

SINCE 1925

KEYSTONE

SAFETY ↔ CLEANROOM PRODUCTS

PURECLEAN™ 1421B TYVEK® FILLING NEEDLE BAG WITH DRAWSTRING CLOSURE



MATERIAL SPECIFICATIONS:

PureClean™ Filling Needle Bags 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 antistat agent applied to it during its manufacturing process.

- Uncoated Tyvek® on both sides for maximum breathability during sterilization without the chance of residue deposits on equipment, post sterilization
- Convenient Drawstring Closure eliminates the need for autoclave tape or the validation and use of a heat sealer
- Fast and consistent for equipment preparation area
- Strong, sealed seams eliminate sewing threads and greatly reduce particulates
- Resists tearing and punctures
- Superior microbial barrier
- Manufactured and packaged in a certified ISO 6 cleanroom
- Made in the USA
- Certificates of Conformance sent with shipment

Property	Comparable standard test method	Units	Nominal value (range) Tyvek® 1421B
Preliminary product specifications (English units)			
Basis weight	ASTM D3776 ¹	oz/yd ²	1.22 [1.16–1.26]
Delamination	ASTMD2724 ²	lb _f	0.08 [>0.03]
Gurley Hill porosity	TAPPI T460 ³	sec/100 cc	20 [8–36]
Preliminary product specifications (metric units)			
Basis weight	ASTM D3776 ¹	g/m ²	41 [39–43]
Delamination	ASTMD2724 ²	N	0.36 [>0.13]
Gurley Hill porosity	TAPPI T460 ³	sec/100 cc	20 [8–36]

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Property (Continued)	Comparable standard test method	Units	Typical value Tyvek® 1421B
Preliminary miscellaneous properties (English units)			
Thickness	EN ISO 534 ¹	mils	6 (0.15mm)
Tensile strength, MD	EN ISO 1924-2 ²	lb /in	7.6
Tensile strength, CD	EN ISO 1924-2 ²	lb /in	6.4
Elmendorf tear, MD	ASTM D1424	lb _f	2.4
Elmendorf tear, CD	ASTM D1424	lb _f	1.9
Hydrostatic head	AATCC TM 127 ³	in H ₂ O	44
Elongation, MD	EN ISO 1924-2 ²	%	10
Elongation, CD	EN ISO 1924-2 ²	%	15
Puncture resistance	EN 863 ⁴	lb _f	2.7
Mullen burst	ISO 2758	psi	53
Bendsten air permeability	ISO 5636-3 ⁵	mL/min	741
Microbial barrier	ASTM F1608	LRV	~4

MD = machine direction; CD = cross direction

1. Surface 2 cm², pressure 50 kPa.

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

3. Rate of use: 60 cm H₂O/min.

4. Modified for conditioning.

5. Electronic device.

Property	Comparable standard test method	Units	Typical value Tyvek® 1421B
Preliminary miscellaneous properties (metric units)			
Thickness	EN ISO 534 ¹	µm	152
Tensile strength, MD	EN ISO 1924-2 ²	N	34
Tensile strength, CD	EN ISO 1924-2 ²	N	28
Elmendorf tear, MD	ASTMD1424	N	10.6
Elmendorf tear, CD	ASTMD1424	N	8.5
Hydrostatic head	AATCC TM 127 ³	cm H ₂ O	112
Elongation, MD	EN ISO 1924-2 ²	%	10
Elongation, CD	EN ISO 1924-2 ²	%	15
Puncture resistance	EN 863 ⁴	N	12
Mullen burst	ISO 2758	kPa	365
Bendsten air permeability	ISO 5636-3 ⁵	mL/min	741
Microbial barrier	ASTM F1608	LRV	~4

MD = machine direction; CD = cross direction

1. Surface 2 cm², pressure 50 kPa.

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

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KEYSTONE PART NUMBER	DIMENSIONS
6STK0105TD	1" X 4"
6STK0109TD	1" X 8"
6STK0206TD	2" X 5"
6STK0406TD	2.5" X 3"
6STK0709TD	3" X 8"
6STK0314TD	3" X 14"