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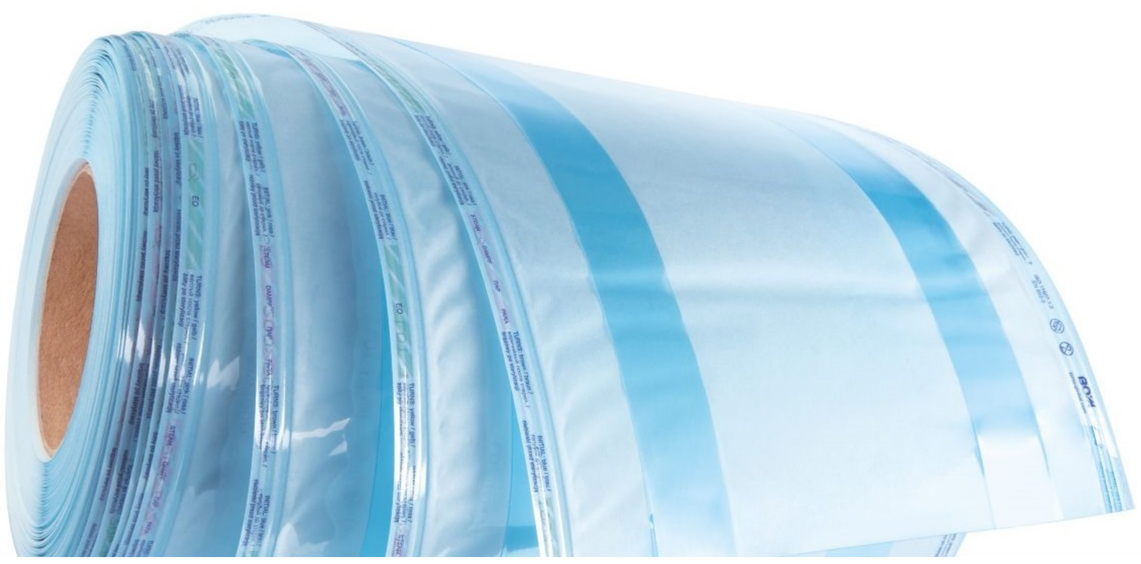
SAFE MEDICAL PACKAGING

GUIDE

This guide
is addressed only
to professionals



SAFE MEDICAL PACKAGING

GUIDE

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STORAGE AFTER STERILISATION

INDICATOR COLOURS*

Paper-film packaging, flat/gusseted

Flat Tyvek®-film pouches

Flat nonwoven-film pouches/reels

* The colour indicated in the sampler may differ slightly from reality

CONTENTS

1 WHAT IS STERILISATION?

The 19th century resulted in the discovery of the causes of some diseases and infections – the culprits turned out to be small bacteria, invisible to the naked eye. Our surroundings are inhabited by numerous microorganisms, the vast majority of which are essential for the proper functioning of life on Earth and maintain the biological balance of ecosystems on our planet. Many bacteria live in our bodies, support their functioning and do not cause any disorders - on the contrary, they are even necessary to live. It means that microorganisms are not dangerous as long as they fulfil their role as symbiotic organisms and do not germinate excessively, which may disrupt the homeostasis of the host organism.

Therefore problems occur only when the already mentioned natural balance is disturbed or when pathogenic microorganisms invade our bodies. That is when we start to get sick. In hospitals and, in particular operating theatres, the environment is favourable for the entry of pathogenic microorganisms into the human body. One of the methods to avoid such a risk is the sterilisation of surgical instruments, dressing materials, clothing, equipment etc.

STERILISATION PROCESS
can be defined as actions leading to remove all living organisms and their survival forms from any material.

Microorganisms vary in terms of their sensitivity to sterilisation methods. The differences result from the microorganism type and depend on water content, the pH of the environment, the age of the cells, the type of spores etc. That means the rate of inactivation depends on factors that are both environmental and related to the type of microorganism.

Currently, we know a lot about the methods of transmission of pathogenic microorganisms. The most common and known method is direct contact with other people and items surrounding them.

To control the above-mentioned contact transmission we ensure a high level of hygiene through frequent and precise cleaning of hands, disinfection and sterilisation, as well as other actions aimed at preventing the transmission of microorganisms. Understanding the importance of hygiene and sterility in the hospital environment is the first step to avoiding a threat to the life and health of a person present there. It may also prevent severe legal and financial effects for hospitals associated with patient infection (which result from the increasingly high damages awarded by the courts).

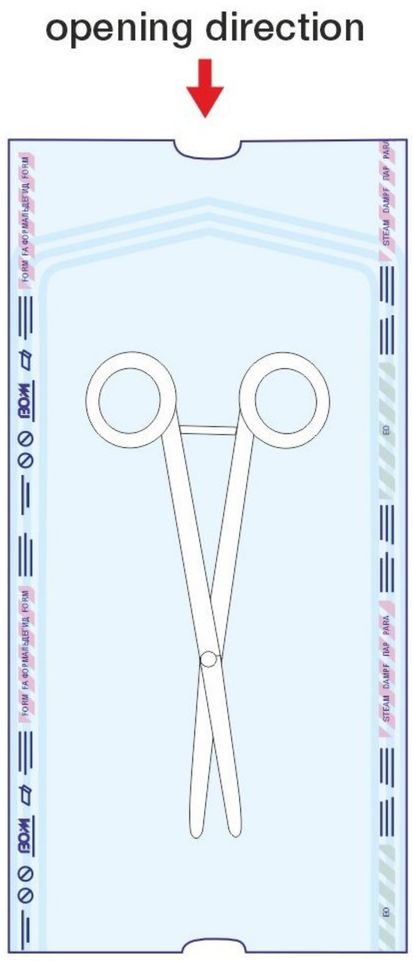
The primary preventive measure to avoid infection is to use appropriate packaging for medical instruments and materials undergoing sterilisation and to control its process.

2 ACTIONS IN PRACTICE

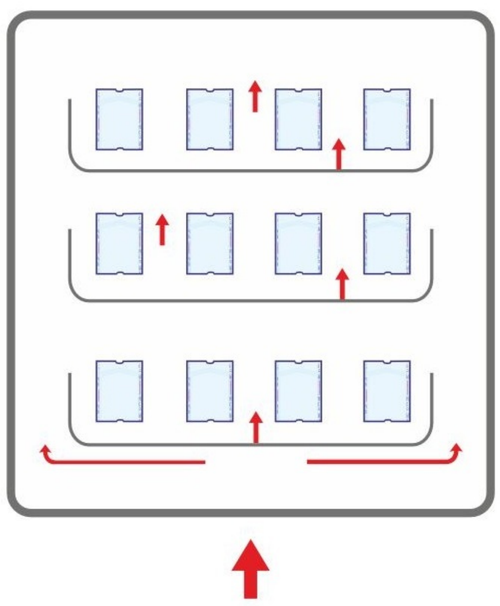
In this part of the Guide, we will describe the method of handling medical instruments between surgeries. We will use scissors sterilised with steam as an example.

The following actions are taken for the scissors after a treatment:

1. Disinfection
2. Cleaning
3. Drying
4. Cleanliness and fitness check
5. Packing



Scissors are placed in suitable packaging (a pouch or reel), individually or in a surgical set.



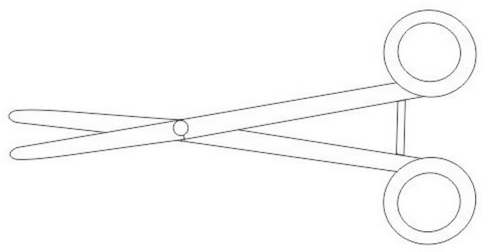
In this case, it is important to put the scissors in a way that makes it possible to remove them aseptically later.

Next, a tightly closed package is loaded into an autoclave in a basket with other sets.

The basket should be loaded in such a way that steam in the autoclave can penetrate the load at any point in the chamber.

Once the steriliser is loaded, the sterilisation process can start. Afterwards, the baskets are removed and checked thoroughly for any damaged sets and to see if the chemical indicator has changed colour. Next, the set is marked with the sterilisation date and/or the expiry date. Scissors sterilised in appropriate packaging can be stored in it under suitable conditions for the time set, and they will remain sterile. The person opening the packaging with the scissors must check it before use. The expiry date and the tightness of the packaging are checked.

CIRCULATION OF SCISSORS USED IN SURGERY



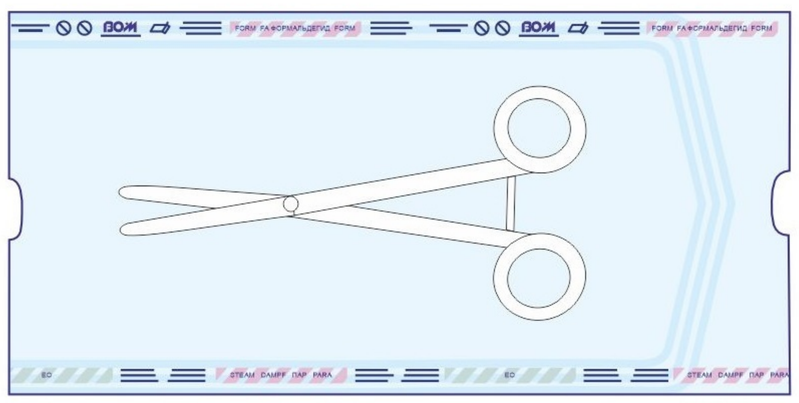
1 Central Sterilisation Department controls if the scissors are properly cleaned and have no contamination, stains or damage.

2 The scissors are put into the packaging, which must be then closed and marked with the sterilisation and/or expiry date. Packages prepared in such a way are placed in the basket.

3 The autoclave is properly loaded.

4 The sterilisation process parameters are adjusted to the load.

5 After finishing the process, the packages are removed and checked for damage.



3 METHOD, CONTROL AND ERRORS OF STERILISATION PROCESSES

Sterilisation methods are simply divided based on the sterilising agent used suitable for the sterilised material.

