Manufacturer`s Statement

steriCLIN® VP MEDICAL PACKAGING

Concerning periods of storage for sterile barrier systems

For sterile barrier systems, it is customary in the industry to specify usability periods of one to five years before sterilisation, and in addition up to a maximum of five years after sterilisation.

In order that sterile barrier systems effectively maintain their required characteristics over an extended period of up to ten years, important preconditions for storage and transport with regard to sterile materials logistics must be observed.

According to the Medical Products Law, responsibility for this lies with the manufacturer and user. As a supplier of high quality, preformed sterile barrier systems, we support our customers by ensuring required barrier characteristics if specific preconditions are complied with.

The following explanations (that however cannot be complete with regard to possibly harmful influences) give important indications for the appropriate and correct logistics of sterile barrier systems and sterile products.

Storage period: we distinguish between two timespans

Usage timespan and period of storage of medical packaging must be divided into two different timespans.

Timespan 1:

- The time period previous to processing of the material or preformed sterile barrier system by the customer (meaning previous to filling, forming, sealing and sterilising),

Timespan 2:

- The time period following processing or sterilisation until usage, meaning usage of the actual medical product.

Timespan 1:
If the recommended storage conditions according to product specification and product designation are complied with, we ensure the functional efficiency of our prefabricated sterile barrier systems (e.g. transparent packaging) and materials (e.g. rolled goods) for timespan 1.

Timespan 1 is specified on the box or container label with Date of manufacture and shelf life, together with complete product and batch designations.

Manufacturer`s Statement

steriCLIN® VP MEDICAL PACKAGING

Storage conditions recommended and specified by VP have proved to be reliable in practice for decades, and functional limitations under appropriate and correct storage are unknown to us.

Influences or incidents that might limit usage timespans are, for example:

Temperature fluctuations:
The higher a selected storage temperature is, the quicker materials can age. An approximate guideline is a doubling of the acceleration of the ageing process with every ten degree temperature increase. If our recommended storage temperature of a maximum of 25° is changed to 35°, the ageing process can therefore proceed almost twice as quickly.

Humidity fluctuations:
Paper reacts very significantly to humidity fluctuations. Thus dimension-dependent parameters such as length, width and curl are distinctly influenced. This may result in a sealing process being incorrectly performed because, for example, curl or modified length dimensions act as a hindrance.

Ingress of light (exposure to UV light, etc.):
Exposure to sunlight, especially its UV component, can inadmissibly modify material characteristics. Storage without the influence of light (e.g. in the closed, original box) is therefore a precondition for the duration of the storage period.

Our experience and documentation indicate that deviations from our recommended storage conditions with respect to temperature and humidity (within the limits of the central European climate) do not represent a loss of functionality of the material or the prefabricated sterile barrier system.

Timespan 2:
For the storage of sterilised medical products, the usage timespans (= timespan 2) must be defined by the marketing authorisation holder or manufacturer (processor) of the sterile goods, in his own responsibility. Additionally, storage conditions must be specified here.

National standards or recommendations such as DIN 58953, Section 7 and 8 include recommended specifications (see attachment: storage period table DIN 58953-8).
With definition of the sterile storage period, please bear in mind that a precondition for the maximum storage period of sterile products is not only an undiminished barrier effect of the packaging, but also a low contamination level of the sterile barrier systems on their exterior surface, e.g. with protected storage and suitable protective packaging. Safe, aseptic presentation of Medical Devices is only possible with low levels of surface contamination.

Manufacturer`s Statement

The loss of sterility during timespan 2 is, as a rule, not due to **general** factors but rather "**particular**" factors of storage or transport. (See DIN EN ISO 11607, 6.1.5. Note: "event-related loss").

General factors: these are identical to the influences or events described for timespan 1.

Particular factors, influences or events during storage or transport can, for example, include:

- Higher levels of mechanical stress (vibration, etc.), e.g. during transport, with mobile first aid kits in vehicles, etc.
- Greater pressure and rapid changes in pressure, e.g. with transport by air
- Higher probability of impact with foreign bodies (e.g. during mobile rescue operations)
- Wetting with chemicals and liquids

Possible interaction of various sterile goods with the sterile barrier system must also be considered. Conceivable situations within timespan 2 must be displayed, evaluated and controlled by the manufacturer of the medical product via risk management (see DIN EN ISO 14971).

Feuchtwangen, 22. September 2017

VP Vereinigte Papierwarenfabriken GmbH
D-91555 Feuchtwangen · Industriestrasse 6
Fon +49 (0) 9852 901-0 · Fax -174

Thomas Lechner

Head of Management Systems VP Group

VP Vereinigte Papierwarenfabriken GmbH
D-91555 Feuchtwangen · Industriestrasse 6
Fon +49 (0) 9852 901-0 · Fax -174

Dr. Jürgen Wirtz-Stark

Head of Development and Applications Engineering

Manufacturer`s Statement

steriCLIN® VP MEDICAL PACKAGING

Attachment: storage period table according to DIN 58953-8:2010-05

Storage period table according to DIN 58953-8:2010-05, sterile goods logistics
Recommended storage duration for sterile medical products in sterile barrier systems according to ISO 11607

Type of packaging	Unprotected storage On storage racks in rooms not corresponding to room class II in accordance with DIN 1946-4:2008-12	**Protected storage** Dust proof in closed storage systems, e.g. in cupboards, drawers or on storage racks in rooms corresponding to room class II in accordance with DIN 1946-4:2008-12
Sterile barrier system	**Provision for immediate use** Immediate use in this case means application or use of the product within a maximum of two days / 48 hours. **Must be avoided as a method of storage!**	**Six months** **But not longer than the expiry date**
Packaging system* If a protective packaging is opened, it must then immediately be sealed without the ingress of dust. Refilling of the protective packaging is not admissible after opening.	**Five years,** **provided that no other expiry date has been specified by the manufacturer.**	

* Combination of sterile barrier system and protective packaging.