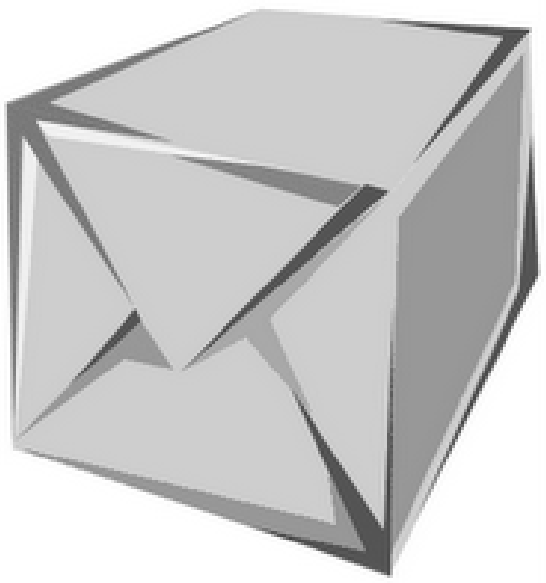
WFHSS ÖGSV

VI

Sterile Supply Packaging



Maria Theresia Enko
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1 Introduction

Packing of medical devices is a subprocess of the medical devices' circuit. The requirements for packaging materials as well as the requirements for handling these packaging materials are specified in standards (EN ISO 11607 Packaging for Terminally Sterilized Medical Devices). The currently valid version of the standard can be obtained from the standardization institutes.

Compliance with this standard shall ensure that the terms contained therein shall be used uniformly in the domain of sterile supply packaging.

When using this Script, the currently valid versions of standards must always be observed.

EN ISO 11607 consists of two parts

Part 1:

- Requirements for materials
- Requirements for sterile barrier systems (SBS)
- Requirements for packaging systems

Part 2:

- Requirements for validation of processes for forming, sealing and assembly.

Validation comprises

1) Installation qualification
2) Operational qualification
3) Performance qualification.

The step "***sterile supply packaging"*** is part of quality assurance. Handling of packaging materials and/or packaging systems should be set out in writing.

The term "packaging system" denotes the combination of sterile barrier system (SBS) and protective packaging.

This Script does **not** deal with packaging facilities for sterile liquids.

2 Selecting the packaging

Already at the time of purchasing packaging material, one must ensure that only materials manufactured as per valid standards are bought.

Medical devices (MDs), e.g. instruments or dressings, must be sterilized inside the packaging since unwrapped sterile supplies cannot be transported or stored.

The packaging protects the sterile contents against recontamination until they are used on the patient.

The most important function of the packaging is therefore to protect the sterile supplies against recontamination after sterilization.

The performance capabilities and stability of packaging systems must be checked – proof of its integrity must be demonstrated after sterilization, handling, distribution and transport.
By selecting the appropriate packaging system the MDs can, before sterilization, be

- packed
- sterilized in the packaging
- then transported and stored in a sterile state
- and withdrawn before use from the packaging free of contamination

The following must be borne in mind:

- the mass, external shape, sharp edges or protruding parts of the MD
- any susceptibility (e.g. kinking, impact) of the MD to damage
- the efficacy of the sterilization process must not be adversely affected by the packaging system
- sterility must be preserved during transport and storage until the point of use
- the MD must be packed such that it can be withdrawn from the packaging at the point of use without recontamination. Reaching prior agreement with the user is decisive here so that the entire contents are used at the same time for a patient – “leftovers” are deemed to be unsterile.

3 Packing lists

The type and size of the packaging system should be specified and documented for each sterile item (component of the packing list).

Packing lists must absolutely be available!

The manufacturer of packaging material must explain to the user how the packaging material is to be used (e.g. for what type of sterilization it is suitable, what sealing temperature is to be used, how the sterilization container is to be cleaned, etc.).

Only if these specifications are observed can an assurance be given that the packaging material is fit for purpose (e.g. protection against recontamination, sterility inside the packaging, etc).

Packing lists are compiled by a responsible staff member who has the necessary expertise.

The staff entrusted with packing MDs must follow the packing lists. In the event of any failure to do so, a qualified staff member must evaluate the situation before proceeding.

Packing lists must be followed!

4 Types of packaging

4.1 Sterile barrier system

The sterile barrier system provides a microbial barrier and allows aseptic presentation of the product at the point of use.

The term sterile barrier system describes the minimum packaging needed to assure the requisite functions.
These are to:

allow sterilization
provide a microbial barrier
allow aseptic presentation of the product

Examples of preformed sterile barrier systems:

- Reusable containers
- Paper, transparent pouches and reels; these are only partially assembled sterile barrier systems before being filled and final closure or sealing.

4.1.1 Types of sterile barrier systems

4.1.1.1 Rigid sterile barrier system

Examples of a rigid sterile barrier system

Example 1

1	Mesh tray	With or without supports
2	Wrapper	Textile, paper, nonwovens
3	Sterilization container	

Example 2

1	Mesh tray	With or without supports
2	Sterilization container	

4.1.1.2 Flexible sterile barrier system

Examples of a flexible sterile barrier system

Example 1

1	Mesh tray	With or without supports
2	Wrapper	Textile, paper, nonwovens
3	Sterilization sheeted paper	Sealed as per standard
4	Sterile supplies' tray	Allows packaging to be stacked in sterilizer

Example 2

1	Transparent reel	Sealed
2	Sterilization sheeted paper	Folded as per standard
3	Sterile supplies' tray	Allows packaging to be stacked in sterilizer

Example 3

1	Sterilization sheeted paper	Folded as per standard
2	Sterile supplies' tray	Allows packaging to be stacked in sterilizer

Example 4

1	Sterilization sheeted paper	Folded as per standard
2	Sterilization sheeted paper	Folded as per standard
3	Sterile supplies' tray	Allows packaging to be stacked in sterilizer

Multiple packaging offers greater safety since it is gradually removed (first the outer packaging, then the inner packaging). This helps remove any contamination present on the outer packaging (dust particles, microorganisms). Make sure that the dust particles released into the air do not become deposited on the sterile supplies (keep to a safe distance).

