MPACK®

Safety from liability

Description

MPACK® Sterilization Packaging is a series of environmentally friendly packaging products for the sterilization of instruments by Steam, Ethylene Oxide or Formaldehyde.

MPACK® Sterilization packaging products are constructed of a non-coated high weight medical grade paper and a clear high-strength tear-resistant multi-layer laminate film.

Key features

- Pre-folded easy quick-sealing, without sealing equipment:
  The self-seal adhesive strip easily and securely seals the pouch, providing a reliable seal until the pouch is opened.
- A well-thought-through design:
  - o Triple band ribbed seal, designed with optimum strength and width to prevent bursting while allowing excellent peel-ability and easy aseptic, clean and fiber-free opening.
  - o Reinforced chevron seal at the opening side to preserve the seal from any damage by the instrument.
  - o Corner tack seals prevent corners from curling after sterilization and dust from collecting at the opening seal (reducing the risk of contamination).
  - o All prints outside the packing area to prevent possible impact on paper porosity and ink offset.
  - o Easy-to-open thumb notch preserving sufficient finger lift.
- Built-in dual lead-free internal and external process indicators (EO & Steam):
  Eliminating the need for an internal indicator strip inside the pouch, the built-in internal indicators ensure correct sterilization is reached where you need it… inside the pouch compartment.
- Superior microbial barrier with high weight 70g medical grade non-coated paper.
- Green tinted see-through multilayer film allowing quick detection of pinholes or tears.

Range

Code	Description	Size	Units/Dispenser	Dispensers/Box	Units/Box
1001	Sterilization pouches, flat, self seal	60x250mm	200pcs	20	4,000pcs
1002	Sterilization pouches, flat, self seal	90x200mm	200pcs	20	4,000pcs
1003	Sterilization pouches, flat, self seal	90x250mm	200pcs	16	3,200pcs
1004	Sterilization pouches, flat, self seal	130x270mm	200pcs	10	2,000pcs
1005	Sterilization pouches, flat, self seal	200x350mm	200pcs	5	1,000pcs
1006	Sterilization pouches, flat, self seal	250x400mm	200pcs	3	600pcs
1007	Sterilization pouches, flat, self seal	300x450mm	100pcs	5	500pcs

Sales Unit: Dispenser/Box.

Technical Summary

mPACK®

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 11607-1:2020, ISO 11607-2:2019 and EN 868-5:2019.
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.

② CE ☂ ☀ [NATURAL LATEX FREE]

Material

Product Part	Raw Material & Characteristic
Paper top web	High weight 70gsm water resistant medical grade paper. Non-coated. Elementary Chlorine Free. Approved for EN 868-3 Process indicators.
Laminate film web	Clear PET/CPP composite multi-layer film (12 µm polyester laminated to 40 µm "shatter less" polypropylene).
Process indicators	Toxic-free, lead-free process indicators ink. Color switches: • Steam: from blue to black. • EO gas: from pink to brown.
Dispenser pack	White paper board
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.
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	5 Years. 12 months shelf life after sterilization.

ONEMED