



# Patient Safety Alert

## Stage One: Warning

*Managing risks during the transition period to new ISO connectors for medical devices*

27 March 2015

Alert reference number: NHS/PSA/W/2015/004

Alert stage: One - Warning

From September 2015, newly designed enteral administration sets (fitted with new connectors) will be introduced into the NHS. **All providers of NHS funded care need to be vigilant and address the risks during the transition period.**

Different types of medical devices can easily be connected using Luer connectors. For example, an inflation tube of a blood pressure monitor can be connected to an intravenous catheter; an enteral feed administration set can be connected to a tracheostomy tube. In the UK and worldwide, such wrong route errors have resulted in patient injury and death.

To reduce the risk of misconnections, the International Organization for Standardisation (ISO) has developed a series of new International Standards for small bore connectors in a range of medical devices (ISO 80369). Currently included are breathing systems and driving gases, enteral feeding, limb cuff inflation devices, neuraxial devices (for spinal and epidural injections), and intravascular/ hypodermic applications (i.e. injections and infusions, for which Luer connectors will be retained). The standards define the design of the connectors for these applications so that the risk of misconnections with other connectors in the series is reduced.

The first devices to be fitted with the new ISO connectors will be **enteral feeding tubes**, with a phased implementation that will begin in September 2015. Initially, only new gravity and pump transition giving sets will be available, together with adapters to allow continued use for current enteral feeding tubes and syringes; newly designed enteral syringes and feeding tubes will be introduced in March 2016. Associated risks during this transition period may include inability to deliver therapy due to device incompatibility, use of adapters, device shortages, logistical issues and awareness problems.

There will be no change to syringes designed for oral use only. A complete range of devices fitted with the ISO **'neuraxial' connectors** are unlikely to be available in the UK before 2017.





A clinical advisory group has been set up to advise NHS England on the safe introduction of devices with the new connectors. The group is linking with similar groups in Wales, Scotland and Northern Ireland to co-ordinate the introduction across the UK.

Various resources to support organisations to prepare for the change can be found at [www.stayconnected.org/index.html](http://www.stayconnected.org/index.html). Information is also available on the NHS England website [www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-bore-connectors/](http://www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-bore-connectors/), and Medication and Medical Device Safety Officers will be informed when new content is added.

## Actions

**Who:** All providers of NHS funded community and inpatient healthcare

**When:** To commence immediately and be completed by no later than 8 May 2015

-  Identify if medical devices affected by the change are being used in your organisation.
-  If these devices are being used, ensure that an action plan is underway to minimise the risks during the transition period.
-  Distribute this Alert to all staff involved in purchasing, training and distribution of affected medical devices.
-  Share locally developed good practice resources as to how to manage this transition safely by emailing [patientsafety.enquiries@nhs.net](mailto:patientsafety.enquiries@nhs.net).

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### Technical notes

#### NRLS search dates and terms

As this Patient Safety Alert relates to the planned nation-wide introduction of new medical devices, a search of the NRLS was not applicable.

#### Stakeholder engagement

The alert was developed by the NHS England Small Bore Connector Clinical Advisory Group. Members of this group include senior and practicing clinicians, representatives from MHRA, NHS Supply Chain, British Standards Institution and industry groups.

It has also been supported by the Medical Specialties Patient Safety Expert Group (for membership see <http://www.england.nhs.uk/ourwork/patientsafety/patient-safety-groups/medical-specialties/>)

#### Useful resources

**NHS England website** <http://www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-bore-connectors/>

This includes:

- Small Bore Connector Clinical Advisory Group terms of reference and minutes of previous meetings.
- A set of safety criteria, which describe the six key safeguards that should ideally be in place before devices with new small bore connectors for a specified clinical application are introduced into the NHS.

As they become available further resources on how to prepare for the new ISO connector standards will be added to the web page and Medication and Medical Device Safety Officers will then be informed.

**Stay connected** <http://www.stayconnected.org/index.html>

This communication platform includes various resources to support organisations to prepare for the change to new ISO connectors, including brochures, videos, webinar recordings and presentation slides and transition checklists.

**Enteral Plastic Safety Group (EPSG) statement** <http://www.peng.org.uk/publications-resources/resources-for-hcps.php>

Joint statement from leading UK enteral feeding device suppliers and clinicians on the introduction of new enteral feeding devices.