Instructions for use

deconex[®] 23 NEUTRAZYM-x

Mild alkaline enzymatic automated cleaning chemistry

For the automated reprocessing of reprocessable medical devices in washer-disinfectors (WD) and endoscope washer-disinfectors (E-WD)



Scope of application

deconex[®] 23 NEUTRAZYM-x is a mildly alkaline enzymatic cleaner for automated reprocessing in washer-disinfectors (WD) and endoscope washer-disinfectors (E-WD) of the following reprocessable medical devices and accessories:

- Thermostable, invasive and non-invasive medical devices such as surgical instruments and ward utensils, minimally invasive instruments and robotic instruments (such as Da Vinci)
- Thermolabile, invasive medical devices such as flexible endoscopes
- Thermolabile, non-invasive medical devices such as anaesthesia and breathing utensils

Properties

deconex[®] 23 NEUTRAZYM-x is a cleaning concentrate developed according to scientific principles on the basis of a special, synergetic combination of enzymes and surfactants which gives the product the following properties:

- Can be used from 45 °C
- Very gentle on materials
- Good cleaning performance against P. aeruginosa biofilm
- Successfully type-tested according to ISO 15883-5
- Can be used with all water qualities
- No neutralisation necessary
- Biodegradable

Application and dosage

The optimum dosage of deconex[®] 23 NEUTRAZYM-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.

deconex[®] 23 NEUTRAZYM-x is used at a concentration of 5 - 10 mL/L (0.5 - 1 %) at $45 - 60 \degree$ C for at least 5 min. Dosing takes place from 35 °C.

For instruments that have been pre-cleaned well or medical devices that are easy to clean, a dose of 2 - 5 ml/l in DI water can be used.

A two-step cleaning process can also be carried out with 5 - 10 mL/L (0.5 - 1 %) deconex[®] 23 NEUTRAZYM-x in a first cleaning phase at 45 °C for 3 min, and a second cleaning phase at 60 °C (or 58 °C for thermally labile, invasive medical devices) for 3 min immediately afterwards. The two steps run in succession without draining the wash solution in between.

Subsequently, sufficient two-stage intermediate rinsing for at least 1 min. 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[®] 23 NEUTRAZYM-x is suitable for stainless steel, (anodised) aluminium, titanium, non-ferrous metals, plastics, elastomers incl. polurethane, silicone, rubber and latex, polytetrafluoroethylene (PTFE, e.g. Teflon), glass and ceramics.

No incompatibilities are known.

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.



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deconex[®] 23 NEUTRAZYM-x

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 in tap water ¹⁾	approx. 9.8 approx. 7.2
Density of concentrate	1.1 g/mL
Appearance of concentrate	clear, yellow

 $^{1)}$ measured in tap water at 25 - 28 °fH / 14 - 16 °dH / 250 - 280 ppm CaCO $_{\rm 3}$

Contents

Surface-active substances, enzymes (proteases), chelating agents, solubilisers, sequestering agents, preservatives

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.

This medical device is frost-sensitive. Avoid whenever possible transportation of this product during the cold periods. If transport during such periods is inevitable, this product must be shipped using temperature controlled lorry / sea container above 5° Celsius, or use protection hoods for short-time transports not longer than 10 hours with transport temperatures not falling below minus 5°C.

CE marking

deconex[®] 23 NEUTRAZYM-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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