

# Q&A: versatile adhesives and coatings solutions for medical devices



Medical devices are becoming more practical and refined with recent technological advancements. These devices serve as instrumentation outside the body as well as diagnostic monitoring and therapeutic treatments inside the body. Among these advancements, polyurethane (PU) and phosphorylcholine (PC) systems have appeared as excellent adhesives and coatings solutions that ensure the safe and effective use of medical devices.

## Where are polyurethane and phosphorylcholine systems used in the medical device industry and what is their benefit?

Many medical devices, such as dialyzers, oxygenators, catheters, pacemakers, biopharmaceutical filters, contact lenses, urological catheters, ECMO and ear ventilation tubes, have stringent requirements. These devices need adhesive and coatings systems which conform to biocompatibility test standards necessary for safe medical use.

Aurorium's Biothane™ Product Line of biocompatible adhesives, sealants and potting compounds can be used in the assembly of diagnostic catheters and other modular medical devices for effective adhesion to membranes, tubing, polymeric and metallic substrates for tubing, sealing ends, and coating sensors. These versatile systems can be designed for use in both thick film (potting solutions) and thin film (surface coatings), imparting the necessary durability for the medical device.

Two key factors that make Biothane Polyurethane Systems highly preferred are their sterilizability and biocompatibility. Sterilizability is the ability of a material to withstand the harsh processes necessary for removal of microbial contamination without compromising its properties. Medical devices often require frequent sterilization to ensure patient safety and Biothane Systems can withstand standard industry cleaning methods, including steam, irradiation, gamma sterilization and e-beam, without suffering degradation or loss of functionality.

Biothane Solutions are biocompatible, meaning they are designed to interact harmoniously with the human body without causing adverse reactions. All Biothane Systems meet the rigorous biological safety standards of ISO 10993 series guidelines, which makes them ideally suitable for medical devices in contact with human blood and tissue.

Aurorium's PC Polymers, are a phosphorylcholine technology solution used in a vast array of medical devices, including contact lenses, drug eluting coronary stents, urological catheters, extracorporeal membrane oxygenators, extracorporeal carbon dioxide removal and ear ventilation tubes. PC Coatings mimic the chemical structure of the outer surface of cell membrane and have multi-functionalities such as blood compatibility, resistance to bacterial adhesion and biofilm formation as well as hydrophilicity.

## **Are there certain medical device substrates in which polyurethanes and phosphorylcholines are particularly compatible?**

Both polyurethane and phosphorylcholine systems are compatible with a wide range of substrates including metal, plastic, glass, and other materials commonly used in medical devices.

Biothane Systems can provide reliable adhesion and are routinely used to bond metal-to-polymer interfaces as well as potting various hollow fiber membrane filters. The systems readily bond to polycarbonate, polysulfone, and a variety of other engineered polymers and recent work has shown bonding and compatibility with plasma-treated polypropylene.

PC Polymer Systems are specifically designed to coat a wide range of medical substrates including metals, glasses, polyethylene, polyethylene terephthalate, polyvinyl chloride, polypropylene, polymethyl pentane, polyamide and polyurethane, but there are many others. A key advantage to this technology is that these substrates can be successfully coated without surface modification. PC Technology™ Polymers can also work with difficult-to-coat substrates like silicone and PTFE and can be applied after surface modification by gas plasma treatment, priming or chemical etching as examples. This compatibility ensures that manufacturers have the flexibility to design medical devices using their preferred materials without compromising on performance or quality.

## **Can phosphorylcholine coatings be used to make polyurethanes more biocompatible?**

Yes, the chemistry allows this synergistic effect to happen. Results of various in-vitro and in-vivo studies have shown that PC Coatings have significantly improved performance of the medical devices that are made with polyurethanes, such as blood-contacting and urological catheters, by significantly reducing protein adsorption and platelet adhesion, hemolysis, and bacterial adhesion.

## **Many medical devices require exposure to chemicals during cleaning and repeated part use. How does that affect the choice of systems?**

Biothane Polyurethane Systems are engineered to withstand exposure to various chemicals without losing their adhesive properties or compromising the integrity of the device. The systems have proven durability over a wide pH range to simulate acidic and caustic exposure employed in the re-use of different filter assemblies. This resilience ensures that medical devices can be effectively cleaned and disinfected without compromising patient safety.

## **I am designing an extracorporeal membrane oxygenator (ECMO) and need a system which will reduce thrombogenicity in this blood circulating device. Do you have any coating suggestions?**

Yes, this is a job for phosphorylcholine polymers. Performance of blood circulating devices has been significantly improved by phosphorylcholine coatings as confirmed by various studies including clinical studies. PC Technology phosphorylcholine-coated cardiopulmonary bypass (CPB), extracorporeal membrane oxygenator (ECMO) and extracorporeal carbon dioxide removal (ECCO2R) have been used in human health care for many years.

## **I need a coating which is hydrophilic, wettable or capable of reducing friction – ideally, it would exhibit all three characteristics. What do you suggest?**

Phosphorylcholine coatings contain numerous zwitterionic phosphorylcholine head groups which are polar and have a strong affinity for water. Upon contacting with an aqueous fluid, PC Coating becomes hydrated and attracts a layer of water, which acts as a lubricant to reduce friction. Phosphorylcholine coated ureteric stents have been shown to have lower friction during insertion than uncoated stents and so patient comfort has been significantly improved. These PC Coatings can be formulated to have different degrees of lubricity to meet variable requirements of coefficient of friction.

## **Which systems can kill bacteria, similar to antibiotics?**

Phosphorylcholine Coatings are resistant to adhesion of a range of bacteria including Gram-negative and Gram-positive and are typically able to reduce biofilm formation. When compared to uncoated substrates, PC Technology coatings reduce bacterial adhesion by 60-90%. Unlike antibiotics, PC Technology Coatings do not kill bacteria, and thus are not biocidal. However, PC Coatings are amenable to complexing with some known antimicrobial actives; for example, in vitro testing of a phosphoryl-silver coating has demonstrated inhibition of microbial activity. Studies have shown a wide range of pharmaceuticals and antimicrobial actives can be loaded into and released by PC Coatings; this loading and release can be tailor-made to meet different requirements.

## **Are PC Coatings bioactive in a comparable manner to heparin coating?**

No, because Phosphorylcholine Coatings are synthetic and bioinert, they are classified as passive. In contrast, heparin is bioactive and classified as a drug by various regulatory authorities which requires considerably higher regulatory hurdles and lengthy approval time. One of the many advantages of PC Coatings is the potential for simpler regulatory approval process and hence a shorter time.

**We look forward to understanding your specific medical technology challenges.  
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