THERMAL METHODS

- Saturated steam
- Dry hot air

CHEMICAL METHODS

- Ethylene oxide
- Formaldehyde
- Plasm
- Chemical substances (peracetic acid, glutaraldehyde)

RADIATION METHODS

- Accelerated electrons
- Isotopes of radioactive elements
- Photon streams (ϒ-rays and X-rays)

Every sterilisation method has some limitations. It applies to low-temperature sterilisation as well.

The inconveniences may include:

- Material damage
- Long sterilisation time
- Difficulties in penetrating thin and long cross-sections
- The necessity to degas (ethylene oxide, formaldehyde)
- Toxicity for the environment and humans
- Special requirements for packaging (plasm) or impossibility to pack (peracetic acid, glutaraldehyde)
- Difficulties in controlling the process

3.1 VALIDATION AND MONITORING OF STERILISATION PROCESSES

Strict adherence to the correctness of the sterilisation process is an essential element of today's hospital practice.

PHYSICAL CONTROL

- Observation of steriliser indications
- Registering parameters with steriliser charts and the printouts of the sterilisation process

BIOLOGICAL CONTROL

Tests containing the spores of bacteria resistant to the sterilising agent.

- **Bacillus stearothermophilus** — sterilisation with steam (Geobacillus stearothermophilus)
- **Bacillus subtilis var. niger** — sterilisation with ethylene oxide (Bacillus athrophaeus)
- **Bacillus subtilis var. niger** — sterilisation with hot dry air (Bacillus athrophaeus)

CHEMICAL CONTROL

- **Gauges** — they react to 1 parameter and make it possible to differentiate materials undergoing the sterilisation process from those that were not sterilised (e.g. tapes with the indicator, pea-type gauze swabs or labels).
- **Temperature indicators** — they measure only the temperature during the process, do not react to time and the presence of steam.
- **Multi-parameter indicators** — they are integrated and react to temperature, time and the presence of steam.
- **Bowie & Dick tests** — they control the readiness of the steriliser to work, detect air residues, differences of temperatures in the control packet, poor steam penetration and the presence of non-condensing gases in steam.

NOTE

The sterilisation process should be controlled with all the methods at the same time, as well as validated and monitored using the schedule set.

A chemical strip indicator showing the incomplete colour change provides an instant visual warning that sterilisation was not carried out correctly. The probable cause of such a situation was incorrect sterilisation parameters (temperature, time, humidity or steam pressure). Another cause could have been incorrect packaging or loading of the steriliser, keeping in mind the point of introducing the sterilising agent in the steriliser chamber. When loading the steriliser, always remember to arrange the paper-film packaging properly against each other.

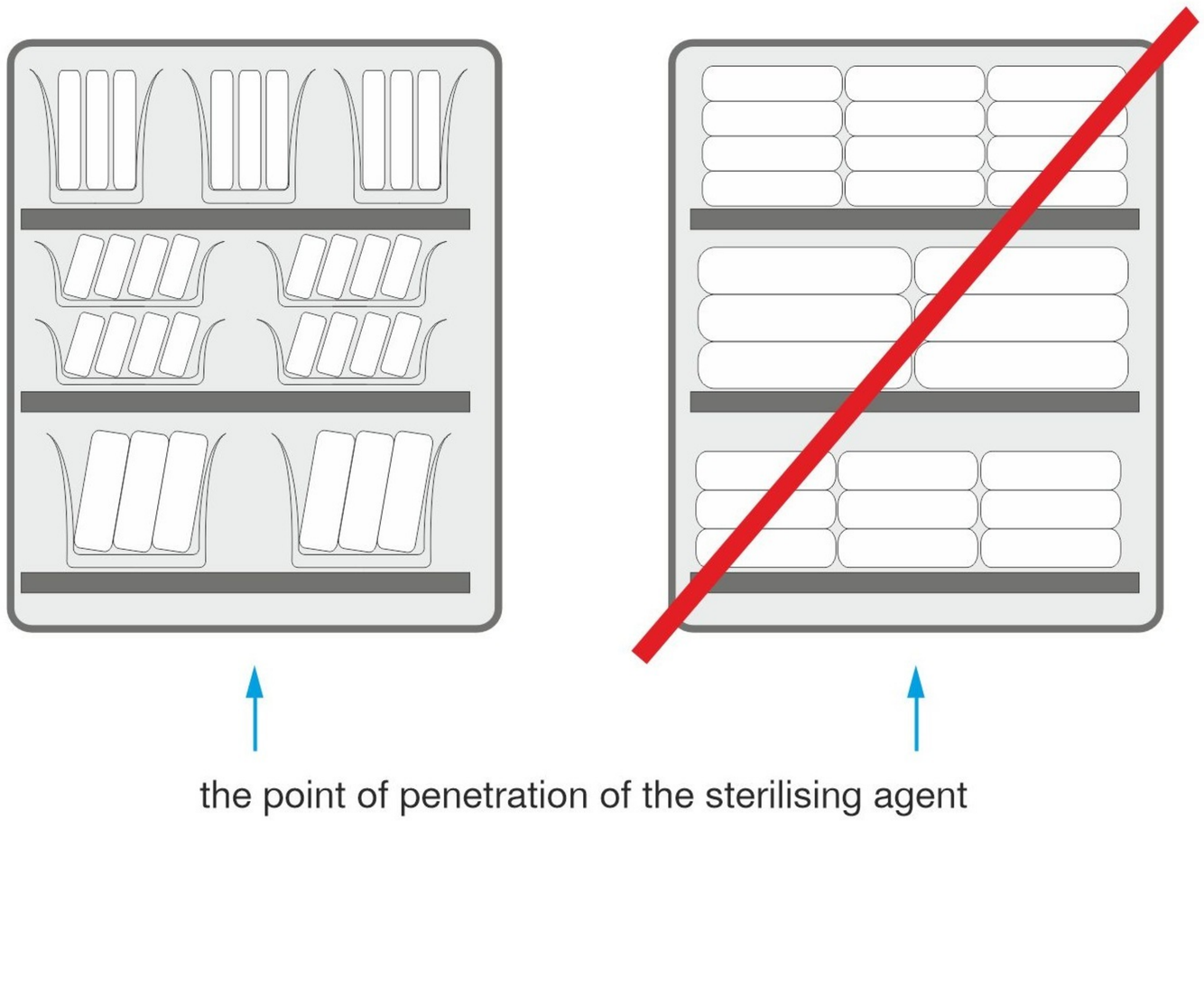
Arrange packaging properly in the sterilising basket – film to film and paper to paper not to limit the migration of the sterilising agent through the packages. Arrange packages not too tightly so that you can put your hand comfortably between them.

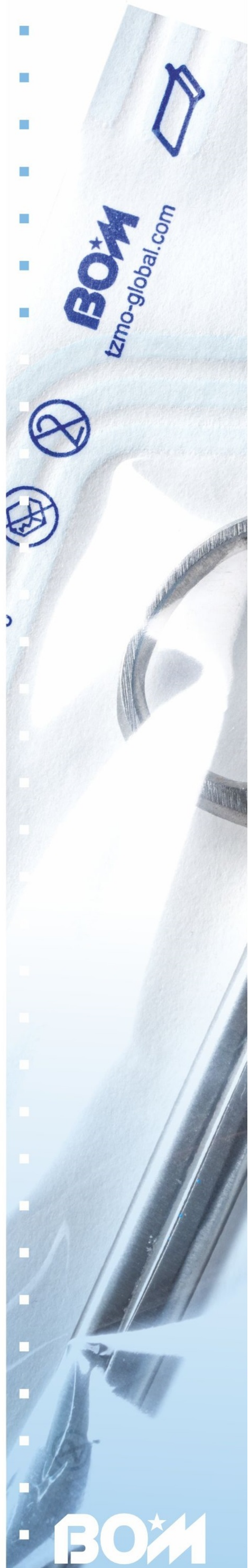
When loading the chamber with the material for sterilisation, follow the principles:

- Place heavy containers with instruments at the very bottom.
- Place lighter containers at the bottom of the steriliser.
- Place instruments packed in paper-film packaging above or next to the containers.
- Place packages with textiles above them.
- Stack light materials packed in paper and film at the very top.

Following this layout is necessary to avoid getting light loads wet with condensing water from heavy packages. A heavily soaked light material may not dry during the drying process and, therefore, the sterilisation process becomes ineffective. The heavier the packages, the more water condensates during the sterilisation process.

LOADING THE AUTOCLAVE





3 MOST COMMON ERRORS DURING STERILISATION

WITH STEAM

- Too large packages
- Packaging impermeable to the sterilising agent
- Overloaded or incorrectly loaded steriliser chamber
- Selecting incorrect sterilisation parameters for the materials and sizes of the packages
- Incorrect selection of packaging for the content
- Incorrect venting of the material before sterilisation
- Poor quality steam (too dry or too wet)
- Instruments are packed on a "full" tray – the path for the sterilising agent is closed, and air penetration through the paper during sterilization is impeded

AT LOW TEMPERATURES

- Incorrect qualification of the equipment for the sterilisation method
- Resterilisation of the equipment/product qualified by the manufacturer as disposable
- No control over the humidity of the sterilised materials
- Overloading or incorrect loading of the steriliser
- Directing the equipment to be used without degassing it and before receiving the confirmation of the biological control results
- Always remember that it is not transport packaging – the packaging provides microbiological protection of the load, and it should be handled carefully both before and after the sterilisation process (during transport, at the Client)

4 RAW MATERIALS USED FOR THE PRODUCTION OF PACKAGING

As a rule, sterilised items must be pre-packed. The primary task of good sterilisation packaging is to keep the packed item sterile until it is used. Apart from that, the sterilisation packaging should also meet additional requirements, such as:

- Enable the penetration of the sterilising agent into the packaging to sterilise the content.
- Enable secure and safe sealing of the packaging.
- Eliminate the possibility of penetration into the packaging of potentially hazardous substances from, e.g. adhesive, print, chemical indicator, etc.
- The packaging must be impermeable to microorganisms and secure the content from contamination.
- Enable aseptic removal of the sterilised content for use.
- Do not get damaged during sterilisation.

PLASTICS

They play an important role in the production of transparent packaging used in hospitals. A transparent film consists of several layers and called laminate. Thanks to the transparent layer of the packaging, its content is visible, and it is possible to close it tightly under pressure at high temperatures, which is called sealing.

