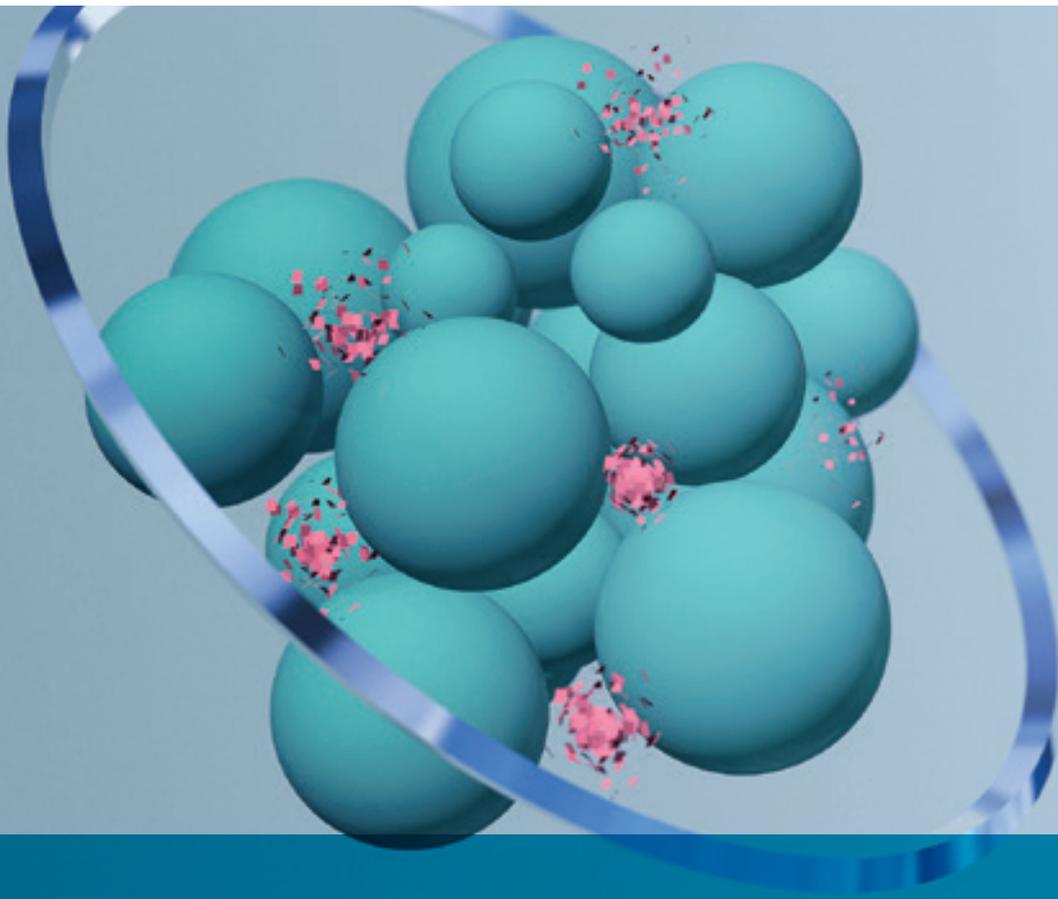


deconex[®] 28 ALKA ONE-x
High alkaline cleaning chemistry with
proven efficacy against prions
For automated instrument reprocessing



