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Storage of sterilized medical products

Unwrapped sterilized instruments cannot be transported or stored without **packaging**. According to WHO (1), sterilized unwrapped instruments must be used on the patient immediately. Packaging protects the sterile contents from re-contamination or soiling until the contents are used on the patient. But how long can wrapped sterile instruments be stored for? Who determines the expiry date? (2)

The loss of sterility fundamentally depends on the external influences present during storage, handling and transportation. When it comes to the possible storage duration, the storage conditions themselves are crucial. A suitable storage place for sterile wrapped instruments **should have the following properties:**

- It should be clean and dry
- It should be segregated from non-sterilized products

In addition, the sterilizer identification and both the sterilization and expiry dates should be noted e.g. on label stickers where the batch number should also be documented for traceability, together with the name of the person in charge.

As soon as any damage is observed during the inspection of the stored packaging, the damaged packaging is to be regarded as no longer sterile and contaminated with germs.

What about stock rotation – First in - First out?

How to operate your stock rotation?

Freshly sterilized wrapped instruments should be stored in the back of the storage so that the ones in the front and thus sterilized at an earlier date will be used next. So – first in will be first out – and prolonged storage times or storage beyond expiry can be avoided.

Important to know: In the case of a sterile wrapped single-use material, the expiry date provided by the manufacturer determines the possible storage period with regard to intact packaging. On average, a five-year storage period is typical for industrially produced sterile goods. Any exceptions are indicated by the manufacturer in question. Good to know: Standards are in place regarding packaging and packaging materials (1;2;3 for more detailed information).

Bibliograpy:

(1) WHO Library Cataloguing-in-Publication Data, Decontamination and reprocessing of medical devices for health-care facilities. World Health Organization. II. Pan American Health Organization. ISBN 978 92 4 154985 1

(2) EN ISO 11607

(3) EN ISO 285, EN 868

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Wet packaging **after sterilization**

Does this matter?

The objective of packaging materials is to provide a **sterile barrier** and to maintain sterility until the materials are used. If the packaging is damp or even wet following sterilization, it can be assumed that the sterilization has not been successful. Due to its altered structure, wet or damp packaging does not constitute a suitable barrier against microorganisms. Under these conditions microorganisms can multiply, and the sterile goods can as such no longer be stored as sterile goods. The following are often responsible: poor-quality packaging material as well as malfunctions in the sterilizer. Damp or wet packaging can be avoided by following the sterilizer manufacturer's instructions concerning the loading method of the trays and chamber as well as not exceeding the maximum mass defined for the selected cycle. **Wet packaging can be effectively prevented by using the following measures:**

- Avoid overloading the sterilizer
- Regular maintenance of the sterilizer
- Adhere to a suitable cooling time (according to EN 13060 any remaining water droplets on the inner side of the film of laminate pouch shall evaporate within 5 min of end of the cycle)
- Use the suitable **packaging material** indicated for steam sterilization
- Use a cycle type compatible with the load to be sterilized
- Do not exceed the declared maximum mass of instruments for the selected cycle
- Do not pile up packages on the trays

In addition to the fact that wet packaging is to be regarded as non-sterile and possibly contaminated with bacteria, the need to perform the complete reprocessing procedure again also entails increased add-on costs; the time and work required to do so constitute an extra financial burden for the practice. There are many reasons why damp or wet packaging occurs after steam sterilization (1).

Important to know: For type B benchtop steam sterilizer, it is unlikely that wet packs appear. These vacuum steam sterilizer type B have a drying step where vacuum plays a major role for the **drying phase**.

Bibliography:

(1) Debabrata Basu, Reason behind wet pack after steam sterilization and its consequences: An overview from Central Sterile Supply Department of a cancer center in eastern India, Journal of Infection and Public Health (2017),10, 235-239.