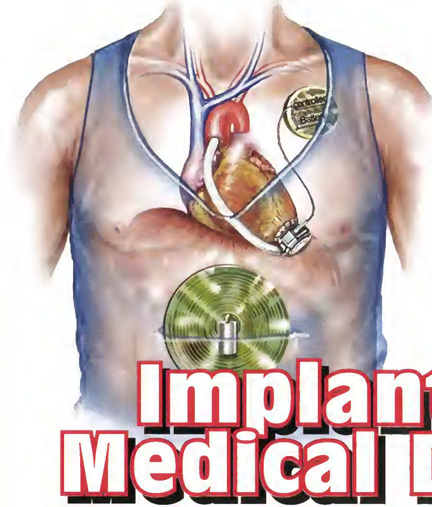


More and more implantable electronic medical devices are being developed to correct deficiencies in bodily function due to disease, accident or simply wear'n'tear. They can range from pacemakers to devices to help bowel function, control epileptic seizures, to block back pain and a wide range of other uses.

By
Dr David Maddison

Implantable Medical Devices

There are hundreds, if not thousands, of implants available. Most people would be familiar with artificial hips and knees, heart pacemakers, coronary stents and eye lenses (for cataract surgery), along with a wide variety of screws and plates used in orthopaedic repairs.

But in this article we will focus on devices that embody some form of electronics rather than those of a purely mechanical nature.

One of the most simple (in principle) implantable electronic devices is the cardiac pacemaker.

The heart is a specialised muscle that is controlled by electricity within its tissues that flows in waves controlled by its natural pacemaker, causing the heart tissue to contract in a certain sequence and then repeat itself.

If this flow is disrupted due to disease, an artificial pacemaker may be required to restore normal function.

The artificial cardiac pacemaker was the first implantable electronic prosthesis and Australia played a significant role in its development in the late 1960s (see later panel on Telectronics).

In its most simple prototypical implementation, the cardiac pacemaker is a simple pulse generator and typical values might be a 5V, 0.5ms pulse, 70 times a minute.

In modern pacemakers, these basic values can be varied according to the requirements of the patient and physical activity.

A related type of implanted prosthesis is a cardioverter for patients whose heart is prone to dangerously fast rhythms. This device detects potentially lethal heart conditions and delivers a shock to reset the heart to a natural rhythm.

The cardioverter may also be combined with a cardiac pacemaker as a single device.

In this article, we will discuss the above and a variety of other implanted electronic devices. We won't be looking at retinal implants as they were covered in the "The Bionic Eye" articles in the June & July 2015 issues.

Nor will we discuss electro-cortical arrays to interface with the brain as these were covered in "Interfacing to the Brain" in January 2015.

A number of other implanted electronic devices, some of them amateur built, were also discussed in the "Biohacking" article of August 2015. Previews of these features can be viewed at siliconchip.com.au – click on the "Articles" or "Browse" tab.

Cochlear implants

The cochlear implant was also developed in Australia, to give people who are profoundly deaf a useful sense of hearing which can dramatically improve their quality of life.

In a normal ear, specialised hair cells in the cochlea respond to sound waves and cause the cochlear nerve to send signals to the brain. If these cells are damaged, hearing is affected.

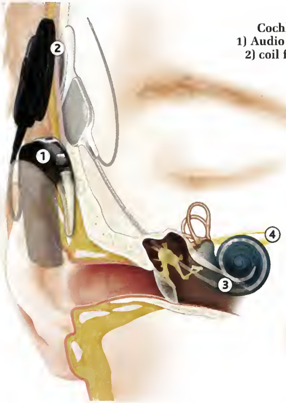
In this case, an electrode array is placed within the spiral cavity of the cochlea to stimulate the cochlear nerve when sounds are present. The cochlear implant provides useful hearing although it is not as good as natural hearing, as would be expected.

The implant consists of an electrode array which, in a particular cochlear model, contains 24 electrodes, a wireless receiver and an earth wire.

Externally, there is a microphone, an audio processor that optimises speech signals for transmission and a wireless transmitter that couples to the implanted wireless receiver coil.

As improved audio processors and software are developed, the external part of the device can be easily upgraded.

For patients who have cochleas that are so damaged that they are not suitable for a conventional cochlea implant or other conditions, Cochlear have developed a brain stem implant described below.



Anatomical positioning of Cochlear Nucleus Profile model. 1) Audio processor and microphone 2) coil for wireless transmission of impulses through the skin 3) cochlear lead 4) cochlea.

Auditory brain stem implants

An auditory brain stem implant is designed for patients who are unsuitable for a cochlea implant.

