

USP Class 6 up to Medical Implantable Grade Coatings

Unmatched Performance of Innovative Medical Coatings

A worldwide network of research and development resources assures the latest technology for customized cost-efficient medical coating solutions.

AMT's innovative medical coatings are manufactured in an unique plasma polymerization deposition process. Monomeric vapors are converted into covalently bonded polymeric coatings directly on the surface of passing tubings/fibers or small components. The unmatched results of this technology are:

- **Extreme durability** of coatings – no peel or strip off
- **Highly biocompatible**
- **Antithrombogenic properties**
- **Lubricity enhancement**
- **Well-bondable** to a wide variety of materials such as polyurethanes, silicones, fluoropolymers, polyamides, polyimides, PVC, polyesters and polycarbonates.
- **Extreme smoothness and thickness consistency** of complete coating surface
- **Flexible micro and macro-bend strength**
- **Excellent thermal and chemical stability**
- **Resistance to organic solvents**

Biocompatibility & Antithrombogenic Characteristics

AMT's coatings are blood compatible being used for invasive medical applications. We use standard biomedical industry test procedures to characterize our coatings' properties:

■ **USP Class 6** Biological Test for Plastic Materials

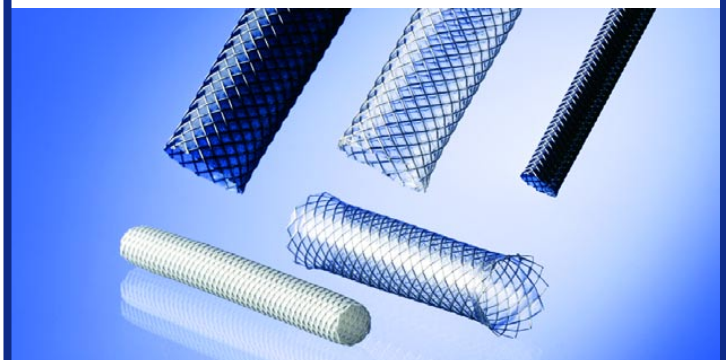
- Systemic Injection Test
- Intracutaneous Test
- 14-Day Implantation Test

■ **USP 14-Day Intramuscular Implantation Test**

■ **Cytotoxicity Evaluation/MEM Elution**

■ **Human Red Blood Cell Hemolysis Test**

Our blood compatible surface coatings can be specially prepared with bioactive sites for subsequent binding of anti-thrombogenic agents such as Heparin or the attachment of Monoclonal antibodies.



Plasma Polymerization Coating Process

Step 1:

Activation of substrate molecules

Step 2:

Growth and bonding between substrate and coating molecules

Step 3:

Homogeneous coverage of plasma coating material

Substrate material prior to plasma polymerization process

Advantages:

- Excellent bonding – no peel-off
- Unlimited combination of substrates and coating materials

VS.

Conventional Coating

Disadvantages:

- Poor bonding – risk of peel-off
- Bonding limited to certain substrates and coating materials

Untreated substrate

Substrate with conventional coating

GMP and Clean Room Manufacturing

All coatings are applied under a **very stringent quality assurance** program. Cleanroom manufacturing capabilities (CLASS 1,000) – including GMP – assure precision and consistently high quality. Spooled products are labeled with **Lot traceability** on every fiber/tubing shipment. A similar procedure is also available for batch production of small components.

AMT can coat the full range of substrate lengths, thicknesses and diameters available from any supplier of **tubing, fibers and flat film material**. Batch production is also available for small components such as **o-rings, valves, fittings, seals and stents**.



Coating Selection Matrix

| | Silglide | Carbond | Fluorcarb | Parylene | Metal/Noble |
|------------------------------|-----------|-----------|-----------|-----------|-------------|
| Bio Compatibility | Excellent | Excellent | Excellent | Excellent | Very Good |
| Lubricity | Excellent | Fair | Fair | Excellent | Fair |
| Bondability | Very Good | Excellent | Fair | Poor | Good |
| Teflon Bondable | No | Yes | N.A. | No | Yes |
| Antimicrobial | N.A. | N.A. | N.A. | N.A. | Excellent |
| Antithrombogenic | Excellent | Very Good | Excellent | Excellent | Good |
| Absorption | Very Good | Good | N.A. | N.A. | Very Good |
| Drug Release | Good | N.A. | N.A. | Excellent | N.A. |
| Insulation | Fair | Fair | N.A. | Excellent | Very Poor |
| Conductivity | N.A. | N.A. | N.A. | Very Poor | Excellent |
| Durability of Coating | Excellent | Excellent | Excellent | Excellent | Excellent |
| Chemical Resistance | Very Good | Excellent | Excellent | Excellent | Excellent |
| STERILIZATION | | | | | |
| Autoclave | Yes | Yes | Yes | Yes | Yes |
| Ethylene Oxide | Yes | Yes | Yes | Yes | Yes |
| Gamma Radiation | Yes | Yes | No | Yes | Yes |



Applied Membrane Technology, Inc.

11558 Encore Circle ■ Minnetonka, MN 55343

(+1) 952-933-5121 ■ fax (+1) 952-933-8839 ■ email: amtechnology@appliedmembranetech.com

Visit our interactive website: www.appliedmembranetech.com

IMPORTANT NOTICE: The information and statements herein are believed to be reliable but are not to be construed as a warranty or representation for which we assume legal responsibility. Users should undertake sufficient verification and testing to determine the suitability for their own particular purpose of any information or products referred to herein. NO WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE IS MADE.