
Sterile barrier systems laminates

Look for the right materials

What the laminate looks like

How the barrier function works

How to use

How to seal

How to pack for sterilization

Storage Conditions

How to find the right laminate

Standards to look for in Medical packaging are

ISO11607- 2

and as a part of it EN 868-3 and -5 for laminates

ISO 11607

Part 1

covers the requirements for materials,
Sterile barrier systems and packing systems
mainly for manufacturer

Part 2

covers packing for terminally sterilized medical devices,
validation requirements for forming, sealing and assembly
processes

this part is the one to guide you to **Quality in your hospital**

Relevant standards for sterile barrier systems

- **ISO 11607: Packaging for terminally sterilized medical devices**
- EN 868 - 1: general requirements of packing materials **replaced by ISO11607**
- EN 868 - 2: Wrapping paper & non woven
- EN 868 - 3: Paper for Paper-film laminates
- EN 868 - 4: Paper bags
- EN 868 - 5: See through pouches and reels
- EN 868 - 6: packing materials for EO gas and radiation sterilization
- EN 868 - 7: adhesive coated papers for ethylene oxide or irradiation
- EN 868 - 8: reusable container
- EN 868 - 9: uncoated nonwoven material (Tyvek)
- EN 868 -10: coated nonwoven material (Tyvek)

Definition of sterile barrier systems as per ISO11607-2

Minimum package (e.g. pouch or wrapping) that prevents ingress of microorganisms and allows aseptic presentation of the medical product at the point of use

If sterility of the medical item is to be maintained till the point of use a packing material with a proven bacterial barrier function must be used.

Ask your supplier for a third party certificate

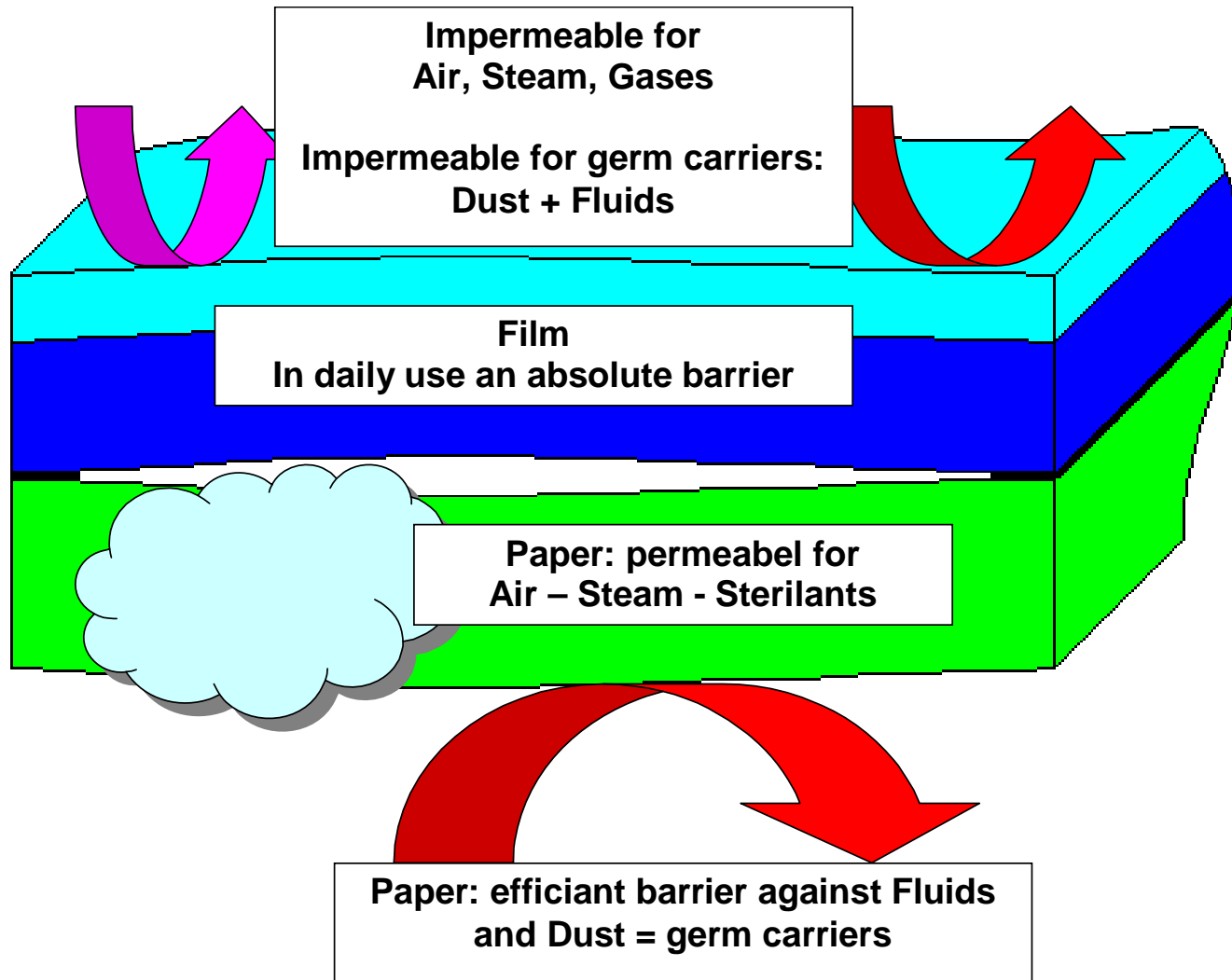
manufacturing of packing material
in a clean room to avoid/minimize
contaminations and dirt's

