Instructions for use

deconex® FOAM PLUS

Enzymatic, disinfectant pre-cleaning foam

For the manual pre-treatment of surgical instruments



Scope of application

deconex® FOAM PLUS is used to prevent the drying and encrustation of blood and tissue on the following reusable medical devices:

 Invasive and non-invasive, thermostable medical devices, e.g. surgical, MIS and robotic instrumentes, incl. Da Vinci, dental instruments and accessories

This ready-to-use product is sprayed directly onto the instruments after use and prior to longer transport and waiting time, until they are reprocessed in the CSSD.

MIS and HF instruments, especially their tips, can be placed directly in the liquid product in order to dissolve coagulated protein and hard to remove residues to simplify the subsequent cleaning steps.

Properties

deconex® FOAM PLUS combines the cleaning effect of enzymes with the disinfecting effect of a pre-disinfection product. It prevents soil such as blood and tissue residue from drying and thanks to the enzymes, starts to break them down, making the next cleaning steps considerably easier. deconex® FOAM PLUS also has the following properties:

- Forms a stable foam
- Spectrum of activity: bactericidal, yeasticidal, active against enveloped viruses
- Prevents microbial contamination of the surroundings and protects users
- Good material compatibility, including with aluminium, thanks to pH-neutral formulation
- Protects against corrosion for at least 72 h
- Biodegradable

Disinfection efficacy

| Spectrum of activity and methodology | Contact time |
|--|--------------|
| Bactericidal (EN 13727, EN 14561) | 5 min |
| Yeasticidal (EN 13624, EN 14562) | 5 min |
| Active against enveloped viruses Suspension test (EN 14476) | 5 min |
| Germ carrier test (EN 17111) | 15 min |

Application and dosage

deconex® FOAM PLUS is ready-to-use and is sprayed directly onto the instruments using the supplied spray head. For best results, application should take place in the transport container immediately after the instruments are used.

To achieve the best possible pre-cleaning and disinfection effect, thorough coverage and wetting of the instruments must be ensured.

MIS and HF instruments and their tips can be treated by placing them in deconex® FOAM PLUS in liquid form.

The instruments must then be reprocessed using their usual validated process.

The holding time between the use of the instruments and their reprocessing should generally be no longer than 6 - 8 hours according to current guidelines and legal or standards-based specifications. The corrosion inhibiting effect of deconex® FOAM PLUS has been demonstrated for up to 72 hours, while the cleaning effect of the enzymes remain intact for longer than this.



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Manual rinsing of the instruments prior to subsequent automated reprocessing or thorough pre-rinsing in the washer-disinfector safeguards the stability of the automated reprocessing stage. It must be established by individual checks, whether omission of the rinsing step may have an unacceptably negative effect on the automated process.

Material compatibility

deconex® FOAM PLUS is suitable for stainless steel, (anodised) aluminium, titanium, non-ferrous metals, polyoxymethylene (POM), polyethylene (PE), polyamide (PA) and polyvinyl chloride (PVC).

Incompatibility can occur with Plexiglas (PMMA), polyetherimide (PEI) and polyphenylsulphone (PPSU).

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.

Chemical-physical data

| pH value of liquid | approx. 7.8 |
|----------------------|-------------|
| Density of liquid | 1.0 g/mL |
| Appearance of liquid | clear, blue |

Constituents

100 g deconex® FOAM PLUS contains:

0.22 g N,N-didecyl-N-methylpoly(oxyethyl) ammonium propionate

0.23 g N-(3 aminopropyl)-N-dodecylpropane-1.3-diamine

Auxiliary ingredients:

Enzymes (protease), surfactant substances, perfume, dye

Attention

Not suitable for final disinfection.

Do not mix with other products. • Contact your local distributor for deconex® products or Borer Chemie AG before changing use chemistries. • 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. • Observe the reprocessing instructions for the medical devices to be treated and the instructions for use for any equipment used for reprocessing.

Distributor / importer:

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 product is frost-sensitive. Whenever possible, avoid transportation of this product during cold periods. If transport during this time of year is unavoidable, the product must be shipped in a temperature-controlled lorry / sea container regulated to at least 5°C. Or use protection hoods for short-time transports no longer than 10 hours with transport temperatures not falling below minus 5°C.

CE marking

deconex® FOAM PLUS meets the requirements for medical devices pursuant to the Medical Devices Directive 93/42/EEC.

Availability

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

Manufacturer:

Borer Chemie AG

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