SOLUTIONS FOR STERILE BARRIER SYSTEMS

TOP TO BOTTOM WEB The perfect match





ETHYPEL® ETHYFORM® ETHYFLEX®



SOLUTIONS FOR STERILE BARRIER SYSTEMS TOP WEB TO BOTTOM WEB : The perfect match





ETHYPEL® Reinforced HP 85 gsm to ETHYFORM[®] FPAE 120 μm



ETHYPEL[®] Reinforced ST 80 gsm to ETHYFORM[®] FOAE 90 μm



ETHYPEL® Reinforced CP 83 gsm to ETHYFORM® FPAE 95 µm



ETHYPEL® Performance CP 63 gsm to ETHYFORM® FOPE 70 µm



ETHYPEL[®] Performance CP 63 gsm to ETHYFLEX[®] HSTP 64 μm 585 **1**

ERHP 85 gsm

^{SBS}

ERST 80 gsm + FOAE 90 µm

ERCP 83 gsm

^{SBS}

EPCP 63 gsm

^{SBS}



STERIMED[®] is the world leader in sustainable breathable medical packaging solutions.

It is the only player in the industry with industrial manufacturing tools exclusively dedicated to healthcare packaging solutions and vertically integrated from porous web making to coating, printing & slitting. Our company has production, converting and warehousing operations in France, Czech Republic, USA and China.

Our product line includes sterile barrier solutions for medical device manufacturers, the coating and converting industry, as well as protection wraps and a full range of solutions for hospital sterilization centers.



→ PACKAGING SOLUTIONS FOR YOUR MEDICAL DEVICE

STERIMED[®] offers a complete range of top to bottom web solutions for single-use medical device packaging.

These full Sterile Barrier Systems (SBS) have been qualified based on seal & peel performance as well as mechanical strength, microbial barrier efficiency and operating window on packaging lines.

The product line includes coated & surface treated porous webs, in pure cellulose or polymer-reinforced, associated to a number of flexible film grades of various structures and thicknesses.

All materials comply with ISO11607-1 requirements.

All materials are available in various roll sizes, printed or unprinted.

→ TOP TO BOTTOM WEB SOLUTIONS on Form Fill Seal packaging machines ETHYPEL® to ETHYFORM®



→ TOP TO BOTTOM WEB SOLUTIONS on 4SS/Platten machines ETHYPEL® to ETHYFLEX®



- Solution for woundcare packaging
- Large operating window at low dwell time
- Seal strength range of 140 180 cN/15 mm

STERILE BARRIER SYSTEM (SBS)	Product		Substrates	Sealing Operating Window	Sterilization	
	ETHYPEL® Reinforced HP	85 gsm	Coated Polymer Reinforced web	Temperature: 140 °C - 170 °C		
	ETHYFORM® FPAE	120 µm	Polypropylene/ Polyamide/ Polyethylene	Time: 1,1-2,3 sec Pressure: 500 Kpa	EO	
2	ETHYPEL® Reinforced ST	80 gsm	Surface Treated Polymer Reinforced web	Temperature: 140 °C - 150 °C Time: 1,0 - 1,7 sec	EO / Irradiation	
	ETHYFORM® FOAE	90 µm	Polyamide/ Polyethylene	Pressure: 500 Kpa		
	ETHYPEL® Reinforced CP	83 gsm	Coated Polymer Reinforced web	Temperature: 140 °C – 160 °C		
3	ETHYFORM® FPAE	95 µm	Polypropylene/ Polyamide/ Polyethylene	Time: 1,2 - 2,4 sec Pressure: 500 Kpa	EO	
	ETHYPEL [®] Performance CP	63 gsm	Coated cellulose based web	Temperature: 135 °C – 160 °C	50	
4	ETHYFORM® FOPE	ETHYFORM® FOPE 70 µm		Pressure: 500 Kpa	EO	
	ETHYPEL® Performance CP	63 gsm	Coated cellulose based web	Temperature: 130 °C – 160 °C	EQ / Irradiation	
5	ETHYFLEX® HSTP	64 µm	Polyesther/ Polyethylene	Pressure: 500 Kpa	EO / Irradiation	

Can be completed with a packaging machine lease program for Global Packaging Solutions (GPS)

- Review Sterile Barrier System options and run pre-qualification trials with the support of STERIMED® technical team.
- Qualify your target sterile barrier system.
- Use part of the savings from new packaging solution to install state of the art packaging line equipment leased by STERIMED®.
- Get full ownership of packaging line at the end of the lease program period.
- → Learn more page 16.



