



# Self-Seal Sterilization Pouch

## Instructions for Use

### Product Description

Getinge Pack Self-Seal Sterilization Pouches are constructed of multilayer PET/PP copolymer film and medical grade paper. Open side of the pouch has an adhesive strip that is used to seal the pouch. Type I process indicators for steam, ethylene oxide and formaldehyde are applied on the medical grade paper surface of the each pouch. After exposure to steam, ethylene oxide or formaldehyde sterilization, the chemical indicator will provide an accurate visual confirmation by color changing, indicating that sterilization conditions were met.

### Intended Use

Getinge Pack Self-Seal Sterilization Pouches are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in steam, ethylene oxide or formaldehyde sterilization method.

Chemical process indicators on the self-seal pouches indicate that the pouch has been exposed to sterilization process by changing color. After the sterilization is completed, the sterility of the enclosed medical device is event related.

### Indicator Color Change

Getinge Pack Self-Seal Sterilization Pouches are printed with water based, non-toxic ink to produce Type 1 chemical process indicators. The indicators are in compliance with ISO 11140-1 standard. Getinge Pack chemical process indicators provide a clear and accurate color change after sterilization. Type 1 process indicator will change color from pink to brown/black after exposure to steam sterilization process and from green to yellow/orange after exposure to ethylene oxide sterilization process and from pink to green after exposure to formaldehyde sterilization process.

### Instructions for Use

1. Complex instruments (e.g. air-powered instruments, endoscopes and instruments with lumen or channels) should be prepared and sterilized according to the manufacturer's instructions.
2. Getinge Pack Self-Seal Sterilization Pouches are ready for use.
3. Do not use if the pack is damaged. Do not reuse. Single use only.
4. Cover sharp ends of instruments with an instrument protector, to prevent puncturing and tearing.
5. Place the item to be sterilized into the pouch. Do not fill pouches to more than 75% of their capacity. Always leave minimum 1.5 cm gap between the material and each seal edge of the pouch for a smooth air flow.
6. Manually remove as much air as possible from the pouch before closing.
7. Remove the protective strip and fold the adhesive area. Press down from the center with both thumbs and move outwards. Apply even pressure while moving thumbs. Repeat at least twice to ensure a proper self-seal.
8. Avoid stress on the seals during handling. For example, fill the pouch horizontally while working on a flat surface.
9. When loading into the sterilizer place the pouches into the basket in a way that film faces film and paper faces paper.
10. Getinge Pack Self-Seal Sterilization Pouches should be put upright in the basket or container and not too tight together; such that a hand can slide in between them.

1. Handle pouches with care when removing from the sterilizer to prevent tearing. Store pouches in an area protected from sunlight, water and other liquids.
2. Do not use wet pouch. Repeat the sterilization process after changing the pouch.
3. To open the pouch, use a thumb and index finger to hold the paper side and a thumb and index finger to pull back the film side of the pouch. Always open the pouch from the direction of the arrow. For a clean peel open the pouch slowly.

### **LOT Number**

Each Getinge Pack Self-Seal Sterilization Pouch is provided with a LOT number printed on the medical grade paper web. The LOT number allows the traceability of the product during the manufacturing process.

### **Storage Conditions**

Getinge Pack self-seal sterilization pouches should be stored in their original packaging at max. +35 °C (+95 °F) and max. 70% RH humidity. Sterilization packaging should be protected from direct light, moisture and excess humidity.

### **Shelf Life / Expiry Date**

The shelf life (pre-sterilization use) of Getinge Pack self-seal sterilization pouches are 5 (five) years after manufacture date under recommended storage and handling conditions. The product must be used within 5 years from date of manufacture. The expiry date, as well as the manufacture date is printed on the inner side of the core and on shipping carton label. The shelf-life (post sterilization) is event related after sterilization using the recommended sterilization process only. The end-user should establish written policies based on their unique internal practices to define procedures intended to maintain sterility of packages until they are used.

This document is intended to provide information to an international audience outside of the US.

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#### **Manufactured for Getinge**

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