This also compensates for any micro-damage of the outer packaging.

Hence multiple packaging will be beneficial only if the proper (gradual) removal method is used.

Avoid using too many layers of packaging (e.g. rolling together) since multilayered packaging would impede entry of the sterilization agent (sterilant).

4.1.1.3 Sets' system

For hygienic reasons, as far as possible the number of sterile instruments and MDs needed per patient should be kept in a single package (set).

A package is deemed to have been used once if it has been opened and may not be reused or stored again.

No provision has therefore been made for collective packaging for several patients or for using single packaging repeatedly for a patient,

4.2 Protective packaging

The protective packaging protects the sterile barrier system and together with this it constitutes the **packaging system**. The protective packaging is the packaging configuration designed to prevent damage to the sterile barrier system and its contents from the time of their assembly until the point of use.
The external part of the sterile barrier system can also be used as protective packaging.

4.2.1 Transport packaging

Materials and preformed sterile barrier systems must be packed such that they will confer the level of protection needed to preserve the performance characteristics during transport and storage.

The transport packaging protects the sterile medical device within its packaging system against contamination, moisture and damage, etc. during transportation and, if necessary, during storage.

The transport packaging is fitted after sterilization and may be a dustproof container, which can be closed, a cardboard box, transport trolley or bag.

The sterile supplies must have cooled down before they are wrapped in the sealed transport packaging since otherwise condensate water could be formed inside the packaging. The transport packaging is removed in the sluice leading to the user's sterile supplies' warehouse. If the user has no sterile supplies' warehouse, the transport packaging is not removed until the time of use.

4.2.2 Storage packaging

Materials and preformed sterile barrier systems must be transported and stored under conditions that ensure that the performance characteristics do not exceed predetermined values.

That can be accomplished by:

a) Furnishing proof that these characteristics are preserved under the specified storage conditions, and

b) Providing assurance that the storage conditions do not exceed predetermined values.

4.2.3 Service life

The service life is the period of time during which all performance requirements are met (e.g. for reusable packaging such as containers or textiles).
If the sterile supplies are not used immediately after sterilization, they must be stored. The storage period of an item does not only depend on the packaging, but also on the handling, transport and storage conditions. After sterilization the packaging is exposed to

recontamination through dust or microorganisms on hands and clothing and this can negate sterility. The onus is therefore on the hospital infection control team to specify and define appropriate storage periods.

5 Packaging material

5.1 Reusable sterilization containers

The sterilization container is a reusable receptacle of stable shape, equipped with an inlet for the sterilant, in which the supplies can be sterilized, transported and stored in a sterile state.

The sterilization container is the ideal form of packaging for instrument sets (all constituents of the set are available at the same time for a procedure).

The sterilization container is composed of:

- bottom (section of container)
- lid
- inlet for sterilant / filter
- seal
- handles

The materials used are: chromium-nickel steel, aluminium, plastics or combinations (e.g. bottom part: aluminium; lid: plastic = hybrid).

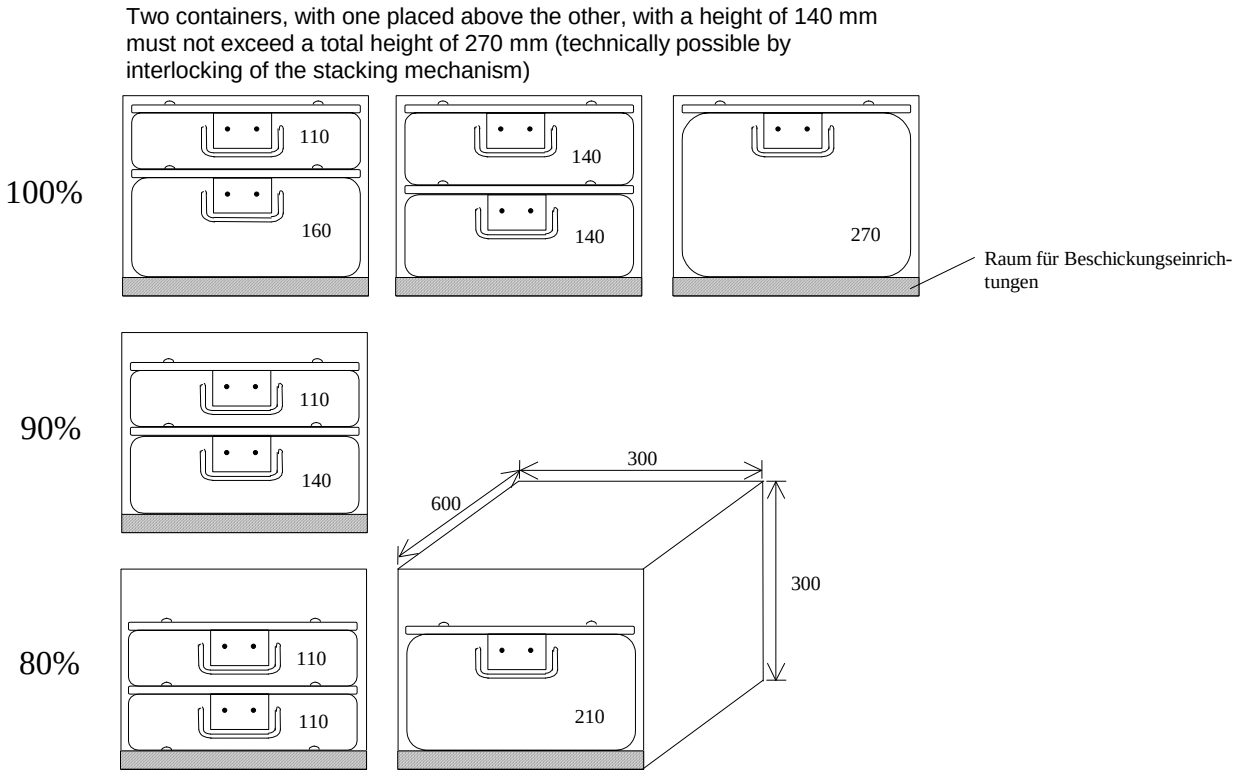
Based on the pertinent standards, sterilization containers are classified in terms of sterilization units (StUs).

