

Self Seal Sterilisation Pouches

Instructions for Use

IMPORTANT

Read this 'Instructions for Use' document before handling. This product is for professional use only.
SPECIALLY FORMULATED FOR USE IN DENTISTRY

IDENTIFICATION

Self- Sealing Sterilisation pouches with Class 1 colour change indicators for use in steam (vapour) and ethylene oxide (ETO) sterilisation system


Product Name	Protect+ Self Seal Sterilisation Pouches
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PRODUCT CODE - REF

PP002/5000 Protect+ Self Seal Sterilisation Pouches 57 x 127mm Box 200
 PP002/5001 Protect+ Self Seal Sterilisation Pouches 85 x 165mm Box 200
 PP002/5002 Protect+ Self Seal Sterilisation Pouches 85 x 253mm Box 200
 PP002/5003 Protect+ Self Seal Sterilisation Pouches 135 x 278mm Box 200
 PP002/5004 Protect+ Self Seal Sterilisation Pouches 190 x 330mm Box 200
 PP002/5006 Protect+ Self Seal Sterilisation Pouches 305 x 420mm Box 200
 PP002/5007 Protect+ Self Seal Sterilisation Pouches 90 x 230mm Box 200
 PP002/5008 Protect+ Self Seal Sterilisation Pouches 140 x 260mm Box 200
 PP002/5009 Protect+ Self Seal Sterilisation Pouches 300 x 450mm Box 200
 PP002/5010 Protect+ Self Seal Sterilisation Pouches 200 x 405mm Box 200

INDICATIONS FOR USE

Intended Use and Features

The Self Seal Sterilisation pouches are widely used in steam (vapour) and ethylene oxide (ETO) sterilisation. Use a CE marked autoclave and follow the manufacturers guidelines. Chemical indicators are printed on each pouch and change colour during sterilization procedure as a visual indicator that pouches have been processed. These indicators must be used in conjunction with biological sterilisation indicators to verify that sterilization has occurred. Make sure that pouches are visibly dry before removing from the sterilizer. 

Packing instruments/devices in the pouch

It is important to allow extra space for sealing the package. It is recommended that the packages should be filled to no more than three quarters of their length and minimum of a 2cm space should be allowed around each instrument. Instruments should be placed inside the pouch, not dropped, to prevent tearing the bottom seal. Medical devices should be positioned inside the pack to enable easy removal from the packaging, to maintain sterility. 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 the pouch

All seals, including the closure should be smooth, i.e., without folds, bubbles, or wrinkles. The coloured plastic film is a darker shade where the seal has taken place, making it easy to check that the seal is intact. Closures that compress the package should not be used, (e.g., ropes, strings, elastic bands, paperclips, staples, or similar items).

Labelling the pouch

The writing instrument should not have the potential for creating a hole or puncturing 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

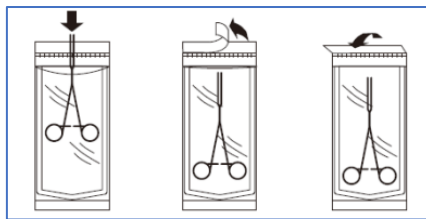
- If possible, the packages should be placed upright in the sterilizer, using a rack if necessary.

- If it is not possible to place the packages upright, they can be placed flat with porous material facing down.
- When loading multiple pouches, ensure the plastic side faces the paper side of the next pouch.
- 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, all pouches must be replaced and repacked prior to being placed into another sterilization cycle.

Inspection

After sterilisation, the packages and products must be allowed to cool down before handling. Sterilization Pouches are marked with a symbol indicating the correct peeling direction top open the pouch. Check each pouch to ensure not damaged during the procedure, any damaged pouches should be discarded and the devices re-processed. Check that the ink has changed to the relevant colour (steam/ETO). Pouches should be clean and dry, if a pouch is wet the devices contained should not be considered sterile – place in a new pouch and re-process.

Process indicators printed on the packaging help distinguish between products that have or have not been autoclaved, but do not provide evidence of sterilization.



Fibre-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.

Caution



Should a serious incident in relation to the product occur, it should be reported to the manufacturer and the competent authority. ***In the event of such an incident please provide the Lot No and 3-digit production number found on the carton. On its own, the Lot No on the pouch does not provide the full traceability needed to allow a full investigation.***

WARNING

1. Check for damage before using.
2. Do not use past expiry date.
3. Do not use if the package damaged.
4. Only use with a CE marked steriliser and follow manufacturer's instructions.
5. Use in conjunction with biological indicators to confirm sterilisation has taken place.



STORAGE and DISPOSAL

Before use store in a cool, dry place. After use sterilization pouches can be incinerated without producing toxic emanations. Of course, any contaminated product must be eliminated using a specialised method. The paper and the PET can be recycled according to local guidelines.



BATCH CODE AND EXPIRY DATE

See the print on the box. Do not use the product after this date.

SHELF LIFE

See box for Lot number and expiration date.



Maximum Shelf life of the pouch is 5 years. After this date the pouches should not be used to maintain sterility of medical devices.

- **Once Steam sterilised, the pouch can be stored for a maximum of 6 months whilst maintaining the sterility of the device.**
- **Once ETO Sterilised, the pouch can be stored for 2 years whilst maintaining the sterility of the device.**



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