For example, they might have damage to both auditory nerves (more correctly the vestibulocochlear nerve), damage to the cochlea due to tumours, or a congenital absence of the cochlea.

The implant is used to electrically stimulate part of the brain stem which is responsible for receiving information from the auditory nerve and relaying it to the rest of the brain, the cochlear nucleus.

The brain stem implant contains 21 electrodes in an 8 x 3mm array. At the time of implant, each electrode is tested to see which causes auditory stimulation, as opposed to non-auditory stimulation.

Those electrodes that don't provide auditory stimulation are turned off. These 21 electrodes replace the 30,000 fibres of the auditory nerve.

The hearing that results from having an auditory brain stem implant is not as good as that of a cochlear implant. It provides more an indication of the presence or absence of sound and it becomes an aid to lip reading.

However users do report being able to distinguish more and more sounds as they and their brains adjust to it, with continued improvement over years.

See https://youtu.be/G3KOEEHSkPk "*What is a brainstem implant?*"

Bone growth stimulators

It has long been known that bioelectricity has a crucial role in bone growth. When a bone fracture does not heal naturally, it can be artificially stimulated to do so.

This is done by the application of a small DC current, of the order of 20μA, across the fracture site.

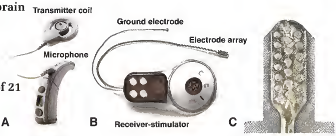
A cathode wire is placed at the fracture site and connected to a power supply implanted just beneath the skin. The metal case of the supply provides the anode connection and hopefully causes bone growth at the fracture.

After healing, the power supply is removed but the cathode wire is left as it usually becomes incorporated into the bone and cannot easily be removed.

In one variant of the device, where spinal fusion is required, two cathode electrodes are fitted. One such model is the Biomet SpF. Its battery and electronics are contained within a titanium case, with a platinum coating in the region of the anode.

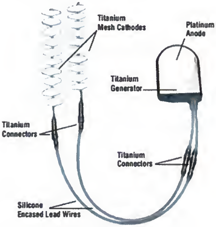
Its lithium manganese dioxide battery lasts at least six months and the leads that go to the cathode are silicone-insulated, with brazed stranded stainless steel wires. The cathode electrodes are made of titanium and connected to the power supply via titanium connectors.


Biomet OsteoGen implantable bone growth stimulator.

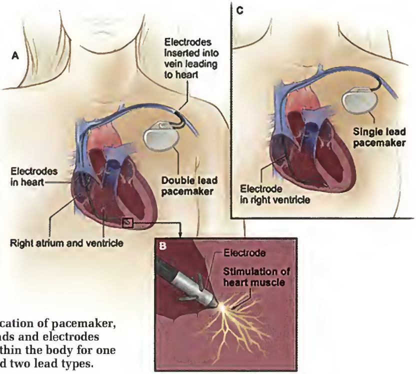


Australian Cochlear Ltd Nucleus 24 auditory brain stem implant. A) The external part of the device worn by the patient. B) The implanted part of the device. C) Detail of 21 electrode array that is implanted into the brain stem.

SpF® Implantable Spinal Fusion Stimulator



Biomet SpF bone growth stimulator for spinal fusion applications.



Location of pacemaker, leads and electrodes within the body for one and two lead types.

Cardiac Pacemakers

As mentioned above, the heart contains a natural pacemaker which regulates it but this natural pacemaker has some redundancy.

The primary pacemaker of the heart is contained within the sinoatrial (SA) node and typically leads to a heart rate of 60 to 100 beats per minute.

If the SA node fails, such as through disease, there is a secondary pacemaker contained within the atrioventricular (AV) node. In the event of a non-functional SA node these cells cause the heart to beat at 40 to 60 beats per minute and will allow a person to live, although their physical activity may be restricted and they will likely need to have an artificial pacemaker fitted.

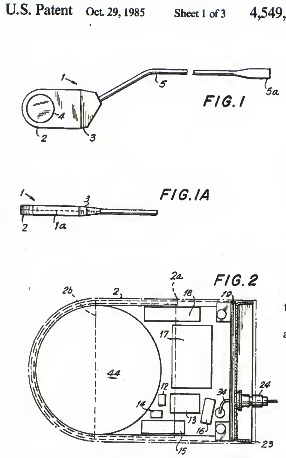


Image from Australian company Telectronics' 1985 US patent for bone growth stimulator with titanium case. Fig.1 shows the electronics package and power source on the left and the cathode lead on the right. Item 5a is a socket into which is plugged a lead connected to the fracture site. Fig. 1A is an elevation view of the device and Fig.2 is a cutaway view of the device showing battery (44), printed circuit board and electrical feed through arrangement.

