

Stericlin[®] informs:

- Sterilisation packaging
- Structure - Testing - Application
- Multiple-packs
- Storage
- Removal



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Table of Contents

	Page
Notes to the English translation	1
0. Packaging - a Life or Death Matter	1
1. Description of Materials	3
See-through Pouches - Composite Films	3
Sterilisation paper	4
Micro-organism Impermeability Test	5
Important Rules	6
2. Marking of Sterile Packs	6
3. Sterilisation Methods and Appropriate Packaging	6
4. See-through Packages EN 868-5 / DIN 58953-4 - Handling	7
5. Loading Techniques	9
6. Sealing units and Sealing	9
7. See-through Packaging made with TYVEK [®] EN 868-9	10
8. Sterilisation Wrap EN 868-2	11
9. Gusseted Paper Bags EN 868-4 / DIN 58953-3	12
10. Stericlin Paper Peel Pouch EN 868-1	12
11. Effects on the Environment - Recycling	13
12. Multiple Packs and Times of Storage	14
13. Multiple Packs - Ways of Combination	16

NOTES TO THE ENGLISH TRANSLATION

Reference is made throughout this paper to the German standard DIN 58953. Readers may be more familiar with the British Standards BS 6256, 6257 & 6871 (and also the prEN 868 series).

In terms of technical specification there are only minor differences between the published standards and indeed VP Stericlin products are tested for conformity to both standards. However the British Standards are descriptive standards only, whereas the DIN standard also includes guidelines for use and application.

As leading suppliers of Hospital Sterilisation Packaging over a period of 30 years, we have included our own experiences and recommendations to produce this information booklet to complement the "official" standards.

0. PACKAGING - A LIFE OR DEATH MATTER

From a very early age, we are all taught a healthy respect for bacteria! We know how sturdy, tough and resilient bacteria are: we also know that the only sure way to counteract them is by "STERILISATION".

A fairly simple concept in principle, but the secret of effective sterilisation is to ensure that a medical device once sterilized maintains that sterility up to the point of use. In the context of healthcare procedures, effective sterilisation requires a packaging material.

If sterility is to be maintained, the packaging material used needs to be a proven bacterial barrier. Instruments, devices, dressings, etc. all need to be sterile at the point of use. To achieve this in today's healthcare environment requires effective packaging.

Very few of us give much thought to the packaging of an operating procedure pack or a single-use syringe. We generally take it for granted that whatever is removed from a pack which has been subjected to a sterilisation cycle is actually sterile when used. What is it that gives us this level of confidence? In short - it can only be the packaging and its integrity!

Without the development of medical packaging materials, the range of devices, packs and kits which accompany the development of increasingly specialised operating techniques would not be possible. It is a point of debate as to whether or not current standards of healthcare practice would be feasible without the availability of a sophisticated range of specially developed packaging materials. Continuing technical development of packaging materials will lead to further improvements within the medical device industry and the hospital.

Sterility is an event-related rather than a specifically time-related function. Packaging suppliers are regularly asked to indicate product shelf-life in terms of time. Providing a relevant and accurate answer to this question is, however, far from easy. Maintenance of pack sterility is not only dependent on the packaging material and the method of sterilisation: it is also dependent on handling, transport and storage conditions. Packs are exposed to dust and airborne micro-organisms and to organisms on the hands and clothes of "handlers" following sterilisation: during transportation to clinic, ward or operating room: during storage and during opening. The degree of contamination varies according to the level of activity i.e. the number of airborne organisms is highest during periods of intense activity. Maintenance of sterility is, therefore, directly related to the ability of the packaging to prevent organisms from reaching the pack contents, to resist physical damage and to the way in which packs are handled during transport, storage and use.

Inadequate packaging will lead to a loss of product sterility which in turn can have a devastating effect on the rate of hospital post-operative infection.

Having established the fact that packaging performs the essential function of protection, we need to consider the long-held view that the level of protection is considerably enhanced by using a minimum of two layers - in other words by double packaging/wrapping.

The vast majority of hospital and industrial packers currently use a double packaging technique without really knowing why - just because it has become the established custom and practice. In today's economic environment where all providers of healthcare products and services are under considerable pressure to reduce costs, it may be viewed as an easily achievable cost saving to cut back on the volume of packaging by eliminating the second layer! Are you - as a healthcare provider - prepared to accept the risk of patient safety of such a move? Are you - as a patient - prepared to accept the risk to your safety of such a move?

Why should packaging with only a single layer be considered as a risk to patient safety? In a nutshell - because it could lead to increased risk of contamination.

Throughout the healthcare industry within Europe, it has long been a recognised fact that packaging is a vital element in the campaign to reduce contamination and consequently infection. Many studies have been made in the area of nosocomial infection: packaging has proved to be an essential factor in the reduction and control of such infections.

In today's climate of strict budgetary control, it is easy to suggest that the established custom and practice of double packaging is not perhaps quite as essential as it was! Consideration, however, of trends in respect to levels of cross-infection within healthcare establishments should provide adequate evidence of the fact that any move to eliminate a layer of packaging is detrimental to the maintenance of an appropriate and acceptable level of healthcare.

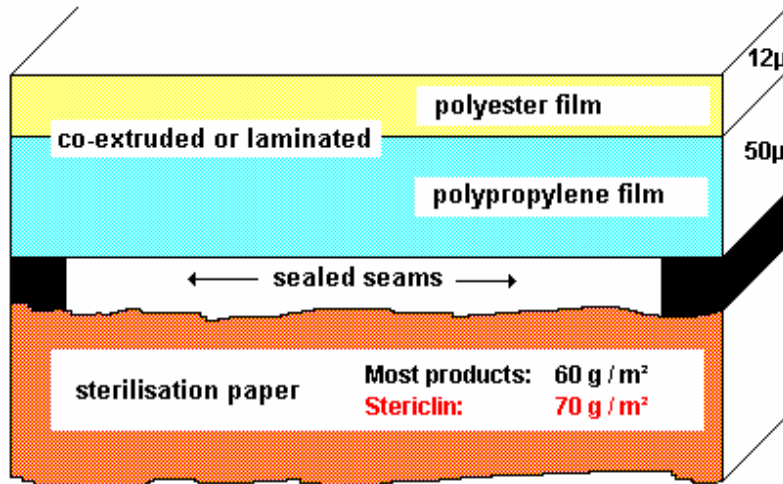
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In the following report the various types of packages and their construction and function are presented after a detailed description of the materials used. It is our intention to explain clearly some well known standards and recommendations concerning handling, which sometimes seem to be overstated. If certain standards and procedures are repeated it is because they refer to the topic being discussed, even if they are also covered in other chapters. In the second part of the report, principles of multiple packages and storage are explained and recommendations for the appropriate removal of sterile items are given.

