Potentials of an alkaline cleaner

Development tendencies for improving process safety

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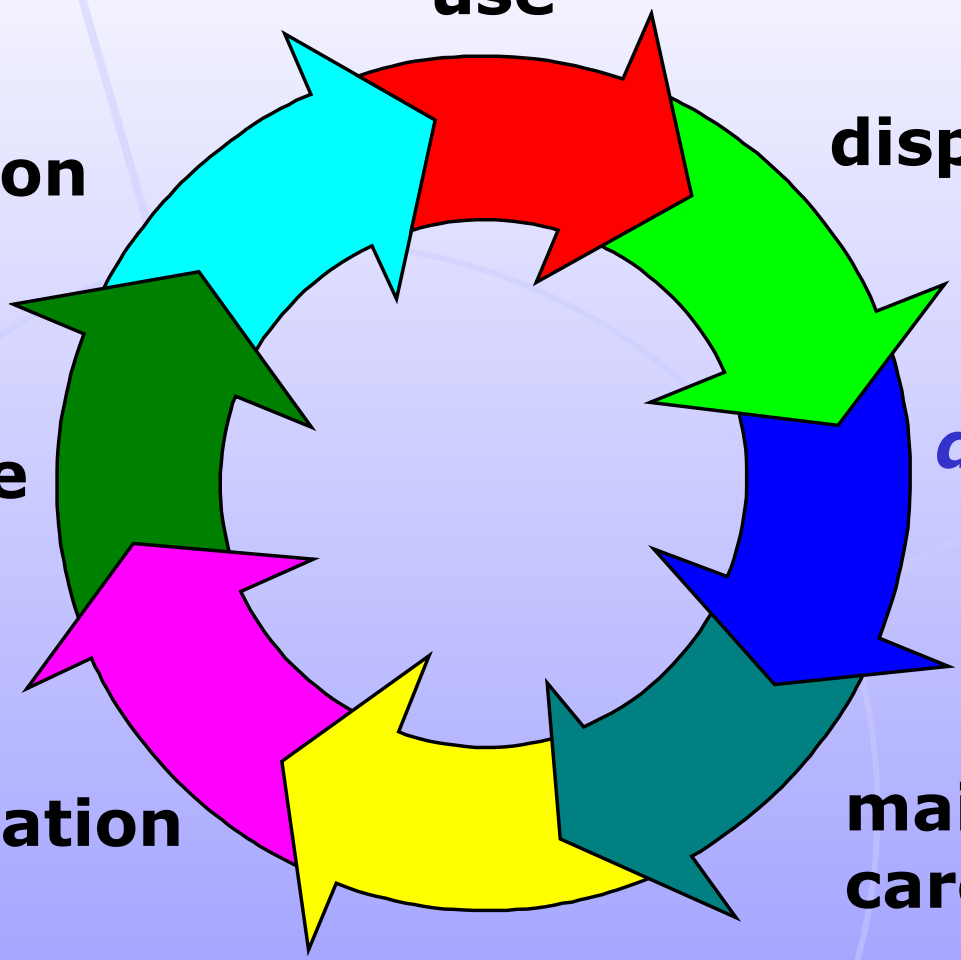
Reprocessing of Medical Devices

- §3 MPG (German Medical Device Act) – defines requirements regarding reprocessing

- risks of reprocessed medical devices result from
  - previous use
  - use, transport and storage so far
- risks of medical devices can be :
  - residues of prior application (blood, secretions, micro-organisms)
  - residues of previous reprocessing
  - change of functional properties

reprocessing cycle



Steps of the Reprocessing Cycle

Cleaning

- Degradation of soiling
- No fixation of the protein and therefore possible fixation of prions
- Removal of soiling
- Removal of proteins (and prions)
- Removal of micro-organisms

Steps of the Reprocessing Cycle

Cleaning

- Important prerequisite for disinfection
- Important prerequisite for sterilisation