One StU has the following dimensions

Height = 300 mm **X** width = 300 mm **X** length = 600 mm

1 STU = 300 x 300 x 600 mm = 54 litres

The various sterilization containers are adapted to this StU measuring unit, e.g. half containers (300x600x150 mm) or quarter containers (300x300x150 mm). Sterilization containers of the same series can be stacked one on top of the other in the sterilizer. To assure optimal utilization of the sterilizer capacity, a combination of various sizes should be used, see drawing:



Two containers, with one placed above the other, with a height of 140 mm must not exceed a total height of 270 mm (technically possible by interlocking of the stacking mechanism)

Space for loading mechanisms

5.1.1 Closure system

The lid is secured to the bottom part of the container by means of seals. It must be possible to easily detect from the sealing system whether the sterilization container has been opened after sterilization.

This is done by using:

- Single-use plastic seals
  the seal tears on opening the sterilization container
- A locking mechanism
  in this system the mechanism becomes automatically locked on exposure to heat during sterilization, a colour marking is generated (e.g. GREEN); on opening the container the system unlocks and the colour changes (e.g. to RED).

5.1.2 Inlet for the sterilant

All systems act are a barrier to microbes and particles, while also assuring air and steam exchange during the sterilization and drying process in the sterilizer. The systems are mainly integrated into the lid of the sterilization container. All other inlet mechanisms (apart from the microbial and particle barrier) must be prevented by seals. Hence the sterilant is forced to gain entry into the sterilization container through the preconfigured sterilant inlet.

Thanks to ongoing research and development, new products are constantly appearing on the market. The user must make sure that the product he chooses complies with the valid standards and is suited to the sterilization process being used.

Examples of filter systems:

5.1.2.1 Reusable textile filters and disposable paper filters

The filter system consists of an opening (normally) in the lid which is covered on the inside by filters, equipped with filter supports with perforations (= round holes) to secure the filter to the lid.

There are textile or paper filters and, as stipulated by the relevant standard, these must be tested by the manufacturer.

Functioning of reusable textile filters must not be impaired by exposure to repeated sterilization cycles or contact with detergent solutions. The manufacturer must specify the maximum number of sterilization cycles. The user must document compliance with the number of sterilization cycles specified.

Paper filters must be replaced after each sterilization cycle (= disposable device).

Note: preference should be given to single-use filters! WHY?
Since the filter is replaced after each cycle, the quality conditions shall be the same for each process. The used filter should be removed at the site of use, inspected to ensure it is in order and disposed of.

5.1.2.2 Valve filters

Sterilisation valves react to the pressure differences occurring during the sterilization process.

During the vacuum phases the valve opens upwards and the air can escape from the sterilization container.

During the pressure phases the valve opens downwards and allows steam to enter the sterilization container.

Outside the sterilizer the sterilisation valve is closed.

The condensate valve in the floor (base) pan is a further accessory for instrument containers. The condensate generated during steam sterilization drops into the sloped floor and collects in the floor drain.

5.1.2.3 Membrane filters

These are porous filters, like a fine sieve. Membranes retain small particles / microbes (example: metal membrane).

5.1.2.4 Deep filters

These are labyrinths that divert the air and steam current which is laden with particles and microbes. By directing these into areas where there are no currents, the particles exit the air and steam current and remain in the labyrinth. The principle underlying the Pasteur loop described here is a retention system providing for separation of solid from gaseous particles.

5.1.3 Handling sterilization containers

The manufacturer's instructions must be observed.

A precondition for problem-free use of sterilization containers is that

- staff have the requisite knowledge
- packing lists be available
- written (standard) operating procedures (SOPs) be available

Reusable sterilization containers must be returned to the medical devices' circuit after use.

Examples of the content of (standard) operating procedures

- information on the service life (number of cycles)
- for reusable filters:
  service life or criteria warranting filter replacement
- how inspection is to be carried out
- information on cleaning and disinfection (use of pH-neutral detergents for aluminium materials and anodized aluminium components)
- information on weight (max. weight)
- information on filling level
  e.g. 2 cm beneath the rim of the bottom section of container
- information on the filling capacity
  e.g. a hand can be easily inserted between the laundry items
- information on filling direction
  e.g. laundry items must be placed vertically in the sterilization container
- information on size and method of using the wrapping cloth
- information on special materials, e.g. for rubberware direct contact with metal components must be prevented by interposing a towel

5.1.4 Labelling sterilization containers

It must be recognizable that

- the sterilization container has been sterilized (e.g. by means of a chemical indicator)
- the sterilization container has not been opened before the sterile supplies are used

Furthermore, the following information should be carefully displayed:

- contents
- batch number or serial number for tracking purposes
- sterilization and/or expiry date
- packer

5.1.5 Accessories

The mesh tray, as the instrument carrier, is the most important component of the sterilization container.

Other accessories:

- partitions
- clamping frame
- fixing clamps
- sorting pins
- clamps
- burled mats
- supports
- container for small items

All these accessories help protect the instruments and facilitate tray arrangement.

5.2 Flexible packaging

Flexible packaging is light, adaptable and can be tailored to the shape and size of the respective item to be sterilized.

