Detergent for reprocessing thermostable and thermolabile instruments

Liquid concentrate

Fields of application:
- Automated cleaning of thermostable and thermolabile instruments including MIS instruments and micro-instruments, flexible endoscopes, anaesthesia equipment, containers and other medical utensils
- Manual cleaning of thermostable and thermolabile instruments in immersion baths or ultrasonic baths
- Also suitable for the manual and automated cleaning of da Vinci EndoWrist Instruments

Performance spectrum:
- Reliably removes residues of dried and denatured blood
- Greatly reduces the amount of organic material and prevents the re-deposition of protein residues
- Fulfills the current recommendations of the German Robert-Koch-Institute (RKI) for minimising the transmission risk of the new variant of the Creutzfeldt-Jakob disease (vCJD) when reprocessing medical devices
- Removes pathogenic prion proteins of different prion test strains; amongst those the vCJD test strain by ≥ 2 lg steps (1 %, 55 °C, 10 min)
- Supports the removal of biofilms
- Suitable for instruments and utensils made of stainless steel, instrument steel, optics, conventional plastics and the materials of anaesthesia equipment
- Anodised aluminium must be tested first for suitability

Special properties:
- Excellent material compatibility
- First-class cleaning activity due to the singular formula based on alkalinity donors, surfactants and enzymes
- When used for manual pre-cleaning the cleaner solution does not have to be rinsed off prior to automated reprocessing
- No neutralising step necessary for automated reprocessing; therefore short program cycles
- No hazard label; non-hazardous product

Application and dosage:
neodisher MediClean forte can be used in washer disinfectors as well as in dip and ultrasonic baths. The dosing amount depends on the respective field of application and the individual degree of contamination of the instruments to be reprocessed. When reprocessing da Vinci EndoWrist instruments neodisher MediClean forte can be used in all manual pre-cleaning steps, for ultrasonic pretreatment and for the automated reprocessing process. The following parameters are recommended when using neodisher MediClean forte:

| Automated cleaning of thermostable and thermolabile instruments | 2 - 10 ml/l (0.2 - 1.0 %)*, e.g. 40 - 60 °C, 10 min |
| Automated cleaning of endoscopes as well as endoscopic accessories | 5 ml/l (0.5 %), 35 - 55 °C, 5 min |
| Automated cleaning of da Vinci EndoWrist Instruments | 8 ml/l (0.8 %), 40 - 55 °C, 10 - 30 min** |
| Manual cleaning of thermostable and thermolabile instruments in dip and ultrasonic baths | 5 - 20 ml/l (0.5 - 2 %)*, max. 40 °C, 10 - 30 min |
| Manual cleaning of endoscopes as well as endoscopic accessories in dip and ultrasonic baths | 5 - 30 ml/l (0.5 - 3 %)*, max. 40 °C, 5 - 10 min |
| Manual cleaning of da Vinci EndoWrist Instruments in dip and ultrasonic baths | 10 ml/l (1.0 %), max. 40 °C |

* the dosing amount depends on the degree of soiling
** depending on the respective recommendation of the washer-disinfector manufacturer

Use suitable dosing devices.

In the cleaning step and in the final rinse the use of delonised water is recommended.

The neutralisation step which is obligatory when using classical alkaline detergents is not necessary. When reprocessing ophthalmological instruments an additional intermediate rinse with water prior to the final rinse is recommended.

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*Evaluation of the ability of neodisher MediClean forte to inactivate and/or remove transmissible spongiform encephalopathy (TSE, Prions) agents from surfaces of medical and surgical devices, after direct inoculation of experimentally contaminated surfaces - Service d’Etude des Prions et des Infections Atypiques

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The working solution for manual cleaning is to be renewed daily and in the case of visible soiling.

Notes on application:
- For professional use only.
- Do not mix with other products.
- Rinse out dosing system including suction hose with water before changing product.
- Reprocessing should comply with all ordinances pursuant to the Medical Device Directive and should be performed with appropriate validated processes.
- The neodisher MediClean working solution has to be rinsed off completely (preferably with deionised water).
- Please observe the medical device manufacturer’s recommendations for use according to the requirements of DIN EN ISO 17664.
- The instructions given by the manufacturer of the washer disinfector are to be observed.

Expert reports:
The process reports for reprocessing da Vinci instruments can be obtained on request.

Technical data:

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>pH-range</td>
<td>10.4 – 10.8 (2 - 10 ml/l, determined in deionised water, 20 °C), in mains water or softened water as well as with carried-over pre-rinsing water, the pH-value can be different.</td>
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<tr>
<td>Density</td>
<td>1.1 g/cm³ (20 °C)</td>
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<tr>
<td>Viscosity</td>
<td>&lt; 10 mPa s (concentrate, 20 °C)</td>
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<tr>
<td>Titration factor</td>
<td>0.77 (according to the neodisher MediClean forte titration instructions)</td>
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</tbody>
</table>

Ingredients:
Ingredients according to Regulation (EC) No 648/2004 on detergents:
- ≤ 5 % nonionic and anionic surfactants
- also: enzymes


Storage information:
Store in a cool but frost-free place. Always store at a temperature between 0 and 25 °C. Usable for 2 years when stored as recommended. For expiry date refer to the stamp mark on the label behind the hourglass symbol.

Hazard and precautionary statements:
neodisher MediClean forte is not a hazardous product according to the CLP-Regulation (EC) No 1272/2008.
Dispose only when container is empty and closed. For disposal of product residues, refer to Safety Data Sheet.
For further safety information see EC Safety Data Sheets. These are available at www.drweigert.com under the headline “Service”.

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