PRACTICAL DENTAL PRACTICE GUIDE
CLEANING AND DISINFECTION OF SURFACES

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

Alpro Medical Cleaning & Disinfection Products

For dental staff • Operational guide • Australia • Version: September 2026

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ALPRO® ALPRO MEDICAL GMBH
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1. Purpose of this guide

This guide gives dental staff a practical way to select and use the listed ALPRO MEDICAL products within a dental practice while aligning the workflow with AS/NZS 5369:2023 (including Amendment 1), the ADA Guidelines for Infection Prevention and Control, the device manufacturer's Instructions for Use (IFU), and Australian TGA/ARTG requirements.

> **IMPORTANT**
> AS 5369 applies primarily to the reprocessing of reusable medical devices (RMDs). The Alpro products are cleaning/disinfection agents used within that reprocessing or environmental/device cleaning workflow. They do not replace the required cleaning, disinfection or sterilisation process for a reusable dental instrument.

2. The three rules staff should remember

1. **CLASSIFY THE DENTAL DEVICE**
   Decide whether the reusable device is critical, semi-critical or non-critical according to its intended patient contact.
2. **FOLLOW THE DEVICE IFU**
   The dental device manufacturer's IFU determines how that particular device may be cleaned, disinfected, packaged and sterilised. Do not use a chemical contrary to the device IFU.
3. **USE THE ALPRO PRODUCT ONLY FOR ITS INTENDED PURPOSE**
   Check the product label/IFU, ARTG status, concentration/ready-to-use form, contact time and material compatibility. Never improvise a dilution or contact time.

ADA PRACTICAL PRINCIPLE

The ADA Guidelines translate infection-control requirements into practical dental workflows. For these products, the key principle is: classify the device or surface, check the manufacturer's IFU, clean appropriately, disinfect where required, and complete the full reprocessing pathway. ADA guidance should be read together with AS/NZS 5369, TGA requirements and the relevant manufacturer IFUs.

3. Spaulding classification — what happens to the dental device?

Device type	Patient contact	Dental examples	Minimum reprocessing principle
CRITICAL	Penetrates sterile tissue, bone or the vascular system.	Surgical instruments; periodontal/ surgical instruments entering tissue; extraction instruments where the procedure creates access to normally sterile tissue.	Cleaning followed by sterilisation. Sterilisation is required.
SEMI-CRITICAL	Contacts mucous membranes or non-intact skin, but does not normally penetrate sterile tissue.	Dental mirrors; reusable impression trays; intra-oral devices; many reusable handpieces/instruments used intra-orally.	Thorough cleaning followed by the reprocessing level specified by the device IFU and AS 5369. In dental practice, heat sterilisation is commonly required for reusable heat-tolerant devices.
NON-CRITICAL	Contacts intact skin only or does not contact the patient.	Dental chair surfaces; external equipment surfaces; handles, control panels and other external surfaces.	Cleaning and appropriate low-level disinfection where required, using a compatible product and following the equipment IFU.

The classification is based on the intended use and contamination risk of the DENTAL DEVICE — not on the name of the cleaning/disinfection chemical.

4. Alpro Medical products covered by this guide

Product	ARTG	TGA class	Manufacturer	Primary role	Where it fits
IC-100	238325	Class I	Alpro Medical GmbH	Non-protein-fixing pre-cleaning agent for medical instruments/ devices.	Pre-cleaning / decontamination before the full reprocessing cycle.
PlastiSept eco	164389	Class IIb	Alpro Medical GmbH	Instrument-grade disinfectant / low-level disinfectant for compatible medical-device surfaces.	Disinfection of compatible medical-device surfaces where the product IFU and device IFU permit.
PlastiSept eco Wipes	293206	Class IIb	Alpro Medical GmbH	Pre-impregnated disinfectant wipes for compatible medical-device surfaces.	Fast surface cleaning/disinfection of compatible dental equipment and medical-device surfaces.
Clean Wipes / IC-100 Wipes	282859*	Class I	Alpro Medical GmbH	Neutral/non-protein-fixing cleaning/decontamination wipes for medical-device surfaces.	Cleaning/decontamination — NOT a sterilisation step and not a substitute for an instrument reprocessing cycle.