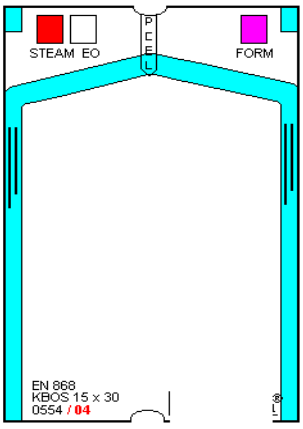
Flexible packaging is disposable packaging and cannot be reused.

Flexible packaging has an expiry date. This expiry date is generally marked on the inside of the rolls (reels) or on cardboard packaging.

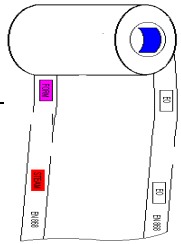
5.2.1 Transparent sterilization packaging

Transparent sterilization packaging is suitable for packing individual instruments and small sets. This packaging, which is composed of plastic composite film and sterilization paper, is available as ready-to-use pouches and reels of different sizes, with and without folds. Transparent sterilization packaging is closed using a heat-sealing method.

5.2.1.1 Transparent pouches



- withdrawal aid (thumb cut-out)
- steam, formaldehyde and EO gas indicators (process indicators = change colour during sterilization)
- as well as key to colour change
- opening symbol showing peeling direction
- label, e.g. size, normative reference
- PNSF = pouch without side fold
- PWSF = pouch with side fold
- article number / batch number / date of manufacture
- manufacturer's name and brand name



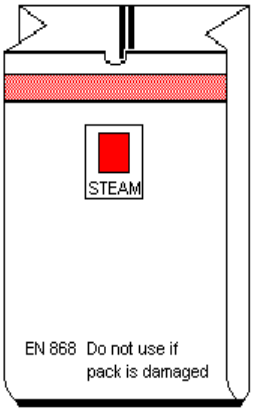
5.2.1.2 Transparent reels

This is the ideal packaging for extra long items undergoing sterilization.

- cut the reels leaving 3-4 cm excess for the top and bottom sealing seam.
- seal such that at least 2-3 cm paper / film is left over as peeling aid at the top sealing seam.
- the edges of the protruding peeling tab should not be cut since this could cause the film to roll up and would create a site where dust could accumulate!
- when packing, bear in mind the subsequent peeling direction (imprint on roll).

5.2.2 Paper pouches

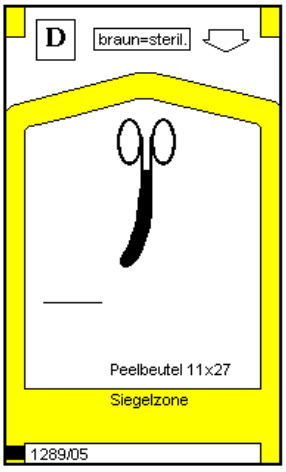
Paper pouches made of sterilization paper are an inexpensive alternative to transparent sterilization packaging. A heat-sealing method is also used to close the paper pouches. Since paper does not permit thermal melting, a coating composed of a material that will melt and, as such can be sealed, is needed.



- thumb cut-out
- heat-sealing coating, coloured and thus visible = sealing zone
- steam indicator
  (process indicator = changes colour during sterilization)
- labelling block with manufacturer's name and brand name, size and date of manufacture
- heat sealed, glued and double-wound base

The packaging can be opened only with a scissors (tearing can lead to contamination of the sterile supplies due to unsterile paper particles emitted from the outside of the packaging).

5.2.3 Paper peel pouches



The paper peel pouch (PP pouch) has been developed as an alternative to the transparent pouch.
The paper peel pouch, like the paper pouch, is composed of sterilization paper but is peelable thanks to its properties.
The paper peel pouch features symbols for standard instruments.
However, the PP pouch cannot completely replace transparent packaging since for some special instruments the contents of the packaging must be visible.

5.2.4 Sterilization sheeted paper

Sterilization sheeted paper is mainly used to pack bigger sterile supplies (instrument and/or laundry sets) and is an alternative to sterilization containers.
Since it can be opened without posing a risk of contamination only if a correct folding method is used, this type of packaging is suitable only if staff have the necessary practical skills

When using sterilization sheeted paper the folding method specified in the relevant standard must be observed!

The inner packaging can be used as a sterile base (certain textiles are unsuitable because of the poor microbial barrier characteristics).

The size of the paper sheets used for wrapping is based on the size of the objects to be packed. The length of the edge of the paper sheet serving as outer packaging should be 10-20 cm longer than the paper sheet used as inner packaging.

When packing, the forces generated during sterilization must be borne in mind. Attention must therefore be paid to ensuring that the sterilization paper is not stretched tightly over either the instruments or over the edges of the instrument trays, but rather that it fits loosely, so that the packaging is free to move in tandem with the pressure changes arising during sterilization.

Handling tips:

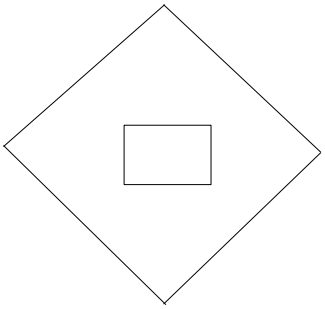
- having different-coloured inner and outer packaging is advantageous (users can immediately recognize whether the outer wrapper has already been removed)
- the use of sterilization trays facilitates stacking and enhances safety during transport

The following packing techniques are to be used:

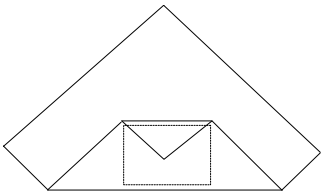
a) Diagonal packing

b) Parallel packing

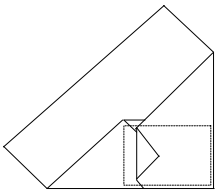
5.2.4.1 Diagonal packing



Packing sequence 1



Packing sequence 2



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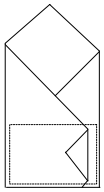

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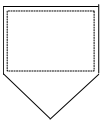

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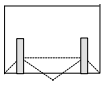


Packing sequence 6

Packing sequence 1

The item to be sterilized is placed in the centre of the sheet of paper such that its edges are at a right angel with the diagonals of the sheet of paper.

