

HYDAK® HYDROPHILIC COATINGS FOR MEDICAL DEVICES

A highly lubricious coating system based on hyaluronan ... nature's own lubricant.



BIOCOAT
I N C O R P O R A T E D

Why choose HYDAK coatings

Biocoat's hydrophilic HYDAK coatings technology represents a major advance in biomedical device coatings. Their **consistent performance** sets them apart from older technologies, such as UV-cured coatings and PVP coatings.

HYDAK coatings are simpler to apply and less expensive than UV-cured coatings. And, they are superior to PVP coatings in terms of their lubricity/durability profile and flexibility.

Biocoat has more than ten years of experience and their coatings have been adopted by leading medical device companies in the U.S., Europe, and the Far East.

Biocoat's quality system is conducted in conformance with cGMP regulations and is ISO 13485: 2003 certified.



Superior Performance:

- Hyaluronan: naturally biocompatible
- Non-thrombogenic in blood contact applications
- Most effective surface to minimize protein adsorption, cellular attachment, and bacterial adhesion
- More hydrophilic and lubricious
- More durable, abrasion resistant
- Ability to coat lumens
- Provides consistent performance on a wide range of polymeric and metallic substrates
- Very thin and flexible

Consider these unique HYDAK attributes for your next device design.

Unique coatings from Biocoat based on nature's own lubricant

HYDAK coatings are based on hyaluronan, a unique biopolymer found in all body tissues and body fluids. As a constituent of synovial fluid, hyaluronan lubricates the joints and separates surfaces that slide over each other. It is extremely hydrophilic and highly lubricious when wet, a property that makes HYDAK coatings especially slippery when exposed to body fluids.

An excellent choice for medical devices

HYDAK coatings can be applied to a wide range of polymeric and metallic substrates as well as lumens. And because hyaluronic acid is a naturally-occurring polysaccharide, HYDAK coatings are biocompatible, biodegradable, non-thrombogenic and resist adsorption of proteins, cells, platelets and bacteria. They are proven to be abrasion resistant and have acceptable shelf life under normal storage conditions. They are best sterilized by ethylene oxide. These properties make HYDAK coatings an excellent choice for many medical devices such as:

- Vascular catheters: peripheral, neuro, cardiac
- Interventional guidewires
- Ophthalmic surgical devices
- Other interventional vascular devices

The HYDAK Two-Coat System

The HYDAK surface modification system is a two-step coating process that begins with the application of a base coat to the substrate, which is quickly dried. Coating is achieved by either conventional dip-coating, spraying, or wiping. This is followed by the application of a hyaluronan top coat which is then heat-cured.

Curing is done in an oven which is simpler and more easily scaled up for volume production than UV-curing.

The advantage of the two-coat system is that the top coat is always covalently bound to the base coat, regardless of the substrate, which guarantees consistent

performance.

Following years of R&D work the scientists at Biocoat have developed a number of new and improved formulations that make the HYDAK coating system more adaptable in achieving the desired results medical device designers look for in a coating.

Base coats are now available as either 1) aqueous-based, or 2) solvent-based providing greater design flexibility in such properties as adhesion, coating density and faster curing times.

The adhesion chart compares Biocoat's aqueous-based and solvent-based coating formulations to illustrate the broad range of substrates that can be effectively coated.

HYDAK Coating Adhesion to Various Substrates (ASTM D3359-78, Method B)		
Substrate	Base Coat in Organic Solvent	Base Coat in Aqueous Dispersion
HDPE	Excellent*	
LDPE	Excellent*	
Nylon 12	Excellent*	Poor
Nylon 6	Excellent*	
Nylon 66	Excellent*	Excellent
70D Pebax	Excellent	Poor
55D Pebax	Excellent	Poor
35D Pebax	Good	Excellent
90A Polyurethane	Poor	Excellent
60A Polyurethane	Excellent	
PEEK	Excellent	Excellent
PET	Excellent	Excellent
PMMA	Excellent	
Polycarbonate	Not Recommended	Excellent*
Polypropylene	Good*	
PVC	Excellent	Excellent
Silicone	Good*	Poor
Stainless Steel	Good	Excellent
Tygon	Not Recommended	Excellent
FEP	Poor	Poor
Teflon	Poor	Poor

* With plasma treatment

FOR MEDICAL DEVICES



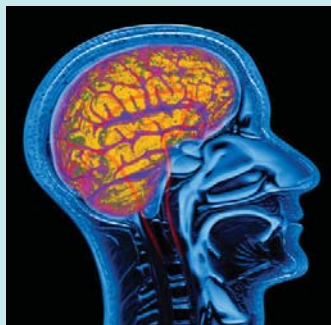
Manufacturing

Biocoat's facility is equipped with state-of-the-art chemical labs and clean rooms for the production of HYDAK coatings.