Ask for a certificate of clean room production
class 8 as per ISO 14644-1 or better

Sterile barrier systems laminates



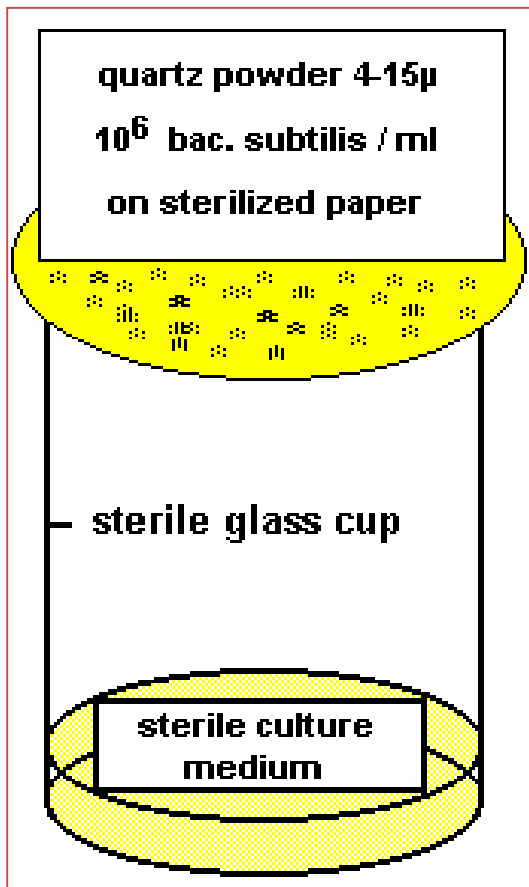
Sterile barrier system – how it works



Sterile Barrier Systems

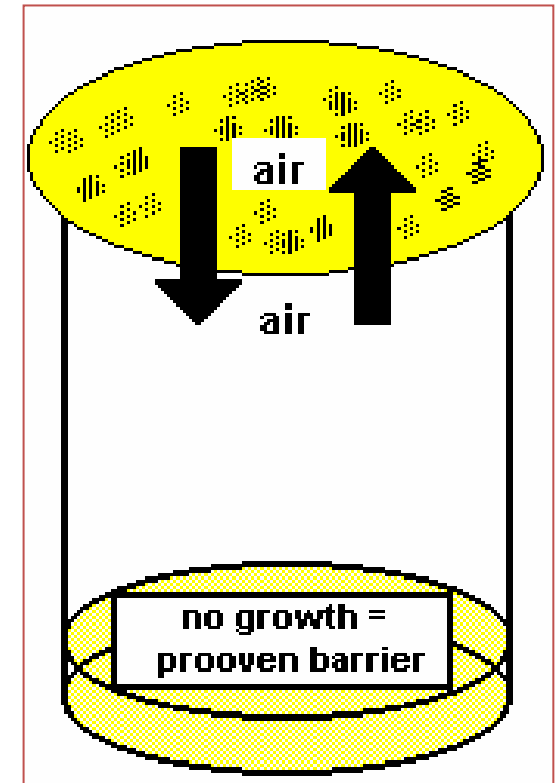
how it is tested

Barrier test 1 (dry conditions)