Steps of the Reprocessing Cycle

Disinfection

- Elimination of (pathogenic) micro-organisms
- Result depends on the initial microbial count

Steps of the Reprocessing Cycle

Processes

- Thermal disinfection (are partially preferred, e.g. in Germany)
- Chemo-thermal disinfection

Steps of the Reprocessing Cycle

Additional requirements:

- Inactivation and removal of prion protein
- Currently a combination of cleaning (alkaline, surfactant-containing, 10 minutes, 55°C) and sterilisation (5 minutes, 134°C) according to German recommendations

The Robert Koch-Institute says:

"… The alkaline cleaning stands out due to its considerable effectiveness regarding the removal of protein- and fat residues and an antimicrobial action …"

(from: Requirements of hygiene in reprocessing medical devices, Bundesgesundheitsbl. (Federal Health Pamphlet 11, 2001)

Advantages

- Disinfection already during cleaning process
- Still cleaning during disinfection process

→ Double safety

Investigations:

Comparative tests of alkaline cleaners and disinfectants on aldehyde basis with special reference to their microbicidal activity.

The test products: 6 alkaline cleaners

Product No.	pH	p-Value	surfactants
1 (neodisher SeptoClean)	12.3	11.2	+
2	12.1	8.9	--
3	12.2	9.8	+
4	10.9	2.2	+
5	12.7	17.5	+
6	12.3	12.3	--

The test products: 2 disinfectants

Product No.	Active substance basis	Application
A	GDA	manually (20°C)
B	GDA / Glyoxal	automated (55°C)

Bactericidal activity of different alkaline cleaners and an aldehyde-based disinfectant following EN 1040 at **20°C**, 10 minutes.

	Enterococcus hirae				Staphylococcus aureus				Pseudomonas aeruginosa			
Product No.	0.1%	0.5%	1.0%	1.5%	0.1%	0.5%	1.0%	1.5%	0.1%	0.5%	1.0%	1.5%
1	✘	✓	✓	✓	✘	✘	✓	✓	✓	✓	✓	✓
2	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
3	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
4	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘	✘
6	✘	✘	✘	✘	✘	✘	✘	✘	✘	✓	✓	✓
A	✘	✓	✓	✓	✘	✓	✓	✓	✘	✓	✓	✓

Bactericidal activity of different alkaline cleaners and an aldehyde-based disinfectant following EN 1040 at **55°C**, 10 minutes.

Product No.	Enterococcus faecium			
	0.1%	0.5%	1.0%	1.5%
1	✘	✓	✓	✓
2	✘	✘	✘	✘
3	✘	✘	✘	✘
4	✘	✘	✘	✘
6	✘	✘	✘	✘
B	✘	✓	✓	✓

Tuberculocidal activity (**Mycobakterium terrae**) of different alkaline detergents following EN 14348 under clean and dirty conditions, 55°C and 10 minutes.

	55°C, 10 min and concentration				
	Clean conditions			Dirty conditions	
Product No.	1.0%	1.5%	2.0%	1.5%	2.0%
1	✓	✓	✓	✓	✓
2	✘	✘	✘	✘	✘
3	✘	✘	✘	✘	✘
4	✘	✘	✓	✘	✘
5	✘	✘	✘	✘	✘
6	✘	✘	✘	✘	✘

Results:

- Aldehyde-based disinfectants show the best microbicidal activity.
- Alkalinity alone (cleaner no. 6, without surfactants) does not show a comparative microbicidal activity with disinfectants.
- The combination alkalinity and surfactants seems to have the best activity amongst the cleaners (cleaner no.1, neodisher SeptoClean).

Robert Koch-Institute requirements on disinfection

for the reprocessing of medical devices

- bactericidal
- fungicidal
- tuberculocidal/mycobactericidal
- virucidal

Disinfecting activity of **neodisher SeptoClean** under application conditions of a chemo-thermal reprocessing process (55 °C, clean conditions) in a washer-disinfector.

