

Joint statement on neuraxial connectors and ISO 80369-6:2016 March 2017

The Australian and New Zealand College of Anaesthetists (ANZCA) and the Australian Commission on Safety and Quality in Health Care (the Commission) support the introduction of neuraxial connectors that comply with International Standard ISO 80369-6:2016 for neural devices as an important adjunct to improving patient safety.

This joint position statement is endorsed by the following organisations:

- Australian Nursing and Midwifery Federation
- College of Intensive Care Medicine
- Cancer Nurses Society of Australia
- Medical Oncology Group of Australia
- Therapeutic Goods Administration
- Medical Technology Association of Australia (with exception of recommendation 6)
- Society for Paediatric Anaesthesia in New Zealand and Australia
- The Society of Hospital Pharmacists of Australia.

This position statement outlines current intentions. Collaboration is expected between the endorsing organisations, the Therapeutic Goods Administration (TGA) and the manufacturers of products with neuraxial connectors. The statement will be revised as appropriate according to product development to ensure that introduction of new devices is managed and communicated for patient safety.

Position

The International Standard ISO 80369-6:2016 *Small bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications* was introduced with the aim of reducing the injection of erroneous substances via intrathecal, epidural and other neural routes. ISO 80369-6:2016 specifies the design and dimensions of small-bore connectors intended for all neural applications, including neuraxial, peripheral and regional applications.¹

The Australian and New Zealand College of Anaesthetists (ANZCA) and the Commission recommend that ISO 80369-6:2016 be adopted in Australia as part of a global initiative to improve patient safety, and that devices incorporating small-bore connectors are classified and regulated in accordance with ISO 80369-6:2016. However, safe implementation of the standard connectors requires careful planning.

This position statement also recommends that:

1. Key clinical groups collaborate to inform the introduction of connectors that comply with ISO 80369-6:2016
2. Health services identify a small number of hospital sites to pilot the introduction of devices that comply with ISO 80369-6:2016
3. Health services piloting these connectors ensure availability of devices with connectors that comply with ISO80369-6:2016 for completion of procedures from end-to-end as part of the pilot
4. Health services strategically plan the full introduction of devices that comply with ISO80369-6:2016 based on lessons learnt from the pilot
5. Educational materials and communication through professional organisations is prepared before full introduction to hospitals, health services or ownership groups
6. Devices with connectors that comply with ISO 80369-6:2016 are labelled with an agreed standard identifier, such as the NRFit™ logo²
7. Colour-coding of connectors is consistent with the *National standard for user-applied labelling of injectable medicines, fluids and lines* (2015)
8. Incident reporting systems are reviewed to ensure that incidents relating to use of devices that comply with ISO 80369-6: 2016 are captured, to support post-implementation monitoring.

Background

Erroneous perineural administration of medicines or substances by the wrong route, including intrathecal and epidural, is a small but highly significant proportion of the overall problem of injection errors in medicines administration. These incidents can be catastrophic and may result in serious permanent harm to the patient, or death. Catastrophic errors can also have a serious impact on the clinicians involved and on the hospital, including the cost of litigation and compensation for permanently harmed patients.

Internationally, safety organisations have tried to reduce the incidence of erroneous injection with multifaceted solutions that include awareness and training of health personnel, route-specific storage, and colouring and labelling of medicines and devices. Despite these recommendations from safety organisations, administration errors continue to occur.

The administration of a medicine by the wrong route is facilitated by the interconnectivity of intravenous, epidural, intrathecal, regional and peripheral nerve devices, including syringes, needles, filters, syringe caps, fluid-dispensing connectors, and three-way taps used for medicines administration and sampling body fluids. The risk involves both injection of the

incorrect fluid into neural sites, and injection of fluids intended for the neural route by other routes (for example, intravenously).

In Australia, connectors universally conform to the Luer system. Because of the lack of effective practice-based strategies to minimise the risk of neural medicine administration by the wrong route, dedicated connectors for neuraxial applications have been developed. This led to the publication in April 2016 of the International Organization for Standardization (ISO) standard 80369-6 for neuraxial connectors.

A roundtable on ISO 80369-6:2016 was convened by ANZCA and the Commission in August 2016. It was attended by representatives from peak clinical groups in Australia and which are included in the list of endorsing groups shown on page 1. The roundtable recommended that ISO 80369-6:2016 was fit for purpose in Australia. The roundtable also agreed that the global manufacture ISO-compliant connectors and their introduction into Australia should occur in a controlled way with strategic planning to avoid patient harm. Moreover, participants advised that improvements in medication safety expected from the dedicated connectors should not be negated by introducing other risks and medication errors.

Regulation of medical devices in Australia

Internationally, it will take some time for vendors to incorporate new connectors into devices and for their regulatory review. Therefore, introduction to market may be gradual and lead to variation in availability across a full range of products for the purposes of a single procedure.

