A correctly designed sterilization package manufactured from reliable materials is an important part of the overall chain of action aiming to assure and improve patient safety.

Steriking® packages are well known among hospital users for their high quality and reliable performance.
The process of designing and developing a sterilization packaging is a complicated and critical endeavor. The medical device components and the packaging system should combine to create a total product that performs efficiently, safely, and effectively. The specific nature of the medical device, the intended sterilization methods(s), the intended use, expiry date, transport and storage all influence the packaging system design and choice of materials.

The goal of a terminally sterilized medical device packaging system is to allow sterilization, provide physical protection, maintain sterility to the point of use and allow aseptic presentation.

Source: ISO 11607: 1997(E)

Sterile supply chains in hospital and other clinical applications with their wide variety of products and sterilization processes place a great deal of strain on the packaging system.
Steriking® products are designed, manufactured and distributed to meet the highest standard in critical aspects such as:

- mechanical, chemical, biological strength and safety
- product performance in the intended use
- easy closing and peel opening features
- environmental considerations
- cost efficiency at use
- product availability

**Product principles**

**STERIKING® Health Care Product range**

- See-through pouches & rolls
- Special pouches, bags & rolls
- Paper & nonwoven wrapping sheets
- Chemical indicator products & tapes
- Equipment & other accessory products
See-through pouches & rolls

See-through pouches, bags and tubings - with or without gussets - have been developed and designed for packing individual items or smaller sets, some larger and heavier items as well as instrument and laundry sets.

• Steriking® packages are designed to facilitate the aseptically safe presentation of the sterilized items.
• The multiple seal is strong to withstand sterilization, yet it provides a clean opening.
• Steriking® heat sealers facilitate the reliable closure of sterilization packs. Optimum sealing temperature and pressure are determined to ensure that the correct seal strength and peel characteristics are obtained.

Safe closure & aseptic opening
The design of a pack is of great importance

1. Visual check of the seal integrity
   When sealed, the film turns to darker green, so you can check that the seal is undamaged and detect any defects.

2. Superior peel of seal
   Pouches feature a specially designed peel-off seal to facilitate opening. Note the correct peel-away direction.

3. Strong performance
   The seal, comprising several narrow parallel seams (Multiline), is extremely strong and durable yet peels off cleanly.

4. Sealed edges
   Heat-sealed upper corners reduce the risk of dust contamination when opened.

5. Easier opening
   Thumb notches at each end make it easier to fill and open the pack.

6. Print design safety
   Indicators and text imprints are outside the actual packing area to avoid the risk of ink contamination.

7. Manufacture traceability
   Each Steriking® package carries a lot code that states its manufacturing year and month (YYMM).

8. Process indicators printed on the packs
   EN 867-2 compliant, providing clearly contrasting color changes.

9. Exclusive materials
   Made of a tough and flexible multilayer plastic film and high grammage medical grade paper.

10. Compliant with EN 868-5
    Transport cartons labelled with a CE-mark. All Steriking see-through packages are manufactured in highly controlled Clean Room conditions to minimize the bioburden of materials.

Advantages of see-through packaging

- **Compact, requires minimal storage space**
  - Wide range of types and sizes

- **Fast and easy packing process**
  - Heat-seal or self-seal
    - Hermetic, bacteria proof closing
    - Green seal visual control of integrity

- **Identification, marking**
  - Process indicators for sterilization imprinted
  - Identification of the packed item through transparent film
  - Labels / markings onto the plastic film

- **Optimal, safe barrier system**
  - Plastic film practically 100 % barrier
  - Special paper with controlled porosity, tortuous fiber path
  - Easy checking of barrier integrity

- **Safe disposal**
  - Land filling without risk of toxic substances
  - Incineration recommended for energy recovery
The wide range of standard sizes gives you the optimum choice of a correctly sized pack for each item and for double packing purposes.

