NHS England

Safety criteria

for the introduction of new design small bore connectors into the NHS

A set of safety criteria have been developed by the NHS England Small Bore Connector Advisory Group, 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.

No	Safety criteria	Further information
1	A final International Standard has been published.	This will include a ISO connector standard and where available and appropriate a ISO device standard.
2	Technical evidence for the safe use of new devices and ancillary products.	Compliance with functional and clinical application tests required by the specific 80369 standard. The ISO connector standard process may not have undertaken all the technical testing required to support safe clinical use e.g. microbiological and physical integrity testing for syringes and syringe caps used to prepare, store, transport and administer intrathecal chemotherapy. Other tests include drug and device stability tests.
3	User evaluation evidence for the safe use of new devices and ancillary products, including labelling and packaging.	Clinical acceptance testing including cross connection and review of labelling and packaging.
4	Evidence that a complete range devices and ancillary products with the new small bore connector for specified clinical application are available.	Evidence that all devices and ancillary products necessary for a specified clinical application e.g. enteral/oral, neuraxial are available prior to implementation.
5	Evidence that there is sufficient stock of new devices and ancillary products in the UK to meet expected demand.	Between 3 – 6 months stock
6	Evidence of industry support to aid the NHS introduce the new devices and ancillary products safely.	Required support includes awareness raising, education and training for procurement, distribution, and clinical staff,

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