Packing sequence 2

The sheet of paper is pulled upwards across the breadth of the item to be sterilized (e.g. sterilization tray) and folded back parallel to the longitudinal edge such that the item to be sterilized is fully covered. A triangle is now formed (point), providing for opening under aseptic (handling that ensures sterility) conditions.

Packing sequence 3

Proceed as in Fig. 2, but now working from the right and from the left.

Packing sequence 4

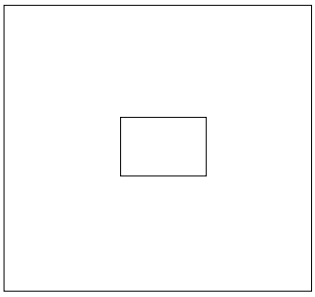
An open pocket is now formed at the top of the package on a longitudinal side.

Packing sequence 5 and 6

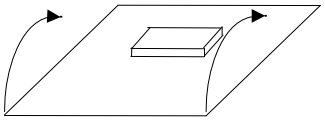
The last part of the sheet of paper is now pulled over the object to be packed and the point of the paper is inserted into the pocket until it just about sticks out.

The paper is then closed with adhesive tape and/or indicator tape. Observe the manufacturer's instructions for using the adhesive tape.

5.2.4.2 Parallel packing



Packing sequence 1



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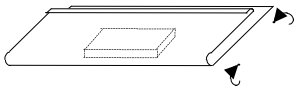

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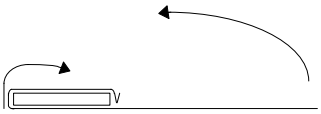

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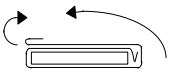

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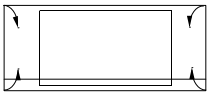
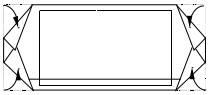


Packing sequence 6



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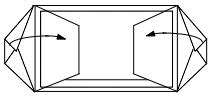
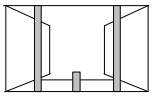


Packing sequence 8

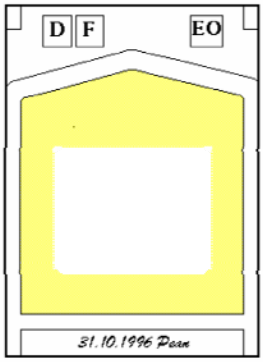


Packing sequence 9

Packing sequence 1 Place sterilization supplies (e.g. instrument tray) on centre of paper	**Packing sequence 5** Fold edge of paper outwards; the paper closes with the front upper edge
Packing sequence 2 Place front of paper over the instrument tray	**Packing sequence 6,7 and 8** Fold paper at the side and place over the sterilization supplies (e.g. instrument tray)
Packing sequence 3 Fold edge of paper outwards, around as high as the sterilization supplies	**Packing sequence 9** Secure paper with adhesive tape and indicator tape
Packing sequence 4 Fold back of paper forwards	The packages thus assembled are then secured with adhesive tape with or without treatment indicator

5.2.5 Labelling flexible packaging

The outside of the sterile supplies packaging must be labelled so that the consumer can clearly recognize that this package has been exposed to a sterilization process. The following information must be given additionally:



- contents
- batch number or serial number for tracking purposes
- sterilization date and/or expiry date
- packer

In principle, flexible packaging should never be labelled with pointed, hard pens (ballpoint pen, pencil).
Sterilization-proof felt pens are suitable for this purpose. However, since these often use ink containing potentially toxic solvents, these must never be used to label the sterilization paper inside the package. This is because there is a risk of the ink penetrating the packaging or the labelled sites would no longer be impermeable to microbes.
Consult the manufacturer of the packaging material as regards the type of pen to be used for labelling.

5.2.6 Labelling transparent packaging

Always outside the enclosure accommodating the sterile supplies e.g. in the floor region
Beneath the sealing seam

5.2.7 Labelling sheets of paper

Here, too, one should avoid direct labelling of the paper itself since ink-containing solvents could penetrate the paper and contaminate the enclosed supplies. The ideal solution is to affix adhesive labels to the fixing or autoclave tape.

5.3 Packing aids

A packing aid is not a form of sterile supply packaging endowed with barrier performance properties, but it underpins that function (e.g. protective containers, wrapping cloths, protective caps for sharp objects, sterilization trays).

