

Recommendations by the Quality Task Group (85)

Recommendations for the storage period for sterile medical devices

This recommendation for the storage period replaces Recommendation 39 issued by the Quality Task Group in 2005.

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. Hence in a comment in EN ISO 11607, Part 1¹, Section 6.1.5, it is expressly stated that loss of integrity of the sterile barrier system is generally related to a specific event rather than to the factor time.

DIN 58953, Part 8, too, points out in Section 7.2 «Storage period» that **→ LOSS OF STERILITY** depends less on the storage period than on the external influences and effects during storage, transport and handling². 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, Part 8 are benchmark values that can be consulted for decision-making.

Responsibility for the storage period and storage conditions is borne by the medical director or the hospital authorities. The storage periods must be defined on the basis of risk factors. The integrity of the packaging system is an important criterion for maintenance of sterility during the storage period.

The **→ PERMITTED STORAGE PERIOD** is stipulated in writing at the storage site by the person responsible for hygiene/infection control, in a hospital, for example, by the Infection Control Committee. Responsibilities can be assigned differently for the various areas and this is set out in the infection control policy.

In principle, the following applies:

The **→ SPECIFIED 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 include the following:

- Packaging contents
- Packaging type
- Type of storage
- Storage conditions for sterile supplies:
 - dry
 - protected against dust/low dust
 - protected against light
 - protected against damage
 - protected against mechanical effects
 - at room temperature (max. 25 °C)
 - protected against extreme temperature fluctuations
 - separate from unsterile products
 - clean
 - free from vermin

→ LOSS OF STERILITY depends mainly on the circumstances relating to storage.

→ THE PERMITTED STORAGE PERIOD is stipulated by the Infection Control Committee after evaluation of the conditions at the respective storage site.

→ THE SPECIFIED STORAGE PERIOD is valid only for storage effected in a proper manner.

1 EN ISO 11607-1:2009, Packaging for terminally sterilized medical devices

2 DIN 58953-8:2010, Logistics for sterile medical devices

The walls, floors and ceiling of the storage room should be smooth and easy to clean and disinfect (can be wiped off). They must, of course, be free of cracks and the paint should not be peeling. 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 in particular for 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 thoroughfare (pursuant to DIN 58953, Part 8, 4.3.1). Besides, products must be stored in hermetically sealed cabinets and/or drawers.

I Recommended storage period for sterile medical devices

Recommended storage period

Table 1: Recommended storage period for sterile medical devices

DIN 58953-8:2010 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, Burggrafenstr. 6, 10787 Berlin, Germany.»

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 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: 2008-12		
(b) Imminent use is understood to mean utilization of the product 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.

I Terms from DIN EN ISO 11607-1:2009:

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

I Transport of sterile medical devices

The operator must:

- clearly define
 - document
 - update
- responsibilities and authorizations for logistical activities related to medical devices. Transportation must not negatively impact on sterile supply properties⁴. ■

Transport

³ The terms sterile barrier system, protective packaging and packaging system are defined in DIN EN ISO 11607

⁴ Transportation of both sterile and used medical devices is described in a separate recommendation by the Quality Task Group