ETHYPEL[®] REINFORCED HP 85 gsm to ETHYFORM[®] FPAE 120 μm



General description:

Sterile Barrier System designed for large and/or puncture prone medical devices that also require wide operating window on packaging lines and high seal strength target level.

The porous top web has been engineered to withstand both EO and Irradiation types of sterilization with high performance for gas desorption and excellent control of bacterial barrier properties.

Top Web:

High fiber cohesion material mixing cellulose and polymer binders. Strong resistance to puncture, tear and burst. An optimized layer of adhesive coating for excellent seal and peel. Perfect aseptic opening and tamper evidence, excellent print-ability and registration control.

Bottom Web:

7-layer cast coextruded medical film grade that associates the formability of a polyamide-based web, with enhanced finish due to polypropylene layer, and excellent run-ability thanks to PE-seal layer.

Application:

Recommended for packaging of drapes, gowns, pre-filled syringes or lab sponges type of products as well as all other medical devices that require mechanical strength, flexibility of web when peel opening and high seal performance for safety during packaging in shipper cases, sterilization and transport.

Package Performances:

Seal strength*, aseptic opening and sealing package have been positively evaluated on blisters manufactured on industrial FFS packaging line.

*Seal strength measured as average value in T-Peel supported angle.



	POROUS WEB			FILM WEB			
Product designation	ETHYPE	L [®] Reinforce	d HP	Product designation	ETHYFORM [®] FPAE		λE
Product description	Coated	Reinforced	web	Product description	F	PP/PA/PE	
Recommended sterilization	EO / Irradiation		Recommended sterilization	EO			
	STANDARD TEST METHOD	UNIT	TYPICAL VALUE		STANDARD TEST METHOD	UNIT	TYPICAL VALUE
Substance	ISO 536	g/m²	85	Thickness	ASTM D374	μm	120
Tensile strength	ISO 1924-2	kN/m	5,0	Tensile strength	ASTM D882	kN/m	3,9
Burst strength	ISO 2758	kPa	400	Elongation	ASTM D882	%	625
Tear strength	ISO 1974	mN	625	Coefficient of Friction F/F	ASTM D1894	-	0,5
Cobb test	ISO 535	g/m²	18	Haze	ASTM D1003	%	4,5
Pore size	EN 868-6 app. D	μm	19	Gloss 45°	ASTM D2457	%	90
Air permeance	ISO 5636-3	µm/Pa.s	2,5	Color	-	-	transparent

STERILE BARRIER SYSTEM PERFORMANCES

		UNITS	VALUES
Recommended	Max deep draw	mm	45
conditions	Sealing temperature	°C	140 - 170
	Dwell time	Sec	1,1 - 2,3
	Seal pressure	kPa	500
Performance	Seal strength average*	cN/15 mm	334
before sterilization	Seal strength variation	%	+/-7%
	Sealing aspect		pass
	Dye penetration test		pass
Performance	Sealing strength after EO	%	-2%
after sterilization	Sealing strength after Irradiation	%	NA

*Sample size : 88 blisters - T-Peel supported angle.

ETHYPEL[®] REINFORCED ST 80 gsm to ETHYFORM[®] FOAE 90 μm





General description:

A unique Sterile Barrier System that associates the technology of porous web reinforcement with the addition of synthetic binders. The patented surface treatment technology replaces the usual offline coated technology.

Top Web:

Embedded adhesive layer impregnating the porous web substrate on both sides for easy run-ability in all directions. Polymer-based binders strengthening the cellulosic mesh for mechanical performance.

Medium porosity levels to optimize EO desorption Controlled maximum pore size to optimize bacterial barrier & safety over event-related shelf life.

Bottom Web:

A standard 7-layer cast coextruded PA/PE medical web grade, in 90 µm.

Good formability and mechanical performance thanks to the Polyamide resins.

PE-seal layer adapted to surface treated top web material.

Application:

A unique solution to reduce the cost of your most demanding packaging designs: high seal strength, easy run-ability, clean peel opening.

Surface treated webs run in a 10°C to 15°C operating window depending on packaging lines.

Particularly adapted to tubings, IV sets, catheters, small drapes and gowns materials as well as procedure kits packed in flexible packaging and pre-filled syringes.

Package Performances:

Seal strength*, aseptic opening and sealing package have been positively evaluated on blisters manufactured on industrial FFS packaging line.

*Seal strength measured as average value in T-Peel supported angle.



