ANZCA
AUSTRALIAN AND NEW ZEALAND COLLEGE OF ANAESTHETISTS

Introduction of neural/neuraxial devices with connectors compliant with the new international standard ISO 80369-6

ADVICE FOR EVERY ANAESTHETIST AND PAIN MEDICINE PRACTITIONER

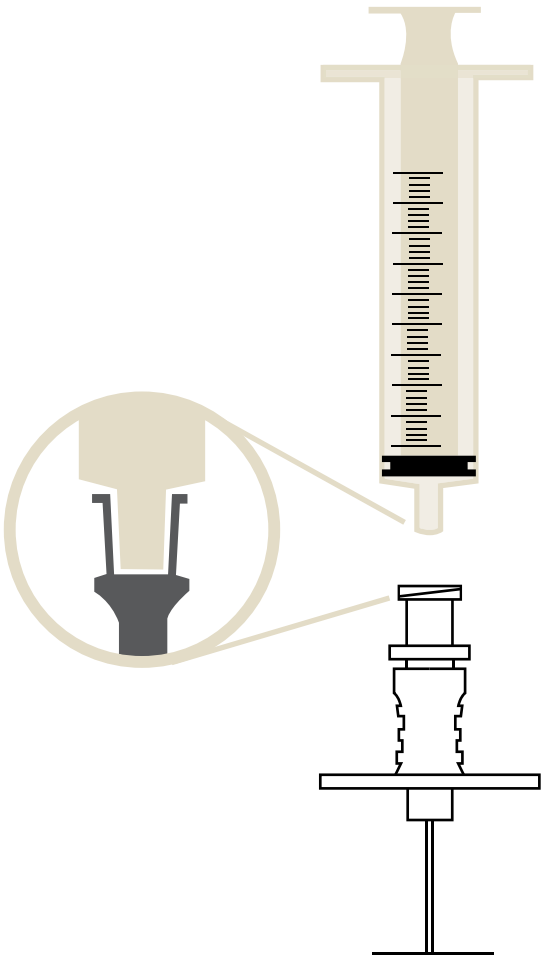
Spinal, epidural and nerve block equipment is changing.

As a safety initiative to avoid wrong route administration of medicines and substances, the International Organization for Standardization (ISO) has overseen the development of a series of connectors for devices used for different clinical applications.

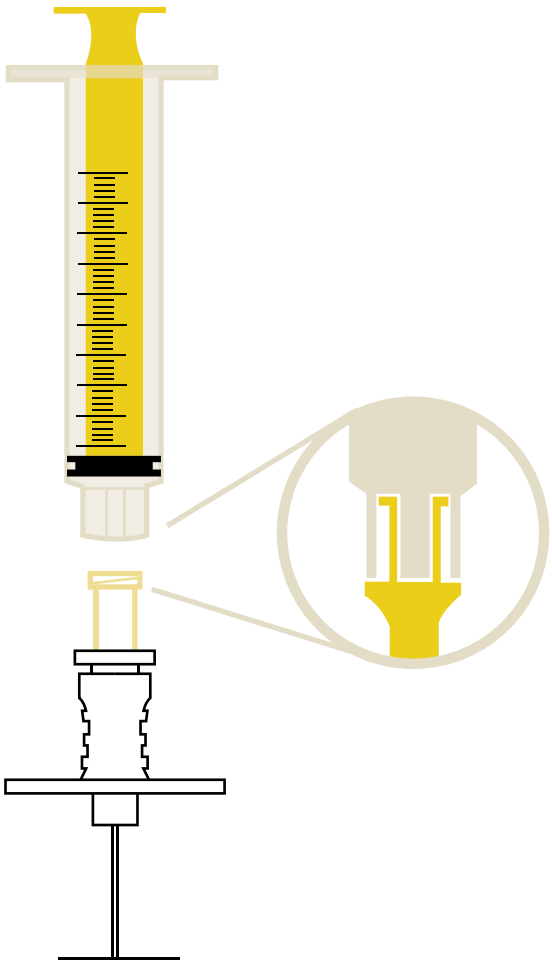
The ISO 80369 series of standards (known as Small Bore Connectors) define the dimensions of the connectors for different clinical uses which cannot couple with each other. Part 6 of this series pertains to connectors used with devices for neuraxial and other neural procedures and is known as ISO 80369-6 *Small bore connectors for liquids and gases in healthcare applications — Part 6: Connectors for neuraxial applications*.

