



Exclusively Medical Coating Applicator applies no-PFOA PTFE and medical grade coatings grade with robotic precision.

Breakthrough, micron-accurate coating equal to medical device tolerances

With most biomedical procedures, success is measured in fractions of an inch—more commonly, microns. Exact friction-free insertion of guidewires, hypotubes, catheters, cannulas, stents, balloons, drug-delivery catheters, cameras, and tissue samplers is critical to the success and safety of every procedure.

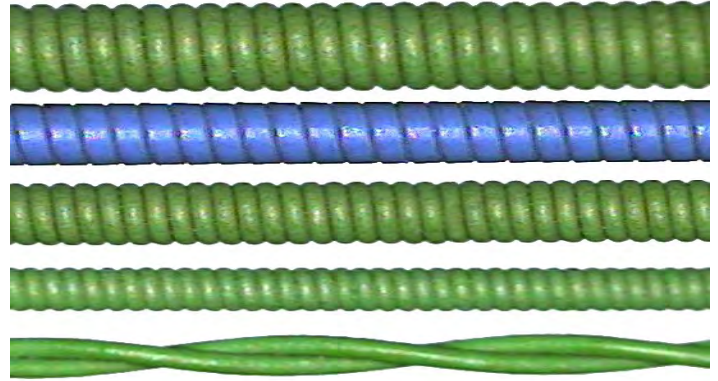
PTFE-coated guidewires are often used in the first step of many minimally invasive medical procedures. The preferred performance of a device is to have the lowest friction at the surface of the wires. Surface Solutions Group, LLC (SSG) of Chicago is a fully automated coating applicator for these and other biomedical devices.

One hundred percent of the guidewires, hypotubes, mandrels and similar devices coated by SSG are coated robotically; with no hand spray. Guided by the trademark phrase, “Every medical device we coat touches lives”, SSG has developed a robotic system that maintains the thickness of PTFE and hydrophilic coatings to the micron level—often to tighter tolerances than requested by the manufacturer.

Guidewire surfaces are essentially wound wire, like a tightly wound spring. Coated with a low-friction fluoropolymer, the outer wound wire is what essentially touches the inner walls of the vasculature during a procedure. SSG coats the OD of these wires with a precise and consistent bonded film of PTFE, with no intercoil bridging, as is common with manually sprayed guidewires. The coating allows easy low-friction movement and manipulation of a guidewire as it is maneuvered or steered through the vasculature.

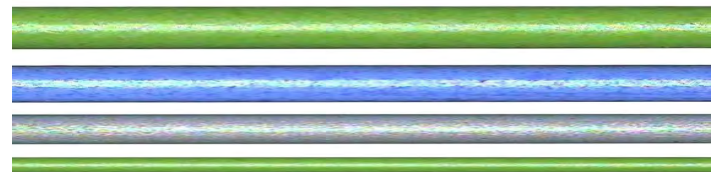
Although ISO 11070 tests for fractures and strength, it does not evaluate coating friction or “feel”, only coating flaking, fracturing, and adhesion.

From the user standpoint, friction “feedback” from the guidewire must be a consistent and smooth, hydraulic-like feel. Unlike the surface of a more conventional mechanical device, wear of the coating on most medical devices is not a technical consideration. What is important is the consistent feel of the device as it is used.



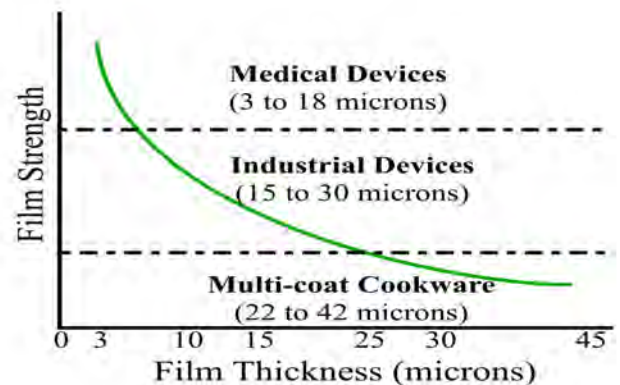
Guidewires (above) PTFE coated with no intercoil bridging.

