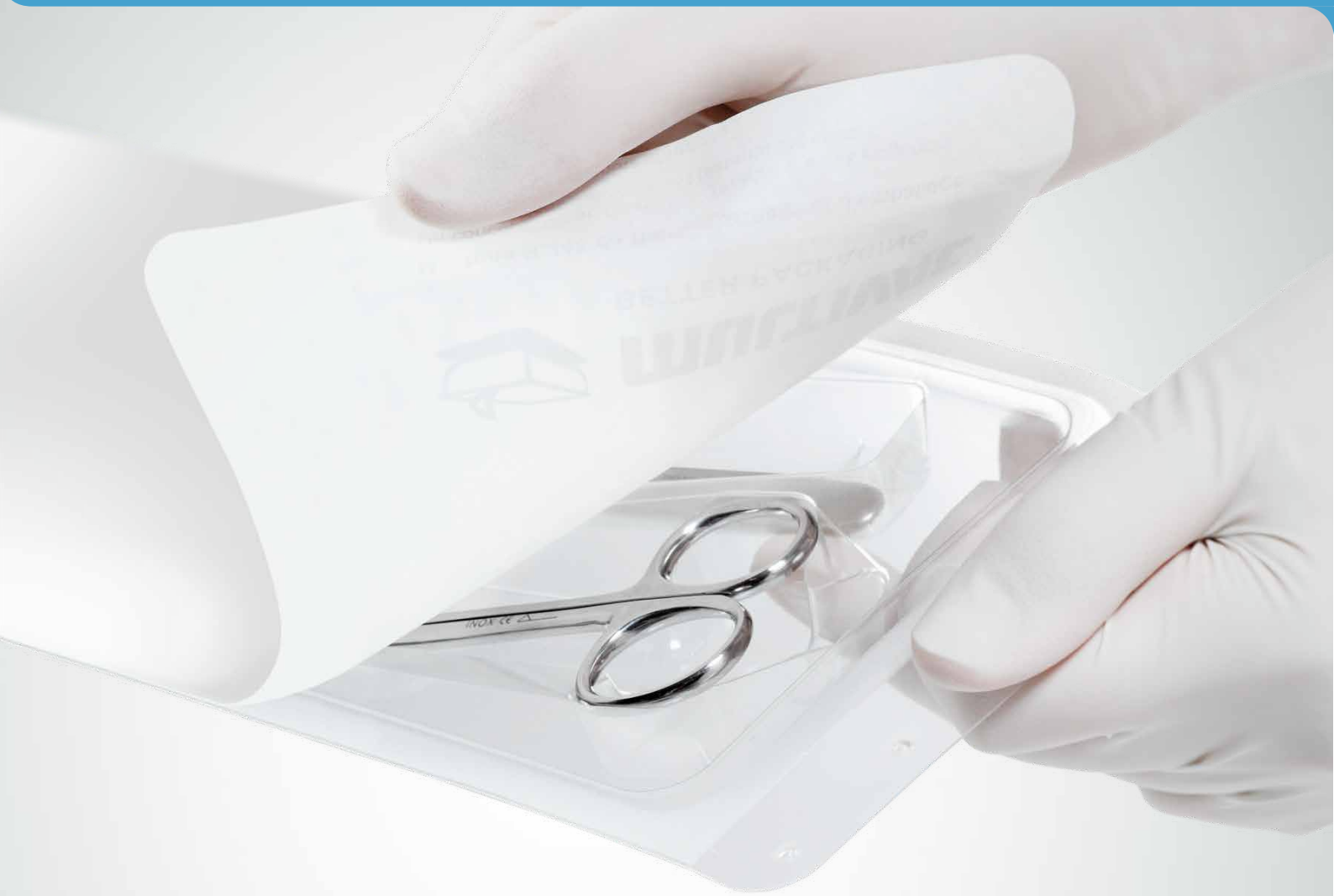


New top-lid packaging solution for rigid blister applications

Polybond™

ETHYPEL® by STERIMED

CONTEXT

Over the years, multiple materials have been developed to serve as a potential cost effective alternative to Tyvek® based packaging.
The first market developments have been observed in the field of flexible formable packaging where coated and surface treated webs made of a mix of cellulose and synthetic binders or fibers have progressively gained markets shared.
Among manufacturing devices that have been transferred, one can mention drapes, gowns, catheters & IV Sets…