Activity	Method	Temperature	Concentration	Time
Bactericidal activity	EN 13727	55°C	1%	5 min
Fungicidal activity	EN 13624	55°C	1%	5 min
Mycobactericidal activity	EN 14348	55°C	1%	5 min
Virucidal activity	RKI/ DVV	55°C	1%	10 min

Virucidal activity of **neodisher SeptoClean** according to method RKI/ DVV with and without protein load at 20°C and 55°C

	required activity was achieved at					
	Without protein load			With protein load		
Test viruses	time	conc.	temperature	time	Conc.	temperature
Poliovirus Type 1	5 min	1.0%	20°C	5 min	2.5%	20°C
Adenovirus Type 5	5 min	0.5%	20°C	5 min	0.5%	20°C
Vacciniavirus Elstree strain	5 min	0.5%	20°C	5 min	0.5%	20°C
Bovine Viral Diarrhea Virus	10 min	0.5%	20°C	5 min	1.0%	20°C
Papovavirus SV 40	5 min	1.0%	20°C	5 min	1.0%	20°C
Bovine Parvovirus	10 min	1.0%	55°C	5 min	2.0%	55°C

Result:

- The tested alkaline cleaner **neodisher SeptoClean** has the potential to show a microbicidal activity incl. activity against viruses, comparative to the activity of aldehyde-based disinfectants.

Additional potentials: activity against vCJD

The Robert Koch-Institute says:

"… Detergents based on NaOH or KOH with surfactants within a reaction time of 10 minutes are expected to achieve the desired results …."

(from:" The Variant of the Creutzfeldt-Jacob Disease (vCJD)" Bundesgesundheitsbl 4, 2004)

Effectiveness against Prions

Examination of the prion effectiveness and the declaration of the results described in:

<u>RKI-discussion suggestion:</u>
"Inactivation and removal of prions when reprocessing medical devices."
A report on testing and declaration of suitable methods.(Bundesgesundheitsblatt Januar 2004)

Effectiveness against Prions

Phase 1a

Pre-testing of processes in vitro in the qualitative suspension test: evaluation eg via Western Blot, basic test, no declaration

(Phase 1a on carriers): Testing for destabilisation via in vitro test on steel pins; evaluation eg via Western Blot on the pin and in the detergent solution)

Phase 1b

Quantitative suspension test, evaluation via animal testing, Declaration as prion inactivating

Phase 2

Quantitative carrier test, evaluation via animal testing. In correlation with passed phase 1b declaration as prion decontaminating

Examinations of the effectiveness of alkaline detergents against prions:

„Activity of an alkaline 'cleaner' in the inactivation of the scrapie agent"

M. Baier, A. Schwarz, M. Mielke
Robert Koch-Institut, Nordufer 20, 13353 Berlin, Germany
Journal of Hospital Infection, Mai 2004

„Decontamination of surgical instruments from prion proteins: in vitro studies on the detachment, destabilization and degradation of PrPSc bound to steel surfaces"

K. Lemmer, M. Mielke, G. Pauli and M. Beekes
Robert Koch-Institut, Nordufer 20, 13353 Berlin, Germany
Journal of General Virology (2004), 85, 3805–3816

Effectiveness of neodisher SeptoClean against Prions

Use conditions	**activity**
0.5%, 5 min., 55°C (RKI)	Destabilisation
0.5%/5 min/55°C (1.step) and 1.0%/10 min/60°C (2.step)	Inactivation Decontamination

Summary:

- Alkaline cleaners have, as experience shows, a considerable cleansing capacity.

- Alkaline cleaners do not fixate proteins

- The alkaline cleansing has the potential to be microbicidal (eg in combination with surfactants)

- Alkaline detergents have the potential to be effective against prions (combination alkalinity and surfactants)

Consequence

Increasing the process safety of reprocessing medical devices if alkaline cleaners with surfactants are used, if these are proven **microbicidal** (bactericidal, fungicidal, tuberculocidal und virucidal) and proven **effective against prions**.

