Sterilisation

Pouches



PRODUCT INFORMATION				
MATERIAL	Medical grade dialysis paper, double sided tape			
COLOUR	Blue (medical composite membrane)			
TYPE	Non-sterile, single-use			
FEATURES	Triple sealed, thumb-notch open design, compatible with steam & ethylene oxide sterilisation			
WEIGHT	60gsm (medical paper), 52 µm (film)			
COUNTRY OF ORIGIN	Taiwan			
STORAGE	Store in original packaging in a cool, dry and well ventilated area, away from dust, direct sunlight, moisture, x-ray and excessive heat. Ideal temperature: 15-35°C (59-95°F). Relative Humidity: 50-70 RH%.			





USAGE GUIDELINES

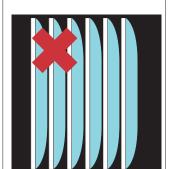
STACKING MULTIPLE POUCHES

CORRECT METHOD

Place pouches film to film and paper to paper.

Pouches are stacked back to back with the paper side of the pouches facing each other. This allows a freeflowing in-and-out stream of air and steam between the pouches.

INCORRECT METHOD



The film of the adjoining pouch covers part of the paper side of the next pouch.

This causes a reduced surface area for the penetration of air & steam.

AUTOCLAVE USAGE

Adhere to your Autoclave Manufacturers guidelines when sterilising. Below are recommended guidelines:



Follow your Autoclave instruction manual for the best Pouches should never touch the Autoclave or be position for pouch placement.



overcrowded.

GRADUATED PROCESS INDICATOR EXPOSURE

EO STERILISATION	STEAM STERILISATION			
Unacceptable Acceptable	Unacceptable Acceptable			

Indicators turn from blue to golden brown when processed 100-120min at 50°C, 60-85% RH, and EO concentration of 600 mg/L.

ISO 11135

Sterilisation of health care products - Ethylene oxide-Requirements for the development, validation & routine control of a sterilisation process for medical devices.

Indicators turn from pink to cocoa when processed 30min at 121°C. Indicators turn from pink to cocoa when processed 4min at 134°C.

ISO 17665

Sterilisation of health care products - Moist heat

QUALITY STANDARDS

AUDIT STANDARDS

Manufactured in an NS EN ISO 13485:2016 facility

TEST STANDARDS

2009-RGC-MDD-0001 - Conforms to Class I device

TEST STANDARDS RESULTS								
ITEM	PROPERTIES	UNITS	STANDARDS / METHODS	TYPIC				
	Substance	g/m²	ISO 536	60.0				
	Bendtsen Porosity	ml/min	ISO 5636-3	1000				
	Air Permeance	µm/Pa.s	ISO 5636-3	11.4				
	Bendtsen roughness FS	ml/min	ISO 8791-2	375				
	Bendtsen roughness WS	1111/111111	ISO 8791-2	375				
	Pore Size	Mm	EN 868-2:2009 Annex E	21.0				
Medical Paper (A-0101)	Thickness	141111	ISO 536	83.0				
	Tensile strength MD	kN/m	ISO 1924-2	6.4				
	Tensile strength CD	KIN/III	130 1924-2	3.4				
	Wet tensile strength MD	kN/m	ISO 3781	2.1				
	Wet tensile strength CD	KIN/III	130 3761	1.1				
	Burst strength	kPa	ISO 2758	350				
	Wet burst	KPa	ISO 3689	150				
	Tearing strength MD	mN	ISO 1974	600				
	Tearing strength CD		130 1974	650				
	Cobb test (60s)	g/m²	ISO 535	15.0				
	Water repellency	S	EN 868-2:2009 Annex D	35.0				
	Fluorescence	pts/d m ²	EN 868-2:2009 Annex B	0.0				
	Thickness	μm	DIn 53370	38.0				
Film	Tensile strength at break MD	N/mm²	ASTM D-882	41.0				
(B-BU38)	Tensile strength at break TD	14/111111	A3111 D-002	21.0				
(2 2 3 3 3)	Elongation at break MD	- %	ASTM D-882	500				
	Elongation at break TD	76	A3111 D-002	600				
	Thickness	μm	ASTM E-252	12 (±5%)				
	Tensile strength at break MD	N/mm²	ASTM D-882	≥ 19.0				
Film (B-PET12)	Tensile strength at break TD	IN/IIIIII	A3111 D-002					
	Elongation at break MD	- %	ASTM D-882	≥ 80.0				
	Elongation at break TD	70	ASTITIO 002					

EAGLE ORDERING INFORMATION							
CODE	SIZE	PURCHASE UNIT	CARTON DIMENSIONS (LxWxH)	CARTON WEIGHT	CUBIC METRE		
412900	134x280mm	1 carton of 2000 pouches (200/box x 10 boxes/ctn)	31 x 30 x 34.5cm	10.1kg	0.03m³		



Contact us today to receive samples or for more information on this product.

Eagle Protect

sales@eagleprotect.co.nz eagleprotect.co.nz 0800 633 468

