Instructions for use

deconex[®] **ENDOMATIC**

Disinfectant for automated flexible endoscope reprocessing - pH-neutral





Scope of application

For the automated, chemo-thermal disinfection of thermo-labile, non-invasive and invasive medical devices i.e. cleaned flexible endoscopes and endoscopy accessories in endoscope washer-disinfectors (E-WD).

Bactericidal, yeasticidal, tuberculocidal, mycobactericidal, fungicidal and virucidal.

For professional use only.

Application and dosage

deconex® ENDOMATIC is supplied as a concentrate. The connection is made according to the E-WD manufacturer's instructions.

Chemo-thermal disinfection is carried out with deionised or mains water (≤ 30 °fH, or 16.9 °dH / 300 ppm CaCO₃) at ≥ 40 °C at a concentration of 7.5 - 10.0 mL/L. Disinfection is carried out at 55-60 °C for 5 min.

Ensure that the channels of the endoscope are sufficiently rinsed with the water quality required by the endoscope manufacturer and dried after using deconex® ENDOMATIC.

Advisory

- Not suitable in combination with amine-containing products, e.g. disinfecting pre-cleaning agents.
- Do not use for non-thermo-labile instruments.

Important

Read the instructions for use carefully before each use and keep them in a safe place.



Symbol indicates safety instructions - please observe.

Disinfection efficacy according to EN 14885

Spectrum of activity and method	Concentra- tion	Contact time	Tempe- rature
Bactericidal activity (EN 13727, EN 14561)	0.5 %	5 min	55 °C
Levurocidal activity (EN 13624, EN 14562)	0.5 %	5 min	55 °C
Tuberculocide activity (<i>M. terrae</i>) (EN 14348, EN 14563)	0.5 %	5 min	55 °C
Mycobactericidal activity (<i>M. avium</i>) (EN 14348, EN 14563)	0.5 %	5 min	55 °C
Virucidal activity (murine parvovirus, <i>MVM</i>) (EN 14476, EN 17111)	0.5 %	5 min	55 °C
Fungicidal activity (<i>A. brasiliensis</i>) (EN 13624, EN 14562)	0.5 %	5 min	55 °C

The test was carried out with water of standardised hardness (30 °fH or 16.9 °dH / 300 ppm CaCO₃) and under low load conditions.





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Chemical-physical data

Appearance / colour

1 % solution	
pH value in mains water ¹⁾	approx. 7.1 ¹⁾
pH value in deionised water	approx. 7.1
Concentrate	
Density	1.04 g/ml

transparent, green

¹⁾ Measured in tap water at 25 - 28 °fH / 14 - 16 °dH / 250 - 280 ppm CaCO₃

Contents

100 g deconex[®] ENDOMATIC contain: Active substances: 20 g glutaraldehyde

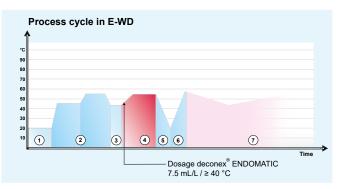
Ancillary ingredients: Surface-active substances, solubilisers, corrosion inhibitor, perfume, dye

Recommended use

The following process is a recommendation based on experience. The parameters must be adjusted according to the local conditions. These process examples do not remove the user's obligation to check any processes installed at their facility to ensure sufficient performance and compliance with local legislation, local authorities and standards.

Typical reprocessing process in the E-WD with deconex[®] ENDOMATIC:

- 1. Pre-rinse: with cold tap water, 2 min.
- 2. Cleaning: with deionised / soft water with the addition of e.g. an enzymatic cleaning agent e.g. deconex® 23 NEUTRAZYM-x
- 3. Intermediate rinse: with cold mains water, 1 min.
- 4. Chemo-thermal disinfection with deionised or mains water (≤ 30 °fH, or 16.9 °dH / 300 ppm CaCO₃), Dosing of deconex[®] ENDOMATIC at ≥ 40 °C, 7.5 - 10 mL/L, disinfection at 55-60 °C for 5 min
- 5. Intermediate rinse: with cold sterile DI / soft water for 1 min
- 6. Final rinse: with sterile soft or DI water, at 58 °C, 1.5 min.
- 7. Drying



Material compatibility

- Suitable for: Stainless steel, aluminium, anodised aluminium, non-ferrous metals, rubber, latex, glass, plastics.
- Conditionally suitable for polymethyl methacrylate (PMMA, » acrylic glass).
- Not suitable for polystyrene (PS) and EPDM.

For information on materials not mentioned or questions about material compatibility with endoscopes, E-WDs or chemistry delivery systems, please contact the local sales partners or Borer Chemie AG.



- Only use undamaged and original, sealed containers.
- Do not open the canister if it is inflated.
- Do not use if the colour of the concentrate changes.
- Do not use after the expiry date.
- Do not mix with other products or residues.
- For single use only.
- Only use completely cleaned medical devices for disinfec-_ tion with deconex® ENDOMATIC.
- Ingredients may cause allergic reactions. _
- Do not inhale vapours. _

Storage & transport

Store deconex[®] ENDOMATIC at temperatures between 5 and 25 °C and protect from sunlight.

Disposal

When disposing of the empty containers and used solution, local waste and waste water regulations must be observed.

Consult the safety data sheet for occupational safety and proper disposal of unused product.



Description of symbols used

Explanations of the symbols used can be found in the pictogram key on the website:

https://www.borer.swiss/downloadcenter



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Notes

We recommend using the product in validated processes.

Follow the reprocessing instructions for the medical devices to be treated and the instructions for use for equipment used for reprocessing.

Regular microbiological checks on the endoscope help to detect resistance, especially mycobacteria.

Before changing the product, please contact your local sales partner or Borer Chemie AG.

Comply with legal, regulatory and standard requirements for medical devices.

If a serious incident occurs with this product, it must be reported to the manufacturer and the responsible authority.

The latest version as well as other language versions of this document can be found on this website: <u>http://www.borer.swiss/en/download-center-medical</u>







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