Recommendation by the Quality Task Group (85: 2023)

Recommendation for the storage period for sterile medical devices

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This recommendation for the storage period replaces Recommendations 39:2005 and 85:2014. The period during which sterile medical devices can be justifiably stored depends to a large extent on the external influences and conditions prevailing during storage, transport and handling. DIN EN ISO 11607-1:2020-05 [1] states that loss of integrity of the sterile barrier system is generally related to a specific event rather than to the factor time.

DIN 58953-8, too, points out that **LOSS OF STERILITY** depends less on the storage period than on the external influences and effects during storage, transport and handling [2].

LOSS OF STERILITY is related to a specific event and depends on influences during storage, transport and handling.

To define the storage period, these conditions must be verified and evaluated at the respective storage site for the sterile products to be stored. The information given in the tables in DIN 58953-8 are benchmark values that can be consulted for decision-making.

Responsibility for the storage period and storage conditions is borne in principle by the operator. The **PERMITTED STORAGE PERIOD** at the storage site is stipulated in writing by the operator and the person responsible for hygiene/infection control, in a hospital, for example, by the Infection Control Committee. In medical practices, the operator of the practice assumes this task. Due to the different storage conditions, the specifications may vary for the different areas and this is set out in the infection control policy and in individually compiled standard operating procedures and work instructions.

THE PERMITTED STORAGE PERIOD AT THE STORAGE SITE is stipulated in writing by the operator and the person responsible for hygiene/infection control.

The following applies in principle: The **MAXIMUM STORAGE PERIOD** is valid only for storage that is effected in a proper manner and which takes account of specific circumstances. The recommendations for the storage period prescribed for a sterile item should also limit the risk of contamination during transportation and when opening the sterile barrier system. The criteria for definition of the expiry date or of the storage period include the following:

THE MAXIMUM STORAGE PERIOD is valid only for storage that is effected in a proper manner.

- Packaging contents
- Packaging type
- Type of storage
- Storage conditions for sterile supplies

The following conditions must be met (see also Checklists in the Annex to the DGSV Guideline for storage of reprocessed medical devices and transport for supply and collection of reprocessable medical devices between the RUMED and site of use [4] as well as DIN58953-8):

- dry
- protected against dust (e.g. doors and drawers with sealing lips)
- protected against light
- protected against damage
- protected against mechanical effects
- preferably at room temperature (18°C – 25 °C)
- protected against extreme temperature fluctuations, e.g. to prevent condensate formation during transport, note dew point
- separate from unsterile products
- clean
- free from vermin

Walls, shelves, cabinets, drawers, the floor and ceiling of the storage room must be smooth and easy to clean and disinfect (disinfection proof). There should be enough free space (around 30 cm) left between the lowest shelf level and the floor to permit cleaning of the floor.

The storage conditions have implications not only for sterility of the medical device but should also guarantee aseptic presentation of the medical devices at the point of use.

The storage conditions are met by storing products on shelves in Room Class I or II rooms pursuant to DIN 1946-4. The rooms should not be used as a general passageways (pursuant to DIN 58953-8:2019-5).

If there is no appropriate room available for storage, the sterile supplies must be stored in tightly closed cabinets, drawers, boxes, etc.

Recommended storage period for sterile medical devices

Tab. 1: Recommended storage period for sterile medical devices
DIN 58953-8:2019-03 Table 1: "Reproduced with permission of DIN Deutsches Institut für Normung e. V. (German Standardization Committee). Permission to use the DIN standard is subject to utilization of the latest version issued, which can be obtained from Beuth Verlag GmbH, Burggrafenstrasse 6, D-10787 Berlin or at www.beuth.de"

Packaging type	Unprotected storage (a)	Protected storage
Sterile barrier system	Suitable for supplies intended for imminent use (b) To be avoided as a type of storage!	6 months, but not after expiry date
Packaging system [3] (combination of sterile barrier system and protective packaging)	5 years if the manufacturer has not specified a different expiry date	
(a) On shelves in the case of rooms that do not correspond to Room Class I or II rooms pursuant to DIN 1946-4: 2018-09, (b) Imminent use is understood to mean utilization of the device within two days/48 hours		

Note 1 on protected storage: Based on the KRINKO Recommendation jointly issued in 2012 by the Commission for Hospital Hygiene and Infection Prevention at the Robert Koch Institute (RKI) and the Federal Institute for Drugs and Medical Devices (BfArM): "The storage period depends on the quality of the packaging material, impermeability of the sealing seams and the storage conditions. Any storage periods exceeding six months will also depend on this." Note 2: For sterile supply containers the use of inner wrapping can enhance aseptic presentation.

Storage for longer than 6 months as set out above may be specified depending on the manufacturer's sterile barrier system validation parameters or in-house tests based on DIN EN ISO11607-1 Annex B and in-house risk assessment.

Terms from DIN EN ISO 11607-1:2020-05

1. Packaging system = Combination of sterile barrier system and protective packaging.
2. Sterile barrier system = The minimum packaging that prevents ingress of microorganisms and allows aseptic presentation at the point of use
3. Protective packaging = Configuration of materials designed to prevent damage to the sterile barrier system and its contents from the time of assembly to the point of use

References

1 DIN EN ISO 11607-1:2020-05, Packaging for terminally sterilised medical devices
2 DIN 58953-8:2019-03, Logistics of sterile medical devices, including Section 4.3.2 Environmental Monitoring
3 DIN 1946 -4:2018 -09 Ventilation systems in buildings and rooms in the healthcare sector, including: Section 1.1.3 Sterile supply store
4 2018_Guideline compiled by the German Society of Sterile Supply (DGSV) for storage of reprocessed medical devices and transport for supply and collection of reprocessable medical devices between the RUMED and site of use (in German) https://www.dgsv-ev.de/fachinformationen/leitlinien/