General Information on Application Technologies, Disinfection and Detergents in Automatic Reprocessing of Medical Devices

Dr. Jürgen Staffeldt
Chemische Fabrik Dr. Weigert
Hamburg, Germany
Decontamination Life Cycle of Instruments

1. **OP-Theatre**
   - Transportation from OP-theatre to CSSD

2. **Washer Disinfector**
   - Cleaning, disinfection, rinsing, drying
   - • Functional Inspection
   - • Lubrication
   - • Package
   - • Testing for cleanliness and absence of damage, care and maintenance, testing of technical and functional safety, marking, packing

3. **Steam-Sterilizer**
   - • Sterilisation
   - • Reprocessing ends with documented approval

4. **Sterile Storage**
Robert Koch-Institute, Germany:

- Effective sterilisation can only be obtained with clean medical equipment. 
  **Cleaning is therefore of particular significance in the overall process of surgical instrument preparation!**

- Alkaline cleaner based on sodium- or potassium hydroxide with surfactants
Washing cycle for Instruments in Washer Disinfector:

1. Prewash with cold water

2. **Main wash with alkaline detergent at 50 to 60°C**

3. Optionally neutralisation with acidic neutraliser

4. Intermediate rinse

5. Final rinse and thermal disinfection (90°C, 5 min) with DI water, dosage of lubricant or rinse aid possible

6. Drying

   - neodisher MediClean forte (universal)
     Liquid alkaline (pH 10,5) enzymatic cleaner with surfactants: **High material protection**, neutralisation not necessary
   
   - neodisher SeptoClean (special)
     Liquid alkaline (pH 11-12) cleaner, **Prion efficiency and disinfection**
Alkaline, enzymatic cleaner with surfactants suitable for:

Silicon

Anodized aluminium, eg. Aesculap, KLS Martin

MIS instruments and rigid endoscopes, eg. Storz

Chrome plated brass, silver and tin connections, glued connections, gaskets, Plastic and rubber coverings (e.g. colour codings, electrical insulations), Fiber-glass optics and other optical/anti-reflex surfaces
Alkaline, enzymatic cleaner with surfactants suitable for:

- Titanium Implants
- High frequency instruments
- Flex. Endoskope
Advantages of this alkaline, enzymatic cleaner with surfactants for universal use in washer disinfector

- Meets requirements of Robert Koch-Institute
- High material protection
- Good cleaning performance
- Short Program cycle
- No neutralization with first rinse water necessary (some medical devices are acid sensitive)
- Instruments and chamber of washer disinfector look shiny
- No dangerous transport good
Washing cycle for Instruments in Washer Disinfector

1. Prewash with cold water

2. **Main wash with alkaline detergent at 50 to 60°C**

3. Optionally neutralisation with acidic neutraliser

4. Intermediate rinse

5. Final rinse and thermal disinfection (90°C, 5 min) with DI water, dosage of **lubricant** or **rinse aid** possible

6. Drying

   - neodisher MediClean forte (universal)
     - Alkaline (pH 10,5) enzymatic cleaner with surfactants: High material protection, neutralisation not necessary
     - or
   - **neodisher SeptoClean** (special)
     - Alkaline (pH 11-12,5) cleaner, **Prion efficiency and disinfection**
Prions are types of infectious agent made only of protein without nucleic acid.

Prions are believed to infect and propagate by refolding abnormally into a structure which is able to convert normal molecules of the protein into the abnormally structured form.

