New recommendation on storage duration for sterile medical devices

Publication
Recommendation of the Committee of Experts on Quality (85)

At a glance

- **Contaminated surgical instruments, deficits in the Central Sterile Supply Department (CSSD) or errors in the cleaning, disinfection or in the process of sterilisation of surgical materials are disastrous.**
- **Single-use instruments in sterile packaging are an alternative to reprocessing standard reusable instruments because error-prone cleaning steps are unnecessary.**
- **Correct storage of instruments must be considered. For this reason, the German Society for Sterile Supply (DGSV) has issued a "Recommendation on storage duration for sterile medical devices" (85).**

Background

Contaminated surgical instruments, deficits in the Central Sterile Supply Department (CSSD), or even "hygiene scandal". No matter what we call it – errors in the cleaning, disinfection or in the process of sterilisation of surgical materials are disastrous. They allow germs to penetrate into fresh wounds and, in the worst case, can be deadly for patients. This is why negative incidences in this extremely sensitive hospital sector regularly make the headlines.

But there is an alternative to reprocessing standard reusable instruments: single-use instruments in sterile packaging. With single-use products, complicated and error-prone cleaning steps are unnecessary, and the instruments can be used immediately. Even with single-use instruments, however, certain aspects such as correct storage must be considered. For this reason, the German Society for Sterile Supply has issued a "Recommendation on storage duration for sterile medical devices" (85). This document by the society's expert committee on quality replaces its Recommendation 39 from 2005.

Results

According to the recommendation, the permissible storage duration depends less on the manufacturer's data than on the actual conditions on the premises. "The relevant hygiene commission must assess the circumstances, specify these in writing and publish them in the hygiene plan", the expert committee states. The use-by date printed on the packaging is only valid under appropriate and compliant storage conditions and depends on the contents, type of packaging and the storage conditions of the medical products.

Of particular importance is that the storage location has a maximum room temperature of 25 degrees, is dry, clean, protected from light and dust, and is free from all unsterile objects. The required interior and architectural framework is provided by the respective Central Sterile Supply Department of a hospital or by the hospital's internal hygiene commission. Walls, floors and ceilings should be easy to clean and disinfect. Storage racks should also be located at least 30 centimetres (about 12 inches) above the floor.

The recommended storage duration also depends on the respective packaging system. For the DGSV experts, this refers to a combination of a sterile barrier system and a protective packaging. The sterile barrier system consists of direct packaging that prevents the immediate entry of microorganisms. The outer protective packaging, on the other hand, prevents damage to this sterile barrier system – beginning at production through transport to actual use in the operating theatre.

Significance for work in a patient-oriented environment

Depending on the packaging system, hospital staff must observe various measures to ensure safe handling of single-use instruments. This is because the type of packaging and means of storage – on open shelves or in

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locked cabinets and drawers – have a significant effect on the shelf life and the absolute guarantee of sterility. Some manufacturers are starting to offer special dust-protection packaging.

Although such sterile storage packaging is protective and generally durable for five years, instruments in single packaging must be used within 24 hours if left unprotected on the shelf. However, when they are stored in a dust-protected cabinet or drawer, they may be used in the operating theatre for a period of up to six months. All employees in the Central Sterile Supply Department of a hospital monitor adherence to these regulations. They assume great responsibility for their colleagues in the operating theatre, and above all for the patients, regardless of whether they use disposable or reusable instruments. “We can’t afford any form of carelessness here. Hygiene is paramount,” said ZSVA head Edeltraut Habeth from the University Clinic Gießen-Marburg (UKGM) in an interview with the Oberhessische Presse (Upper Hessen newspaper). The CSSD there has received a certificate for its exceptional quality in the reprocessing and care of medical devices. According to Habeth, real-time computer recording of each individual batch, test sensors in machines, as well as labels on the sterilised boxes and optical tests ensure “maximum cleanliness and safety”.

The reprocessing of reusable instruments consists of several steps: First, surgical instruments that are contaminated with tissue, bone or blood residues are stored on the unclean side of the sterilisation system. As soon as the soiled instruments have passed through various cleaning and disinfection chambers, they are regarded as low in germs, but must not yet be used in the operating theatre. Only when clamps, forceps and tweezers, and all hooks and scissors have been cleaned and disinfected mechanically in a separate clean room, they are considered germ-free again and ready for the next operation.

Reusable instruments reduce material costs, are durable and, when sterilised correctly, are permanently sterile. Compared to single-use instruments, they appear more sustainable: no packaging waste and no use-by date. However, the consequences of human error or mechanical failure are far-reaching and unnecessarily increase the risk of contamination. This is because reusable instruments must be returned to their sterile condition every time. Single-use instruments, on the other hand, are always delivered sterile and only have to be stored correctly so that they do not lose quality. Unnecessary risks to the health of patients can thus be minimised.

Requirements for the storage location