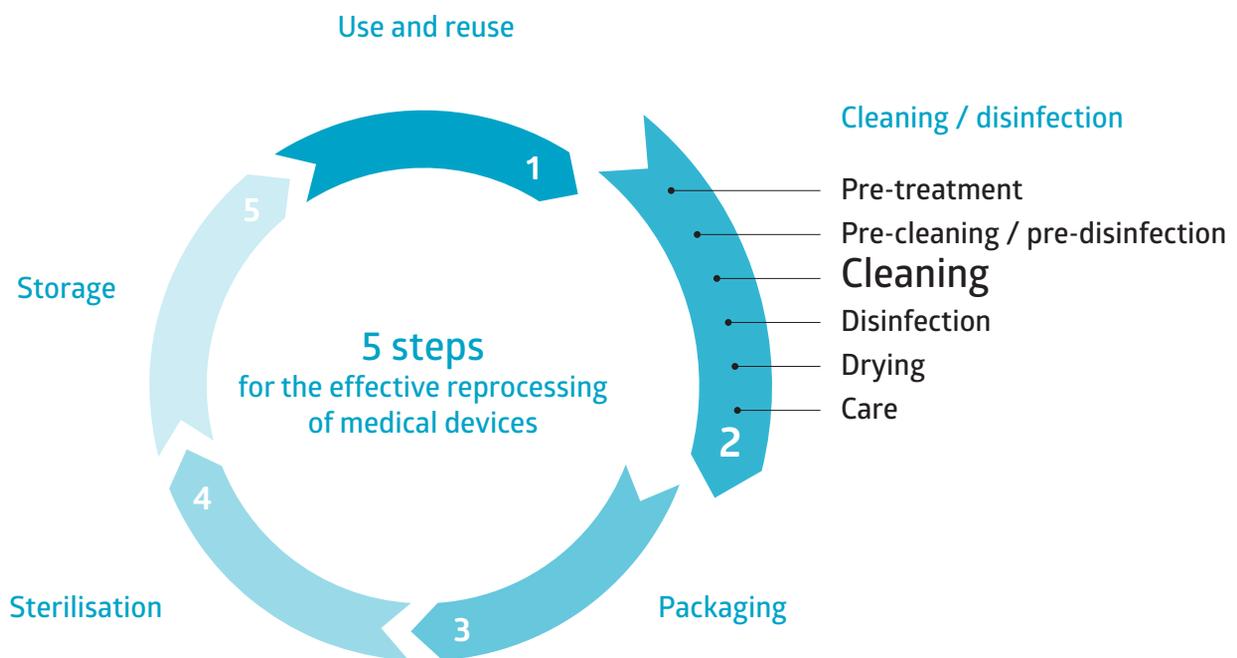
deconex® 28 ALKA ONE-x

Cleaning and prion efficacy in a single product



While manufacturers of reprocessable medical devices focus primarily on the material compatibility of the detergent used, consistently high cleaning performance as well as maintaining the rinsing pressure of the washer-disinfector are equally important aspects when it comes to assessing a products performance.

Although there are currently no standardised methods for checking cleaning performance, national and international laws, recommendations and guidelines require that, in order to minimise the risk of CJD, automated reprocessing in a WD should include a cleaning step in an alkaline environment combined with a process temperature – depending on the product used – followed by sterilisation in an autoclave at 134 °C ^{[1], [2], [3]}. There are also few chemistries with peer-reviewed efficacy against prions.



^[1] KRINKO recommendation „Hygiene requirements for the reprocessing of medical devices“ recommendation of the commission for hospital hygiene and infection prevention (KRINKO) at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM), Federal Health Gazette 2012 55:1244-1310

^[2] NICE Guidance 2020 National Institute for Health and Care Excellence „Reducing the risk of transmission of Creutzfeldt-Jakob disease (CJD) from surgical instruments used for interventional procedures on high-risk tissues“

^[3] BMG „Guideline for protection against transmission of Creutzfeldt-Jakob disease during invasive procedures“ 1, 2016

Prion inactivation and destruction

The ultimate combination!

Prion decontamination of 5-6 log₁₀ levels with deconex® 28 ALKA ONE-x⁽⁴⁾

Prion inactivation

Prion proteins are not inactivated by ordinary sterilisation processes and are difficult to remove and inactivate. Special precautions must therefore be taken when reprocessing medical devices for use in patients with clinically likely or possible CJD infections. Any applicable national guidelines must be taken into account when reprocessing devices exposed or potentially exposed to such a patient. These provide, for example, for quarantine of the instruments or, in the case of confirmation or unexplained cause, destruction by incineration. Reprocessing with deconex® 28 ALKA ONE-x provides an additional safety margin in routine reprocessing, e.g. if the patient's CJD infection remains undetected.

