AUSTRALIAN COMMISSION ON SAFETY AND QUALITY IN HEALTH CARE

ANZCA
AUSTRALIAN AND NEW ZEALAND COLLEGE OF ANAESTHETISTS

ISO 80369-6:2016 neural connector devices to reduce misconnection errors

Guidelines for implementation in Australia

December 2019

Contents

Summary

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 erroneous, harmful administration of fluids via intrathecal, epidural and other neural routes and reducing erroneous administration of substances intended for neural routes to other sites.[1]

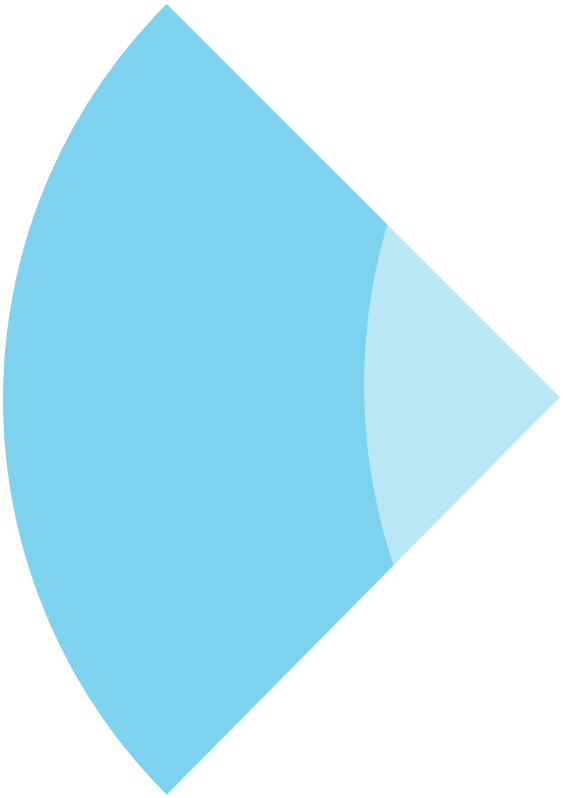
In 2017, the Australian Commission on Safety and Quality in Health Care (the Commission) and the Australian and New Zealand College of Anaesthetists (ANZCA) published a joint statement recommending that medical devices incorporating small-bore connectors be adopted in Australia as part of a global initiative to improve patient safety. Neural, including neuraxial, devices with connectors are required to be compliant with ISO 80369-6: 2016 and safe implementation must be carefully planned.[2,3,4]

In this document, the Commission and ANZCA provide information to facilitate the safe introduction of neural devices with connectors that comply with ISO 80369-6:2016 across Australia. This includes a guideline for implementation and a safety checklist. ANZCA has also published a safety alert including an explanation of the new equipment with diagrams and a list of impacted devices.[5]

As ISO 80369-6 compliant devices are introduced, medical devices for neural procedures with Luer connectors will be withdrawn. Expedient and well constructed change management plans will need to be introduced by all health services involved in neuraxial and regional anaesthetic procedures.

For the purposes of this document:

- Neural devices with connectors compliant with ISO 80369-6:2016 shall be described as 'ISO 80369-6 devices'.
- Devices that use the Luer connector will be described as 'Luer devices'.
- The ISO 80369-6:2016 standard refers to 'neuraxial' devices. However, devices for both central and peripheral neural routes are impacted by the standard. Hence, these guidelines are prepared for neural devices developed according to the ISO 80369-6:2016 standard for neuraxial applications.



Introduction

Erroneous neuraxial and peripheral neural administration (including intrathecal and epidural) of medicines or fluids intended for administration by other routes is a small but highly significant proportion of the number of injection errors in medicines administration. Moreover, the administration of medicines intended for neural procedures can be erroneously given by other routes. These incidents can be catastrophic for patients and may result in serious permanent harm or death.

Administration of a medicine by the wrong route is facilitated by the interconnectivity of intravenous devices with epidural, intrathecal, regional and peripheral nerve devices, including syringes, needles, filters, syringe caps and lines. These wrong route medication errors have been made possible due to the universal use of the Luer connector that has no physical barrier to prevent unintentional misconnection of devices.[6]

The International Organization for Standardization (ISO) developed a standard for neuraxial connectors, ISO 80369-6:2016 to address this system deficiency.[1] Devices compliant with this standard will only connect with other ports for neural delivery of medicines. This reduces the risk of misconnections and wrong route administration of a medicine or fluid.

