luer devices for these other procedures until the full range of NRFit™ devices is available should be considered.

Another option is to revert to Luer connectors for all procedures until supply of NRFit™ devices for all neuraxial procedures and regional blocks can be assured.

There is a balance of risk for these organisations between potentially using neuraxial devices with different connectors (that is, NRFit™ and Surety®) during this interim phase and continuing to run the risk of administering medication through the wrong route, eg intrathecal bolus administration.

4. Summary

In deciding the best way forward organisations need to consider the risk of having more than one type of device in use (that is, NRFit™, Surety® and Luer) and the importance of planning any changes rather than bringing them in abruptly.

In their transition planning all organisations need to consider the resources required to train staff and establish effective ordering and stock management systems.

All organisations need to identify any risks that may arise during their transition period and develop and implement action plans to mitigate these.

NHS Improvement continues to work with NHS Supply Chain, DH and industry colleagues to facilitate the safe roll out of the ISO compliant devices for the UK.

5. Links to further resources

- The Patient Safety Alert: *Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks* is available on the NHS Improvement website.
- A short video of a [PowerPoint presentation](#) explaining the transition to new safe connectors for neuraxial infusions is also available on the NHS Improvement website.
- The NHS Improvement webpage: *Small bore connectors: an introduction to safe use* provides further information to support organisations during this transition period.
- Supplier user guides and implementation guidelines are also available on the Barema website [<http://www.barema.org.uk/content/barema-neuraxial-sig-portal>].

6. Useful contacts

- Organisations seeking information on product availability can contact [NHS Supply Chain](#) or GBUK via NRFIT@GBUKGroup.com
- Usage issues such as malfunctions and failures should be reported to the MHRA via <https://yellowcard.mhra.gov.uk/>
- For other issues relating to patient safety, organisations can contact NHS Improvement via patientsafety.enquiries@nhs.net

7. References

1. 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>
2. 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
3. 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>
4. 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>
5. *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/>
6. *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/>

This publication can be made available in a number of other formats on request.

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