



Lozopren plus AF

Concentrate for preparation of a working solution for manual disinfection of invasive medical devices in an immersion bath

Product Description

- Lozopren plus AF is a concentrate based on quarternary ammonium compounds and amine for preparation of a working solution for manual disinfection of invasive medical devices in an immersion bath.

Application

- Lozopren Plus AF is suitable for dental and surgical instruments as well as rotating precision instruments.
- Suitable for:
 - mirrors
 - forceps
 - probes
 - root canal instruments
 - polishers
 - reamers
- Not suitable for final disinfection.**
- Not suitable for endoscopes.**
- Not suitable for disinfection of skin and hands.
- Not tested for food and veterinary area.
- Do not use for spraying.

Advice for Users

- Application should be carried out only by qualified personnel
- Do not mix with other products.
- Clean immersion bath and application aids thoroughly prior to the first application of the product, after application of other products, and at the end of the working day.
- Do not pour concentrate that has been removed back into the original container.
- Report serious incidents related to this product to the manufacturer and the respective authority.

Shelf Life and Expiry Date

- The shelf life of the working solution is 1 day.
- Renew immediately in the case of visible contamination.
- See the product label for its expiry date.
- Do not use the product after its expiry date.

Composition

- Active ingredients in 100g:
 - 19.05g N-(3-Aminopropyl)-N-dodecylpropan-1,3-diamine,
 - 5.60g N,N-Didecyl-N-methyl-poly(oxyethyl)-ammonium-propionate
 - 2.10g Didecyl dimethylammonium chloride
 - 9.97g 2-propanol

Characteristics

- Appearance: clear, yellowish liquid
- pH value: 11.0 - 12.0
- Density: 0.940 - 0.999 g/cm³

Application

Put on protective clothing, eye protection, face mask and protective gloves before each disinfection! Do not allow debris to dry on the instruments. Thoroughly clean the opened and disassembled instruments.

Disinfection in immersion bath:

- Prepare working solution in the desired concentration with water (approx. 20°C, of at least drinking water quality).

Example for a 0.25% working solution: Provide 997.5 ml water, add 2.5 ml concentrate and mix.
- Immerse the cleaned, opened, disassembled instruments in the working solution. All surfaces and cavities have to be wetted.
- After the contact time has elapsed: Rinse the instruments thoroughly with water (at least drinking water quality*) and dry them.
- Check instruments for cleanliness and integrity. Comply with the instrument manufacturer's recommendations for reprocessing as well as with national requirements for reprocessing.

**use demineralized water in case the instruments are supposed to be sterilized.*

See page 2 for efficacy spectrum and information on material compatibility.

Expert opinions and further information

- Lozopren plus AF has been assessed by independent laboratories.
- For further details on expert opinions, more information on the product or individual questions contact us by e-mail (info@airande.global) or telephone (+61 2 9844 5846).
- Airandé is certified by BSI to ISO 13485
- PLIWA Hygiene GmbH has a manufacturing authorisation as per §13 German medicines act as well as a GMP- and an EN ISO 13485 certificate.
- For further information on the reprocessing of medical devices, recommendations are available on the homepage of the Robert Koch-Institute. (Recommendation from the Commission on Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) on the "Hygiene Requirements for the reprocessing of medical devices".
- See also the specific guidance on this topic given by your local regulators.



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Labelling

CE 0123 MD IIb

Labelling according to Regulation (EC) No 1272/2008 (CLP)

For information on labelling according to Regulation (EC) No 1272/2008 (CLP) see safety datasheet and label.

Detailed spectrum of efficacy

Disinfection by immersion: Efficacy under dirty conditions (tested at room temperature)	Test Standard	Conc.	Contact Time
Bactericidal			
<i>S. aureus, E. hirae, P. aeruginosa, E. coli</i>	EN 13727	0.25%	1 min
<i>S. aureus, E. hirae, P. aeruginosa</i>	EN 14561	0.1%	15 min
Yeasts			
C. albicans	EN 13624	0.25%	1 min
	EN 14562	0.25%	5 min
Viruses			
Enveloped Viruses			
<i>Vaccinia Virus strain Elstree</i>	EN 14476	0.25%	15 min
Non-enveloped viruses			
<i>SV40 Polyomavirus</i>	EN 14476	1.0%	30 min

Packaging and Ordering

Single Pack	Units Per Carton	Product Number
1-litre dosing bottle	18	AIR_10-0061
5-litre canister	1	AIR_10-0064
Accessories		
Dosing pump	For canisters	AIR 50006
Drainage tap	For canisters	AIR_50009

Examples for the preparation of working solutions

Concentration Required	Volume of Water	Concentrate
0.25%	997.5 ml	2.5 ml
1.0%	990 ml	10 ml

Material Compatibility

Metals	Stainless Steel
Plastics	Polyvinylchloride, Polysulfone, PE
Further Materials	Ceramics
Advice	Upon compliance to the intended use as well as the indicated contact time and concentration, no material damage is to be expected with the above mentioned materials. With copper, aluminium and brass, colour changes may occur upon prolonged contact. With natural and synthetic rubber as well as silicone changes, deformation and loss of elasticity may occur. Test material compatibility for polyacrylates, polycarbonates, as well as for materials not mentioned here.



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