Laminate layers:

The internal layer of the laminate touches the paper and melts gradually when sealing the packaging layers. The resistance of the laminate film to physical and chemical factors is high enough to resist the sterilisation process, and it still is a barrier for microorganisms after the process. The laminate we use to produce the paper-film packaging does not contain toxic substances and can be recycled thermally.

PAPER

We use two types of medical paper to produce packaging, depending on the sterilisation method. The result is packaging with optimum properties adjusted to the conditions during the sterilisation of objects of different sizes.

Key features:

- Appropriate porosity allowing penetration of the sterilising agent
- Layout and size of the pores constituting the barrier for microorganisms after the sterilisation process
- High resistance to moisture and stress during sterilisation
- Resistance to damage after sterilisation

Sterilisation paper used for the production of packaging is a porous material with a filtering effect. The filtering effect of the paper means it is permeable to sterilising agents while still impermeable to microorganisms' carriers, such as dust or liquids. To protect the paper, reels are covered with laminate on the outside, with the paper on the inside.

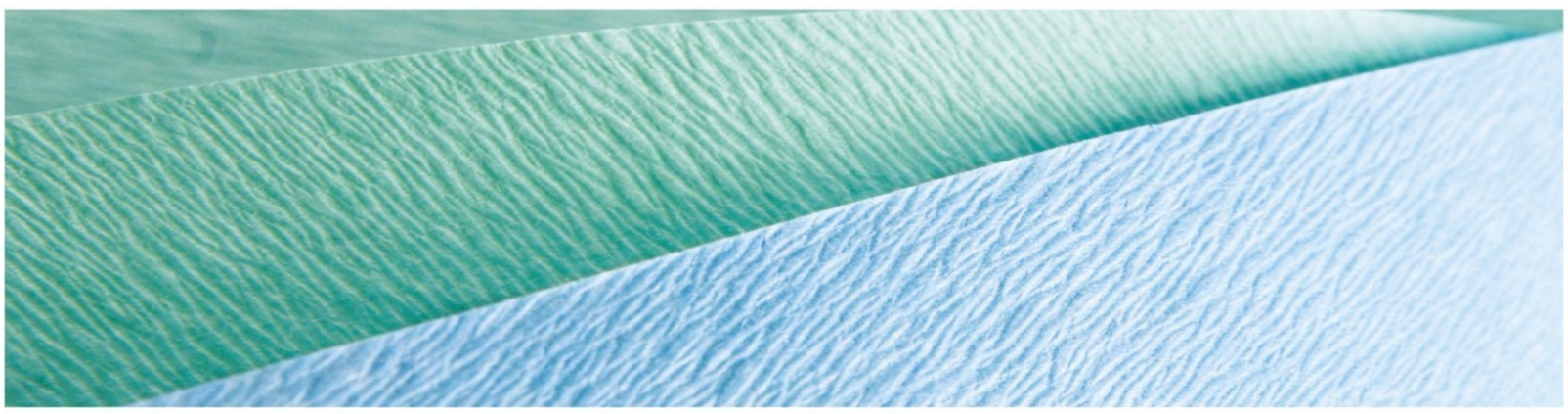
Remember that the pores in the paper are not holes arranged in a straight line in the material. The route of the sterilising agent through the paper into the inside of the packaging resembles a maze that only particles of a particular size can navigate.
Due to such a feature of the paper, bigger particles which are the carriers of microorganisms and other contamination, cannot pass through it. Paper in line with EN 868-3 can remain a barrier to microorganisms only after single sterilisation.
Subsequent sterilisation processes, in particular with saturated steam under positive pressure, damage the structure of cellulose fibres and the fibre-binding substance, and therefore, the paper loses its filtration properties and ceases to be a barrier to microorganisms.

Therefore, paper-film packaging can be sterilised only once!

NONWOVEN

The nonwoven used to produce packaging made of nonwoven and film consists of cellulose and synthetic fibres, ensures better permeability for the sterilising agent, and therefore, it is recommended for the sterilisation of porous loads, e.g. textiles. The nonwoven is a more durable material than paper, so it is perfect for packing heavy loads.
The nonwoven meets the requirements of EN 868-2.

Nonwoven-film packaging can be sterilised only once!



TYVEK®

This latest-generation material combines the best features of paper, nonwoven, film and woven. It is made of high-density polyethylene fibres joined under temperature and pressure without binders, fillers and colourants. Tyvek® is characterised by very high resistance to piercing and puncturing.

Tyvek®-film packaging can be sterilised only once!

PACKAGING PRODUCED BY TZMO SA
has excellent functional properties while being economical and environmentally friendly.

All raw materials used in the production of the packaging meet the requirements of European Standards.

5 PACKAGING TYPES

One of the essential stages of the sterilisation process of medical materials is to select proper sterilisation packaging. When embarking on this task, obtain the following data:

- What sterilisation method is recommended by the manufacturer of the material to be sterilised?
- Do you have this type of sterilisation?
- Find packaging suitable for the method selected.
- Check if the packaging selected makes it possible to pack the load securely.

Based on the properties of the raw materials used in the packaging production, they can be categorised into different sterilisation methods because some materials withstand individual sterilisation media better or worse.

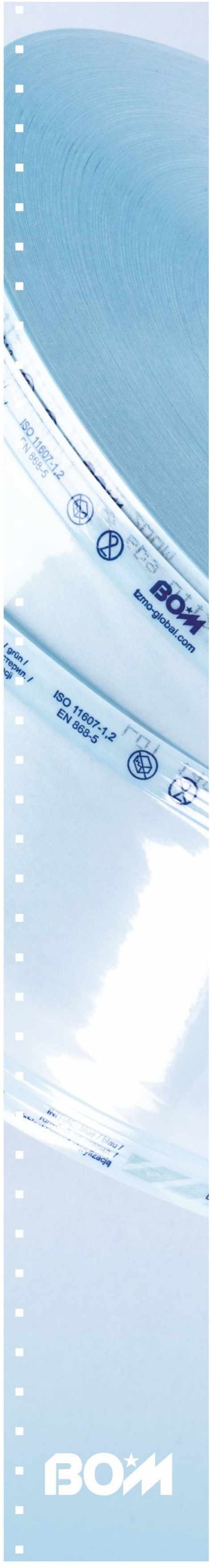
The table below shows the purpose of different packaging types for different sterilisation methods.

Type of sterilisation packaging	Steam STEAM	Ethylene oxide EO	Formaldehyde FORM	Plasm VH2O2	Radiation IRRAD
Paper-film packaging (blue film)	YES	YES	YES	NO	NO
Nonwoven-film packaging	YES	YES	YES	NO	NO
Tyvek®-film packaging	NO	NO	NO	YES	NO
Crepe paper in sheets	YES	YES	YES	NO	YES
Cellulose nonwoven	YES	YES	NO	NO	YES
SMS nonwoven	YES	YES	YES	YES	YES

The most common packaging type for the sterilisation of medical materials is pouches and reels. They can be divided by the raw material type they are made of:

- paper-film
- nonwoven-film
- Tyvek®-film

Reels are an option for self-packaging in the dimensions required by the user. A desired length can be cut from a roll and closed on the free side of the packaging, using the sealing machine, to form a pouch.



5.1 PAPER-FILM POUCHES AND REELS

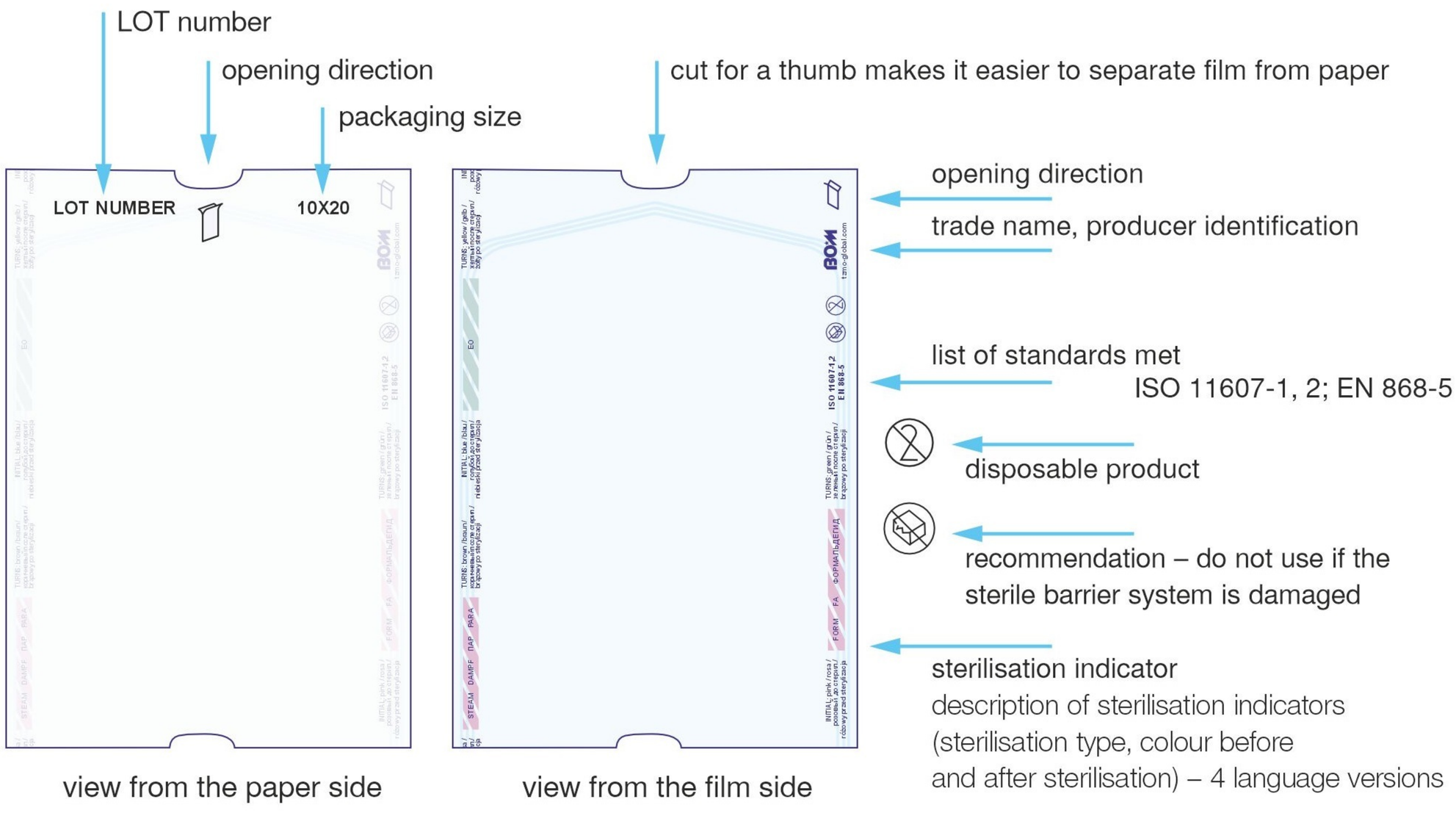
They are intended for packing items which are to be sterilised with steam under positive pressure, ethylene oxide or formaldehyde.