Prion destruction

While most micro-organisms can be killed or inactivated comparatively easily, prions are very resistant to common disinfection or sterilisation procedures. In the KRINKO recommendation, „dry heat“ is listed under „ineffective or fixing procedures“.

Therefore, for an additional margin of safety, 2-step procedures for the destruction or inactivation of prions should be used, consisting of cleaning, disinfection and subsequent sterilisation. Extra safety can be achieved if a cleaning agent is used whose effectiveness against prions has been proven in tests. The Robert Koch Institute (RKI) therefore recommends an approach to risk minimisation in routine reprocessing in which several prion-inactivating procedures are combined.

Expert reports

Both *in vitro* suspension and germ carrier experiments followed by Western blot experiments and germ carrier experiments followed by *in vivo* infection assay have demonstrated an inactivating or decontaminating effect of deconex® 28 ALKA ONE-x against prions of 5-6 log₁₀ levels (reference ⁽⁴⁾).

In a novel experimental setup with Real-Time Quaking-Induced Conversion (RT-QuIC), prion proteins bound to instrument

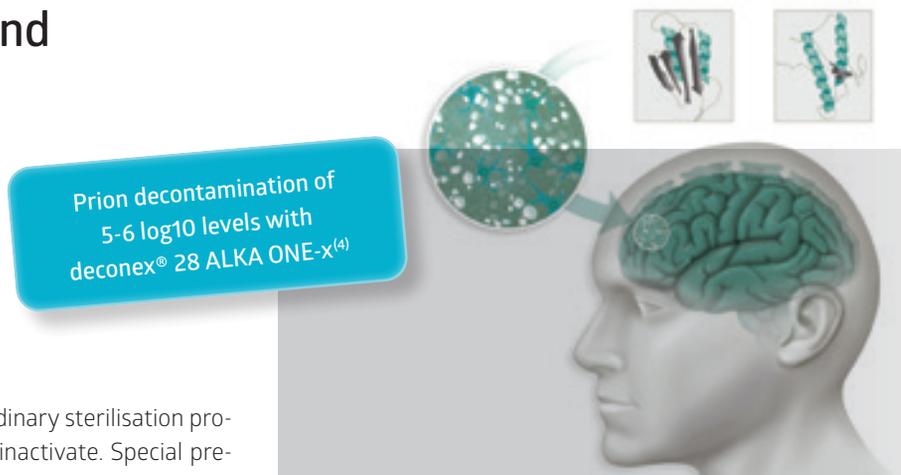
What are prions?

Prions are mis-folded proteins that occur in correctly folded form in the nerve tissue of healthy humans and animals. Unlike bacteria, fungi or viruses, they do not belong to the family of micro-organisms. A mis-folded prion protein can cause the refolding of previously correctly folded prion proteins. These then aggregate into protein fibres and lead to the death of affected neurons because they cannot be degraded and recycled by the proteases of the cellular disposal mechanism. These mis-foldings are believed to trigger neurological damage with a fatal outcome. Mis-folding can occur sporadically, as a result of genetics or through transmission.

Prion diseases include scrapie in sheep, BSE (bovine spongiform encephalopathy) in cattle and Creutzfeldt-Jakob disease (CJD) and its variant form (vCJD) in humans. Variant Creutzfeldt-Jakob disease is usually due to infections by bovine BSE prions, but hospital infections of vCJD through blood and blood products have also been reported.

steel were treated with deconex® 28 ALKA ONE-x and their ability to refold previously correctly folded prion proteins was investigated. The results, in conjunction with a specifically defined process, demonstrate anti-prion effectiveness. **Inactivation of prion proteins by >5 log₁₀ steps was confirmed in the mouse model.**

⁽⁴⁾ Working group of the Institute of Neuropathology, University of Zurich, manuscript in preparation



