MEDICAL BIONICS

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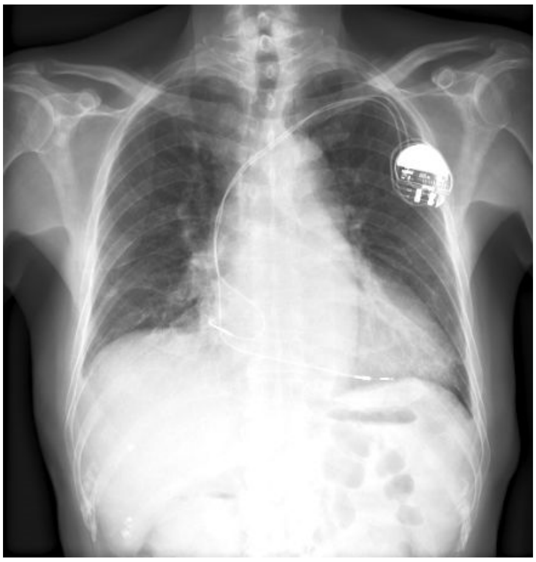
Medical Bionics is a multidisciplinary field of research combining bio(logy) and (electro)nics to develop implantable devices designed to provide long-term safe and effective sensory or motor function following damage to nerve or muscle tissue.



Chest Xray with Pacemaker
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Since the introduction of the first heart pacemakers in the late 1950s there have been a number of bionics devices approved for clinical use, resulting in a dramatic impact on the quality of life of millions of people. Commercially, implantable heart pacemakers and defibrillators are a multi-billion dollar per annum industry with Medtronic Inc. alone having over $5 billion in net sales in 2008. Although the neural prosthesis industry is much younger, with commercial devices first appearing in the late 1970s, this is now a $1.8 billion industry with annual growth rates of 10-15%. Four devices dominate this field; spinal cord stimulators for treatment of chronic pain; cochlear implants that provide auditory cues to the severe-profoundly deaf; Vagus nerve stimulators for control of epilepsy; and Deep Brain Stimulation (DBS) for motor control in Parkinson's disease and essential tremor.

Importantly, there are a large number of devices currently undergoing development, fuelling expectation that this field will undergo major expansion over the next decade. These devices include retinal prostheses to provide visual cues for the blind; Functional Electrical Stimulation (FES) to assist paraplegics stand and walk; DBS to treat severe depression and related psychiatric disorders; vestibular prostheses to assist patients with severe balance disorders; and recording/feedback devices such as brain computer interfaces and peripheral nerve recording arrays to control computer assisted devices including artificial limbs.

While the field is extensive, many of the essential components of these devices are common across applications, including: the use of biocompatible materials; the design of electrode arrays that are mechanically stable and allow safe surgical placement; reliable leadwire assemblies; effective hermetic sealing techniques; versatile low power electronics and safe electrical stimulation strategies. Although

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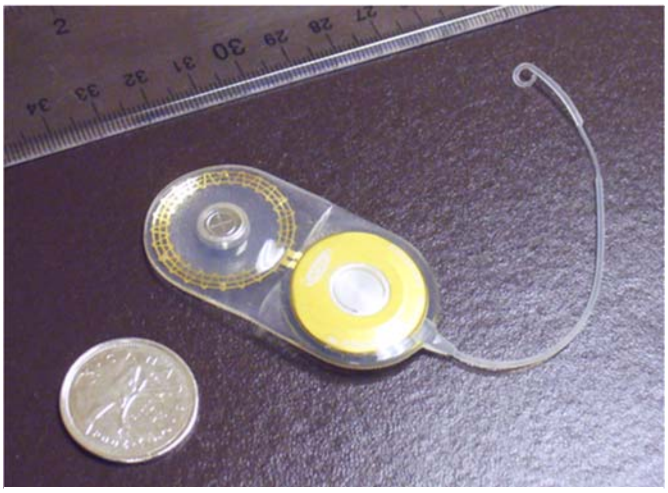
the field was pioneered in the 1950s and 1960s by visionaries such as Graeme Clark, using the available materials and technologies of the time, key improvements in technologies - including low power electronics, improved battery technology, wireless power and data communication, materials science, electrode fabrication and hermetic sealing techniques – are combining with more than 50 years of clinical experience to fuel a new revolution in the development of bionic implants designed for a lifetime of use.



A Cochlear Implant by Advanced Bionics (2009)
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A key design criteria associated with the long-term reliability of any bionic implant is the efficacy of its hermetic seal. These seals are primarily designed to protect the enclosed electronics from biological fluids, but also to protect the surrounding tissue from potentially harmful products leached from the package. The gold standard for hermetic encapsulation of implants is a titanium can sealed using laser welding. Other materials that have been used in implantable devices include (in decreasing order of hermeticity) ceramics; glass; epoxy and silicone. While having good hermetic properties, ceramic and glass are brittle, increasing the risk of breakage associated with an impact injury. An epoxy based hermetic seal is typically confined to use in prototype devices, while silicone is relatively permeable to water molecules.

An electronically active implant requires a source of electrical energy during operation. In existing implantable devices, there are two alternative locations of the energy source in common use. For implants such as heart pacemakers and DBS devices, energy is typically provided by an implanted battery. This battery may be either primary, meaning that it must be replaced when the energy is exhausted, or rechargeable. In the latter case, the battery must be charged periodically, for example using power transferred inductively from an external unit. For other devices, including cochlear implants, energy is provided from an external source whenever the implant is in use. This avoids the need for an implanted battery and the periodic surgical procedure required to replace it. An inductive link between the external source and the implant is generally suitable for the power supply across which energy is transferred by means of a radio-frequency carrier signal.

Bionics is by necessity multidisciplinary; relying on both fundamental and technological advances in science, engineering and clinical research. There are many potential challenges and new technologies that can influence the success of future bionic devices including; the development of objective fitting technologies, allowing devices with large numbers of electrodes to be programmed for an individual patient's needs; the provision of feedback controls to allow, for example, a patient to adjust the force used in grasping via a robotic limb; the potential to power implanted devices using energy derived from within the body; the use of optical stimulation to provide greater control over the spatial extent of excitation patterns; to maximize the plastic brain in order to enhance the clinical performance of neural prostheses; the development of more efficient inductive links for power and data transmission; the development of improved battery technology for greater capacity in both primary and rechargeable batteries, and; the development of new biomaterials for use in electrodes and hermetic seals.

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