SUCH PACKAGING COMES AS:

- flat pouches and reels
- gusseted pouches and reels

Gusseted packaging is intended for packing thicker items with more complicated shapes. Remember that laminate overlaps forming gussets make it more difficult to seal such packaging because three layers of film laminate must be sealed. When it is possible to choose between flat or gusseted packaging, it is recommended to use flat packaging of a correctly selected size.

CONSTRUCTION OF A PAPER-FILM POUCH



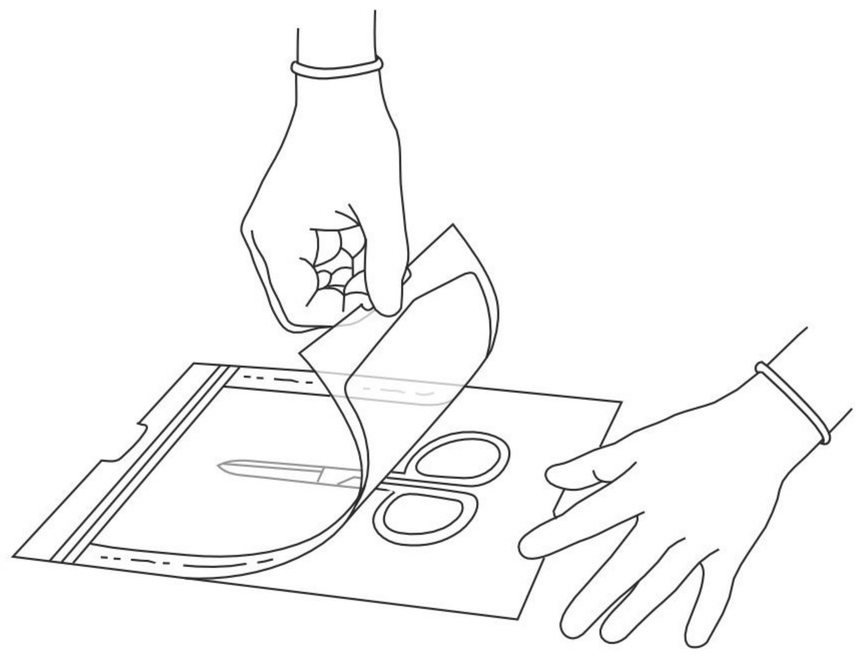
A critical moment of the aseptic exposure of the sterile material is to open the paper-film packaging correctly. The packages have the opening direction printed in the form of a pictogram, looking like an open bag, which in the case of packages made of reels, makes it possible to find the correct package opening direction. High-quality materials used in packaging production and a validated technological production process ensure an excellent "peel" effect of dust-free opening. This feature minimises the risk of contamination with cellulose particles which may detach while opening the packages.

The factory-sealed shorter side of the pouch is in the open V shape, which makes it possible to collect the instrument aseptically, thanks to the possibility of separating the film from the paper at the tip of the V shape. This feature is particularly important in a hectic, stressful situation when the patient's life is at risk. When opening a pouch, always remember to separate the film from the paper and never the other way around. Pulling the paper may rip it because it is a material with lower tensile strength than film laminate. The factory-made seals must not be too weak as they may tear in the autoclave, nor too strong so that the packaging tears when opened.

Diagram of the correct opening of paper-film packaging, nonwoven-film, Tyvek®-film

- Open the packaging following the aseptic principles, avoiding contact between dirty surfaces and sterile contents.
- Find the opening direction visible on the packaging in the form of a pictogram looking like an open bag.
- Rip the film from the paper at the corners of the packaging.
- Open the packaging with two hands at the seal point by separating the film layer from the paper layer.
- Slowly and carefully separate the film from the paper by pulling the film layer.
- OPEN THE PACKAGE IN A SMOOTH MOTION, AVOIDING TUGGING ON THE FILM AND PAPER

FIGURE SHOWING THE CORRECT OPENING OF PAPER-FILM PACKAGING

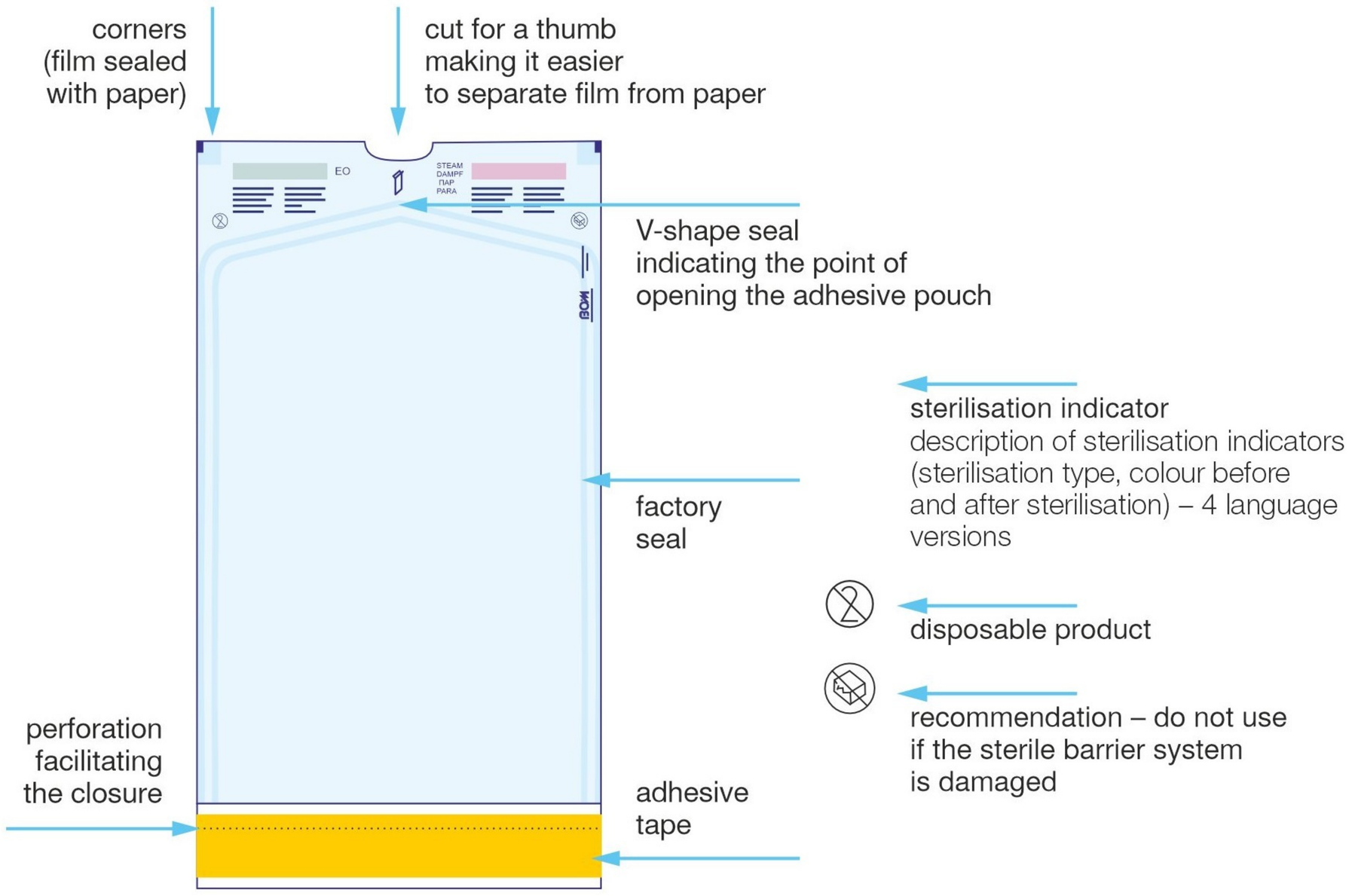


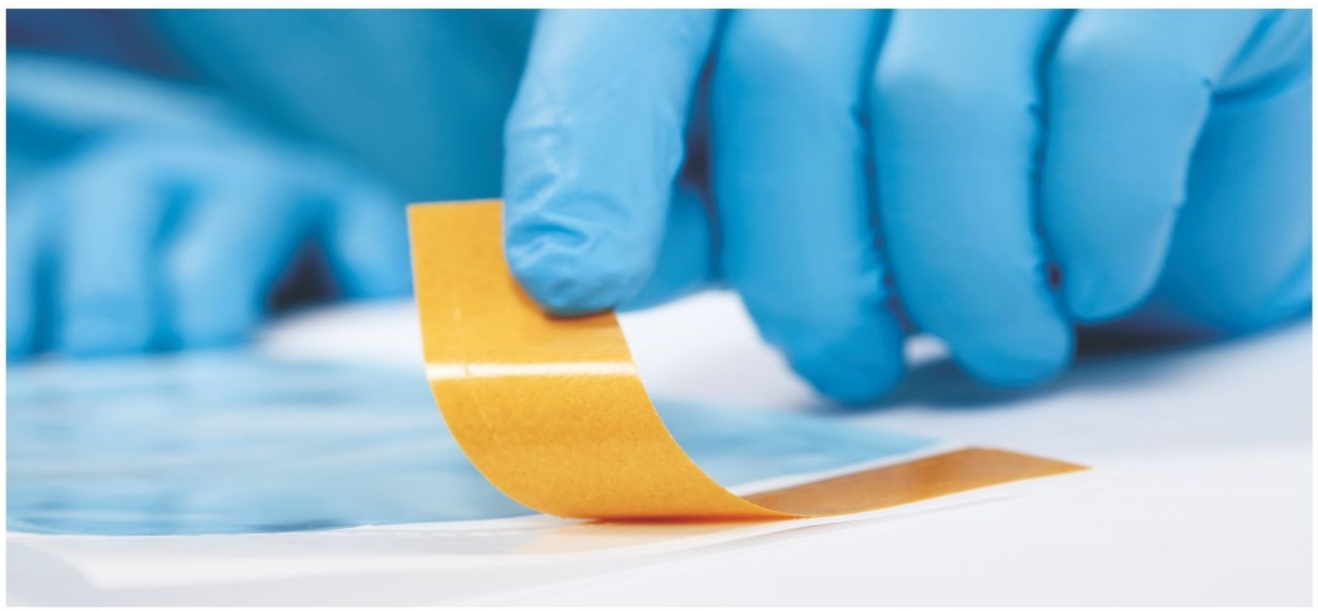
PAPER-FILM POUCHES AND REELS

Do not open by cutting the paper with a sharp tool or in the opposite direction to the pictogram on the packaging.

