

WHITE PAPER

POLYURETHANE FILM ON PAPER WITH CONTROLLED RELEASE

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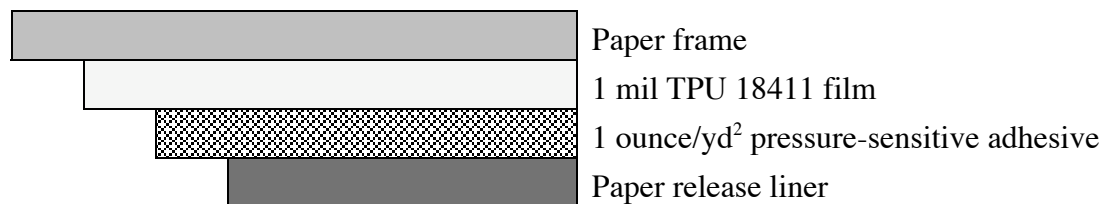
Value Proposition

Medical adhesive coaters, converters and distributor/retailers now have an alternative film source that will allow them to participate in frame-type wound dressing and surgical drape markets. Argotec, Inc. of Greenfield, Massachusetts U.S.A., has developed **ArgoMedPLUS**[®] thermoplastic polyurethane (TPU) film on paper with controlled release.

Background

There are many wound dressing designs, including film, island, frame or combinations thereof. Contract medical manufacturers and professional medical supplies distributors have enjoyed a wide variety of material choices for all but frame-type dressings. Challenges to successful marketing of frame dressings include patent and material source issues, as well as creating a film product with the correct peel release* between the paper and film. (Similar technical challenges and processes are present in surgical drape applications.)

A typical frame dressing has the following layers:



* We refer to this practice of managing peel force properties as controlled release.

The peel release between the paper carrier (which eventually becomes the frame) and the tpu film is critical throughout the dressing manufacturing process. The release must be:

- tight enough so the film and paper remain intact during the psa coating and slitting process,
- loose enough so the kiss/cut window can be detached from the tpu film either by vacuum or adhesive tape removal techniques,
- tight enough so the frame remains affixed to the tpu film after the kiss-cut/window removal,
- loose enough so when the medical practitioner applies the dressing the frame will separate from the tpu without forcing the adhesive away from the patient.

For over 10 years Argotec has supplied **ArgoMed[®] 18411** aromatic polyether polyurethane film (on a polyethylene carrier) for use in IV site and other dressing/drape applications. The 18411 product satisfies the film requirements in these uses and is also suitable in other dressing applications.

Solving the Problem

The controlled release problem as described above is well understood throughout the medical dressing supply chain. Meeting the specific controlled release requirements while maintaining all other finished product and process criteria was the challenge.

The properties for a superior wound dressing and drape include:

- Comfort
 - Tensile/elongation – stretch/recovery
 - Moisture vapor transmission (breathability)
- Bio-compatible – USP Class IV or VI
- Viral and blood-borne pathogen barrier

- Compatible with downstream processes
 - High film surface tension for medical grade adhesive application
 - EtO and gamma sterilization

- Cost competitive

ArgoMed 18411 tpu film has the proper balance of these properties. Other polymers, such as polyolefins, are low cost and can be processed, but they don't have the comfort of a polyurethane film. Silicones meet many of the requirements, but are expensive.

The ultimate solution to the controlled release problem was choosing the right paper and modifying the tpu extrusion coating process to control the peel release values between the paper and tpu film.

New TPU Product and Capital Investment

As stated above, Argotec's 18411 tpu film already had the correct balance of properties for medical dressings and drapes. The next step was to test a variety of papers in concert with extrusion process changes to manage the tpu peel force as it released from the paper.

The test methodology was to:

- (1) extrude 1.0 mil x 60" wide 18411 film on papers under consideration;
- (2) adjust process conditions as appropriate; and
- (3) measure the resulting paper peel from tpu film (over time).

Throughout the testing period, new engineering designs and capital equipment were installed.

Test Method:	PSTC-15 1-inch strip TPU film mounted to stainless-steel plate Paper removed at 90° angle at 144 inches/minute
Target:	190 grams/linear inch in the cross and machine directions.

- Target Basis†: < 150 gli
- Adhesive confusion occurs during coating
 - The frame may peel with the window during converting
- > 240 gli
- Adhesive pulls away from patient when removing the frame during dressing delivery.

† By comparison, standard 18411 film on polyethylene has a peel force of about 15 gli.

Parameters:

The papers tested were primarily 50-80# SCK, with a coating on at least one side.

The extrusion process changes included proprietary, in-line equipment and the normal controls available to commercial extrusion operations.

Results:

After a number of iterations, a combination of tpu film, paper, propitiatory capital investment and process conditions yielded a viable product that successfully met the target release. The new 18411 film-on-paper product is called **ArgoMedPLUS 18411**.

ArgoMedPLUS Manufacturing Process Validation

Three separate extrusion production runs were made using different lots of tpu resin and paper. These lots were then shipped to medical film coaters and converters who concluded:

- (1) the controlled release problem was solved;
- (2) the coating and converting processes were repeatable at commercial yield and rates; and
- (3) the resulting frame dressing would be marketable.

ArgoMedPLUS can be unwound, adhesive coated or laminated, rewound and slit to 12-inch rolls, die (kiss)-cut/converted, packaged, sterilized and used as frame dressings or incise drapes. All these downstream processes can be accomplished with commercially available technology.

Conclusion

Medical supply distributors/retailers, converters and adhesive coaters now have a viable, cost-effective film-on-paper option to choose for the manufacture of incise drapes and frame-type dressings: **ArgoMedPLUS 18411**.

About Argotec

Argotec is a privately held, global supplier of custom-engineered, high-performance, polyurethane film and sheet for a wide variety of critical applications. In addition to flat-die, cast-on-carrier and blown-film-extrusion technologies, the company also has expertise in extrusion coating, multi-layer constructions and closed-cell polyurethane foam sheet extrusion. Argotec provides film & sheet products globally to the international specialty films market, adhesive coaters, plastics converters and fabricators, as well as to OEM's.

Further information may be obtained by calling (413)772-2564, faxing (413)772-2565, e-mailing info@argotec.com, or visiting the Argotec website: www.argotec.com.