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Questions about Foundation?
Email: quality@rnzcgp.org.nz

FOUNDATION STANDARD 12.1 – INFECTION CONTROL

Reprocessing reusable medical devices against NZ/AS 5369:2023: FAQs and a quick checklist for practices

Who this resource is for

This resource supports the Foundation Standard guidance for criterion 12.1 – infection prevention and control. It is for general practices that reprocess reusable medical devices or are deciding whether to continue reprocessing them onsite.

- Reusable medical devices are items designed to be used more than once and reprocessed between patients.
- This includes instruments used for minor surgery, wound care or other procedures where cleaning, disinfection, packaging or sterilisation is required before reuse.
- This resource does not apply to practices that only use single-use sterile instruments, unless they also reprocess other reusable items.

What has changed

- AS/NZS 5369:2023 replaces the previous office-based reprocessing standard and applies to health care organisations that reprocess reusable medical devices, including general practices.
- The new standard has a stronger focus on quality systems, risk management, documented processes, training, traceability, facility design and validation.

In relation to AS/NZS 5369:2023, the Foundation Standard expects practices to show that reprocessing is safe, risk based, documented and monitored, and that it is appropriate for the type of instruments and procedures they undertake.

The Royal New Zealand College of General Practitioners
Te Whare Tohu Rata o Aotearoa

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FAQs about reprocessing reusable medical devices against NZ/AS 5369:2023

1 Do all practices need to comply with AS/NZS 5369:2023?

No. AS/NZS 5369:2023 applies when a practice reprocesses reusable medical devices. If a practice uses only single-use sterile instruments and does not reprocess any reusable medical devices, the reprocessing requirements do not apply.

If the practice does reprocess reusable medical devices, it needs to understand the requirements of AS/NZS 5369:2023 and apply them in a way that is proportionate to the services provided, the instruments used and the practice environment.

2 What evidence does the Foundation Standard expect?

For criterion 12.1, practices that reprocess reusable medical devices should provide practical evidence that reprocessing is managed safely. Evidence may include a documented policy and procedure that covers the relevant sections of the College's reprocessing guide, an RMD register, a process map or flow diagram, a risk assessment, training records, steriliser monitoring records, validation records and evidence of remedial action where needed.

3 Do we need a separate RMD register?

The practice needs to be able to identify the reusable medical devices it reprocesses. This can be recorded in a separate RMD register or included in the existing medical equipment register, as long as it clearly shows the device, its intended use, Spaulding classification, manufacturer instructions for use, reprocessing method and storage requirements.

- Critical devices usually require sterilisation and sterile storage.
- Semi-critical devices usually require sterilisation where possible, or high-level disinfection where sterilisation is not compatible with the device.

4 Do we need to keep manufacturer instructions for use?

Yes. Manufacturer instructions for use are important because they explain how the device should be cleaned, disinfected, packaged, sterilised, stored and maintained. Practices should have access to these instructions and use them when developing local procedures.

- If instructions are missing, ask the supplier or manufacturer for a copy.
- If instructions cannot be obtained, the practice should assess whether it is safe to continue using and reprocessing the device.

5 Do we need a process map or flow diagram?

A process map or flow diagram helps the practice show how reusable medical devices move from dirty to clean. It should show the steps from point of use, transport, cleaning, inspection, packaging, sterilisation or disinfection, release, storage and use.

The map does not need to be complex. It just needs to make the workflow clear and show how the practice prevents cross contamination, including separation of dirty and clean activity.

6 Do we need two sinks?

Two dedicated cleaning sinks are recommended because they support safe separation of cleaning and rinsing. If a practice does not currently have two sinks, it should complete a risk assessment, document how cross-contamination is being managed, and make a realistic plan for improvement if changes are needed.

7 Ventilation – do we need 12 air changes per hour?

Ventilation needs to be considered as part of the practice's risk assessment for reprocessing. The key issue is whether airflow could move contamination from dirty areas towards clean or sterile instruments. The Foundation Standard evidence should focus on how the practice has assessed and managed this risk in its own environment.

If the reprocessing area does not meet preferred facility design expectations, the practice should document the gap, apply risk controls, and include any planned changes in its risk register, quality plan or asset management plan.

8 Do we need to test water quality?

Water quality is important because poor water quality can damage instruments and affect reprocessing. For Foundation Standard assessment, practices are not expected to provide independent water testing reports as a routine evidence item unless testing is required by the manufacturer, the service provider, the equipment used, or the practice's risk assessment.

The practice should use water that is suitable for the process being undertaken, follow the manufacturer's instructions, and respond to signs of water quality issues, such as staining, corrosion, scale, pitting, blocked lumens or reduced equipment performance.

9 What does validation mean for a steriliser?

Validation confirms that the steriliser and the selected cycle can consistently achieve the required result for the types of loads being processed. Validation should be completed before a steriliser or cycle is first used for reprocessing, then at least annually, and after significant changes such as major repair, relocation, changes to load type or changes to cycle parameters.

Practices should keep validation reports, routine monitoring records, maintenance records and evidence that any faults or failed cycles have been followed up.

10 What does traceability mean in general practice?

Traceability means the practice can link a reprocessed reusable medical device, particularly a critical device, back to the steriliser cycle or reprocessing record. At a minimum, this should show the cycle used, that the cycle parameters were met, and who was responsible for loading, checking and releasing the load.

This does not need to be a complex electronic tracking system. A clear paper-based or electronic log may be enough if it reliably links instruments or instrument packs to the relevant reprocessing record.

11 What if we outsource reprocessing?

Outsourcing reprocessing is acceptable if the practice can show the external provider is appropriate for this work. The practice should keep evidence such as the provider's credentials, service agreement or written confirmation of the arrangement, and relevant quality assurance records, such as validation, calibration or servicing reports where applicable.

The practice should also describe how used instruments are safely transported, how clean or sterile instruments are returned and stored, and how any concerns, failures or recalls would be managed.

12 What if our reprocessing area does not fully meet the facility expectations yet?

If the practice identifies gaps, it should document these in a risk assessment, apply controls to reduce the risk of cross contamination, and record a realistic plan for improvement. This may include actions in the practice risk register, quality plan or asset management plan.

The assessor will be looking for evidence that the practice understands the risk, has controls in place, and is actively managing any gaps while working toward a safer and more suitable reprocessing setup.

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Quick checklist for practices reprocessing reusable medical devices against NZ/AS 5369:2023

Have we identified all reusable medical devices that are reprocessed?	☐ Yes	☐ No
Have we applied the Spaulding classification to each device or group of devices?	☐ Yes	☐ No
Do we have access to manufacturer instructions for use?	☐ Yes	☐ No
Do we have a documented policy and procedure for reprocessing reusable medical devices?	☐ Yes	☐ No
Have we completed a process map showing dirty to clean workflow?	☐ Yes	☐ No
Have we assessed and documented risks in the reprocessing environment?	☐ Yes	☐ No
Are team members trained and competent for their role in reprocessing?	☐ Yes	☐ No
Are steriliser monitoring, servicing and validation records current?	☐ Yes	☐ No
Can we trace critical instruments or packs back to the relevant steriliser cycle or reprocessing record?	☐ Yes	☐ No
Have we documented actions for any gaps, failures or non-conforming items?	☐ Yes	☐ No

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