Biocompatible Materials Drive the Success of Implantable Medical Devices

Tom Kannally, Hypertronics Medical Industry Manager

The market for implantable medical devices is estimated at over $40 billion. The recent growth is spurred from significant contributions by the semiconductor industry where new chip technologies revolutionize health care treatments. For instance, new technology now paves the way for health care treatment to become interactive in nature and collect data from within the human body and transmit it directly to the physician via cell phone or PC. Key to the success of these implantable medical devices is the selection or design of biomaterials that resist degradation within the body. Traditionally, design engineers have sought to develop unique biomaterial that performs the desired function with respect to medical therapy without eliciting any undesirable local or systemic effects in the recipient. Recently, the focus has shifted even further with biocompatible materials to select or develop material that generates the most appropriate beneficial cellular or tissue response in that specific situation and to optimize the performance of the device. The evolution of medical devices to implantable has driven the need for biocompatible material in all components.

Component Manufacturers Supply Biocompatable Materials

Designers of medical devices rely on component manufacturers to supply biocompatible materials. Component suppliers provide anything from the base material to the interconnect or contact system to the coatings. “The old age material used in implantable devices was stainless steel,” explains Dave Cutter, Medical Product Development, Pacific Aerospace & Electronics.

Figure 1. Hypertronics’ ImplanTac contacts.

“But the shift has been to platinum iridium and titanium, materials more suitable.” Another material developed specifically for implantable devices is PEEK-OPTIMA polymer, developed by Invibio Biomaterial Solutions in 1999. PEEK is the first implantable grade polyetheretherketone,

exhibiting excellent strength, flexural and tensile properties; compatibility with x-ray, MRI and CT imaging techniques; advantageous electrical insulation and telemetry properties; and the ability to be processed by injection molding, extrusion or machining. PEEK-OPTIMA has proven to perform better than ceramics, metals and other polymers, in numerous applications, according to company data, and Invibio continues to develop additional advances in their products for the medical device market.

New Contacts Made from Biocompatible Material Ensure the Device Works

The reliable transmission of current via an electrical connector is a vital – and often lif-critical -- component to guarantee a medical device's reliability, often life critical. For this reason, Hypertronics, a manufacturer of ultra reliable medical connectors for 40 years has developed ImplantTac contacts for use in pacemakers, neurostimulators, defibrillators and other newer applications in implantable devices such as orthopedic, visual and sensory aids, implantable patient ID and active monitoring systems. Commonly, interconnect companies use brass material for the body of the connector and beryllium copper, standards in connectors. However, in developing ImplanTac, the body material in the connector was changed to a biocompatible stainless steel material commonly used in medical products, 316LVM. For the wires, a proprietary composite with a platinum contact surface was chosen.

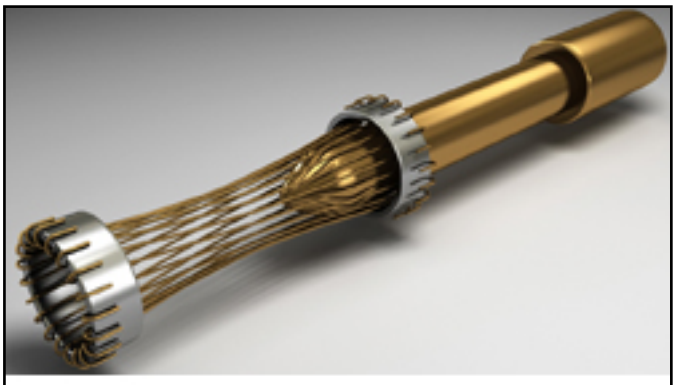

Figure 2. Hypertronics' Hypertac wire basket technology surrounds the male pin for continuous signal integrity.

The key to ImplanTac's ultra reliability is the unique contact design characterized by the Hypertac wire basket technology (see Figure 3) which surrounds the male pin and guarantees continuous signal integrity especially critical in medical applications where low force and low resistance are critical. Since the devices have to be implanted in the body by a surgeon and historically set screws were needed to secure the device in place were commonly the cause for failure, ImplanTac was designed to be inserted without the need for set screws.

Recently stent manufacturers such as Medtronics have been applying surface coatings to the implantable devices to eliminate the problems of restenosis (re-blocking), which results in the artery closing over time. Clinical trials are now in process with stents that are "coated" or "medicated" with a pharmacologic agent (drug) that is known to interfere with the process of restenosis (reblocking). Some

companies such as Abbott and Germany-based Biotronik are testing a completely bioabsorable stent which will totally disappear.

FDA Approval, Clinical Trials and Tesing

The United States is very strict when it comes to testing and FDA approval of medical devices. Clinical trials and tests for effectiveness and biocompatibility are very expensive. “Ultimately, the responsibility for testing on biocompatibility relies on the device manufacturer,” explains Dave Cutter. Tests for biocompatibility are conducted at outsourced labs such as MicroMed. “Testing on implantable devices start at $45,000,”said David Frank, Sales Manager MicroLab. “But the type of testing done depends on where the product is being marketed.” US medical device manufacturers are finding significant growth abroad in emerging countires like China, Brazil, India and Russia where often the requirements are much loser.

Innovations in Implantable Devices

The implantable systems in development now at major medical device companies will revolutionize health care in the coming decades. “Neurostimulators of many sizes and shapes for combating numerous symptoms beyond the classical back pain, new innovations on the cochlear implant that use different stimulation paths, and intelligent sensor-based pharmaceuticals are just some of the medical device applications on the horizon, to name a few,” says Cutter.

Figure 3. Medtronics’ Activa RC neurostimulator.

In developing products ranging from neurostimulation to orthopedic electronic stimulus to hearing aids, the largest medical device manufacturers are turning to medical connector vendors like Hypertronics whose custom design engineers work with them to create interconnect

systems that will ensure their devices will work. One of the newest advances is for orthopedics where electrical impulse technology designed originally for pacemakers now sends nerve stimulus to prosthetics and/or body parts where nerves are damaged. For example, Neurostep, currently in clinical trial, is being used to stimulate the proper muscles to lift the foot during walking for people who suffer from drop foot.

Other new implantable devices under development are designed to reduce the use of pharmaceutical drugs to treat disease, thereby eliminating the damaging side effects of drugs. For instance, a neurostimulator called Activa RC was recently developed at Medtronic to control the symptoms of Parkinson's disease by delivering Deep Brain Stimulation (DBS) Therapy.

It is no doubt that the implantable medical device market is improving healthcare and as the search for new applications continues, the development of advanced biocompatible materials will continue as well.

For more information

Hypertronics: www.hypertronics.com [1]

Implantac:
http://www.hypertronics.com/en/Technology/HypertacTechnologies/ImplanTac.aspx
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