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	POROUS WEB			FILM WEB			
Product designation	ETHYPE	L [®] Reinforce	d ST	Product designation	ETHYFORM [®] FOAE		Έ
Product description	Surface Trea	ated Reinford	ced web	Product description		PA/PE	
Recommended sterilization	EO / Irradiation		Recommended sterilization	EO / Irradiation			
	STANDARD TEST METHOD	UNIT	TYPICAL VALUE		STANDARD TEST METHOD	UNIT	TYPICAL VALUE
Substance	ISO 536	g/m²	80	Thickness	ASTM D374	μm	90
Tensile strength	ISO 1924-2	kN/m	5,8	Tensile strength	ASTM D882	kN/m	2,5
Burst strength	ISO 2758	kPa	440	Elongation	ASTM D882	%	475
Tear strength	ISO 1974	mN	700	COF Film / Film	ASTM D1894	-	0,25
Cobb test	ISO 535	g/m²	15	Haze	ASTM D1003	%	4,5
Pore size	EN 868-6 app. D	μm	18	Gloss 45°	ASTM D2457	%	95
Air permeance	ISO 5636-3	µm/Pa.s	6,2	Color	-	-	transparent

STERILE BARRIER SYSTEM PERFORMANCES

		UNITS	VALUES
Recommended	Max deep draw	mm	35
conditions	Sealing temperature	°C	140 - 150
	Dwell time	Sec	1,0 - 1,7
	Seal pressure	kPa	500
Performance	Seal strength average*	cN/15 mm	321
before sterilization	Seal strength variation	%	+/-8%
	Sealing aspect		pass
	Dye penetration test		pass
Performance	Sealing strength after EO	%	-7%
after sterilization	Sealing strength after Irradiation	%	-7%

*Sample size : 88 blisters – T-Peel supported angle.

ETHYPEL® REINFORCED CP 83 gsm to ETHYFORM® FPAE 95 µm



General description:

Sterile Barrier System comprising a polymer-reinforced breathable web associated with a multi-layer formable cast film for heat seal application.

Packaging solution optimized in substance to enhance cost-efficiency, polymer-reinforced binders & Polyamide layers for high level of mechanical resistance.

Top Web:

Synthetic binders associated with renewable cellulosebased raw materials for a strong top web solution which can withstand both EO & Irradiation sterilization.

Web flexibility in large peel angle, excellent printability and registration make it easy to run material on newer Form Fill Seal packaging lines.

Bottom Web:

7-layers cast coextruded medical film grade that associates the formability of a polyamide-based web with enhanced finish thanks to Polypropylene layer and excellent run-ability thanks to PE-seal layer.

Application:

The combination of reinforced materials and medium thickness gauge is particularly adapted for the packaging of medical devices that require a large peel angle.

The repeatability of the seal performance also provides a high level of safety.

A sterile barrier system particularly fit for catheters, tubings, infusion sets, but also for small gowns or

kits which are packed in flexible formable packaging.

Package Performances:

Seal strength*, aseptic opening and sealing package have been positively evaluated on blisters manufactured on industrial FFS packaging line.

*Seal strength measured as average value in T-Peel supported angle.



Porous web



Time



	POROUS WEB				FIL	M WEB	
Product designation	ETHYPE	_® Reinforce	d CP	Product designation	ETHYFORM® FPAE		
Product description	Coated	Reinforced v	web	Product description	P	P/PA/PE	
Recommended sterilization	EO / Irradiation		Recommended sterilization	EO			
	STANDARD TEST METHOD	UNIT	TYPICAL VALUE		STANDARD TEST METHOD	UNIT	TYPICAL VALUE
Substance	ISO 536	g/m²	83	Thickness	ASTM D374	μm	95
Tensile strength	ISO 1924-2	kN/m	5,8	Tensile strength	ASTM D882	kN/m	2,6
Burst strength	ISO 2758	kPa	400	Elongation	ASTM D882	%	625
Tear strength	ISO 1974	mN	625	COF Film / Film	ASTM D1894	-	0,5
Cobb test	ISO 535	g/m²	16	Haze	ASTM D1003	%	4,5
Pore size	EN 868-6 app. D	μm	17	Gloss 45°	ASTM D2457	%	90
Air permeance	ISO 5636-3	µm/Pa.s	2,4	Color	-	-	transparent

STERILE BARRIER SYSTEM PERFORMANCES

		UNITS	VALUES
Recommended	Max deep draw	mm	35
conditions	Sealing temperature	°C	140 - 160
	Dwell time	Sec	1,2 - 2,4
	Seal pressure	kPa	500
Performance	Seal strength average*	cN/15 mm	268
before sterilization	Seal strength variation	%	+/-8%
	Sealing aspect		pass
	Dye penetration test		pass
Performance	Sealing strength after EO	%	On going
after sterilization	Sealing strength after Irradiation	%	NA

*Sample size : 88 blisters - T-Peel supported angle.