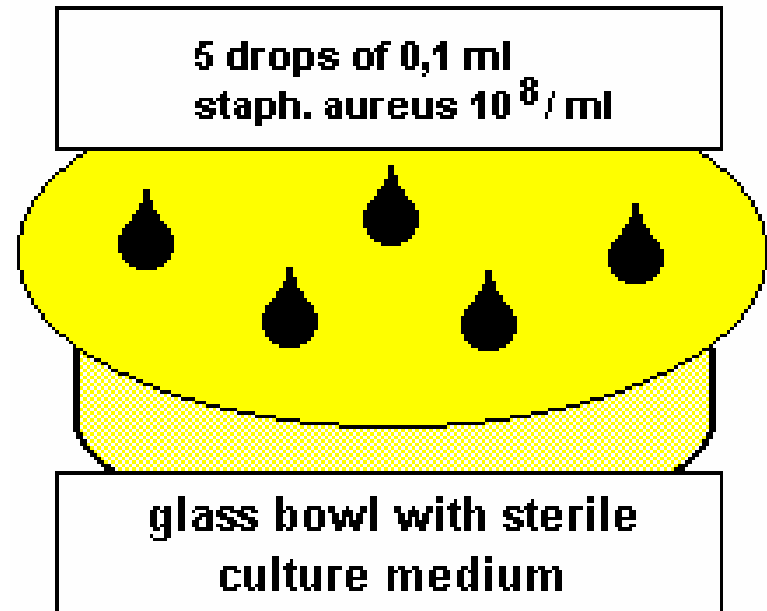
Air flow is created by
heating up to 50°C and
successive cooling to
10°C

Repeated 5 times



Sterile barrier systems(wet) how it is tested

Contaminated liquid challenges the
sterilized paper for 6 hours
DIN 58953, part 6 allows max. 20%
penetration



Stericlin® = 0% penetration
tested by an independent laboratory

Thickness of paper

60g/m² is the minimum weight for reels and pouches

70g/m² for quality reels and pouches as per market experience
means higher safety standard and much better performance for aseptic
presentation – less paper fiber tear while peeling

Visual appearance of the product overall

no damage
same sealing seam width around the pack
no wrinkles at the film or paper
cutting edges around the laminate are clean
no dirt or foreign matter in the paper and film

