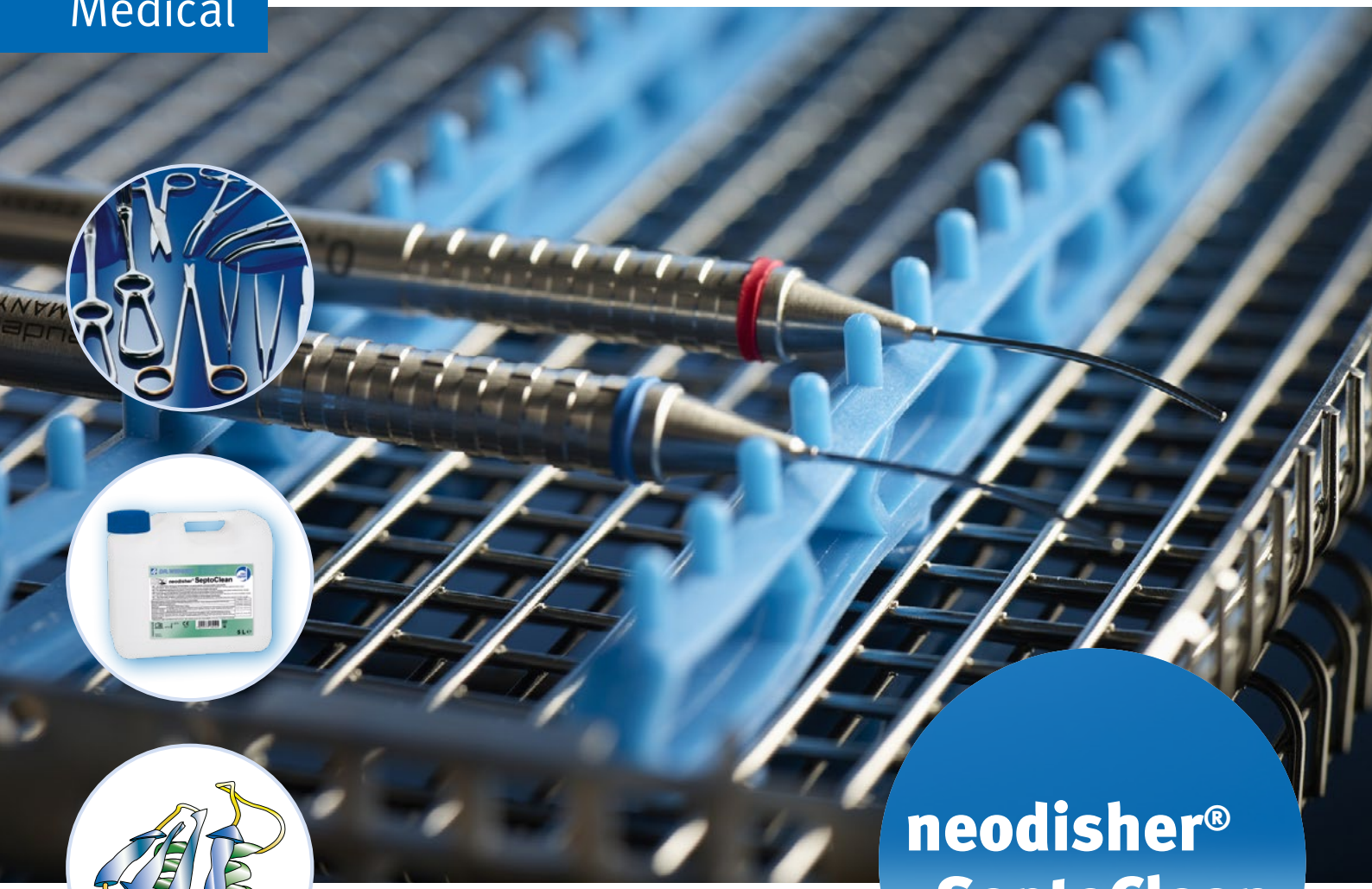
neodisher®

DR. WEIGERT
Systematic Hygiene

Medical



neodisher® SeptoClean

Multifunctional Detergent for Cleaning, Disinfection and Proved Prion Inactivation.

