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Implementing Medical Devices With Safer Connectors

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Medication Practice and Medical Devices

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The ‘Universal’ Connector

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Patient safety alert 19

Promoting safer measurement and administration of liquid medicines via oral and other enteral routes

The National Patient Safety Agency (NPSA) is advising healthcare organisations on how the design of medical devices and the methods used to measure and administer oral liquid medicines* can improve patient safety.

A review of data from the NPSA's National Reporting and Learning System (NRLS) shows 33 patient safety incidents involving intravenous administration of oral liquid medicines between 1 January 2005 and 31 May 2006.

Incorrect intravenous administration of oral liquid medicines has resulted in three reported deaths between 2001 and 2004.[1-3] and there are reports of four incidents of harm or near misses between 1997 and 2004.[4-7] This risk has been recognised in the Department of Health report Building a safer NHS for patients: Improving medication safety[8] and in other publications worldwide.[9-19]

Alert

28 March 2007

Action for the NHS and the independent sector

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Action for the NHS

1 Design and supply of syringes used to administer oral liquid medicines

- Only use well-labelled oral and enteral syringes that cannot be connected to intravenous catheters or ports to measure and administer oral liquid medicines.
- Do not use intravenous syringes to measure and administer oral liquid medicines.
- Make sure stocks of oral and enteral syringes are available in all clinical areas that may need to measure and administer oral liquid medicines in a syringe.
- If patients or carers need to self-administer oral liquid medicines with a syringe then supply them with oral or enteral syringes.

2 Design of enteral feeding systems

- Enteral feeding systems should not contain ports that can be connected to intravenous syringes or that have end connectors that can be connected to intravenous or other parenteral lines.

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Safer Enteral Devices

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Device connectors & infusion spikes

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THE AGONY OF HINDSIGHT

Wayne Jowett - 2 February 2001

Vincristine inadvertently administered intrathecally

Mayra Cabrera - 11 May 2004

Bupivacaine inadvertently administered intravenously

Joseph Gibbs - February 2007

Bupivacaine and fentanyl inadvertently administered intravenously

'We just hope something gets done now within the industry. It's so fundamental.'

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Saturday 3 February 2001
BMJ

Don Berwick
Institute For Healthcare Improvement

Not again!

Preventing errors lies in redesign—not exhortation

The answer is surprisingly mundane. It is this: we are human, and humans err. Despite outrage, despite grief, despite experience, despite our best efforts, despite our deepest wishes, we are born fallible and will remain so.

The remedy is changing the system of work and better design.

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DH Department of Health

Health Service Circular

Series Number	HSC 2003/013
Issue Date	2 October 2003
Review Date	2 October 2005
Category	Quality
Status	Action

sets out a specific action on the part of the recipient with a deadline where appropriate

Updated National Guidance on the Safe Administration of Intrathecal Chemotherapy

October 2003

For action by: Strategic Health Authorities (England) - Chief Executives
NHS Trusts - Chief Executives

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Rapid Response Report

NPSA/2008/RRR004

From reporting to learning — 11 August 2008

Using Vinca Alkaloid Minibags (Adult/Adolescent Units)

Issue

There have been further reports of fatal and serious incidents from hospitals outside the UK in which doses of vinca alkaloids intended for intravenous administration have been administered by the intrathecal (spinal) route in error. These include three cases where doses of vincristine had been diluted to 10ml and 20ml in syringes.

Previous guidance to the NHS in England and Wales was to dilute doses of vinca alkaloids to 10ml or greater in a syringe in order to reduce the risk of wrong route errors. This guidance needs to be updated following the learning from these incidents in other countries. The World Health Organisation (WHO) has issued guidance (see supporting information) recommending that doses of vinca alkaloids should be prepared and administered in intravenous minibags to further minimise the risk of wrong route errors.