5.2 ADHESIVE PAPER-FILM POUCHES

It is a convenient form of packing whenever sealing machines are not available. The packaging is closed by bending along the perforation and pressing a specially elongated paper part to an applied adhesive layer onto the film layer of the pouch.





5.3 PROTECTIVE AFTER-STERILISATION BAGS

They are made of non-toxic polyethylene and closed using adhesive tape. The packaging is used to protect sterile packages during their storage and transport.

It secures a sterile package from dust, moisture and damage and minimises the risk of contaminating the sterile product during opening and removing it from the sterile packaging. The following information is placed on each protective after-sterilisation bag:

Protective after-sterilisation bag –
sterilised materials must be dried and cooled before packing in the protective bag.

6 HOW TO STORE MEDICAL MATERIALS AFTER STERILISATION

Sterile items require proper storage and should be handled carefully, even if the packaging material is of good quality.

It is recommended to use additional protective packaging that secures a sterile package from dust and dirt. It extends the post-sterilisation period of the useful life of the item. Hospitals should have special sterile material stores with cabinets for storing items after sterilisation, which considerably extends the period of useful life after sterilisation compared to storing them on racks.

It is important not to pile too many packages and not to bind them together. The room should be dry, at a constant temperature and free of dust and pathogenic microorganisms. Sterility of medical materials in paper-film, Tyvek®-film, as well as nonwoven-film packaging correctly closed with a seal can be maintained provided the following requirements are met:

1. The sterilisation process of the item was carried out in line with the requirements, the sterilisation was effective, and the process was validated.

2. The packaging was not damaged, e.g. by tearing, puncturing, damaging the closure, handling the package incorrectly, storing under improper conditions etc.

3. Storage took place under the following conditions:

- Fixed selected temperature between 5°C and 35°C
- Maintained relative humidity <70%
- No direct exposure to the sun or sources of harmful radiation or heating equipment
- No dust or pathogenic microorganisms in the environment
- In storage rooms, keep packages in sealed cartons.

In hospital practice, it is useful to have a guideline system for assessing post-sterilisation storage time based on the principle of assigning a particular number of points to such factors as:

1. Type of packaging
2. Type of the second layer of the material used for packaging
3. Additional protection of the package
4. Place of direct storage after sterilisation
5. Storage conditions
6. Means and conditions of transport
7. Location of the package storage after sterilisation
8. Correct parameters of the sterilisation process

Depending on the combination of the factors involved, total points determine the permitted storage time after sterilisation. However, remember that if the expiry date of the packaging itself (resulting from its production date) comes before the storage time determined by the total points, the package can be stored only until the expiry date of the packaging.

Also, individual point values assigned to a factor cannot be used selectively or to assess the storage time separate from other factors. Points for the factors mentioned above are given below.

Direct packaging type (selected examples)

- crepe paper in sheets* 20
- nonwoven* 40
- paper-film packaging 80
- Tyvek®-film packaging 80
- nonwoven-film packaging 40
- sterilisation container/receptacle with internal primary packaging 210

* types of materials which should always be used with the second layer of the packaging material

Using the additional layer of packaging in which the item is sterilised. The below points are not added if the additional packaging layer is treated as a part of the sterilised item and its external part is also to be sterile (selected examples).

- crepe paper in sheets* 60
- nonwoven* 80
- nonwoven-film packaging 80
- paper-film packaging 100
- Tyvek®-film packaging 100

Additional protection to secure against external damage or contamination (selected examples)

- protective after-sterilisation bag, completely closed 400
- dust cover for the container 250
- closed box (for sterile medical supplies only) 250

Direct storage place:

- cart for sterile items 0
- open rack 0
- closed cabinet, drawer 100

Storage place location:

- hospital corridor/patient room 0
- treatment room 50
- storage in a hospital ward 75
- sterile storage in a hospital ward 250
- sterile storage in an operating theatre 250
- central sterile storage 300

Control humidity and temperature
at the medical material storage location.

TOTAL POINTS	APPROXIMATE STORAGE TIME
1 - 25	24 hours
26 - 50	1 week
51 - 100	1 month
101 - 200	2 months
201 - 300	3 months
301 - 400	6 months
401 - 600	1 year
601 - 750	2 years
> 750	5 years

To sum up: a sterilised item packed in a paper-film pouch (80 points) can be stored in a closed cabinet (100 points) in sterile storage in a hospital ward (250 points) for 1 year (total: 430 points), and additionally, it can be placed in a closed box (250 points) for up to 2 years (total: 680 points).

NOTE

storage times are determined by the manufacturer of the sterile material

The blow table shows approximate storage times based on the packaging type used.

The approximate storage times of sterile items

Type of packaging	Storage without dust protection on shelves in a room without controlled storage conditions.	Storage with dust protection in closed cabinets, drawers or on shelves in rooms with controlled storage conditions.
Primary packaging The sterile barrier system, single sterile packaging and double sterile packaging with or without the internal packaging.	**Intended for immediate use – must not be stored!**	**6 months** but not longer than the packaging expiry date
Dust protection (storage packaging) Dust cover (storage) can be used for more than one primary packaging, but it must be closed immediately after removing the sterile packaging. Reusing the dust cover is forbidden.	**Maximum 5 years** (in storage packaging) or in line with the maximum storage time recommended by the producer. The user can use their own storage system instead of storage packaging for sterile items. The original marking of the packaging must be made appropriately.	

Sterile items intended for use in operating theatres should always be provided in double packaging. The external packaging is removed before the operating theatre, and the sterile item is removed from the internal packaging in the operating theatre. With this procedure, aseptic conditions can be maintained, even after a long storage time of the sterile item in double packaging.

7 OUR OFFER

Toruńskie Zakłady Materiałów Opatrunkowych SA offers disposable packaging and materials for sterilisation. The offer of sterilisation packaging includes a wide range of technologically advanced **pouches and reels** for sterilisation with saturated **steam** under positive pressure, **ethylene oxide, formaldehyde, hydrogen peroxide or radiation**.

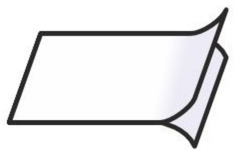
The raw materials used in the production, as well as the finished products, meet the requirements of European Standards. The products are registered in the **Register for Medical Devices at the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products**.

We hold certificates of conformity to the following standards: **ISO 9001 and ISO 13485.**

7.1 QUALITY OF THE PACKAGING COMPONENT CONNECTIONS

The technology of combining paper-film laminate was developed to achieve the best combination of the packaging strength during sterilisation and its ease of opening. It incorporates the properties of carefully selected materials (including the fabric type and the paper structure, the structure and characteristics of the film) and the value of the sealing pressure and temperature, which is continuously monitored by measuring sensors with an accuracy of ± 1°C. An optimal strength of the connection with seals was determined for each pouch size and each reel width. Production lines work according to parameters set in such a way. Each seal undergoes a cooling stage to ensure its full stability before the cross-cutting process. The sealing mould for the opening side of the packaging is shaped to avoid sharp angles where the seals join and intersect.

It guarantees additional strength during sterilisation and, at the same time, gives a better effect when the package is opened later. The sealing on the packaging is multi-track. The sealing width is selected to meet the European Standard. Finished products undergo ongoing quality control, which is documented.



Opening in a way indicated by the pictogram keeps the peel effect, so the packaging is opened in a safe, aseptic and dust-free way.

STERILISATION INDICATORS ON PACKAGING

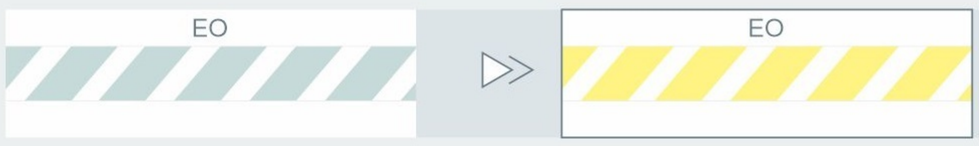
Easy-to-read chemical indicators on individual packs make it possible to differentiate sterilised packages from those not sterilised and provide evidence that the sterilisation process has been carried out. There is information about the indicator colour before and after sterilisation at each indicator to make it easier to read.

The following chemical indicators are used in the packaging:

Sterilisation with steam under positive pressure — in the form of a pink rectangle which turns brown after sterilisation using this method.

before sterilisation — after sterilisation

Sterilisation with ethylene oxide — in the form of a green and blue rectangle which turns yellow after gas sterilisation.