ETHYPEL[®] PERFORMANCE CP 63 gsm to ETHYFORM[®] FOPE 70 μm



General description:

A safe Sterile Barrier System solution for medical devices thanks to a lightweight coated porous web associated with a designto-cost PP/PE heat seal formable film.

Light weight coating on top web for large operating window and stability in packaging process and peel-open performance.

Top Web:

Porous Web comprising more than 90 % of renewable resources, with a light weight adhesive layer enhancing seal ability & peel ability.

Solvent fiber coating technology with higher initiating temperature provides great storage stability.

Bottom Web:

7-layer PP/PE coextruded cast formable web material, for small size packaging.

Application:

Qualified for the packaging of gauzes, sutures, IV sets, hydrophilic catheters and syringes.

Also recommended for markets where storage conditions or local use operations require good stability of material to rather high level of temperatures during storage and/or converting.

Package Performances:

Seal strength*, aseptic opening and sealing package have been positively evaluated on blisters manufactured on industrial FFS packaging line.

*Seal strength measured as average value in T-Peel supported angle.



	POROUS WEB			FILM WEB			
Product designation	ETHYPEL	Performan	ce CP	Product designation	ETHYFORM [®] FOAE		
Product description	Coatec	l Cellulose w	veb	Product description		PP/PE	
Recommended sterilization	EO / Irradiation		Recommended sterilization	EO			
	STANDARD TEST METHOD	UNIT	TYPICAL VALUE		STANDARD TEST METHOD	UNIT	TYPICAL VALUE
Substance	ISO 536	g/m²	63	Thickness	ASTM D374	μm	70
Tensile strength	ISO 1924-2	kN/m	4,8	Tensile strength	ASTM D882	kN/m	1,6
Burst strength	ISO 2758	kPa	330	Elongation	ASTM D882	%	840
Tear strength	ISO 1974	mN	525	COF Film / Film	ASTM D1894	-	0,5
Cobb test	ISO 535	g/m²	18	Haze	ASTM D1003	%	6,0
Pore size	EN 868-6 app. D	μm	11	Gloss 45°	ASTM D2457	%	85
Air permeance	ISO 5636-3	µm/Pa.s	1,0	Color	-	-	transparent

STERILE BARRIER SYSTEM PERFORMANCES

		UNITS	VALUES
Recommended	Max deep draw	mm	10
conditions	Sealing temperature	°C	135 - 160
	Dwell time	Sec	1,0 - 1,8
	Seal pressure	kPa	500
Performance	Seal strength average*	cN/15 mm	154
before sterilization	Seal strength variation	%	+/-7%
	Sealing aspect		pass
	Dye penetration test		pass
Performance	Sealing strength after EO	%	-2%
after sterilization	Sealing strength after Irradiation	%	NA

*Sample size : 88 blisters - T-Peel supported angle.

ETHYPEL[®] PERFORMANCE CP 63 gsm to ETHYFLEX[®] HSTP 64 μm





General description:

A very solid sterile barrier packaging solution for woundcare applications. Designed for run-ability on continuous and intermittent sealing equipment. Tested in speeds varying from 20 to 50 m / min Overall light weight coating for stability in process and higher versatility to machine and process conditions.

Top Web:

Porous Web comprising more than 90 % of renewable resources, with a light weight adhesive layer enhancing seal-ability & peel ability.

Solvent fiber coating technology with higher initiating temperature provides great storage stability.

Bottom Web:

2 layer laminated PET/PE with optimized heat-seal layer.

Application:

Gloves, gauzes and active woundcare of all shapes and sizes.

Package Performances:

Seal strength*, aseptic opening and sealing on package have been positively evaluated on blisters manufactured on industrial FFS packaging line.

*Seal strength measured as average value in T-Peel supported angle.