The artificial pacemaker delivers electrical pulses to the heart in one or more locations, via leads inserted into the heart or, in the latest technology, with a leadless pacemaker.

In the leaded pacemaker, a pulse generator is implanted beneath the skin and leads are inserted into the heart via the subclavian vein.

The leadless pacemaker is implanted within the heart or on its external surface.

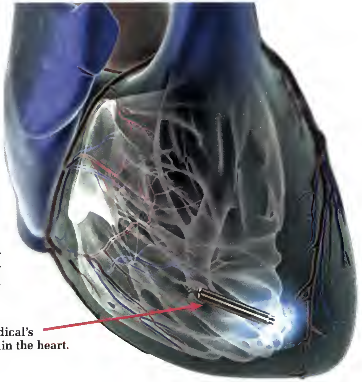
Modern pacemakers are all wirelessly programmable, while some earlier models were programmed by stroking a bar magnet across the surface of the device to open and close a reed switch.

Like many modern electronic systems, modern pacemakers have an event logging system to record changes in cardiac rhythms and other system events.

In one case in Melbourne, reported in the Journal of Pacing and Clinical Electrophysiology in 2002, a pacemaker record was instrumental in solving a murder case.

Two days after a man was murdered, his pacemaker was analysed and it

(Above): Nanostim leadless pacemaker from St. Jude Medical. It is smaller than a AAA battery and does not need a lead as it is implanted directly within the heart.



(Right): the location of St. Jude Medical's leadless Nanostim pacemaker within the heart.

was used to determine the time the man awoke, the time he spent walking around, his attack by an intruder and the time he was finally killed.

A total of 37 hours of data was retrieved from the pacemaker of which 1 hour and 13 minutes was intensively examined to determine the sequence of events and the exact time of the man's death.

For more information on conventional cardiac pacemakers see https://youtu.be/lSdl2jVfpxs "*Permanent Cardiac Pacemaker - NIK NIKAM, MD*".

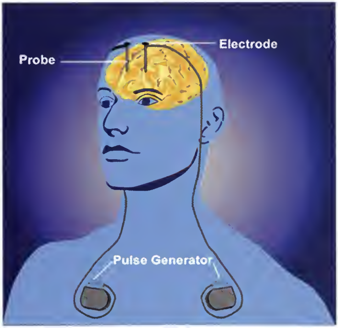
For a video of the implant of the leadless pacemaker see https://youtu.be/tUtg5p64Y-A "*Leadless Cardiac Pacemaker.*"

For a video of an amateur tear-down of an old pacemaker which shows construction techniques and componentry see https://youtu.be/kUsP23pBRXk "*Pacemaker teardown*".

The first development of an external cardiac pacemaker in the world was done by University of Sydney physics tutor Edgar Booth for Dr Mark Lidwell and was first used to revive a stillborn infant in 1926 at the Crown Street Women's Hospital in Sydney.

Deep brain stimulator

Deep brain stimulation (DBS) involves providing electrical stimulation to selected parts of the brain to treat a number of conditions, such as chronic pain, dystonia, essential tremor, major depression, obsessive-compulsive disorder and Parkinson's disease.



(Left): diagram showing location of pulse generators, leads and electrodes for deep brain stimulation. (At right): St. Jude Medical Infinity deep brain stimulator pulse generator unit and section of lead. The lead electrodes don't go all the way around the circumference of the lead but are only on certain sections, giving some directionality to the electric field. The device can be programmed with an iPhone.

Partial cutaway view of Boston Scientific Dynagen implantable cardioverter defibrillator, which features an extended battery life of up to nearly 12 years. The leads are not shown. This device is wirelessly programmable. This model also acts as a rate responsive pacemaker and has an accelerometer to detect levels of patient activity. Its dimensions are 54 x 78 x 10mm and it weighs around 70g. It can deliver a shock energy of up to 35 joules. The long life is enabled by the Li/MnO2 battery chemistry with a usable capacity of 1.9Ahr.

See the video https://youtu.be/abHuHFt_izI *"Deep Brain Stimulation .... How does DBS work"*

Doctor in a cell

A "doctor in a cell" is a biomolecular DNA-based computer concept conceived by Professor Ehud Shapiro of the Weizmann Institute of Science in Israel.

The long term vision is to produce nano-scale biological computers programmed with medical knowledge that would be injected into a person and roam within the body, detecting and treating disease with the targeted delivery of a specific drug molecule.

