Microelectronics Packaging for Medical Implants

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Expect Great Things from Crane!

Crane Electronics, Inc.
Shortly after the development of practical transistors in the mid-1950s, the U.S. Army Signal Corps and RCA developed hybrid microcircuits as dense assemblies of transistors and other components.

Hybrid circuits comprise one or more transistor chips and passive components like resistors and capacitors mounted on a ceramic substrate and interconnected with wires and conductive traces.

Ref. Computer History Museum, The Silicon Engine
In 1965, Intel co-founder Gordon Moore predicted exponential growth in the number of transistors incorporated on a single chip.

As "Moore's Law" became widely known, it became a self-fulfilling prophecy that emerged as one of the driving principles of the semiconductor industry.

Since Moore's prediction, IC transistor counts have doubled every two years, allowing ever increasingly complex functions to be integrated on a single chip.

Ref. Computer History Museum, The Silicon Engine
The complexity of functions implemented in hybrid circuits has increased in parallel with the complexity of integrated circuits.

Early hand crafted hybrid circuits were labor intensive and expensive to produce.

Multichip modules (MCM) and packages (MCP) are modern machine assembled hybrids used in high performance, high volume applications like automotive controls, cell phones and wireless networks.
Early hybrids used simple ceramic substrates with a single layer of metal interconnection on the surface.

The simple hybrid substrate evolved into high temperature co-fired ceramic (HTCC) substrates incorporating many layers of circuitry, fused together at 1600°C.

With the addition of soldered or otherwise attached ring frame and the metal lids, the HTCC substrates became complete packages incorporating complex functions.
HTCC packages became a platform for many medical implants
Application background - Cochlear Implants

- Hearing loss is one of the most common sensory impairments and affects 28 million Americans.

- Approximately 1-3 out of 1,000 newborns has impaired hearing.

- The elderly are more commonly affected with 40-50% of people over age 75 having hearing loss.

- Depending on the degree of hearing loss, many affected individuals can be successfully fitted with hearing aids that amplify sound.

- For patients with hearing loss that is not mitigated with hearing aids, a cochlear implant may provide an opportunity for hearing.

Ref. Medical Device Today, April 2010
Cochlear implants are surgically implanted devices for individuals with severe to profound hearing loss who only receive limited benefit from amplification with hearing aids.

A cochlear implant provides direct electrical stimulation to the auditory nerve via electrodes, bypassing the usual transducer cells that are absent or nonfunctional in deaf cochlea.

As of 2005, an estimated 85,000 patients worldwide have received cochlear implants. However, this number represents only a small number of the estimated 250,000 hearing-impaired individuals who may benefit from a cochlear implant.
Although individual responses to cochlear implants are highly variable and depend on a number of physical and psychosocial factors, the trend toward improved performance with increasingly sophisticated electrodes and programming strategies has dramatically expanded indications for cochlear implantation.

Ref. Medical Device Today, April 2010
Throughout the 1970s, the Food and Drug Administration (FDA) recommended that devices be implanted only in adults with profound hearing loss.

Over time, indications have been broadened to include adults with severe hearing loss who may achieve some benefit from conventional amplification (hearing aids).

In 1980, the FDA allowed children at least 2 years of age to be implanted.

The age limit has recently been lowered to 12 months for all 3 devices available in the United States (Advanced Bionics, Med-El, and Cochlear Corporation devices).
Cochlear Implants

Some of the greatest solutions come in the smallest packages. Crane’s expertise in chip scale packaging and microelectronics assembly helped create the new generation electronic assembly for the Cochlear™ Nucleus® 5 hearing implant device. Our technical expertise and advanced capabilities supported Cochlear Ltd. in developing a product that is small, thin, and water resistant. As the leaders in microelectronics advanced packaging, validation testing, and obsolescence management Crane Aerospace & Electronics is the turn-key supplier of choice.

Could you ever imagine something so small making such a big difference?

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Cochlear implants consist of both an externally worn component and an internally implanted component.

The external component includes a microphone, an external sound processor, and an external transmitter.

The internal component is surgically implanted and includes an internal receiver placed within the temporal bone and an electrode array that extends from the receiver into the cochlea through a surgically created opening in the round window of the middle ear.
Cochlear Implants

Sounds that are picked up by the microphone are carried to the external sound processor, which transforms sound into coded signals that are then transmitted transcutaneously to the implanted internal receiver.

The receiver converts the incoming signals to electrical impulses that are then conveyed to the electrode array, ultimately stimulating the auditory nerve.
Several cochlear implants are commercially available in the U.S.: the Nucleus family of devices, manufactured by Cochlear Corporation; the Clarion family of devices, manufactured by Advanced Bionics and the Combi 40+ device, manufactured by Med El Corporation.

Over the years, subsequent generations of the various components of the devices have been approved by the U.S. Food and Drug Administration (FDA), focusing on improved electrode design and speech-processing capabilities.
Furthermore, smaller devices and the accumulating experience in children have resulted in broadening of the selection criteria to include children as young as 12 months.

The first cochlear implant electronics were produced on HTCC substrates with hermetically sealed cavities. Enclosed in the cavity were ASICs (application-specific integrated circuits) with supporting active circuitry. Passive components were mounted external to the cavity.
The microelectronics circuit was assembled, electrically tested and environmentally screened to the prescribed customer specification.

The assembly and screening sequence was based on the MIL-PRF-38534 specification that establishes the general performance requirements for hybrid microcircuits, Multi-Chip Modules (MCM) and similar devices, along with the verification and validation requirements for ensuring that these devices meet the applicable performance requirements.
Placing the devices in children as young as 12 months old required lighter and smaller implants.

The second generation of the implant electronics was assembled on green organic board with ASICs configured into CSPs (chip scale packages).

The changes in the configuration and assembly techniques allowed for the additional weight and size reduction without compromising device reliability.
The CSPs were produced as sub-assemblies using known good dice (KGD) and connectivity was validated via in-line X-ray.

To add more functionality while further reducing size and weight of the micro-circuit, the latest implant generation uses CSP ASICs mounted on hard-flex substrates.
Cochlear Implants

This assembly configuration presents unique challenges, requiring specialty fixturing throughout the assembly process as well as electrical testing and environmental screening. The end result is a robust and reliable product suitable for long term medical implant.
The market for neurostimulation products in the US was valued at approximately $1.3 billion in 2009 and it has not yet scratched the surface of its potential.

According to "US Markets for Neurostimulation Products," a report published in March by the Medtech Insight division of Elsevier Business Intelligence, this market is projected to grow at a healthy compound annual rate of almost 16%, reaching more than $2.7 billion five years from now.

Ref. BCC Research, Market Forecasting, May 2011
There are three main modalities of implantable neurostimulation therapy — \textit{vagus} nerve stimulation (VNS), \textit{spinal cord} stimulation (SCS), and \textit{deep brain} stimulation (DBS).
Future challenges for medical implants

Each therapy modality poses a different challenge and requires a different technology. The common factors among all of neurostimulators will be ever smaller footprint, higher density and tighter spacing of the components.
Medical Implants

**Takeaways:**

- The common factor among all medical implants – small size, light weight, high reliability
- Continuous size reductions made possible through innovative miniaturization techniques
- Emerging neurostimulation VNS and DBS devices will require further developments in materials and implant configurations
- Maintaining High reliability, while reducing Size, Weight and Cost of the implants are key focus for the future
Thank you

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