1. DESCRIPTION OF MATERIALS

SEE THROUGH PACKAGES (referred to hereafter as "pouches")

Pouches can be used as a good example to explain the design and function of sterile packages. For these packages materials conforming to EN 868 and DIN 58953 for sterile packages are used.



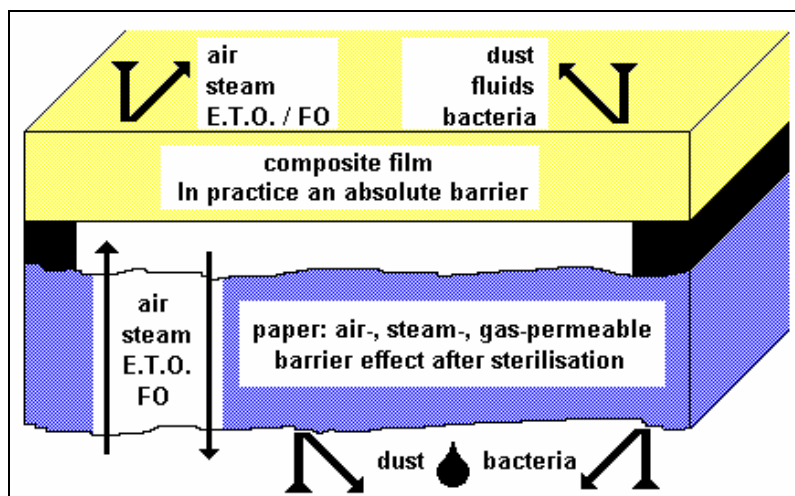
COMPOSITE FILMS

Composite films used for steam sterilisation pouches according to EN 868-5 and DIN 58953 consist of polyester (PETP) and polypropylene. In comparison to paper the composite film is very homogeneous; in the drawing this is shown by even surfaces.

Film and paper are bonded by heat-sealing. During the sealing process the inner polypropylene film softens (=> sealing temperature 180° - 200°) and bonds to the paper. The result is a sealed seam resistant to mechanical loads and bacteria.

Industrial packers who sterilise with EO-gas and γ -rays are supplied with pouches made out of a polyester/polyethylene composite film (PETP/PE). PETP/PE film cannot be sterilised by steam and therefore is not used in hospitals - with one exception - for the newly developed low temperature plasma sterilisation, pouches made of TYVEK® and PETP/PE films are required.

PETP/PP and PETP/PE composite films are derived from crude oil cracking and do not contain chloride as PVC does. Therefore they cannot form dioxins and furanes when incinerated or land-filled. When land-filled, composite films do not harm the ground water and when incinerated they do not give off noxious substances.



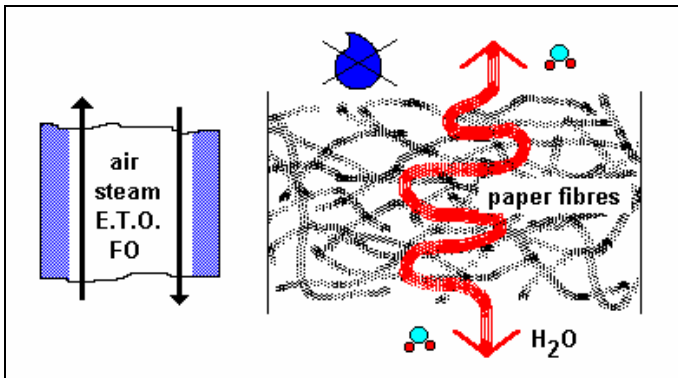
Composite films are essentially impermeable to liquids, air and gas and therefore 100% impermeable to bacteria.

As a result of this, strict rules regarding double-packages (paper to paper, film to film) and recommendations for loading of sterilisation baskets have to be followed. (See Chapter 5)

STERILISATION PAPER

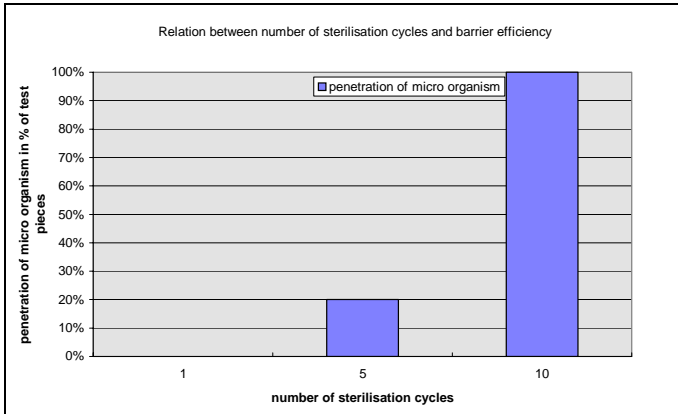
Sterilisation paper consists of a complex of cellulose fibres. For sterilisation paper especially long and strong fibres are used which leads to high mechanical stability. The cellulose fibres are formed into a sheet with water resistant size. Water resistant size is needed to make the paper sterilisation resistant and to avoid penetration of water during storage. The penetration of liquids into the package would lead to contamination.

The filter effect of the sterilisation paper is shown by the above drawing. The special filter effect of the sterilisation paper - pervious to air and sterilisation media, but not to micro-organism bearing particles and liquids - is achieved by a defined porosity based on the selected fibres and the special fabrication of the paper.



“Pores” are not linear passages. When air and water vapour molecules penetrate the paper structure they have to move through labyrinthine passages which cannot be penetrated by bigger particles or drops of water (= bacteria carrier). This is the filter effect of the paper.

It is quite wrong to believe that the pores open and reclose during autoclaving. However the question arises as to why sterilisation packages may not be sterilised for a second or several times. This question can easily be answered by a test evaluation:



The sterilisation paper used by VP Stericlin is guaranteed bacteria resistant for one sterilisation. After 5 sterilisation processes 20% of the test pieces showed penetration of bacteria and after 10 sterilisation processes all test pieces were contaminated.

