

Miniaturization in the Medical Interconnect Market “The Fantastic Voyage”

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Four men and one woman reduced to a microscopic fraction of their original size, boarding a miniaturized atomic sub and being injected into a dying man's carotid artery. Fighting their way past giant antibodies, passing through the heart itself, entering the inner ear where even the slightest sound would destroy them, battling relentlessly into the cranium. Their objective...to reach a blood clot and destroy it with the piercing rays of a laser gun. At stake...the fate of the entire world.The Fantastic Voyage, 1969

The topic of miniaturization in the Medical market has been around for many years. In the movie *The Fantastic Voyage*, shrinking the medical team and injecting them into the human body to navigate to a clot saves the world. The team boards the submarine *Proteus* and heroically faces navigation through the human body to the clot where they zap it with a laser.

As fantastic as it seemed in 1969, it foreshadowed the future developments in the Medical market. Miniaturization in the medical device and equipment market is following the paradigm established by Gordon Moore of Intel in 1965. Known as Moore's law it theorizes that transistors on integrated circuits double about every two years. The doubling of the density allows for more performance out of less physical space as demonstrated by the downscaling of computing technology and electronics as a whole.

In the consumer marketplace there are several examples of products scaling down in size. In the early '80s we were fascinated by the first cellular phones which were the size of small appliances. In old episodes of *Miami Vice*, Crocket is seen talking into what appears to be a television set with a thick antennae sticking out. Today the mobile telephone has exceeded the functionality of

yester year's best personal computers while shrinking to sizes that are approaching too small for human handling.

At Minneapolis-based Medtronic, Inc. (www.medtronic.com), where the mission is to create devices to alleviate pain, restore health and extend life for millions of people around the world, small devices are the wave of the future.

“The new products under development at Medtronic are either implantable or wearable devices that need to be easily concealed, so all of the components have to become smaller,” commented David Warren Lee, Medtronic. “At the same time, the compact devices that we are developing have higher levels of data acquisition and signal processing so the new standards in medical devices are greater density on a smaller form factor.”

One product in neurostimulation that was recently developed at Medtronic to control the symptoms of Parkinson's disease using Deep Brain Stimulation (DBS) Therapy is the Aactiva RC. Using the technology developed for pacemakers, and applying electrical impulses to an area of the brain, the symptoms of the disease are all but eliminated in many patients.



Figure 1-

Incontinence is one of the fastest growing markets in neurostimulation. Medtronic has a new product called InterStim[®] Therapy that is a safe and effective treatment for this troubling condition using sacral nerve stimulation and an external hand held patient programmer.

According to Dr. Attila T. Barabas, who specializes in Urologic Surgery in Lancaster, NH, "InerStim is advancement in patient care that applies Neurostimulation to a targeted area in the body near the tailbone called the sacral nerve. It uses sacral nerve stimulation, which is an intervention that addresses the nerve component of urinary control by applying mild electrical pulses."

Once Interstim is inserted in the patient, the doctor can program the device right in the physician's office. "Adjustments to the stimulation can be made using a hand-held programmer and the implanted generator gets replaced every 7-9 years," comments Dr. Barabas. "The InterStim Therapy is also reversible - it can be programmed off at any time. By using this therapy, patients can resume their activity level and lead a normal life."

The world market for neurostimulation devices is forecast to reach \$5.2 billion by 2012 and the vast array of implantable neurostimulators are increasingly being used to improve the quality of life for patients coping with conditions that range from chronic pain to epilepsy to Parkinson's disease and more. "Implantable devices that provide relief of symptoms with electrical nerve impulses are of great value to patient quality of life," commented Dr. Barabas. "Based on the positive response from patients, nerve stimulation seems to have endless possibilities to provide pioneering treatments of many neurological disorders that lack a known cure."

"Consumers who use neurostimulators to control pain, incontinence or other health care issues want the device to be small and discreet and about the size of an iPod or cell phone," commented David Lee, Sr. Principal Mechanical Engineer for Medtronic Neuromodulation Division. "But unlike cell phones that routinely break over time; our device has to be durable enough to withstand every day usage. If our device drops on the floor, it still has to work."