ANZCA and the Commission recommended in a joint safety statement that devices for neural procedures compliant with ISO 80369-6:2016 be adopted in Australia as part of this global initiative to improve patient safety.[2]

Context

The joint statement makes recommendations on the safe and strategic introduction of ISO 80369-6 compliant devices within Australian health services to reduce the risk of patient harm. These ISO compliant devices facilitate dedicated neural medicine delivery and a systems solution to the wrong route hazard. System redesign and introduction of physical barriers is the most effective human factors engineering strategy to mitigate use-related hazards. However, potential improvements in medication safety should not be negated by introducing other risks. The implementation risk must be considered and addressed proactively.

Incomplete pathways of connection systems may be detrimental to patient safety. Therefore, a core set of medical devices within a complete interconnected system should only be introduced when each of the elements can be supplied with a connector that complies with ISO 80369-6:2016 and that supply is guaranteed.

Any introduction should be consistent with the Commission's National Quality and Safety Health Service (NQSHS) Standards,[7] in particular, where these standards relate to governance and medication safety. This includes the National standard for user-applied labelling of injectable medicines, fluids and lines.[8]

Background

The safe, controlled and appropriately managed introduction of devices that comply with ISO 80369-6:2016 will involve a wide range of products. A core set of medical devices within a complete interconnected system should only be introduced when each of the elements can be supplied with a connector that complies with ISO 80369-6:2016. A complete system with interconnectivity between medical devices used for neural route procedures must include needles, syringes, epidural and neurosurgical catheter connecting devices and infusion lines.

ANZCA's safety alert published in August 2019 includes diagrams of the new equipment with further information.[5] A list of devices and components impacted by the changeover is also available on the ANZCA website at **www.anzca.edu.au/documents/sau_neuraxial-products-list_20190816.pdf**. Information around the introduction of non-Luer neural medical devices in other jurisdictions is available from the Association for Anaesthetic and Respiratory Device Suppliers (Barema, UK)[3] and the Global Enteral Device Supplier Association (GEDSA, USA).[4] In addition, a multicentre clinical simulation evaluated a number of devices with ISO 80369-6:2016 connectors as 'fit for purpose'.[9]

Guidelines for the implementation of medical devices using connectors specified in the ISO 80369 series have been proposed by ISO/TC 210 Joint Working Group 4.[10] These guidelines have been used as the principal source of information for the following guiding principles and implementation safety checklist (**Appendix 1**).

Guideline principles

Objective

To support health services plan the introduction of neural devices compliant with ISO 80369-6:2016 to clinical practice in Australia.

Scope

This guideline is intended for health service organisations and service providers involved in the changeover from medical devices for neural route procedures with Luer connectors to medical devices with ISO 80369-6:2016 compliant connectors. In particular, the guideline is provided for hospital services when or where neural procedures are conducted including anaesthesia, intensive care, emergency services, surgery, radiology, haematology, oncology and pain medicine.

This guideline considers the essential steps for the changeover and includes:

- Governance
- ISO 80369-6 device availability and procurement
- ISO 80369-6 device identification
- Education and training
- Pre-introduction planning
- Communication
- Managing the introduction
- Post-introduction feedback and actions.

The ISO 80369 series of standards for small bore connectors aims to provide a safe engineered system to reduce the risk of unintentional medical device misconnection. This guideline covers neural devices compliant with ISO 80369-6:2016.

Benefits and risks

The universally used Luer device connection system permits connection between medical devices used for fluid administration, breathing systems and some monitoring equipment. This is convenient but poses a high risk of unintended misconnections between medical devices and the possibility of incorrect route medicine administration. In some cases, fatalities have occurred.

The introduction of a series of small bore connectors each for a specific clinical application represents a systems solution to reducing the risk of misconnections. For example, an ISO 80369-6 connector designed specifically for neuraxial procedures physically prevents an intravenous line with Luer connectors from being connected to an ISO 80369-6 epidural catheter connector.

Benefits will be realised when all end-to-end neural procedures use ISO 80369-6 compliant devices.