It's all about the process

A plus for safety

Prion efficacy vs. prion removal vs. prion inactivation

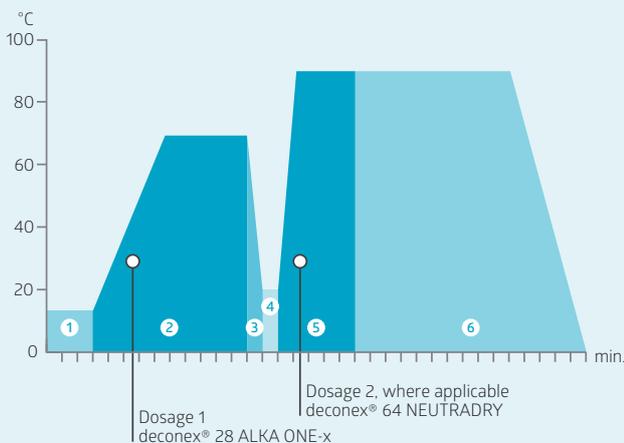
A good cleaning process is able to detach prion proteins from surfaces, keep them in solution and remove them from instruments through rinsing steps. Washing processes are assumed to achieve a 2-3 log₁₀ reduction. deconex® 28 ALKA ONE-X offers a greater safety margin, not only removing the prion proteins but also chemically inactivating them.

deconex® 28 ALKA ONE-x is incredibly flexible with regard to dosage, application temperatures and exposure times. The effectiveness and material compatibility are correspondingly high. The following are process examples:

1

Prion-inactivating process

To proactively minimise risk of CJD/vCJD transmission and in cases of unconfirmed, suspected CJD/vCJD, the following process can be used. To achieve the demonstrated prion-inactivating effect, a higher dose in combination with the contact time and temperature must be maintained in the cleaning step. This is followed by sterilisation in an autoclave, ideally involving an extended sterilisation process at 134 °C for 18 min. This process can be used routinely for stainless steel instruments. Aluminium instruments should be reprocessed accordingly a maximum of 12 times.



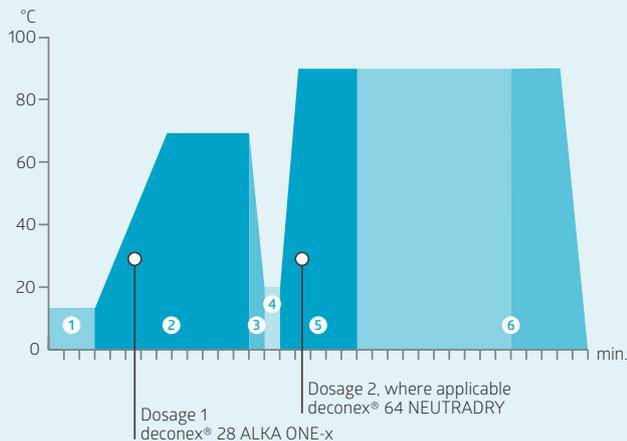
1. **Pre-rinsing:** with cold tap water, 3 min.
2. **Cleaning:** with fully demineralised (deionised, softened) or tap water;
Dosage: 1 % deconex® 28 ALKA ONE-x at 30 °C;
Cleaning: 10 min. at 70 °C
3. **Intermediate rinse 1:** with tap water, 1 min.
4. **Intermediate rinse 2:** with deionised or softened water, 1 min.
5. **Thermal disinfection:** with fully demineralised, deionised water, e.g. for A₀=3000, if necessary dosage of deconex® 64 NEUTRADRY as drying aid at 90 °C
6. **Drying:** 5–15 min.
Followed by steam sterilisation according to national guidelines

Risk minimisation with regard to prion-contaminated instruments has already been implemented and successfully validated in the CSSD of the Hôpital du Valais (Switzerland).

2

Standard WD process

For the reprocessing of surgical instruments, among others, in washer/disinfectors.