At the end of the year 2000s, a first attempt had been made with the launch of Ovantex® by Oliver, which was a product development associating

- the coating technology of the by-then Oliver company
- to a versatile cellulose-based web material encompassing synthetic fibers & binders to enhance material mechanical strength & cohesion
- the total gauge of the material was of 101 g/m^2
- enhanced mechanical properties
- material had been tested and complied with requirements for EO & Irradiation sterilization

In the early 2010s, polymer-reinforced webs were introduced with surface treatment technology helping to drive costs down by removing the need for additional coated layer on base web material.
The solution could be used on regular grades of film, granted that they were comprising a standard layer of Polyethylene for sealing & peeling performances, and has quickly found its market in the field of industrial peel pouch & roll stock packaging solutions for drapes, gowns, lap sponges and IV sets.
Nevertheless, specific requirements of sealing to rigid packaging could not be answered by this new solution, due to

- seal behavior to PVC, APET, PETG or HIPS being different from the one of a Pe- EVA
- peel angle and mechanical stress when opening a rigid blister being more challenging from aseptic opening requirements than the flexible packaging solutions.

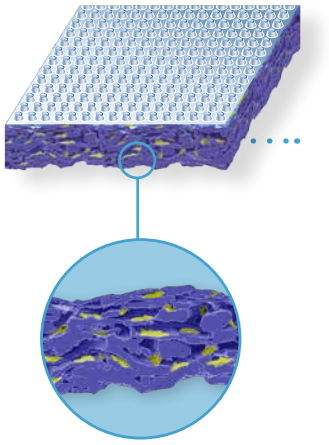
NEW PRODUCT DEVELOPMENT

Hence the development over the last 3 years of new materials aiming at bridging the gap and delivering the right level of performance for blister needs:

- stronger intense cohesion of material
- flexibility and stretch enhancement for large peel angle requirements
- bespoke coated adhesives adapted to the different film natures that can be found on market

POLYBOND AGP 90 gsm & POLYBOND BHP 85 gsm are the result of these product developments to satisfy unanswered customer needs.

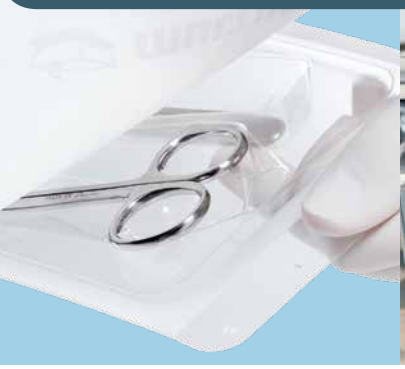
1. **POLYBOND AGP 90 gsm** for sealing to PVC, which is still commonly used in Asia and on some European market, and to APET
2. **POLYBOND BHP 85 gsm** for sealing to HIPS



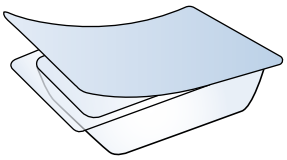
MATERIAL:
fiber mesh of cellulose and polymer binders, with grid coating pattern

Polybond AGP 90 gsm

ETHYPEL by STERIMED




FOCUSING ON POLYBOND AGP 90 gsm TESTING & RESULTS



• Typical properties

POLYBOND AGP 90 gsm has been designed for sealing to PVC and APET rigid material and tested on several web thicknesses, from 300 to 700 µ, and form fill seal packaging lines. It's unique fiber mesh structure mixes cellulose together with a high content level of synthetic binders.

It allows for a very flexible material, and for superior performance in regard with prevention of the risk of break, puncture & burst. The choice of a water-based coating technology in addition to a significant share of renewable resource based raw material also make it a quite environmental friendly solution to your packaging needs. Available in roll stock or for converting into die cutted top lid.

• Illustrating material performance through packaging line testing

POLYBOND AGP 90 gsm is a coated reinforced web which complies with all requirements of international standards as illustrated by the below table detailing typical values and relevant test methods for the developed packaging material.

