PRACTICAL DENTAL PRACTICE GUIDE

AS/NZS 5369:2023 + ADA IPC GUIDELINES + ARTG + MANUFACTURER IFU

ALPRO MEDICAL

CLEANING, DISINFECTION & REPROCESSING OF INSTRUMENTS

IC-100 • BC-San 100 • BIB forte • WL-clean • Alprozyme

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1. Purpose of this guide

This guide helps dental staff consistently select and use the listed ALPRO MEDICAL products within a compliant reprocessing and infection-prevention pathway. The central principle is that the reusable device and its intended patient contact determine the required reprocessing level. The chemical product supports that pathway; it does not redefine the device classification or replace the device manufacturer's IFU.

It follows the practical framework of the supplied guide: classify the device, follow the device IFU, use the ALPRO product only for its intended purpose, complete every required cleaning/disinfection/sterilisation step, and retain evidence that staff are trained and competent.

2. The five rules staff should remember

- **Classify The Device** — determine whether the reusable device is critical, semi-critical or non-critical according to intended patient contact.
- **Follow The Device Ifu** — the instrument/equipment manufacturer determines permitted cleaning, disinfection, packaging and sterilisation methods.
- **Follow The Alpro Ifu** — use the correct product, concentration, preparation method, exposure/contact time and application procedure. Never guess a dilution.
- **Do Not Confuse Cleaning With Disinfection Or Sterilisation** — a cleaning step does not automatically make an item disinfected or sterile.
- **Document & Train** — the practice should be able to show a defined procedure, current IFUs, staff training, competency and relevant process records.

3. Spaulding classification – what happens to the device?

Purpose
For dental staff in Australia: use before an audit, for regular in-office infection-control training, competency review and as an ongoing practical reminder. This guide applies the same principles and audit logic as the supplied ALPRO instrument cleaning/ disinfection guide.

Key rule: classification is determined by the intended use and patient contact of the reusable device – not by the name of the cleaning or disinfecting chemical.

4. ALPRO products covered by this guide

Category	Patient contact	Dental examples	Minimum principle
CRITICAL	Penetrates sterile tissue, bone or vascular system.	Surgical instruments; instruments entering normally sterile tissue.	Clean thoroughly, then sterilise.
SEMI-CRITICAL	Contacts mucous membranes or non-intact skin.	Dental mirrors; reusable intra-oral instruments; many reusable handpieces.	Thorough cleaning followed by the reprocessing level required by the device IFU and AS/NZS 5369; heat sterilisation is commonly required for heat-tolerant devices.
NON-CRITICAL	Contacts intact skin only or does not contact the patient.	External equipment surfaces; handles; control panels.	Clean and disinfect where required using a compatible product and relevant IFU.

5. Where these products fit in the reprocessing pathway

- **Remove Contamination Promptly** — prevent blood, tissue and other organic material from drying where the device IFU requires immediate pre-cleaning.
- **Pre** — CLEAN – IC-100 may be used for compatible device/instrument pre-cleaning according to its IFU. WL-clean is specifically intended for internal cleaning/pre-treatment of compatible hollow dental instruments.
- **Clean Thoroughly** — cleaning must remove contamination sufficiently for subsequent disinfection or sterilisation to be effective. Alprozyme may be used only within its current validated IFU conditions.
- **Disinfect Where Required** — BIB forte is a low-level instrument disinfectant for compatible applications. BC-San 100 has a specific disinfection/processing role and must not be substituted for a general instrument process unless its IFU expressly permits that use.
- **Sterilise Where Required** — critical instruments, and heat-tolerant semi-critical devices where required, must continue through the complete validated sterilisation pathway.
- DRY, INSPECT, PACKAGE & STORE – complete the remaining steps according to AS/NZS 5369, the device IFU and the practice's validated procedure.

6. IC-100 – ARTG 238325

Australian product documentation describes IC-100 as a non-protein-fixing cleaning solution/foam for pre-cleaning surfaces of medical devices and instruments. It is a CLEANING/PRE-CLEANING product – not a substitute for required disinfection or sterilisation.

- [ ] Confirm the device is compatible with IC-100 and the device IFU permits the process.
- [ ] Apply only by the method stated in the current IC-100 IFU.
- [ ] Ensure gross soil, blood, tissue and protein residues are removed as required.
- [ ] After pre-cleaning, continue to the validated cleaning/disinfection/sterilisation process required for that device.
- [ ] Do not describe an IC-100 pre-cleaning step as sterilisation.

7. BC-San 100 – Excluded from TGA registration

BC-San 100 is a special-purpose ALPRO product used for processing/disinfection of pressure bottles in stand-alone procedural water systems and, where specified by the IFU, final disinfection of selected compatible medical-device surfaces. Australian supplier information describes overnight bottle processing as a typical application. The current Australian IFU must control the exact dilution, contact time, rinsing and restart procedure.

- [ ] Use only for applications specifically permitted by the current BC-San 100 IFU.
- [ ] For pressure bottles, follow the exact preparation, exposure time, rinsing and recommissioning steps in the current IFU and dental-unit/bottle-system IFU.
- [ ] Observe material-compatibility restrictions and required PPE.
- [ ] Do not assume BC-San 100 is interchangeable with an instrument disinfectant or routine dental-unit waterline treatment product.
- [ ] Retain the current Australian product documentation/IFU confirming its regulatory status.

