



(Parylene C coating for NdFeB magnets)

Summary

Biocompatible coatings are a critical in the medical device world, especially in implantable applications. Dexter Magnetic Technologies (Dexter) has developed its own process for coating NdFeB magnets with BarrierMax Parylene C, which provides superior performance. Parylene C is a thin, pin-hole free, conformal coating that has ideal barrier and corrosion resistant properties required for medical applications.

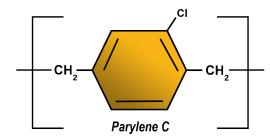
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Dexter BarrierMax 1 Parylene Coating



Permanent Magnet Basics and the Effects of Corrosion

There are four main kinds of rare earth permanent magnet materials: Alnico, Hard Ferrite, Samarium Cobalt, and Neodymium Iron Boron. Neodymium magnets are the strongest magnets made to date. They contain Neodymium, Iron, Boron, and small amounts of Dysprosium and Terbium. The mixture and ratios of these elements can alter a magnet's performance properties.

For strong Neodymium magnets, the material is created through a sintering process. Simply, this process means powdered elements are pressed together in the presence of a magnetic field to align the magnetic orientation. This block is then sintered and aged to create a final magnetic material. However, because this material is pressed from a powder, the final form is porous, which can be detrimental due to corrosion.

Corrosion not only breaks down the material, but also can drastically affect performance when the magnets are small. For medical applications, magnetic materials are not biocompatible, and with corrosion, they must be contained in some way to prevent them from being absorbed by the body. Some devices will encapsulate the magnet entirely, while in other cases the magnet is coated with biocompatible metals such as gold. In this case, with the magnet material being porous, it makes coating difficult. Moreover, being porous, it's much easier for cracks to propagate through the material either from the surface or internally.

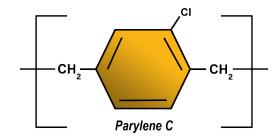
Parylene Basics

Parylene is a chemical vapor deposited polymer that was developed and commercialized in the 1960s and 1970s by Union Carbide (source: SCS). It has a long history in the medical device world being used as a protective, biocompatible coating. It is a transparent, pin-hole free coating that coats very thinly and provides coverage on any surface's features.

Parylene N and Parylene C dominate the Parylene market. Parylene N is the basic member of the Parylene polymer series and Parylene C was the second commercially available member. It is produced from the same monomer and modified with the substitution of a chlorine atom for two of the aromatic hydrogens. It is useful in the medical device world since it is a biostable, biocompatible coating with excellent barrier properties. (source: SCS)



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Parylene Basics (cont.)

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The Dexter Coating Process

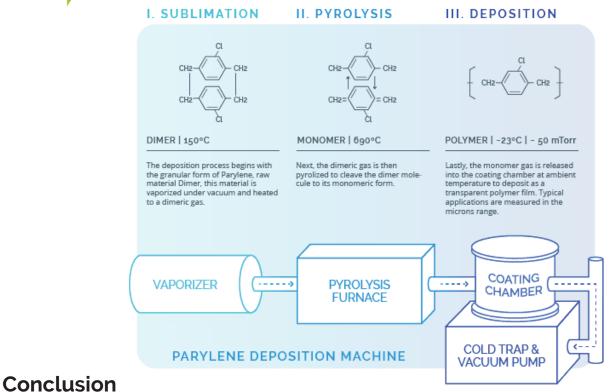
Prior to coating, the magnets are subjected to a thorough pre-coat preparation process. First, the magnets are thoroughly cleaned. Then the magnets go through an adhesion promotion process. Finally, the magnets are mounted and loaded into the coating chamber.

The coating process is comprised of three stages: sublimation, pyrolysis, and deposition. The coating process begins with raw material (dimer) being heated under vacuum and vaporizing at approximately 150°C into a dimeric gas (See I. Sublimation below). The dimeric gas is then pyrolized (thermally decomposed at an elevated temperature in an inert atmosphere) at a temperature of 650°C to a monomer gas (See II. Pyrolysis below). Then, finally, in the room temperature deposition chamber, vaporizing at approximately 150°C into a dimeric gas (See I. Sublimation below).

The dimeric gas is then pyrolized (thermally decomposed at an elevated temperature in an inert atmosphere) at a temperature of 650°C to a monomer gas (See II. Pyrolysis below). Then, finally, in the room temperature deposition chamber, the monomer gas deposits under vacuum of about 0.1 Torr on all surfaces as a thin, transparent polymer film (See III. Deposition below). (source: SCS)



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Dexter began developing it's in house BarrierMax 1 Parylene C coating process in 2018 and tailored its formulation to optimize performance on NdFeB magnets. Process variables were systematically tested and adjusted through a series of rigorous accelerated life and adhesion tests which included:

- ·Cut and lift testing
- ·Salt spray per ASTM B117
- •Elevated temperature Saline bath submersion
- Highly accelerated temperature and humidity stress test (HAST)

Dexter's BarrierMax 1 has been successfully deposited onto a Class 3 implantable end user's product and met the device's durability and biocompatibility requirements in accordance with ISO 10933-5. The device manufacturer has progressed through 510(k) submission for BarrierMax 1 coating as a second source and is expecting FDA approval by Q2-2020.

Dexter continues to advance its technology and leverage customer needs based on what the end user is striving to achieve. Whatever your needs, Dexter can produce the highest quality Parylene C coating for your implantable applications with BarrierMax 1.

Jon Murphy Manufactuing Engineer

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