Sealing seam

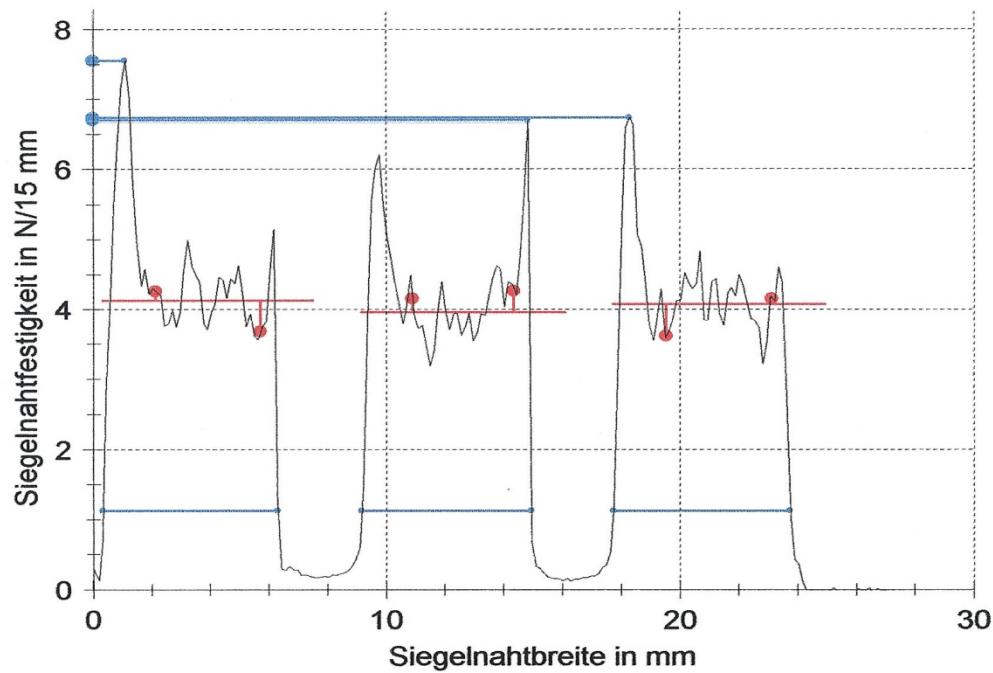
one line = minimum standard



three lines = higher safety factor



Sealing seamstrength test



Visual quality of indicator print

clear print

no color change when sealing seam cross the indicator

minimum size of each indicator 100mm²

printing requirements

In case manufacturer is validated **only ISO11607** can be printed
All other standards printed are not valid for Sterile Barrier Systems

Single use only

Date of manufacturing to calculate the shelf life

No printing at the filling area as the medical item is not allowed to
get in touch to the printing color

Printing rapport on reels shall not be less then 155mm

Do not use if pack is damaged

Lot number

Manufacturers name or brand

Indicators

Peel direction for reels

Size or size code

No bleeding of indicator colors
can be tested by hot water test as per ISO6588-2

Sealing seem width similar at all sides of the pack

Minimum sealing seam width 6mm

Thumb cut as opening support must be provided

It is recommended doing peeling tests with same size of pack from different lots
to check whether it is a stable production

It is recommended to do quality test for each incoming delivery.

no sealing failures (channels or holes at the sealing seam)
can be tested by sealing seam integrity test (blue colored test liquid)



No channel= sealing seam is **integral** channel=sealing seam is **not integral**

How to use Sterile Barrier Systems

- Never sterilize a flexible sterile packing system twice
- Do not fill up pouches and reels more than 75% of the filling area
- Sterilized packs must be dry within 30 minutes after sterilization otherwise consider those packs as not sterile
- check the peel direction by the opening symbol
- never peel against the peel direction to avoid tear off paper fibres (contamination)



How to use Sterile Barrier Systems

marking of sterile barrier systems

like pouches and reels

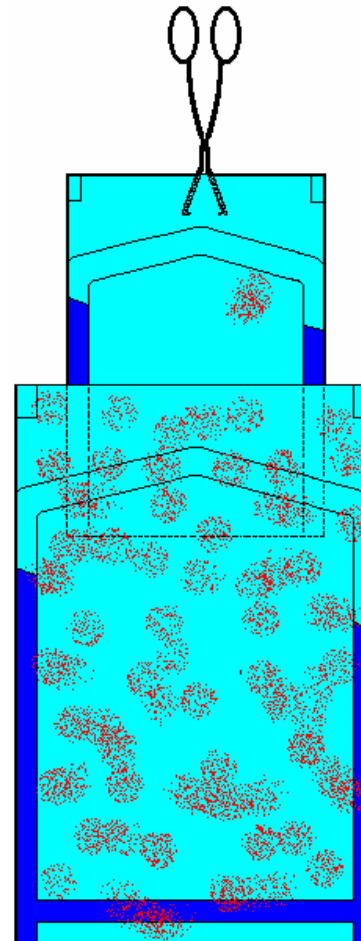
- Marking at film side only and if you have to do on the paper side just outside the filling area
- A steam resistant solvent free soft tip pen should be used
- Hard tip pens are not usable as they can damage the packing material



Sterile barrier system double packing

Double packaging / double wrapping minimizes the risk of recontamination during the opening process.

Double wrapping gives a second shield against package damages during storage and transport



Sterile barrier system double packing

configuration of materials designed to prevent damage to the sterile barrier system and its contents until the point of use



single



double

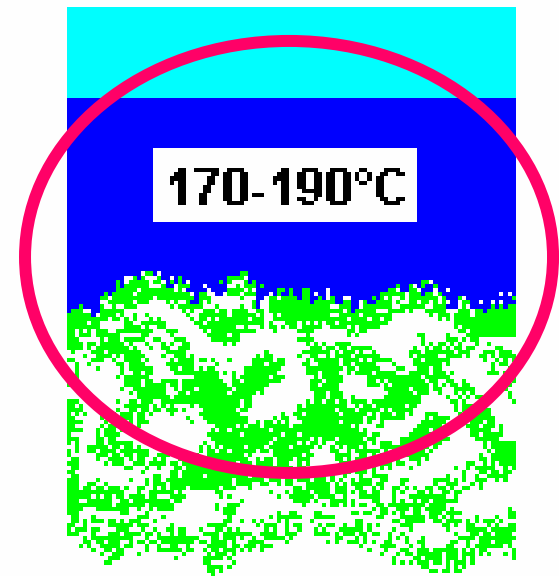
Sterile barrier systems as per ISO 11607-2

