Addressing Critical to Quality indicators

In 2015, amid increased FDA industry communications on particulates, the Agency issued a memorandum to device manufacturers, Critical to Quality Indicators: Hydrophilic Coated and Hydrophobic Coated Vascular and Neurological Devices. These identified common features of coated devices that have the greatest impact on device safety and effectiveness, and described how these features are typically controlled in design and manufacturing.

Surmodics is committed to helping customers effectively address these CQI indicators and meet the highest standards of quality in manufacturing. The company's unique partnership model includes collaboration with customers in testing, analysis, quality systems, and regulatory preparation.

Surmodics collaborative partnership model
Unmatched lubricity. Low particulates.

Low-friction hydrophilic coatings have played a critical role in improving vascular access. In the past, however, manufacturers who wanted optimal coating lubricity had to accept higher particulate generation as a result. With regulatory attention increasingly focused on particulate reduction, Surmodics – the global leader in surface technology – has produced a breakthrough solution.

Serene™ coatings: the first no-compromise solution

Surmodics Serene™ hydrophilic coatings combine unmatched lubricity and durability, including dramatically improved particulate reduction (figures 1-3) – an industry first. They covalently bond to a wide variety of substrates (figure 4), and have a proven regulatory record with leading coronary, peripheral, neurovascular and structural heart devices.

Serene™ SC (single coat) now available

New Serene™ SC solutions provide excellent lubricity and low particulates through a one-coat UV curing process. Not only does this eliminate the need to change existing one-coat manufacturing, Surmodics’ enhanced single-coat formulas can deliver substantial reductions in production time (figure 5) and reagent costs.

PhotoLink® coating technology

Medical device companies rely on Surmodics innovations to advance the performance of their products and improve process efficiencies. Surmodics’ proprietary PhotoLink® UV curing process covalently bonds surface treatments to substrates at ambient temperature, for markedly reduced production time compared to both thermal-curing and alternative light-activated processes. This flexible technology can easily be incorporated into existing manufacturing processes and applied to a broad range of medical device substrates.

Leading the way in surface technology

From access to therapy, Surmodics is the recognized global leader in surface technology for medical devices. The company’s high-performance hydrophilic, drug-delivery, and hemocompatible coatings are used on industry-leading devices in all major vascular categories.

Serene™ coatings: proven performance and productivity

In head-to-head benchmark tests of devices treated with Serene™, Serene™ SC, and competitor hydrophilic coatings, the Serene™ family of coatings demonstrated markedly superior lubricity and tracking, durability, and particulate reduction. Manufacturing time for Serene™ SC coatings, which are applied using Surmodics’ proprietary PhotoLink® technology, was also sharply lower than manufacturing time for competitor light-activated or thermal-curing applications.