Prions are generally quite resistant to denaturation by protease, heat, radiation, and treatments with aldehydes.
Identical amino acid sequence, but different conformation (tertiary structure)

One protein with two “different faces”

Prions are misfolded structures of a cellular protein!
The effectiveness of a method against prions should be tested and declared in phases based on efficacy testing of bactericidal and virucidal substances; Use of brain homogenates of hamsters infected with scrapie strain 263K

<table>
<thead>
<tr>
<th>Phase 1a</th>
<th>Phase 1 b</th>
<th>Phase 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Preliminary testing of procedures in vitro, Evaluation in the qualitative suspension test; eg with western blot</td>
<td>Quantitative suspension test Evaluation in animal experiments</td>
<td>Quantitative carrier test Evaluation in animal experiments</td>
</tr>
<tr>
<td>Basic test, no declaration</td>
<td>Declaration as being “prion inactivating”</td>
<td>In conjunction with successfully passed Phase 1b test, declaration as being “prion decontaminating”</td>
</tr>
</tbody>
</table>

If necessary, already in **Phase 1a** an in vitro test can be conducted on carriers. Such a test variant is based on recent research into this topic. The method is based on the fact that steel pins layered with brain homogenate containing Prp\textsuperscript{Sc} are exposed to the test solution under defined conditions. On expiry of the exposure time, the portion of homogenate remaining on the steel pin as well as that dissolved is tested for Prp\textsuperscript{Sc} that cannot be degraded by proteinase K using western blot. Because of its design, the results of this test permit inferences to be drawn on the test's suitability for degrading, **destabilising** and dissolving prions.
Summary:
The capacity of a routinely available alkaline cleaner* for medical devices to inactivate the causative agent of a transmissible spongiform encephalopathy (TSE) was tested.

The co-incubation of brain homogenates, prepared from terminally ill scrapie-infected hamsters, with the cleaner led to the denaturation of misfolded protein as the proteinase K-resistant prion protein was no longer detectable after such treatment.
In addition, intra-cerebral inoculation of hamsters with the alkaline cleaner-treated and subsequently neutralized samples reduced the level of infectiousness of the material below the limit of detection.

This report shows the possibility that a routinely available alkaline cleaner could reduce the infectiousness of TSE agents and so minimize the risk of iatrogenic transmission of TSEs by asymptomatic carriers.
This study is intended to encourage further investigations in this field.

*The tested cleaner neodisher FA forte is identical to neodisher SeptoClean
Summary:
The commercially available alkaline cleaner* considerably reduced the load of prion protein attached to the wires apparently at least in part by mediating substantial release of PrP into the cleaning solution.

Digestion with Proeinase K led to a complete disappearance of visible residual PrPSc/PrP27-30 contamination.

Taken together, these observations show that the alkaline cleaner exerted a detaching and a strong destabilizing effect.

*neodisher SeptoClean
Decontamination of surgical instruments from prion proteins II: in vivo findings with a model system for testing the removal of scrapie infectivity from steel surfaces

Karin Lemmer, Martin Mielke, Christine Kraxel, Marion Joncic, Muhsin Özel, Georg Pauli and Michael Beekes
Robert Koch-Institut, Nordufer 20, 13353 Berlin, Germany
Journal of General Virology (2008), 89, 348 - 358

Summary:

"Incubation of the wires in the commercially available alkaline cleaner* at a concentration of 1% (pH 12,2 as measured at room temperature) for 10 minutes at 55°C or for 60 minutes at 23°C resulted in complete removal of detectable infectivity and a titre reduction of 5,5 ≥logs."

"Decontamination procedures found in the 263K steel wire model should be validated for human TSE agents on different types of instrument surfaces"

*neodisher SeptoClean
Summary of prion tests

Based on these and other results from SMP Tübingen the Notified Body for Medical Devices in Germany approved the declaration of

destabilisation, inactivation and decontamination of prions

for neodisher SeptoClean for surgical instruments which have been used on asymptomatic carriers/patients incl. TSE risk tissue

(CE mark as class 2a medical device)
Innovative Aspects

This liquid cleaner based on potassium hydroxide, silicates, phosphates and different surfactants:

- Efficiency against prions
- For reprocessing of surgical instruments including MIS-Instruments and rigid endoscopes approved by Storz
- Works also as a chemical disinfectant (bactericidal, fungicidal, tuberculocidal, mycobactericidal, virucidal) (1.0 %, 10 min, 55 °C) in washer disinfectors
- Suitable for all types of washer disinfectors
1. Prewash with cold water