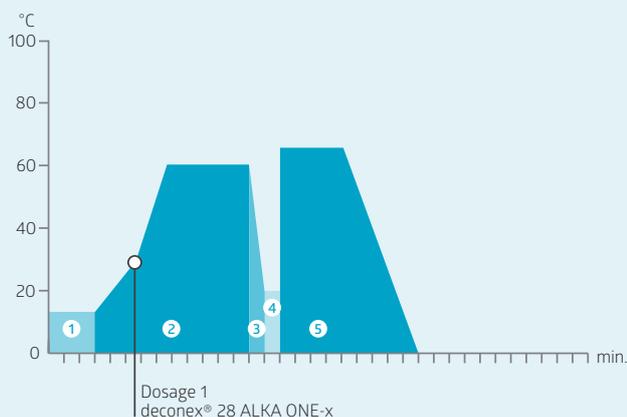


1. **Pre-rinsing:** with cold tap water, 3 min.
2. **Cleaning:** with fully demineralised (deionised, softened) or tap water;
Dosage: 0.5 % deconex® 28 ALKA ONE-x at 30 °C;
Cleaning: at 70 °C, 5–10 min.
3. **Intermediate rinse 1:** with tap water, 1 min.
4. **Intermediate rinse 2:** with deionised or softened water, 1 min.
5. **Thermal disinfection:** with deionised water, e.g. for A0=3000, if necessary dosage of deconex® 64 NEUTRADRY as drying aid at 90 °C
6. **Drying:** 5–15 min.
Followed by steam sterilisation according to national guidelines

3

Standard WD process for the reprocessing of operating theatre shoes

Operating theatre shoes are thermolabile materials that are not reprocessed with an A₀=3000 process. Depending on the manufacturer, maximum temperatures for the reprocessing of operating theatre shoes of between 60 and 70 °C are stated.

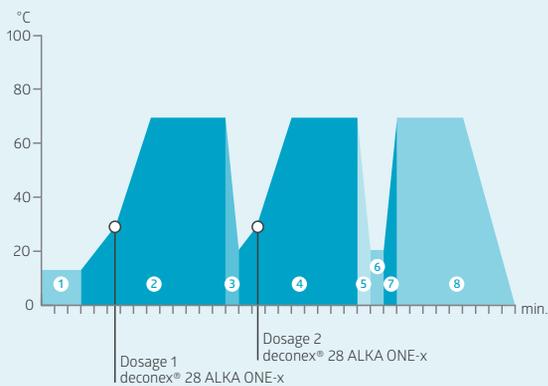


1. **Pre-rinsing:** with cold tap water, 1–3 min.
2. **Cleaning:** with fully demineralised (deionised) or tap water;
Dosage: 0.5 % deconex® 28 ALKA ONE-x at 30 °C;
Cleaning: at 60 °C, 5–10 min.
3. **Intermediate rinse:** with tap water, 1 min.
4. **Final rinse:** with fully demineralised (deionised) or tap water, 1 min.
5. **Drying**

4

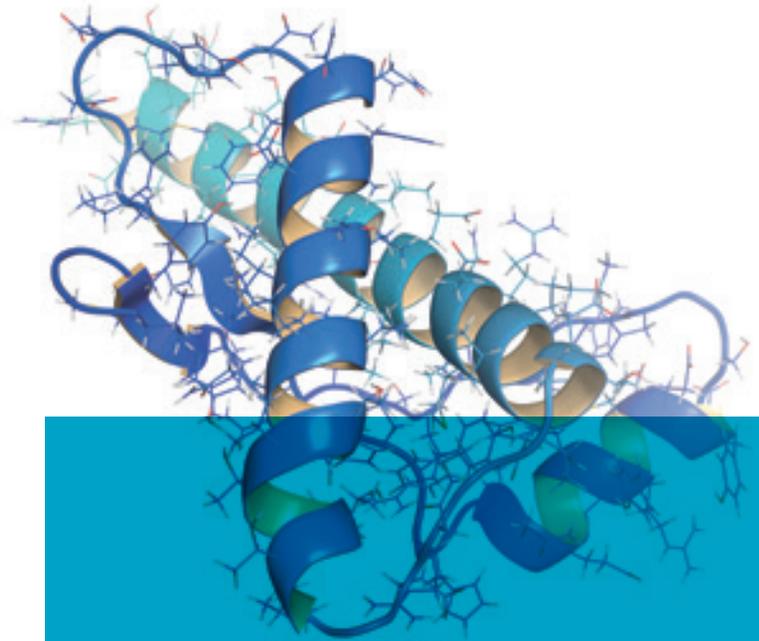
Reprocessing of non-critical medical devices and non-medical devices

To support thermal disinfection at 70 °C through the alkalinity of the cleaning chemistry, the product can also be used in the subsequent process.



