

Container Preparation for Reuse in Light of the Recommendations Issued by the Robert Koch Institute (RKI) Concerning the Creutzfeldt-Jakob Disease Variant (v-CJD)

In February 2002, the RKI published a report on the issue of minimizing the risk of iatrogenic v-CJD transmission by medical devices, especially surgical instruments.*

According to this report, general instrument preparation should be based on a combination of at least two different procedures:

- Mechanical cleaning/disinfecting with alkaline cleaning agents, resulting in a cleaning solution with a pH value greater than 10.
- Final steam sterilization at 134 °C, with a minimum retention time of 5 minutes.

This raises the following important question with regard to **aluminum** containers (incl. supply containers used for both sterile-supply and disposal purposes):

[Do these containers have to be treated with an alkaline solution so they can comply with this guideline?](#)

- The RKI guideline applies only to medical products – especially surgical instruments – that come in direct contact with the tissue.
 - ⇒ The container is not a medical device that makes direct contact with tissue.
- The final Task Force Report is based on a risk assessment (e.g. with regard to infection channels) which indicates that indirect transmission possibilities do not have to be taken into account.
 - ⇒ This means that it is not mandatory to treat containers “re-contaminated” by contaminated instruments with alkaline cleaning agents.

This statement is not a subjective interpretation because it is also supported by the RKI (e.g. as discussed during the meeting of the Spectaris industry association’s “Medical Technology” technical commission held on 04 November 2002, with Prof. M. Mielke, of RKI, among the participants).

Therefore, the information on pH-neutral cleaning as given in the pertinent Instructions for Use remains valid.

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In agreement with the above conclusions, we treated our container boxes with “**neodisher mediclean forte**”, a product that not only complies with the manufacturer’s requirements for anodized surfaces but with the RKI recommendations as well, using a specially recommended washing/cleaning program.

Program sequence:

- Cleaning: mediclean forte, 55 °C, 10 minutes, demineralized water
- Intermediate rinse with demineralized water, no additives
- Final rinse with demineralized water, thermal disinfection at 94 °C for 10 minutes.
- Drying

The boxes were alternatingly washed and sterilized (standard procedure: steam, 134 °C, 5 min.) in more than 50 cycles.

Results:

- The container box showing no traces of mechanical damage or previous use at the start of the test series successfully passed the tests without reservation.
- The container box showing some traces of mechanical damage or previous use at the start of the test series exhibited a slight aggravation of the damage in these places. However, the deterioration process stabilized (i.e. came to a halt) after approximately 10 cycles.
- **Consequently, the neodisher® mediclean forte cleaner (manufacturer: Chemische Fabrik Dr. Weigert, Hamburg) can be recommended for use when processing our containers mechanically for reuse. However, we also recommend you to inform customers about the chemical reaction that takes place if the container is damaged or shows traces of use.**

* “Die Creutzfeldt-Jakob-Krankheit (vCJK), Epidemiologie, Erkennung, Diagnostik und Prävention unter besonderer Berücksichtigung der Risikominimierung einer iatrogenen Übertragung durch Medizinprodukte, insbesondere chirurgische Instrumente – Abschlussbericht der Task Force vCJK zu diesem Thema“ (The Creutzfeldt-Jakob disease variant (v-CJD) – Epidemiology, identification, diagnostics and prevention, with special consideration to the issue of minimizing the risk of iatrogenic transmission by medical devices, especially surgical instruments – Final report of the v-CJD Task Force“.