

Instructions for use

deconex® 28 ALKA ONE-x

High alkaline automated cleaning chemistry

For the automated reprocessing of medical devices in washer/disinfectors



Scope of application

deconex® 28 ALKA ONE-x is used in the washer/disinfector for the following reprocessable medical devices and accessories:

- thermally stable, invasive medical devices such as surgical instruments, ward utensils, minimally invasive surgery instruments
- thermo-stable and thermo-labile, non-invasive medical devices

Properties

deconex® 28 ALKA ONE-x is based on a tried-and-tested, highly alkaline formula which, thanks to the omission of caustic alkalis (e.g. KOH or NaOH), has excellent material compatibility despite its high pH value. The product also offers the following properties:

- Proven prion deactivation for the preventive minimisation of risk of transmission of CJD/vCJD* and in cases of proven non-confirmed suspected cases of CJD/vCJD* (see corresponding process parameters under "Application and dosage")
- Prion-deactivating process can also be used for aluminium (see "Material Compatibility")
- pH > 10 (RKI-compliant)
- Exceptional anti-corrosion and complexing properties
- Excellent cleaning performance, rapidly and efficiently removes all contamination on surgical equipment
- Can be used with all qualities of water
- Requires no neutralisation
- Residue-free rinsing
- Prevents deposits on the load and washer/disinfector chamber
- Foam-free
- Free from materials that are potentially harmful to the environment or human health
- Biodegradable

Application and dosage

The optimum dosage of deconex® 28 ALKA ONE-x is influenced by various factors, such as the type and amount of soiling, the water hardness and the instruments' stand time. The use of fully demineralised water generally leads to better cleaning results and is recommended.

Reprocessing in the washer/disinfector

deconex® 28 ALKA ONE-x is used at a concentration of 0.3 – 0.7 % or 3 – 7 mL/L at 70 - 90 °C for at least 5 minutes. Doses are added at ≥ 30 °C.

Prion-deactivating process*

For the preventative minimisation of risk of CJD/vCJD transmission and in cases of proven non-confirmed suspected cases of CJD/vCJD:

deconex® 28 ALKA ONE-x is used at a concentration of 1 % or/ 10 mL/L at 70 °C for at least 10 minutes. Doses are added at ≥ 30 °C.

Locally applicable specifications and guidelines on how to handle prion-contaminated instruments must be followed.

Subsequently, sufficient two-stage intermediate rinsing for at least 1 minute each with tap water or demineralised water must be carried out. Ideally, demineralised water will be used for the second intermediate rinse.

Neutralisation is not required.

Material compatibility

deconex® 28 ALKA ONE-x is suitable for stainless steel, chrome-plated materials, plastics, rubber, latex and ceramic materials.

Incompatibility can occur with PET, PC and PS plastics.

* Claims may be subject to local regulatory approval / acceptance

deconex® 28 ALKA ONE-x

The process recommended for the normal reprocessing of medical devices is not suitable for (anodised) aluminium or titanium. The prion-deactivating process is compatible with (anodised) aluminium for up to 12 cycles.

For other sensitive materials, compatibility tests may need to be carried out. If necessary, contact your local deconex® products distributor or Borer Chemie AG directly.

For material compatibility with cleaning and disinfection equipment, contact your local deconex® products distributor or Borer Chemie AG directly.

Chemical-physical data

pH value 1 % solution

in demineralised water	approx. 12.0
in tap water ¹⁾	approx. 11.6

Density of concentrate	1.4 g/mL
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Appearance of concentrate	clear, colourless to yellow
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¹⁾ measured in tap water at 25 - 28 °fH / 14 - 16 °dH / 250 - 280 ppm Ca²⁺/ Mg²⁺

Contents

Alkali, surfactant compounds, complexing agents, sequestering agents, corrosion inhibitors

Attention

Do not mix with other products. ▪ Please contact your local deconex® products distributor or Borer Chemie AG before changing the product. ▪ The product is for single use only, not for reuse. ▪ The legal and standards-related requirements for medical devices must be complied with. ▪ For professional use only. ▪ We recommend using the product in validated processes. ▪ Observe the reprocessing instructions for the medical devices to be treated and the instructions for use for equipment used for reprocessing.

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

Safety instructions and disposal

Information regarding safety in the workplace and the correct disposal of the unused product can be found on the safety data sheet.

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

Containers, seals and labels are made from recyclable polyethylene.

Storage and transport

Store the product at temperatures between 5 and 25 °C.

CE marking

deconex® 28 ALKA ONE-x meets the requirements for medical devices under the Medical Devices Directive (EU) 2017/745.

Availability

Please contact your local deconex® products distributor for available container sizes.

Distributor / Importer:

Manufacturer:

Borer Chemie AG

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