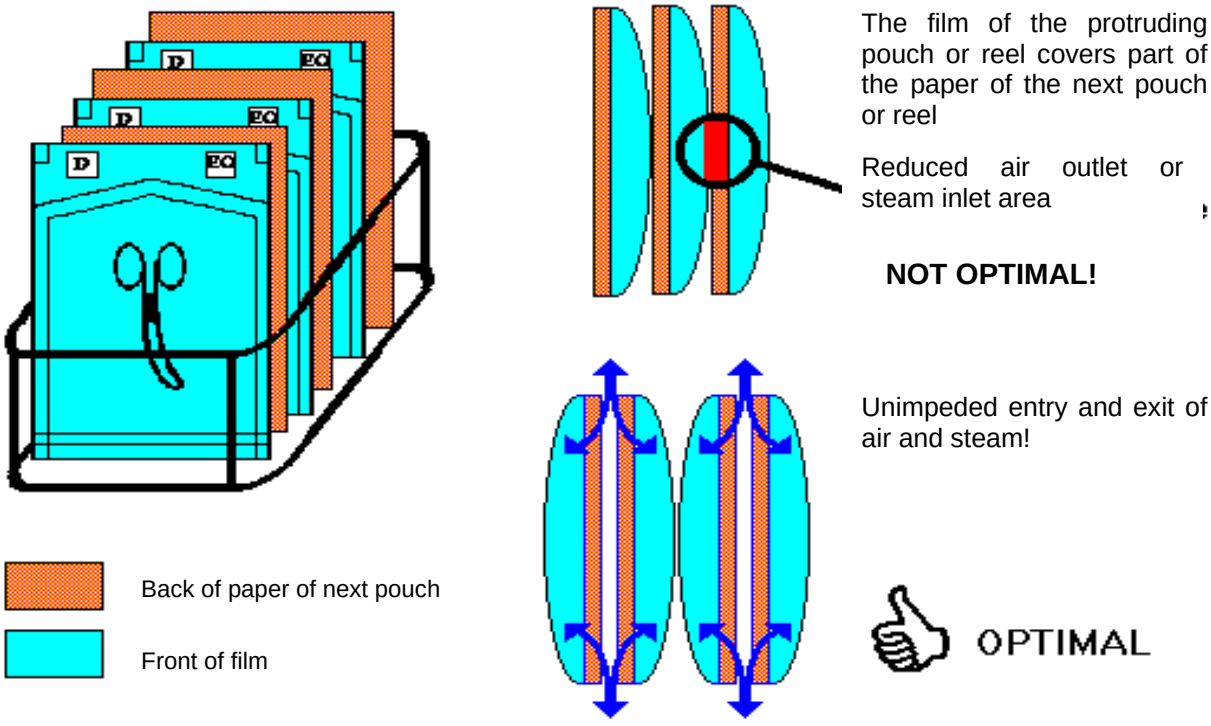
5.3.1 Towels without barrier performance for use as inner wrapper

Die inner wrapper makes it easier for the user to remove sterile supplies from the packaging. This must be done in a manner that ensures that recontamination is ruled out. This removal method is known as aseptic presentation (= an opening technique that preserves sterility)**.**

5.3.2 Sterilization trays

How to “properly” load sterilisation trays with transparent sterilization packaging is something that is discussed time and again. On the one hand, the alternating method whereby “film side against film side, paper side against paper side” is recommended but, on the other hand, the “film side against paper side” is also advocated.

The manufacturer’s instructions must absolutely be observed.



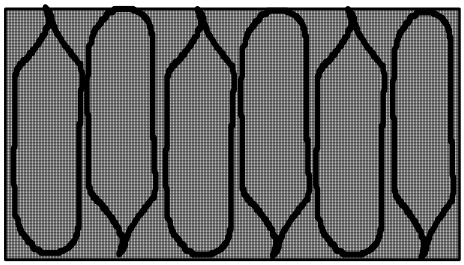
(Figure 2007.06.11. from internet scheer_dü_0107[1])

Examples of the content of operating procedures

- information on the load weight (maximum weight)
- information on the filling height e.g. do not fill beyond the rim
- information on the filling direction
  e.g. place sterilization packaging vertically in the sterilization tray

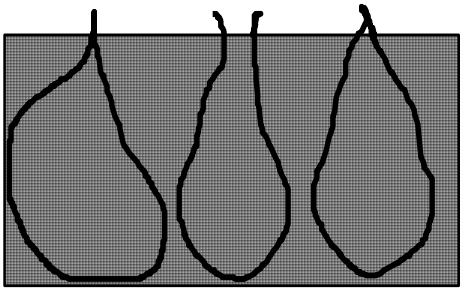
- information on special materials
  e.g. place heavy individual instruments horizontally (this helps distribute the weight contents over a greater surface)
- information on the filling capacity
  e.g. a hand can be easily inserted between the laundry items
- e.g. fill sterilization trays completely to prevent “bursting”

CORRECT



The sterilization tray is optimally loaded, and the items of flexible packaging can bestow mutual support during sterilization

INCORRECT



Too few items of flexible packaging in the sterilization tray
Sealing seams, adhesive seams or adhesive sites could tear