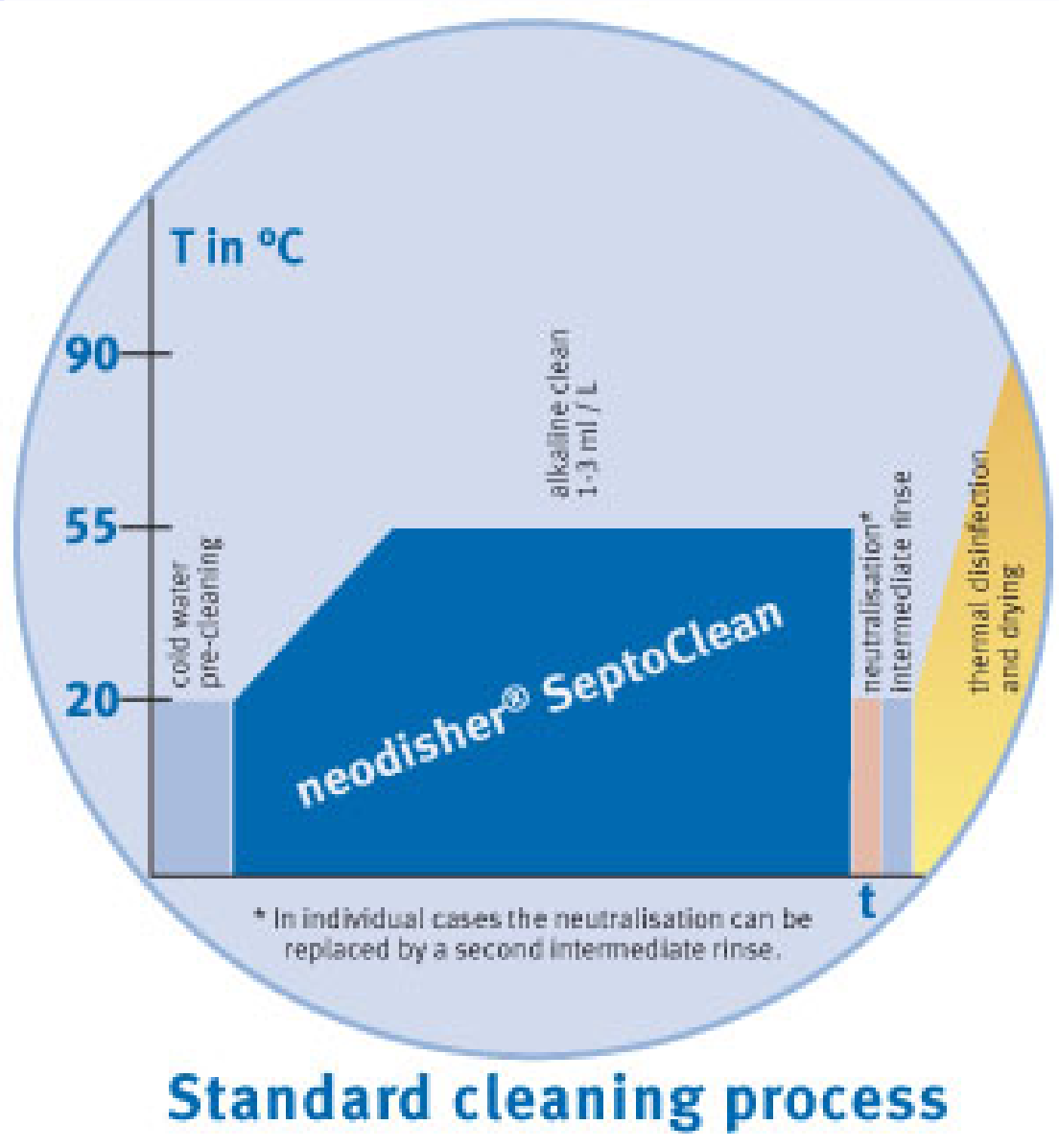
Opening new possibilities for future processes