* ARTG verification note: TGA lists ARTG 282859 as 'Medical device cleaning/disinfecting wipe', Class I, sponsored by Alpro Medical Australia Pty Limited and manufactured by Alpro Medical GmbH. The Australian market product 'Clean Wipes – soaked in IC-100' is sold as a ready-to-use cleaning/decontamination wipe. Confirm the exact Australian product/packaging and current IFU before relying on the ARTG number for a particular SKU.

ADA GUIDELINES — PRACTICAL APPLICATION TO ALPRO PRODUCTS

The Australian Dental Association (ADA) publishes Guidelines for Infection Prevention and Control to help dental practitioners apply national standards and infection-control requirements in dental settings. The Fifth Edition – Amended (2026) is particularly relevant to management of clinical contact surfaces, contaminated zones, barriers and compatible cleaning/disinfection of dental equipment and medical-device surfaces. ADA guidance must be used together with the equipment/device manufacturer's IFU, applicable AS/NZS 5369 requirements, TGA/ARTG requirements and the Alpro product IFU.

For the Alpro products covered by this guide, the following ADA recommendations are particularly relevant:

- Contaminated-zone surfaces: ADA guidance treats surfaces and items within the contaminated zone as contaminated by the treatment in progress. Items must be disposed of, decontaminated, or appropriately reprocessed before the next patient.
- Between patients: Clinical contact surfaces in the contaminated zone that are not protected by a barrier should be cleaned after each patient. The practice should have a documented, consistent method for surface management across operatories.
- PlastiSept eco / PlastiSept eco Wipes: Use on compatible medical-device and dental-equipment surfaces only where both the Alpro IFU and equipment/device IFU permit. Achieve complete surface coverage and the specified contact time. Surface disinfection does not replace sterilisation where an RMD requires sterilisation.
- IC-100 / Clean Wipes: Use for compatible cleaning/decontamination applications permitted by the product and equipment/ device IFUs. Cleaning removes contamination but does not by itself constitute disinfection or sterilisation.
- Barriers and difficult-to-clean surfaces: ADA guidance recommends considering protective barriers for difficult-to-clean equipment. Where the manufacturer's IFU requires a barrier, that direction should be followed. Barriers must not be used to avoid a required cleaning, disinfection or sterilisation process.
- Manufacturer IFUs and material compatibility: Follow the dental equipment or medical-device manufacturer's instructions for surface management. Do not use a chemical or process that is incompatible with the surface, and do not substitute surface wiping where the IFU requires another validated reprocessing method.

- Clean/contaminated zoning: Keep clean storage and clean-touch areas separate from contaminated clinical surfaces. Staff should use a workflow that prevents contaminated gloves, devices or materials from transferring contamination into clean zones.

5. Practical surface workflow after every patient

IDENTIFY THE SURFACE	Is it a clinical contact surface, an external medical-device/equipment surface, or another environmental surface within the contaminated zone?
CHECK THE EQUIPMENT / DEVICE IFU	Confirm the manufacturer permits the proposed cleaning/disinfection product, application method and material contact.
REMOVE VISIBLE SOILING	Clean visible contamination promptly using the approved method. Cleaning must precede or form part of disinfection where required by the applicable IFU.
CLEAN	Use IC-100 / Clean Wipes for compatible cleaning/decontamination applications where permitted by the current product and equipment/device IFUs.
DISINFECT WHERE REQUIRED	Use PlastiSept eco / PlastiSept eco Wipes on compatible medical-device surfaces where permitted, ensuring the specified coverage and contact time.
MANAGE BARRIERS	Remove contaminated barriers between patients without contaminating the underlying surface; clean/disinfect the surface where required and replace the barrier before the next patient.
PREVENT CROSS	CONTAMINATION — Maintain clean and contaminated zones and avoid touching clean drawers, supplies or controls with contaminated gloves.
FINAL CHECK	Confirm the required contact time/process is complete, the surface is ready for safe use, and any practice documentation or incident record is completed.

