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User Instruction

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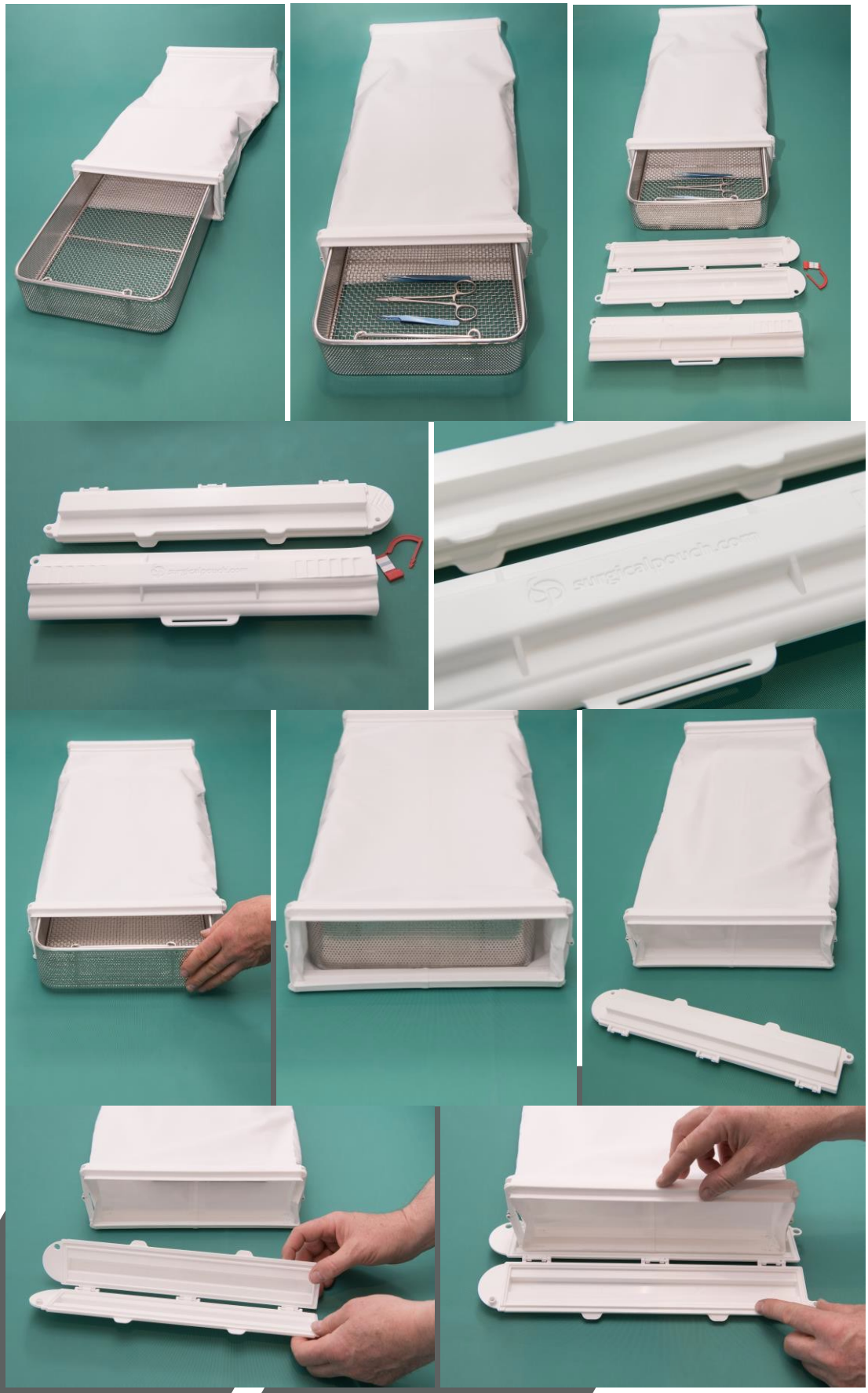
