



Safety from liability



Product
Data
Sheet

Description

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

MPACK® sterile barrier products are constructed of a non-coated high weight medical grade paper and a clear high-strength tear-resistant multi-layer laminate film. They are available as sized pouches or customizable reels (for over-sized and odd-shaped instruments), both in flat or gusseted version.

Key features

- Superior microbial barrier with high weight 70g medical grade non-coated paper.
- Superior multilayer film puncture and abrasion resistance reducing the risk of pinholes.
- Green tinted see-through film allowing quick detection of pinholes or tears.
The darker green color of the seal will allow for easy visual checking of potential defects (channels, air bubbles, wrinkles, etc.)
- 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

Flat reels

Code	Description	Size	Units/Box
1201	Sterilization reel, flat, heat seal	50mmx200m	12
1202	Sterilization reel, flat, heat seal	75mmx200m	8
1203	Sterilization reel, flat, heat seal	100mmx200m	6
1204	Sterilization reel, flat, heat seal	150mmx200m	4
1205	Sterilization reel, flat, heat seal	200mmx200m	2
1206	Sterilization reel, flat, heat seal	250mmx200m	1
1207	Sterilization reel, flat, heat seal	300mmx200m	1
1208	Sterilization reel, flat, heat seal	350mmx200m	1
1209	Sterilization reel, flat, heat seal	400mmx200m	1
1210	Sterilization reel, flat, heat seal	120mmx200m	4
1212	Sterilization reel, flat, heat seal	50mmx100m	16
1213	Sterilization reel, flat, heat seal	75mmx100m	8
1214	Sterilization reel, flat, heat seal	100mmx100m	8
1215	Sterilization reel, flat, heat seal	150mmx100m	4
1216	Sterilization reel, flat, heat seal	200mmx100m	4
1217	Sterilization reel, flat, heat seal	250mmx100m	2
1218	Sterilization reel, flat, heat seal	300mmx100m	2
1219	Sterilization reel, flat, heat seal	400mmx100m	2
1220	Sterilization reel, flat, heat seal	500mmx100m	1
1221	Sterilization reel, flat, heat seal	50mmx31m	48
1222	Sterilization reel, flat, heat seal	75mmx31m	32
1223	Sterilization reel, flat, heat seal	100mmx31m	24
1224	Sterilization reel, flat, heat seal	150mmx31m	16
1225	Sterilization reel, flat, heat seal	200mmx31m	8
1226	Sterilization reel, flat, heat seal	250mmx31m	8
1227	Sterilization reel, flat, heat seal	300mmx31m	8

Gusseted reels:

Code	Description	Size	Units/Box
1301	Sterilization reel, gusseted, heat seal	75x25mm 100m	8
1302	Sterilization reel, gusseted, heat seal	100x50mm 100m	6
1303	Sterilization reel, gusseted, heat seal	150x50mm 100m	4
1304	Sterilization reel, gusseted, heat seal	200x55mm 100m	2
1305	Sterilization reel, gusseted, heat seal	250x60mm 100m	2
1306	Sterilization reel, gusseted, heat seal	300x65mm 100m	2
1307	Sterilization reel, gusseted, heat seal	350x70mm 100m	2
1308	Sterilization reel, gusseted, heat seal	400x75mm 100m	2
1309	Sterilization reel, gusseted, heat seal	300x80mm 100m	2

Technical Summary



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.



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/PP 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: <ul style="list-style-type: none">• Steam: from blue to black.• EO gas: from pink to brown.• Formaldehyde: from pink to green.
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 165-200°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	5 Years. 12 months shelf life after sterilization.



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