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Alert

28 March 2007

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Action for the NHS and the independent sector

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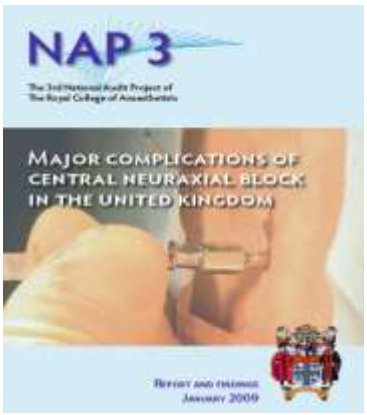
Royal College Epidural Audit

- Technical solutions, such as non-interchangeable connections, should be pursued with vigour, but must encompass the whole system from fluid reservoir to patient.
- They should only be introduced after careful assessment that they themselves do not introduce problems as a result of 'unintended consequences'.



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NRLS incident reports

1st January 2008 – 31st July 2009

Wrong route incident type	Number of incidents
Epidural medicine administered by the intravenous route	9
Intravenous medicine administered by the epidural route	9
Intravenous medicine administered by the regional anaesthetic route	3
Regional medicine administered by the intravenous route	1

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House of Commons Health Committee: Patient Safety

Paragraph181

We are alarmed at the lengthy delay in implementing Professor Toft's 2001 recommendation regarding the development of spinal needles that cannot be connected to a Luer syringe. It is totally unacceptable that an identified and simple technical solution to a catastrophic problem should take so long to be put into practical use. The Chief Executive of the NHS must explain why this delay has taken place and ensure that such delays never occur again. It is unacceptable that the NHS does not have a mechanism to ensure that changes such as this, which impact seriously on patient safety, occur in a timely fashion.

House of Commons Health Committee
Patient Safety Sixth Report of Session 2008–09, *Volume I* HC 151-I, The Stationery Office Limited, 3 July 2009

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2000
European Standards Agency - CEN

- DS DS/CEN/CR 13825
- Luer connectors - a report to CEN Chef from the CEN forum task group ”Luer Fitting”.

- Luer connectors should be restricted to intravenous and hypodermic devices.

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ISO TC 210

Small-bore connectors for liquids and gases in healthcare applications — Part 1: General Requirements

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- *Part 1: General Requirements*
- *Part 2: Connectors for breathing systems and driving gases applications*
- *Part 3: Connectors for enteral applications*
- *Part 4: Connectors for urethral and urinary applications*
- *Part 5: Connectors for cuff inflation applications*
- *Part 6: Connectors for neuraxial applications*

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A two step process is required

Safer devices

Standardised single design

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External Reference Group for Neuraxial Devices

Welsh Assembly Government

Depart of Health and Social Services – Northern Ireland

Department of Health – England

Royal College of Paediatrics and Child Health

Royal College of Anaesthetists

Royal College of Midwives

College of Operating Department Practitioners

Royal College of Nursing

NHS Supply Chain

National Network of Clinical Procurement Specialists

Cancer network nurse

Association of Paediatric Anaesthetists

Association of Anaesthetists of Great Britain and Ireland

National Patient Safety Agency

Cancer network Pharmacist

Association of Obstetric Anaesthetists

British Anaesthetic and Recovery Nurse Association

Barema where appropriate

Medicines and Healthcare Products Regulatory Agency

Cancer network Doctor

Suppliers of medical devices where appropriate

Representative from the UK delegation to the ISO Standards group

WHO World Alliance For Patient Safety

Association of Healthcare Industries where appropriate

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Equipment types

Spinal

- Spinal syringes
- Drawing-up needles
- Drawing-up syringes
- Spinal filters
- Spinal manometers
- Spinal catheters
- Spinal administration sets
- Infusion bags/bottles

Epidural

- Spinal/epidural needles
- Epidural syringes
- Drawing-up needles
- Bacterial filter
- Epidural catheters
- Epidural administration sets
- Infusion bags/bottles

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Equipment types

Regional

- Regional syringes
- Drawing-up needles
- Regional catheters
- Wound perfusion catheters
- Regional administration sets
- Infusion bags/bottles

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Alert

Patient Safety Alert

NPSA/2009/PSA004A
24 November 2009

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National Reporting and Learning Service

Safer spinal (intrathecal), epidural and regional devices – Part A

From 1 April 2011 all spinal (intrathecal) bolus doses and lumbar puncture samples should be performed using syringes, needles and other devices with connectors that **will not** also connect with intravenous equipment.