When sterilised several times sterilisation papers lose their barrier effect - therefore:

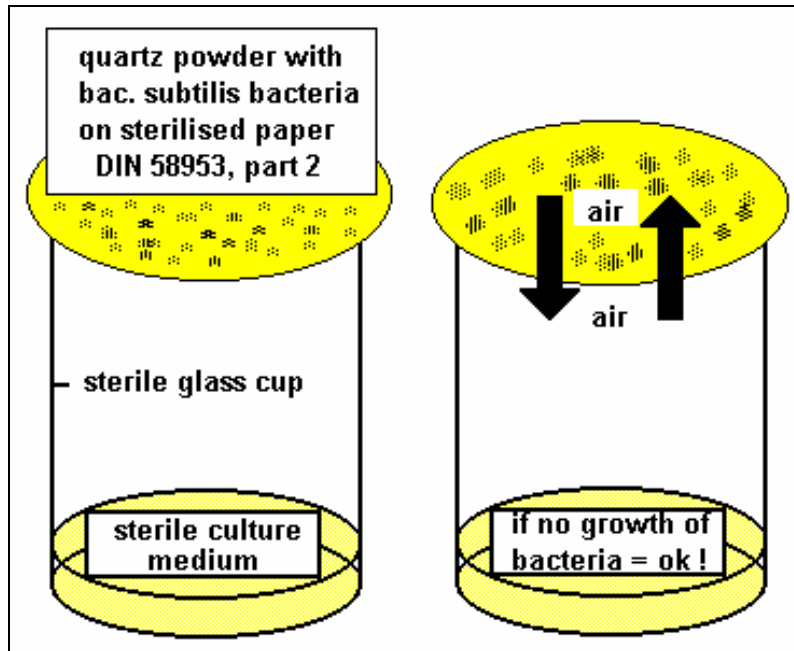
- **Safety first - Sterilise packages only once in accordance with the imperative advice of EN 868 and DIN 58953, Part 7 !**

During sterilisation, especially during steam sterilisation, the sizing and the fibre structure of the paper have to stand a lot of stress. After one sterilisation the paper is reliably resistant against bacteria. This is constantly tested. After repeated sterilisations the barrier effect is reduced - therefore sterilise packages only once.

You will certainly be interested now how sterilisation papers conforming to DIN 58953, Part 6 are tested for impermeability to micro-organisms.

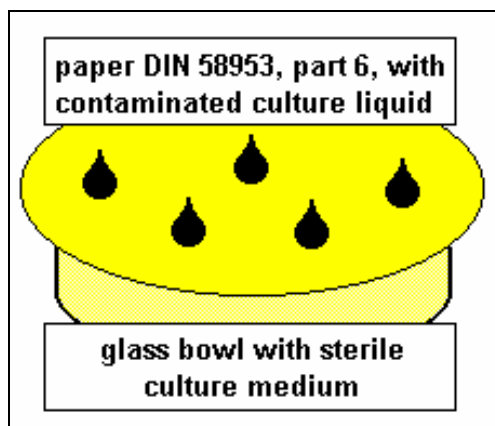
MICRO-ORGANISM IMPERMEABILITY TEST

Micro-organism impermeability test in dry conditions, DIN 58953, part 6:



A sterile glass cup containing a culture medium is covered with sterilised paper which is contaminated from outside. The glass cup is heated up to 50°C and then cooled down to 10°C in an incubator. A vacuum is created inside the glass and air is taken in through the contaminated quartz powder and the paper. After having repeated this procedure 5 times the culture medium is grown. No growth of micro-organisms should be evident.

This test arrangement simulates the constant air penetration through the packaging material during storage of sterile products. Pressure differences are created by atmospheric air pressure variations (high - low - high) and changes of the air pressure in small rooms, e.g. door opening.



Bacteria impermeability test under moist conditions, DIN 58953, Part 6:

5 drops of a culture medium/liquid with a defined amount of bacteria are placed on each test piece and dried for 6 hours.

If there is any penetration, a second test is made.

If a second test is necessary, DIN 58953 accepts papers that show penetration of bacteria on only 20% of the test pieces (of 25 test pieces).

Why does VP-Stericlin use papers with a substantially higher substance ?

High quality sterilisation papers have 0% penetration of bacteria during the bacteria impermeability test in moist conditions - the sterilisation paper used by VP-STERICLIN consistently shows zero-growth. Our philosophy of patient safety determines that we use a paper with a higher substance. In this regard following quotation out of DIN 58953, Part 2, Item 3.4 is relevant:

"Remark: The required qualities of sterilisation papers can be more safely achieved with higher substance because inhomogeneities of the paper fabrication as well as variations of the substance due to technical conditions have to be taken into account regarding the safety of the sterile goods."

Stericlin pouches are manufactured with 70g/m² paper which guarantees a higher mechanical strength. Furthermore the important barrier qualities can be more safely achieved - a heavier and therefore thicker paper offers more security against penetration of bacteria.

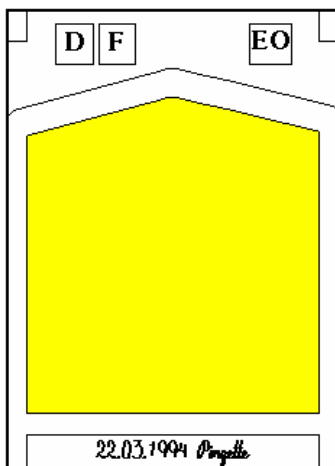
The DIN method tests bacteria impermeability under moist conditions over 6 hours - in practice residual moisture is only allowed for 30 minutes (DIN58953, Part 7). DIN 58953 is therefore providing a safety margin because during storage further impacts of moisture can occur (higher air humidity for short time, accidental contamination with water drops) for which a safety margin is required.

Sterilisation paper offers short time protection against wetting with water and therefore contamination of the sterile goods. Aggressive liquids like alcohol, disinfectants etc. on the other hand, destroy the water resistant sizing leading to a quicker reduction of the filter effect against bacteria.

Summary of important rules:

- **Use/sterilise sterilisation packaging only once**
- **Re-pack after interrupted sterilisation process or after expiry (DIN 58953, clause 7.9)**
- **Packages that are still moist 30 minutes after sterilisation have to be regarded as not sterile and therefore must be separated and re-packed!! (DIN 58953, clause 7.7)**
- **Packages containing residual moisture should never be touched, or only with disinfected hands**
- **Humidity and water drops must be avoided during storage.**
- **Storage conditions: ordinary room climate with 15°-25°C, 40 - 60% RH, short time and non condensing max. 70% RH.**
- **Avoid: contact with disinfectants. Take care when disinfecting sterile storerooms and cupboards.**

2. MARKING OF STERILE PACKS



In general sterile packs should not be marked with sharp or hard writing utensils (pen, pencil). Soft and sterilisation resistant markers are recommended. As for these markers, often solvent based colours with possibly toxic ingredients are used, so avoid writing inside the filling area because the colours may penetrate and/or make the inscribed zones pervious to bacteria. Therefore it is important to get used to always marking the packs beyond the filling area in the lower part below the heatseal.

