



BIVKIT1ST PRE-STERILIZED EM PLATE TRANSPORT KIT

Description:

GEPCO's Media Plate Transport Kit is designed to provide a protective, disposable system for media plates. Use of this kit eliminates the risk of "false positives" that are often attributed to the transport/handling process of settle and contact plates. This can often occur during their transport from Grade A space through lesser classified areas, or by the lab personnel.

The system consists of multiple sterile, breathable self-sealing Tyvek incubator compatible pouches, where the plates are inserted and closed by the EM technicians while still inside Grade A space. Multiple sealed Tyvek incubator pouches are then placed into the sterile plastic transport tray, while inside Grade A space. Finally, the filled tray is placed inside the pre-sterilized, self-sealing impervious plastic transport bag and closed via the self-sealing closure, also within Grade A space. At this point, the sealed impervious transport bag can be removed from Grade A and transferred to the lab in the normal manner. All of the components of this system are designed to be sealed and opened without the use of any sterilized tools or additional machines. All components and packaging of this pre-sterilized system are compatible with VHP surface sterilization, so they can be used with isolator technology, as well as conventional filling lines and RABs.

MATERIALS

COMPONENT	QTY	DESCRIPTION
TRAY	1	Tray, Size: 9.5" X 12.25"
01011TWBSSSD	2	Tyvek Breather Bag With Easy Chevron Peel Feature & Self Seal Closure, Size: 10" x 11"
3322	1	Sterility Maintenance Bag, Self Seal, Size: 16" x 22"

Material Specification:

TRAY

PHYSICAL PROPERTIES
Material – Thermoformed Polystyrene. Size (base): 9.5 in. x 12.25 in. Thickness: 0.045 in.
Color – White

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TYVEK BREATHER BAG

Polyester-Based Flexible Film Side

PHYSICAL PROPERTIES		
Material – Proprietary lamination of polyester and polyolefin film bonded with a thermoset adhesive.		
Gauge	2.6 mil 65.0 microns	
Yield	10,500 sq. in. / lb. 15.0 sq. m / Kg	
STRENGTH PROPERTIES – (MD signifies machine direction; CD signifies cross direction.)		
Tensile at Break (MD CD)	50 59	N / sq. mm
Impact Strength	450	g
Tear Strength	12 17	N / sample
Burst Strength	210	KN / sq. m

Tyvek® Side

PHYSICAL PROPERTIES		
Material – TYVEK® (Spunbonded Olefin) Type 1073-B Merge 18025. Adhesive self-sealing strip.		
Basis Weight	2.2	oz. / sq. yd
Thickness	8	mil
STRENGTH PROPERTIES – (MD signifies machine direction; CD signifies 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.
BARRIER PROPERTIES		
Hydrostatic Head	62	in. H ₂ O
Microbial Barrier (per ASTM F1608-95 for microbial ranking of various materials) – LRV of 5.3 verses LRV of 1.9 for an autoclave paper pouch. (The higher the log reduction value (LRV) the more resistant the package is to bacteria and micro-organisms. A log difference of 3 signifies a difference of 1,000 units.)		

NOTE: Microbial Barrier must be validated for individual Users' processes.

Adhesive Self-Sealing Strip

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

Seal

STRENGTH PROPERTIES	
Seal Strength	> 1.5 lbs. / in.

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STERILITY MAINTENANCE BAG

PHYSICAL PROPERTIES		
Material – 3 mil thick medical grade polyolefin material		
Gauge	3.0 mil 76 microns	
Basis Weight	43.2 lbs. / ream 70.3 gr. / sq. M	
Yield	10,000 sq. in. / lb. 14.22 sq. M / Kg	
Haze	70 %	
STRENGTH PROPERTIES – (MD signifies machine direction; CD signifies cross direction.)		
Tensile (MD CD)	3,500 2,000 lbs. / sq. in. 24.13 13.79 n / sq. mm	
Tensile Modulus (Youngs) (MD CD)	11,000 15,000 lbs. / sq. in. 75.84 103.40 n / sq. mm	
Elongation (MD CD)	300.0 700.0 %	
Elmendorf Tear (MD CD)	30 120 grams 0.29 1.23 n	
Spenser Impact	12,000 lbs. / sq. in. 82.73 n / sq. mm	
COF	0.5	

Assembly:

The above will be packaged as follows:

- 1 - Tray
- 2 - 01011TWBBSSSD placed inside the tray
- 1 - 3322 Folded in half and placed under the tray
- The above placed inside a 18" x 24" Tyvek Mylar Pouch

Sterilization Method: Ethylene Oxide Gas (ETO) sterilization

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