Advantages of New TPEs over PVC IN FILM BAGS AND POUCHES

by **Ross Van Royen**, Senior Medical Market Manager, the Thermoplastic Elastomer Division of Teknor Apex Company

Medical-grade PVC film has long been a widely used and trusted material for fluid bags and pouches, and Teknor Apex Company is well established as a supplier of PVC compounds for use by film producers. Increasingly, however, issues such as those focusing on the phthalate plasticisers used to make PVC flexible are causing some film manufacturers—or their customers—to look for alternative materials. Until now the proposed replacements have failed to duplicate the advantages of PVC in terms of cost, properties, or ease of fabrication.

New MD-500 Series compounds in the Medalist range of medical thermoplastic elastomers (TPEs) from Teknor Apex promise to provide the first practical alternative to PVC in such applications as: cushioning bladders (for mattresses, wheel chairs, and gurneys); IV and saline bags; medicine storage and delivery pouches; bags for enteral and parenteral nutrition storage and delivery; dialysis bags; and surgical pouches. Bags produced from these compounds (illustration 1 page on 22) are comparable to PVC in processing, assembly, and clinical handling. The difficult bonding issue has been addressed by RF welding, heat welding, and/or new design.

At the same time, tests by Teknor Apex and collaborating companies have shown that these TPEs provide a number of property improvements over PVC, along with substantial savings in weight and cost.

Properties Superior to PVC Film at Less than Half the Thickness

To maximise the potential of Medalist MD-500 compounds as replacements for PVC, Teknor Apex worked with companies having expertise in medical film manufacture and pouch fabrication. One of these was O'Sullivan Films, based in Winchester, Virginia, USA, a specialist in producing film using the calendering process. Until now, few polymers other than PVC have been used successfully in calendering, but as a result of innovation by Teknor Apex, the Medalist MD-500 Series includes not only extrusion grades but also the first TPE compounds that can be calendered on large production-scale equipment.

In comparisons of PVC and TPE films, both produced by calendering, the TPE products exhibited substantial cost-performance advantages:

- **Raw material economy.**

Even at a little less than half the thickness of PVC (15 mm for PVC versus 7 mm for TPE), film made from TPE exhibited the same degree of physical strength, substantially greater elongation, and significantly greater tear resistance (see table 1). This indicates that TPE can be down-gauged to a considerable degree without compromising strength.

- **Weight savings.**

Because the TPE compounds are 30% less dense than flexible PVC and can be made into thinner films, finished products can be 66 to 70% lighter, enabling savings on shipping costs.

- **Enhanced end-use properties.**

Even when down-gauged by 54% in comparison with PVC, the TPE film exhibited better moisture and nitrogen barrier and substantially greater low-temperature resistance as measured by a -40 °C cold impact test (table 1).

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<< Table 1: Properties of Class III / Class VI Medical Film: TPE versus PVC >> **SOURCE: O'Sullivan Films**

PROPERTY		SINGLE-PLY TPE (7 MIL / 0.18 MM)	UNSUPPORTED FILM PVC (15 MIL / 0.38 MM)	ASTM TEST METHOD
Tensile strength, MPa	MD CD	19.97 15.31	19.37 16.81	D-882
100% modulus, MPa	MD CD	12.18 5.97	8.31 7.36	D-882
Elongation, %	MD CD	932 997	309 494	D-882
Tear strength ©, MPa	MD CD	3.07 3.03	1.90 2.03	D-1004
Hardness, Shore A (15 sec. dwell)		88	80	D-2240
Dimensional stability (MD / 10 min. @ 100 °C.), %		-1.5	3.5	D-1204
-40 °C Cold impact (Masland)		10 of 10 pass	0 of 10 pass	D-1790
Moisture vapor transmission - rate, g/h•m²		0.0465	0.1610	E-96
Oxygen permeability, P (CM2/SEC-ATM)		2.30158 E-07	2.25206 E-07	D-1434 (V)
Nitrogen permeability, P (CM2/SEC-ATM)		6.88857 E-09	8.47040 E-09	D-1434 (V)

<< LEFT | Illustration 1: New technologies make possible medical film products, such as this pouch, that combine the advantages of thermoplastic elastomers (TPEs) over PVC, the quality benefits of calendering, and the sealing efficiency of radio frequency (RF) welding. >>

<< Illustration 3: Using the established ecoGenesis welding process, it is now possible to switch a PVC media reservoir bag, being mandrel-welded using a Teflon-coated tooling setup, to TPE. >>

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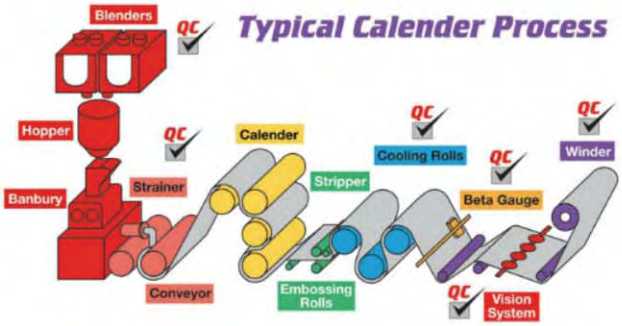
In testing by O'Sullivan Films and an independent medical device designer, the TPE films underwent gamma sterilisation with no colour change. A valuable property of the TPE film cited by O'Sullivan Films is that it is optically clear when filled with a non-opaque solution—important for many clinical applications, especially infusion.