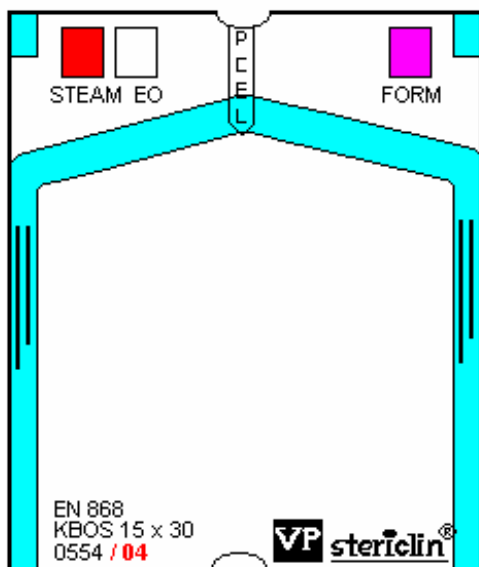
Pouches can also be marked on the film within the filling area because the film is impermeable. This is the only exception to the rule.

3. STERILISATION METHODS and APPROPRIATE PACKAGING

Packs according to EN 868 & DIN 58953 are suitable for the common methods of sterilisation in hospitals: steam, EO-gas and Formaldehyde. Due to the characteristics of the materials used the packages differ in their suitability for the different sterilisation methods. The recently introduced low temperature plasma sterilisation requires totally different packaging due to its effect on organic materials. The following schedule shows clearly the suitability of the sterilisation packaging for different sterilisation methods.

sterilisation: packaging:	steam	formaldehyde	E.T.O-gas	H ₂ O ₂ -plasma	hot air
see-through EN 868 - 5	yes	yes	yes	no ¹⁾	no ²⁾
wrapping paper EN 868 - 2 paper bag EN 868 - 4	yes	only partly recommended ³⁾	yes	no ¹⁾	no ²⁾
TYVEK® + PETP / PE	no ⁴⁾	very good ⁵⁾	very good ⁵⁾	yes	no ²⁾
PA-film	no	no	no	no	yes
PETP / PE:	polyester / polyethylene				
TYVEK®:	spun bonded polyethylene fibres, high resistance to tearing, excellent barrier qualities, lowest adsorption of sterilisation gases				
PA:	polyamide (nylon), air impervious, only for dry heat				
1)	The H ₂ O ₂ - low temperature plasma sterilisation method is incompatible with the cellulose of the paper, therefore no paper based packaging.				
2)	All paper packages are not sufficiently heat resistant and therefore inflammable.				
3)	Paper-Film-Pouches maintain lower residual Formaldehyde than pure paper packages.				
4)	TYVEK® as well as PE-films are not resistant to the temperatures during steam sterilisation!				
5)	TYVEK® absorbs in comparison to paper 100 times less formaldehyde or E.T.O-gas = lower residues, shorter degassing times.				

4. SEE-THROUGH PACKAGES EN 868-5 / DIN 58953-4 - Handling



thumb cut-out

non-toxic steam, ETO-gas and formaldehyde indicators as well as explanation of indicator colour change with peeling direction

printing details:
manufacturer and brand name, description/size, VP article/batch number (or date of manufacture)

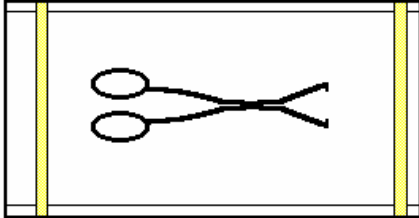
thumb cut-out

Advantages of see-through pouches:

- Good visibility of the sterile goods
- Opening and sterile removal is possible by peeling
- Unrestricted suitability for steam, ETO gas and Formaldehyde sterilisation
- Easy and safe sealing with rotary sealing machines
- Thumb cut-out enables easy filling and peeling; opening should be started from the point of the chevron seal
- See-through pouches are often cheaper than see-through reels especially when taking into account possible wrong cut-offs and the additional work.!

- The filling of see-through pouches and reels should not exceed $\frac{3}{4}$ of the package length otherwise adequate sealing is not possible and the risk of the package bursting increases.
- In case of multiple packs it is necessary to pack paper to paper because penetration of air and steam is only possible through the paper side .

Special advice for see-through reels:



The ideal package for over-length items. Cut the see-through reels with an additional 3-4cm for the top and bottom seal. When sealing keep 2-3cm paper / film free above the top seal in order to facilitate easier peeling. The corners with the extended side seal tabs should not be cut off because this would allow the film to curl back and create a space where dust can collect.

If the seal strength is too high (see page 10, 6. sealing units and sealing) the pouches cut from the reel cannot be peeled without leaving fibre residues or because the film tears. Therefore test your seals and reduce the seal strength by reducing the sealing temperature.

Bursting of see-through pouches

Under some critical conditions see-through pouches can burst during sterilisation. There could be several reasons:

1. The pouch is overloaded; the contents put stress on the seals and the pouch billows out.
2. The steriliser evacuates too fast - steriliser manufacturers often try to increase the process speed by quick pressure changes (pre-vacuum, proceeding to drying phase), which leads to more or less inevitable bursting of the packs. In this case install a reduction valve in the vacuum suction pipe (an easy and cheap solution).
3. When using containers the consequences may not be obvious but be careful - filters can tear leading to non-sterility of the container.
4. When loaded with textiles, pouches can burst even when handled correctly. Textiles hold the air longer inside the pack (like a sponge). During the fractionated vacuum the pack is inflated like a balloon and may burst. In this case it is better to use pure paper packs which can ventilate air all over their surface. See-through pouches on the other hand, having one half made of impermeable film, can only ventilate air through half their surface.

Remark.

