

## PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP)

### Product Description

PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP); are constructed of multilayer PET/PE copolymer film and uncoated Tyvek®. A process indicator is applied on the Tyvek® surface of the each pouch exterior. After exposure to vaporized hydrogen peroxide (VHP) sterilization, the chemical indicator will provide an accurate visual confirmation by color changing, indicating that sterilization conditions were met.

### Intended Use

PMSSteripack Sterilization Pouches (TP) and Rolls (TY) made of DuPont™ Tyvek® with Chemical Indicator; are intended to provide healthcare workers with an effective method to enclose medical devices intended for sterilization in vaporized hydrogen peroxide (VHP) sterilization method.

PMSSteripack Sterilization Pouches (TP) made of DuPont™ Tyvek® with Chemical Indicator is a device intended to be used to enclose another medical device that is to be sterilized by a healthcare provider. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed devices until used.

### The recommended (and validated) sterilization cycle parameters are:

**The Steris V-PRO 1 PLUS LUMEN CYCLE is a single preprogramed standard sterilization cycle with NO cycle parameter variables allowed by the end user.**

Chemical process indicator on the exterior of the PMSSteripack Sterilization Pouches (TP) made of DuPont™ Tyvek® indicates that the pouch has been exposed to V-PRO 1 Plus, Lumen Cycle sterilization process by **changing color from red to blue or (lighter)**.

Devices with stainless steel lumens with the following internal diameter (ID) and maximum length can be processed in V-PRO 1 Plus, Lumen Cycle.

**Table 1. Lumen Claims**

Pouch Size (in.)	Max. lumen length (mm)	Min diameter (mm)	Max # Lumens
2 x 8	50	1.5	1
6 x 12	200	3.0	1
14 x 24	400	3.0	1

### **Worst Case Load:**

- The worst case load for the 2 in. x 8 in. pouch is 0.058 lbs. of instruments.
- The worst case load for the 6 in. x 12 in. pouch is 0.630 lbs. of instruments.
- The worst case load for the 14 in. x 24 in. pouch is 3.054 lbs. of instruments.



## PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP)

### Indicator Color Change

**PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP);** are printed with water based, non-toxic ink to produce Class 1 chemical process indicators. The indicators are in compliance with ISO 11140-1 standard. PMSSteripack chemical process indicators provide a clear and accurate color change after sterilization.

Class 1 hydrogen peroxide indicator will change color from **red to blue (or lighter)** after exposure to vaporized hydrogen peroxide (**VHP**) sterilization process.

### Instructions For Use

1. Instruments e.g.endoscopes, and instruments with single lumens or channels should be prepared and sterilized according to the manufacturer's instructions. The sterilization process has only been validated for lumens as defined in Table 1.
2. Do not use the device for sterilizing air-powered instruments, endoscopes, and instruments with lumens or channels. The Device is not validated for air powered instruments using V-Pro 1 Plus sterilization system.
3. PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP); are ready for use.
4. Do not use if the pack is damaged. Do not reuse. Single use only.
5. Cover sharp ends of instruments with an instrument protector, to prevent puncturing or tearing.
6. Place the item to be sterilized into the pouch. Do not fill pouches to more than 75% of their capacity.
7. Always leave minimum 1.5 cm gap between the material and each seal edge of the pouch for a smooth air flow.
8. Manually remove as much air as possible from the pouch before closing. Close the open end of the pouch with a calibrated and validated sealing device. The recommended sealing temperature is between 105°C and 125°C and 1-6 second dwell time.
9. Avoid stress on the seals during handling, for example fill the pouch horizontally, working on a flat surface.
10. When loading into the sterilizer place the pouches into the basket in a way that film faces film and paper faces paper.
11. PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP); should be put upright in the basket or container and not too tight together; such that a hand can slide in between them.
12. Handle pouches with care when removing from the sterilizer to prevent tearing. Store pouches in an area protected from sunlight, water and other liquids.
13. Do not use wet pouch. Repeat the sterilization process after changing the pouch.
14. 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.



## **PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP)**

### **Double Pouching For PMSSteripack Sterilization Pouch made of DuPont™ Tyvek®**

Double pouching is also applicable for PMSSteripack Sterilization Pouch made of DuPont™ Tyvek® with Chemical Indicator (TP), and has been validated for double pouching (PMS Test Report-Double Pouching Efficiency Steam Sterilization).

A single peel pouch is adequate unless the package contains more than one item or would be complicated to open aseptically with only one peel package (e.g., very small items).

If the item is to be double-packaged, two sequentially sized pouches should be used (i.e., the sealed inner pouch should fit inside the other pouch without folding). When assembled, the pouches should be positioned so that paper side of the inner pouch faces the paper side of the outer pouch. Doing so enables the sterilant to enter through the paper side of the pouch.

### **LOT Number**

Each **PMSSteripack Sterilization Pouch made of DuPont™ Tyvek® with Chemical Indicator (TP)**; is provided with a LOT number printed on the Tyvek® grade web. The LOT number allows the traceability of the product during the manufacturing process.

### **Storage Conditions**

PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP) should be stored in their original packaging at max. +35°C 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 **PMSSteripack Sterilization Pouches made of DuPont™ Tyvek® with Chemical Indicator (TP)**; are **3 (three) years** after manufacture date under recommended storage and handling conditions. The product must be used within **3 years** from date of manufacture. The expiry date, as well as the manufacture date is printed on the outer pouch wrap and the shipping carton label. It is intended to allow sterilization of the enclosed medical devices and also maintain sterility of the enclosed devices until used.

P/N: PMS-TKL-04 Rev.C

