Bringing medical devices into Southern Cross Healthcare facilities policy

Guidance on the process for bringing medical equipment and devices that have not yet been approved for use at Southern Cross Healthcare (SCH) into our facilities.

Who is the policy for?

Medical practitioners, suppliers, and hospital teams

Why is it important?

It ensures a robust review and assessment process occurs that ensures SCH hospital teams are well prepared in correct use, application, and care of newly introduced technologies that meet regulatory and safety standards and outline individual accountabilities.

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Definition

The Medsafe medical device definition describes any device, instrument, apparatus, appliance, article, or material of a kind intended to be used in or on human beings for a therapeutic purpose.

What this policy does not cover

The policy does not cover the review and health technology assessment of newly developed equipment and devices. This process is detailed in the associated Health technology assessment (HTA) policy.

In the first instance separate guidance supports the requirements for new technology or techniques, research studies.

Guiding principles

SCH is committed to providing up to date equipment and devices into its facilities. In doing this, we must comply with the Medicines Act regulations for the importing, supply, and sale of medical devices in New Zealand.

When new medical devices and equipment are introduced to our facilities SCH hospital teams are well prepared to use and maintain these in ways that are consistent with relevant legislation, standards, manufacturer's instructions and accepted good practice.

What practitioners do

If new equipment, supplies are required, meet with the General Manager or their delegate, at your earliest opportunity to discuss your request, giving rationale and benefits (clinical and commercial) and New Zealand supplier details.

Allow sufficient time before required use for the hospital and procurement to facilitate an efficient process.

What we do

- We will confirm that the item is registered on the Medsafe database
- Every endeavour will be made to supply a Practitioner's preferred choice of products and materials. If the national procurement requirements mean that it may not be possible, the closest-possible and most appropriate substitute will be offered
- Liaise directly with the supplier
- We can leverage pricing and delivery with our preferred suppliers
- Store sterile items in appropriate temperature / humidity-controlled areas to ensure the integrity is not compromised.
- Where required, arrange biomedical / electrical compliance testing.
- Cleaning disinfection and sterilisation (if needed) is undertaken according to the manufacture's specifications
- Arrange for any staff training for new technologies and appropriate instructions for use are provided and readily available.
- Action or initiate any device failures with suppliers and Medsafe.
- Manage device related adverse event notification and reviews

What we cannot do

We cannot allow Medsafe unapproved medical devices brought into the hospital by practitioners or suppliers.

- This could include individually owned equipment, implants, samples, items purchased from supplier, borrowed from other facility, homemade.

Accept any pre-sterilised items to be introduced except

- Those sterilised by the manufacturer
- From other organisations where there is a current Southern Cross Hospitals "External Facility Reusable Medical Devices Reprocessing" Services agreement" in place.

Re-sterilise any items that are labelled single use only.

Associated documents

- Credentialling and practice guide – access privileges for health practitioners
- Medical company representatives or technical support person in the operating theatre
- Health Technology Assessment Policy
- SCH New Technology Framework and Charter
- Sterilising services Policy
- Single use device policy
- External facility reusable medical device reprocessing
- Management of instruments on loan or evaluation
- Cleaning, disinfection, and sterilisation of patient equipment
- Health and safety risk management: specific considerations and requirements
- Safe use of hazardous substances
- Guidelines for safely managing surgical plume
- Laser safety
- Supplier loan or consignment equipment checklist
- New supplier details required form
- Medical device product evaluation form
- Agreement for medical device evaluation

References

- Medsafe New Zealand Medicines and Medical Devices Safety Authority – Definition of Medicines and Medical Devices
- Ngā Paerewa Health and Disability Services Standard NZS 8134:2021 Part 5: Infection prevention and antimicrobial stewardship*
- AS/NZS 4187 2014 Reprocessing of reusable medical devices in health service organisations

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