The Product with
Triple Action:
neodisher® SeptoClean.

Higher Demands on Quality and Safety:

New challenges such as prions as pathogens of transmissible spongiform encephalopathies (TSE)*, e.g. CJD and vCJD, as well as modern complexly constructed medical devices demand special innovative solutions for reprocessing.
A safe reprocessing of medical devices is a crucial precondition for excluding infections to the greatest possible extent.

A qualified reprocessing demands a high degree of expertise and experience – trust neodisher®!

The Outstanding Talent.

neodisher® SeptoClean is an innovative detergent on the basis of a synergetic combination of alkaline substances with surface-active components.
The unique property of **neodisher® SeptoClean** is its unrivalled triple action:

- excellent cleaning performance
- disinfecting properties: bactericidal, yeasticidal and virucidal
- prion inactivating and prion decontaminating activity

This spectrum offers manifold purposes of use and new perspectives for future innovative reprocessing, e.g. the possibility for setting new standards when reprocessing thermally sensitive medical devices which cannot be autoclaved.

More Safety for Patients and Personnel.

The unique properties of **neodisher® SeptoClean** guarantee optimum safety for patients and personnel within the scope of application.

The use of **neodisher® SeptoClean** is recommendable for several processes when automatically reprocessing medical devices which had contact with TSE risk tissue. The infection risk is minimised significantly. This is in particular of great importance with symptomless respective non-diagnosed carriers of vCJD and CJD.

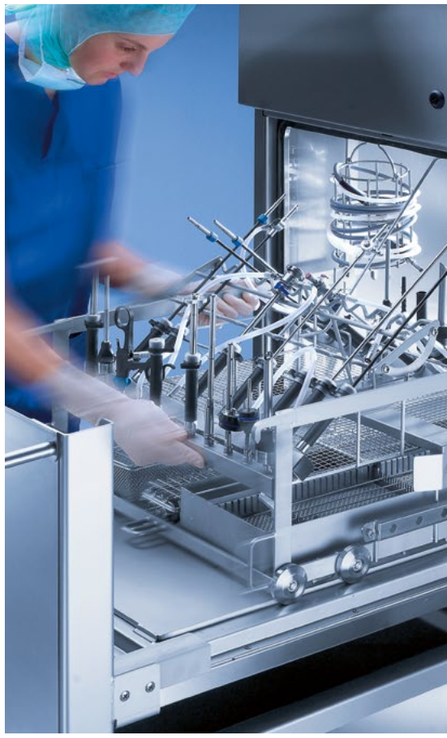
Cleaning Only.

A residue-free cleaning is of essential importance within the context of reprocessing medical devices. **neodisher® SeptoClean** removes blood, protein and all other typical operation residues. The surfactants play a key role: Due to their surface-active properties they remove fatty and hydrophobic soiling. At the same time, the redeposition of solved particles is prevented as a result of the excellent dirt-lifting capacity of **neodisher® SeptoClean**. The especially developed surfactant combination guarantees a nearly foam-free use in all washer disinfectors on the market, thus guaranteeing their functional and mechanical efficiency.

Material Compatibility = Preserving Instruments

A good detergent is gentle on material. Even sensitive MIS instruments and rigid endoscopes can be reprocessed with **neodisher® SeptoClean**.
This has been confirmed by leading manufacturers.

Even chromium plated surfaces, soldered junctions made from silver and tin, glue joints and sealings, plastic coatings (e.g. colour codes, electric insulations), fibre optics and optic surfaces with antireflex coatings as well as high-grade anodised aluminium are not attacked by **neodisher® SeptoClean**.



for reprocessing Approval* of medical devices

STORZ
KARL STORZ — ENDOSKOPE

DR. WEIGERT

* The term TSE stands for transmissible spongiform pathogene changes in the brain. Among others these are the diseases known as „Creutzfeldt Jakob disease“ (CJD) and „variant Creutzfeldt Jakob disease“ (vCJD)

* The approval of company Karl Storz for neodisher® SeptoClean encompasses the automated reprocessing of MIS instruments and rigid endoscopes incl. optics. The report of approval is available on request.

neodisher® SeptoClean
Sets New
Standards.

