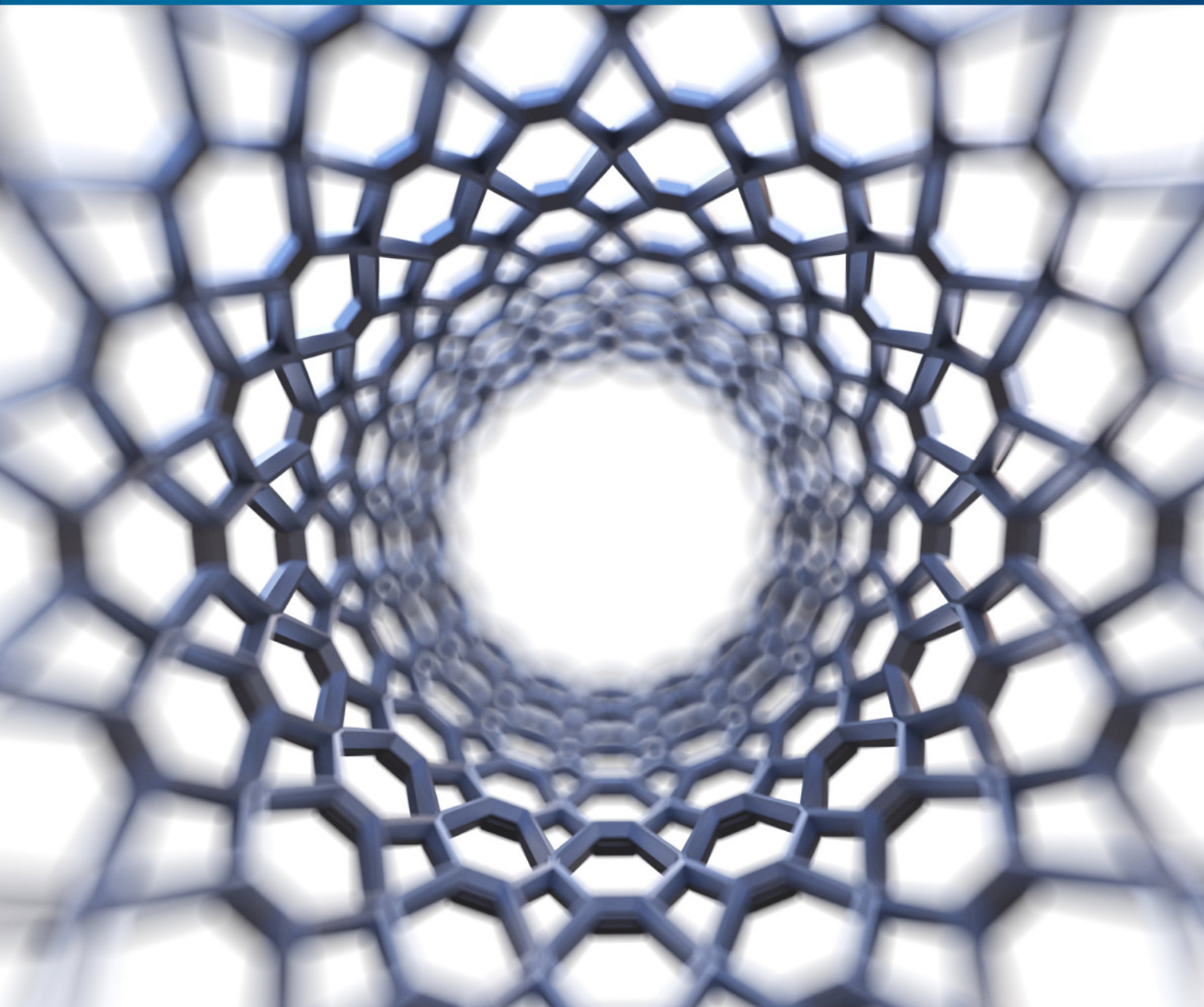




CASE STUDY

USING DATA TO SUPPORT THE DEVELOPMENT OF A NEUROVASCULAR CATHETER

Biocoat specializes in supplying lubricious hydrophilic coatings,
custom coating services, and coating equipment for medical devices



INTRODUCTION

There are many challenges to overcome to successfully acquire the approval of a medical device to regulatory authorities. During the design and planning for a guide catheter for neurovascular applications, the development company reached out to Biocoat to support their hydrophilic coating requirements. Biocoat supported the development company by identifying, testing and applying the hydrophilic coating that offers industry-leading performance in lubricity, durability and particulate counts. This coating was instrumental in the final 510k approval of the device.