However, implementation risk of changeover to the new devices is readily identifiable and must be well managed to reduce the risk of patient harm. Risks have been identified where:

- Therapy is delayed if all components of an end-to-end procedure are unavailable
- Adaptors are used to overcome component unavailability. This negates the benefit of changeover to ISO 80369-6 devices and adaptors must not be used
- Patient is transferred to a ward or other facility not yet converted to the ISO 80369-6 devices. Mistakes are made when selecting the ISO 80369-6 devices instead of Luer devices in the supply chain or in clinical use
- ISO 80369-6 devices perform differently to Luer devices which may lead to a higher rate of technical failure in the early phase post changeover as users become familiar with equipment.

Principles for changeover

General principles apply to the changeover from Luer devices to ISO 80369-6 devices for safe neural delivery of medicines.

- ISO 80369-6 devices for neural use will replace existing Luer devices. Replacement is essential and adapters are not appropriate for procedures involving neural delivery of medicines. Risk assessment has shown adapters imply products for different purposes no longer misconnect and the potential for mis-connection remains and may even increase
- All medical devices in an interconnected end-to-end procedure must be available before changeover of devices for that procedure
- A simple name or terminology for use in verbal and written communication is determined to clearly differentiate the new devices from the old. For example, 'ISO 80369-6 devices' or 'NRFit™ devices'
- ISO 80369-6 devices must be easily identified and differentiated from the existing Luer devices. This identification may be through addition of ISO 80369-6:2016 wording and/or the NRFit™ logo by the manufacturer or through application of distinctive labelling on receipt and storage by the health service
- Application of colour-coding should be consistent with the *National standard for user-applied labelling of injectable medicines, fluids and lines (2015)* [8]
- Planning for replacement medical devices for neural use incorporates all procedures involving neural delivery of injectable medicines, including 'off label' use
- Consider medicines supplied in pre-filled syringes and how these will be procured in syringes fitted with ISO80369-6:2016 connectors. Availability and use of ready-to-use pre-filled syringes eliminates a number of steps in preparation of injectables and greatly reduces the risk of harm from a medicine.

Governance

The health service executive in collaboration with clinicians must take overall responsibility for the changeover. Early in the process, an oversight group should be established and should include representatives of the executive.

The composition of the group should reflect the size and complexity of the health service organisation. In hospitals, the group could comprise staff from anaesthesia, intensive care, emergency medicine, perioperative care, pain medicine, obstetrics, oncology, radiology, haematology, neurology, neurosurgery, paediatrics, pharmacy, quality and safety, procurement and medical engineering.

The changeover should be managed by a multi-disciplinary team across departments and wards. The team should include representatives from each clinical situation where procedures involving neural medicine delivery are impacted by the changeover.

A risk management strategy should be agreed and include plans to:

- Identify and analyse the risks prospectively
- Develop, plan, initiate, and implement risk control measures
- Communicate the risks and risk control measures through education, training, and other methods
- Review and amend existing clinical guidelines and protocols
- Regularly audit the safe handling of the new medical devices, and
- Provide for public access to relevant patient safety findings related to the changeover process and the use of the new medical devices.

The health service executive must inform all impacted employees of the changeover process and timing along with the oversight groups managing the changeover. Tasks and responsibilities should be outlined at an early stage.

Implementation planning

Product availability and procurement

In all clinical areas, make a comprehensive inventory of all equipment used to access and/or deliver medicines to the central or peripheral nervous system that have a Luer connector. These will be impacted by the changeover. In the audit consider the following:

- The names describing different procedures and variation in clinical practice to identify if some procedures use small-bore connector devices unlicensed for that purpose or are used 'off label'
- Ready-to-use pre-filled syringes that may be impacted. These reduce medication error and should be sourced fitted with the ISO 80369-6 compliant connectors to maintain this level of safety
- Documentation to identify the ISO 80369-6 compliant device manufacturer(s) and product identification codes. These codes should be different for the ISO 80369-6:2016 and Luer devices
- All medical devices within an end-to-end procedure which are not fitted with a connector but which are indispensable and necessary to complete the procedure (from here on referred to as components)
- Who holds responsibility for procurement and the authorisation process to change supplier, for each inventory item.