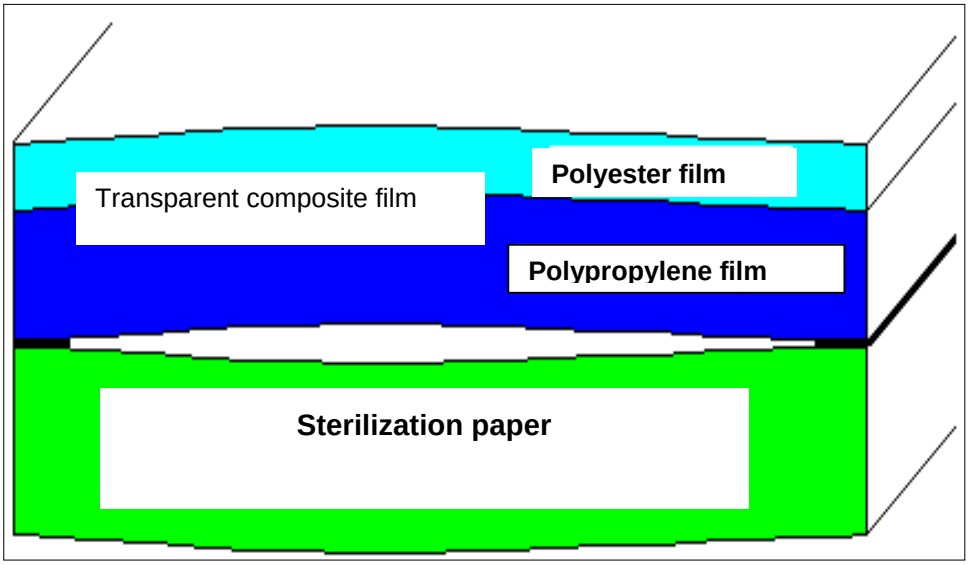
5.3.3 Autoclave tape

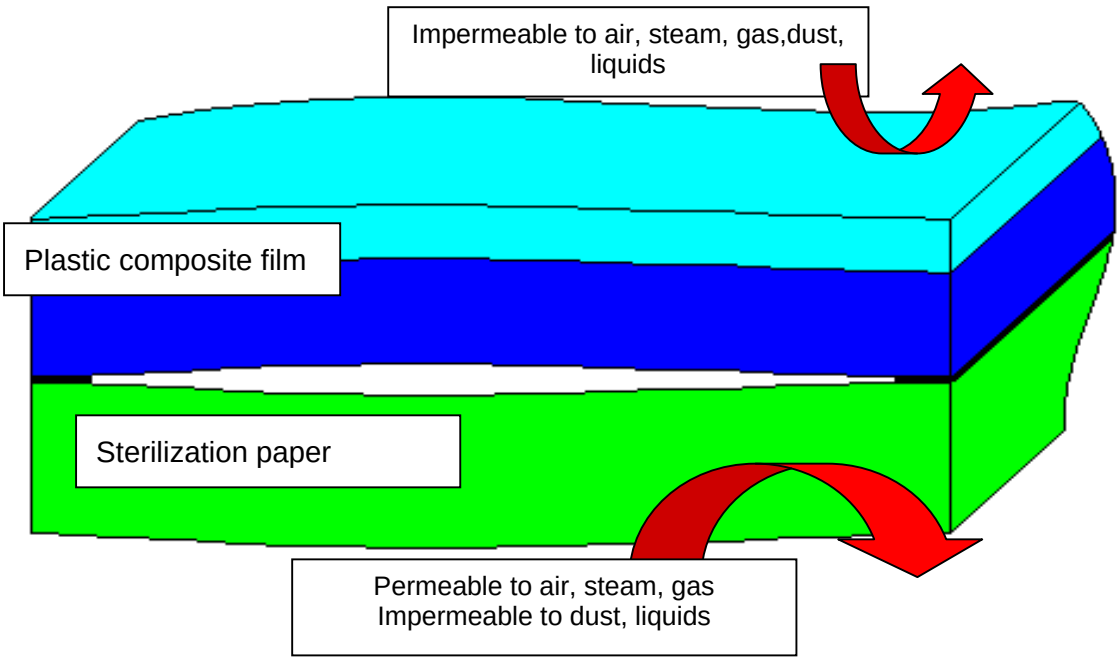
Autoclave tape is used to secure the sterilization sheeted paper and is available with and without an indicator strip.
The crêpe material of which the tape is made expands during sterilization, thus preventing bursting of the packaging.
The manufacturer’s use instructions must be observed. There may be length restrictions when using the autoclave tape with indicator.

6 Material science

6.1 Plastic composite film

This is a transparent composite film comprising at least two different layers (e.g. inner layer of polypropylene and outer layer of polyester).
Plastic composite film is impermeable to liquids, air and gases. Therefore air exchange has to take place across the paper side.



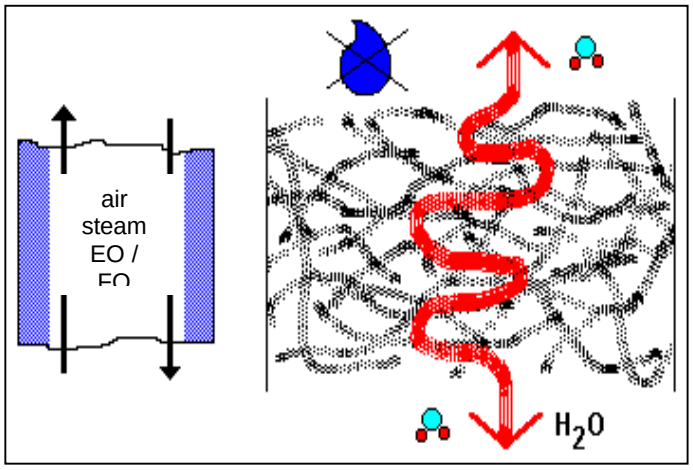


6.2 Sterilization paper

This is used for production of transparent sterilization packaging, paper bags or sterilization sheeted paper. It is made of cellulose fibres that are held together by means of waterproof glue. Thanks to this waterproof glue the paper is able to tolerate the sterilization process (permeable to air and the sterilant, but impermeable to particles and liquids). Aggressive liquids such as alcohol or disinfectants destroy the waterproof glue and, as such, also the barrier performance. Therefore the sterilization paper must never come into contact with these liquids.

The sterilization paper's special properties - permeable to air and the sterilant, but impermeable to particles and liquids – is assured by virtue of predetermined pore sizes.

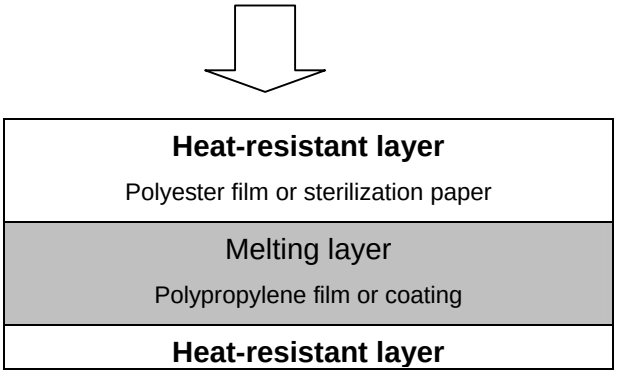
When we speak about "pores" we certainly do not mean "passages". If air or steam molecules pass through the paper structure, this would constitute a labyrinth passage that cannot be crossed by bigger particles (e.g. dust) or water drops (= microbial carriers – this is the principle on which the paper's filter effect is based!
pores do not "open and close "



7 Sealing

7.1 The sealing process

After filling, transparent sterilization packaging (pouches, reels), paper pouches and paper peel pouches are closed using a heat-sealing method. This is done with special heat-sealing devices specifically designed for sterilisation packaging (this is different from the foil sealers used in private households).



