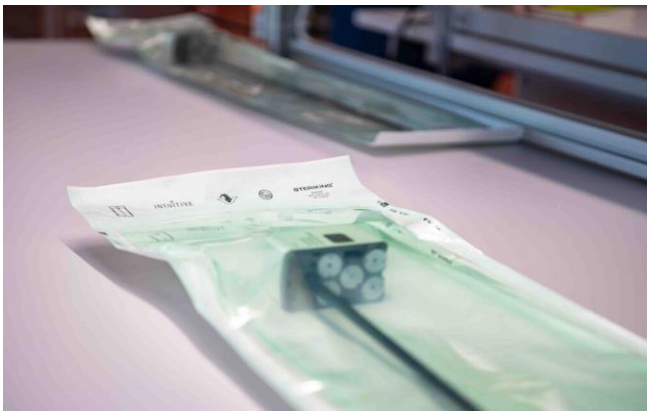
STERIKING® – Instructions For Use

Steriking® Pouch for Intuitive Endowrist Robotic Instruments

Product references: SdV10; SdV20; SSdV10; SSdV20



Indications for Use

Steriking Pouch for Intuitive Endowrist Robotic Instruments serve as an enclosure for Intuitive Endowrist Robotic Instruments during steam sterilization that maintains the sterility of the enclosed medical devices until they are used.

Pouches are intended for use as packaging material of Intuitive Endowrist Robotic Instruments, and other long devices for steam sterilization in health care establishments. The products are for single use only. Benefit of pouches is to allow sterilization, maintain sterility and enable aseptic presentation of packed medical device.

The recommended sterilization cycles are as follows:

- Pre-vacuum steam at 132°C for 4 minutes; Drying time of 20 minutes
- Pre-vacuum steam at 135°C for 3 minutes; Drying time of 16 minutes

Steriking Pouch for Intuitive Endowrist Robotic Instruments consists of a paper backing (Bleached wood pulp, grammage 100 g/m2) with transparent plastic film laminate front (2 sheets of laminated plastic with a total grammage of 55 g/m2, 1 sheet of oriented polyester 12 microns thick, 1 sheet of coextruded polypropylene 40 microns thick. The plastic laminate is triple heat sealed to the backing paper.

Steriking Pouch for Intuitive Endowrist Robotic Instruments consists of pouch sizes that can be heat sealed, and pouch sizes that are self-sealed.

For heat-sealed sizes: The open end of the pouch is to be heat sealed once a device is inserted. Heat sealing parameters to provide a sterile barrier are 165°C-200°C (329°F - 392°F).

Steriking Pouch for Intuitive Endowrist Robotic Instruments have Dimensional heat-seal configurations (2 sizes 200mm x 800mm, 250mm x 900mm).

Steriking Pouch for Intuitive Endowrist Robotic Instruments with heat-seal maintains the sterility of the enclosed devices for up to 1 year post Steam sterilization and before sterilization has a maximum shelf life of 5 years from the date of manufacture.

For self-sealed sizes: The open end of the pouch is to be self sealed once a device is inserted. Self-sealable pouches are featured with adhesive strip allowing tight, impermeable closing of a pack. The closing flap is pre-folded to facilitate the closure. When closing the self-seal pouch the paper flap shall be folded along the pre-folded line. Flap should be pressed firmly against the laminate from the center working outwards to ensure a good, even seal.

Steriking Pouch for Intuitive Endowrist Robotic Instruments have Dimensional self-seal configurations (2 sizes 200mm x 800mm, 250mm x 875mm).

Steriking Pouch for Intuitive Endowrist Robotic Instruments with self-seal maintains the sterility of the enclosed devices for up to 1 year post Steam sterilization and before sterilization has a maximum shelf life of 3 years from the date of manufacture.

Packaging

The sizes of the preformed pouches have been designed to accommodate the da Vinci Intuitive Endowrist Robotic Instruments. Pouches can also be used for packing other long instruments, with a maximum load of a single Intuitive Endowrist Robotic Instrument or other medical devices with a combined weight of metal and plastics of 2.6 pounds or less.

The da Vinci Intuitive Endowrist Robotic Instruments should be oriented housing to the opening end, to ensure aseptic presentation - easy removal of the packaging. It is recommended that the pouches should be filled to no more than 3/4 of their length and a minimum of 2 cm of empty space should be allowed around each instrument.