The new design is similar to Luer with a slightly smaller mating interface. It has been deemed fit for purpose (Cook et al). A trademark name associated with devices compliant with this standard is NRFit™.

TRADITIONAL LUER CONNECTOR



NEW ISO 80369-6 CONNECTOR (NRFIT™)



Manufacturers are now producing neural devices with ISO 80369-6 connectors. The production line of legacy products such as those with Luer connectors will be shut down.

Thus changeover to ISO 80369-6 compliant devices is obligatory although the timeframe is as yet undetermined.

ANZCA is collaborating with the Australian Commission for Safety & Quality in Health Care to provide guidance on the introduction of this equipment into clinical practice in Australia and New Zealand, and with other authorities as required.

Internationally there has been introduction of some of these products into healthcare facilities and clinical practice. Based on the changeover experience in the UK of non-Luer spinal and epidural devices and internationally of enteral devices (ISO 80369-2 connectors), recommendations have been made for implementation into healthcare facilities. **It is crucial that ad hoc introduction of this equipment is avoided as risks to optimal patient care are significant**.

GENERAL PRINCIPLES

- Rigorous planning for change over.
- Institutional leadership.
- Identification, communication and engagement with the range of stakeholders: manufacturers, suppliers and logistics departments, clinicians.
- Appraisal of the range of equipment across a facility that will need to change.
- Awareness of variations in clinical practice and “off label” uses.
- Education and communication.
- Monitor and audit incidents.
- Risk register.
- Application specific considerations.

SPECIFIC RECOMMENDATIONS:

- Co-ordination of introduction between purchasing officers/supply departments, clinicians and pharmacy (where appropriate) is crucial.
- End-to-end supply of all products required for a specific procedure must be ensured.
- There must be no possibility of ISO 80369-6 compliant and non-compliant product availability in the same work space.
- Changeover to ISO 80369-6 compliant devices should be planned to occur on one day.
- Adaptors must not be used.
- To aid correct product identification institutions should require suppliers to provide products that are labelled with the ISO 80369-6 label or NRFit™ logo. This cannot be mandated by the Therapeutic Goods Association in Australia or Medsafe in New Zealand.

REFERENCES AND RESOURCES:

- ANZCA equipment list
- ISO 80369-6 Implementation of neuraxial/neural devices in the UK. June 1 2016 https://anaesthetists.org/Portals/0/PDFs/Safety/ISO_80369-6_Implementation_of_neuraxial_and_neural_devices_in_the_UK.pdf?ver=2018-09-25-155719-277
- Guidelines for the implementation of medical products using small bore connectors specified in the ISO 80369 series. http://stayconnected.org/wp-content/uploads/2017/03/ISO80369-White-Paper-ISO-Guideline-for-the-implementation-of-medical-products-using-small-bore-connectors-specified-in-the-ISO-80369-series.pdf
- Litman et al, New Solutions to reduce wrong route medication errors, Paed Aneas. 2018 (28) 8-12
- ANZCA-and-Commission-position-statement-on-neuraxial-connectors-2017Mar
- Cook TM, Wilkes A, Bickford Smith P, Dorn L, Stacey M, Kinsella SM, Sharpe P, Phillips P. Multicentre clinical simulation evaluation of the ISO 80369-6 neuraxial non-Luer connector Anaesthesia 2019 (74) 619–629

Dr Phoebe Mainland FANZCA prepared a report in 2017 on how other countries are preparing for the introduction of medical devices with new connectors, and the lessons that can be learned to help Australian implementation. This can be accessed here:
https://www.churchilltrust.com.au/media/fellows/Mainland_P_2015_reducing_misconnections_between_medical_devices.pdf

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