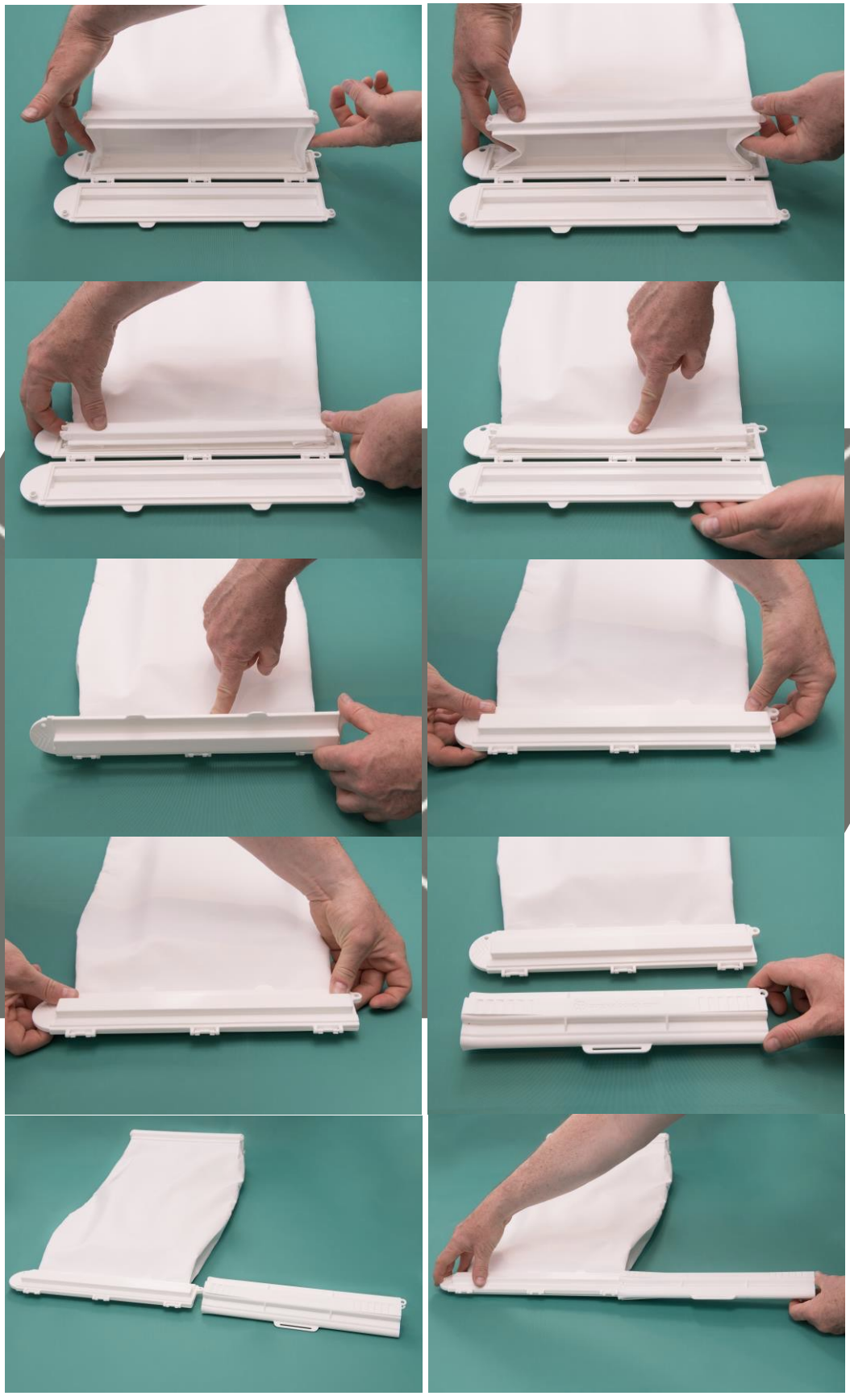
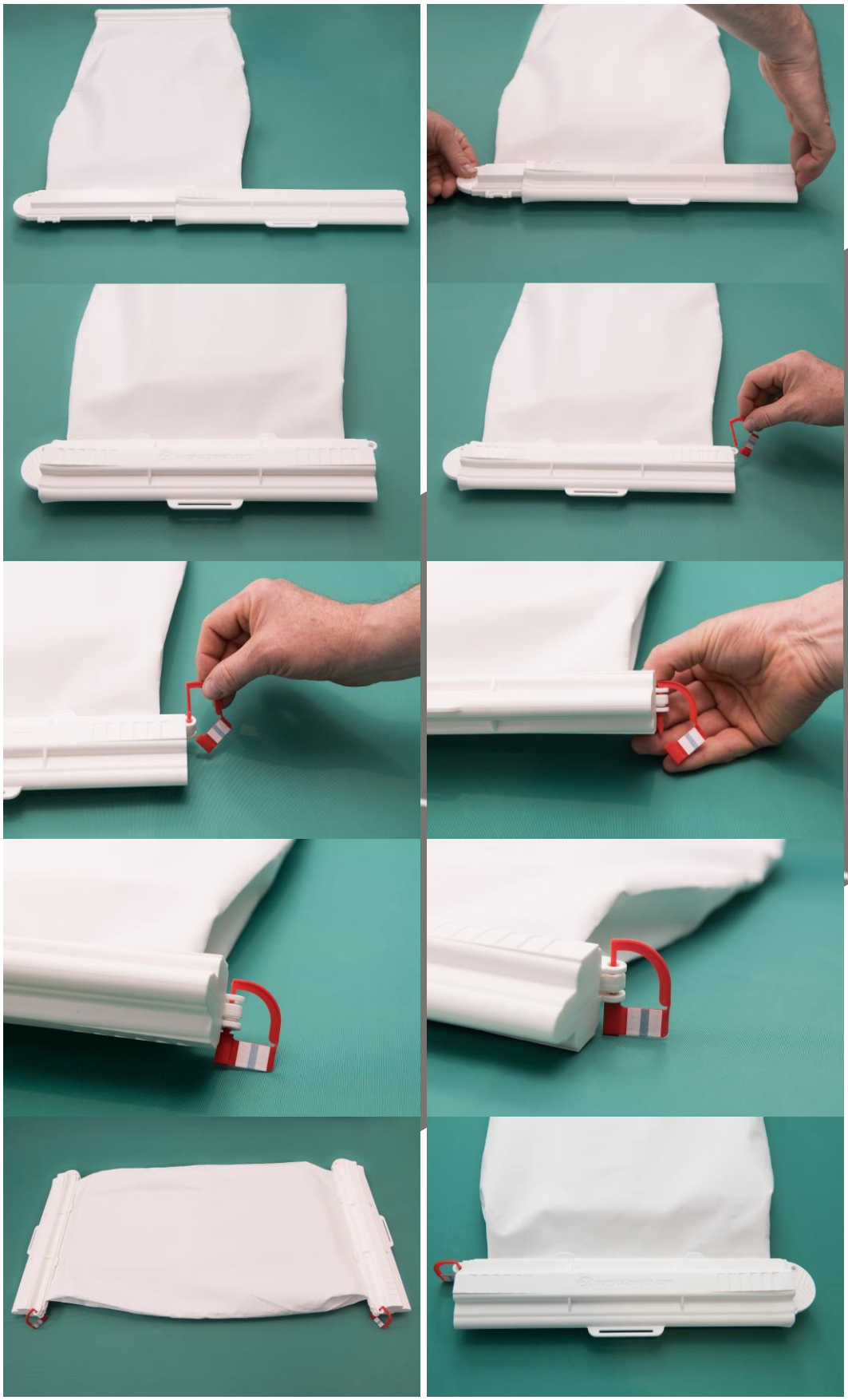
