



Description

MPACK® 'PLASMA' Sterilization Packaging range is a series of see-through heat-sealable pouches and reels intended for use as packing material for medical devices for sterilization by gas plasma and vaporized hydrogen peroxide.

With the use of proper class of indicators, MPACK® 'PLASMA' sterile barrier products are also compatible with other methods of low temperature sterilization (such as EO sterilization).

MPACK® 'PLASMA' sterile barrier products are constructed of a high-grade uncoated Tyvek® * non-woven polyethylene medical fabric and a clear high-strength multi-layer laminate film.

Key features

- Uncoated Tyvek® 1073B provides the highest level of protection, making it the ideal choice for medical device packaging that requires high strength and superior microbial barrier.
- Superior multilayer film puncture and abrasion resistance reducing the risk of pinholes.
- Transparent see-through film allowing quick detection of pinholes or tears.
- Clean peel: the triple band ribbed seal is designed with optimum strength and width to prevent bursting while allowing excellent peel-ability for clean, fiber-free opening and aseptic presentation of the product.
- All prints outside the packing area to prevent possible impact on paper porosity and ink offset.
- A peel symbol indicates the correct opening direction.

Sales Unit: Dispenser/Box.

Range

Code	Description	Size	Units/Box
1601	PLASMA STERILIZATION REELS, flat, heat seal	75mmx70m	5
1602	PLASMA STERILIZATION REELS, flat, heat seal	100mmx70m	4
1603	PLASMA STERILIZATION REELS, flat, heat seal	150mmx70m	2
1604	PLASMA STERILIZATION REELS, flat, heat seal	200mmx70m	2
1605	PLASMA STERILIZATION REELS, flat, heat seal	225mmx70m	2
1606	PLASMA STERILIZATION REELS, flat, heat seal	250mmx70m	2
1607	PLASMA STERILIZATION REELS, flat, heat seal	300mmx70m	1
1608	PLASMA STERILIZATION REELS, flat, heat seal	350mmx70m	1
1609	PLASMA STERILIZATION REELS, flat, heat seal	400mmx70m	1
1610	PLASMA STERILIZATION REELS, flat, heat seal	500mmx70m	1

(* Tyvek® is registered trademark of DuPont™)

Regulations

Compliance with legal requirements:	Medical Devices Regulation 2017/745, Class I. CE marked. FDA compliant.
Compliance with product quality standards:	ISO 11140-1:2014, ISO 11607-1:2019, ISO 11607-2:2019 and EN 868-5:2018.
Label information and packaging compliance:	EN ISO 15223-1 and EN 1041
REACH regulation:	The product covered by this data sheet does not contain carcinogenic, mutagenic or toxic substances, including any of the Substances of Very High Concern (SVHC) as listed in the latest available version of the Candidate List published by the European Chemicals Agency (ECHA).

The product complies with legal requirements for medical devices. It is manufactured under ISO 13485 quality assurance standard.



Materials

Product Part	Raw Material & Characteristic
Top web	75 gsm Tyvek® 1073B Medical Packaging Material made of high-density polyethylene (HDPE), Non-coated. Elementary Chlorine Free. Approved for EN 868-3 Process indicators.
Laminate film web	Clear PET/PE composite multi-layer film (12 µm polyester laminated to 45 µm "shatter less" Polyethylene).
Type I Process indicators	Toxic-free, lead-free process Type I indicators for hydrogen peroxide sterilization. Compliant with ANSI/AAMI/ISO 11140-1 Sterilization of healthcare products- Chemical indicators- Part 1: General requirements. Provides distinct color change when exposed to H ₂ O ₂ : <div style="border: 1px solid black; padding: 2px; display: inline-block;">VH2O2</div> : switch from green to yellow.

Packing Part	Raw Material & Characteristic
Paper core tube	Bobbin Fibre Paper
Shrink wrap film	POF Film
Transport box	Corrugated paper + Kraft paper
Packing Tape	Transparent, PVC-free


Warnings and Recommendations

Warnings	The product is single use. If reused performance of product may deteriorate, cross contamination may occur.
Sealing parameters	Recommended sealing temperature is 120-140°C, depending on set pressure and time.
Storage Recommendation	Recommended storage in clean, dry space in ambient temperature. Products should be protected from direct sun light and other intensive light sources.
Disposal Recommendation	Dispose in accordance with local regulations.
Shelf Life	Shelf Life of Unprocessed Pouches/Rolls: 3 years. Maintains sterility for 180 days after sterilization.



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