COMPOSITE REINFORCED COATINGS

The future of medical device coatings

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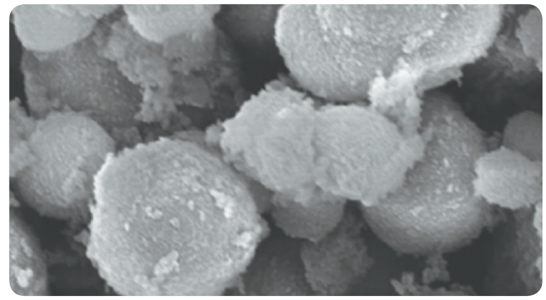

Since the advent of Perfluorooctanoic acid (PFOA) free coating materials,[1] the medical device industry as a whole has observed increased levels of coating-related issues.[2] Underlying these issues is the concern that PFOA-free coating materials demonstrate reduced levels of fluoropolymer layer adhesion and cohesion, resulting in increased risks of coating failure.

Polytetrafluoroethylene (PTFE) is by its very nature an unforgiving processing material. The removal of PFOA, a processing aid employed within the polymerisation of fluoropolymers, has changed the landscape for many coating applicators. While the jury may still be out in relation to the impact of PFOA elimination on coating adhesion, what cannot be disputed is the need for applicators to adapt their processes in response to a significant materials formulation change.

The typical response of coating applicators in dealing with the newly created challenges of PFOA-free materials is to focus on aspects of materials processing. Increased attention to substrate cleanliness, controlling layer thicknesses and applying thinner coating layers are the improvement areas of interest for many applicators. Merit Medical does not dispute this line of thought. In fact, it is in this area where Merit has worked and focussed its research for more than 15 years. With our unique reel-to-reel coating technology, thin layers of coating are applied on high volumes of wire with minimal wall thickness variation (figure 1).

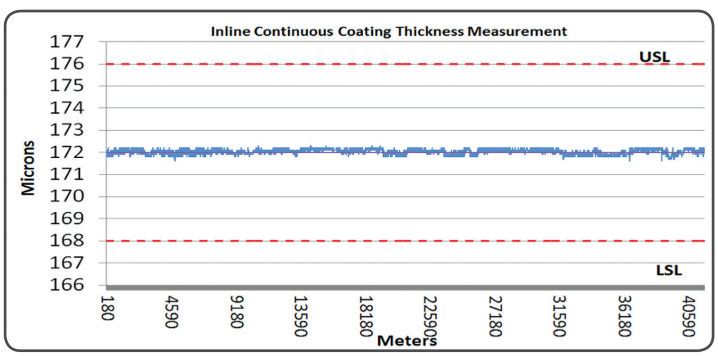

Figure 1, Inline diameter control (Merit pre-coated wire)

The end result is a coated wire with uniform thin layer wall thickness over the full length of the spool. This dimensional stability, coupled with excellent substrate adhesion due to our aggressive substrate inline cleaning process, results in supplied material that is very predictable in nature. The predictability allows our customers to efficiently set up and automate processes, potentially reducing costs.

For an example of the benefits of pre-coated material, one can look at the market for diagnostic guidewires, where the use of pre-coated coating techniques is replacing the former standard of post-coated techniques such as spraying (figure 2).

Figure 2, Pre-coated (top) coil vs Spray-coated coil (bottom)

While improving the coating technique may address the issue of substrate and inter-layer adhesion for the PFOA-free coatings, this is merely returning coating performance to levels observed prior to the PFOA-free materials introduction. In order to remain competitive in the increasingly price sensitive medical device market, opportunities to reduce cost and further improve product performance are critical.

Materials Improvement Challenge

Since the introduction of PFOA-free fluoropolymer coatings, Merit has focused on understanding and addressing any associated detrimental effects related to processing performance or end-use application performance.

Underlying this material science problem is a fundamental dilemma: how might we retain the positive aspects of PTFE -non-stick, high lubricity, high temperature resistance and chemically inert - while reducing or eliminating unfavourable characteristics such as poor substrate adhesion, insufficient layer cohesion and low wear performance.