MATERIAL DESCRIPTION

			POROUS WEB		
Product designation			POLYBOND AGP 90 gsm		
Product description			GRID COATED POLYMER-REINFORCED WEB		
	Standard Test Method	Unit	Typical value before sterilization	Typical value EO* sterilization	Typical value IR** sterilization
SUBSTANCE	ISO 536	g/m²	90	90	90
TENSILE STRENGTH	ISO 1924-2	kN/m	75	75	60
BURST STRENGTH	ISO 2758	kPa	415	385	305
TEAR STRENGTH	ISO 1974	mN	630	650	535
COBB TEST	ISO 535	g/m²	18.7	17.0	16.5
MAX PORE SIZE	EN 868-6 app C	µm	18.7	19.7	18.6
AIR PERMEANCE	ISO 5636-3	µm/Pa.s	1.7	2.3	1.7

* EO: Time 6h, Temperature 35°C at 50 % RH, EO concentration 1 Kg/m³. ** Irradiation : 28.6 kGy

Polybond AGP 90 gsm

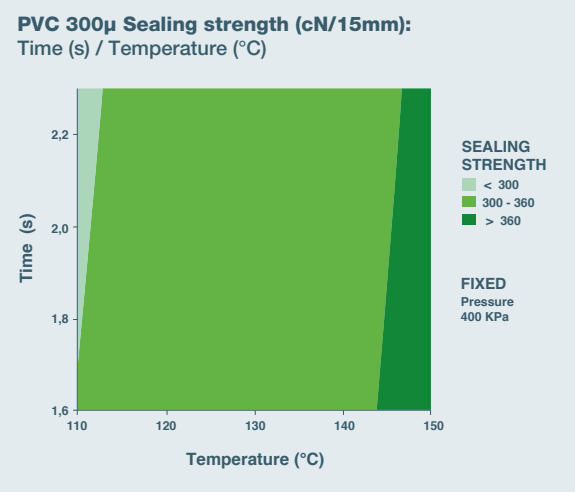
Polybond AGP 90 gsm has been recently evaluated on:
- Multivac R 145 model
- To APET and PVC film materials
- In thicknesses of 600 and 300 µ respectively

60 different blisters have been manufactured and tested, opened & characterized. Mechanical, seal strength and 180° peel angle peel opening properties have been evaluated before and after sterilization.
Sterilization conditions that have been used are as follow:
- EO on 6 hours with a temperature 35°C at 50 % RH and a concentration of 1 Kg/m^3
- Irradiation with 28.6 kGy

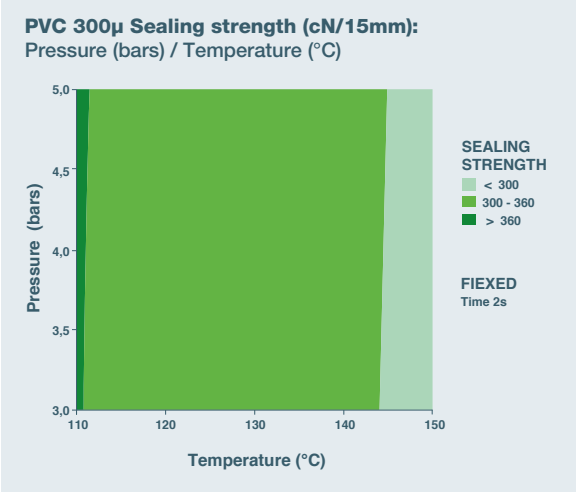
Running conditions on packaging lines have been:
- Range of sealing temperature: 110-160°C – 230-320 Fahrenheit
- Tested dwell time: 1,6-2,4 second
- Range of pressure: 300-500 KPa

Results of design of experiment:
- Medium to high seal strength levels have been achieved both when sealing to APET and PVC material
- Pressure applied on packaging line during manufacturing process has no noticeable impact on packaging seal and peel performance (real gas test diameter: 60 shore)
- A wide operating window (temperature, pressure, dwell time) has been identified as illustrated through the below charts

