

> Newform™ Cleansteam™ and Easy-Tear Cleansteam™ Bags

Ultra-Clean, Sterilizable and Breathable Packaging



Overview

Newform™ 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.

Cleansteam bags are compatible with a variety of sterilization methods, such as Steam and ETO sterilization. The bags are made from breathable, medical grade Tyvek and in-house extruded medical grade HDPE.

The Easy-Tear Cleansteam bag allows 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 may occur when using cutting devices, making it safer and more efficient to use in an isolator or sterile environment.

Applications

For Steam or ETO Sterilization of:

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

Also compatible with other sterilization methods such as Vaporized Hydrogen Peroxide (VPH), Gamma irradiation or electron-beam

Benefits

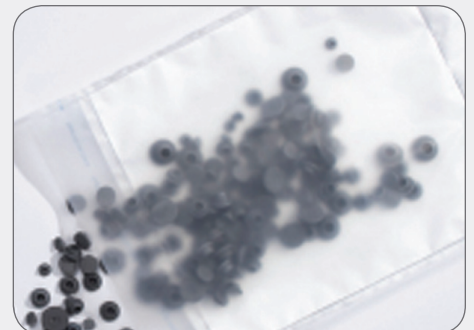
- Ultra pure & clean bag with low particle, bioburden & endotoxin level (certified cleanliness level)
- Outstanding resistance to microbial penetration
- High sterility integrity until package is opened
- Low particle generation when opening the bag (Easy-Tear version)
- Strong bag with high resistance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

Highlights & Features

- Vertically integrated production process with in-house extrusion of the HDPE from certified virgin resins without the use additives in ultra clean environment
- In-house cleaning of uncoated Tyvek 1073B
- Production in ISO class 5 cleanrooms
- Market leader
- Change notification policy in place
- Certificate of conformance with every delivery
- Dye-penetration test (methylene blue) to show packaging integrity
- cGMP certified and focussed company, exclusively servicing the life sciences industry
- Easy-Tear option for better opening and sealing
- Standard items available from stock
- Flexibility towards customized products



Cleansteam Easy-Tear bags allow easy opening without the use of cutting devices..



Cleansteam bags are designed to meet industry standards of cleanliness, material and seal strength, and microbial barrier properties.



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Medical Compliances

Newform™ Cleansteam and Easy-Tear Cleansteam bags are compliant to

- FDA Title 21 CFR 177.1520 “Olefin Polymers” (food contact approval)
- EU Commission Directive 2002/72/EC (food contact approval)
- USP<87> biological reactivity test *in vitro*
- USP <88> biological reactivity test *in vivo*, class VI
- EP paragraph 3.1.3 “Polyolefins”
- EU directive 2002/95/EC (RoHS)
- EMEA/410/01 (animal spongiform encephalopathy agents transmission risk minimization)

Ordering Information – Cleansteam

Part Number	Outer Bag Size	Inner Bag Size	Pieces / Carton
TY8E16P0000-0001	11.8”L x 7.9”W (200mmW x 300mmL)	9.8”L x 7.3”W (185mmW x 250mmL)	1000
TY8E16P0000-0002	17.7”L x 12.6”W (320mmW x 450mmL)	15.7”L x 12.0”W (305mmW x 400mmL)	1000
TY8E16P0000-0003	19.7”L x 15.7”W (400mmW x 500mmL)	17.7”L x 15.2”W (385mmW x 450mmL)	700
TY8E16P0000-0004	25.6”L x 19.7”W (500mmW x 650mmL)	23.6”L x 19.1”W (485mmW x 600mmL)	500
TY8E16P0000-0005	47.2”L x 47.2”W (1200mmW x 1200mmL)	45.3”L x 46.7”W (1185mmW x 1150mmL)	375

Ordering Information – Easy Tear Cleansteam

Part Number	Outer Bag Size	Inner Bag Size	Pieces / Carton
TY8ET6P0000-0001	13.4”L x 7.9”W (200mmW x 340mmL)	11.4”L x 7.3”W (185mmW x 290mmL)	1000
TY8ET6P0000-0002	17.7”L x 12.6”W (320mmW x 450mmL)	15.7”L x 12.0”W (305mmW x 400mmL)	1000
TY8ET6P0000-0003	19.7”L x 15.7”W (400mmW x 500mmL)	17.7”L x 15.2”W (385mmW x 450mmL)	700
TY8ET6P0000-0004	25.6”L x 19.7”W (500mmW x 650mmL)	23.6”L x 19.1”W (485mmW x 600mmL)	500
TY8ET6P0000-0005	47.2”L x 47.2”W (1200mmW x 1200mmL)	45.3”L x 46.7”W (1185mmW x 1150mmL)	375

- Customized sizes are available upon request
- Inches expressed as LxW (Length x Width) and mm expressed as WxL (Width x Length)
- Width equals opening of bag
- All bags are double-packed per 100 pieces (except TY8E16P0000-0005 and TY8ET6P0000-0005 which are double-packed per 25 pcs.)

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