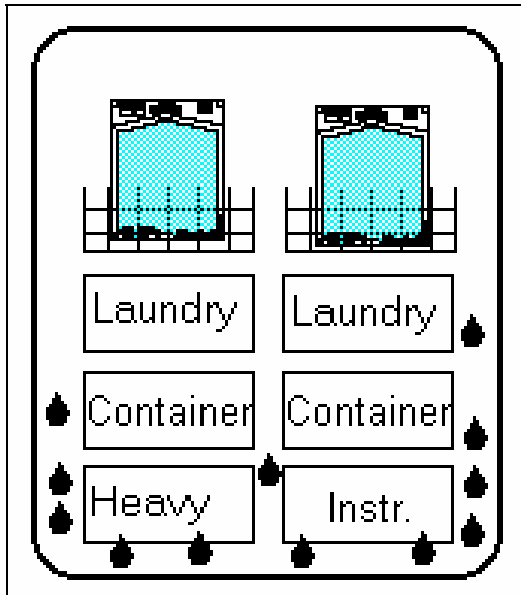
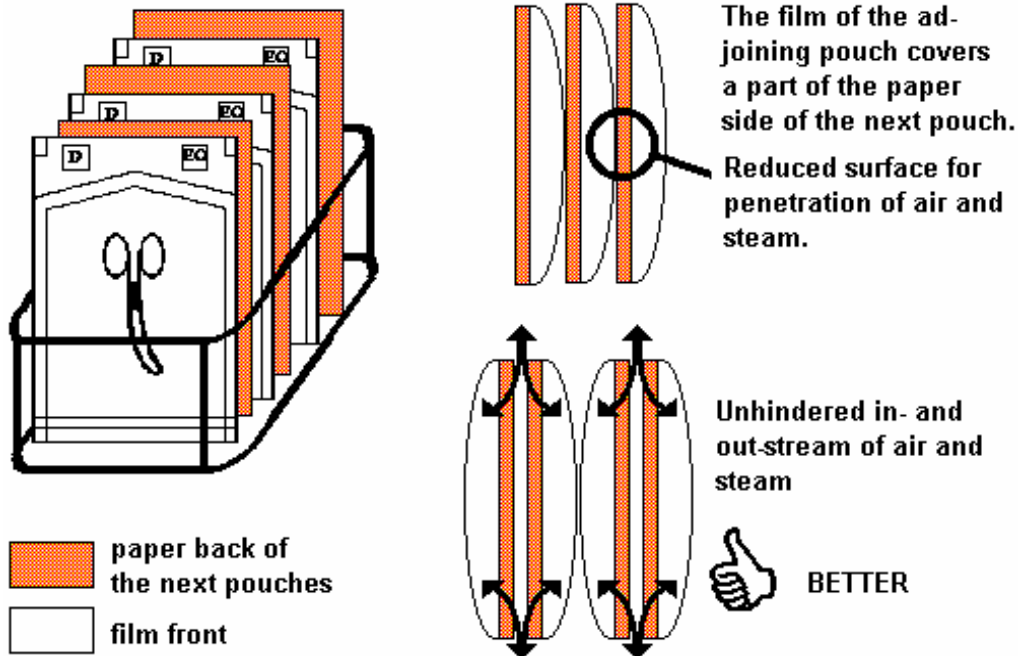
Bursting of see-through pouches when used under critical conditions could be avoided by the pouch manufacturers with following actions

1. Increase of seal strength: This leads on the other hand to a loss of the clean peel effect. Strongly "welded" pouches tear when opened with a high release of fibres - therefore this solution is not recommended.
2. Increase of the air permeability of the paper. With a higher air impermeability the air can flow through the pack quicker. This can only be done within certain limits. A higher air permeability can only be reached by reducing the fibre density thereby increasing the pores of the paper, which increases the risk of losing the barrier to bacteria/germs. Air-permeability is expressed in terms of so called "Bendtsen Porosity" which according to our experience should not exceed 1200-1300 ml air/min/dm² (Bendtsen Porosity), beyond this the risk of insterility is likely. The maximum air permeability should be clearly below this limiting value - VP Stericlin does not exceed 800 ml air/min/cm² in order to have sufficient safety margin left in accordance with the principle:

- **Safety First = Maintenance of sterility is the most important quality criteria for sterile packs**
- **Burst packs can be seen - but contamination cannot be seen**

5. LOADING TECHNIQUES

The ideal loading of sterilisation baskets with see-through-pouches is to place them film to film and paper to paper.



Correct loading of chamber:

When loading chambers the following rules have to be considered.

- Light sterile goods in flexible packs should be loaded on the very top.
- individually packed instruments in flexible packs should be packed below or beside
- Containers should be placed below
- heavy containers with instruments should be placed at the bottom of the chamber.

Reasons:

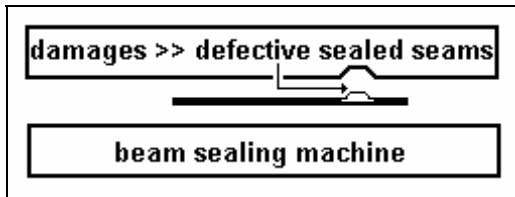
- The heavier the items are, the higher is the amount of condensing water which forms during sterilisation.
- Lighter packs must be protected against drops of condensing water because wet light packs do not dry sufficiently.

6. SEALING UNITS and SEALING

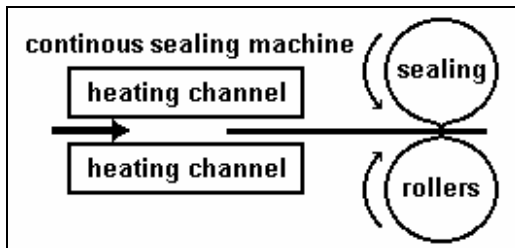
Continuous rotary sealers pull packs, which are fed in at one end, through a heating channel and afterwards through two spring-loaded rotating sealing rollers. This method has decisive advantages for sterilisation packaging: unlimited pack width and - more important - continuous instant sealing with sealing rollers which is neither sensitive to variations of the thickness of the packaging material nor to distortion or wear of the sealing rollers.

For sealing see-through pouches and paper bags specially designed heat sealing machines should be used. The general packaging industry uses two different systems: Impulse or continuous heat bar sealers. The packs to be sealed being placed between two sealing bars.

The costs for these units are usually low and of course each sealer has its own fixed width. Furthermore unnoticed distortion or wear of the bars may lead to defective seals.



Bar sealers can easily be damaged, distorted or worn, in which case an equal sealing pressure over the whole width and therefore a uniform seal strength, cannot be guaranteed.