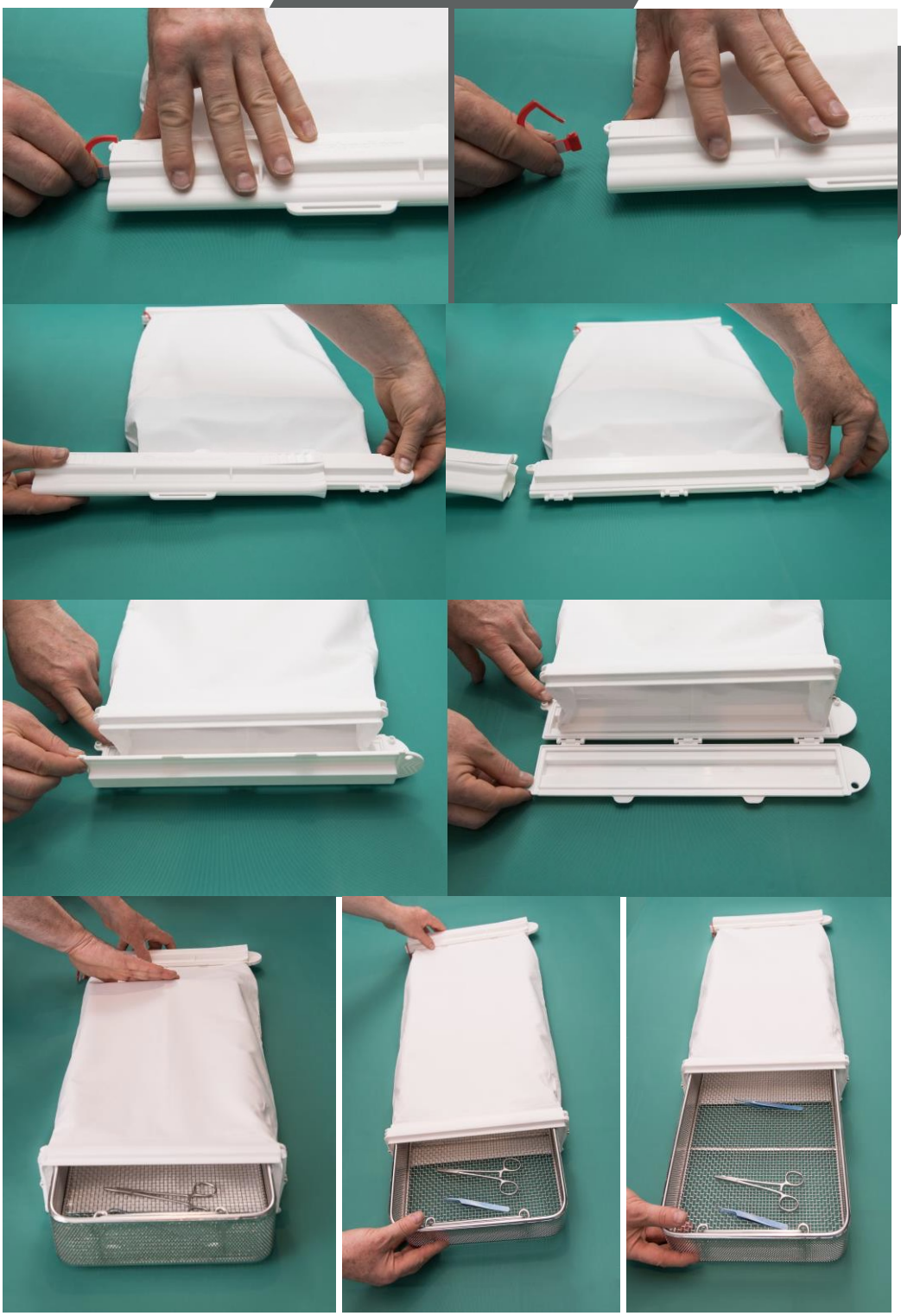
Pictures of the device, including the dimensions.









