CASE STUDY

PhotoPrime® SR Case Study- Silicone Drainage Catheters

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Introduction

Silicone rubber is increasingly used in medical devices, implantables, and wearables due to its biocompatibility, flexibility, and stability in the body (biodurability), as well as its lack of leachable chemicals, like BPA, or immunogenic materials that may cause allergic reactions. Silicone rubber is relatively easy to manufacture and form into complex shapes, further lending to its draw as a key medical device material. Examples of medical device and implantable applications include drainage catheters, delivery catheters, endotracheal tubes, feeding tubes, IUDs, permanent implants used in plastic surgery, cerebrospinal shunts, and more.

When it comes to applying a lubricious (slippery) coating to silicone rubber, challenges arise. Silicone is quite tacky to the touch; whereas some medical devices need to slide smoothly over skin and other body tissues. In addition, the surface energy of silicone rubber is very low, and hence it is difficult for coatings to stick reliability; furthermore, silicone rubber contains highly mobile small molecular weight polymers that move through the surface and ultimately disrupt any applied coatings. Plasma treatment is sometimes used to modify the surface to accept a coating; however, this has an extremely short life-span, sometimes less than an hour. PTFE (commonly known as Teflon) is sometimes used, and while this can help, it has a higher coefficient of friction (COF) than a lubricious hydrophilic coating and hence requires more force to move inside the human body.

Challenge

A large multinational medical device manufacturer was seeking to develop a drug-eluting silicone catheter. They had previously worked with a different coating solution company only to find their coating technology failed in animal trials and hence a replacement product was needed. They reached out to ISurTec with an RFP that profiled the catheter and requested a given drug loading and elution profile at 3 days and 7 days.

ISurTec responded to the RFP and was one of a handful of companies selected to develop a proof-of-concept (POC) coating. ISurTec was the only company to successfully develop a POC that could load the drug on the catheter at the specific loading level. In the next phase, ISurTec designed and delivered the POC drug-eluting coated silicone catheter with the desired loading level and elution profile [Figure 1] within 1 month.

CASE STUDY

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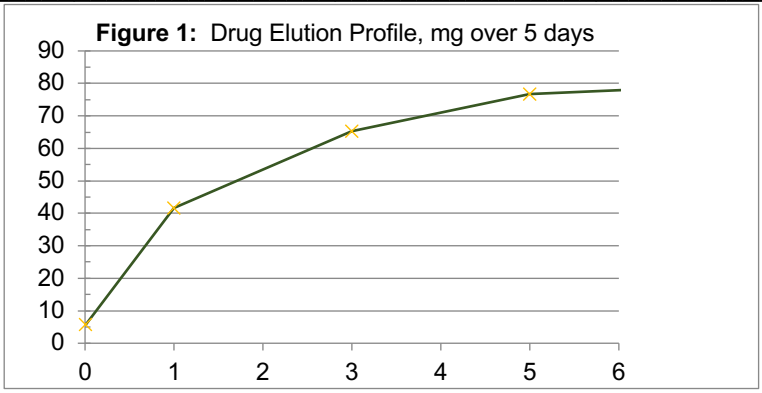
Figure 1: Drug Elution Profile, mg over 5 days