The following information should be collected and documented:

- The departments, wards and areas impacted
- The clinical situations where procedures involving neural delivery of medicines are impacted
- The medical devices and ready-to-use pre-filled syringes used across departments, including the sterile kits or packs containing neural devices and related consumables such as those used in patient controlled epidural analgesia
- Stock levels for all medical devices, noting the criticality if the device were unavailable and the anticipated demand or supply levels for each ISO 80369-6 device
- The demand and supply patterns for each ISO 80369-6 device impacted by the changeover, including medical devices and all components to perform the end-to-end procedure. This should include consideration of any clinical impact by changing supplier of any of the procedure components.

For each end-to-end procedure check the availability of the ISO 80369-6 devices and components without a connector. Good communication is needed between hospitals within the health service and manufacturers/suppliers. All parties must be mindful of the terminology used to define the devices and procedures involved. If only a small number of procedures or devices are impacted, the procurement for a changeover process may be simple. If many medical devices are impacted at the same time, then it will be critical to ensure adequate and timely communication and planning for all impacted employees and departments.

Usability testing and familiarity handling should be thoroughly conducted by relevant, clinical end users conversant with the intended use of the devices. Usability testing should involve scenario based simulation in conjunction with education to avoid problems when handling the ISO 80369-6:2016 devices. They should be tested before ordering.

Changeover should only be started and executed:

- When all the corresponding ISO 80369-6 compliant devices and components are available and have been tested
- When all staff are informed and educated to a standard set by the implementation group.

Product identification

ISO 80369-6 devices must be clearly differentiated. The devices may be marked with 'ISO 80369-6:2016' and/or the NRFit™ logo to indicate the product incorporates an ISO 80369-6 connector. It is not mandatory for products to carry the NRFit™ logo. Therefore, each health service should devise a way to consistently differentiate old Luer devices from the new ISO 80369-6 devices and components, depending on the range of devices used in that facility. Preferably the differentiation would be standardised across health services.

Education and familiarisation

Health services need to identify all staff who will be impacted by the changeover to facilitate communication and coordinate familiarisation with ISO 80369-6 devices before implementation. The documentation should include staff affiliation, for example ward, role, and department.

The number of sample sets of the ISO 80369-6 devices and components required for testing and familiarisation will need to be estimated and ordered.

Education activities for all impacted staff should focus on competency and familiarisation through simulation processes. These should:

- Be held prior to the changeover process multiple times
- Be held close to the scheduled changeover
- Include practical handling of the new ISO 80369-6 devices and components.

Participation in these events should be documented.

Additional individual education and familiarisation should be held. This is particularly necessary for staff who were absent during changeover, including night staff.

An e-learning module could be developed to support the education and familiarisation. Manufacturers may produce videos or other materials to educate staff on the ISO 80369-6 devices and connectors and their use.

Nominated qualified staff should be available during and subsequent to the changeover. These, health services staff will have the competence and expertise to provide instruction and guidance on the practical implementation of the ISO 80369-6 devices and connectors.

Pre-introduction planning

Using sample sets of the new ISO 80369-6 devices and components, staff should be given the chance to see, touch and try out the new devices. Sample sets of the new ISO 80369-6 devices and components should be made available in designated wards, departments and perioperative areas as appropriate.

Conduct a risk assessment with the staff involved in procedures involving neural delivery of medicines to identify training requirements. Document and communicate the results of this risk assessment and training delivery.

Timelines for changeover should be available and updated as necessary in all departments concerned. The documentation should indicate the current stage of planning and implementation. It should be clearly communicated and understood when the new ISO 80369-6 devices and components will arrive and the date of changeover.

The changeover process can be carried out in various ways. Implementation may be on a small scale with sequential changeover in individual departments or the entire hospital or health service may changeover on a designated date and time. The preference is a single day facility wide changeover as evidenced by introductions in other jurisdictions.[11]

It is recommended that the changeover process is documented in an action plan to:

- Avoid new device connection problems within the health service
- Maintain a simple and clear changeover process
- Learn from one department changeover process before commencing the next in the case of small scale, sequential changeovers.

If individual sites of a health service are to change over consecutively any exchange of education, training and communication materials should be planned and managed.

Devices with different connectors must not be available within the same site. Old devices to be moved to a site which will changeover at a later time must be quarantined. For example, a private hospital group makes the changeover first at one hospital then another.