Where double packaging is implemented, 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.

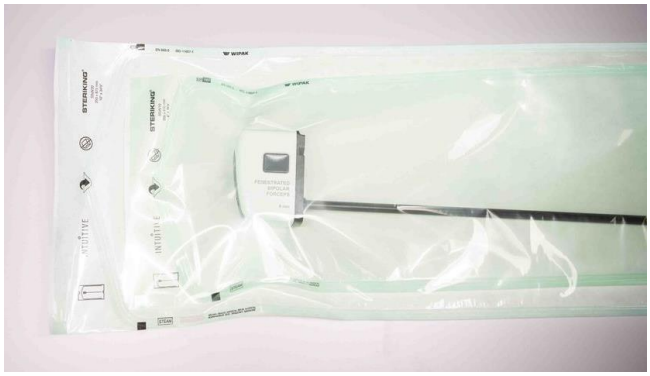
► Wipak Oy
Wipaktie 2
FI-15560 Nastola
Finland

► Mailing Address
POB 45
FI-15561 Nastola
Finland

► Telephone
+358 (0) 20 510 311
E-mail: info.fi.wn@wipak.com
firstname.lastname@wipak.com

► Business ID FI 20791815
Registered Domicile Nastola

www.wipak.com



Limitations for Use

The Pouches for Robotic Instrument are not suitable for sterilization by irradiation, by hydrogen peroxide, or by hot, dry air, or at temperatures over 140°C.

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°-200°C (329-392°F).

The seals need to be strong to withstand the most vigorous sterilization process and handling. A manual test should be carried out for controlling the seal strength.

Self-sealable pouches are featured with adhesive strip allowing tight, impermeable closing of a pack. The closing flap is pre-folded to facilitate the closure. When closing the self-seal pouch the paper flap shall be folded along the pre-folded line. The flap should be pressed firmly against the laminate from the center working outwards to ensure a good, even seal. Apply even press while moving thumbs. Repeat at least three times to ensure a clean and air-tight seal. After closuring, it must be checked that the seal is free of air channels.

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 LOT-number, 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.

Packages should be loaded into the sterilizer per the sterilizer manufacturer's instructions for use. Packages should be placed in the sterilizer loosely allowing the sterilizing agent to penetrate the pack. Packages placed on edge in relation to the cart or shelf should be oriented with the paper side of one pouch next to the plastic side of the next pouch (ANSI/AAMI ST79: 2017 Comprehensive guide to steam sterilization and sterility assurance in health care facilities). If a sterilization cycle must be repeated due to a malfunction or a cycle is aborted before completion, products must be repacked prior to being placed into another sterilization cycle.

Pouches are intended for single use only; product characteristics and performance cannot be guaranteed if the pouch is sterilized more than once.

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. In any unclear or ambiguous situation (e.g. wetness in pack) items should be considered as unsterile.

► Wipak Oy
Wipaktie 2
FI-15560 Nastola
Finland

► Mailing Address
POB 45
FI-15561 Nastola
Finland

► Telephone
+358 (0) 20 510 311
E-mail: info.fi.wn@wipak.com
firstname.lastname@wipak.com

► Business ID FI 20791815
Registered Domicile Nastola

www.wipak.com

Storage and transportation

It is recommended that products shall be kept in their original closed transportation carton and are stored in dry and clean conditions protected from direct sunlight and excessive moisture before they are taken into use.

After sterilization the 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 relative humidity of 30 to 70 % and a temperature of 15-25°C.

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.

Fiber-free opening and aseptic presentation

Follow the opening direction indicated on the pack. 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 fibers from breaking and thereby possibly causing contamination. Open only ⅓ - ⅔ of the packaging length. 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 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.

Serious Incidents

If any serious incident occurs in relation to the pouches, those should be reported to Wipak and the national competent authority in which user is established.

Waste management

After use Steriking® sterilization pouches can be incinerated without producing toxic emissions. Of course, any contaminated product must be eliminated using a specialized method.

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steriking@wipak.com · www.steriking.com

We care that you pack safely!

WIPAK

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► Wipak Oy
Wipaktie 2
FI-15560 Nastola
Finland

► Mailing Address
POB 45
FI-15561 Nastola
Finland

► Telephone
+358 (0) 20 510 311
E-mail: info.fi.wn@wipak.com
firstname.lastname@wipak.com

► Business ID FI 20791815
Registered Domicile Nastola

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