Hypotubes and Mandrels (below) precisely coated with PTFE



Less is more

SSG’s technical staff, with more than a half-century of combined experience, has shown that unlike conventional oils and greases, fluoropolymer lubricants perform better as bearing surfaces when they are applied in thin—even super-thin—coats. At micron thicknesses—“ μ -coats”—both film strength and load-carrying ability are dramatically improved. Only the outer molecule of the PTFE coating on the surface provides friction reduction. This is why these consistently uniform and thin, robotically applied coatings maintain an even coefficient of friction.



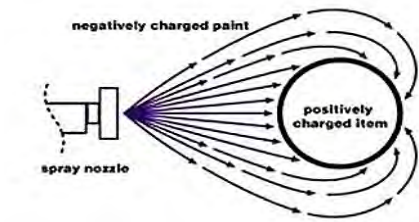
The strength of the lubricating PTFE film increases as film thickness decreases. At thickness in the micron range, the fluoropolymer film begins to take on the strength of the metal to which it is bonded.

SSG technology applies the PTFE with absolute consistency at micron levels on guidewires and hypotubes that typically range in OD from 0.003” to 0.038”. It is then monitored by laser micrometers for verifying coating thickness.



Precisely fixtured, thousands of uncoated guidewires and hypotubes in a clean, air filtered and climate-controlled storage area are staged for robotic coating.

The SSG-developed robotic system results in film uniformity that is a monument to advancement in efficiency. More than 20,000 individual wires are coated each day along with a similar length of continuous wire supplied on reels or spools; with the coating applied to a film thickness of 10 microns—±2 microns, even on 560cm guidewires. This is a tolerance of a total of 4 microns of PTFE on a 22-ft guidewire. Hypotubes and mandrels often are coated with ultra-thin films of 4-6 microns using the same machinery developed by SSG.

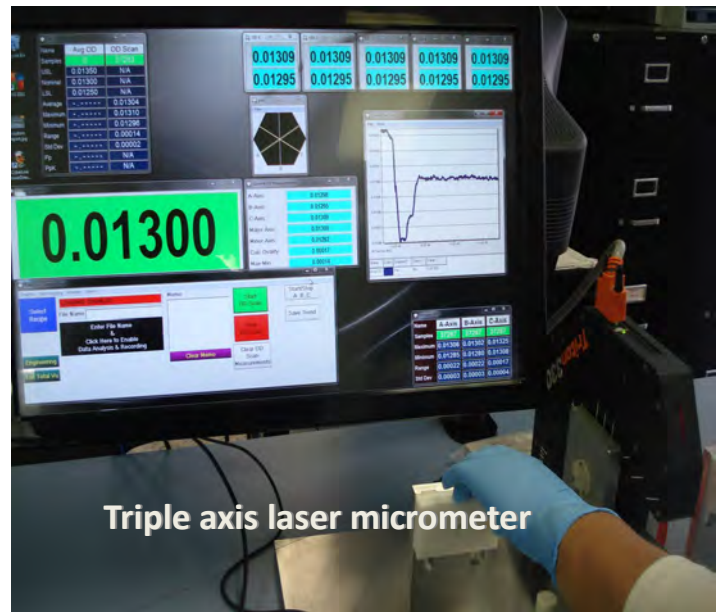


100 Kilovolt cloud of PTFE particles Electrostatically uniformly, coating a round shape.

The electrostatic technology employed by SSG uses the basic principles of Coulomb’s Law of physics. When compared to the force of gravity, modern ultra-high voltage electrostatic forces are 30+ times the strength of gravity. This phenomena when harnessed, helps equalize the coating of a device wire because deposited particles are instantly neutralized and are good electrical insulators; as is the case with PTFE and various other coatings. This results in negatively-charged particles in the electrostatic cloud to seek out uncoated areas of the product, selectively coating the uncoated area.

