

# Cleansteam™

## AND EASY-TEAR CLEANSTEAM BAGS

Cleansteam™ and Easy-Tear Cleansteam bags fulfil the stringent requirements for 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 ethylene oxide (EtO) sterilization, and are made from breathable Tyvek and our in-house extruded high density polyethylene (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.

The features and benefits of Cleansteam and Easy-Tear Cleansteam bags include:

- HDPE film produced from virgin resins in an ultra-clean environment
- In-house cleaning of uncoated Tyvek 1073B
- Manufactured under ISO Class 5 at rest conditions
- Dye-penetration test (methylene blue) to show packaging integrity
- Low particle generating Easy-Tear option for easier opening and sealing
- Customized products available on request
- Ultra-pure, clean bag with low particle, bioburden and endotoxin level (certified cleanliness level), with outstanding resistance to microbial penetration
- High sterility integrity until package opened, with high resistance to tear and puncture
- Sterilization indicator switching color when exposed to steam



**Fig 1.** Cleansteam bags are available in a range of standard sizes or can be customized to suit your process.

## 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 are suitable for sterilization with hydrogen peroxide, as well as other methods, such as gamma irradiation and electron-beam sterilization.

## Quality

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

Regulatory compliances:

- Food contact compliant <sup>1</sup>
- U.S. Pharmacopeia (USP) <87>, USP <88> Class VI, and USP <661> compliant
- European Pharmacopeia (EP) 3.1.5 compliant
- Restriction of hazardous substances (RoHS) and registration, evaluation, authorization and restriction of chemicals (REACH) compliant
- Bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathies (TSE) safe

<sup>1</sup> 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.

## Ordering information <sup>2</sup>

### Cleansteam bags

Outer bag size (W × L)	Inner bag size (W × L)	Packaging	Product code
200 × 300 mm (7.9 × 11.8 in.)	185 × 250 mm (7.3 × 9.8 in.)	1000/box	TH1E16P0000-0001
320 × 450 mm (12.6 × 17.7 in.)	305 × 400 mm (12.0 × 15.7 in.)	1000/box	TH1E16P0000-0002
400 × 500 mm (15.7 × 19.7 in.)	385 × 450 mm (15.2 × 17.7 in.)	700/box	TH1E16P0000-0003
500 × 650 mm (19.7 × 25.6 in.)	485 × 600 mm (19.1 × 23.6 in.)	500/box	TH1E16P0000-0004
1200 × 1200 mm (47.2 × 47.2 in.)	1185 × 1150 mm (46.7 × 45.3 in.)	375/box	TH1E16P0000-0005
650 × 900 mm (25.6 × 35.4 in.)	635 × 850 mm (25.0 × 33.5 in.)	250/box	TH1E16P0000-0006

### Easy-Tear Cleansteam bags

Outer bag size (W × L)	Inner bag size (W × L)	Packaging	Product code
200 × 340 mm (7.9 × 13.4 in.)	185 × 290 mm (7.3 × 11.4 in.)	1000/box	TH1ET6P0000-0001
320 × 450 mm (12.6 × 17.7 in.)	305 × 400 mm (12.0 × 15.7 in.)	1000/box	TH1ET6P0000-0002
400 × 500 mm (15.7 × 19.7 in.)	385 × 450 mm (15.2 × 17.7 in.)	700/box	TH1ET6P0000-0003
500 × 650 mm (19.7 × 25.6 in.)	485 × 600 mm (19.1 × 23.6 in.)	500/box	TH1ET6P0000-0004
1200 × 1200 mm (47.2 × 47.2 in.)	1185 × 1150 mm (46.7 × 45.3 in.)	375/box	TH1ET6P0000-0005
650 × 900 mm (25.6 × 35.4 in.)	635 × 850 mm (25.0 × 33.5 in.)	250/box	TH1ET6P0000-0006

<sup>2</sup> 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).



**Fig 2.** Pink steam sterilization indicator turns brown when exposed to steam.

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