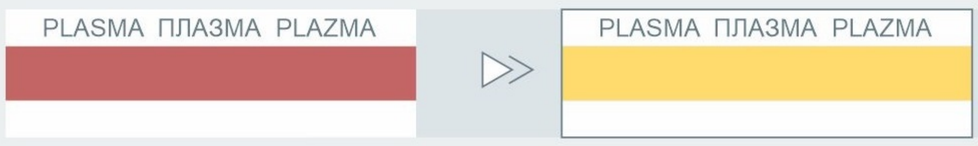


before sterilisation — after sterilisation

Sterilisation with formaldehyde — in the form of a pink rectangle which turns green after sterilisation.

before sterilisation — after sterilisation

Sterilisation with plasma — in the form of a red rectangle which turns yellow after sterilisation.

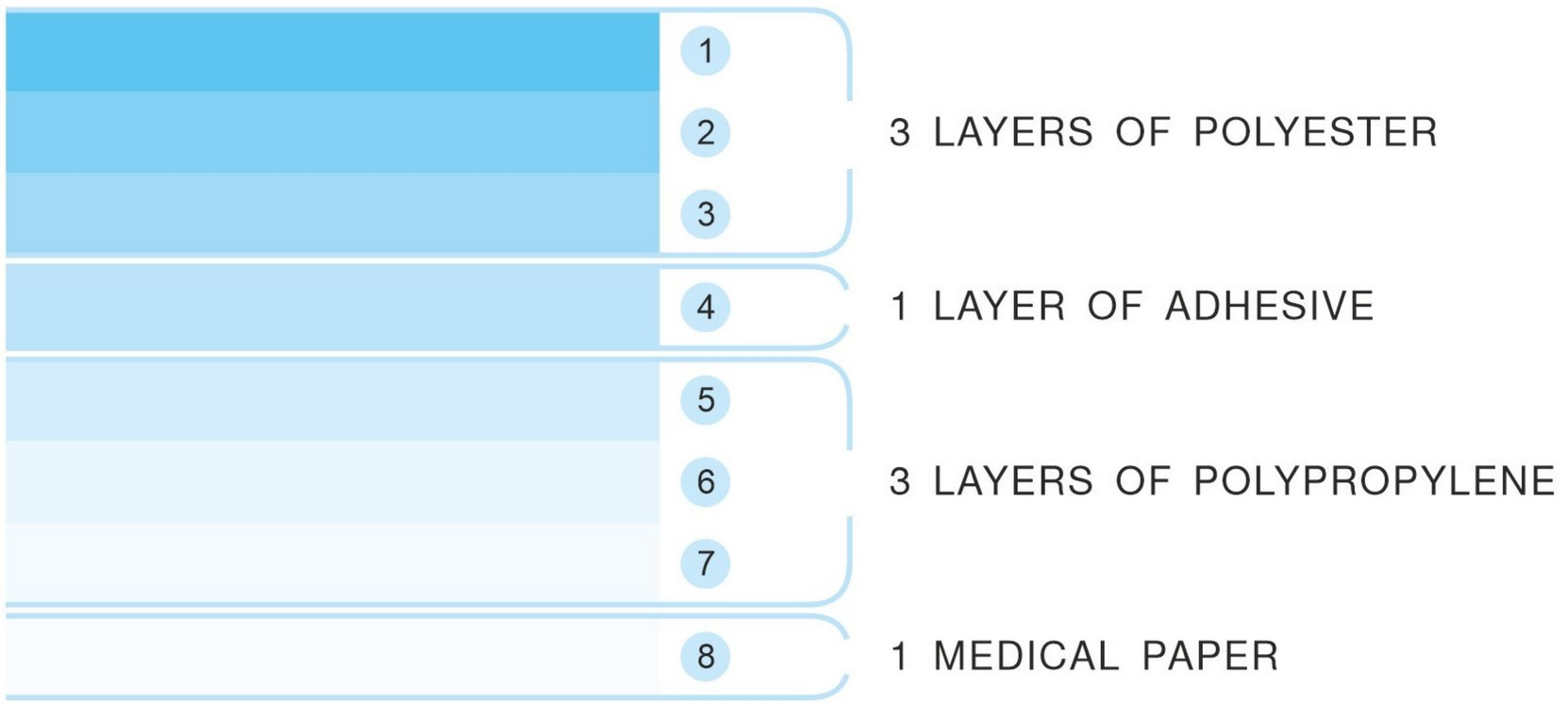


before sterilisation — after sterilisation

Indicators for steam, ethylene oxide, formaldehyde and plasma, as well as other texts are printed in the form of a strip on paper/nonwoven/Tyvek® in the sealing area under the film. The indicators placed in such a way during the storage after sterilisation and the medical material visible under the film layer are on the same side of the packaging, so there is no need to turn the package during control.

Each of the indicators printed has an area of at least 100 mm^2 in line with the requirements of EN 868-5. Thanks to the contrasting colour change of the indicators on our packaging, the sterilisation type of the package is easy to recognise.

CONSTRUCTION OF PAPER-FILM PACKAGING



7.2 EUROPEAN STANDARDS

The goods are manufactured based on the currently applicable editions of European standards:

- EN 868-2
  Packaging for terminally sterilised medical devices – Part 2:
  Sterilization wrap – Requirements and test methods
- EN 868-3
  Packaging for terminally sterilised medical devices – Part 3:
  Paper for use in the manufacture of paper bags (specified in EN 868-4)
  and in the manufacture of pouches and reels (specified in EN 868-5) – Requirements
  and test methods
- **EN 868-5**
  Packaging for terminally sterilised medical devices – Part 5:
  Sealable pouches and reels of porous materials and plastic film construction –
  Requirements and test methods
- EN 868-6
  Packaging for terminally sterilised medical devices – Part 6:
  Paper for low temperature sterilization processes – Requirements and test methods
- EN 11140-1
  Sterilization of health care products
  – Chemical indicators – Part 1: General requirements
- **EN ISO 11607-1**
  Packaging for terminally sterilised medical devices – Part 1:
  Requirements for materials, sterile barrier systems
  and packaging systems
- **EN ISO11607-2**
  Packaging for terminally sterilised medical devices – Part 2:
  Validation requirements for forming, sealing and assembly processes

8

PACKAGING ADVANTAGES

Each product we offer meets rigorous requirements. Key parameters of paper-film packaging, nonwoven-film, Tyvek®-film.

SAFETY

- High-quality raw materials resistant to damage, as well as durable sealing guarantee the appropriate strength of packaging.
- Sterilisation process indicators are placed outside the loading area for safety.
- Indicator colours before and after the process make it easy to read.
- The suitable sizes of the pictograms and markings, as well as the standardised frequency of their appearance on the packaging, minimise the risk of making mistakes when assessing packaging after the sterilisation process. Pictogram and marking parameters are in line with EN 868-5.
- Dust-free opening of the packaging (the "peel" effect) increases safety in the operating theatre.

RESPONSIBILITY

- The packaging is a medical device - the label bears the CE and MD marking.
- Each package has an identification of the European standards met.
- Each package has a full identification of the product, its size, LOT, opening direction and producer identification.
- Each package has a pictogram marking it as for disposable use.
- The information on the packaging expiry date is given on the label and, in the case of reels, also inside the reel, which is why such information can be verified until the end of the use of a given roll of the reel.

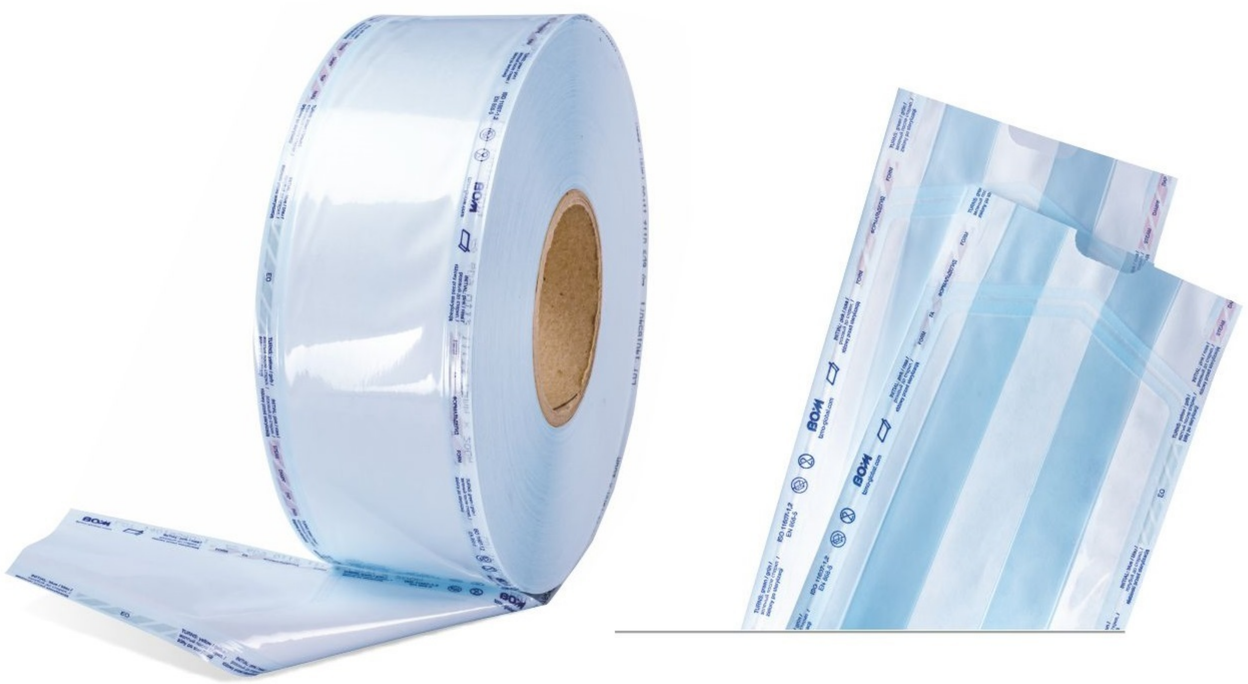
COMFORT

- Transparent laminate allows for easy identification of the contents.
- Pictograms indicating the opening direction are placed on the packaging and are visible on both sides, which facilitates its correct opening.
- Packaging has two cuts for a thumb – one makes it easier to insert the content, and the second one makes it easier to open the packaging (it does not apply to adhesive pouches and reels).
- The fold allows for packing of larger or non-standard sized items (in the case of gusseted packaging)

8.1 FLAT AND GUSSETED PAPER-FILM POUCHES AND REELS

STEAM / EO / FORM

They are intended for sterilisation with saturated steam, ethylene oxide and formaldehyde.
The sterilisation indicator is placed within the seal and outside the loading area.