8. BIB forte – ARTG 167778

Australian product information identifies BIB forte as an instrument-grade low-level disinfectant for compatible non-critical instruments/devices. The current Australian IFU is the controlled source for concentration, preparation, contact time, solution life, ultrasonic use, rinsing and disposal.

- [ ] Check the device IFU for chemical compatibility and permitted disinfection method.

- [ ] Clean first unless the current product/device IFUs establish a validated combined process.
- [ ] Prepare the working solution exactly as specified; never estimate concentration.
- [ ] Maintain the required exposure/contact time and do not exceed the permitted working-solution life.
- [ ] Continue to any required rinsing, drying, packaging and sterilisation stages.
- [ ] Do not describe low-level disinfection as sterilisation.

9. WL-clean – ARTG 203023

Australian product information describes WL-clean as a ready-to-use solution for non-protein-fixing internal cleaning prior to disinfection/sterilisation of medical and dental hollow-part instruments, including turbines, handpieces, contra-angles and internally cooled instruments. It is an internal cleaning/hygienic pre-treatment step, not sterilisation.

- [ ] Confirm the handpiece/instrument manufacturer permits the process and chemical.
- [ ] Use the correct ALPRO adapter/interface for the device.
- [ ] Ensure the product reaches the internal channels requiring cleaning.
- [ ] Follow the current ALPRO process instructions exactly.
- [ ] Purge/dry/continue to lubrication and sterilisation as required by the device manufacturer’s IFU and the practice procedure.
- [ ] Never treat completion of WL-clean as completion of the full reprocessing cycle.

10. Alprozyme – In the process of obtaining ARTG

Alprozyme is an enzymatic instrument-cleaning product. Alprozyme is in the process of obtaining ARTG inclusion. Until the ARTG process is completed, the current Australian product documentation/IFU for the supplied product should be used as the controlled reference. The procedure should record the approved concentration, water temperature, contact time, application method, instrument compatibility and whether manual, ultrasonic or other use is permitted.

11. Practical workflow after every patient / procedure

12. Practical audit checklist for staff

- [ ] I can explain the difference between cleaning, disinfection and sterilisation.
- [ ] I know how the practice classifies critical, semi-critical and non-critical devices.
- [ ] I know the intended role of IC-100, BC-San 100, BIB forte, WL-clean and Alprozyme.
- [ ] I can locate the current ALPRO IFU and the reusable-device/equipment manufacturer’s IFU.
- [ ] I know the correct concentration/preparation method and contact time for every product I use.
- [ ] I do not improvise a dilution or substitute instructions from another product.
- [ ] I know that pre-cleaning or low-level disinfection does not equal sterilisation.
- [ ] I know when a device must proceed to sterilisation.
- [ ] I know what to do if an instrument remains visibly contaminated after cleaning.
- [ ] I know how to report a chemical, equipment or reprocessing problem/non-conformance.

13. What an auditor should be able to see

- [ ] Current AS/NZS 5369:2023 implementation/reprocessing procedure.
- [ ] Device classification list or equivalent risk-based reprocessing procedure.

- [ ] Current manufacturer IFUs for reusable instruments, handpieces, water-bottle systems and relevant equipment.
- [ ] Current IC-100, BC-San 100, BIB forte, WL-clean and Alprozyme IFUs/product information and SDSs.
- [ ] Evidence of ARTG status/linkage for applicable Australian products.
- [ ] Documented cleaning, disinfection and sterilisation procedures.
- [ ] Evidence of staff induction, training and competency assessment.
- [ ] Validation and routine monitoring records for reprocessing equipment where applicable.
- [ ] Records of non-conformances, incidents and corrective actions.
- [ ] Traceability records where required by the practice governance system.

14. Simple decision tree

15. Key audit message for dental staff

The ALPRO product is one component of a validated reprocessing pathway. It does not determine the device's Spaulding classification and does not replace the complete process required by the reusable-device manufacturer, AS/NZS 5369 and the practice's infection-prevention system.

16. Regular staff training use

Use this guide not only immediately before an audit but also during regular staff meetings and practical in-office training.

- Demonstrate classification of representative critical, semi-critical and non-critical dental devices.
- Demonstrate IC-100 pre-cleaning on an appropriate compatible item.
- Demonstrate WL-clean internal handpiece cleaning with the correct adapter and subsequent pathway.
- Demonstrate preparation/use of BIB forte according to the current Australian IFU.
- Review BC-San 100 pressure-bottle processing using the current IFU and the dental-unit/bottle-system IFU.
- Review Alprozyme only with the verified current Australian IFU present.
- Ask staff to explain why cleaning and disinfection do not automatically equal sterilisation.
- Record staff attendance, competency and retraining/corrective action according to the practice quality system.