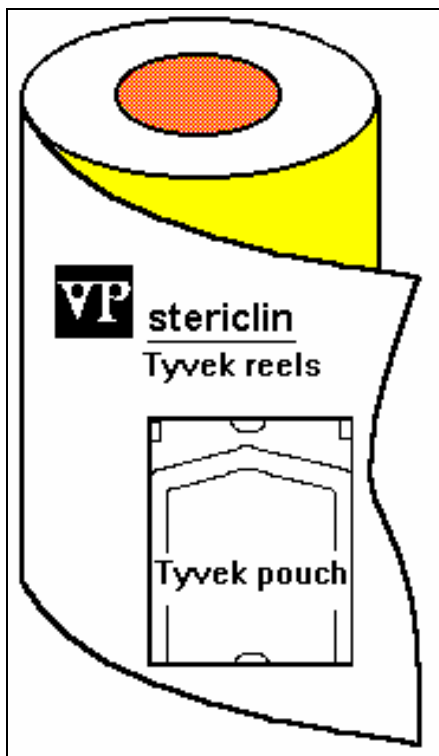
Using continuous sealing machines this risk hardly exists because the sealing rollers always seal at the point of contact.

Furthermore all gusseted packages are sealed with equal pressure = uniform seal strength, especially where there is a change from 2 to 4 layers of material. This is the reason why we always recommend continuous rotary sealers.

DIN 58953, Part 7, Item 6 requires that the seal width has a minimum of 8mm and that the sealing tool "enables faultless sealing over the whole surface"

Seal strength: The seal produced by your sealing unit should be a little bit stronger than the manufacturer's seal. This can easily be tested in practice by slow peeling. You can feel the difference of strength of the seals. The seal strength can be adjusted by increasing or reducing the sealing temperature or by changing the pressure of the sealing rollers in accordance with the instructions for use of the sealing unit.

7. SEE-THROUGH PACKAGING MADE WITH TYVEK® - EN 868-9



Structure - construction - purpose of use

TYVEK® 1073 B (registered trademark of DuPont) with hydrophobic coating plus polyester/polyethylene composite film, printed with Plasma-Indicator.

These packs are suitable especially for low-temperature plasma sterilisation.

Special advantages:

These packs have excellent barrier-qualities, a high mechanical stability, a excellent fibre free peeling behaviour and very important for gas sterilisation, up to 100 times less residues of ethylene oxide and formaldehyde after sterilisation. This shortens the degassing period and reduces the absolute levels of residues of sterilisation gases.

Special processing advice:

Sealing temperature about 120 - 130°C ! Attention: when using higher temperatures TYVEK® can melt and therefore damage the sealing machine! If possible install a separate packing table with an extra sealing machine with a fixed temperature of about 125°C.

TYVEK®- packages are not suitable for steam sterilisation because the material melts at 126°C.

8. STERILISATION PAPER / WRAP EN 868-2

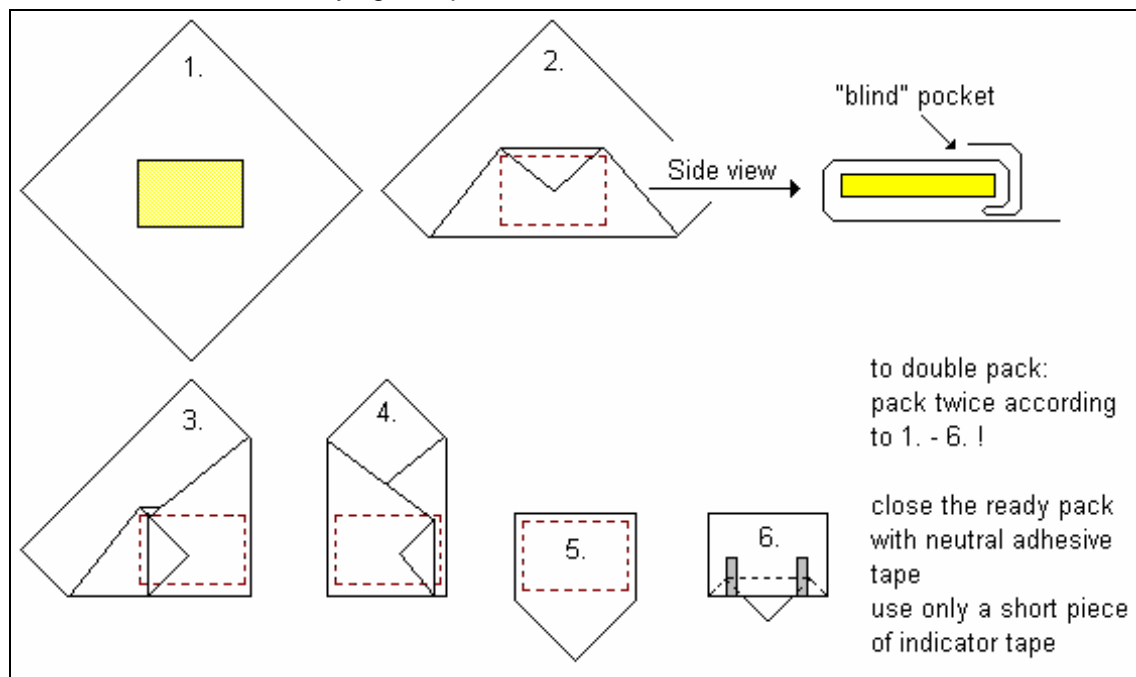
Advantages of this package :

- the inner wrap can be used as a sterile field
- using the correct packing technique, sterile removal is safe and easy
- easy penetration of air during evacuation, maximum possible steam penetration
- Minimal forming of water condensate because of 100% steam permeable surface
- low dead-/pack-weight, especially important for instrument trays
- low requirement for storage space
- available in several sizes and various colours (e.g. for coding)
- very economical (no costs for cleaning, disinfection, repair of containers, filters etc.)

Wrapping method:

The wrapping method according to DIN 58953, part 10, should be followed. Only wrapping twice forms a double pack, not using two layers of paper in a single wrapping operation pack.

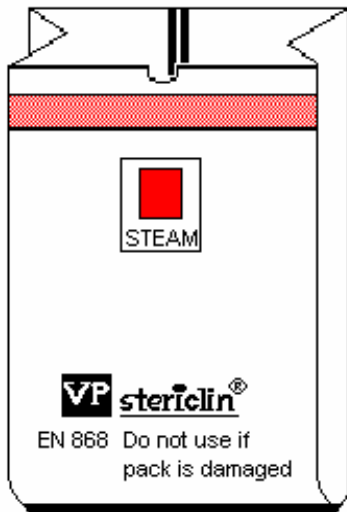
- For papers tested according to EN 868-2 and DIN 58953, Part 5 no special colours or qualities have to be used for the inner or outer package. Any combination is possible!
- A short strip of indicator tape is necessary for identification of sterilised packs.
- A textile cover as security against puncture from inside is recommended.