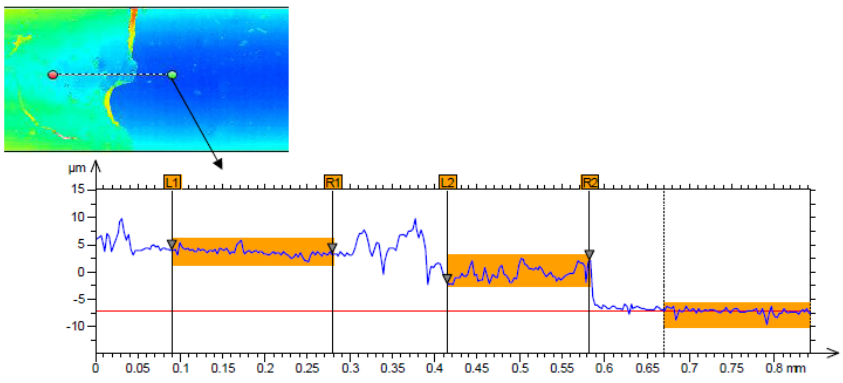


Solution

The total coating was developed in three distinct layers. The first step ISurTec undertook was ensuring durable adhesion to the silicone catheter. Complicating this step was the need for the coating to be conducive to the drug layer, neither harming it nor preventing it from being released while also ensuring flex in the catheter did not slough off the drug. ISurTec leveraged one of its newest technologies, PhotoPrime SR, primer, to coat silicone rubber and allow it to durably bind the drug layer.

After demonstrating initial loading feasibility, ISurTec developed methods for titrating and measuring drug elution. Instead of a hydro*philic* lubricious layer, ISurTec needed a hydro*phobic* restraining layer that would control drug release to the desired schedule. ISurTec developed a custom hydrophobic drug-eluting coating for this step, ISurCoat™, and interestingly also leveraged PhotoPrime SR as part of this top coat. In effect, PhotoPrime SR was a vital component creating the sandwich in which the drug layer resided – as both the priming surface adherent bonding the catheter to the drug coating and then as part of a top hydrophobic restraining layer creating the correct elution profile. ISurTec modeled coating weight parameters to control drug elution and worked to ensure a smooth, uniform, ~10µm coat [Figure 2].

Figure 2: Surface Profilometry and Step-Height Analysis of Coating Thickness



CASE STUDY

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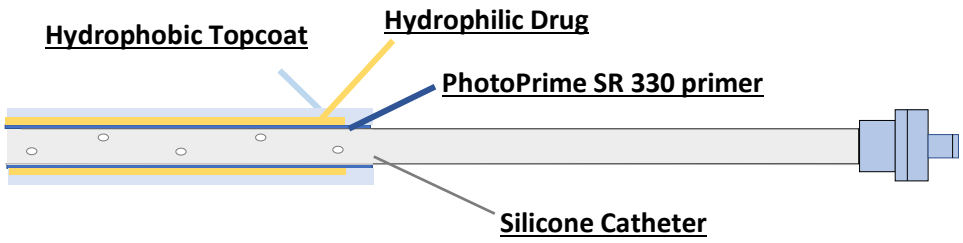
Result

At this point ISurTec had a three-layer coated catheter [Figure 3]: the first coating to adhere the drug, the second coating of the drug itself, and the third layer to create the proper dilution profile. After successful testing with the partner company, ISurTec developed coating parameters, coating procedures, and pilot-scale coating compositions then executed a technology transfer to the partner's coating provider under good laboratory practice (GLP) conditions. A large animal trial was conducted successfully. ISurTec then assisted in the process to produce the coated product for human use in clinical trials, performing assay development, design of experiments work, and providing V&V support.

Figure 3: Tri-Layer Coating



In clinical trials there were no adverse reactions specific to the coating and the coating remained on the catheter upon removal after multiple months in the body.

PhotoPrime SR Utility

ISurTec went on to test the application of PhotoPrimer SR as a bonding enabler (primer) for coating, stainless steel, nitinol, aluminum, PEEK, and HDPE, as well as common semiconductor substrates such as ceramics, silicon, and silicon nitride.

About ISurTec

Founded in 2004, ISurTec began with creating the first pre-mixed, ready-to-use hydrophilic coatings for the medical device market, significantly reducing cost and complexity for the industry. Today ISurTec is a global leader in surface modification technologies for medical devices and biotech applications, manufacturing hydrophilic coating solutions sold under the ISurGlide®, Lubricent®, PhotoPrime®, and Tylicent® brand names as well as ISurCell™ ultra-low attachment and ISurTherm® thermoresponsive cultureware products. ISurTec's ready-to-use and custom coatings have been used by over 100 small and major medical device manufacturers both in the US and overseas. IsurTec manufactures all coating solutions locally

CASE STUDY

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in Minnesota and routinely partners with customers to develop tailored coating solutions for specialty applications. Contact team@isurtec.com for more information.