<table>
<thead>
<tr>
<th>Inner packaging</th>
<th>Outer packaging</th>
<th>Examples of medical devices to be packed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Art. code</td>
<td>Size (mm)</td>
<td></td>
</tr>
<tr>
<td>S17</td>
<td>50 x 200</td>
<td>S18 75 x 300 Small drill bits, special needles, tip protection</td>
</tr>
<tr>
<td>S1</td>
<td>50 x 250</td>
<td>S19 100 x 350 Probes, guiding probes, orthopedic pins</td>
</tr>
<tr>
<td>S24</td>
<td>75 x 150</td>
<td>S5 100 x 270 Drill bits, saw blades, pallets, beads, small connectors</td>
</tr>
<tr>
<td>S23</td>
<td>75 x 230</td>
<td>S5 100 x 270 Testers, cotton swabs</td>
</tr>
<tr>
<td>S2</td>
<td>75 x 200</td>
<td>S8 100 x 300 Eye instruments, small scissors, dissecting forceps</td>
</tr>
<tr>
<td>S4</td>
<td>75 x 270</td>
<td>S9 100 x 350 Separate pinces, sensors, probes, suction tips, skin hooks, grasping forceps, electrodes</td>
</tr>
<tr>
<td>S18</td>
<td>75 x 300</td>
<td>S9 100 x 350 Instruments, drains</td>
</tr>
<tr>
<td>S22</td>
<td>75 x 520</td>
<td>R41 100 x … Orthopedic nails and pins, Kirschner wires, long instruments</td>
</tr>
<tr>
<td>S25</td>
<td>100 x 150</td>
<td>S6 150 x 270 Small cotton tampoes, small instruments</td>
</tr>
<tr>
<td>S3</td>
<td>100 x 200</td>
<td>S20 150 x 300 Separate connectors</td>
</tr>
<tr>
<td>S5</td>
<td>100 x 270</td>
<td>S13 150 x 400 PEAN, scissors, needle holders, different blades (larynx, tongue), nose specula, dentist instruments</td>
</tr>
<tr>
<td>S8</td>
<td>100 x 300</td>
<td>S13 150 x 400 Instruments, gauze pads, drains, sample tubes, tampons</td>
</tr>
<tr>
<td>S19</td>
<td>100 x 350</td>
<td>S28 150 x 520 Long forceps, organs</td>
</tr>
<tr>
<td>S9</td>
<td>100 x 400</td>
<td>S28 150 x 520 Long forceps, organs, delicate instruments</td>
</tr>
<tr>
<td>S12</td>
<td>100 x 570</td>
<td>R42 150 x … Long instruments, Kirschner wires</td>
</tr>
<tr>
<td>S27</td>
<td>120 x 400</td>
<td>S28 150 x 520 Wire cutting pliers, biopsy tongs</td>
</tr>
<tr>
<td>S15</td>
<td>150 x 200</td>
<td>S10 205 x 400 Breast rubbers, milk collectors</td>
</tr>
<tr>
<td>S6</td>
<td>150 x 270</td>
<td>S10 205 x 400 Instruments, bandages, preparation glasses, sponges, tampons, gauzes, scissors, pincets, cannule, procedure and skin washing sets</td>
</tr>
<tr>
<td>S20</td>
<td>150 x 300</td>
<td>S10 205 x 400 Separate small instruments, bowls, max. puncture sets, elastic bandages</td>
</tr>
<tr>
<td>S26</td>
<td>150 x 350</td>
<td>S11 250 x 500 Different kind of separate instruments or sets</td>
</tr>
<tr>
<td>S13</td>
<td>150 x 400</td>
<td>S21 300 x 500 Forceps, needle holders, amnioscopes</td>
</tr>
<tr>
<td>S28</td>
<td>150 x 520</td>
<td>R43 200 x … Drains, suction hoses</td>
</tr>
<tr>
<td>S34</td>
<td>160 x 600</td>
<td>R43 200 x … Rigid endoscopes, long instruments</td>
</tr>
<tr>
<td>S7</td>
<td>205 x 270</td>
<td>S16 250 x 380 Diathermia leads, bowls, irrigation bottles, gauze pads, elastic bandages</td>
</tr>
<tr>
<td>S10</td>
<td>205 x 400</td>
<td>S14 300 x 570 Kidney bowls, diathermias, small instrument sets</td>
</tr>
<tr>
<td>S16</td>
<td>250 x 380</td>
<td>S21 300 x 500 Diathermias</td>
</tr>
<tr>
<td>S11</td>
<td>250 x 500</td>
<td>R45 300 x … Light cables, aluminium/thermal sheets</td>
</tr>
<tr>
<td>S29</td>
<td>270 x 350</td>
<td>S21 300 x 500 Silicon hoses, small instrument sets, dentist instruments</td>
</tr>
<tr>
<td>S30</td>
<td>270 x 440</td>
<td>S14 300 x 570 Small instrument sets, dentist instruments</td>
</tr>
<tr>
<td>S21</td>
<td>300 x 500</td>
<td>R47 400 x … Small instrument sets, dentist instruments</td>
</tr>
<tr>
<td>S14</td>
<td>300 x 570</td>
<td>R47 400 x … Suction bottles, -caps, -tubes</td>
</tr>
<tr>
<td>S31</td>
<td>420 x 500</td>
<td>Procedure instrument sets, OR textiles</td>
</tr>
<tr>
<td>S32</td>
<td>420 x 600</td>
<td>Procedure instrument sets, OR textiles, laser fibers</td>
</tr>
</tbody>
</table>
**Pros and cons**

The choice between a heat seal and self seal product.