Small steps toward this ambitious goal have already been demonstrated in the test tube, such as

1) molecular based automatons controlled by DNA "software";
2) an automaton using DNA as "fuel";
3) a molecular automaton which can follow rules and
4) implementing input and output mechanisms such as detecting a cancer cell (input) and delivering a drug molecule to target the cancer cell (output).

In 2009 Shapiro and a student demonstrated an "autonomous programmable molecular system" based on DNA which was capable of performing logical deductions, using a simple programming language.

The team has also developed a compiler to translate between high level code and the specific DNA sequences to implement that code.

In 2012 Shapiro developed a "genetic device" that can be placed in a bacterium, which can search for specific abnormalities and mount a response. A possible response might be to cause cell death in the event abnormalities are detected.

Implantable cardioverter defibrillator (ICD)

An ICD is a cardiac pacemaker that continuously monitors a person's heart rhythm and when it detects an abnormal pattern such as a dangerously high heart rate, it delivers an electric shock to the heart muscle to "reset" it to a normal rhythm.

The specific conditions that cause rapid abnormal heart beat are ventricular fibrillation – uncoordinated contraction of the ventricles of the heart and ventricular tachycardia – an abnormal rapid heart beat originating in the ventricles. These conditions are usually fatal if not treated as soon as they occur.

ICDs can perform several functions: in anti-tachycardia pacing, a series of small electrical pulses are delivered to a heart that is beating too fast, in order to restore normal rhythm. Typically, tachycardia is considered to be a resting heart rate of over 100 beats per minut in an adult.

In cardioversion, a low energy electrical shock is applied to the heart at a certain point in the cardiac cycle, to restore normal rhythm.

By contrast, defibrillation applies a high energy electrical shock at a random moment in the cardiac cycle, to a dangerously fast-beating heart to restore normal rhythm. This is similar to the function of defibrillators used by ambulance personnel, in hospital emergency rooms and now becoming commonplace in most sporting clubs, schools, offices and factories (See "Defibrillators Save Lives", Silicon Chip February 2016).

Finally, bradycardia pacing, as in a normal pacemaker, speeds up a heart that is beating too slowly.

ICDs are available in two types, those in which leads are inserted into

MRI and other sources of interference

Because of the possible presence of magnetic materials, certain implants are incompatible with MRI scans due to the strong magnetic fields generated. The high magnetic fields can also interfere with device electronics.

Increasingly, however, manufacturers are designing devices that are compatible with MRI machines, although some still require a reduction in the magnetic field strength used in the scan.

Interference with device electronics may also occur due to medical equipment used in operations such as use of an external defibrillator, RF catheter ablation, electrocautery, radiation from radiotherapy, lithotripsy (shock wave breakup of kidney stones, for example) and mobile phones.

All these sources of interference must be taken into account when implantable devices are designed.

the heart or a type which is installed beneath the skin (subcutaneously) with a wire placed above the rib cage.

To see an animation of the implant procedure for the subcutaneous device, go to https://youtu.be/VgHf0lRwMnw "*New ICD implanted subcutaneously*".

The production of these devices has only been possible due to the development of very small, high energy capacitors that have enabled the units to be miniaturised.

There is an amateur video of a tear-down of an old ICD (purchased on ebay!) which will reveal some of the construction and componentry at https://youtu.be/Gzw6c3Bi4TU "*Implantable defibrillator teardown*".

Note the triggering of the critical malfunction alarm during the tear-down process.

Implantable loop recorder

The implantable loop recorder is a device that stores episodes of abnormal heart activity in a memory "loop", ie, the memory is filled and the oldest data is erased to make way for new data.

Abnormal cardiac episodes can be either recorded automatically or by patient activation of the device by a remote control.

The device is used when a patient's abnormal heart activity is not revealed by normal short-term clinical tests and extended monitoring is required to reveal evidence of the condition.

One particular model of device is the Medtronic Reveal LINQ Insertable Cardiac Monitoring System. It is tiny – with a volume of about 1cc or about a third that of an AAA battery – and it has a battery life of about 3 years. It is able to store 30 minutes of patient activated episodes or 27 minutes of

Medtronic Reveal LINQ superimposed on a recorded ECG waveform. It is around the length of a AAA battery but one third the volume, smaller than a typical USB flash drive.

Telectronics – Australian pioneers in pacemakers

Telectronics was started by Australian medical device pioneer Noel Gray in 1963 to manufacture a variety of medical electronic equipment including the implanted cardiac pacemaker.

