As the global life expectancy continues to get longer, the demand for electronic medical implantable devices is growing. The increasing number of geriatrics suffering from degenerative and cardiovascular diseases is expected to be the primary growth driver in the implant market, forcing the electronics industry to advance at comparable rates to the improvements seen in the health care sector. Mark Skoog, Hi-Rel Product Manager of Knowles Precision Devices (KPD), explores.

Advancements in engineering and scientific technology in the digital age is bringing a change to the nature of health care delivery. The number of life enhancement implantable products is expanding exponentially due to rapid technological innovations. Implantable cardioverter defibrillators (ICD) and pacemakers for the heart, for example, have seen growth at a steady rate with increased functionality thanks to developments in wireless communication. The maturity of the ICD and pacemaker products has pushed this industry closer to being commodity items. However, the pricing pressure on the market players poses a challenge for the growth of the market.

Due to rapid technological innovations leading to super miniaturization of the electronic circuits, as well as advancements in capacitor materials and designs, the electronics industry is responding to the requirements for new products of reduced size, increased functionality and enhanced reliability. There are Neurostimulation products for pain management, hypertension, sleep apnea, brain/spinal cord problems among many others, while implantable devices for heart monitoring, loop recorders, and cochlear advancements, continue to expand. As devices get smaller, making implant surgery simpler for the physician, the one constant that must remain if the device is to deliver its lifesaving or enhancing function, is its reliability.
Medical implantable devices are highly regulated by the countries regulatory bodies to maintain the highest level of reliability. Tight controls placed on the design, development and manufacture of these devices filter right down to the suppliers of the component parts.

Having worked in the field of medical grade capacitors for a number of years, the operational processes, testing and quality assurance provided by KPD brand Novacap is tightly controlled. We work closely with both mature and start-up medical companies to help create, or fine tune, source control drawings (SCD) governing the capacitors supplied. SCD’s provide an engineering description, qualifications and acceptance criteria for the delivery of specialized components for critical applications.

The two main SCD specifications for medical components are MIL-PRF-55681 and MIL-PRF-123. The MIL-PRF-55681 is the one most widely used in the field of medical implantable devices. It defines a mid-K stable dielectric designated as BX. The BX specification has voltage temperature limits in addition to temperature limits of capacitance. ‘Voltage Conditioning’ is performed on 100% of the capacitors, which entails loading them into an oven at 125°C with twice the rated voltage for 100 hours. The post voltage conditioning screening includes 100% Dielectric Withstanding Voltage, Insulation Resistance at 25°C, Capacitance, and Dissipation Factor.

The MIL-PRF-123 specification covers the general requirements for high reliability, general purpose (BX and BR) and temperature stable (BP and BG) ceramic dielectric fixed capacitors, through-hole and SMD and affords an increased reliability level over MIL-PRF-55681. This document includes a 20 cycle Thermal Shock (-55°C to +125°C) prior to the Voltage Conditioning which, as before, entails loading the capacitors into an oven at 125°C with twice the rated voltage. The time the capacitors are left for varies from 168 to 264 hours and are then monitored to determine the failure rate during the last 48 hours of
the test. The requirement per MIL-PRF-123 is a maximum of 0.1% percent defective allowable. Post voltage conditioning screening is similar to that for MIL-PRF-55681 with the exception of insulation resistance conducted at both 25°C and 125°C.

At Novacap, all capacitors are also 100% visually inspected for medical implantable devices. The primary ‘Quality Conformance Inspection’ would be a Group A to either one of the above documents. The Group A testing ensures no maverick lots escape. Environmental Inspections can be performed on a lot basis according to SCD requirements, while Voltage Conditioning is designed to remove any infant mortality or early-failure period capacitors from the lot.

Novacap has over 20 years of experience partnering with implantable device manufacturers and understand the long-term commitment from customers - from engineering sample order, pre-production, regulatory approval right through to full production. The company provides an engineering sample early-on in the process that will reflect the implantable grade in full production. During our long tenure, we have not had a single capacitor failure resulting in explant, thanks to our tight Quality Assurance systems which ensure strict ‘no change rules’ and documentation storage requirements. The flexibility of operating from our state of the art facilities in Valencia (USA) and Suzhou (China), allows KPD to cope with custom designs or unique application needs.

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