Steriking® See-Through Reels meet the requirements of hospital sterilization procedures: steam, ethylene oxide and formaldehyde. Each product is compatible with the ISO 11607, part 1 and 2 as well as with part 5 of the EN 868 demonstrating that the packaging for terminally sterilized medical devices meet the international and EU requirements. The scopes of these standards apply to health care facilities and wherever medical devices are packaged and sterilized.

**Packaging**
The continuous roll or reel type of packaging is unwound and cut to the desired length. When measuring the size, it is important to allow extra space for sealing the package and also for a flap with which the package can then be easily opened. It is recommended that the packages should be filled to no more than three quarters of their length and minimum of 2 cm of empty space should be allowed around each instrument. The medical device should be oriented to ensure aseptic presentation — in other words positioned correctly inside the pack to enable easy removal of the packaging. Steriking® rolls are marked with a symbol indicating the correct peeling direction.

Where double packaging is required, it is important to position porous material against porous material and laminate against laminate because penetration of air and steam is only possible through the paper side. The inner packaging must not be folded so that the passage of steam remains unhindered.

**Sealing**
All seals, including closure seal/seals should be smooth, i.e. without folds, bubbles, or wrinkles. The colored plastic film turns a darker shade where the sealing has taken place, making it easy to check that the seal is intact.

Heat sealing devices must be capable of attaining the sealing conditions suitable for each specific sterile barrier system construction. Correct temperature, pressure and sealing time/speed combination need to be met. Preferably, only sealing devices manufactured and intended for medical use should be used. The sealing temperature shall be in the range of 165°-190°C.

The seals need to be strong to withstand the most vigorous sterilization process and handling, yet providing a clean peel. Closing too strongly should be avoided when sealing rolls as one of the seals needs to be opened fiber free. A manual test should be carried out for controlling the seal strength.

Closures that compress the package should not be used, (e.g. ropes, strings, elastic bands, paperclips, staples or similar items).
Labeling and writing
Writing or printing on pouches should only take place on the film side or on the paper outside the seals. Writing instrument should not have a potential for creating a hole or puncture in the sterile barrier system, i.e. ballpoint pens should not be used. Only markers intended for appropriate method of sterilization should be used. If labels are used they must not impede the sterilization process, i.e. must not block the breathable area of the package. Labels must not cover the seals or any necessary information such as indicators etc.

Loading the autoclave
If possible, the packages should be placed upright in the sterilizer, using partitions if necessary. If it is not possible to place the packages upright, they can be placed flat with porous material facing down. The packages should not be folded and they must not touch the chamber walls. The basket should not be packed too full, as the packages expand during the sterilization process and they must also be allowed to breathe freely. If a sterilization cycle must be repeated due to a malfunction or a cycle is aborted before completion, packages must be repacked prior to being placed into another sterilization cycle.

Inspection
After sterilization, the packages and products must be allowed to cool down before handling, checking and sorting them. Each product is checked as to whether the packaging is intact, the changes communicated by the process indicator have taken place, and the product is clean and dry. Wet packages are considered non sterile. Class 1 process indicators printed on the packaging help distinguish between products that have or have not been autoclaved, but do not provide evidence of sterilization. Indicators with a higher classification convey information on whether the sterilization process has attained the parameters controlled by the indicator.

Storage and transportation
The sterilized products are sorted for storage or delivery to the wards. The products should be stored in a dust-free place protected from sunlight, preferably in closed cabinets. It is recommended that the room climate has a humidity of 40 to 60% and a temperature of 15-25ºC. Maintenance of pack sterility is not only dependent on the packaging material and the method of sterilization: it is also dependent on handling, transport and storage conditions. Any unnecessary handling of the packages should be avoided, as this would increase the risk of contamination. The level of protection is considerably enhanced by using a minimum of two layers - in other words by double pouching.

In cases where the transport or storage circumstances are particularly challenging, protective packaging such as a pouch made of impermeable multi-layer film can be used to protect the sterilized packages.

Fiber-free opening and aseptic presentation
The seals on the upper corners of the packs should be unattached first. The package should then be opened by pulling the laminate away from the paper material slowly and evenly to prevent the fibres from breaking and thereby possibly causing contamination. When opening large and/or heavy packages they need to be supported by a table or a tray. Assistance may be needed to prevent any contamination of the packed instrument/instrument sets by accidentally touching the non sterile outer surface of the packaging material. Double packaging ensures safe and sterile opening. The inner pack remains sterile even on its outside until it is removed.

Waste management
After use STERIKING® sterilization pouches can be incinerated without producing toxic emanations. Of course, any contaminated product must be eliminated using a specialised method.