Consideration needs be given to patients transferring with non-ISO 80369-6 compliant devices from another department during changeover, especially sequential changeover. Similar consideration is required for situations arising where patients are likely to be transferred from another hospital still using non-ISO 80369-6 compliant devices and connectors. Contingency plans which do not rely on otherwise unnecessary re-siting of devices should be prepared.

Private stock caches should be removed.

Communication

Communication should be targeted to those directly impacted by the changeover. The reason and justification for the changeover should be clearly conveyed, including that:

- There is generally no need to learn new processes
- Change will focus on making the correct medical devices available in the locations they are required. This includes ensuring that all necessary ISO 80369-6 devices and components to perform an end-to-end neural procedure are available
- Impacted medical devices will have new connectors that will not connect with Luer connectors
- Changeover to ISO 80369-6 devices and connectors will ensure safer neural delivery of medicines to patients
- Changeover to ISO80369-6 devices will better support clinicians through improved system design.

Targeted communication within and across these units must be prioritised. Within health services, impacted departments will include anaesthesia (operating suites and perioperative care), pain medicine, intensive care, emergency, medical and surgical wards, obstetrics, radiology, neurology, neurosurgery, oncology, haematology, procurement, pharmacy, sterile supply units and medical engineering.

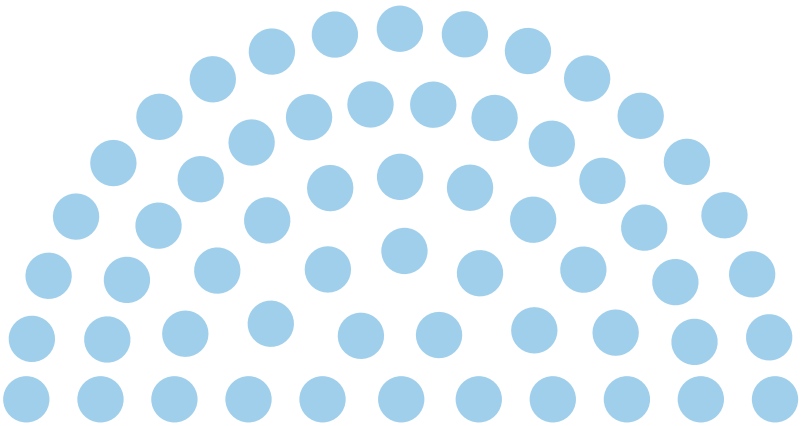
Transfer of patients, medical devices, information, services, and staff between departments within a health service or hospital and between different health service and hospitals are important interfaces.

Pathways for continuous patient care should be identified. For example, pathways for transfer between healthcare facilities.

Communication pathways across the internal and external interfaces must be identified, documented and any gaps in transmission of information addressed as part of the education around the changeover.

Education and communication departments should be engaged when available. Multimedia may be used to convey training and information about the new ISO 80369-6 devices and connectors. This may be via a combination of communication channels, for example, simultaneous word-of-mouth, intranet, email, brochures and posters. Overseas experience indicates approximately four months should be allowed to prepare for the changeover in large health care services or hospitals.

Communication is critical at all stages in the changeover process. Timely, stepped information releases are encouraged with a publicised timeline and countdown to the changeover date.



Managing the introduction

Changeover

When all stakeholders have finalised the implementation and action plan, and agree on the introduction, a changeover date/period should be nominated.

At or immediately prior to the commencement of the changeover period and only when the planning stages are complete:

- Procure a suitable range of ISO 80369-6 devices and connectors for each of the designated end-to-end procedures
- Ensure delivery, and allocation to wards and departments is completed at a time prior to the scheduled changeover date with stock quarantined until that date
- Allow a safety period in case of incomplete or delays in delivery
- Nominate trained procurement and supply personnel to replace the ISO 80369-6 devices and connectors immediately prior to the appointed changeover date.

In addition,

- Ensure the procurement and supply personnel responsible for the restocking of neural medical devices complete the changeover process at the same time to ensure the availability of ISO 80369-6:2016 devices and connectors
- Procurement should ensure that only medical devices which conform to ISO 80369-6:2016 are tendered and ordered before and after the changeover process
- Suitable measures should be taken to avoid mix-ups during the changeover, for example, removal of remaining stock of Luer devices; consistent labelling of storage shelving
- Assign internal reference numbers and forms of identification for the new range of medical devices. Differentiate in a unique, uniform and consistent manner (unless already done by the manufacturer) by applying distinctive labelling in all places where these devices are stored and referred to (for example on the products themselves, in storage places, packaging, documents and posters). A suitable identifier is 'ISO 80369-6' or the NRFit™ logo.

