MEDICAL M DEVICES

Coating

- where medical meets semiconductor

facility dedicated to conformal coating has opened in Ireland to serve the surrounding area. Initially, Alpha Metals is using parylene, a type of thermoplastic polymer, to coat critical telecoms PCB assemblies for Motorola, but can apply the same procedure to applications in the biomedical field.

Originally developed as an environmental protective coating for electronics assemblies, parylene has proved a stable and protective coating for medical implants. Few materials meet the dual requirements of implantation:

- resistance to a variety of corrosive body fluids, electrolytes, proteins, enzymes and lipids;
- compatibility with body tissue inert and nontoxic.

As a replacement for Teflon, parylene can improve the lubricity of catheters, mandrels (steel casing over which plastics are formed), medical scals and other single-use items. The dielectric and environmental isolation provided by parylene benefits pacemakers, cannulae (small tubes for pipettes and syringes), pressure sensors and miniature components like magnets or solenoids.

Parylene combines a true uniformity and completeness of coverage while its physical, electrical, chemical, mechanical and barrier properties meet the requirements of a USP Class VI plastic.

The dry film lubrication properties of parylene complement prosthetic components such as bone pins and artificial joints. Coating screws and nuts used with temporary bone pins and plates can prevent seizing, corrosion and metal fragmentation. Its hyrophobic and lubricous properties can minimise residual fluid build-up on both the inner and the outer surfaces of needles and other medical components, aiding cleanup. Parylene is particularly effective in sealing the microporosity of metals that could trap and retain contaminants.

Parylene is ideal for both medical and semiconductor device coating. Jan Noordegraaf explains the advantages and describes the cleanroom facilities used by Nova Tran.

WHAT IS PARYLENE?

Parylene is the generic name of xylylene polymer - poly(chloro-p-xylylene). This optically-clear coating isolates surfaces both electrically and chemically from contaminants from the surrounding environment. There are three common forms of the parylene polymer, as shown in Figure 1: Parylene C, Parylene N and Parylene D. Each has its own unique properties that make it suitable for particular applications.

COATING TECHNOLOGY

The aspect of parylenes most likely to prompt their use is their formation at room temperature from a gas phase.

Parylene is vacuum deposited onto the surface of a product in an evacuated chamber (~0.1 Torr) by means of gasphase polymerisation. A solid coating of parylene is formed on surfaces directly from the monomer gas rather than being applied as a liquid in conventional

Parylene C

Parylene D

Figure 1: Structures of parylene N, C and D.

coating methods. As a result, surface tension is not a problem and parylene can grow outward from the surface, producing a conformal layer of uniform thickness. The coating thickness is very controllable and can range from just 100 Angstroms to over 75 µm. Pinhole-free and conformal coverage, even on complex surfaces, is achieved with a film of only 0.5 µm.

Room temperature growth of parylene does not require a cure cycle, so products are not subject to cure forces, solvents, liquid phase or elevated temperature. No testing is required to confirm that full cure has occurred.

CLEANROOM REQUIREMENTS

With such a variety of applications, a cleanroom environment for production is clearly preferable. While the ultimate regulator for all biological applications - the FDA - does not require the use of cleanrooms, the industry prefers this practice. Nova Tran's requirements dictated the choice of a flexible wall approach, without compromising quality.

The ideal solution was found in a flexible wall cleanroom developed for the Cookson Technology Centre.

Back at Nova Tran's facility in Northampton, UK, a unit consisting of three-by-three segments of thick gauge transparent PVC allows coating machines to be introduced into the cleanroom, while leaving the remaining auxiliary systems outside the accessible for routine maintenance. Figure 2 shows the cleanroom set-up certified according to BS 5295. The frame runs down to an antistatic floor and is scaled with RTV silicone. This creates a positive pressure bubble that can be controlled by varying

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It was like going for GCSEs and passing with A-levels without extra study.

the opening of polycarbonate valves so that a pressure of 30-50 cmHg water is maintained. The air lock for product and personnel is maintained at a slightly lower pressure to prevent contamination of the clean area.

Two Class 100 laminar flow cabinets recirculate the air inside the cleanroom and contribute to maintaining the required level of cleanliness. Much to our surprise, although aiming for a Class 100,000 cleanroom, the actual measurements performed by an independent certifier confirmed a level of nearer Class 1000.

The need for a cleantiness level of Class 10,000 was easily met as this was determined by the type of garments used

rather than the cleanroom itself. It was concluded that by simply upgrading the HEPA filters, a Class 1000 cleanroom could be obtained for very little extra cost. Such capability provides a good base for future development. As far as we can ascertain, this is the only cleanroom of its kind in the UK.

Observing this experience, it is difficult to understand why companies spend so much money on hard-wall cleanrooms when the targets for a controlled environment can be obtained for considerably less money without concessions to quality by using a flexible wall cleanroom

concept.

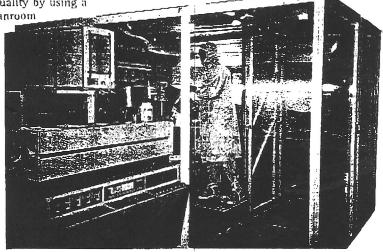
Figure 2: An operator at Nova Tran's Northampton facility inside the Class 10,000 flexible wall cleanroom showing how and where materials can be introduced into the coating chamber.

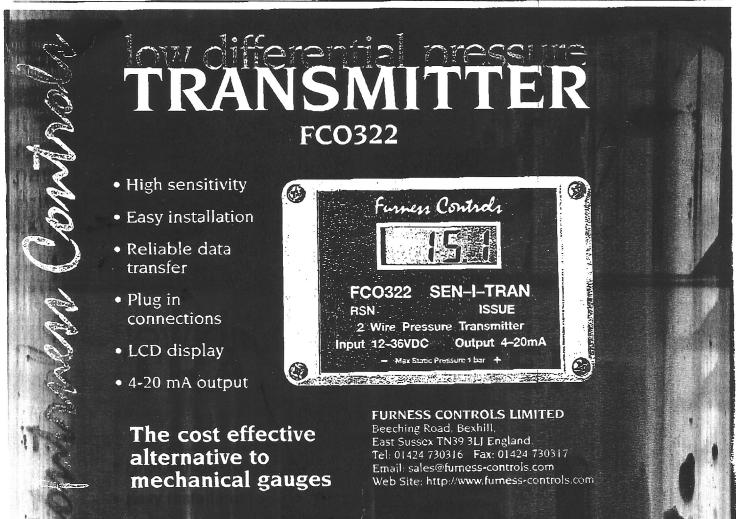
Indeed, a transparent wall allows the unit to be constructed virtually anywhere without being considered as a room within a room or increased requirements for fire certification. The unit has contributed greatly to the growth of our company and as I walk past every time I feel very proud that we managed to realise such an efficient cleanroom.

Author: Jan Noordegraaf, General Manager, Nova Tran Ltd UK.

For further information

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