



PRODUCT DATA SHEET

PART #: BBMGTVKSS1020
Self-Sealing Tyvek® Steam Sterilization Peel Pouch With Steam Indicator, 10.125" x 20"

Keystone Cleanroom Products Autoclaveable, Self-Sealing Tyvek® Peel Pouch With Steam Indicator are made from medical grade DuPont™ Tyvek® and a polyester-based flexible film. The bags are manufactured in a certified ISO7 cleanroom and packaged in ISO6.

The Tyvek® side is an effective bacterial barrier, post sterilization. The clear film side offers excellent clarity combined with strength and durability. These bags feature a convenient adhesive strip for consistent and efficient self-sealing. When opened, virtually no particulates are generated.

Medical Grade DuPont™ Tyvek® 1073B Side:

PHYSICAL PROPERTIES		
Basis Weight	2.2	oz. / sq. yd
Thickness	8	mil
STRENGTH PROPERTIES – (MD machine direction; CD cross direction.)		
Strip Tensile (MD CD)	52 45	lbs. / in.
Elongation to Break (MD CD)	25 28	%.
Elmendorf Tear (MD CD)	0.82 0.84	lbs.
Mullen Burst	178.0 in.-lbs.	/ sq. in.
Spencer Puncture	50.0 in.-lbs.	/ sq. in.
THERMAL PROPERTIES		
Tyvek® has been shown to meet packaging criteria for steam sterilization under controlled conditions (250°F to 260°F [121°C to 127°C] at 30 psi for 30 minutes).		
BARRIER PROPERTIES		
Hydrostatic Head	62 in.	H2O
Microbial Barrier	5.2*	
*Microbiological barrier testing of sterile barrier materials (ASTM F1608). ASTM F1608, Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method), measures the ability of porous sterile barrier materials to prevent bacterial spore penetration. A completely impermeable control sample (microbial penetration is zero) is challenged with one million or 106 colony forming units (cfu). The number of cfu 106 has a log10 value of 6. If a sample challenged in the same way as the control allows 10 cfu (log 10=1) to penetrate, then its log reduction value (LRV) is 5 (6–1=5). Therefore, the higher the LRV, the more resistant the packaging is to microorganisms.		

FILM SIDE: TPF-0563B

PHYSICAL PROPERTIES	
Material – Proprietary lamination of polyester and polyolefin film bonded with a thermoset adhesive.	
Gauge	2.6 mil 65 micron
Yield	10,500 15.0
STRENGTH PROPERTIES – (MD machine direction; CD cross direction.)	
Tensile at Break (MD CD)	50 59 N / sq. mm
Impact Strength	450
Tear Strength	12 17
Burst Strength	210
THERMAL PROPERTIES	
For best results do not exceed steam sterilization temperatures of 257°F / 125°C.	

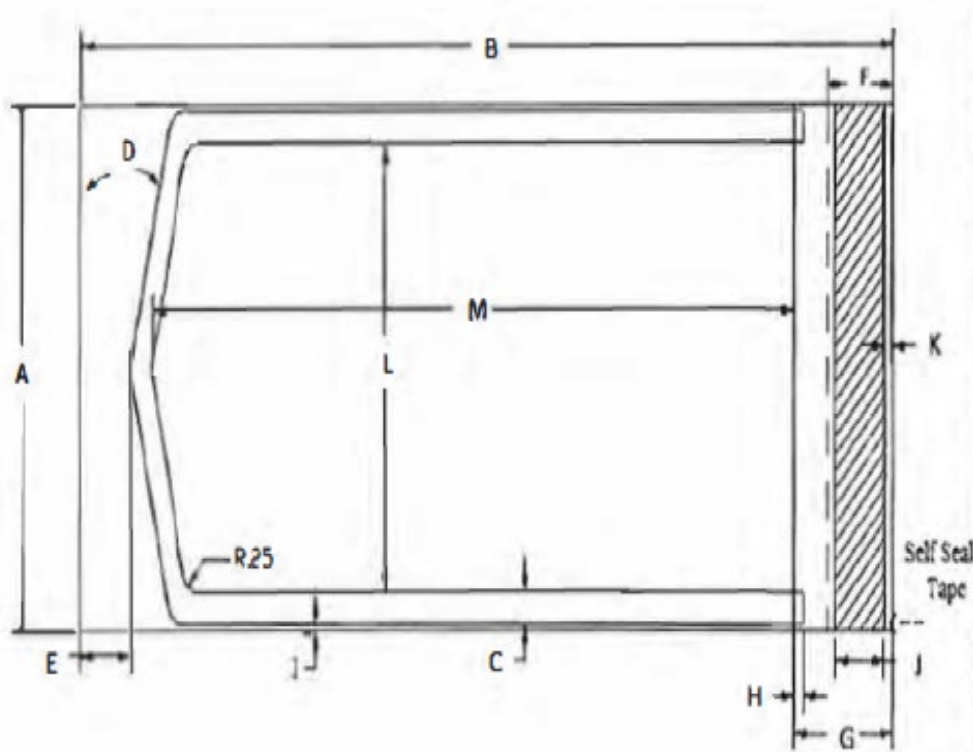
ADHESIVE SELF-SEALING STRIP: 90132

DESCRIPTION
256M acrylic adhesive double coated to PET film with 60# semi bleach silicone treated densified kraft paper.

FACTORY SEAL STRENGTH PROPERTIES
Seal Strength / Acceptance Criteria > 1.5 lbs. / inch

STEAM STERILIZATION PROCESS INDICATOR: ETIGAM BV #4.01

THERMAL PROPERTIES
<p>Steam sterilization process indicators undergo a significant color change from pink to dark brown when exposed to steam. Designed for use in steam autoclaves operating at 121°C / 1 bar or 134°C / 2 bar. The color change of the sterilization process indicators is dose dependent.</p> <p>11140-1:2009 "Sterilization of health care products - Chemical indicators - Part 1: General requirements".</p> <p>Sterilization process indicators are not dosimeters. Color change of the sterilization process indicators indicates exposure to the process. The process itself needs to be validated in order to assure the sterility of the products.</p>



KEY DIMENSIONS				
		Dimension Inch	Default Dimension	Tolerance +/-
B	Length (OD)	21.00		
A	Width (OD)	10.13		
C	Seal Width		0.38"	0.06"
D	Chevron Angle		15°	5°
E	Chevron Tip to Cut Off	0.63	0.75	
OTHER SPECIFICATIONS				
F	Perforation Line		1.00	0.13"
G	End Flap		1.50	0.13"
H	Seal Extension		0.13	0.06"
I	Side Flange Width	0.06		0.13"
J	Tape Width		0.75	REF
K	Tape Position		0.13	REF
L	Width (ID)			REF
M	Length (ID)			REF
Peel Strength				
<i>Peel Minimum</i>		1.5 lb / inch		1.0 lb / inch
<i>Test method</i>		unsupported		

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