Comparison of different qualities of wrapping paper:

Criteria	<u>crepe paper</u>	<u>non woven</u>
EN 868-2 standardised	yes	yes
Drapeability	standard	excellent
Water resistance	good	very high
Alcohol resistance	low	good
Suitable as sterile drape (inner packing)	no	very good
Useful as outer packing layer	yes	in case special high protection against humidity is necessary
Cost	low	high
Recyclability	yes	no

9. GUSSETED PAPER BAG EN 868-4 and DIN 58953-3



Double glued back-seal, coloured adhesive for easy visual control of the glue-line

Thumb-cut-out

Heatseal coating

Steam indicator changes from pink to dark brown during sterilisation.

Printed area with manufacturer and trademark, standard-reference and dimensions as well as order no. and batch number (after oblique stroke) on backside.

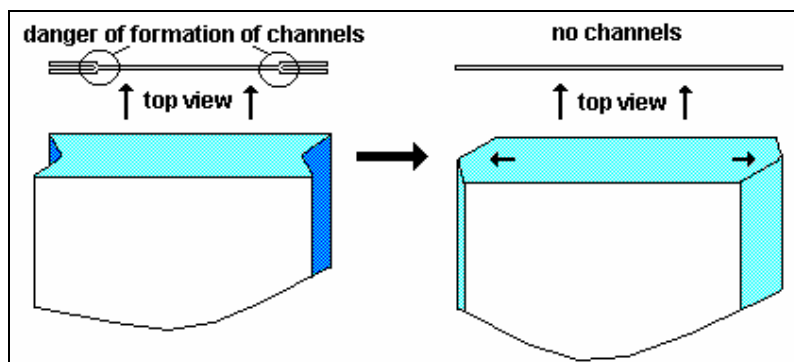
Double folded, heatsealed and glued bottom seal

Advantages of this package: sterile pack with lowest cost with regard to the volume of contents, the package is fully recyclable and therefore protects the environment.

Method of use: Correct opening is only possible with scissors (tearing paper bags can lead to contamination of the sterile contents with unsterile dust - and paper particles from the outside of the bags). These gusseted paper bags can be used as safe and sterile inner packs because the outside keeps sterile until the outer package is opened.

In case of problems during sealing - channels may occur in the top seal, especially when using bar sealing machines, at the point where it changes from two to four layers of paper across the gusset. The impermeability of the seal can be tested as follows (also applicable for see-through pouches)

Test: Cut the bottom off an empty sealed bag, fill with coloured water and wait for 5 minutes to see if water penetrates through the top seal.



Solution to the problem:

Before sealing pull side fold of sealing area outwards (not when using gusseted see-through pouches) in order to avoid thickness variation from 2 to 4 layers of paper.

10. STERICLIN PAPER PEEL POUCH EN 868-1

Development

The paper peel bag was developed by VP-STERICLIN as an alternative to the see-through-pouch which, being a composite package made from paper and polyester/polypropylene, is not recyclable. A pure paper package has the advantage that when used it can be collected and recycled together with waste paper without any separation of the materials. The well known gusseted paper bags which have been known since the 1960's are not peelable. On the other hand see-through pouches can be opened aseptically by peeling without using scissors. The Stericlin paper peel pouch combines this advantage with the recyclability of paper.



Material and construction

The paper peel pouch consists of sterilisation paper which conforms to DIN 58953, Part 2 & 6. The heatseal coating is in accordance with BGA and FDA recommendations and is applied as a water dispersion which minimises the environmental impact both during production and disposal. It can also be composted. The sealing zone in the bottom area is wide enough to enable sealing with all common rotary sealing machines. The sealing temperature, at about 180°C, is the standard value for see-through pouches.

Concept of application

The paper peel pouch offers a lot of advantages in comparison to see-through pouches but it has one disadvantage: the contents are not visible. Therefore these pouches are printed with symbols or text for standard instruments. But when using them for packing standard instruments it will be beneficial because these packs are needed in big quantities. In regard to waste disposal costs this is an important economic as well as ecological consideration. Nevertheless paper peel pouches are presently not able to replace see-through pouches completely. The main reason

being that visibility is often necessary, especially when using special instruments. The use of paper peel pouches is also limited due to their construction: the heat-seal coating strength increases after steam sterilisation about 0,5 - 0,8 N/15mm. To enable correct peeling after sterilisation, the seal strength before sterilisation will not be as high as for see-through pouches. When packing big paper peel pouches, which are usually filled with heavy items, the seams might be pressed open.

Summary:

The paper peel pouch is a recyclable alternative to the see-through pouch. Regarding the whole concept of reducing waste in hospitals it may be only a modest contribution, but each small step counts.

11. EFFECTS ON THE ENVIRONMENT - RECYCLING

In many ways sterilisation packaging is nowadays constructed and produced in an environmentally responsible way - at least for VP Stericlin packages this is true:

Measures of VP-Stericlin for production with minimum environmental impact.

For all medical packaging we use **oxygen bleached paper** - it can be recycled or composted and is harmless when land-filled or incinerated. The printing inks used are water based thus avoiding atmospheric pollution both when producing the inks and when printing - disposal also has no environmental impact.

The glues and heatseal coatings for paper packages are also water based dispersions, they conform to BGA and FDA recommendations, can be composted and are harmless when land-filled or incinerated. The film laminates used, consist of polyester and polypropylene or polyethylene (no PVC). These composites are derived from crude oil refining, do not emit harmful substances and are neutral to ground water if land-filled.

Recycling possibilities

Packages made of sterilisation paper are recyclable contrary to popular comment. Sterilisation packaging cannot be made out of any kind of paper - sterilisation paper has to be water resistant, otherwise you would hold a pulp of cellulose fibres in your hands after sterilisation. Water resistant paper is more difficult to recycle compared to other papers. However as modern recycling plants shred and mix the waste paper before recycling into secondary pulp, experience has shown that up to 10% water resistant paper is acceptable. Investigations show that the amount of water resistant sterilisation papers in the total amount of waste paper in hospitals is between two and five percent, so collection together with their ordinary waste paper is no problem.

