Publications Gateway Reference 03935

NHS England Small Bore Connector Clinical Advisory Group

Position Statement

On the adoption of medical devices for use in neuraxial procedures fitted with (non-luer) ISO 80369-6 compliant connectors

The NHS has previously demonstrated their commitment to enhance patient safety through the adoption of non-Luer connectors through various initiatives over the last six years, including the deployment of proprietary non-Luer connectors in parts of the NHS. Other parts of the NHS are specifically waiting for ISO 80369-6 compliant devices to become available before deploying non-Luer devices. We note that:

- the medical device industry are supporting international requirements, which would see the introduction of devices with non-Luer connectors for epidural and neuraxial use in January 2016 (see http://leginfo.legislature.ca.gov/faces/billNavClient.xhtml?bill_id=201520160AB444)
- by 2017, industry should therefore supply a comprehensive range of medical devices utilising the ISO 80369-6 connectors.

The NHS (as the instigator of this patient safety initiative globally) and other stakeholders:

- require early/ prompt access to the ISO 80369-6 compliant devices;
- through this position statement are signalling to the global medical device industry that the NHS intends to start deployment of ISO 80369-6 devices as soon as the NHS requirements for the safe introduction of these devices have been met (see safety criteria at http://www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-bore-connectors/)
- require this to be a single phase process
- intend to liaise with industry during 2015 to ensure industry understand the UK requirements and to allow industry the opportunity to share their deployment plans with the UK Health Services to ensure an orderly coordinated change without compromising patient safety.

The NHS is looking forward to working with industry to facilitate a prompt, safe and co-ordinated rollout of the ISO compliant devices for the UK.

13 August 2015