Protective packing for a sterile barrier system

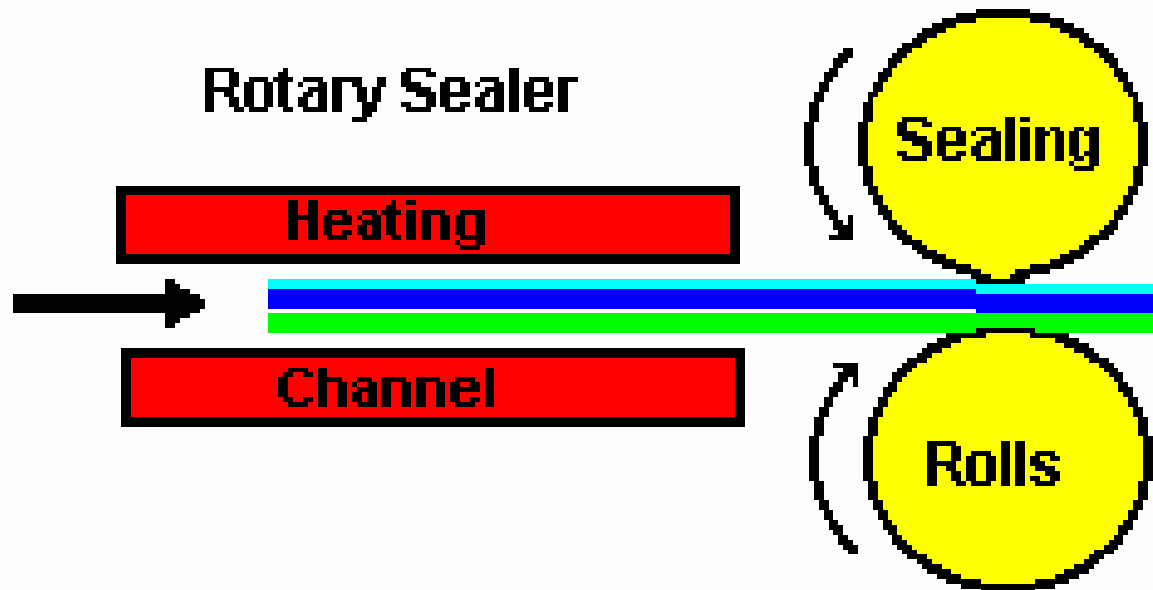


Sealing of Sterile Barrier Systems

Starting at a temperature of $> 150^{\circ}\text{C}$, Polypropylene melts and gets liquid. The pressure of the sealing rolls squeezes the film into the paper fibres. The bond between paper and film must withstand mechanical stress during the sterilisation process and must allow easy separation = peeling



Function of a rotary heatsealer



Sealing = Temperature + pressure + processing time

Validation of sealing process

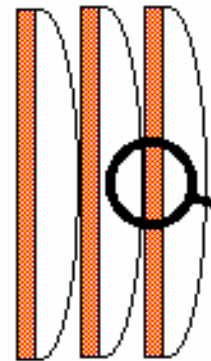
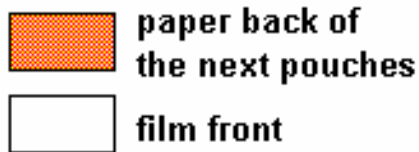
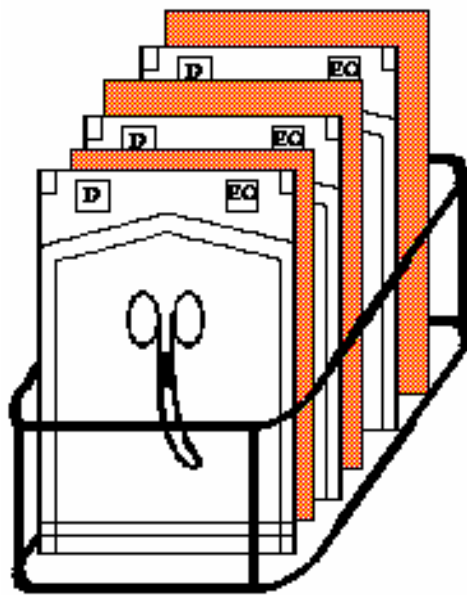
A rotary sealer is much more reliable than a bar sealer



