

# Instruction for use

【 **Product name** 】 Self-Seal Sterilisation Pouches

## 【 **Product description** 】

The Self-Seal Sterilisation Pouches are intended to be used to enclose another medical device that is to be sterilized by a health care provider. It is intended to allow sterilization of the enclosed medical device and also to maintain sterility of the enclosed device until used. The Self Sealing Sterilization Pouches are intended for sterilization of dental instruments, excluding complex devices (endoscopes and instruments with lumen/channels). The recommended sterilization cycles are as follows:

- **Steam Sterilization: 4 minutes at 134°C (270° F); 10 minutes dry time for gauze and plastic loads, and 20 minutes dry time for metal loads.**
- **Ethylene Oxide (ETO) Sterilization: 8 hours at 50°C (122° F); relative humidity between 30%- 90%; ethylene oxide concentration is 700mg/L, 7 days aeration time at 23°C(73.5 ° F).**

The Self-Seal Sterilisation Pouches are made with medical grade paper and medical compound film. The Self-Seal Sterilisation Pouches maintain the sterility of the enclosed devices for up to 6 months post Steam or ETO gas sterilization, and before sterilization has a maximum shelf life of 3 years from the date of manufacture. The pouch's external chemical ink indicators are designed to indicate to the user that the pouch has undergone either a steam or ETO sterilization process. Sterilization indicator will change color according to the sterilization method (ethylene oxide, steam). Ethylene oxide sterilization indicator color change from pink before sterilization to yellow after sterilization. The steam sterilization indicator color change from blue before sterilization to dark green after sterilization.

## 【 **Packaging** 】

### 1. Preparation of items before sterilization

Place items to be sterilized into an appropriate sized pouch. The pouch should only be filled 3/4 of the packing volume to allow proper air evacuation and sterilant penetration. Carefully press the excess air out of the pouch and ensure there is at least one (1) inch between the adhesive strip and items. After removing the protective strip, seal the pouch by folding the adhesive strip onto the pouch. Apply pressure from the center of the adhesive, towards the edges. Repeat this motion an additional time for extra security. If you are using a double pouching method, the pouch sizes should be selected so the inner pouch can be placed inside the outer pouch without folding. The inner pouch must also be sealed. The paper side of both pouches should face the same way. For example, paper towards paper and film towards film.

### 2. Loading

- The loading capacity of downward displacement sterilizers shall not exceed 80% of the chamber volume; for pre-vacuum sterilizers, it must not exceed 90% of the chamber capacity. Additionally, pre-vacuum and pulse-vacuum steam sterilizers must maintain minimum loading volumes of 10% and 5% of the chamber capacity respectively to prevent the "small load effect," where residual air compromises sterilization efficacy.
- Whenever possible, items of the same category should be sterilized together. If different types of items must be processed simultaneously, the sterilization parameters (temperature and time) required by the most difficult-to-sterilize item should be adopted.
- Items should be spaced appropriately in all directions (top, bottom, left, and right) to facilitate steam displacement of air. For large sterilizers, items should be placed on racks within the chamber or on trolleys. Small and medium-sized sterilizers without racks may use mesh baskets.
- Hard-to-sterilize large packages should be placed on the upper shelves, while smaller, easier-to-sterilize packages should go below. Metal items should be positioned at the bottom, with fabric packs placed above. Items must not touch the door or chamber walls to avoid excessive condensation absorption.
- For items with glossy coating or surface, like mirrors, sensor protective covers, handpieces with laser head, please wrap the glossy area or sensor area with CSR wrap before placing it to the package;
- For items with chemical coating or liquid, like handpieces with lubricant liquid, please wrap the handpieces with CSR wrap before placing it to the package.
- For large metal item, like metal instrument trays, please have the concave side facing the paper side. If it's large flat metal items, please wrap it with CSR wrap before placing it to the package and place it in the sterilizer with vertical bracing.

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## Table of Maximum load

Product code	Specification Inch.	Maximum load		
		Gauze	Plastic	Metal
GBS480	2.25"x3.7"	2g	13g	17g
GBS481	2.75"x9"	31g	36g	40g
GBS482	3.5"x 5.3"	45g	49g	54g
GBS483	3.5"x 7.9"	45g	55g	100g
GBS484	3.5"x 9"	50g	60g	130g
GBS485	5.3"x 10"	204g	208g	217g
GBS486	7.5" x13"	226g	320g	460g
GBS487	9.8"x 14.6"	281g	580g	775g
GBS488	12"x16.9"	350g	650g	980g

### 【 Loading the sterilizer 】

Carefully place items into pouches and remove any excess air before sealing. Where possible, use a pouch rack to stand the pouches on edge during sterilization to facilitate the process. When loading multiple pouches into the sterilizer, do not stack them with plastic side against plastic side or paper side against paper side. Instead, leave space between each pouch and position them so that the plastic side of one pouch faces the paper side of the next.

### 【 Storage and disposal 】

Ensure the sterile storage area is well-ventilated and provides protection against dust, moisture, insects and extreme temperature and humidity. Sterilization pouches should be stored in a cool and dry environment (temperature 59-86 °F / 15-30 °C ; humidity 40~70%). The items should be positioned so that packaging is not crushed, bent, compressed, or punctured so the package integrity is not otherwise compromised.

After use, the self sealing 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.

### 【 Shelf life 】

Maximum shelf life of the pouch is 3 years. After this date the pouches should not be used to maintain sterility of medical devices. Once Steam or ETO sterilized, the pouch can be stored for a maximum of 6 months whilst maintaining the sterility of the device.

### 【 Aseptic presentation 】

The sterilized pouch should be peeled off gently and opened slowly from the chevron end.

### 【 Warning 】

- Check the package completeness before using.
- Do not use past expiry date.
- Do not use if the package damaged or contaminated.
- Do not place non-autoclavable item in the package for steam sterilization.



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