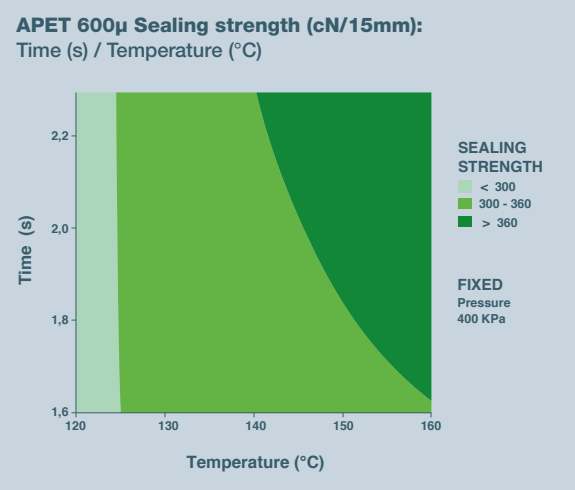
DESIGNED FOR A LARGE OPERATING WINDOW ON YOUR PACKAGING LINES



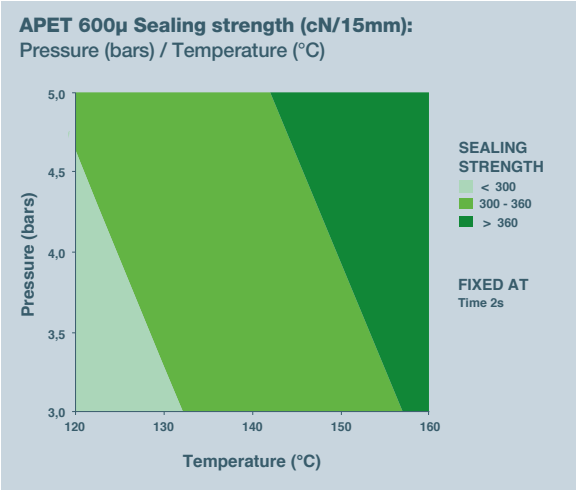
Design of Experiment of Polybond AGP 90 gsm to PVC 300µ sealing strength, 60 tested samples



Design of Experiment of Polybond AGP 90 gsm to PVC 300µ sealing strength, 60 tested samples



Design of Experiment of Polybond AGP 90 gsm to APET 600µ sealing strength, 60 tested samples



Design of Experiment of Polybond AGP 90 gsm to APET 600µ sealing strength, 60 tested samples

More data on product testing and results:

STERILE BARRIER SYSTEM PERFORMANCES

			POROUS WEB			
Product designation			POLYBOND AGP 90 gsm			
Product description			GRID COATED POLYMER-REINFORCED WEB			
		Unit	Before sterilization PVC 300µ	After EO sterilization PVC 300µ	Before sterilization APET 600µ	After Irrad. sterilization APET 600µ
TESTED CONDITIONS	Tray Dimensions	mm	337x151x20	337x151x20	156x136x20	156x136x20
TYPICAL USES CONDITIONS	Sealing temperature	°C	130	130	140	140
	Dwell time	s	2	2	2	2
	Sealing pressure	KPa	400	400	400	400
PERFORMANCE	Seal strength average*	cN/15mm	330	-	300	-
	Seal strength variation**	%	4	-	9	-
	Seal visual inspection		Pass	Pass	Pass	Pass
	Dye penetration (seal integrity)		Pass	Pass	Pass	Pass
	Aseptic opening		Fiber free	Fiber free	Fiber free	Fiber free

* Sample size ; 60 blisters - 180° Peel angle. **Average per pouch. *** Irradiation: 28.6 kGy.
*** EO: Exposure Time 6h, Temperature 35°C at 50 % RH, EO concentration 1 kg/m^3.

More extensive trials are currently being run at customer's facilities in Asia, Europe and United States of America.

NEXT STEPS

POLYBOND AGP 90 gsm is now currently under performance assessment and final testing review with several medical device manufacturers in Asia, Europe & United States of America.
The purpose of these testings is to gather more data on product behavior

- with different grades of PVC & APET films,
- different geometry of packaging
- different types of production lines (technology, age, maintenance policy)
- more significant statistical data

POLYBOND BHP 85 GSM, designed for sealing to HIPS material, is currently going through the first test assessment of performance as per POLYBOND AGP 90 gsm qualification protocol.

Interested in helping us learning more about product behavior, and qualifying it on your packaging lines?

STERIMED INFORMATION

From STERIMED, your Infection Control Partner:

- Largest range of sterilization packaging substrates in the world
- Sales in more than 70 countries
- Packaging education programmes for medical device industry and hospital staff

Accreditations:

- ISO 9001:2008 • ISO 14001:2004 • ISO 50001:2011 • ISO 13485:2003

Interested in helping us learning more about product behavior, and qualifying it on your packaging lines?

Send us an E-mail: contact@sterimed.us

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