	POROUS WEB			FILM WEB			
Product designation	ETHYPEL	Performan	ce CP	Product designation	ETHYFLEX® HSTP		þ
Product description	Coatec	l Cellulose w	veb	Product description	l	PET/PE	
Recommended sterilization	EO / Irradiation		Recommended sterilization	EO / Irradiation			
	STANDARD TEST METHOD	UNIT	TYPICAL VALUE		STANDARD TEST METHOD	UNIT	TYPICAL VALUE
Substance	ISO 536	g/m²	63	Thickness	ASTM D374	μm	64
Tensile strength	ISO 1924-2	kN/m	4,8	Tensile strength	ASTM D882	kN/m	2,3
Burst strength	ISO 2758	kPa	330	Elongation	ASTM D882	%	41
Tear strength	ISO 1974	mN	525	COF Film / Film	ASTM D1894	-	0,3
Cobb test	ISO 535	g/m²	18	Haze	ASTM D1003	%	12
Pore size	EN 868-6 app. D	μm	11	Gloss 45°	ASTM D2457	%	NA
Air permeance	ISO 5636-3	µm/Pa.s	1,0	Color	-	-	transparent

STERILE BARRIER SYSTEM PERFORMANCES

		UNITS	VALUES
Recommended	Max deep draw	mm	No forming
conditions	Sealing temperature	°C	130 - 160
	Dwell time	sec	0,5 - 1,1
	Seal pressure	kPa	500
Performance	Seal strength average*	cN/15 mm	162
before sterilization	Seal strength variation	%	+/-8%
	Sealing aspect		pass
	Dye penetration test		
Performance	Sealing strength after EO	%	-1%
after sterilization	Sealing strength after Irradiation	%	-1%

*Sample size : 88 blisters - T-Peel supported angle.



→ PRODUCT SPECIFICATIONS

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REEL SPECIFICATIONS

Mandrel

 Core mandrel: Material: Cardboard - Inner diameter: 76 mm (+/-0.2 mm)

Tolerances

• Length*: +/- 100 meters - Width: +/- 1 mm Diameter: +/- 10 mm

Splices & patches

- Splices: Butt join cross deckle splice identified with red tape on both sides and red pastel on reel edges
- Patches: Red patch identified by blue pastel on 1 reel edge
- · Maximum 2 patches or/and splices per roll

* A limited number of rolls of shorter length might be produced from time to time, in which case an information on manufactured size will be sent to customer prior to shipment



PACKAGING & PALLETIZATION

Reel packaging specifications

- · Individual film wrapping around each roll
- Film tightened to reel with plastic core plug
- Reels stacked upright on pallet

Pallet packaging specification

- · Several reels per layer, and several layers of stacked reels per pallet
- Only 1 size of reel per pallet
- Size of pallet adapted to target outer diameter of reels
- Number of reels per layer & layers per pallet varying according to size and weight of rolls
- Corrugated sheets line tops & bottoms of rolls for added protection
- Overall film wrap around pallet

Labelling

- · Small label on core plug
- · Label on outer layer of roll (removable & repositionable by customer for better traceability)
- Pallet label and pallet list



SHIPMENT

- Stacked pallets up to 2,2 m max
- In full truck, full container, or by groupage



Both options can be used depending on types of defect.



Design of top & bottom web protections of rolls depending on pallet size.





Detailed loading conditions to be confirmed based on target sizes or reels to be shipped.



→ SERVICES:

ROLL STOCK FINISHES

STERIMED® top web materials can be delivered in different size and finishes.

- Width varying from 80 mm to 700 mm
- Standard outer diameter of reels: 30, 35, 40, 50 & 60 cm
- Other dimensions may be available depending on material please enquire
- Material can be printed up to 4 colors
- Possibility of 2-side printing
- Rolls are individually wrapped
- Plastic mandrels available upon request

Bottom web materials available in outer diameters of 33 cm and 53 cm, in width of 80 mm to 700 mm depending on material.

PACKAGING LINE LEASE PROGRAM

STERIMED[®] has developed a packaging line lease program for companies willing to invest in new equipment and to qualify new packaging materials.

It is designed to help medical device manufacturers capture the savings of qualifying new packaging solutions in 2 ways.

- Savings thanks to new packaging line(s) paid through a lease program; with machines optimized in design and performance and benefiting from the newest technology for good process control.
- Savings thanks to a decrease in packaging consumable price by transferring currently existing solutions to STERIMED[®] top and bottom web materials.

Technical support is provided throughout the packaging qualification phase.

Joined trials can be organized with the packaging machine manufacturer to speed up qualification line.

The design of equipment and the conditions of the lease program are developed based on packaging materials which have been qualified for the medical device.

The lease program period can run from 3 to 7 years, with transfer of ownership to the medical device company at the end of the period.



SD_SBSSampler_160201

STERIMED[®], a partner at your side:

- 1. World leader in breathable medical device packaging solutions
- 2. Industrial assets fully dedicated to the production of healthcare products only
- 3. Vertically integrated with coating / printing / slitting capacity in house under 1 quality control system
- 4. Optimal safety, traceability & cleanliness of products





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