Telectronics came up with many innovations, including the hermetically sealed welded titanium case in 1969, to replace the standard epoxy encapsulation at the time that was prone to moisture ingress along the lead ports. An important part of the titanium case was the electrical lead-throughs. These involved ceramic bushes which were hermetically sealed to the titanium by a process of metal-ceramic bonding. This process was developed by Taylor Ceramic Engineering in Mortdale, Sydney.

Titanium encapsulation is now the basis of many of the implantable devices described in this article. A process to sinter tiny platinum beads together for one type of pacing lead tip was also developed by Taylor.

Another innovation by Noel Gray was the determination that the pacing pulse could be reduced to 0.5ms from the standard 2ms pulse, as well as reducing the voltage from a nominal 7V to 5V. This improved battery life and also ensured more efficient pacing.

Noel Gray also established the cause of problems with mercury cells used in pacemakers before the development of lithium cells. These were prone to premature failure. It was found that when the batteries were sent via air from the US to Australia they were transported in the unpressurised cargo hold of an aircraft and the low pressure caused damage to the cells.

Thereafter pilots were asked to carry a briefcase containing the batteries on board the aircraft where they would be kept warm and at normal cabin pressure. When they arrived in Australia they were X-rayed to ensure quality.

According to the recollection of former colleagues, Noel Gray also made an experimental pacemaker when he worked at Kriesler in 1956, although this device was not implanted.

Among his visionary ideas was the leadless pacemaker and his belief that the usual location of attaching the pacing leads in the ventricle of the heart was not optimal. It was subsequently proven in 2004 by Dr Tim Lasky of Medtronic that this supposition was correct and the ideal site for pacing leads was the left ventricular apex.

The leadless pacemaker was to be implanted on the outside of the heart not the interior, as per the commercially available device described elsewhere in this article. Noel Gray's patent for the leadless pacemaker, which was proposed to be encased in either plastic or a ceramic material, can be see at https://docs.google.com/viewer?url=patentimages.storage.googleapis.com/pdfs/US5674259.pdf

The custom-made integrated circuits used in later models of Telectronics pacemakers were made by AWA in Sydney to rugged military specifications.

In addition to pacemakers, Telectronics also made bone growth stimulators for a time and a patent in this area is mentioned elsewhere in this article.

An early 1974 Telectronics titanium case pacemaker can be seen at http://from.ph/55591 and a model of a Telectronics "Guardian" implantable defibrillator can be see at http://from.ph/82663

Telectronics was taken over by Pacific Dunlop in 1994, who then sold the assets to the American St. Jude Medical Inc. in 1996. There are no longer any pacemaker production facilities in Australia.

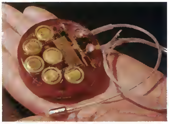
For those interested in more details, a history of Telectronics was published in 1993 by Christopher and Noel Gray called "Telectronics, the early years", ISBN 0646151347.

The Author once worked at Telectronics at Lane Cove, NSW, in 1984. In that time he was involved in lead development and obtained the following US patents:

https://docs.google.com/viewer?url=patentimages.storage.googleapis.com/pdfs/US4798206.pdf

https://docs.google.com/viewer?url=patentimages.storage.googleapis.com/pdfs/US5330520.pdf

https://docs.google.com/viewer?url=patentimages.storage.googleapis.com/-pdfs/US5554176.pdf



An early pacemaker model P4 by Telectronics. Photo courtesy Christoper Gray, son of Telectronics founder Noel Gray.

automatically detected episodes.

The data can be wirelessly downloaded for analysis by a patient at home and automatically transferred to the medical specialist.

The device is inserted beneath the skin with an insertion tool into a small cut in the chest.

Implantable gastric electrical stimulator

There is a condition known as gastroparesis which involves partial paralysis of the stomach and results in an inability to properly move food out of it and into the small intestine.

Normally, the muscles of the stomach would contract to push food onward (peristalsis). These contractions can be affected if the vagus nerve becomes damaged – by diabetes mellitus, for example.

Symptoms of gastroparesis include chronic nausea, vomiting and a feeling of fullness after just a few mouthfuls of food.

The condition can be treated with alterations to the diet or drugs but if these don't provide a satisfactory result, a gastric stimulator implant is considered.

The device is implanted beneath the skin of the abdomen and two leads run through the abdominal wall and then attached to the exterior of the stomach. The leads are connected by a keyhole surgery.

The natural contractual rhythm of the stomach is about three contractions per minute but the rate provided by the gastric stimulator is about 12 contractions per minute.

To give an idea of the type of electrical stimulation provided by the Medtronic device, it can provide electrical pulses up to 10.5V in amplitude with a pulse width of between 60 and 450µs at between 2 and 130Hz.