Any medical device supplied in Australia must be included in the Australian Register of Therapeutic Goods (ARTG) unless the device is exempt under the legislation. The TGA requirements for including medical devices on the ARTG are described in Introduction to the Premarket Assessment of Medical Devices – TGA regulation July 2016.³

Depending on the manufacturer's labelled intended use, a medical device may be classified as Class I (low risk; such as a connector), Class IIa (low-to-medium risk; e.g. a cannula or needle with a connector) or Class III (high risk; e.g. neuraxial connectors attached to devices that enter the spinal canal such as a spinal cannula or catheter).

The approval process differs depending on the risk classification and intended purpose of the medical device. Class I medical devices can be marketed almost immediately while medical devices with a higher risk classification will require approval prior to marketing. Therefore, the correct and appropriate classification of devices is critical.

Range of products with small-bore neuraxial connectors

The safe, controlled and appropriately managed introduction of connectors that comply with ISO 80369-6:2016 will involve a wide range of products. International experience suggests incomplete pathways of connection systems may be detrimental to patient safety. Moreover, a core set of products within a complete system should only be introduced when each of the elements can be supplied with a connector that complies with ISO 80369-6:2016.

ISO 80369-6 applies to the design and dimensions of all small-bore neuraxial connectors within systems. A complete system that allows interconnectivity between items used for neural route applications includes needles, epidural and neurosurgical catheters, connectors, connecting devices (such as drains, ports, and manometers), infusion lines and syringes.

The full list of products for neural use has not yet been established, but is expected to be extensive.

Other strategies to improve patient safety

Neuraxial connectors are only one element of a comprehensive approach to improving the safety of perineural procedures. Other risk reduction strategies include user-applied labelling of syringes and lines, colour coding of equipment, keeping neurotoxic solutions (e.g. skin antiseptics) remote from the sterile procedure area, education of healthcare professionals and double-checking all connection sites.

Use of colour

ISO 80369-6:2016 does not specify colour. However, colour is used as an identification and differentiation aid in the *National standard for user-applied labelling of injectable medicines, fluids and lines* (the Labelling Standard).⁴ Yellow is used for container and line labels for neural routes. Ideally, manufacturers would also colour-code tubing and lines.

The application of colour to devices is being considered by an ISO technical group.

Pre-filled syringes

The risk of drawing up the wrong solution into the correct syringe is not reduced by introducing unique neuraxial devices. Pre-filled syringes should mitigate this risk while also reducing the risk of infection. Pre-filled syringes could be colour-coded to reflect the intended neural route.

Double checking

All connection sites should be double-checked by two clinicians of at initiation and at every handover to mitigate the risk of medication error.

Education and risk-managed uptake of devices with connectors

A risk-managed-based approach to running down inventory and uptake of new devices is recommended.

This should include:

- national education through professional colleges and societies because clinicians move frequently between jurisdictions
- national consistency in the program of education for the public and private hospital sectors, clinical colleges, and schools of medicine and nursing
- piloting the introduction in champion institutions to inform national implementation
- reconciling an end-to-end system of devices and flow of administration to ensure all procedures may be completed end-to-end before implementation.

Transition, procurement and storage of devices

Healthcare facilities should specify a planned transition for moving to dedicated small-bore connectors for intrathecal and epidural injection.

This should include measures to ensure:

- both types of products are not available concurrently in clinical areas

- devices that comply with ISO80369-6:2016 have dedicated storage areas
- a label is clearly and prominently displayed on devices with connectors that comply with ISO 80369:2016 to differentiate these from devices with Luer connectors. This label may be the NRFit™ logo² or a similar identifier to aid identification. The label would not imply standard compliance.

Note: the Medical Technology Association of Australia does not endorse use of the NRFit™ logo.

Post-market surveillance

Post-market surveillance following the introduction of dedicated small-bore connectors will be conducted through mandatory reporting to the TGA by sponsors for incidents associated with these devices that lead to death or serious injury, and through public and private hospital incident-reporting systems with sentinel sites receiving reports.

The TGA also encourages reporting of any issues, by sponsors and health professionals to the Incident Report and Investigation Scheme (IRIS).

References

1. International Organization for Standardization. Small bore connectors for liquids and gases in healthcare applications – Part 6: Connectors for neuraxial applications (ISO 80369-6:2016) (D16-22135) – not for circulation or networking (copyright protected).
2. NRFit™ Trademark and usage <http://stayconnected.org/neuraxial-nrfit/>
3. Introduction to the Premarket Assessment of Medical Devices – TGA regulation July 2016
4. Australian Commission on Safety and Quality in Health Care. National standard for user-applied labelling of injectable medicines, fluids and lines. Sydney: Australian Commission on Safety and Quality in Health Care; 2015. Available from: www.safetyandquality.gov.au/publications/national-standard-for-user-applied-labelling/

Further information

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Joint Commission. Managing risk during transition to new ISO tubing connector standards. The Joint Commission Sentinel Event Alert: Issue 53, August 20, 2014. Available from: www.jointcommission.org/assets/1/6/SEA_53_Connectors_8_19_14_final.pdf