NHS organisations will need to review and update their purchasing policies, procedures and clinical protocols to include the use of specified devices with safer connectors. NHS organisations should not request further orders for non-compliant devices six months before the 1 April 2011 implementation date.

These devices with safer connectors are not currently available. By

Action by all organisations in the NHS and independent sector

An executive director, nominated by the chief executive, working with clinical and procurement staff should implement a 'Purchasing for Safety' initiative to ensure that:

by 1 April 2011

- all spinal (intrathecal) bolus doses and lumbar puncture samples are performed using syringes, needles and other devices with safer connectors that will not connect with intravenous Luer connectors;

Alert

Patient Safety Alert

NPSA/2009/PSA004B
24 November 2009

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National Reporting and Learning Service

Safer spinal (intrathecal), epidural and regional devices – Part B

From 1 April 2013 all epidural, spinal (intrathecal) and regional anaesthesia infusions and bolus doses should be performed with devices with connectors that **will not** also connect with intravenous equipment.

NHS organisations will need to review and update their purchasing policies, procedures and clinical protocols to include the use of specified devices with safer connectors. NHS organisations should not request further orders for non-compliant devices six months before the 1 April 2013 implementation date.

These devices with safer connectors are not currently available. By

Action by all organisations in the NHS and independent sector

An executive director, nominated by the chief executive, working with clinical and procurement staff should implement a 'Purchasing for Safety' initiative to ensure that:

by 1 April 2013

- all epidural, spinal (intrathecal) and regional infusions and boluses are performed with devices that use safer connectors that will not connect with intravenous Luer connectors or intravenous infusion spikes;

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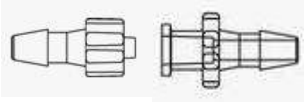
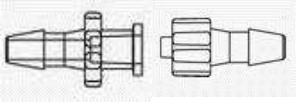
Connector designs

Male to Female



Neurax – B-link
BD
Smiths
Flexicare

Female to Males



Surety

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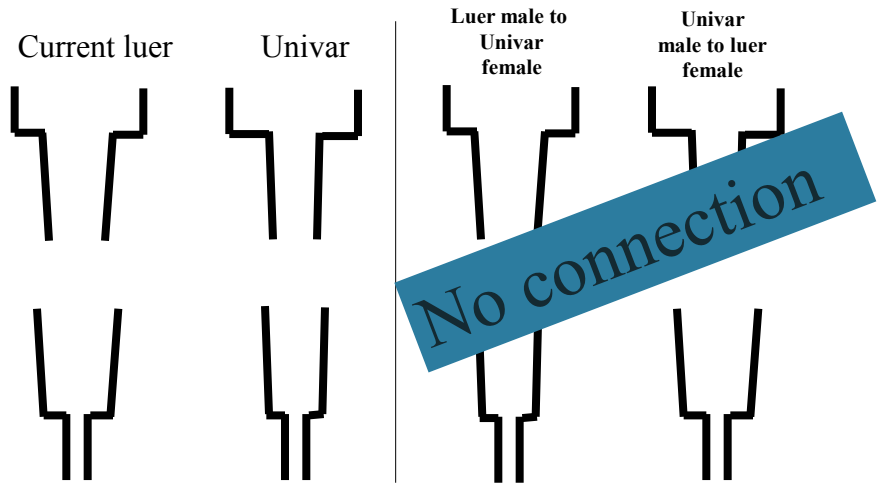
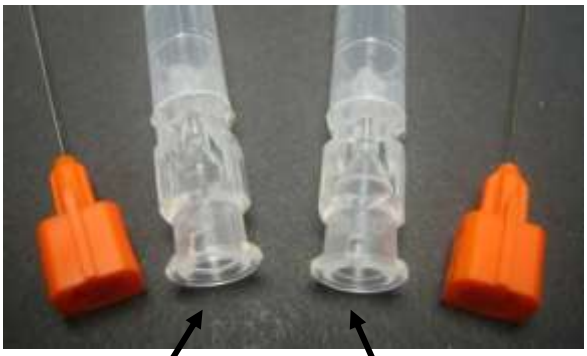
Univia