6. Product-by-product staff instructions

IC-100 — ARTG 238325

Purpose: ready-to-use, non-protein-fixing cleaning foam/solution for pre-cleaning medical instruments. Alpro states that it dissolves blood and other body-fluid residues from medical-device surfaces.

Use when: the current Alpro IFU and the dental device manufacturer's IFU permit IC-100 for that device.

Do not confuse with disinfection or sterilisation: IC-100 is a cleaning/pre-cleaning agent. A cleaned instrument is not automatically disinfected or sterile.

Staff rule: remove gross contamination promptly, apply/use the product according to the current IFU, then continue with the complete validated reprocessing cycle.

PlastiSept eco — ARTG 164389

Purpose: instrument-grade disinfectant / low-level disinfectant. The Australian product information describes it as an alcohol-free ready-to-use disinfecting foam for sensitive medical-device surfaces, including dental units, upholstery, suspension tables, X-ray equipment, instruments and acrylic glass.

Use when: the surface/device IFU permits this disinfectant and the intended application matches the product IFU.

> **IMPORTANT**
> the ARTG listing confirms the product is an Australian-included Class IIb medical device. It does not mean that every dental instrument may be disinfected with it.

Staff rule: use the product exactly as labelled/IFU, including wetting/coverage and contact time. Do not shorten the contact time because the surface looks dry.

PlastiSept eco Wipes — ARTG 293206

Purpose: pre-impregnated disinfectant wipes for compatible medical-device surfaces. Australian product information identifies the product as an instrument-grade disinfectant/low-level disinfectant and gives dental units, upholstery, suspension tables and X-ray-area surfaces as examples.

Use when: the dental equipment manufacturer permits the use of a compatible disinfectant wipe and the surface is within the Alpro IFU/application area.

Staff rule: wipe the entire required surface so it remains visibly wet for the manufacturer-specified contact time, then follow any drying/rinsing instruction in the device IFU.

Do not use these wipes as a substitute for sterilising reusable critical or heat-tolerant semi-critical dental instruments.

Clean Wipes / IC-100 Wipes — ARTG 282859

Purpose: cleaning/decontamination wipes soaked with IC-100. Australian dental supply information describes them as alcohol-free wipes for non-protein-fixing cleaning and decontamination of medical-device surfaces.

Use when: cleaning of an external medical-device surface is required and the equipment manufacturer permits the product.

Do not use as a disinfectant simply because the wipe removes contamination. Cleaning and disinfection are separate functions unless the product IFU specifically establishes both.

Staff rule: follow the wipe/product IFU and the dental equipment manufacturer’s IFU. For devices that require sterilisation, continue with the complete validated sterilisation pathway.

7. ARTG — what staff need to understand

The ARTG is Australia's public register of therapeutic goods that can legally be supplied in Australia, subject to the applicable legislation and exemptions.

For medical-device cleaners/disinfectants, the intended purpose and claims determine whether the product is regulated as a medical device and what classification applies.

TGA guidance states that cleaning/disinfection liquids, sprays, wipes and aerosols intended for use on medical devices are regulated as medical devices. Cleaners without disinfectant/sterilant claims are generally Class I; medical-device disinfectants making disinfectant/sterilant claims are generally Class IIb.

The dental practice should purchase and use the Australian product supplied under the relevant ARTG inclusion and retain product/IFU documentation. Do not substitute an overseas formulation, refill, concentration or SKU merely because it has the same trade name.

ARTG inclusion is not a substitute for following the manufacturer's IFU or AS 5369 reprocessing requirements.