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Surgical Pouch Ltd Batch Number:
Bubble test Maximum pore size:
Complies with EN11607 Parts 1 & 2
DIN58953-6:2016-12
Maximum membrane Pore size 0.2 micron

Secure each end of the Surgical Pouch only with secure Clips provided by Surgical Pouch Ltd prior to placing in the Autoclave for steam sterilization, Gas Plasma sterilization or Ethylene Oxide sterilization.

Each pouch will be individually barcoded with the trusts proprietary bar coding for use tracking.

Instructions for Use

Instruments should be oriented within pouches according to the health care facility's policies and procedures. (Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Section 8.3.4/Figure 8)

When placing pouches in the sterilizer ensure there is sufficient space around the pouch to allow proper air/plasma evacuation and sterility penetration (steam, Gas Plasma or Ethylene Oxide) of the pouch. Check that pouches are dry upon removal.

When packing the pouch ensure the stitched inserts in the open ends of the pouch are pressed together and flush prior to fixing the sealing clip. This will ensure that the material at the end of the pouch, and around the stitched inserts which will contact the scrubbed nurse's hands, are sterile as the tray is withdrawn

Caution. The final sterilization result will differ based on the enclosed instrument and position in the sterilizer. Assure that all medical devices intended to be enclosed within the Surgical Pouch are compatible with and indicated for sterilization. Consult the sterilization instructions from the manufacturer of the device to be sterilized. Note that some devices may require special packing configurations or other sterilization considerations.

The Storage location once autoclaved should be clean, dust free, and away from fluorescent or ultraviolet light. Store at room temperature of 59˚F (15˚C) to 77˚F (25˚C) and relative humidity (RH) of 40% to 60%. The shelf life of a properly processed pouch is event related and dependent upon proper handling and storage. The pouches have been tested and passed the 12 month accelerated sterility test. The pouches should be regularly bubble tested to ensure the material retains the maximum pore size of less than 0.2 micron and the lamination plus stitching remain intact.
Surgical Pouch Ltd can provide the bubble testing service.

Maintaining sterility. Testing supports the maintenance of package sterility for 12 months after steam sterilization and 24 months after EO sterilization provided the Pouch integrity is maintained. If the sterilized instruments are not used immediately please store in a cool, dry, ventilated, and non-corrosive gas environment.

Sterilization Pouches and Tubing should be used in accordance with the preparation, packaging and sterilization chamber loading recommendations of the following standards:

- ANSI/AAMI ST79: Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- ANSI/AAMI ST41: Ethylene Oxide Sterilization in Health Care Facilities

Packaging The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully slide the instrument basket into the open ended pouch ensuring there are no sharp edges protruding through or standing proud of the basket that can puncture the sterilization pouch.

Sealing both ends of the pouch using the clips and sliders provided by Surgical Pouch Ltd only. Correct fitting of the clips, sliders and security tags will ensure the contents

and ends of the pouches are sterile when the basket is being decanted prior to surgery and post autoclave. This will ensure that the ends of the pouch post autoclaving will be sterile and not compromise the basket as it is withdrawn from the pouch. NOTE: Instruments should be oriented within baskets inserted into the pouch according to the health care facility's policies and procedures. (Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Section 8.3.4/Figure 8)

It is recommended to wrap the instrument basket with paper drape prior to inserting into the Surgical Pouch. This drape can be used as a sterile field within the theatres post autoclaving and it will have the same sterile properties as all the contents of the prepped and sterilized Surgical Pouch.

Loading the Sterilizer: If using several pouches at once, when placing pouches in the sterilizer ensure that there is at least 4 inches between pouches to allow proper air evacuation and sterilant penetration. If possible use a pouch rack to eliminate stacking of the sterilization pouches. Check that pouches are dry upon removal.
Loading Surgical Pouches; wire-type baskets to keep the packages in position. (Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Section 8.5/Figure 9d) Plastic pouches, placed on edge (Source: ANSI/AAMI ST79: Comprehensive guide to steam sterilization and sterility assurance in health care facilities; Section 8.5/Figure 9e)

Sterilization Instructions. Please refer to the following recommendations for steam sterilization cycle. Sterilizer Temperature Setting Exposure Time Pressure Setting Drying Time Steam, gravity cycle 250˚F (121˚C) 30 minutes >= 1.2 bar 25 minutes Steam, pre-vacuum cycle 270˚F (132˚C) 4 minutes >= 2.1 bar 20 minutes 273˚F (134˚C) 3 minutes >= 2.1 bar 20 minutes 275˚F (135˚C) 3 minutes >= 2.1 bar 16 minutes

After steam sterilization, the colour of external indicator attached to the clips will change colour depending on the manufacturers instructions. Please refer to the following recommendations for EtO sterilization cycle – paper and low temperature pouch. Process Concentration Temperature Setting Exposure Time Relative Humidity (RH) Ethylene Oxide (EO or EtO) 735 mg/L 130˚F (55˚,-C) 60 minutes 50% - 80% After EO sterilization, the colour of external indicator will change from yellow to brown.