The properties of PTFE are to a large extent a result of the structural characteristics of the polymer. The smooth profile of PTFE chains and their ability to slide relative to one another provides the lubricious, non-stick attributes which have made the material and its many trade brands house hold names. Moreover, the tightly packed polymer chains consisting of carbon atoms wrapped within a ring of strong covalently bonded fluorine atoms provide PTFE with excellent chemical resistance. Re-engineered forms of PTFE such as FEP have attempted to bridge the gap between the desirable and negative aspects of PTFE performance by chemical modification of the material. While chemical modification can yield positive outcomes such as improved processing options, these are achieved at a cost; FEP demonstrates a poorer coefficient of static friction when compared with PTFE and the melting point of FEP is significantly lower than that of PTFE.[3]

Design Solution: Composite Reinforced Coatings

A polymer composite consists of two or more distinct materials, which when combined, create a material that demonstrates increased performance. Such a phenomenon, known as material tribology refers to 'the science and engineering of interacting surfaces in relative motion focusing on the principles of friction, lubrication and wear performance.[4]

The smooth profile of the PTFE chains described above facilitates polymer chains to slide past one another easily, resulting in excellent frictional properties. However, a by-product of this is the high wear rate which PTFE exhibits.[3] During frictional events in which a sliding component contacts with PTFE material, the fluoro-carbon chains elastically deform. This mechanical deformation re-orientates the polymer chains creating active groups that can in turn chemically react with the surface of the sliding component. The end result is structural re-arrangement of the PTFE film producing defects such as particulate, film delamination, surface scratches and surface peeling.[3]

How can polymer composites improve the tribology of PTFE?

The design of a PTFE polymer composite can focus on chemical modification, material mechanical enhancement or a combination of both. While chemical modification has been shown to improve certain aspects of PTFE performance, it is also known that other end use performance properties can be inadvertently affected. The addition of a functional filler can help address this imbalance.

Merit has developed a patent pending* , multi-layer reinforced coating system that eliminates or reduces many of the classical issues associated with PTFE coating films, such as poor wear and mechanical performance. Merit's proprietary coating formulations demonstrate that the addition of specific functional fillers at tightly controlled specifications within specific coating layers, as shown in Figure 3, can be used to maintain the existing positive performance characteristics of PTFE while significantly improving wear resistance, coating mechanical strength, layer adhesion and layer cohesion.

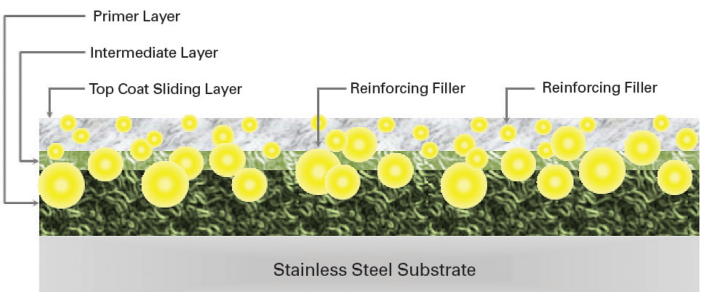

Figure 3, Filler enhanced PTFE coating.

Employing filler(s) demonstrating sub-micron sized particle distributions, Merit has engineered medical device coatings with a unique bearing/sliding surface morphology as shown in Figure 4.

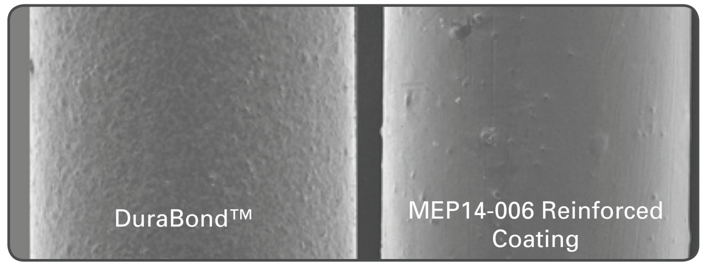

Figure 4, Filler enhanced PTFE coatings display a smooth surface morphology.

Merit's new composite reinforced coating range offers the following advantages to OEM manufacturers, medical practitioners and patients:

- Equivalent lubricity to 100% PTFE film
- Equivalent coating wall thickness to unfilled fluoropolymer solutions
- Increased wear resistance
- Increased compressive strength
- Increases inter-layer adhesion and cohesion
- Biocompatible per ISO 10993-1
- Excellent saline resistance

Critical to the success of the polymer composite is the homogeneity of the composite filler within the coating base material matrix. Additionally, the type of filler particle size and filler particle density must be formulated to ensure that any applied stresses are shared between the filler and matrix material. Once developed and applied correctly, the end result is a fluoropolymer coating of unrivalled functional performance that can stand up to the rigours of today's aggressive processing methods while maintaining and advancing patient safety standards.

* Merit's new composite reinforced coatings have been patent filed as of April 8, 2015. These coatings are currently offered to customers under MERIT part numbers DuraBond and MEP14-006.

References

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[3] Biswas et al. Friction and wear of PTFE – A review, Wear 158 (1992) pg. 193-211
[4] Tribology for Engineers: A Practical Guide, J. Paulo Davim, 2011, Woodhead Publishing for Mechanical Engineering.