

Customer Report: SurModics Inc. - Bringing Solutions to the Surface

Customer Profile

SurModics, Inc. is a leading provider of surface modification and drug delivery solutions for medical-device and biomedical applications. One of the company's core surface-modification technology platforms is its patented drug-delivery polymer matrix technology. Polymers and drugs are coated onto medical devices in order to deliver pharmaceutical agents in a controlled manner from a device to a targeted area of the human body, for example, preventing restenosis in heart stent applications. SurModics technology is well established as the coating of choice among some of the world's leading medical device manufacturers.

Initial Situation

Biomedical researchers at SurModics require the most detailed information possible concerning the structure and

composition of a device surface to better understand and predict how the device will interact with the human body.

Surfaces present a particular characterization challenge: extremely small amounts of material on a medical device surface can dramatically alter biochemical reactions within the human body. Coatings on device surfaces are usually thin, often transparent, and difficult or impossible to see with the naked eye. Surface characterization reveals what is hidden in optical images, allowing scientists to probe the physical properties, chemical composition, and spatial distribution of molecules directly on all types of surfaces.

The goals of the surface characterization efforts at SurModics are to: (1) identify the failure modes of coatings during durability testing, (2) measure any chemical or physical changes during shelf-life stability testing, (3) monitor the consistency of coating processes, (4) identify defects and

contaminants in coatings, and (5) develop a fundamental understanding of the drug release mechanisms of coatings.

Instrumentation

For coating and surface investigations, SurModics uses the WITec alpha300 R confocal Raman microscope.

The alpha300 R combines an ultrahigh throughput confocal microscope with an extremely sensitive spectroscopy system. Its sensitive setup allows nondestructive imaging of chemical properties without specialized sample preparation. Due to the confocal principle, depth information on the coatings can be easily obtained. Not only can thickness and uniformity measurements be performed, but also the degree of mixing or segregation of the ingredients within the coating can be determined.



Fig. 1: Confocal Raman Microscope alpha300 R.



Fig. 2: Dr. Klaus Wormuth, Director of Characterization Sciences at SurModics.

“The increased understanding of a coated device obtained through our surface characterization results in faster problem solving and increased confidence in technical solutions.”

Dr. Klaus Wormuth, Director Characterization Sciences

Typical Results

The alpha300 R is used to measure the coating thickness of devices with large variations in diameter and coating thickness. For applications such as these, the depth profiling capabilities of the Alpha300R play a crucial role. The Raman spectrum (Fig. 3) provides a fingerprint of the coating chemistry, which can be used to generate color-coded images of the coatings' depth profile. Figure 4 shows a cross-sectional Raman image of a SurModics PhotoLink™ hydrogel coating without any

drug on a polyurethane catheter. For coatings with a drug on a metal stent, Raman images show how well the drug mixes into the polymer matrix (Fig. 6).

Not only can Raman images yield information about coating thickness and the uniformity of the distribution of the drug in polymer coatings, but also drug polymorphs are identified and imaged. Even though the Raman spectra of amorphous and crystalline drugs differ only slightly (Fig. 5), the sensitivity of the WITec confocal Raman system clearly distinguishes drug polymorphs in coatings

Achieved Improvements

The Surface Characterization Laboratory of SurModics selected the WITec alpha300 R due to its ability to generate three-dimensional images of the chemical proportions of their coatings at the highest resolution. Since using the alpha300 R, the R&D department has benefited from a clearer understanding of the structure and behavior of their coatings, resulting in a less time consuming yet more thorough development process.

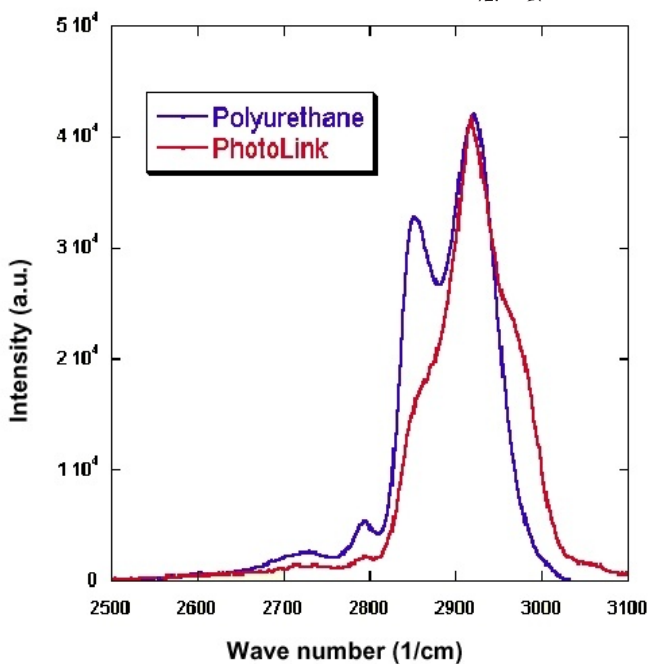


Fig. 3: Raman spectrum of PhotoLink coating and polyurethane catheter.

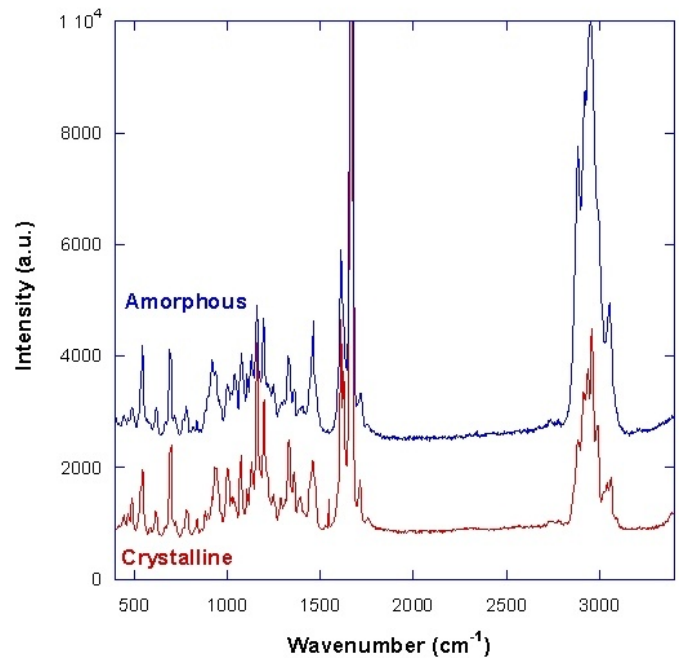


Fig. 5: Raman spectra of amorphous and crystalline drug.



Fig. 4: Raman cross sectional image of a coating on a polyurethane catheter.

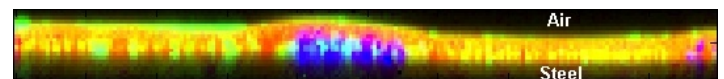


Fig. 6: Raman cross-sectional image of a coating of a drug plus polymer on a stent. Polymer (red), amorphous drug (green), crystalline drug (blue), polymer + amorphous drug (yellow). Bar = 10 microns

"The knowledge gained with the WITec Alpha300R allows us to see product development issues more clearly, enabling innovative solutions to technical challenges in the development of medical devices"

Dr. Klaus Wormuth, Director Characterization Sciences