Sterilisation indicators – see page 21.

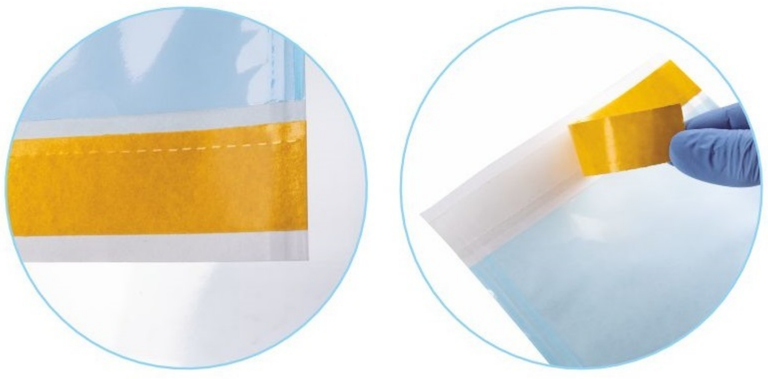
Sizes:
pouches: width 40 mm - 600 mm,
length 90 mm - 1200 mm
reels: width 50 mm - 650 mm,
length 60 rm - 200 rm

Expiry period: 5 years.

8.2 ADHESIVE PAPER-FILM POUCHES

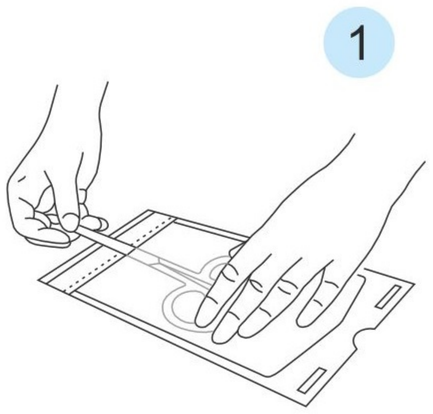
STEAM / EO

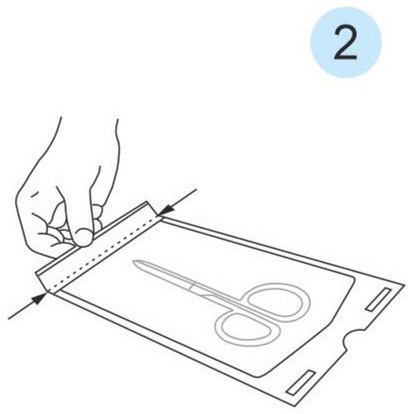
They are intended for sterilisation with saturated steam, ethylene oxide and formaldehyde (using a correct indicator). The indicators of sterilisation with steam and ethylene oxide are located on paper, in the upper part of the pouch, outside the seal line and the loading area.

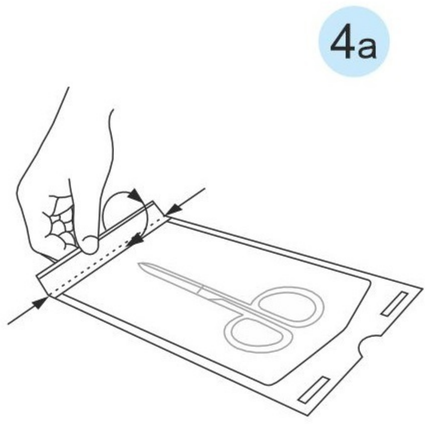


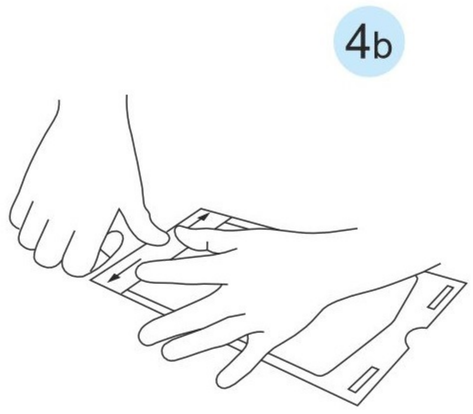
Thanks to the elongated paper part with an adhesive layer applied to close the pouch, a sealing machine is not needed.

Perforation makes it easier to close the packaging.









DIRECTIONS FOR USE

1. Put the sterilised item in an optimally selected pouch with the grip part towards the chevron (V-shaped seal). Remove excess air from the packaging.
2. Fold the pouch edge along the perforation.
3. Peel off the paper strip securing the adhesive.

4 ab. Close the packaging by carefully pressing the adhesive layer over the entire surface, starting from the centre towards the edges of the pouch. Check if the adhesive layer adheres uniformly over the entire surface.

After the sterilisation process, open on the opposite side.

Sterilisation indicators – see page 21.

Sizes:

width 50 mm - 600 mm,
length 90 mm - 800 mm

Expiry period: 5 years.

8.3 TYVEK®-FILM POUCHES

VH2O2

We offer a special group of packaging intended for plasma sterilisation. They are made of top-quality materials which do not contain cellulose and consist of transparent film and a white synthetic Tyvek® material.
Tyvek® is a super-strong material made of high-density polyethylene fibres bonded together using high temperature and pressure. Tyvek® contains no adhesive, binders or other foreign materials. It is characterised by high tear and puncture resistance.

Tyvek® — registered trademark of DuPont.

Sterilisation indicators – see page 21.

Sizes:
width 50 mm - 650 mm,
length 70 rm - 100 rm

Expiry period: 5 years.

8.4 FLAT NONWOVEN-FILM POUCHES AND REELS

STEAM / EO / FORM

These are packaging recommended for packing heavier and larger items, such as tools or linens. One side is made of a high-quality blue nonwoven, and the other side is made of film laminate. Pouches and reels can be sterilised with steam, ethylene oxide and formaldehyde.

Sterilisation indicators – see page 21.

Sizes:
pouches: width 50 mm - 600 mm,
length 150 mm - 900 mm
reels: width 50 mm - 900 mm,
length 60 rm - 100 rm

Expiry period: 5 years.

9 KEY PARAMETERS OF PAPER IN SHEETS

Crepe paper is used for packing medical materials assigned for sterilization by steam, ethylene oxide, formaldehyde or radiation.

SAFETY

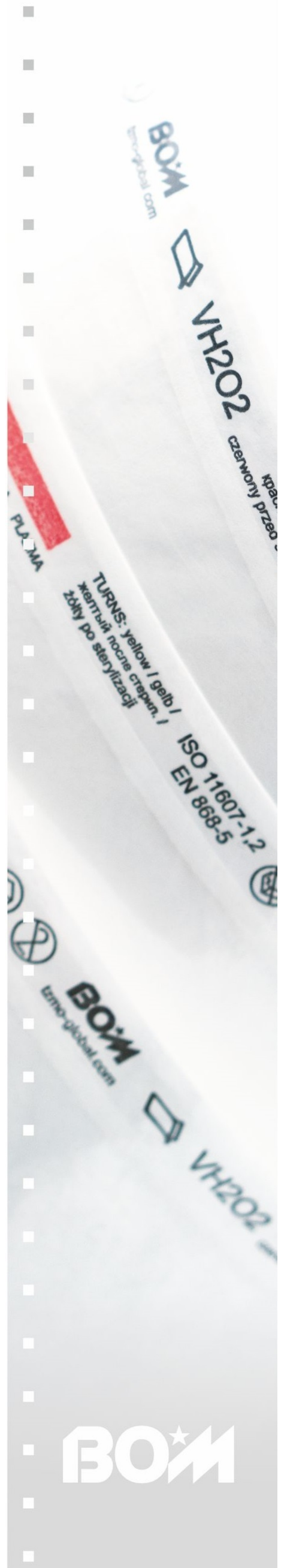
- Excellent permeability for the sterilising agent in numerous sterilisation methods.
- A non-toxic, dust-free product ensures the safety of use.
- High strength parameters and the easiness to shape.
- The most eco-friendly and fully biodegradable packaging for sterilisation (100% cellulose) without chlorine.

RESPONSIBILITY

- Each pack has a full identification of the product, its size, producer identification and the CE and MD marking.

COMFORT

- Packing in two sheets of paper of different colours makes it easier to verify possible damages to the sterile barrier.
- Dimensional stability when dry and wet.
- Antistatic product.
- A wide range of sizes and colours facilitates the choice of appropriate packaging.



9.1 CREPE PAPER IN SHEETS

STEAM / EO / FORM / R

Paper sheets are available in three colours – white, green and blue.

Sizes:
300 mm x 30 mm to 1200 mm x 1500 mm

Expiry period: 5 years.

9.2 CREPE PAPER ALTERNATELY PACKED

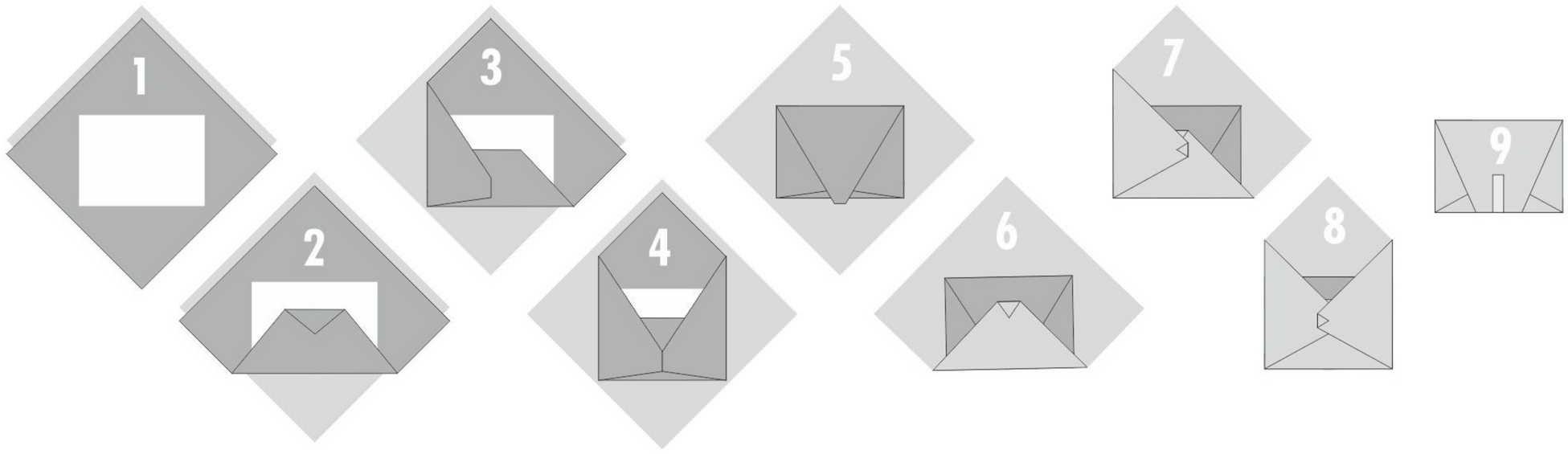
STEAM / EO / FORM / R

We have developed a special offer for crepe paper. Paper sheets in two colours (white and green) are packed in one box and arranged alternately. It will increase the comfort of work and facilitate and accelerate the process of double packing.

