Event Related Sterility

The shelf life of a packaged and sterilized item is regarded as event-related rather than time related.

The shelf life strongly depends on the storing and handling conditions of a sterile product. An event must occur to compromise package content sterility. Determination of sterility maintenance time of a final sterile product is in responsibility of the final pack manufacturer that has assembled the sterile barrier system or packaging system in the healthcare facility.

The shelf life of the sterile barrier system and packaging material is an important criterion for this evaluation, but not the single one. Other factors like storage and transportation means and conditions, the amount of sub-handling processes, sterilization parameters and process fulfillment, the properties of the packed item etc. have to be taken into consideration for the final decision about the sterility maintenance time.

All sterile barrier systems need to be inspected for integrity prior to their use. If the package as sterile barrier system is damaged, the content must be re-processed.

Earlier clinical tests and shelf life studies (e.g. Lexamed Procotocol: 13-L032) made with Steriking® peel pouches and reels have indicated that theoretically, and in single test conditions, integrity of the sterile package can be maintained up to several years if proper handling and storing conditions are provided by the manufacturer of the final pack. Therefore we can conclude that the Steriking® peel pouches and reels can be used for Event Related Sterility.

Sincerely,

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