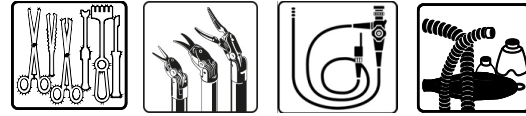# neodisher® MediClean forte

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
- Automated and manual cleaning of personal protective equipment (PPE)[1]

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
- Fulfils 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)[2]
- 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 unique 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 with neodisher MediClean forte
- 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 immersion and ultrasonic baths. The dosing amount depends among other things 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 pre-treatment and for the automated reprocessing process.

Personal protective equipment[1] cleaned in an immersion bath must be completely wetted with the application solution during the entire immersion time. Then rinse thoroughly under running water of at least drinking water quality.

The following parameters are recommended when using neodisher MediClean forte:

Automated and manual cleaning of instruments:

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

Automated and manual cleaning of personal protective equipment[1]:

Manual cleaning of breathing apparatuses/respirators and their accessories in immersion baths	10 ml/l - 30 ml/l (1.0 % - 3.0 %)*, cold water up to max. 40 °C, 15 - 30 min
Automated cleaning of specific personal protective equipment[1] (clearance in accordance with manufacturer's information), breathing apparatuses/ respirators and their accessories in washer-disinfectors and/or washer extractors (program specifications in accordance with manufacturer's information)	10 ml/l (1 %), 55°C, 2 min

* the dosing amount depends among other things on the degree of contamination

** 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 deionised water is recommended. When using deionised water in the final rinse water stains are avoided and anodised aluminium is protected at the same time.

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.

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 regulations on medical devices and should be performed with appropriate validated processes
- The neodisher MediClean forte working solution has to be rinsed off completely (preferably with deionised water)
- Processing of medical device: Please observe the reprocessing recommendations of the medical device manufacturers according to the requirements of the DIN EN ISO 17664
- Processing of personal protective equipment[1]: Please observe the reprocessing recommendations given by the manufacturer of the personal protective equipment
- The instructions given by the manufacturer of the washer disinfector are to be observed

Expert reports:

The process report for reprocessing da Vinci EndoWrist instruments can be obtained on request.

neodisher® MediClean forte was used and positively assessed by various testing and certification bodies in the context of personal protective equipment[1] certification with regard to material compatibility

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neodisher® MediClean forte

Technical data:

pH-range	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.
Density	approx. 1.1 g/cm³ (20 °C)
Viscosity	< 10 mPa s (concentrate, 20 °C)
Titration factor	0.77 (according to the neodisher MediClean forte titration instructions)

Ingredients:

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

CE-marks: CE [MD]

neodisher MediClean forte complies with European guidelines for medical devices.

If a serious incident occurs with the product, report it to the manufacturer and the relevant national authority.

Storage information:

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

Changes in the colour of the product may occur when storing in factory-sealed trade units. This has no impact on the properties of the product which are relevant for application.

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 Safety Data Sheets. These are available at www.drweigert.com under the headline "Service/Downloads".

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[1] Personal protective equipment (PPE), protective clothing against chemicals
[2] 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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With the above information, which is appropriate to our current knowledge we describe our product regarding possible safety necessities, but we do not involve any quality description or promise certain properties.