Applying PTFE to a wire is vastly more challenging than coating a surface that is flat or nearly flat. The key to maintaining extreme uniformity of films is in eliminating process variables and electrostatics.

Verification of uncoated and coated diameters is done using a triple-axis laser micrometer with full report capability. In statistical terms, CPK values of over 1.7 are normal and are continuously monitored and recorded. Laser micrometers measure the entire 360-degree cylindrical surface of a wire or other device; checking 2,000 measurements per second with a verified accuracy to ±0.001 mm (±0.000040 in.).



Triple axis laser micrometer

100% robotic machine coating application consistently provides what manual or hand spray cannot provide.

SSG eliminates excess coating as shown below.



When coatings are applied as thick films to guidewires, coil-to-coil “bridging” can occur; altering the flexibility of the wire and introducing the possibility of loose flakes of coating. These guidewires cannot be reworked and will fail ISO 17070.

Verification of uniform coating thickness

Consistent surface friction of coated devices is a function of coating thickness too. Out-of-specification (thicker and thinner) coatings can cause problems.

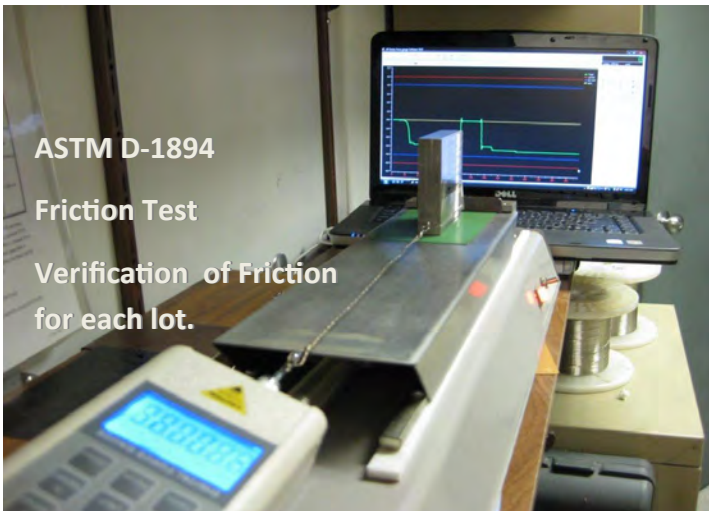
Some coatings need only a few microns of bonded coating thickness. However, out-of-specification or thick coatings may result in interference fits or erratic insertion forces. The thicker the coating the less effective the bond.

The benefits of robotic micron-coating accuracy are shown in the consistency of insertion and steering forces.

Like any device involving manual dexterity—from the artist's brush to dentist's drill—touch familiarity is paramount. Once doctors and technicians become accustomed to the unique touch of a device, constancy becomes a real virtue. That is what they expect to work with on unit after unit. This means that the positioning of wires and other devices can be made without erratic motion, even when the wire is flexed to navigate the twists and turns of the vasculature system. The result is friction feedback that remains dependable and consistent for every wire in a production lot, year after year.

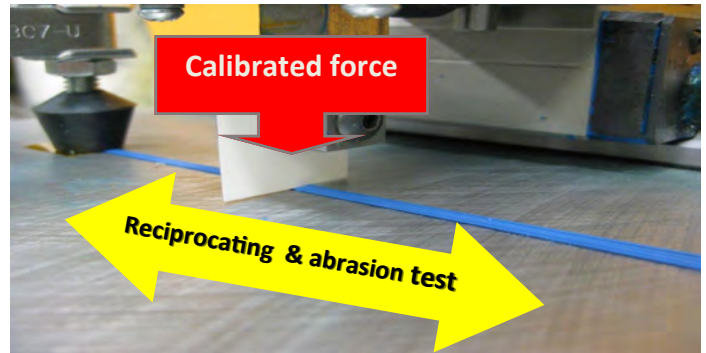
Clean Environment

As the saying goes, in the SSG processing room for guide-wires, nothing is left to chance. In addition to the robotic coating process, the environment is controlled through a Hepa-filtered and humidity controlled, air-conditioned, air makeup system.