In its default setting it remains on for 0.1 second and then turns off for 5 seconds. Its power source is a hybrid cathode silver vanadium oxide cell with a capacity of 4.5Ah.

Implanted insulin pump

Implanted insulin pumps contain a reservoir of insulin and control electronics for controlled delivery of the insulin into the body.

This is periodically refilled by injecting a new supply through the skin into the chamber of the device.

However, these devices remain relatively rare, mainly due to unpopularity with patients as they cause a large bulge in the skin at the implant site and there are many technical and other problems.

Medtronic Synchromed II intrathecal pump for drug delivery. It can hold either 20cc or 40cc of drug product and has a battery life of 4 to 7 years. The drug delivery schedule is wirelessly programmable. Drug replacement is typically made through the skin every one to two months.

Targeted drug delivery pump

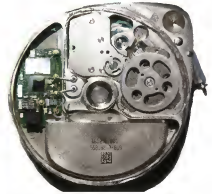
A targeted drug delivery pump delivers pain or spasticity-relieving medication directly into the fluid around the spine (also known as the intrathecal space).

Hence these devices are also referred to as intrathecal pumps. The pump and catheter are implanted beneath the skin; the end of the catheter goes into the intrathecal space.

See https://youtu.be/IFzrjOctQC8

Medtronic Enterra II gastric electrical stimulator. The device is shown without the leads that are attached to the stomach and without the external programming unit. Note the similarity of construction to the cardiac pacemaker. This device is 55mm tall, 60mm in length and weighs 45g.

X-ray showing position of gastric stimulator unit and leads going to stomach. Within the gastric stimulator can be seen the battery on the right and the control electronics on the left.



Cutaway view of Medtronic Synchromed II showing battery at bottom, electronics package on left, mechanical pump at top right and self-sealing silicone plug into which replacement drugs are injected at centre.

(Above): VeriTeQ human implantable RFID chip. The small coil visible in the device is the antenna.

(Right): method of reading the VeriTeQ RFID device.

"*Intrathecal Pump Implantation*".

MedRadio & MICS/MEDS

The Medical Device Radiocommunications Service (MedRadio) and MICS/MEDS (Medical Implant Communications Service and Medical Data Service) are almost identical US and European specifications, which operate at frequencies in the 400MHz and 2360-2400MHz bands specifically for communication between an implanted medical device and an external device.

In the 400MHz band, transmit power from the internal device is set at 25μW.

The higher frequency band is for use in the Medical Body Area Network or MBAN which is used by implanted, surface-mounted and wearable devices to communicate with each other.

It is not clear from the ACMA (Australian Communications and Media Authority) website whether this protocol has been implemented in Australia but there are several letters on the site (dated 2009 and 2010) from medical device manufactures requesting that they do so.

RFID implants

VeriTeQ make an RFID (radio frequency identification) chip specifically approved for human implant; it is similar to those used in animals. The chip is about the size of a grain of rice and is inserted beneath the skin by injection. The chip is encoded with a unique 16-digit number which can be used to access a person's medical record from a password-protected database.

The chip does not allow the person possessing it to be tracked, a common concern of users. The only way this could be done would be by the installation of millions of readers everywhere people might go. The device communicates at between 30 and 500 kHz; the manufacturer does not specify the precise frequency.

As with typical RFIDs, the device is passive, with no internal battery and is powered from the radio signal received from the reader. It can be read at a distance of between 30cm and 3m. Thousands of people have had the device implanted.

VeriTeQ is also developing elements of this technology to be incorporated into other implanted medical devices, in order to be able to accurately identify them with a unique number. The company has also developed an implanted temperature sensor chip that can be used to monitor tissue temperatures during radiation treatment.

This same chip can also be implanted in pets that may otherwise be resistant to having their temperature taken by the conventional method. An owner or vet could simply interrogate the chip to determine the animal's temperature to see whether treatment is required.

Incidentally, there are now many low-cost tiny devices, externally-worn (eg, around the neck) which *can* be used to track people, such as children, those suffering from dementia and even pets. They can be used in conjunction with a mobile phone to locate a person very accurately (Search for "trackr" on ebay, for example).

Neurostimulation for epilepsy

Around 40% of patients with focal epilepsy have seizures that are resistant to drugs. According to one 2014 study, using a neurostimulation device can reduce these seizures by 53% after two years and 66% after five years.

The location of the seizures is first determined by monitoring brainwaves

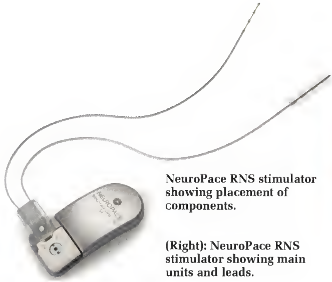
Security of implanted devices against hackers

With the wireless programming capability of many devices – and this feature being incorporated into more devices all the time, the security against a malicious individual taking control of the devices has become a serious concern.