CHALLENGE #1

PROVIDE TESTING AND ONGOING DEVELOPMENT SUPPORT

SOLUTION:

To support the coating development process, Biocoat worked to test and create solutions that allowed the coating and device to complement each other and perform as designed. This device went through several different developmental versions prior to the final materials being locked in. The Biocoat team was there to support this process with rapid follow-up times, regular status updates and a dedicated in-house development team.

"We needed a coating partner that not only has a good coating, but can handle everything we throw at them."

Chief Executive Office / Marblehead Medical

CHALLENGE #2

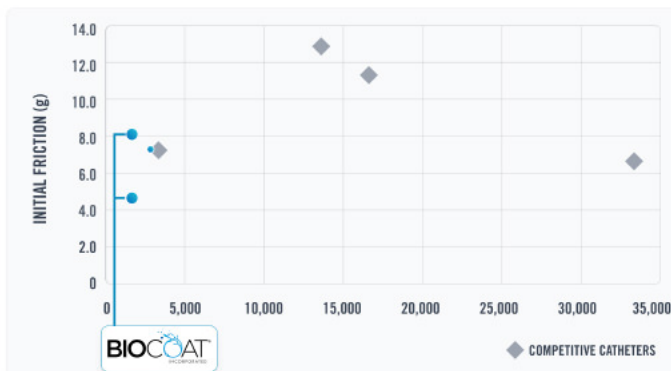
DEMONSTRATE LOW PARTICULATE COUNTS

SOLUTION:

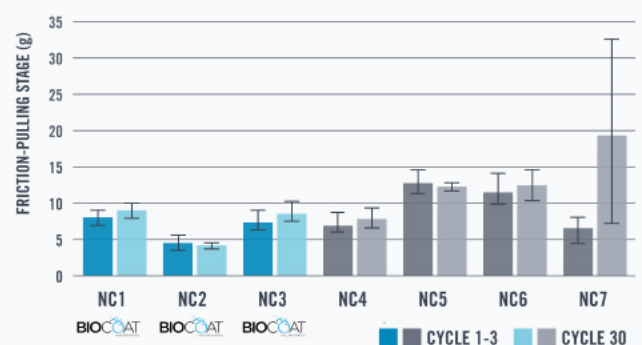
During the initial conversations with the development company, the two primary criteria for selecting a coating vendor were overall coating performance and low particulate counts, which would eliminate potential adverse events in the patient. Biocoat had previously completed a research project in which 12 commercially available catheters (six neurovascular microcatheters and six PTCA dilatation catheters) were tested to compare the overall performance of their coatings. Of the 12 catheters tested, three were coated with Biocoat's HYDAK® coatings, which acted as a baseline for performance. The testing results showed that Biocoat's HYDAK coatings offered best-in-class performance for both particulate generation and overall performance. This data analysis led the development company to select Biocoat as the supplier of hydrophilic coatings for their product.

As the development company was preparing their materials for submission to the regulatory authorities, they ran an in-house particulate test. The testing results were then shared with Biocoat to compare the results from Biocoat's data of commercially available microcatheters. This comparison allowed the development company to better understand their studies' results and to confidently present their data to the regulatory authorities during the submission process.

INITIAL FRICTION VS PARTICLES FOR NEUROVASCULAR MICROCATHETERS



COATING LUBRICITY - MICROCATHETERS (n=3)



"I appreciate other people using their expertise, especially for device performance — which means it is just done better."

Chief Executive Office / Marblehead Medical

CHALLENGE #3

DEVELOP A SOLUTION TO SUPPORT COATING APPLICATION

SOLUTION:

Biocoat's Contract Coating Services were leveraged in this project to support the development company's production process, as they preferred not to apply the coatings in-house. Biocoat's Contract Coating Services offering allows for the manufacturer's devices to be uniformly coated to precise specifications identified during the development process. The Coating Unit offers the flexibility for the manufacturer to design a fulfillment process that meets their requirements and is adaptable to increased sales volumes.

CHALLENGE #4

DESIGN AND IMPLEMENT A PRICING PROGRAM

SOLUTION:

Biocoat worked with the development company to develop and set up a pricing program that allowed for the product lifecycle to grow, but offered terms that were friendly to the organization which was bringing their first product to the marketplace.

"Biocoat was very easy to work with on the pricing structure. They were very upfront with us, and there were no challenges in negotiating the pricing agreement."

Co-Founder and Principal / Switchback Medical

CONCLUSION

The development company worked with Biocoat from beginning to end to develop a hydrophilic coating for their medical device. Although there were challenges along the way, Biocoat successfully met the company's needs throughout the entire process and now have an ongoing partnership for future device development projects.

[Talk to our Coating Experts](#)