Potentials and Possibilities of Application

Today:

- alkaline cleaning in standard reprocessing
- alkaline cleaning with prion destabilisation
- chemo-thermal reprocessing of thermo-sensitive medical devices (substitute aldehydic disinfectants)
  - No protein fixation
  - Better cleaning properties
- two-step programme with proven effectiveness against prions in risk areas (eg reprocessing of ophthalmological instruments)

Application Examples no 1

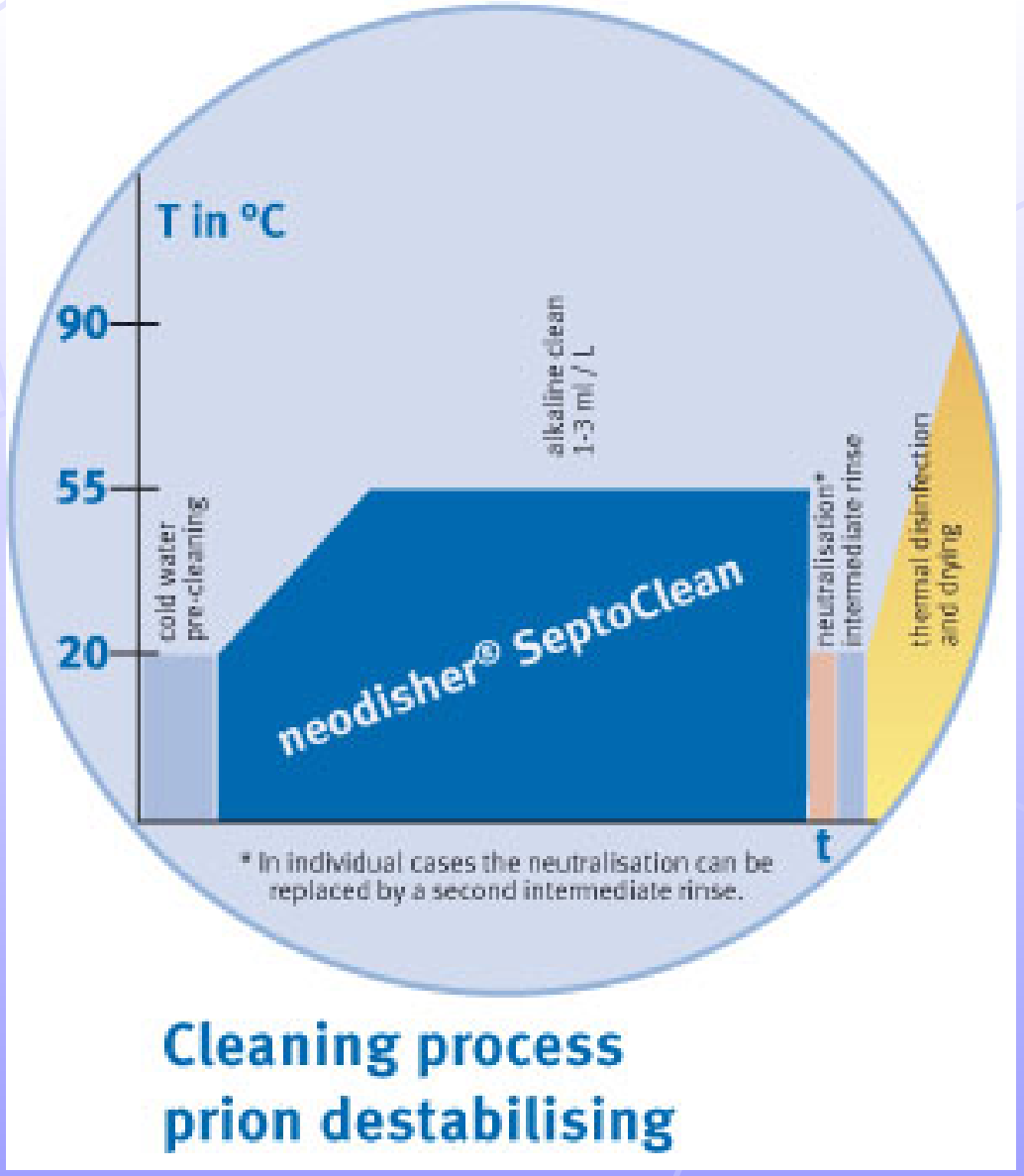


Application Examples no 2

0.5 %

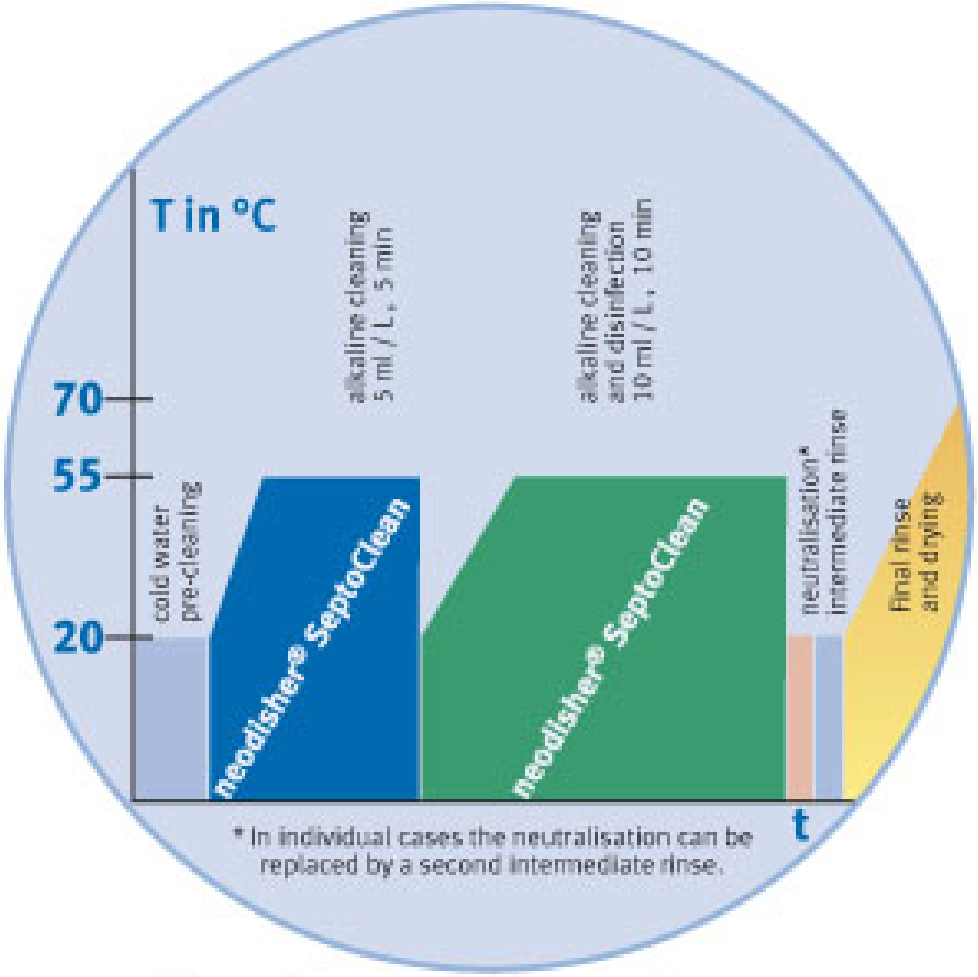
5 min

55°C



Cleaning process prion destabilising

Application Examples no 3