Sizes:
300 mm x 300 mm to 1200 mm x 1500 mm

Expiry period: 5 years.

METHOD OF PACKING IN PAPER AND NONWOVEN



We also offer adhesive tapes (with or without sterilisation indicators) for closing packages.

10 KEY PARAMETERS OF NONWOVEN IN SHEETS

SAFETY

- Excellent permeability for the sterilising agent in numerous sterilisation methods.
- Non-toxic, dust-free – ensures the safety of use.
- High parameters of tear, puncture and tensile strength, as well as high softness.

- High resistance to permeation by water and low-voltage liquids, including alcohol (in line with European Standards).
- Packing in two sheets of a nonwoven of different colours makes it easier to verify possible damages to the sterile barrier.
- This material is recommended for packing medium and large sets, e.g. orthopaedic instruments.
- No chlorine

RESPONSIBILITY

- Each pack has a full identification of the product, its size, producer identification and the CE and MD marking.

COMFORT

- Colour variants allow for introducing additional identification procedures.
- Anti-static, anti-reflective, non-sticky product

10$_1$ **CELLULOSE** NONWOVEN IN SHEETS

STEAM / EO / FORM / R

The nonwoven is intended for sterilisation with steam, ethylene oxide, formaldehyde and radiation. The nonwoven is made of cellulose pulp reinforced with synthetic fibres. Thanks to the high mechanical tear and tensile strength of the nonwoven and its high softness, the material is recommended for packing medium and large sets, for example, orthopaedic instrument sets, etc. The sheets of nonwoven are available in two colours: green and blue.

- Raw materials: cellulose pulp bleached without chlorine, synthetic fibres and binder.

Sizes:
green:
500 mm x 500 mm to 1300 mm x 1500 mm,
blue:
500 mm x 500 mm to 1370 mm x 1830 mm

Expiry period: 5 years.

10$_2$ SMS NONWOVEN IN SHEETS

STEAM / EO / FORM / VH2O2 / R

The nonwoven is intended for sterilisation with steam, ethylene oxide, formaldehyde, VH2O2 (plasm) and radiation. The nonwoven is made of synthetic fibres (100% polypropylene), is characterised by increased mechanical break strength and is recommended for packing heavy sets. The sheets of nonwoven are available in two colours: green and blue.

Sizes:
600 mm x 600 mm to 1370 mm x 1370 mm

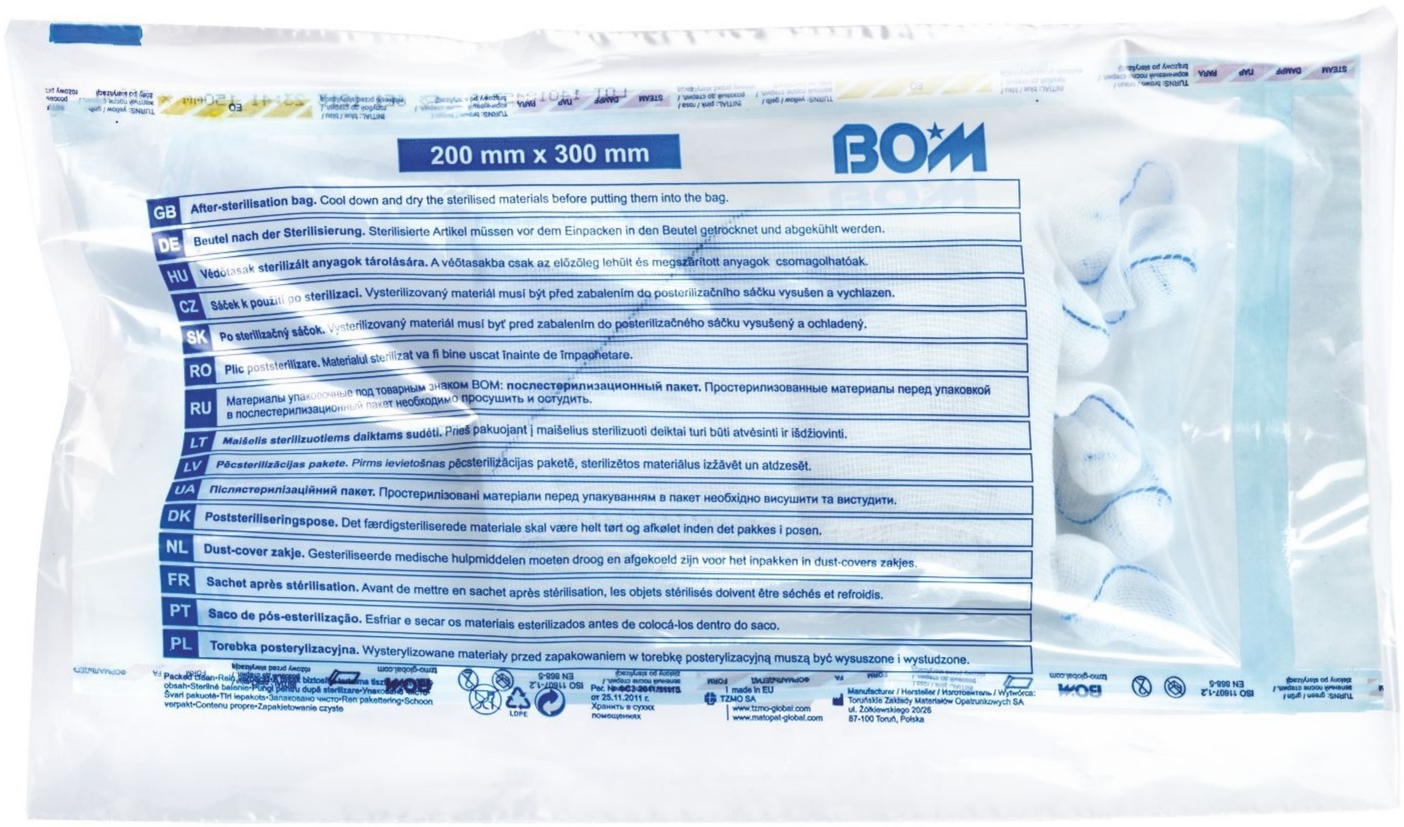
Expiry period: 5 years.

11 AFTER-STERILISATION ADHESIVE BAGS

They are used to secure sterile packages and provide anti-dust protection. Closed bags provide additional protection to extend the immediate storage period after sterilisation.

They effectively protect the packs from dust and moisture.

Such packaging can also be used for other hospital purposes – as disposable protection for contaminated material before and during disposal.



Sizes:

width 150 mm - 600 mm,
length 250 mm - 760 mm

Expiry period: 5 years.

12 PACKAGING STORAGE CONDITIONS

- temperature 5°C — 35°C,
- relative humidity <70%,
- away from direct sunlight and radiation,
- away from heaters, ethylene oxide tanks and autoclaves,
- protect from dust and moisture.

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SAFE MEDICAL PACKAGING

STORAGE AFTER STERILISATION

Depending on the combination of the factors involved, total points determine the permitted storage time after sterilisation. However, remember that if the expiry date of the packaging itself (resulting from its production date) comes before the storage time determined by the total points, the package can be stored only until the expiry date of the packaging. Also, individual point values assigned to a factor cannot be used selectively or to assess the storage time separate from other factors. Points for the factors mentioned above are given below.

Direct packaging type (selected examples)

crepe paper in sheets*	20
nonwoven*	40
paper-film packaging	80
Tyvek® -film packaging	80
nonwoven-film packaging	40
sterilisation container/receptacle with internal primary packaging	210

* types of materials which should always be used with the second layer of the packaging material

Using the additional layer of packaging in which the item is sterilised. The below points are not added if the additional packaging layer is treated as a part of the sterilised item and its external part is also to be sterile (selected examples).

crepe paper in sheets	60
nonwoven	80
nonwoven-film packaging	80
paper-film packaging	100
Tyvek®-film packaging	100

Additional protection to secure against external damage or contamination (selected examples)

protective after-sterilisation bag, completely closed	400
dust cover for the container	250
closed box (for sterile medical supplies only)	250

Direct storage place:

cart for sterile items	0
open rack	0
closed cabinet, drawer	100

Storage place location:

hospital corridor/patient room	0
treatment room	50
storage in a hospital ward	75
sterile storage in a hospital ward	250
sterile storage in an operating theatre	250
central sterile storage	300

Control humidity and temperature at the medical material storage location.

TOTAL POINTS	APPROXIMATE STORAGE TIME
1 - 25	24 hours
26 - 50	1 week
51 - 100	1 month
101 - 200	2 months
201 - 300	3 months
301 - 400	6 months
401 - 600	1 year
601 - 750	2 years
> 750	5 years

This document is addressed only to professionals.

To sum up: a sterilised item packed in a paper-film bag (80 points) can be stored in a closed cabinet (100 points) in sterile storage in a hospital ward (250 points) for 1 year (total: 430 points), and additionally, it can be placed in a closed box (250 points) for up to 2 years (total: 680 points).

NOTE

storage times
are determined by the
manufacturer of the sterile material

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