HYDAK base coat formulations are generally based on adhesive acrylic polymers or co-polymers. These polymers can be supplied as either a solution in organic solvent, or a colloid dispersed in water. Different compositions have been developed to achieve strong bonding characteristics, depending on the substrate material being coated.

There are also a number of HYDAK top coat formulations available. The simplest top coat that will provide a uniform hydrophilic layer is an aqueous solution of sodium hyaluronate that has had a surfactant added. The sodium hyaluronate molecule reacts with functional groups on the surface of the base coat and becomes immobilized. Higher binding densities are achieved by formulating with proprietary additives or by modifying sodium hyaluronate to make it suitable for crosslinking via a patented process.

The sodium hyaluronate Biocoat uses is purchased from suppliers who manufacture it from bacterial cultures.



PRODUCT: Neurovascular catheter

"Following evaluations, we selected the HYDAK coatings system for our device because of their ability to lay down a micro-thin coating that was not only biocompatible, but also biodegradable. Being naturally lubricious and hydrophilic, the coating had to be easily tolerated by the body without any rejection, an important consideration for our device that was designed to inject embolization material into delicate blood vessels within the brain."

The technical people at Biocoat spoke our language and were able to provide us with a great deal of the information we required on cross-linking, surfactants and the general chemistry of their HYDAK coatings making our overall experience with them very positive and productive."

Principal Process Engineer, PhD.
Endovascular Medical Device Company



PRODUCT: Intraocular Lens Cartridge

"Our lens delivery cartridges are made from polypropylene and the implant lenses are a soft acrylic, a material which tends to stick to nearly every kind of surface it contacts. Our challenge was to find a lubricious coating for the inside of our IOL delivery cartridge that would allow the folded lenses to slide smoothly into the eye when hydrated by a viscoelastic."

Of the five final companies we evaluated, only Biocoat was able to engineer a coating system that met all our requirements and testing. It was an excellent overall result that couldn't have come to fruition without Biocoat's extremely knowledgeable people who were also always available to us, whenever we needed them throughout every stage of development."

Senior Project Manager,
Vision Technologies Company

Give your product a “natural” competitive edge

Put HYDAK coatings to the test in your next design. Biocoat will work closely with your company to develop the best coating formulation to meet your device's design requirements. They have the capability to perform extensive in-house testing on your prototypes, if required, and can assure quality standards are consistently met at all stages.

Licensing

Biocoat develops applications of its patented technologies in partnership with established medical device manufacturers, who license the technology and apply it to their own products.

For more information on Biocoat and their HYDAK coatings technology visit

www.biocoat.com.

Or, call 215-734-0888.



Biocoat, Inc.

211 Witmer Road
Horsham, PA 19044
Tel.: 215-734-0888
www.biocoat.com

HYDAK Specifications

Thickness: HYDAK hydrophilic coatings can be very thin (2-3 microns) without loss of effectiveness, leaving substrate materials flexible. When hydrated, they can swell to about 10 microns.

Shelf Life: HYDAK coatings can remain stable for at least two years, providing they do not experience extreme temperature and humidity conditions. They will also withstand ethylene oxide sterilization.

Lubricity: HYDAK coatings are extremely lubricious and slippery when wet, particularly when in contact with bodily fluids. This allows the physician the ability to steer and manipulate vascular devices more easily, minimizing trauma and reducing tissue abrasion.

Abrasion Resistance: HYDAK coatings show superior abrasion resistance since the hyaluronan is immobilized with covalent chemical bonds. This allows catheters and guidewires to be used during longer procedures with no loss of effectiveness.

Wettability/Surface Tension: Hyaluronan has a high affinity for water. Contact angles for fully hydrated HYDAK hyaluronan coatings are on the order of 30°.

Stability: HYDAK coatings are currently in use on many products that reside in the body from minutes to hours without losing their effectiveness.

Biocompatibility: The biocompatibility of hyaluronan-modified surfaces has been well established and confirmed in both *in vitro* and *in vivo* testing. HYDAK coatings are non-thrombogenic and are more effective than other surface modification techniques in reducing adsorption of proteins, adhesion of bacteria, and platelet activation. HYDAK coatings are based on hyaluronan from bacterial sources. No animal products are used in their manufacture.

Fluids Resistance: HYDAK coatings show excellent resistance to aqueous fluids and many non-aqueous fluids, such as isopropyl alcohol, DMSO, hexanes, etc. The resistance profile will vary, however, depending on coating formulation and substrate.

Regulatory: HYDAK coatings are used on devices which are approved or cleared by the U.S. Food & Drug Administration and are approved for marketing in the European Community and by the Japanese Ministry of Health. Clearances are given to the finished device and not for the coatings alone.

FDA Master File: Data on Biocoat's HYDAK coatings is compiled in an FDA Device Master File, which can be referenced by companies submitting pre-market applications to the FDA.