Please Inspect the Surgical Pouch for damage, moisture, or any sign of potential contamination prior to opening and again after opening but before use of contents. Caution: Do not use contents if there is any damage or contaminants present, as sterility could be compromised. Reprocess the contents using a new Surgical Pouch if any of these conditions are noted.

Open packages aseptically in accordance with the health care facility's policy. Precaution: The final sterilization result will differ based on the enclosed instrument and position in the sterilizer. Assure that all medical devices intended to be enclosed within the Surgical Pouches are compatible with and indicated for sterilization via the modality and parameters described in the Indications for Use section of these directions. Consult the sterilization instructions from the manufacturer of the device to be sterilized. Note that some devices may require special packing configurations or other sterilization considerations, some of which are described in ANSI/AAMI ST79.

Storage location should be clean, dust free, and away from fluorescent or ultraviolet light. It's recommended that sterility maintenance of package sterility for 6 months after steam sterilization and 12 months after EO sterilization provided the Pouches integrity is maintained. After sterilization if not used immediately please store in a cool, dry, ventilated, and non-corrosive gas environment.
Surgical Pouches can be manufactured to specific sizes requested by sterile services departments

Information about the applied design stages.

The main component of the pouch is the mono-component polymer membrane laminated between two polyester layers. The membrane has a maximum pore size of 0.2 micron and acts as a bio barrier protecting the sterilized surgical instruments inside from bacterial contamination from the outside environment.

The outer two layers of polyester fabric act to protect the integrity of the filtration membrane and provide strength to the overall pouch.

The dimensions of the pouch allows for the easy of insertion of the metal basket holding the surgical instruments. Once the basket is centralised within the pouch there is enough excess pouch at either end to allow the ends to be sealed using the Surgical Pouch clips and security sliders. This ensures that post autoclaving when the pouch is opened the ends and contents remain sterile. This ensures the scrubbed nurse extracting the instrument basket from the pouch is not compromised.

The stitching along the seam of the pouch is of the French stitch format which provides a robust seam. This seam is then sealed along the stitches to prevent any bacteria entering the pouch via the seams. The thread in the stitching is of the polymer type.

The polyester laminates on either side of the polymer Membrane are designed to give durability to the material and withstand rough treatment when placing and removing from store room shelving, but should still be handled with care.

The Surgical Pouches have been developed in conjunction with several NHS Trusts to achieve the most practical and safe sterilization pouch both in user welfare and sterility protection.

Identification of all sites where design and manufacturing activities are performed.

Design is performed at two sites

Surgical Pouch Ltd. 8 Homestead Close, St Albans, Hertfordshire, UK. AL2 2TB
Surgical Pouch Ltd. 40 Peter Street, Manchester, UK. M2 5GP

Manufacture of the laminated Membrane and the finished Pouch are performed at various sites all located within the UK

The Clinical Evaluation Report.

Please see ISEGA test report 18797/1

The post market clinical follow-up plan and evaluation report.

Individual hospitals test the pouches every 6 months to ensure they continue to meet requirements in the EN11607 standard. The Authorised person within the Sterile Services Departments will carry out the tests. We recommend the hospitals track the usage of individual pouches with barcodes and dispose of any pouches that reach over 100 autoclave cycles.

We will implement a study to be carried out in partnership with our NHS Trust users to specifically analyze the deterioration in performance experienced by the Surgical Pouches due to multiple sterilizations. Performance test carried out at several laboritories have indicated a sub 10% degradation in gas/vapour permeability over the life time of the pouches with no detrimental effect on the maximum pore size of 0.2micron.We can perform bubble tests on random used pouches that have registered predefined usage cycles within the Trust. This will allow accurate performance deterioration data to be acquired that is particular to that individual trust, and be further isolated to individual Sterile Service departments. From this data we will provide a higher level of safety to accurately track the performance of pouches and give reliable data on the historical sterility of instruments used in theatres. A 10% margin of error will be built into the recommendations to ensure that Pouches will not exceed their effective safe usage life, in accordance with the approved labelling.

The Company

surgicalpouch.com

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