8. What an auditor should be able to see

- [ ] Current AS 5369:2023 implementation procedure / reprocessing policy.

- [ ] Device classification list showing critical, semi-critical and non-critical reusable dental devices.
- [ ] Current manufacturer IFUs for the reusable dental devices.
- [ ] Current Alpro product IFUs / product information and SDS where applicable.
- [ ] Evidence that the Alpro products used in the practice correspond to the Australian ARTG-included products.
- [ ] Documented cleaning, disinfection and sterilisation procedures, including responsibilities and competency/training.
- [ ] Evidence of validation, routine monitoring and maintenance of reprocessing equipment as applicable.
- [ ] Traceability records for critical and semi-critical reusable devices where required by the practice's governance system.
- [ ] Records for non-conformances, equipment failures, product incidents and corrective actions.
- [ ] Staff competency assessment showing that staff understand the difference between cleaning, disinfection and sterilisation.

9. Simple decision tree for staff

Is the item reusable?

NO → Follow the single-use product instructions and discard as required. YES → continue.

Does it enter sterile tissue/bone?

YES → CRITICAL → clean + sterilise. NO → continue.

Does it contact mucous membrane or non-intact skin?

YES → SEMI-CRITICAL → clean + reprocess to the level required by the device IFU/AS 5369. NO → continue.

Does it contact intact skin/external equipment only?

YES → NON-CRITICAL → clean and disinfect when required using a compatible product.

Which Alpro product? Cleaning/pre-cleaning → IC-100 / Clean Wipes where permitted. Surface disinfection → PlastiSept eco / PlastiSept eco Wipes where permitted.

Final check Does the product IFU AND the dental device IFU permit this use? If not, STOP and obtain the correct validated method.

10. Key audit message for dental staff

REMEMBER

Identify the surface → check the equipment/device IFU → select the correct Alpro product → clean → disinfect where required → observe contact time → prevent cross-contamination.

The surface type, contamination risk and equipment/device manufacturer’s IFU determine the required surface-management process. The Alpro product is selected only where its intended purpose and IFU match that application.

11. Sources and verification references

Therapeutic Goods Administration (TGA), ARTG 238325 — Alpro Medical Australia Pty Limited, Medical device cleaning agent; Class I; manufacturer Alpro Medical GmbH.

TGA, ARTG 164389 — Alpro Medical Australia Pty Limited, Disinfectant, surgical instrument; Class IIb; manufacturer Alpro Medical GmbH.

TGA, ARTG 293206 — Alpro Medical Australia Pty Limited, Medical device cleaning/disinfecting wipe; Class IIb; manufacturer Alpro Medical GmbH.

TGA, ARTG 282859 — Alpro Medical Australia Pty Limited, Medical device cleaning/disinfecting wipe; Class I; manufacturer Alpro Medical GmbH.

Australian Commission on Safety and Quality in Health Care — AS 5369:2023 transition guidance and requirements for reprocessing reusable medical devices in primary/community healthcare.

Standards Australia — AS 5369:2023, Reprocessing of reusable medical devices and other devices in health and non-health related facilities.

ALPRO MEDICAL — IC-100 product information: non-protein-fixing pre-cleaning of medical instruments.

ALPRO MEDICAL / Australian product information — PlastiSept eco and PlastiSept eco Wipes.

Australian Dental Association (ADA), Guidelines for Infection Prevention and Control, Fifth Edition – Amended (2026).

Australian Dental Association, Policy Statement 6.1 – Infection Prevention and Control (reviewed February 2026).

Document control note: Document control note: This is a practical staff guide, not a replacement for the licensed AS/NZS 5369 standard, current TGA requirements, the current ADA Guidelines for Infection Prevention and Control, or the latest manufacturer IFUs. Before issuing this document as the practice's controlled procedure, the practice infection-control lead should verify the current IFU revision, exact Australian SKU/ARTG association, contact times, material compatibility, waterline management requirements and the practice's validated reprocessing equipment/process.