Neurostimulation can create a new area of treatment that reduces the side effects caused by prescription medications and even decrease the amount of medication a patient takes. The Syncromed pump developed by Medtronic is used to inject medicine directly into the patient using a hand held device. By injecting the medication directly where it is needed into the body instead of orally, the patient only needs to use 1/100 the amount, significantly reducing side effects caused from the medication. It is an implantable pump with a reservoir for the drug. These were originally the size of a hockey puck and are now small like cell phones.

This higher level of durability that applies to medical devices demands extreme robustness in every component, and this especially applies to the connectors. The traditional tuning fork style connector is frequently the cause for failure in everyday consumer electronics. For this reason, companies like Medtronic's seek out high quality connector manufacturers like Hudson-based Hypertronics (www.hypertronics.com) known for their unique basket of wires technology that creates a 360° wiping action, ensuring continuous signal reliability.

"The biggest factor about interconnects in medical devices is robustness", commented Lee. "We use the Hypertronics connectors in our external neuro stimulator because we needed an extremely durable, very reliable connector. It's a medical device and it has to work."

According to advamed.org, miniaturization is the number one hottest trend and innovation expected in medical technology. Breakthroughs in nanotech will even produce microscopic devices that can deliver treatment to individual diseased cells.

The exponential decrease in device diameters dating from the 1960's to current day parallels the challenges we see in the medical connector space; smaller, lighter & able to sustain portability.

Each step change provides a technical challenge of scaling down interconnect without compromise to performance of the system. In addition the human factors of easy of connecting and disconnecting must be met as these devices move from the hospital or clinic settings to the home. For example portable insulin pumps provide for convenience and self regulation – great attributes but wearing a pump is not always aesthetically complementary unless hidden under clothes. Miniaturization of the pump system and implantation has scaled the device down dramatically.

Another example of a step change in scale is the advances that have been made in pneumatic drivers that power the world's only approved Total Artificial Heart, the SynCardia temporary CardioWest™ Total Artificial Heart. Since the 1980s, the Total Artificial Heart has been powered by a 400-lb driver the size of a washing machine. Due to the driver's robust size and need for a qualified technician to monitor it, Total Artificial Heart patients who are otherwise healthy must remain in the hospital while they wait for a matching donor heart. However, in the last decade the driver has been downsized to a 20-lb portable driver in use in Europe since 2003, and now a 12-lb discharge driver under development that is no larger than a woman's purse - the Freedom™ driver.

Hypertronics worked in parallel with SynCardia Systems, Inc. (www.syncardia.com) to design an interconnect system for the Freedom™ driver that delivers unmatched reliability for this critical application. Design engineers from both companies collaborated to develop the interconnect solution that ensures signal reliability for this lightweight system.

“With the Freedom™ driver, for the first time in the US, Total Artificial Heart patients will be able to enjoy life at home while they wait for a matching donor heart,” said Rodger Ford, CEO and President of SynCardia. “The reliability of the

interconnect system from Hypertronics is critical to ensuring that our patients can enjoy their second chance at life.”



Figure 2

As these medical devices migrate from the institution setting to the convenient lifestyle realm, the burden of lighter, smaller, low risk and absolute performance become unconditional.

Interconnect systems are following suite to the log scale decline in sizes which are creating innovative products of “mini” scale. Component manufacturers that supply products for medical devices need to apply resources to develop mini scale components to meet their needs.



As such, Hypertronics developed the New Mini Circular Connector series reducing the form factor by 30%. “Medtronic was excited to hear about Hypertronics new mini technology because we love the ultra reliability of their current connectors, but size was starting to become a problem,” commented David Lee, Medtronic.



Figure 3-

The growth rate of the medical device market has attracted many investors creating an exciting environment of innovation and technology expansion. And

the projection for the future is continued expansion; in 2006 the US market size was \$86 billion and it is now over \$100 million.

As the market continues to flourish and investment into research explodes, scientists and engineers can develop newer applications. While the technologies and innovation of the last decade astounded many scientific researchers, the breakthroughs in miniaturization provide opportunities in health care that are seemingly as futuristic as the *Fantastic Voyage*.