Water resistant sterilisation papers consist of special high quality, long fibre cellulose which increases the strength of the secondary recycled pulp considerably. Furthermore an average of only 10% of the surface of medical packaging is printed so it adds very little to the requirement for de-inking during the recycling process. Recycled medical paper can therefore be considered a valuable secondary raw material.

On the other hand a very important pre-condition for re utilisation has to be assured. Medical packaging provided for recycling must be absolutely free from infectious contamination. The danger of contamination is low and contamination is usually obvious. When used in laboratories or infectious wards the relevant instructions for potentially contaminated waste must be followed. Fear of possible contamination is often the main reason for refusing sterilisation papers for recycling.

Laminated films are not recyclable. For this reason see-through pouches are in practice not recyclable unless the film and paper (or the TYVEK[®]) are separated.

12. MULTIPLE PACKS AND TIMES OF STORAGE

An important question: why do we double pack ?

Isn't it really redundant? From time to time "prehistoric" sterile goods are discovered which are still sterile when the package isn't damaged.

It is important to note that the packaging material does not become permeable during storage - storage times are limited because the risk of recontamination while opening the package increases if the contamination of the surface increases

Sterile packs conforming to DIN keep their contents sterile for years when they are used and stored in the right way, nevertheless the DIN 58953 Storage Time Table sets limits for the period of usability.

The restrictions regarding storage times are based on following considerations:

- Even in sterile storage rooms which conform largely to clean room conditions, but especially when transported through unsterile rooms, there is dust which settles onto the sterile packages.
- Dust is usually contaminated and therefore represents a source of contamination. While peeling open the package the dust on the surface of the package is disturbed and may fall into the package which might contaminate the sterile contents!
- Therefore a protected storage and multiple pack is required for longer storage times.

What is the effect of a double / multiple pack?

Contamination of the outer packaging increases when the storage period is extended or when stored unprotected during the same period of time.

The inner pack remains sterile even on its outside until it is removed. It is important that the inner pack which protects the sterile goods directly, remains sterile even on its outside, until it is used. In principle there is a risk that sterile goods can be contaminated by bacteria which cover the outside of the pack while the pack is opened. The lower the dust burden of the outermost pack the lower is the risk of recontamination of the sterile goods while being opened and removed.

Multiple or double packing is not necessary because a single pack becomes permeable over time (provided that it is stored under the above conditions) but it is necessary in order to reduce the level of contamination of the outside of the pack after a longer period of time and therefore the high risk of contamination during opening step by step. These relationships are shown once more in the following chapter "removal techniques". After removal of the outer or storage pack, only the storage times for the remaining single or double packs are valid.

The question arises repeatedly as to whether industrially produced sterile products are more sterile than sterile goods prepared in hospitals because users in surgeries and hospitals discover single packed material with a remaining shelf life of up to 5 years.

Degrees of sterility do not exist of course. The above question is often based on wrong handling and storage of single use products.

The recommendation for storage times for industrially sterilised goods are identical to those of sterile goods prepared in hospitals - the wording of the revised DIN 58953 published in February 1993 is identical to the storage time recommendations of DIN 58953, part 7, see below.

Following the statement in the table it becomes clear that single or double packed sterile single use products can only be stored during the complete printed shelf life if kept in a storage pack which often is presented as a dispenser. Once they are removed they should not be stored for weeks e.g. on a dressing trolley.

Therefore it is important that only the immediately required amounts are taken out of the store or dispenser pack. If it is not clear whether the removed amounts are going to be used directly or in case of removal from the original storage pack and distribution by the central sterile supply department, a re-closable new storage pack should be used if possible. In this case transparent protective storage packs made of recyclable PE are recommended which have a resealable self adhesive closure and allow clear identification of the contents and removal as required.

<p style="text-align: center;">Storage time table according to DIN 58953, part 8, October 2003</p> <p style="text-align: center;">Recommended storage times for medical products, including sterile single-use products, which are packed in sterile barrier systems according to the EN 868</p>		
Type of package	Storage not protected from dust in shelves in rooms not under clean room conditions	Storage protected from dust dust protected, e.g. in cupboards or drawers or in shelves in room under clean room conditions.
<p>Primary pack <i>Sterile barrier system</i></p> <p>Sterile single package and sterile double package with or without inner wrapping.</p>	<p>Intended for immediate use, not to be used for storage!</p>	<p>6 months but not longer than maximum shelf life.</p>
<p>Dust Cover</p> <p>Dust Covers with more than one primary pack may be used, but must be reclosed immediately after removal. Reuse of dust covers is not allowed.</p>	<p>Max. 5 years or according to the recommended maximum shelf life of the manufacturer. Hospitals can use own package systems as substitute for sterile storage packages. The marking of the original package has to be carried out in a suitable way.</p>	

Translations made by Bernhard Schilling and Olaf Trier

- **Whenever aseptic handling is necessary, especially in theatres, double packs should be used in order to guarantee contamination free removal, particularly after longer storage times.**

13. MULTIPLE PACKS - Possibilities for combination

Basic principle:

If you are using double wrapping, the inner wrap should have an air permeability higher than, or equal to, the outer wrap.

Wrapping materials without barrier properties:

- glove packing/wrapping
- textile fabrics
- paper wrapping which is not folded and closed according to DIN 58953, Part 10,

Single wrap materials with barrier:

- paper bags
- see-through pouches and reels
- one layer of wrapping paper
- Container

Sterile - double wraps

- paper bags in paper bags/see-through pouches/wrapping paper/container
- See-through pouches in see-through pouches
- paper bags or wrapping paper in see-through pouches
- wrapping paper in container/double pack wrapping paper

These double wraps consist of two layers of barrier material. After removal of the outer pack the storage times for single packs are applicable.

Sterile packs consisting of an inner wrap and a sterile pack:

- glove wrapping in bag
- fabric wrapping (around tray) in container
- fabric wrapping (around tray), packed in one layer of wrapping paper DIN 58953, Teil 5

Special handling conditions apply:

These double packs consists of an inner wrap without barrier and an outer barrier wrap. As soon as the outer pack is removed the sterile item must be used.

Dust cover / storage pack:

- A storage pack can be a third sterile pack or a dustproof container in which the sterile goods are packed after sterilisation: carton, container, corrugated case, film bag etc.

Be careful when using non-permeable dust covers:

Before sterile goods are stored in hermetically closed storage packs (e.g. film bags) the sterilised item has to be cooled down and absolutely dry otherwise condensing water vapour will form an ideal culture medium for bacteria inside the storage pack.

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