Devices which are not clearly differentiated should not be used and should instead be removed to a separate storage area and quarantined. It is important to document, investigate and resolve these types of issues in order to prevent the risk of harm resulting from distribution of potentially non-ISO 80369-6 compliant devices. These issues should also be communicated to other hospitals, wards departments and other hospitals downstream of the medical device supply chain.

Timing

For each procedure involving neural delivery of medicines an individual action plan, including timetable for the changeover should be created. This should include:

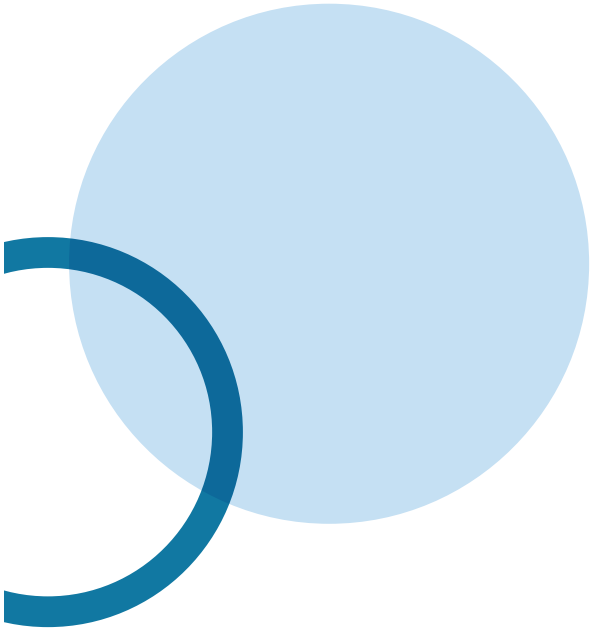
- The timeframe in which the existing Luer device stock levels are reduced and the replacement ISO 80369-6 devices and connectors are introduced
- Delivery times from manufacturers. Changeover must not commence until replacement ISO 80369-6 devices and connectors are available for all end-to-end procedures for neural delivery of medicines performed within the health service
- The changeover time period. This should be as short as possible and should be achieved on a single day for a given single site. This eliminates or reduces the amount of time that existing and replacement devices are used in parallel
- Consider timing of the introduction is in a period of lower activity, such as weekends
- When staff who will be using the replacement medical devices are to be informed about the changeover process
- When staff will receive appropriate training, including consideration of staff availability, leave and rosters.

The timetable and action plan should contain details on the lead times expected for the procurement of the replacement IS0 80369-6 devices and connectors.

Cost

Project expenditure should be incorporated as part of the changeover planning. This will include calculating the anticipated budget for the replacement medical devices and the training and implementation resources and materials. Some costs may be mitigated by careful planning and moving current stock to another facility. Stock levels should be managed to minimise equipment that is destroyed from a cost and environmental impact perspective.

An overall or individual budget or expenditure plan could be prepared for each end-to-end procedure. This provides project transparency when considering budget requirements. Any high level evaluation of the cost of the changeover should be considered in terms of the benefits versus the risks. For instance, consider the benefit of introducing medical devices that provide a safe, engineered device design versus the risk of unintentional device connection resulting in wrong route administration of a medicine to a patient. International manufacturers have indicated that they will focus on manufacturing only ISO 80369-6 compliant devices into the future. Therefore, it is important to factor in costs early as Luer devices become unavailable.



Storage

Storage should be centralised as far as is practical, ensuring that the ISO 80369-6 devices and connectors and Luer devices are stocked separately.

Existing storage space for the range of Luer devices continues to be required until the changeover process is completed.

Additional, separate and differentiated storage space is recommended for the replacement ISO 80369-6 devices and connectors. This storage space should be easy to access, use, identify and secure, including the ability to quarantine stock until the changeover day.

In large health care services or complex hospitals with separate campuses/sites phased changeover has the advantage that temporary additional storage spaces in cabinets, etc. can be used at other sites.