A vulnerability in an implanted insulin pump was demonstrated in 2011 by Barnaby Jack whereby control of the device was demonstrated to be possible from 100 metres away; similarly in 2012 Barnaby Jack demonstrated that a laptop could be used to control an implantable defibrillator from 10-15 metres away.

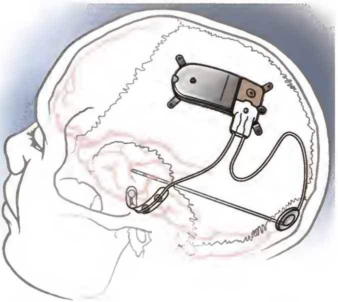
The concern with hackers taking control of devices was real and US Vice President Dick Cheney even had the wireless functionality of his implantable defibrillator disabledwhen it was installed in 2007 before Barnaby Jack demonstrated that taking control of such a device was possible.

Dick Cheney's comments on the issue along with a fictitious scene from the TV series "Homeland" where such an assassination attempt is portrayed can be seen at https://youtu.be/N-2iyUpnUwY "*Dick Cheney Worried About Remote Assassination Attempt Via Pacemaker*"



NeuroPace RNS stimulator showing placement of components.

(Right): NeuroPace RNS stimulator showing main units and leads.



by means of electroencephalography during a seizure.

When the seizure site (or sites) has been located, electrodes are implanted and connected to the neurostimulator device.

The neurostimulator constantly monitors brainwaves and when abnormal activity is detected, an appropriate series of electrical pulses is delivered. In this way, abnormal activity might be detected and corrected, even before a patient is aware of anything being amiss.

In the NeuroPace RNS system, neurological data can be wirelessly collected at home and transmitted to the treating doctor, who is then able to make adjustments to the device if necessary.

Sacral nerve stimulator

The sacral nerves S2-S4 control functions within the pelvic floor area such as those for the bladder and the bowel. If there is a disorder causing a lack of effective communication between the brain and the sacral nerves, incontinence can result.

Stimulation of the sacral nerves to replace the missing or defective signal from the brain can help restore continence.

The Medtronic InterStim II sacral nerve stimulator is an example of one such stimulator device The nerves are stimulated by a lead that is implanted adjacent to them, near the base of the spine. Typical stimulation parameters are a pulse width of 180-240μs at a rate 10-14Hz, an amplitude of up to 8.5V and off/on cycle of 8 to 16 seconds. There are four electrodes in a single lead. The battery has a capacity of 1.3Ah, giving a device life of between 2.9 and 5.4 years, depending on stimulation parameters. As well, the device can be wirelessly programmed.

A lumbar anterior root stimulator is a similar type of device but as the name suggests, it stimulates the lumbar nerves.

See https://youtu.be/ONaa8d96m8Q "*Overview of Sacral Nerve Stimulation for Urinary Control*".

Spinal cord stimulator to block pain

A spinal cord stimulator delivers electrical impulses to the spinal cord in order to block the transmission of pain signals. It does not eliminate the actual cause of the pain.

Electrodes are placed within the spinal canal in the epidural space and these are connected to a pacemaker-like pulse generator implanted subcutaneously within the lower abdominal or gluteal region (buttocks).

The pulse generator is wirelessly programmable and in addition, the patient is also able to control some of the device's settings.

Many different types of electrical stimulation patterns are possible, including constant current, constant voltage or variable current and voltage as well as different waveform patterns. A typical pulse for stimulation is 100 to 400μs with a frequency from 20 to 120Hz.

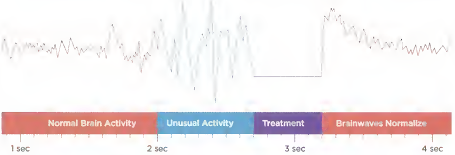
See https://youtu.be/ctTSivqcgoY "*Spinal Cord Stimulation Overview*".

Vagus nerve stimulator

A vagus nerve stimulator provides an electrical pulse to the vagus nerve of about 30 seconds duration every 3-5 minutes. It is used to treat certain forms of epilepsy and treatment-resistant depression. See https://youtu.be/rphsTyMdA2A "*Cyberonics / VNS / The VNS Therapy System*".