Univia



Safety spinal needle

Conventional spinal needle

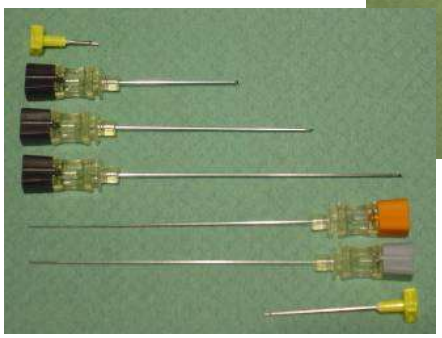
CorrectInject® Safety System – Spinal Solution

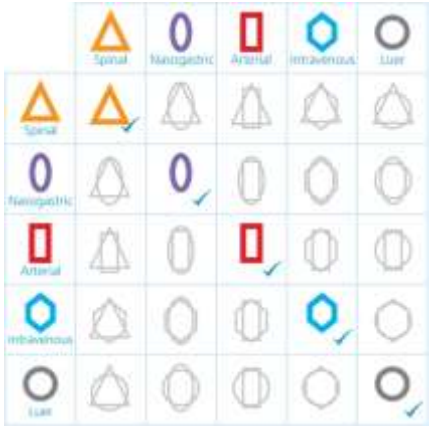
smiths medical
bringing technology to life

Surety connectors

neurax®

designed to prevent misconnections





- Haptic perception
- Visual shape recognition
- Colour recognition

HALL LOCK

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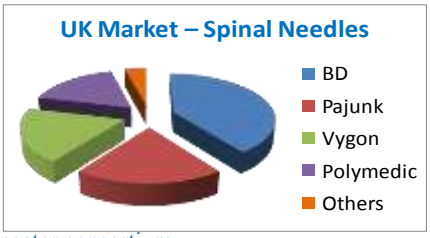


Surety – Connector consortium

Polymedic

BBraun

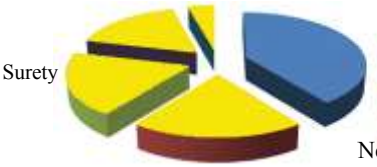
Sarstedt

Pajunk

Vygon

Aspen Medical

Rocket Medical



5 connector designs in response to NPSA Alert

New market entrants

Flexicare
Neurax B-link
Smiths

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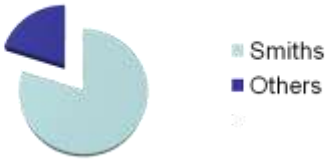
UK Market Epidural Needles



Surety – Connector consortium

Polymedic

BBraun

Sarstedt

Pajunk

Vygon

5 connector designs in response to NPSA Alert

New market entrants

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Neurax B-link
BD

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Process to place new medical devices on the UK market

EU Medical Devices Directive
CE Mark

The amount of clinical testing is NOT = to that required for medicines

For new critical devices – like neuraxial devices – more clinical testing information is required by purchasers

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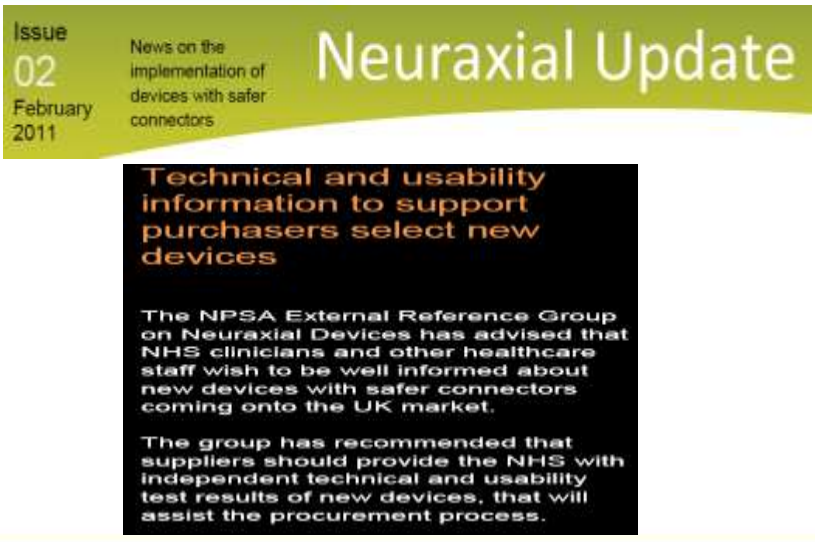