1. **Pre-rinsing:** with cold tap water, 3 min.
2. **Cleaning:** 5 min. at 70 °C with fully demineralised (deionised) or tap water; dosage of deconex® 28 ALKA ONE-x 5 mL / L at ≥ 30 °C
3. **Intermediate rinse 1:** with tap water, 1 min.
4. **Chemo-thermal disinfection:** 5 min. at 70 °C, with deionised water; dosage of deconex® 28 ALKA ONE-x 5 mL / L at ≥ 30 °C
5. **Intermediate rinse 2:** with tap water, 1 min.
6. **Intermediate rinse 3:** with deionised or softened water, 1 min.
7. **Final rinse:** 1 min at 70 °C, with deionised water¹⁾
8. **Drying**

¹⁾ For maximum performance, deionised (DI) water is recommended. Other water qualities can also be used, depending on availability.



The formulation that can do even more

Outstanding cleaning performance

Thorough cleaning is the basic prerequisite for subsequent disinfection and sterilisation in the context of patient and staff safety.

deconex® 28 ALKA ONE-x features outstanding cleaning performance. The combination of alkalinity and temperature efficiently breaks down protein and carbohydrate-rich contaminants, such as mucus, and facilitates their removal. This cleaving of biological molecules not only takes place with blood and tissue residues, but also with a number of germs, which can not only be cleaned, but also deactivated. This also reduces the risk of spreading through waste water.

High material compatibility

deconex® 28 ALKA ONE-x exhibits high material compatibility. This includes suitability for stainless steel, chrome-plated materials, plastics, rubber, latex and ceramic materials. The product is not suitable for the routine reprocessing of alkali-sensitive materials, instrument containers and lids made of (anodised) aluminium or titanium. If the prion programme is used with an increased dosage of deconex® 28 ALKA ONE-x, they can be reprocessed up to 12 times without any harm.



Contact us for comprehensive advice.
We're happy to help!

medical@borer.ch

deconex® 28 ALKA ONE-x

More than residue-free cleaning

deconex® 28 ALKA ONE-x is a high alkaline specialised clean chemistry which effectively and safely removes a wide variety of contamination from proteins, fats, carbohydrates and other organic components. As the product contains neither KOH nor NaOH, it offers excellent material compatibility with metallic instruments.



^[4] Working group of the Institute of Neuropathology, University of Zurich, manuscript in preparation

Borer Chemie AG: specialists in cleaning and disinfection.

Expertise and innovation - worldwide

Since 1965, we have been researching, developing and producing products in Switzerland for demanding applications in the field of cleaning and disinfection. We distribute our branded products and proven processes for professional applications in industry, hospital hygiene, laboratories, the pharmaceutical sector as well as in the field of hand and surface disinfection worldwide through a network of subsidiaries and distribution partners, as well as through direct sales.



Cleanliness and hygiene in clinical settings

In all healthcare settings, cleanliness and hygiene are essential. Benefit from decades of expertise acquired by our process specialists and allow us to advise you on a comprehensive and perfectly coordinated approach to hygiene. Alongside our deconex® portfolio of products for the processing of medical devices, we offer an extensive array of services - from derouging and passivation to maintenance and product and application training - at Borer's testing and training centre.



A unique service: the deconex® test and training centre

At our in-house technology centre, you have the opportunity to try out tailor-made systems technology and chemicals for perfectly coordinated reprocessing, using state-of-the-art technologies and with the support of our specialists.



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