Cleaning process with chemo-thermal disinfection

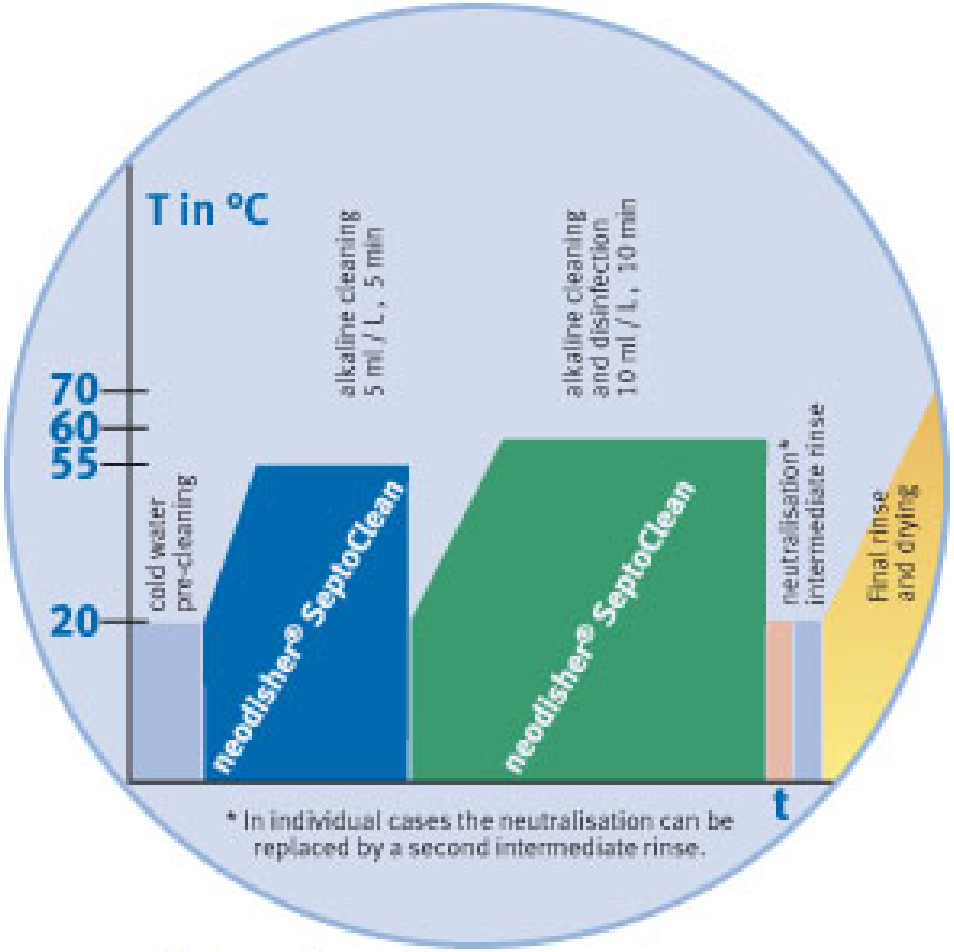
Disinfection

1%

10 min

55°C

Application Examples no 4



Cleaning process prion inactivating and decontaminating

Prion decontamination and disinfection

1%

10 min

60°C

Today:

1 product → 4 different application possibilities

Potentials and Possibilities of Application

Tomorrow:

- vCJD safe reprocessing of complex medical devices which cannot be sterilised with steam via proven prion effective detergents

- Saving of time and energy by a new process forming
  - Shortening of reprocessing processes via chemo-thermal instead of thermal disinfection??
  - One-step processes with simultaneous cleansing, disinfection and possibly effectiveness against prions??

M. Mielke, Robert Koch Institute:

"Considering the **simplification of cleansing and disinfection processes** new examinations in combination with further analysis of alkaline detergents with prion efficacy are interesting in regard to their antimicrobial properties."

("The significance of cleaning in the framework of reprocessing medical devices-basic aspects" "Zur Bedeutung der Reinigung im Rahmen der Aufbereitung von Medizinprodukten – Grundlegende Aspekte" M.Mielke, forum Nr. 3/ 2006)

Thank you for your attention!