

**CURTISS -
WRIGHT**

Parylene

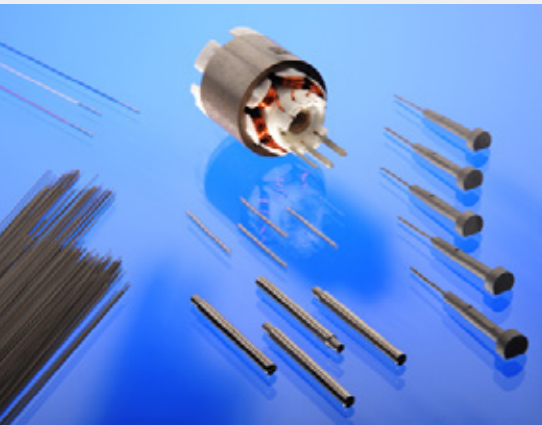
Solutions for the medical industry

www.parylene.co.uk

COMPANY PROFILE

Curtiss-Wright Surface Technologies (CWST) offers a single source solution and point of contact for all your surface treatments. We can reduce your turnaround times and costs through our network of over 75 worldwide facilities.

Our proven surface treatments meet industry demands for lighter materials, improved performance and life extension in key markets such as Aerospace, Automotive, Energy and Medical. We can prevent premature failures due to fatigue, corrosion, wear, galling and fretting.



Surface Technologies is a Division of Curtiss-Wright (NYSE:CW) a global innovative company that delivers highly engineered, critical function products and services to the commercial, industrial, defense and energy markets. Building on the heritage of Glenn Curtiss and the Wright brothers, Curtiss-Wright has a long tradition of providing reliable solutions through trusted customer relationships.

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For applications that require a protective conformal coating that's bio-medically compatible and conforms to USP Class VI and ISO 10993 standards, Parylene provides the answer. This unique coating is transparent and pin-hole free, with a thickness that is both critically controlled and extremely consistent.

It offers a level of protection for critical devices unequaled by other coating alternatives. Parylene is biocompatible, pinhole-free, extremely thin, and protects against the effects of fluids and solvents.

The benefits of Parylene are clear:

- Biocompatible, biologically stable and chemically inert
- Non-toxic
- Impervious to sterilization by E-beam, gamma ray, EtO, autoclave
- Conforms precisely to contours
- Excellent dry film lubricity
- Protects against chemicals, moisture and bodily fluids
- Ultra-thin with deep crevice penetration
- Excellent dielectric properties
- Adds minimal weight and volume

Implants

Parylene provides an ideal coating for coronary stents, pacemakers, defibrillators and many other implantable medical devices. It protects the device as well as provides a surface suitable for tissue contact.



Elastomers

Catheters, medical seals and similar products utilizing medical grade silicone or rubber require high flexibility, low friction coatings that resist contaminants and discoloration. Parylene, by Curtiss-Wright Surface Technologies answers those challenges.



Medical Electronics

Electronic devices require protection from moisture, body fluids and gases which will cause premature and critical use device failure. Parylene has proven to protect devices from the body and the body from the device.



For more information on all our services and full worldwide contact details: www.cwst.co.uk

Medical Electronics

Parylene offers significant advantages for coating mandrels and stylets. Its low coefficient of friction enhances the reusability of mandrels. In conjunction with its dry film lubricity and bio-stable/bio-inert characteristics, Parylene provides an ideal coating for stylets, such as extensively applied to vascular therapy devices including:

- Stents
- Stent grafts
- Angioplasty catheters
- Guiding catheters
- Guide wires and diagnostic catheters
- Embolic protection
- Atherectomy devices
- Septal defect repair and other occlusion devices



Parylene coating and Dimer testing

| Study | Standard | Parylene type | Result |
|---|--------------|---------------|------------------------------|
| ASTM Hemolysis Complete (Direct and Indirect) | ISO 10993-4 | C & N | Meets Requirements |
| ISO Partial Thromboplastin Time | ISO 10993-4 | C & N | Meets Requirements |
| ISO Lee & White Clotting Time - Human Blood (Direct) | ISO 10993-4 | C & N | Meets Requirements |
| ISO Lee & White Clotting Time - Human Blood (Indirect) | ISO 10993-4 | C & N | Meets Requirements |
| ISO In Vitro Hemocompatibility (Direct) | ISO 10993-4 | C & N | Meets Requirements |
| ISO In Vitro Hemocompatibility (Indirect) | ISO 10993-4 | C & N | Meets Requirements |
| ISO Cytotoxicity Test - Neutral Red Uptake 4 Concentrations | ISO 10993-5 | C & N | Meets Requirements |
| ISO MEM Elution Cytotoxicity | ISO 10993-5 | C & N | Extracts Confirm Suitability |
| ISO Implant/Muscle/2Weeks | ISO 10993-6 | C & N | Classified as Nonirritant |
| ISO Implant/Muscle/13Weeks | ISO 10993-6 | C & N | Classified as Nonirritant |
| ISO Implant/Muscle/26Weeks | ISO 10993-6 | C & N | Classified as Nonirritant |
| ISO Klingman Maximization/2 Extracts/35 Animals/Concurrent (+) controls | ISO 10993-10 | C & N | Meets Requirements |
| ISO Rabbit Pyrogen-Material Mediated | ISO 10993-11 | C & N | Meets Requirements |
| USP Physiochemical/Plastics | USP | C & N | Meets Criteria |
| USP Physiochemical Test For Plastics - Non Volatile Residue | USP | C & N | Meets Criteria |
| USP Class VI Test Parylene C | USP | C | Meets Criteria |
| USP Class VI Test Parylene N | USP | N | Meets Criteria |
| RoHS Compliance Parylene Type C | EU | C | Compliant |
| RoHS Compliance Parylene Type N | EU | N | Compliant |
| Reach Compliance Testing Per Regulation 1907/2006 Parylene C | ECHA | C | Passes |
| Reach Compliance Testing Per Regulation 1907/2006 Parylene N | ECHA | N | Passes |

Results of these studies are available on request. Additionally, we maintain device and drug master files with the US FDA. These files include the results of biological studies commissioned by CWST and are available for reference by commercial coating service customers.

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www.cwst.co.uk/parylene-coatings.html / www.paryleneinc.com

For more information on all our services and full worldwide contact details: www.cwst.co.uk