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### Heat Seal

**Heat Seal is a mechanical bond**
- Hermetic closure by heat and pressure
- Fast and easy closing process can be validated
- Safe and tight barrier against contamination
- Visual check of seal integrity
- No deterioration of seal integrity upon time
- Seal strength is not affected by storage conditions and time
- Lower unit price
- Wide choice of tubings or ready made pouches
- Sealer investment pays back in terms of safety and speed

### Self Seal

**Self Seal is a chemical bond**
- Quick and easy to apply closing by hand
- Seal integrity dependent on handling by the end-user
- Closure quality more demanding to control
- Careful closing to avoid air channels in the seal
- Shelf life affected by sterilization & storage conditions as well as time
- Tape provides a limited shelf life (glue dries out)
- Higher unit price
- Available as flat pouches
- Cost advantage as no investment in sealer required

Both heat seal and self seal pouches are available in the Steriking® range.

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### FAQs about the use of see-through packaging

<table>
<thead>
<tr>
<th>Question</th>
<th>Suggestion</th>
</tr>
</thead>
</table>
| The package does not seal properly?                | Check the sealing temperature and pressure settings.  
  |                                                   | Recommended temperature 155-180 °C                |
| Double packaging?                                  | Paper to paper, film to film                    |
|                                                    | Folding of package edges not recommended        |
| The package bursts open during sterilization?      | Check the loading of tray and/or chamber         |
|                                                    | Pack each pouch up to 3/4 of the theoretical packaging area |
| Packages are moist after sterilization?            | Allow the load to cool down                     |
| Water droplets on the film?                        | Check the cooling process and vacuum pulses      |
| The package tears on opening?                      | Peel off in the right direction; check the peel symbol |
|                                                    | Follow the correct sealing and opening procedure |
|                                                    | Make sure your opening seal is not too strong when producing the package from tubing |
Cover Bags

Cover Bags are designed for use in healthcare facilities to provide extra protection against contamination to sterilized medical items. They are a safe choice when extra sterility time is needed or the proper hygiene conditions cannot be met, for example during outdoor transportation.

A dust cover bag protects a product in its primary sterile packaging against dust and environmental agents.

Transport and storage without suitable secondary packaging involves a certain risk for sterile goods. The right choice of packaging for transport and storage extends the shelf life of sterile medical devices.
Steriking® dust cover bags are made of an extremely tough and durable multilayer plastic film providing superior peel-open characteristics compared to conventional tear-off bags. The cover bags protect sterile packages during transport and storing. Sterilized items are cooled down after sterilization before packing into a dust cover.

Two product versions are available:

CB - TRADITIONAL COVER BAG
- Heat sealable with an impulse or rotosealer.

DCSS - THE SELF SEAL VERSION OF COVER BAG
- Made with a tape strip that enables closing without heat sealing equipment.

Steriking® Seal Control is designed for operational qualification of the sealing process.

Where medical devices are packed for sterilization the user is responsible for assuring the performance of the final closing seal of a package. Steriking® Seal Control is designed for operational qualification of the sealing process.

Exclusive designed and patented by Wipak

Seal Control sheet

Where medical devices are packed for sterilization the user is responsible for assuring the performance of the final closing seal of a package. Steriking® Seal Control is designed for operational qualification of the sealing process.

Some points to observe when using the Seal Control sheet

1. Set the temperature of the sealer unit to 155-180 °C (324-376 °F) in accordance with the manufacturer’s recommendation.

2. Run the upper part of the Seal Control sheet through the sealer and seal the film to the paper back.

3. Check the quality of this test seal: the sealed lines should be continuous darker green with no white areas.

4. Fill in the form preprinted on the paper back of the Seal Control sheet, sign and file the document.
Sterilization wraps of nonwoven or paper are best suited for larger instrument trays and fabrics. The nonwoven materials are ideal for wrapping heavy and sharp items.

**Paper & nonwoven wrapping sheets**

- **SMS - HIGH PERFORMANCE POLYPROPYLENE WRAP**
  - For the most demanding applications
  - Also for low temperature sterilization (e.g. hydrogen gas plasma).

- **SCB - SOFT CREPED PAPER**
  - Improved strength and drapeability.

- **SPC - SPECIAL GRADE CREPED PAPER**
  - Improved flexibility.

- **NWG - NONWOVEN FOR DEMANDING APPLICATIONS**
  - Superior softness and toughness.

- **NWB - NONWOVEN FOR GENERAL USE**
  - For laundry and instrument sets.

- **SCB - SOFT CREPED PAPER**
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  - Superior softness and toughness.

- **NWB - NONWOVEN FOR GENERAL USE**
  - For laundry and instrument sets.
Sterilization tapes
These specific tapes are developed for closing paper and nonwoven wrapping materials.

