



## Self-sealing Sterilization Pouches



This product is intended for professional use only.

- #60180 - 2.25" x 4"
- #60181 - 2.75" x 9"
- #60182 - 3.5" x 5.25"
- #60183 - 3.5" x 9"
- #60184 - 5.25" x 10"
- #60185 - 5.25" x 6.5"
- #60186 - 3.25" x 11"
- #60187- 4.25" x 11"



### INTENDED USE AND FEATURES

The Packard Healthcare self-sealing sterilization pouches are intended to provide healthcare workers with an effective method to devices intended for sterilization in steam or Ethylene Oxide sterilizers. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or EO sterilization process.

Packard Healthcare pouches are composed of medical grade paper (60g/m<sup>2</sup>) and medical compound film (52µm), it is intended to be used to contain medical devices and equipment for sterilization using EO or steam sterilization.

### USAGE

- The sterilization pouch is heat sealed on three sides, the fourth side has an adhesive strip that is used to seal the pouch.
- Place device(s) into the sterilization pouch, remove the release film from the adhesive strip of the pouch and fold along the perforated line for proper closure (seal) of 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 2 cm space should be allowed around each instrument allowing steam to navigate around each instrument/device.
- Devices should be placed into the pouch by sliding them in to prevent tearing or perforating the bottom seal.
- Devices should be positioned inside the pouch to enable easy removal from the packaging, to maintain sterility.
- **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 packaging must be folded along perforated fold, so that the passage of steam remains unhindered and a proper seal is created.**

Category	Ethylene Oxide	Class B Pre-Vacuum Dynamic Air Removal	Class S Steam Flush Pressure Pulse Dynamic Air Removal
Temperature	131°F (55°C)	270°F (132°C) - 275°F (135°C)	270°F (132°C) - 275°F (135°C)
Sterilization Time	600 mg/L Concentration for 6 hrs	3 min - 4 min	3 min - 4 min
Drying Time	40-90% relative humidity for 7 days	20-45 min (varies by load)	20-45 min (varies by load)
Type IV CI Before	Pink	Blue	Blue
Type IV CI After	Yellow	Dark Green/Grey	Dark Green/Grey



Spaulding's Classifications

#### maxill inc.

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### LOADING PACKAGES

If possible, the packages should be placed upright in the sterilizer (vertical loading), using partitions if necessary. If it is not possible to place the packages upright, they can be placed flat (horizontal loading) with porous material (paper) facing down, or according to your sterilizer manufacturer's instructions for use.

- Devices must be clean and dry before placing inside the pouch.
- The packages should not be folded and they must not touch the chamber walls.
- The trays 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 before being placed into another sterilization cycle.

### INSPECTION

- After sterilization, the packages and products must be allowed to cool down before handling.
- Sterilization pouches are marked with a symbol indicating the correct peeling direction to open the pouch.
- Check each pouch to ensure there is no damage during the sterilization process.
- Any damaged pouches should be discarded and the devices must be re-processed.
- Check that the external (Type I) and internal (Type IV) chemical indicators have changed to the relevant colour (steam/EO).
- 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. A wet pouch is a semi-permeable membrane.

### WARNINGS AND CAUTIONS

1. The product is single use only;
2. Check for damage before using. Do not use if the package is damaged;
3. Sterilization shall be carried out in accordance with the sterilization methods specified on the sterilization pouch;
4. The seal needs to be strong to withstand the most vigorous sterilization process and handling yet provide a clean peel. To achieve this, pouches must be sealed by folding along the perforation. Do not overfold pouch seal.

The sterilization pouch maintains the sterility of the enclosed devices for up to 24 months post Steam or EO gas sterilization, and before sterilization has a maximum shelf life of 5 years from the date of manufacture.



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