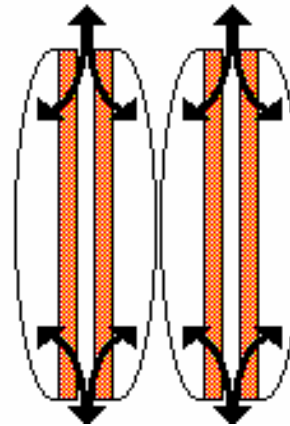
Critical parameters are temperature, pressure and time

Sterile Barrier Systems - laminates

loading of sterilization baskets



The film of the adjoining pouch covers a part of the paper side of the next pouch.
Reduced surface for penetration of air and steam.



Unhindered in- and out-stream of air and steam



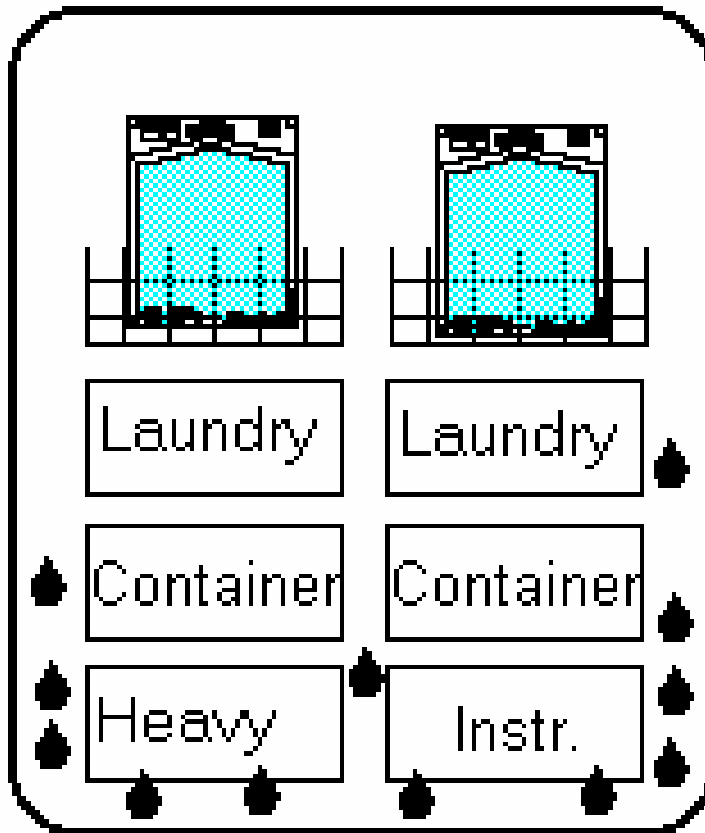
BETTER

Sterile Barrier Systems loading of sterilizer chamber



Sterile Barrier Systems

Loading of sterilizer chamber



Light items on top

Heavy items at the bottom

Storage time recommendations

Storage time table according to DIN 58953, part 8		
type of sterile barrier system compliant with ISO 11607 / EN 868	storage unprotected (without dust protection, e.g. on shelves)	storage protected (dust protected, e.g. in cupboards or drawers)
Primary packings: sterile single wraps and / or sterile double wraps	intended for immediate use not to be used for storage time longer than 48hours	6 months , but not longer than maximum shelf life
Storage packings: single or double wraps in a sterile storage package = dust cover, not opened or opened and re-closed	max 5 years if no other statement from the manufacturer site	

Sterile Barrier Systems

Storage conditions as per DIN58953-7/8

- Storage room must be dry, dark, airconditioned and easily to clean
 - Room climate: 15°-25°C
 - Relative humidity: 30 - 60%
- Storage room must be free from insects
 - No influence by sun light (UV light)
- No contacts to desinfectants and solvents as it can break the sterile barrier of the paper
 - Storage room is not accessible for everybody