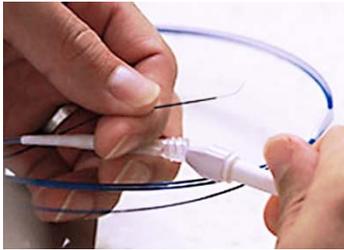


## Whitepaper

### Discuss These Ten Essential Elements with your Supplier Before Starting a Hydrophilic Coating Program

Advances in surface enhancements for medical devices, especially low friction hydrophilic coatings, have accelerated minimally invasive surgery’s growth. Lubricious, low-friction coatings positively influence a variety of clinical areas such as cardiovascular, urological, peripheral and neurological procedures.

Medical OEMs have many choices to make when selecting a coating methodology for their medical device. With all the options on the market, it is important to find a solution that best suits your requirements. Involving the coating supplier early in the product development cycle is



extremely beneficial and can positively affect the speed, efficiency and cost of the program.

Here are some essential elements to consider when selecting a coating program for medical devices such as catheters, guidewires, introducers and other devices:

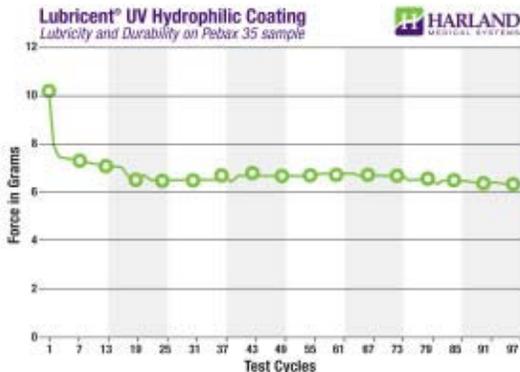
#### Coating requirements for the medical device

The first step of the process is to define what type of materials and chemistries are available on the market that will meet your requirements. What performance parameters are crucial to your device’s clinical success? Once you define these requirements, you can begin the process of selecting a coating.

Typical requirements:

##### *Lubricity*

High lubricity is very important because it provides reduced friction forces compared with an uncoated device surface. This enhanced surface performance increases the device’s ability to navigate through tortuous anatomical pathways, improves device control, reduces tissue damage and adds to patient comfort.



Lubricity and Durability of Harland Hydrophilic Coating on Pebax 35 Sample

##### *Durability*

Durability is crucial to the coating surface. The ideal chemistry will provide the photochemical covalent bond to the substrate, producing superior adhesion and wear resistance while minimizing particulate formation.



### *Low Particulate Generation*

Chemistry alone will not deliver high performance hydrophilic medical coatings. Both chemistry and the process by which the coating is applied determine the successful properties of the coating. The combination of state-of-the-art chemistry and the optimum method of application is what delivers low particulate properties.

### *Biocompatibility*

For applications where biocompatibility is required, it is important to confirm the coating has been successfully tested by an independent testing facility for ISO10993 biocompatibility. Specific tests included Cytotoxicity, Irritation, Acute Systemic Toxicity, Hemocompatibility, Allergenic Potential, and Pyrogenicity.

### *Compatible Materials*

Work with the supplier early in the product development cycle to determine the hydrophilic coating chemistries that are compatible with the possible device substrate material. This ensures the highest degree of success in the finished product.

Ensure the company you work with encourages close customer participation throughout the product development process. From understanding your coating objectives to developing the exact balance of properties to meet these objectives and validating the process to ensure your coating is fully ready for production, either at your plant or the selected external coating services facility.

### **Costs for coating materials and processing**

Material consumption and processing costs are difficult to determine up front because every device is different and requires a different process to coat. It is highly recommended to complete a full analysis or feasibility to determine the true cost of the materials and coating process.

Find a supplier that is dedicated entirely to serving medical device customers, offering a magnitude of experience and a highly efficient coating process. Coating processes can be inefficient and expensive when utilizing suppliers that lack experience and do not fully understand the technical aspects of the coating process.

### **Royalty and licensing fees**

In many cases, coating companies charge license fees and royalties on the sale of the final device. Beware of these costs, they can add up to significant costs throughout the life of your product. Once you select the appropriate chemistry and materials, make sure to ask your supplier about license and royalty costs. You should only expect to pay for the chemistry on your devices.