17. Regulatory and document-control note

This is a practical staff guide and is not a replacement for the licensed AS/NZS 5369 standard, current Australian Dental Association infection-prevention guidance, TGA requirements, current ALPRO product IFUs or reusable-device/equipment manufacturer IFUs. Before controlled issue, the practice infection-control lead should verify the exact current Australian SKU, ARTG linkage, intended purpose, concentration, preparation method, contact time, compatibility and applicable process for each product.

ARTG references included in this version: IC-100 – 238325; BIB forte – 167778; WL-clean – 203023. BC-San 100 is excluded from TGA registration. Alprozyme is in the process of obtaining ARTG inclusion.

Product	ARTG	Primary role	Where it fits
IC-100	238325	Ready-to-use, non-protein-fixing cleaning foam/solution for pre-cleaning.	Pre-cleaning of compatible medical devices/instruments and surfaces before the validated subsequent reprocessing step.

Product	ARTG	Primary role	Where it fits
BC-San 100	EXCLUDED FROM TGA REGISTRATION	Disinfection/processing product for pressure water bottles and selected compatible medical-device surfaces.	Special-purpose bottle/system processing and final surface disinfection only where the current Australian IFU permits.
BIB forte	167778	Instrument-grade low-level disinfectant; non-protein-fixing cleaning/disinfection for compatible non-critical instruments/ devices.	After/with validated cleaning as permitted by the current product and device IFUs; not a sterilant.
WL-clean	203023	Ready-to-use, non-protein-fixing internal cleaning/hygienic pre-treatment.	Internal cleaning of compatible turbines, handpieces, contra-angles and similar hollow instruments before required disinfection/ sterilisation.
Alprozyme	IN THE PROCESS OF OBTAINING ARTG	Enzymatic instrument-cleaning product.	Use only according to the current Australian IFU for the exact supplied product, including concentration, temperature, time and permitted process.

ARTG verification note
IC-100 ARTG 238325, BIB forte ARTG 167778 and WL-clean ARTG 203023 are supported by Australian product documentation. BC-San 100 is excluded from TGA registration. Alprozyme is in the process of obtaining ARTG inclusion. Retain the current Australian product documentation/IFU for both products and update the guide when Alprozyme receives its ARTG number.

Staff rule
Do not transfer concentration, temperature or contact-time instructions from BIB forte, IC-100 or any other ALPRO product to Alprozyme. Use the current Alprozyme IFU for the exact Australian product supplied to the practice.

1. STOP & ASSESS	Is the item reusable or single-use?
2. CLASSIFY	Critical, semi-critical or non-critical?
3. CHECK DEVICE IFU	Confirm permitted reprocessing method and chemical compatibility.
4. CONTAIN & TRANSPORT	Move contaminated reusable instruments safely to the designated reprocessing area.
5. PRE-CLEAN	Remove gross contamination promptly using the approved method; IC-100 or WL-clean may have a role where specifically appropriate.
6. CLEAN	Use the validated cleaning process/product; Alprozyme only under its verified IFU conditions.
7. INSPECT	Confirm visible soil/deposits are removed; repeat cleaning if required.
8. DISINFECT	Where required, use the validated product/process such as BIB forte for compatible applications.
9. STERILISE	Complete validated sterilisation for devices requiring sterilisation.
10. DRY / INSPECT / PACKAGE / STORE	Follow device IFU and practice procedure.
11. RECORD / TRACE	Complete required records, traceability and any non-conformance documentation.

DEVICE DECISION PATH
Reusable? → NO: follow single-use instructions. → YES: continue. Penetrates sterile tissue/bone? → CRITICAL → clean + sterilise. Contacts mucous membrane/non-intact skin? → SEMI-CRITICAL → clean + reprocess to the level required by device IFU/AS 5369. External/intact-skin contact only? → NON-CRITICAL → clean and disinfect where required. Protein/soil pre-cleaning needed? → IC-100 where the device/product IFUs permit. Internal hollow instrument cleaning? → WL-clean where the device/product IFUs permit. Instrument low-level disinfection? → BIB forte where the validated application permits. Enzymatic cleaning selected? → Alprozyme only according to its verified current Australian IFU. Pressure bottle/specific final surface disinfection? → BC-San 100 only according to its current IFU. IF product IFU and device IFU conflict → STOP and obtain the correct validated method.

REMEMBER
CLASSIFY → CHECK THE DEVICE IFU → PRE-CLEAN/CLEAN → DISINFECT WHERE REQUIRED → STERILISE WHERE REQUIRED → INSPECT → DOCUMENT.

18. References / source framework

- Supplied ALPRO MEDICAL Instrument Cleaning & Disinfection Practical Dental Practice Guide, Version September 2026 – structural, audit and staff-training model.
- AS/NZS 5369:2023, including applicable amendments – reprocessing of reusable medical devices.
- Australian Dental Association infection prevention and control guidance – use the current edition adopted by the practice.
- Current manufacturer IFUs for each reusable dental instrument/device, dental unit, bottle system and reprocessing equipment.
- Current ALPRO MEDICAL Australian product information/IFUs and SDSs for IC-100, BC-San 100, BIB forte, WL-clean and Alprozyme.
- Australian TGA/ARTG records and current Australian sponsor/product documentation.

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