Wireless power transmission and artificial hearts

Lithium batteries might be adequate for many years' operation of devices such as pacemakers but cannot supply nearly enough power for an implant



The NeuroPace device monitors brainwaves for abnormal activity and when it is detected it delivers appropriate electrical pulses to normalise the activity.

such as an artificial heart or left ventricular assist device (LVAD).

An LVAD does not replace a heart but is designed to provide assistance to improve the function of a diseased heart.

Conventional approaches to artificial hearts or LVADs involve the use of either electrical or pneumatic leads that pass through the skin to an external power source.

Any permanent penetration of the skin is problematic because of the high risk of infection. An alternative way to deliver electric power into the body is via wireless transmission, similar to what you would find in consumer devices such as electric toothbrushes.

Traditional approaches to wireless power transmission such as inductive coupling through the skin require very accurate alignment of a pair of transmission and receive coils and it works only over distances of a few millimetres.

Overheating of flesh is also a potential problem, so this approach is not suitable for delivering power into the human body subject to constant movement.

The Free-range Resonant Electrical Energy Delivery (FREE-D) wireless power system is designed to provide wireless power to an LVAD over metre distances.

There is a receive resonator coil implanted in a patient's body and there are external power transmission coils which may be installed in a vest worn by the patient.

Alternatively, in a home environment power transmission coils might be installed in specific rooms, or even throughout the house, enabling the patient to not wear the vest.

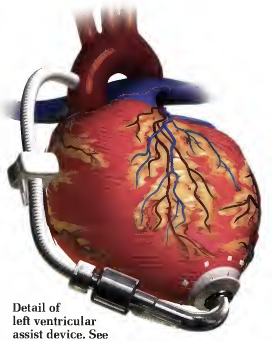
The FREE-D system is based on the Wireless Resonant Energy Link (WREL).

This system can transmit large amounts of power (up to hundreds of watts, far more than is required for a LVAD) at reasonable distances (of around one metre).

It works even when the transmit and receive resonators are in poor misalignment and maintains high power transmission even as the range and load varies, as it uses adaptive tuning techniques.

Uniquely, there is a certain "magic" regime, as the inventors call it, where efficiency does not fall with distance.

For more information see the videos at https://youtu.be/AMgnQ-NHOZk "*Wireless Power Transfer (WREL) - Auto-tuning and relay resonators*" and the first 28 minutes 40 seconds of https://youtu.be/6UfVLSYz33g "*Cutting the Cord: Wireless Power for Implantable Devices*". **SC**



Detail of left ventricular assist device. See illustration on page 22 which shows location of reserve battery and electronics pack and wireless power transmission coil for this device.

Nuclear powered hearts and pacemakers

There were serious efforts to build an atomic-powered artificial heart in the US in the 1960s.

This shows how small a nuclear power supply can be made and how useful it could be. The device was to be powered by a radioisotope thermoelectric generator which produces electricity from heat derived from the radioactive decay of plutonium-238. This is the same type of nuclear power generator used in all of NASA's nuclear powered spacecraft.

A nuclear powered heart would possibly be viable, assuming any radiation shielding, mechanical aspects of the heart design and biocompatibility issues were resolved. However the project did not go ahead as there were concerns with radiation levels in patients.

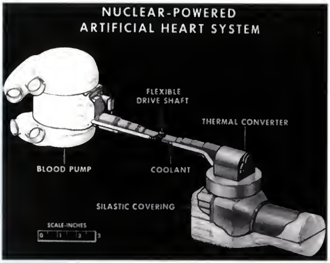
It was also thought that terrorists might kidnap people with atomic-powered hearts, remove them and use the nuclear material as a weapon to spread radioactive contamination, for example.

The plutonium-238 could not be used to make a nuclear explosive device however, as it is too unstable and generates too much heat.

While the atomic heart did not go ahead, a nuclear powered pacemaker did, which was first experimentally implanted in a dog in 1969 before being approved for human use. There are still people alive today who have nuclear powered plutonium-238 pacemakers.

The devices will still operate after 88 years when half the original plutonium has decayed, compared to a modern lithium battery powered devices which lasts 10-15 years.

The nuclear pacemakers were designed to withstand gunshots and cremation. You can see some pictures of these devices along with instructions at http://osrp.lanl.gov/Documents/Pacemaker%20Fact%20Sheet.pdf "*What to do if you find a nuclear-powered cardiac pacemaker*"



Another type of nuclear-powered pacemaker that was used is based on the decay of promethium-147 which emits electrons and these interact with a specially designed p-n junction to produce electricity in much the same way as when photons strike a solar cell.

You can visit http://www.prutchi.com/pdf/implantable/nuclear_pacemakers.pdf for more information on these devices.