- INDICATOR TAPES
  - With Steam, EO-Gas and Hot-Air Indicator.
- NEUTRAL TAPES
  - Closing Tape with no imprint.
- TAPE DISPENSER

Chemical indicators
Exclusively developed indicator system for the continuous monitoring of sterilization processes.

- NEW DC - TEST PACK
  - Ready-made Pack for Bowie & Dick Test.
- NEW DT - TEST SHEET
  - For Bowie & Dick Test with a cloth package.
- NEW AC DOUBLE STRIPS
  - Chemical indicator for steam.
- NEW FO DOUBLE STRIPS
  - Chemical indicator for formaldehyde.
Sterility maintenance is an event related, rather than a time related function

Retention of sterility of the item is dependent, not only on the barrier material and method of sterilization, but also on the challenges it meets after packing and sterilization. These include, but are not limited to, exposure to humidity, airborne micro-organisms and to organisms on the hands of personnel. It can occur during transportation to the clinic, ward or operating theatre, during storage and when opened.

Sterilization Barrier: single use or re-usable

Commonly available barrier materials fall into two categories: Single use and Re-usable. Single use materials consist of papers, non-woven and plastic materials used singularly and in various combinations. Textiles (commonly known as linen) and rigid containers represent the re-usable category.

The major factors which should be considered when deciding on the most appropriate method for a particular application are performance, integrity, storage, transportation and handling, environmental considerations and last, but by no means least, cost.

Sterilization Performance and Integrity

The barrier material must allow complete penetration of the sterilant to all component parts. When using a gaseous sterilant, the barrier system must allow for its easy entrance and removal during the process. A distinct advantage for single use barrier materials over containers is that, even when double layering is used, as recommended, their high surface area and permeability compared to small filter ports, facilitates efficient sterilization of full and bulky loads.

The high surface area and permeability of single use barrier materials is also an advantage when seeking to ensure the removal of condensate generated when steam sterilizing heavy metal objects, aluminium containers, and large instruments.

Single use materials offer proven microbial barrier properties. Provided that the manufacturer’s instructions are followed, these materials ensure a very high degree of protection during storage, handling, transportation and aseptic opening.

Conventional textiles, whilst allowing for sterilization processing, provide a very poor microbial barrier. Repetitive uses may result in minor damage and reduced barrier properties, which are not always obvious.

Rigid containers offer good barrier characteristics, especially when new. They are, however, susceptible to damage and need frequent and thorough cleaning and inspection of filters, valves, lid clips, gasket seals and assemblies during their life cycle. Containers are much more likely to require an absorbent liner wrap to limit the effects of excess moisture. In addition, single use barrier materials, being of light weight, require much less energy during the heating cycle of the sterilization process.

Storage, Transportation, Handling & Aseptic presentation of a sterile item

Storage begins before any product is actually used. Single use barrier materials require minimal storage space and are supplied in a wide range of quantities and sizes. Similar comments can be made about textiles, but both containers and textiles need a larger inventory and large areas of multiple storage spaces. The limited size range of containers restricts their loading capability in the sterilizer. Additionally, single use barrier materials add virtually no extra weight to a procedure pack or theatre tray.

The wide range of sizes and types of single use sterilization materials allows for convenient and more economic solutions to barrier problems. Another benefit is that peeling open or unwrapping sterilization materials allows aseptic presentation at the point of use and may also provide a sterile field at no extra expense.

Cost Issue

Single use material costs are limited to the initial purchase price and disposal costs. Costs associated with re-usable products include their initial purchase price, storage, capital costs, component replacement costs, labour, energy, inspection, repairs (material and equipment), losses, rejection rates, chemicals, maintenance, water treatment, and eventually replacement costs. The cost of the various systems will vary from user to user and from application to application.

Environmental Considerations

Calculating the environmental burden of different types of materials is difficult. Whether comparing the impact of energy required to produce aluminium, or the fossil fuel to produce plastics, or a managed renewable resource, such as trees for paper, the analyses are not straightforward.

Re-usable containers may appear to offer a more environmentally acceptable option. However, these systems require replacement of the inner wraps, filters, indicators, labels and closures. In addition, containers and textiles need large quantities of water, detergents, disinfectants and energy on a daily basis.

Single use materials, on the other hand, may be difficult to recycle because they have been contaminated by infectious materials, or they are made of composite materials. They may however be incinerated, using approved combustion tech-niques. The energy recovered from that process makes them an environmentally acceptable option. To provide a complete answer to these questions a life cycle assessment for each system is required. This is an extremely complex and costly study, which may be subject to interpretation.

Source information: Sterile Barrier Association Ltd.

The introduction of single use products into hospitals in the early 1960’s led to a large reduction in nosocomial infections. A significant factor for this improvement was the replacement of textiles by single use materials.