Cleaning Plus.

The alkaline surfactant-containing detergent **neodisher® SeptoClean** complies with the recommendations of the German RKI[1] statement „The Variant of the Creutzfeldt Jakob Disease (vCJD)“[2].
Furthermore, considering the corresponding operation conditions, **neodisher® SeptoClean** possesses even in a single step cleaning process a prion inactivating and prion decontaminating activity that has been successfully proved according to several international accepted test methods – a milestone for the prophylaxis against prions when reprocessing instruments.

Cleaning Special “CJD/vCJD“.

Particularly in TSE risk areas, e.g. in neurosurgery or in ophthalmic surgery[3], measures for minimising the risk of transmitting CJD/vCJD are recommended. This also applies for patients who are not suspected to suffer from CJD/vCJD.

By using a detergent that has been tested and found effective against prions in accordance with approved method proposals, patient safety can be increased. It is not enough to demand a higher pH-value in the detergent.[4] The cleaning process with the operation conditions 1 % **neodisher® SeptoClean** at 55 °C for 10 minutes with its tested an proven prion inactivating and prion decontaminating action is the best choice.

A European process patent was granted for the prion inactivating formula: The use of **neodisher® SeptoClean** for inactivating prions during instrument reprocessing is protected by the European Patent EP 1 470 211 under the process conditions defined therein.

[1] Robert Koch-Institute

[2] The Variant of the Creutzfeldt Jakob Disease (vCJD), Epidemiology and Protective Measures for Preventing a Human-to-Human Transmission, M.Beekes P24 - Transmissible Spongiform Encephalopathies, Robert Koch-Institute, Berlin (published in the Bundesgesundheitsblatt 06/10), date of publication 14 June 2010

[3] Current Hygiene Standards in Ophthalmic Surgery Part 2: Instrument Reprocessing: Step by Step, M. Knoche, S. Grisanti, K.-D. Lemmen Stadthagen, Tübingen, Düsseldorf OPHTHALMO-CHIRURGIE 18: 252 - 259 (2006)

[4] ww.rki.de›Infection Prevention›Infection Control and Hospital Hygiene › Reprocessing Medical Devices › Reprocessing Medical Devices

Methods to Test the Effectiveness Against Prions:

As of today there are no standards that are internationally agreed upon for testing effectiveness against prions. However method proposals have been published by the RKI in Germany[5], the Agence nationale de sécurité du médicament et des produits de santé (ANSM)[6] in France and the World Health Organization (WHO)[7].

In Germany the method proposals of the RKI stipulate that a prion inactivating or prion decontaminating performance is to be claimed depending on the test method.
A prion inactivating performance can be confirmed with a successfully carried out quantitative suspension test. A prion decontaminating performance can be claimed if an additional germ carrier test with implantable stainless steel wires is carried out successfully. The prion inactivating and prion decontaminating effectiveness of **neodisher® SeptoClean** has been tested and confirmed in accordance with the RKI[5] method proposals.

Apart from the Scrapie 263 K prion strain predetermined by the RKI method proposals, two more prion strains have been successfully tested in accordance with the method proposals of the WHO and the ANSM. These strains are the BSE strain 6PB1 adapted to mice and a vCJD strain. In addition, an effectiveness of **neodisher® SeptoClean** was proved both in-vitro and in-vivo with the application parameters 1.0%, 10 min, 55 °C using the two above-mentioned strains. Based on these test results a prion inactivating effectiveness of **neodisher® SeptoClean** has been confirmed by the ANSM (for the corresponding listing cf. www.ansm.sante.fr).

Additionally, prion efficacy tests were carried out on corroded and therefore rough stainless steel surfaces using all three above-mentioned prion strains. The results of these tests also showed a prion inactivation of **neodisher® SeptoClean** using the application parameters 1.0%, 10 min at 55 °C!

