Connecting with medical needs

Connectors are playing a vital role in implantable electronics. By **Chris Parsonage.**

The rapidly growing market for implantable medical devices, estimated to be worth more than £25billion a year, is on the verge of revolutionising healthcare treatment and disease prevention by becoming interactive; allowing data to be collected from the body and transmitted directly to a doctor's phone or pc.

As medical devices become a prominent part of future health care strategies, the reliable transmission of current via an electrical connector is a vital component to guarantee device reliability. For this reason, Hypertronics, a business unit of Hypertac, has developed ImplantTac contacts for use in pacemakers, neurostimulators and defibrillators, as well as for the more recent orthopaedic, visual and sensory aids, implantable patient ID and active monitoring systems.

The market for implantable devices began with the development in 1959 of the pacemaker by Drs Chardack and Gage, in conjunction with electrical engineer Wilson Greatbatch, This development has been acknowledged as one of the two major engineering contributions to society during the last 50 years.

The pacemaker, which provides electric signals to the heart to make it beat properly, was followed in 1980 by the implantable defibrillator and, over time, the two were combined into an implantable cardioverter defibrillator. While the first pacemakers were external and so large that they required the patient to move them around on a trolley, modern ones are implantable and weigh less than 25g.

Modern devices used in pacing for cardiac and neuromodulation are miniaturised for portability and privacy and can handle data acquisition levels previously unimaginable. "Miniaturisation and battery life are going to lead to smaller devices being deployed for much broader ranges of medical indications," explains Mark Manasas of Cambridge Consultants. "Previous generations of implantable devices had limited life spans, due to battery life issues. Current generations are incorporating the ability to charge the devices transcutaneously."

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According to David Warren Lee, senior principal mechanical engineer in neuromodulation with US company Medtronic: "New products under development at Medtronic are either implantable or are wearable devices that need to be easily concealed, so all components have to be smaller." These implantable devices are controlled by a hand held unit programmed by the doctor and carried by the patient, so the products have to be robust and withstand everyday use.

This is where interconnect becomes critical. "We have to have a durable, reliable connector," explains Lee. "It's a medical device and it has to work."

Anthony Kalajaikas, Hypertronics' Global Industry Director, noted: "The miniaturisation trend is driven by a number of factors, including the movement of therapy and/or monitoring from the clinic to the home, as well as treatment for chronic conditions without a disruption in lifestyle. The natural progression is to miniaturise the device so it resides in the body, which will require biocompatible materials."

The evolution of implantable medical devices has driven the need for biocompatible material in all components. Commonly, interconnect companies like Hypertronics use brass materials for the connector body and standard beryllium copper contacts. However, in developing ImplanTac, the connector body material was changed to 316LVM, a biocompatible stainless steel material commonly used in medical products.

The selection of the contact material was more challenging as there was nothing available that matched the specifications needed in the marketplace. So Hypertac developed a proprietary composite with a platinum contact surface. The mechanical and electrical spring properties of the wire are significant for the performance of the contact.

While this is the standard product, customised products with materials such as MP35N can also be used for the same application.

Contacts are becoming increasingly smaller as the demand for miniaturisation continues. The International Standard Organisation governs the geometry and performance of interconnect interfaces. IS-1 leads – 2.66mm in diameter – are commonly used for pacemakers, while more sophisticated next generation neurostimulation products require more contacts as more leads need to be connected. While contact size for implantable devices vary, they can be as small as 1.27mm in diameter.

The key to Hypertac's reliability is the contact design characterised by the Hypertac wire basket technology, which surrounds the male pin. This guarantees continuous signal integrity; crucial in medical applications, where low force and low resistance are critical. ImplanTac's insertion force is very low. The wire basket design creates a 360° contact, which ensures contact reliability, eliminating electrical intermittencies and fretting which can be an issue with many connectors.

Advances in medical technology – including implantable devices – mean the need for innovative and reliable connector technology is becoming crucial

The devices have to be implanted in the body by a surgeon and, in the past, the set screws that secured the device in place were commonly the cause for failure. ImplanTac was designed to be inserted without the need for set screws to eliminate this problem.

Device failure can also be caused by contact damage during mating. Connectors that have a single wire coiled inside the contact can fail if the wire is damaged. The design of ImplanTac uses between 6 and 10 independent wires inside each contact (depending on the size of the contact), ensuring a reliable connection even if one wire is broken.

Nano sized implantable devices

The implantable systems currently under development will revolutionise health care in the coming decades. The US National Institute of Health has predicted that, in the next 20 or 30 years, nano sized implantables that can search out and destroy cancer cells or repair tissue will be developed. The ability of recent devices to receive data from the body and store and transmit it changes how we are able treat disease and monitor health drastically.

Some new implantable devices under development are designed to reduce the use of pharmaceutical drugs to treat disease, thereby eliminating the damaging side effects. For instance, Medtronic recently developed the Activa RC neurostimulator to control the symptoms of Parkinson's disease by delivering Deep Brain Stimulation (DBS) Therapy. Using the technology developed for pacemakers, and applying electrical impulses to an area of the brain, symptoms of the disease such as tremors can be eliminated in many patients. The new technology, which is smaller and offers more advanced programming than previous models, is also the first rechargeable DBS device.

Another implantable device, the Syncromed pump, injects medicine directly into the patient using a hand held device. By injecting the medication directly where it is needed in the body, instead of orally, the patient only needs to use 1% of the dose, reducing significantly the side effects caused by medication.

Other new practical applications under development in areas like orthopaedics use electrical impulse technology designed originally for pacemakers to send 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 muscles used to lift feet during walking for people who suffer from foot drop.

"The trend is towards less invasive devices and less invasive procedures," said Manasas. "Natural Orifice Surgery is poised to take off for the implantation of devices. Improved imaging, including CT, MRI and ultrasound, are going to be more prevalent and necessary as these procedures become less 'open' surgery and more 'keyhole' surgery."

Advances in medical technology mean the need for innovative and reliable applications, such as ImplanTac contacts for the medical device market, is crucial and offers opportunities for quality healthcare which were previously considered impossible.

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