This crystal clarity is one of several advantages of Medalist MD-500 Series compounds over traditional TPEs. In addition they are also stronger, provide greater oxygen barrier, are more gamma stable, and have a more PVC-like "feel".

O'Sullivan Films reports that there has been commercial use of its calendered TPE films involving storage of fluids for extended periods of time. In development are applications for infusion and stem cell processing. Research continues on possible use of TPEs for processing of blood components.



<< Illustration 2: The typical calender process. >>

The calendering process such as that employed by O'Sullivan Films has long been used for PVC medical films. Indeed, Teknor Apex's Vinyl Division uses the process to make medical-grade products. In calendering, producers fuse flexible compound and pass it through a series of synchronised nip rolls (see illustration 2). The process yields certain advantages over extrusion, including tighter gauge control, more uniform product, and wider rollstock for higher-volume bag production. O'Sullivan Films produces calendered films in widths up to 84 inches (2.1 m) at an annual output of 80 million lb (36 million kg).

RF Welding Now Usable for TPEs as Well as PVC

Besides being calendered successfully on large production-scale calendering equipment, an additional breakthrough for TPEs involved another collaborator: Genesis Plastics Welding based in Indianapolis, Indiana, USA. Genesis is a contract manufacturer of medical and other film bags and pouches using the radio-frequency (RF) welding method.

While RF welding is widely employed for fabricating bags made of PVC and thermoplastic polyurethane (TPU) elastomer, the process has not been applicable to other thermoplastic elastomers without use of special additives. In light of the versatility of RF welding, this has been a disadvantage for TPEs. Beyond the straight-line bonds produced with standard heat sealing, RF welding can produce bonds in complicated shapes, a wide range of sizes, varied weld widths, and combinations with non-film products such as fabrics or foams.

With a well established and trademarked technology called ecoGenesis, which Genesis both employs as a contract manufacturer and licenses to other fabricators, these advantages are now available for TPE films. For example, it is now possible to switch a PVC media reservoir bag, like that shown in illustration 3, being mandrel-welded using a Teflon-coated tooling setup, to TPE.

Conventional RF welding works well with "high dielectric loss" or "polar" polymers such as PVC and TPU elastomers. Under the influence of an electromagnetic field, these otherwise electrically neutral polymers tend to align themselves with the field—hence the term "polar". The styrenic and olefinic polymers used in formulating the less costly, more widely used types of TPE such as those in the Medalist range are non-polar and until now have not been bondable with RF welding. The same has been true for certain polymers to which TPEs might be bonded, such as polypropylene and polyethylene.

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The ecoGenesis RF plastics welding technology developed by Genesis enables film produced from a Medalist elastomer to form strong permanent bonds with itself and with polypropylene and similar polymers. Genesis describes this proprietary technology as a "bolt-on" addition to conventional RF welding systems, such as those already widely employed for medical and non-medical applications. For users of the technology, there is no need to invest in alternative capital equipment, and welding of non-polar materials is accomplished without need for plasticisers or other additives that in the past have been used to render such material RF-weldable.

With the addition of non-polar materials to the capabilities of RF welding, this process can now be used to heat seal virtually any thermoplastic to itself or in combination with compatible polymers in the form of films, laminates, woven fabrics, nonwovens, and foams. Films as thin as 0.00025 inches (0.006 mm) can be welded.

Alternative to PVC and TPU with Advantages over Both

Three technological breakthroughs have come together to make Medalist TPEs a strong contender to replace both PVC and TPUs in a range of medical bag and pouch applications: 1) development by Teknor Apex of Medalist formulations with the rheological and thermal properties required for calendering; 2) successful deployment of these novel TPEs by O'Sullivan Films in production of commercial-grade medical films; and 3) Genesis Plastic Welding's development of an RF-welding innovation that gives TPEs the same advantages as PVC and TPU in bonding and sealing.

Medalist TPEs can serve as lower-cost alternatives not only to TPUs (which have generally cost more than widely used TPEs based on olefins or styrenics) but also to traditionally lower-cost PVC. At the same time, TPEs exhibit a number of substantial performance benefits over PVC and even some advantages over TPUs.

All compounds in the Medalist range contain no phthalates such as DEHP, nor any other plasticisers, and they are free of mineral oils, animal-derived materials, and bisphenol A (BPA). They are compliant with relevant FDA, CONEG, RoHS, REACh, SVHC, and California Proposition 65 directives. Teknor Apex manufactures all Medalist TPEs in ISO13485-certified plants in the USA and the UK.

Medalist is a registered trademark of Teknor Apex Company. Teflon is a registered trademark of DuPont and EcoGenesis is a trademark of Genesis Plastics Welding.

About the author:

Ross Van Royen is senior medical market manager for the Thermoplastic Elastomer Division of Teknor Apex Company. He has been employed by Teknor Apex for over 20 years and held a number of commercial, manufacturing and engineering positions. Prior to Teknor Apex Company he was employed by ENSR Consulting and Engineering. Ross Van Royen has an MBA from Bryant College and a BS in Chemical Engineering from the University of Massachusetts, USA.