[5] J. Bertram, M. Mielke, M.Beekes, K. Lemmer, M. Baier, G.Pauli, Robert Koch-Institut, Berlin; Inactivation and Removal of Prions when Reprocessing Medical Devices - An Article on Testing and Declaring Suitable Methods Bundesgesundheitsbl - Gesundheitsforsch - Gesundheitsschutz 2004 • 47:36–40

[6] ANSM - Agence nationale de sécurité du médicament et des produits de santé: PROTOCOLE STANDARD PRION, Novembre 2011

[7] World Health Organization (2006): WHO Guidelines on Tissue Infectivity Distribution in Transmissible Spongiform Encephalopathies ‹ Decontamination: new procedures (JP Deslys)

Proven Action Against Prions for Maximum Safety:

neodisher® SeptoClean has been tested successfully against the following prion strains in different accepted test models:

- **Scrapie 263 K**
- **BSE strain 6PB1**
- **vCJD**

and has a prion inactivating and prion decontaminating action within the context of the process conditions 1.0%, 55 °C, 10 minutes.

The Comparison Reveals:

neodisher® SeptoClean is Incomparable!

neodisher® SeptoClean

… stands out due to its proven wide microbicidal activity sprectrum: bactericidal, yeasticidal and virucidal.

These properties are the result of synergetic effects of the surfactant formula in neodisher® SeptoClean and are an especially unique characteristic of this detergent – proven and confirmed by specific examinations and reports.*

Microbicidal Activity – The Special Property:

A wide microbicidal activity is unique for a detergent which has only cleaning components and none of the known disinfecting substances in an effective concentration – a special unique property of **neodisher® SeptoClean**.

Comparative examinations with other alkaline detergents on the market have shown that none of these products have nearly the effectiveness of **neodisher® SeptoClean** (table 1). Furthermore, the comparison to an aldehyde based disinfectant demonstrates the unique properties of the detergent: Its activity is comparable to the activity of aldehyde based disinfectants.

neodisher® SeptoClean is the best choice for all non-fixing chemical disinfecting processes.[1]

Effectiveness under dirty conditions	Concentration	Exposure Time	Temperature
Bactericidal (EN 13727, EN 14561) Pseudomonas aerugionosa Staphylococcus aureus Enterococcus hirae	10 ml/l (1.0 %)	5 min	55 °C
Yeasticidal (EN 13624, EN 14562) Candida albicans	10 ml/l (1.0 %)	5 min	55 °C
Virucidal (EN 14476, EN 17111) Bovine parvovirus	10 ml/l (1.0 %)	10 min	55 °C

Tab. 1: Microbicidal effectiveness of neodisher® SeptoClean in the cleaning process with chemo-thermal disinfection

The SeptoClean process.

The instrument program for automated cleaning with prion destabilising, inactivating and decontaminating activity and chemo-thermal disinfection* with **neodisher® SeptoClean:**

Process step	Parameters
Pre-cleaning	Cold water
1. Cleaning step	5 ml/l (0.5 %), 5 min, 55 °C
2. Cleaning step incl. chemo-thermal disinfection* (bactericidal, yeasticidal, virucidal)	10 ml/l (1.0 %), 10 min, 55 °C
Neutralisation (optional)	1 ml/l (0.1 %) neodisher® Z
Intermediate rinse	
Final rinse	Deionised water, 55 °C - 70 °C

Tab. 2: Program cycle for achieving a prion destabilising, inactivating and decontaminating activity

Our **Competence** – Your **Benefit:**

- all-purpose detergent, based on alkalis and surfactants
- prion inactivating and prion deconta-minating activity confirmed by certification
- excellent material compatibility
- with disinfecting activity – only one product for cleaning and disinfection

- reliably removes blood, protein and other typical operation residues
- recommended for a preventive minimisation of the infection risk of prion-related diseases (TSE), that is with all patients without an express suspicion of CJD /vCJD
- suitable for surgical instruments made of stainless steel, titanium, chromium-plated or nickel-plated brass and hard metal as well as for anaesthetic utensils
- no mix-ups of detergent and disinfectant; simplified logistics and storage

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* The expert reports are available on request.
[1] Schmidt V, Staffeldt J, Wagemann W, Heeg P, Roth K, Efficacy of a Multifunctional Detergent against Microorganisms, Viruses and Prions, Zentralsterilisation (2007) 15 (5), 341-347

* Not suitable for high level disinfection of semi-critical medical devices

neo disher®

DR. WEIGERT
Systematic Hygiene

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