

SINCE 1925

# KEYSTONE

SAFETY ⇄ CLEANROOM PRODUCTS

## PureClean™ Autoclavable Stopper Bowl Cover with Tunnelized Elastic and Verify™ Window, Made with 1421B Tyvek®

PureClean™ Autoclave Stopper Bowl Covers are made from 1421B DuPont™ Tyvek®, which is a new grade of uncoated, untreated, flexible Tyvek® material specifically designed for pharmaceutical use in steam sterilization applications. Keystone's PureClean™ Tyvek® material does not have a water soluble anti-stat agent applied to it during its manufacturing process.

The covers are manufactured using a tunnelized sewing technique to encapsulate the latex-free, talc-free elastic. After sterilization, the covered critical surfaces are protected from particulate and microbial contamination during the aseptic installation and setup activities. The clear film Verify™ Window allows for easy visual inspection of sterilized parts, as required by EU GMP Annex 1.

### Description

- Uncoated Tyvek® for maximum breathability during sterilization without the chance of residue deposits on equipment, post sterilization
- The tunnelized elastic reduces the risk of fiber shedding
- Clear Film Verify™ Window enables visual inspection to verify dryness of sterilized parts, as required by EU GMP Annex 1
- Tyvek® has the highest microbial barrier properties among all steam sterilization wrapping materials
- Manufactured and packaged in a ISO Certified Cleanroom
- Individually Poly bagged for complete protection up to point of use
- Each package is labeled with Lot Number and Date of Manufacture for traceability
- Eliminates Autoclave Tape Residue



Tyvek® is a trademark of affiliates of DuPont de Nemours, Inc.

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Property	Comparable standard test method	Units	Nominal value (range) Tyvek® 1421B
<b>Preliminary product specifications (English units)</b>			
Basis weight	ASTM D3776 <sup>1</sup>	oz/yd <sup>2</sup>	1.22 [1.16–1.26]
Delamination	ASTMD2724 <sup>2</sup>	lb <sub>f</sub>	0.08 [>0.03]
Gurley Hill porosity	TAPPI T460 <sup>3</sup>	sec/100 cc	20 [8–36]
<b>Preliminary product specifications (metric units)</b>			
Basis weight	ASTM D3776 <sup>1</sup>	g/m <sup>2</sup>	41 [39–43]
Delamination	ASTMD2724 <sup>2</sup>	N	0.36 [>0.13]
Gurley Hill porosity	TAPPI T460 <sup>3</sup>	sec/100 cc	20 [8–36]
<b>Preliminary miscellaneous properties (English units)</b>			
Thickness	ENISO 534 <sup>1</sup>	mils	6 (0.15mm)
Tensile strength, MD	EN ISO 1924-2 <sup>2</sup>	lb <sub>f</sub> /in	7.6
Tensile strength, CD	EN ISO 1924-2 <sup>2</sup>	lb <sub>f</sub> /in	6.4
Elmendorf tear, MD	ASTM D1424	lb <sub>f</sub>	2.4
Elmendorf tear, CD	ASTM D1424	lb <sub>f</sub>	1.9
Hydrostatic head	AATCC TM 127 <sup>3</sup>	in H <sub>2</sub> O	44
Elongation, MD	EN ISO 1924-2 <sup>2</sup>	%	10
Elongation, CD	EN ISO 1924-2 <sup>2</sup>	%	15
Puncture resistance	EN 863 <sup>4</sup>	lb <sub>f</sub>	2.7
Mullen burst	ISO 2758	psi	53
Bendsten air permeability	ISO 5636-3 <sup>5</sup>	mL/min	741
Microbial barrier	ASTM F1608	LRV	~4

MD = machine direction; CD = cross direction

1. Surface 2 cm<sup>2</sup>, pressure 50kPa.

2. Modified for speed, sample width 2.54 cm (1 inch).

3. Rate of use: 60 cm H<sub>2</sub>O/min.

4. Modified for conditioning.

5. Electronic device.



**Tunnelized Elastic reduces risk of fiber shedding.**

Fits Openings with Diameters	Keystone Part No.
12" to 20"	BCTK24TWW
14" to 22"	BCTK26WW
20" to 26"	BCTK30TWW
26" to 30"	BCTK36TWW
28" to 23"	BCTK38TWW
28" to 35"	BCTK42TWW
30" to 40"	BCTK48TWW
35" to 45"	BCTK54TWW
40" to 50"	BCTK60TWW