

USD 2956b

Cleansteam[™] and Easy-Tear Cleansteam Bags



Ultra-Clean, Sterilizable and Breathable Packaging

Features

- HDPE film produced from certified virgin resins without the use of additives, in an ultra clean environment
- In-house cleaning of uncoated Tyvek 1073B
- Manufactured in ISO Class 5 cleanrooms
- Dye-penetration test (methylene blue) to show packaging integrity
- Easy-Tear option for easier opening and sealing
- Standard items available from stock; customized products on request

Benefits

- Ultra pure, clean bag with low particle, bioburden and endotoxin level (certified cleanliness level)
- Outstanding resistance to microbial penetration
- High sterility integrity until package opened
- Low particle generation when opening bag (Easy-Tear version)
- > Strong, with high resistance to tear and puncture
- Sterilization indicator switching color when exposed to steam
- Increased process efficiency

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Cleansteam and Easy-Tear Cleansteam bags are designed to fulfill the most stringent requirements in the sterilization process of critical components, and have outstanding performance in terms of cleanliness, material and seal strength, as well as microbial barrier properties. They are compatible with a variety of sterilization methods, such as steam and ETO sterilization, and are made from breathable, medical grade Tyvek[•] and own in-house extruded medical-grade HDPE.

Easy-Tear Cleansteam bags enable easy opening without the need for knives or scissors. This innovative feature virtually eliminates the risk of particle generation and accidental damage to gloves that could occur when using cutting devices, making it safer and more efficient to use in an isolator or sterile environment.

Applications

Steam or ETO sterilization of:

- Stoppers, caps and closures
- Vials and containers
- Syringe components
- Stainless steel lab or process equipment
- Medical devices
- Cleanroom garments

The bags also have an excellent chemical compatibility with Hydrogen Peroxide and are compatible with other sterilization methods such as Vaporized Hydrogen Peroxide (VPH), gamma irradiation or electron-beam.

Quality

A Certificate of Conformity (CoC) is provided with each delivery.

Regulatory compliances:

- Food contact compliant¹
- ▶ USP <87>, USP <88> Class VI and USP <661> compliant
- ▶ EP 3.1.3 compliant
- RoHS and REACH compliant
- ▶ BSE/TSE safe
- 1 Manufactured from materials which are listed for food contact in FDA 21 CFR part 177 and are compliant with Commission Regulation (EU) Number 10.2011 relating to plastic materials and articles intended to come into contact with food.



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Ordering Information

Cleansteam Bags

Part	Outer Bag	Inner Bag	Pkg
Number	Size (W x L)	Size (W x L)	
TH1E16P0000-0001	200 mm x 300 mm	185 mm x 250 mm	1000/
	(7.9 in. x 11.8 in.)	(7.3 in. x 9.8 in.)	box
TH1E16P0000-0002	320 mm x 450 mm	305 mm x 400 mm	1000/
	(12.6 in. x 17.7 in.)	(12.0 in. x 15.7 in.)	box
TH1E16P0000-0003	400 mm x 500 mm	385 mm x 450 mm	700/
	(15.7 in. x 19.7 in.)	(15.2 in. x 17.7 in.)	box
TH1E16P0000-0004	500 mm x 650 mm	485 mm x 600 mm	500/
	(19.7 in. x 25.6 in.)	(19.1 in. x 23.6 in.)	box
TH1E16P0000-0005	1200 mm x 1200 mm	1185 mm x 1150 mm	375/
	(47.2 in. x 47.2 in.)	(46.7 in. x 45.3 in.)	box
TH1E16P0000-0006	650 mm x 900 mm	635 mm x 850 mm	250/
	(25.6 in. x 35.4 in.)	(25 in. x 33.5 in.)	box

Easy-Tear Cleansteam Bags

Outer Bag Size (W x L)	Inner Bag Size (W x L)	Pkg
200 mm x 340 mm	185 mm x 290 mm	1000/
(7.9 in. x 13.4 in.)	(7.3 in. x 11.4 in.)	box
320 mm x 450 mm	305 mm x 400 mm	1000/
(12.6 in. x 17.7 in.)	(12.0 in. x 15.7 in.)	box
400 mm x 500 mm	385 mm x 450 mm	700/
(15.7 in. x 19.7 in.)	(15.2 in. x 17.7 in.)	box
500 mm x 650 mm	485 mm x 600 mm	500/
(19.7 in. x 25.6 in.)	(19.1 in. x 23.6 in.)	box
1200 mm x 1200 mm	1185 mm x 1150 mm	375/
(47.2 in. x 47.2 in.)	(46.7 in. x 45.3 in.)	box
650 mm x 900 mm	635 mm x 850 mm	250/
(25.6 in. x 35.4 in.)	(25 in. x 33.5 in.)	box
	Size (W x L) 200 mm x 340 mm (7.9 in. x 13.4 in.) 320 mm x 450 mm (12.6 in. x 17.7 in.) 400 mm x 500 mm (15.7 in. x 19.7 in.) 500 mm x 650 mm (19.7 in. x 25.6 in.) 1200 mm x 1200 mm (47.2 in. x 47.2 in.) 650 mm x 900 mm	Size (W x L) Size (W x L) 200 mm x 340 mm (7.9 in. x 13.4 in.) 185 mm x 290 mm (7.3 in. x 11.4 in.) 320 mm x 450 mm (12.6 in. x 17.7 in.) 305 mm x 400 mm (12.0 in. x 15.7 in.) 400 mm x 500 mm (15.7 in. x 19.7 in.) 385 mm x 450 mm (15.2 in. x 17.7 in.) 500 mm x 650 mm (19.7 in. x 25.6 in.) 485 mm x 600 mm (19.1 in. x 23.6 in.) 1200 mm x 1200 mm (47.2 in. x 47.2 in.) 1185 mm x 1150 mm (46.7 in. x 45.3 in.) 650 mm x 900 mm 635 mm x 850 mm

Customized sizes available upon request

Width equals opening of bag

All bags are clean double packed per 100 pcs (refs -0001 to -0004), per 50 pcs (refs -0006) or per 25 pcs (refs -0005)

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