Recommendations by the Quality Task Group (39) Recommendations for the Storage Period for Sterile Medical Devices

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, transportation and handling. Hence EN 868, Part 1, Section 4.6 "Retention of sterility" expressly points out that loss of integrity of the sterile packaging is generally related to a specific event rather than to the factor time.

DIN 58953, Part 9, too, points out in Section 8.2 "Storage period" that ➜ **LOSS OF STERILITY** depends less on the storage period than on the circumstances relating to storage.

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

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 and 9, are benchmark values which can be consulted for decision-making.

The ➜ **PERMITTED STORAGE PERIOD** is stipulated in writing at the storage site by the Infection Control Committee. These specifications can vary for different areas and are published in the Infection Control Plan. The medical supervisor or the hospital authorities are responsible for the storage period and storage conditions.

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

The following applies in principle:

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 are intended as a means of limiting the risk of contamination during transportation and at the time of opening the sterile packaging, because as the storage period increases, so does the risk of contamination of the outer surfaces rise as a function of the storage conditions.

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

Criteria for definition of the expiry date

Criteria for definition of the expiry date or of the storage period:

- Contents of the packaging
- Type of packaging
- Type of storage
- Storage conditions for sterile supplies:
- dry
- low dust
- protected against light
- protected against damage
- protected against mechanical effects
- protected against fluctuations in external temperatures
- separate from unsterile products

Walls, floors and ceiling of the storage room should be smooth, easy to clean and disinfect. Shelves must be at least 30 cm above floor level.

The storage conditions are met by storing products in a Class I Room as per DIN 1946-4:1999-03, Table 2, or storage in hermetically sealed cabinets and/or drawers.

Transportation

Transportation of sterile medical devices

The operator is responsible for, and in charge of,

- clearly defining
- documenting
- updating

all logistical matters relating to medical devices.

The properties of the sterile supplies must not be adversely affected during transportation.

Sterile medical devices should preferably be delivered in transport packaging[1] in addition to the primary and secondary packaging if they traverse zones with different

hygiene requirements (e.g. from the CSSD to wards or outpatient departments)
The primary and secondary packaging may be opened only immediately before use.

It must be ensured that the storage packaging[2] is free of dust before opening it.

Any storage packaging opened must be closed again immediately after removal of any part of its contents.

Nothing may be newly added to be storage packaging once opened.

Recommended storage periods

Recommended storage period for sterile medical devices ; DIN 58953-8:2003 Table 1

Type of Packaging	Unprotected Storage (a)	Protected Storage
Primary packaging	Suitable for supplies intended for imminent use (b) To be avoided as a form of storage!	6 months, but not after expiry date
Storage packaging	5 years if manufacturer has not specified a different expiry date (c)	

(a) On shelves in the case of rooms that do not correspond to Class I Room pursuant to DIN 1946-4;1999-03, Table 2

(b) Imminent use is understood to mean utilisation of the product within two days/48 h at the latest

(c) The hospital may use its own packaging systems as a substitute for the original secondary packaging. The labelling used on the original packaging must be reproduced in an appropriate manner.

Recommended storage period for sterile supplies in sterile containers; DIN 58953-9:2002-10, Table 2

Sterile packaging	Type of packaging	Storage Period
Sterile containers as per DIN EN 868-1 or DIN EN 868-8	Single-wrapped sterile supplies	6 months
	Double-wrapped sterile supplies	

Note 1:
The specifications in Table 2 are recommendations intended to reduce the risk of contamination during transportation and at the time of opening the sterile container. As the storage period increases, so does the risk of contamination of the outer surfaces rise accordingly. This alone does not result in recontamination of the contents of the package during storage, but does increase the risk of contamination during transportation or at the time of opening the sterile packaging. The information in Table 2 refers to storage under dry conditions with supplies protected against dust. A longer storage period is possible subject to the conditions prevailing at the respective site.

Note 2:
The inner wrapping of double-wrapped sterile supplies enhances aseptic presentation and its use is thus recommended.

The operator can define the storage period by consulting the aforementioned table. Stipulation of a 6-month storage period for in-house sterilised medical devices has proved beneficial in practice. Extension of the storage period for practical or economical reasons has not proved advisable.

In particular, the conditions prevailing on the wards or in functional units (not the OR or CSSD) must be noted as often these conditions do not permit a long storage period. Furthermore, it should be borne in mind that a long storage period in such areas also means capital tie-up that can be avoided.

1) Transport packaging: can enclose a single or several sterile products in primary and/or secondary packaging and is used for protection during transportation and storage

2) Storage packaging: can enclose a single or several sterile products in primary and/or secondary packaging and is used for protection during long-term storage.
The secondary packaging can also serve as storage packaging.