### **Coating method development**

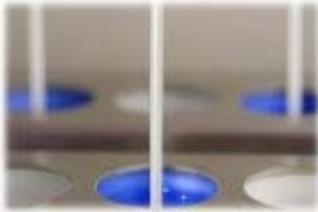
Coating application method development includes processes and protocols that effectively and efficiently apply medical device coating to substrate materials. The application process is just as important as the coating solution in providing optimum medical device coating performance. Before you commit to a full-production coating program, work with your coating supplier to

complete a feasibility to prove the coating method is successful, repeatable, and meets your device requirements.

### Coating machines and equipment

Device manufacturers should have the choice of purchasing coating equipment to coat in their own facility or select a supplier that has capability and machine expertise to provide complete coating services. Ensure the coating equipment you select is designed and manufactured to meet the critical coating, testing and processing requirements for your medical devices. During this selection, it is very important to test the software that runs the machines to make sure it is straightforward and intuitive for the operator. Machines should offer remote access for service with the ability to quickly provide operational help or diagnose problems.

### Coating technique



*Dip Coating Process*

Hydrophilic coatings can be applied to surfaces in a number of ways. Dip coating is the most common process used to coat medical devices. The dip coating process lowers the devices into a liquid coating solution and then lifts them up at a controlled speed. The coating adheres to the surface when extracted from the solution.

Spray coating is another technique used to apply coatings. The coating is sprayed onto the device surface; however, this process can be very inefficient and wasteful.

After a coating is applied, the next step is to dry or cure the device. The two major methods for curing hydrophilic coatings are ultraviolet light (UV) and heat. In UV curing systems, coatings are exposed to UV light causing a chemical reaction to cure it very quickly.

In a heat cure system, ovens dry the products for a specific amount of time. Controlled heating accelerates drying and any necessary chemical reactions taking place within the coating that allow it to adhere to the surface.

Other options to consider:



*Automated multi-station coater*

#### *Single station or multi-station coaters*

Single station coaters provide process versatility and flexibility in one compact unit. Higher volume multi-station systems provide even more functions with modular stations available for device cleaning, surface pre-treatment, dipping and drying processes.

#### *Manual to fully automated operation*

Depending on your requirements, you will need to decide what type of coater automation is right for you. Single station coaters offer a simple process change at an economic price. Higher volume

production applications may require medical coaters with a high level of automation. The operator simply scans the part identifier and the coater selects the proper coating protocol. Parts are loaded and the rest of the process is operator-free. The operator is notified when the batch of parts is complete and the coater is ready for a fresh batch of uncoated devices.

#### *Maximum device length*

Verify that the coater will support the maximum length of your device and the length of surface requiring a coating.

#### *Local language capability*

Depending on where your facility is located, you may require local language capability for the equipment.



*FTS 6000 Friction Tester*

#### **Test equipment to measure the surface friction of the medical device**

Friction test systems measure both surface friction and coating durability by drawing the test sample between two silicone rubber pads clamped at a programmable force. This type of equipment is an ideal surface-property management tool for coating development, quality control, and product benchmarking.

For years, the “pinch test” method has been the standard for measuring the performance of lubricious coatings. Make sure the supplier offers equipment that makes creating, running, and analyzing these tests simple and fast.

#### **Coating manufacturing services**

Once you have completed the application development process, the next step is to determine the coating manufacturing strategy.

If you are considering outsourcing your coating services, there are significant benefits of having a single supplier in one location to provide all your coating and equipment needs. Typically, process stability increases because there is less room for error and quality is easier to manage.

If you perform coating application in your facility, make sure you consider the equipment capabilities if manufacturing is in a different location from where the coating application development was originally performed. It is crucial to manage the chemistry and understand the equipment and coating process.

#### **Quality management**

Before starting a coating program, ensure your supplier has a quality management team available to support your coating program, and operates in compliance with ISO 13485 standards or other applicable standards. Visiting the facility for an initial quality audit is also highly recommended.

#### **Regulatory support**

Make sure your supplier offers experienced in-house regulatory personnel to help advise you on



the most effective and efficient regulatory submission pathway(s), including, where necessary, those involving combination drug/devices.

**Conclusion**

As hydrophilic medical device coatings continue to emerge and positively influence minimally invasive procedures, it is very important for medical OEMs to ask all the appropriate questions to find the best coating program supplier to meet their specific requirements.