2. Main wash with pH-neutral or alkaline detergent at 50 to 60°C

3. Optionally neutralisation with acidic neutraliser

4. Intermediate rinse

5. Final rinse and thermal disinfection (90°C, 5 min) with DI water, dosage of lubricant or rinse aid possible

6. Drying

Based on phosphoric acid for neutralization or to remove or avoid discoloration and rust or based on citric acid for neutralization of alkaline residues on medical device
1. Prewash with cold water
2. Main wash with pH-neutral or alkaline detergent at 50 to 60°C
3. Optionally neutralisation with acidic neutraliser
4. Intermediate rinse
5. Final rinse and thermal disinfection (90°C, 5 min) with DI water, dosage of lubricant or rinse aid possible
6. Drying

Lubricant based on paraffinum perliquidum and emulsifiers

Rinse aid based on surfactants and reduces the surface tension of water
Surface Tension of Water
Surface Tension of Water

high

low
Surface Tension

Drinking water: 73,8 mN/m
Softened water: 73,6 mN/m
Deionized water: 73,3 mN/m

Deionized water with 0,5 ml/l neodisher MediKlar: 32,0 mN/m
Properties of a Rinse Aid for Medical Devices

- pH-neutral and special designed for medical devices like surgical instruments incl. eye instruments, endoscopes, implants, anaesthesia equipment, OP-shoes, containers, baby bottles....
- Reduced surface tension of water
- Reduction of adherent moisture, less water drops
- Toxicological risk assessment in accordance with EN ISO 10993-1 (biological assessment of medical products)
- Completely biodegradable
- Recommended dosage: 0,3-1,0 ml/l to final rinse water
- Shorter drying time of 30 to 70%
- Reduction of reprocessing time
1. Prewash with cold water
2. Main wash with pH-neutral or alkaline **detergent** at 50 to 60°C
3. Optionally neutralisation with acidic **neutraliser**
4. Intermediate rinse
5. Final rinse and thermal disinfection (90°C, 5 min) with **DI water**, dosage of **rinse aid** possible
6. Drying

**Deionised water**
<table>
<thead>
<tr>
<th>Contents of drinking water</th>
<th>Effects in the washer disinfecter</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness formers</td>
<td>Scaling and deposits in machine and on instruments</td>
</tr>
<tr>
<td>Heavy and non-ferrous metals (iron, manganese, copper)</td>
<td>Dark discolouration and deposits, inactivate water softeners</td>
</tr>
<tr>
<td>Silicic acid/silicates</td>
<td>Stubborn yellowish-brown or bluish-violet glaze-like deposit</td>
</tr>
<tr>
<td>Chlorides</td>
<td>Pinhole-like pitting corrosion on stainless steel instruments</td>
</tr>
<tr>
<td>Evaporation residue</td>
<td>Spotting, deposits</td>
</tr>
</tbody>
</table>
Constituents in tap water, which may cause problems

**Water hardness** (Calcium, Magnesium) provokes: **Calcification and lime deposits**
Constituents in tap water, which may cause problems

Heavy and non-ferrous metals (Fe, Mn, Cu) provoke:
- dark discolorations and deposits
- inactivation of water softener
Constituents in tap water, which may cause problems

**Silicic acid/ silicates**

provoke:
stubborn yellow-brown, blue-purple or rainbow coloured deposits
Constituents in tap water, which may cause problems

Chlorides provoke:
Pitting corrosion
Reprocessing of surgical instruments in Washer disinfectors; Final rinse water:

**Deionised water, because**

- No spots or deposits
- No increase of dissolved water ingredients during drying
- RKI: No crystalline residues which will harm the sterilisation success
- Protection and stabilisation of anodised aluminium surfaces
Water is very important!

In Nature

In CSSD