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Technical and usability testing information

Technical laboratory testing results should include:

- measurements of key dimensions, for consistency of manufacture;
- security of connection;
- ease and force of separation;
- leakage tests;
- ease of thread engagement;
- cross connectivity with Luer and other small bore connectors;
- microbiological integrity testing of prefilled syringes.

Clinical simulation test results using an anatomically realistic spinal trainer manikin should include four simulated clinical settings:

- spinal anaesthesia;
- epidural analgesia and anaesthesia;
- intrathecal chemotherapy;
- lumbar puncture.

Simulation results from the clinical settings above should include:

- clinical acceptability;
- user satisfaction;
- cross connectivity with Luer and other small bore connectors.

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The first patient safety incident with a spinal needle with a safer connector

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Rapid Response Report

NPSA/2011/RRRXX

From reporting to learning

XXX November 2011

DRAFT

Minimising Risks of Mismatching Spinal, Epidural and Regional Devices With Incompatible Connectors

Issue

Spinal, epidural and regional devices, with safer connectors that will not connect with intravenous equipment are being placed on the market by industry in response to the NPSA Patient Safety Alert issued in 2009.[1] Although the use of these devices will minimise the risks of wrong route errors, it is essential that effective controls are in place to minimise the risk of mis-selection and supply of devices with incompatible connectors that could cause delay in clinical procedures and harm patients. The NPSA has recently received details of a patient safety incident, where a spinal needle with the wrong connector was supplied and used in error.

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1. Alert healthcare staff who order, receive, transport, restock and clinically use spinal, epidural and regional devices of the risk of mis-matching connectors
2. Check current stocks of spinal, epidural and regional devices to ensure these devices are compatible.
3. Amend written distribution and clinical procedures and establish training programmes for staff to confirm the identity of the connectors used in devices. Checks should not solely rely on catalogue code numbers. The term 'Luer' and where safer connectors are fitted, the device trademark should be used identify different connector designs. Currently Correctinject, Hall Lock, Neurax, Surety, Univar are trademarks being used. Only devices with the same connector descriptors are compatible. In addition other design elements such as colour, text and symbols should assist users identify the type of connector used in the device.
4. Use procedure packs where feasible and appropriate to ensure that all the devices required for a specified procedure are compatible and readily available
5. Apply additional labels, to clearly identify the connector design, to devices where the manufacturers labelling, packaging and shipping carton provides insufficient differentiation.
6. Require clinical staff to check that all devices for a procedure are fitted with the same connector design before commencing the procedure.

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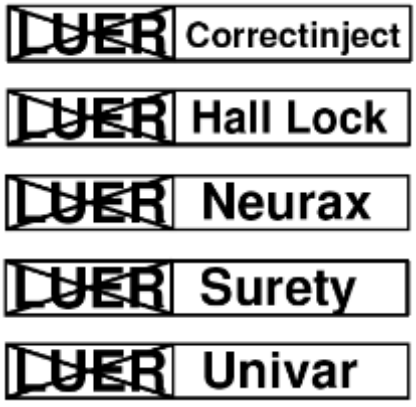
Possible Non-Luer symbols

Version 0.1 - 24/10/2011



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New non-IV infusion spike design

‘NonivLok’

Chapter

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Target implementation dates for the NHS

- Part A – Spinal bolus / lumbar puncture
  - 1st April 2012
- Part B – Epidural, Spinal Infusions, Regional Anaesthesia
  - 1st April 2013
- Ongoing Commitment for the initiative
  - Health Ministers
  - Department of Health
  - NHS Commissioning Board

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