Procurement, planning and approval

The changeover process can only be carried out when the entire range and stock of replacement ISO 80369-6 devices and connectors for each end-to-end procedure are available. Manufacturers should list and manufacture adequate quantities of their range of ISO 80369-6 compliant devices. However, supply is likely to be a function of demand.

Procurement should include pricing, delivery times, second source suppliers, packaging and labelling differentiation, storage volumes and electronic stock control.

The changeover action plans should be reviewed as relevant by the governance teams and the executive giving sufficient time to discuss and incorporate any required changes, including a timeline adjustments or changeover postponement.

Health services should reduce current stock of Luer devices leading up to the changeover, and consider any requirement to retain a contingency supply of Luer devices for unexpected emergencies if the predicted date of supply of ISO 80369-6 devices is delayed.

Create checklists to ensure all planning and implementation stages are carried out. **Appendix 1** gives broad headings from which to customise a detailed safety checklist for an individual department or hospital.

The approved plan should be communicated via the facility's intranet and any other noticeboards/ portals where it is accessible to everyone. The published timetable and action plan should be updated throughout the entire process with any postponements communicated promptly.

A prominent banner could appear on the initial (landing) intranet page to raise awareness of the forthcoming changeover. This could include a link to a separate and dedicated information page giving the details on the changeover and its implementation.

Immediately prior to changeover:

- Sort and place all new replacement ISO 80369-6 devices into the designated, centralised and secure storage location
- Ensure that the replacement ISO 80369-6 devices are not used until the designated changeover date
- Check for completeness of the range of replacement ISO 80369-6 devices using the specially prepared checklists
- Ensure procurement and store personnel and hospital staff know how to identify and differentiate the replacement ISO 80369-6 devices from Luer devices within verbal and written communication
- Ensure staff have had experience in practical handling of the ISO 80369-6 devices and are aware of the designated storage locations. This includes all locations and which apply across ward/department and central locations.

Changeover Day

New and old storage locations should by now be clearly marked. Storage systems will be marked to reinforce that products are different and new and old devices must not be mixed.

The new storage location is opened.

Remove incorrectly sorted devices immediately after discovery and inform staff in the department concerned.

Nominated clinical project leads should be on call for trouble shooting within a department or site according to resources but including provision for after-hours and emergency cases. A telephone hotline may also be useful especially for after hours. This longer-term support is necessary to reach persons absent on changeover day.

The changeover should be documented including details and timing of all staff training; changeover implementation; problem resolution and removal, quarantine and disposal of the Luer devices.

Post-introduction feedback and actions

Issues related to the changeover processes should be recorded within established incident reporting systems, including actual and near miss events. Incident reports should be reviewed in real time to identify and examine the causes of any issues. Measures must be taken to control any identified risks. This may include central as well as local collation of incidents to guide other sites as the changeover is implemented. For emergency cases the governance group should be available via telephone and email 24 hours a day. A dedicated email address for the changeover may be helpful.

Ensure hospitals and departments not changing to ISO 80369-6 devices have a reporting mechanism. For the reporting of incidents to the relevant national authorities, regional or national legal or regulatory requirements need to be taken into account. The TGA promotes and encourages users to report any issues or adverse event reports related to these devices, particularly in the initial roll out phase. Monitoring the safety and performance of medical devices is an important part of the TGA's role. Adverse events can be submitted via TGA's web forms at **www.tga.gov.au/reporting-problems**.

Once the changeover is established any remaining stock of Luer devices should be destroyed, returned to the manufacturer or transferred to another health service or hospital with a future nominated changeover date. Investigate if manufacturers offer return or exchange of unused Luer devices.

After a department has completed the changeover process, the governance group should debrief staff to address and document problems or weaknesses detected during the changeover. Any identified issues should be used to improve the changeover process in other departments, hospitals or health services.

Health services that have successfully adopted ISO 80369-6 devices are encouraged to share their experience and lessons learned with the Commission **mail@safetyandquality.gov.au** or ANZCA **SQ@anzca.edu.au**

Recommendations

The introduction of neural devices compliant with ISO80369-6:2016 into Australian health services is recommended as part of a global initiative to improve patient safety.