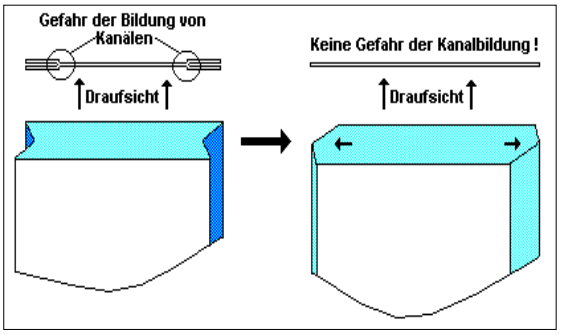
Sterilization paper

In the heat-sealing process a layer interposed between two (other) layers of materials is heated to melting point, pressed together while exerting force and then left to cool down – this causes the different layers of material to stick together. This process is called thermal melting. In the case of transparent sterilization materials, the inner layer of film (polypropylene) melts, while in paper pouches and paper peel pouches it is the coating that melts.

The quality of the sealing seam is a function of the parameters set on the heat-sealing device (temperature, pressure). The sealing temperature can be different for each product (see specifications in the manufacturer's technical data sheet). The most common sealing temperatures are between 150°C and 220° C.

The sealing seam must be continuous, even and free of any faulty sites.

The sealing seam width of the closing seam must be at least 8 mm.



Risk of channel formation
Draufsicht = top view
No risk of channel formation

The sealing seam is composed of either a continuous sealing seam or of 3 to 4 fine grooves (whereby the sum of the area of the grooves must also be at least 8 mm). Individual grooves are easier to peel and are more noticeable (colour difference).

An optimal sealing seam is always a compromise between strength and better peeling characteristics.

When using flexible packaging with a side fold, channel formation in the transition region from 2 to 4 layers must absolutely be avoided.

7.2 Releasing the sealing device

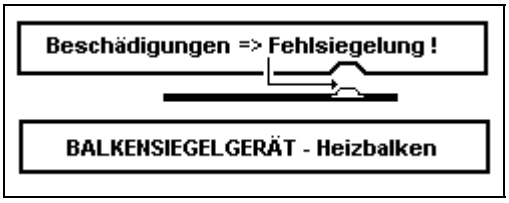
The sealing device must be inspected each day before it is placed in operation and then released for operation throughout the day (documentation!).

Quick and objective verification of the criteria contact pressure and sealing temperature.

There is also equipment for testing heat-sealing devices for safe and continuous validation of sealing processes as per ISO 11607/EN 868-5.

The sealing device must be maintained in accordance with the manufacturer's instructions and must be inspected at regular intervals.

7.3 Impulse or bar sealing devices



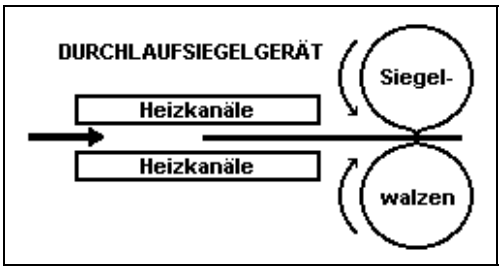
Beschädigungen = Fehlsiegelung = Damage = Faulty sealing!
BALKENSIEGELGERÄT – Heizbalken = BAR SEALING DEVICE – hot bars

These devices seal by means of sealing bars between which the sterile supply packaging is inserted.
These are easy to use and inexpensive devices.

Bar sealing machines are very susceptible to damage, and in such a state a uniform sealing pressure, and hence uniform sealing seam strength, can no longer be assured.
Such devices should not be used for medical device packaging.

7.4 Rotary sealing machines

These devices automatically draw the packaging through a heating channel and then through two rotating sealing rollers.



DURCHLAUFSIEGELGERÄT = ROTARY SEALING MACHINE

Heizkanäle = heating channels

Siegelwalzen = sealing rollers

Continuous dotted sealing as effected by sealing rollers is less susceptible to minor damage and to wear and tear of the sealing rollers.
An integrated printing mechanism for labelling the sterilisation packaging facilitates documentation and permits labelling of the sealing seam during the sealing process.

8 Validation

There is an international standard for validation of packing processes:

EN ISO 11607-2: Validation requirements for forming, sealing and assembly processes.

Validation consists of
1) Installation qualification
2) Operational qualification
3). Performance qualification

8.1 Installation qualification

This demonstrates that the instrument was supplied and installed in accordance with its specifications. Identification of the critical parameters.
Example – sealing device: perfect condition, suitable for sealing, suitable installation site (pay attention to environmental conditions!)
The device is properly connected to a power supply; appropriate operating procedures and qualified staff are available
Alarm systems if critical parameters are infringed
Calibration, maintenance and cleaning policy required

8.2 Functional qualification

This demonstrates that the instrument operates within predetermined limits.
Critical process parameters:
- Sealing temperature,
- Pressure and time

A test specimen must be obtained using the predetermined limits.

8.3 Performance qualification

The medical device consistently performs under the specified operating conditions in accordance with predetermined criteria.
Inspection of the test specimen = performance qualification
- Sealing seam size
- Strength,
- Peeling characteristics

Quality assurance is based on regular checks carried out during routine operations!
Revalidation is needed if:

- changes have been made to the device or packaging materials that could adversely affect the sterility, safety or performance of the sterile medical devices.

9 Practical exercises

In the practical part, theoretic knowledge is to be supplemented with practical exercises and application of the packaging techniques learned or studied in greater depth. Participants will have an opportunity to discuss in detail any queries they have.

Practical exercises should be conducted under the supervision of persons who have the requisite expertise.

Examples:

- folding techniques
- sealing
- types of packaging
- inspection of sealing seams (visual inspection, ink, carbon, sealing seam strength, etc.)