ASTM D-1894
Friction Test
Verification of Friction
for each lot.

Friction test of each lot of coatings provides assurance of low friction values. This ASTM D-1894 friction test provides digital force values which are computer logged.



Abrasion testing of coated hypotubes or wires provides both adhesion testing of the coating to the substrate and also inter coat adhesion of the coating.



Laser Micrometer and digital magnification
inspection prior to final packaging.



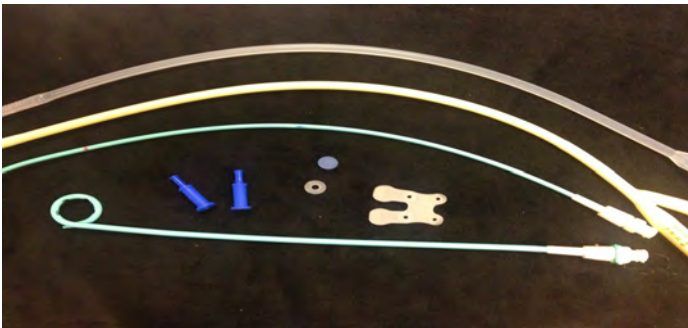
12,000 , .014" hypotubes
coated with Blue PTFE prior to
final measurement , inspec-
tion and packaging.

More medical applications and coatings

A wide range of medical grade coatings can be applied at SSG with their well developed, robotic electrostatic coating application system. This allows the medical device designer or engineer to specify not only PTFE coatings, but hydrophilic and electrically insulative coatings. The SSG electrostatic application cell machinery will accommodate all types of liquid coatings applied to metal, plastic and even rubber products.

Continuing research provides successful application of the latest water and solvent-base coatings, including hydrophilic coatings on guidewires and metal products. SSG now successfully processes rubber catheters and tubing with hydrophilic and low friction silicone coatings.

Surface Solutions Group, LLC is exclusively devoted to the



medical industry. **All—100%—of the products coated at SSG are used for the medical industry.** As specialists, we are familiar with the technical requirements and compliance procedures necessary for the medical industry; including cytotoxicity, sensitization, irritation, systemic toxicity and hemocompatibility, 510K certification and maintain extensive files.

We provide technical assistance to engineers and designers for American and International firms along with really rapid response for prototype processing. No matter where you are, we are your coating specialists. Tell us about your design objectives and we will help you get your project into production.

Verifying the Chemistry

Coating formulations are certified by an independent laboratory to be PFOA-free—data that is supplied to each customer. Additionally, every lot of coating is tested prior to application to verify its friction and adhesion properties.

PTFE formulations that withstand gamma radiation are also tested in actual gamma radiation environments.

SSG maintains complete physical samples of each and every prototype and production run, including samples of the coating on coated panels.

PTFE Certified and Tested

**FluoroMed®
No PFOA**

100% compliant with 2015 EPA regulations

No PFOA—Acid-Base Coatings:

BL2-7282-ZP GREEN, BLUE, BLACK, CLEAR, GRAY
UB2-MA-847-ZP GREEN, BLUE, BLACK, CLEAR, GRAY,
PURPLE, WHITE, RED

Special multi-coat, high build .0015"+ thickness available

No PFOA—No Acid PTFE Coatings:

UK3-5597-ZP GREEN, BLUE, BLACK, CLEAR, GRAY
ON2-115 GREEN, BLUE, ORANGE, YELLOW, RED,
CLEAR, BLACK, GRAY

BR2-7361-ZP BLACK

No PFOA—No Acid—Low Temp Coating for Nitinol:

ON2-115 GREEN, BLUE, ORANGE, YELLOW, RED,
CLEAR, BLACK, GRAY

No PFOA—No Acid—Gamma Stable Coating:

ON2-115 - GS GREEN, BLUE, ORANGE, YELLOW, RED,
CLEAR, BLACK, GRAY

AquaGlide® Hydrophilic coatings, please inquire.

**Exclusively
Medical**



**ISO Certified
9001:2008**

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