These guidelines support the Commission and ANZCA joint safety statement and are recommended to assist health services with the implementation of neural devices.[2]

References

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11. Reducing misconnections between medical devices. **www.churchilltrust.com.au/media/fellows/Mainland_P_2015_reducing_misconnections_between_medical_devices.pdf**

Other useful resources

From NHS Improvement (UK)

Patient Safety Alert: Resources to support safe transition from the Luer connector to NRFit™ for intrathecal and epidural procedures, and delivery of regional blocks **https://improvement.nhs.uk/documents/1556/NRFit_Patient_Safety_Alert_supporting_information_August_2017v2.pdf**

Small bore connectors: an introduction to safe use 13 March 2017 **https://improvement.nhs.uk/resources/small-bore-connectors-safety-introduction/**

Managing risks during the transition period to new ISO connectors for medical devices 27 March 2015 **https://improvement.nhs.uk/documents/721/psa-managing-risk-during-transition-iso-connectors.pdf**

ISO 80369-6 Implementation of neuraxial / neural devices in the UK. 1 June 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**

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- Australian Nursing and Midwifery Federation
- Cancer Nurses Society of Australia
- Clinical Excellence Commission
- Medical Technology Association of Australia
- Safer Care Victoria
- The Society of Hospital Pharmacists Australia
- Society for Paediatric Anaesthesia in New Zealand and Australia
- Therapeutic Goods Administration
- State and territory health departments

Appendix 1

A safety checklist to guide introduction of ISO 80369-6 compliant neural devices. This is derived from the examples on the GEDSA website[4]

Phase	Actions
Governance	Establish an oversight group for the introduction of ISO 80369-6 compliant neural devices
	Consider including representatives from anaesthesia, intensive care, perioperative care, pain medicine, oncology, radiology, paediatrics, obstetrics, haematology, neurology, neurosurgery, pharmacy, medical engineering, supply and procurement
	Seek peak body oversight for education as clinicians move frequently between jurisdictions
	Consider oversight of transitions of care
	Develop and agree a risk management strategy
Implementation planning	
For each clinical area	▪ Establish the procedures changing to ISO 80369-6 compliant neural products ▪ Make an inventory of neural medical devices, components and pre-filled syringes used for these procedures ▪ Establish which ISO 80369-6 compliant neural devices are available ▪ Ensure a complete end-to-end procedure can be achieved ▪ Practice connecting all components for the procedure with ISO 80369-6 compliant neural devices ▪ Address any issues with the manufacturer
Product identification	Consider how the new products will be differentiated from the old in each facility ▪ Label components clearly and prominently ▪ Ensure labelling is sufficiently differentiated from Luer devices ▪ Use a standardised labelling, such as 'ISO 80369-6' or the NRFit™ logo
Education and training	Establish a clinical education team and nominate champions for introductory training
	Educate clinicians on the importance of neural connectors for patient safety and the proposed changes to clinical practice
	For each end-to-end procedure ▪ Demonstrate how each component of the procedure will connect ▪ Use simulation, on multiple occasions to ensure all clinicians have hands-on training

Phase	Actions
Pre-introduction planning	
	Establish a changeover team and nominate super users. These super users should be from intermediate rather than superior grade positions
	Identify a hospital or department within a hospital to introduce complete system procedures. Establish and resolve any issues before extending to other health services
	Avoid overstocking neural devices with Luer connectors
	For each procedure to be completed with ISO 80369-6 compliant neural products ▪ Ensure all the components for each end-to-end procedure are available ▪ Procure ISO 80369-6 compliant neural products on an end-to-end procedure basis ▪ Place ISO 80369-6 compliant devices in clearly labelled designated storage areas ▪ Update medication and delivery order sets for the new products
	Ensure all clinicians are aware and prepared for the changeover
	Establish a date/period for introduction, preferably a single day for a given site
Introduction	
	Ensure at least one super user will be available at each shift
	Record, evaluate and communicate any issues with the changeover team
	Reduce the risk of selection and preparation error by ▪ Providing an appropriate work environment ▪ Using standard processes for selection supported by technology (such as bar code scanning)
Post introduction	
	Audit each end-to-end procedure where neural devices compliant with ISO 80369-6 have been introduced
	Report any issues to TGA (Incident Report and Investigation Scheme) and private and public hospital incident reporting systems

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