

Melbourne Biomedical Precinct.

Research Platform 07

Medical devices and implantables

Defining medical devices and implantables

A medical device is any instrument, apparatus or appliance used to diagnose, prevent or treat injury or disease. Medical devices range in complexity from an app on your smartphone through to computerised diagnostic machines. Implantable devices include an artificial hip, pacemaker or Cochlear bionic ear. Medical and implantable devices can be used for a wide range of applications, such as diagnostics (for example, a blood pressure monitor) or to replace injured parts of the body (for example, a 3D-printed shinbone). Some can restore or improve function, such as a robotic prosthetic arm.

The Melbourne Biomedical Precinct is ready to capitalise on the spectacular growth in medical devices and implantables that are changing the lives of patients who have limited treatment options. This offers potential to spark a new advanced manufacturing industry in Victoria.

Medical device technology has advanced rapidly in recent years, thanks to significant improvements in advanced manufacturing, computing power, machine learning and battery technology, along with significant reductions in cost. This means that equipment that once required an entire laboratory to house and operate can now be inexpensive and compact enough to wear – or even implanted into the body.

An example of the capability of modern medical devices is the Cochlear bionic ear, which was developed in Melbourne by Professor Graeme Clark. The Cochlear ear has restored hearing to over 100,000 people worldwide and spawned a local company with a value of more than \$9 billion. The next 20 years will likely see the emergence of many new high-tech medical device start-ups and it is possible the next billion dollar 'Cochlear' could be based in Melbourne. A wide range of new medical devices and implantables are currently being developed in the Melbourne Biomedical Precinct to treat diseases and conditions that have limited treatment options. These include spinal cord injury, epilepsy, stroke, blindness and neurological degenerative conditions such as Parkinson's disease and even mental illness. Researchers in the United States are currently testing brain implants that deliver electrical impulses to treat mental illness. In November 2017 the Food and Drug Administration approved the first 'digital' pill that can send messages to smart phones about a patient's compliance.

One flagship project within the Melbourne Biomedical Precinct is the development of the bionic eye. This device will help restore sight and allow the blind to recognise faces and even read. The first prototype was implanted in a patient in 2012 and the latest version is now being developed in the Melbourne Biomedical Precinct.

Another project is developing the Stentrode, a device the size of a matchstick, which is implanted in a blood vessel next to the brain's control centre for movement. It will one day enable people to control robotic limbs and powered exoskeletons simply by thought. The Stentrode has the potential to transform the lives of amputees, as well as people with spinal injuries, motor neurone disease and other conditions. Human trials will begin in 2018. Sixteen different departments at The University of Melbourne participated in the development of the Stentrode.

World-first clinical trials are also set to begin in Melbourne on a device that will deliver medication directly to the brain to control epilepsy, which is the world's most common serious brain disorder, affecting around 250,000 Australians. The device uses an implantable pump in the stomach, connected to the brain via a tiny tube, and promises to provide a more potent response with fewer side effects than current epilepsy drugs. Another device targeted at epilepsy patients is implanted under the scalp and can continuously monitor brain activity to detect or predict a seizure. This will significantly improve the quality of care for epilepsy patients.

One key advantage of medical devices is that they may be substantially cheaper and quicker to bring to market compared with conventional drugs and biological therapies. A typical drug takes well over a decade and about \$2 billion to progress to market. A medical device generally takes half that time and costs a fraction as much to bring to market. This significantly lowers the cost of commercialising devices and means a more rapid return on investment.

Current strengths and opportunities

Interdisciplinary expertise

The Melbourne Biomedical Precinct is home to world-class researchers in fields contributing to the development of medical devices, including bioengineering, data analytics, artificial intelligence and advanced manufacturing. This includes The University of Melbourne's recently established Graeme Clark Institute for Biomedical Engineering.

Collaboration

Strong collaborative ties are building among the research organisations and medical technology companies within the Melbourne Biomedical Precinct and beyond, including with the manufacturing capability across wider Melbourne. Medical devices are already a multi-billion dollar industry worldwide, worth over \$200 billion in the US. Developing medical devices and implantables requires expertise from a wide range of fields, making strong interdisciplinary collaboration across the Melbourne Biomedical Precinct essential.

Supporting business growth

Brand-new facilities for the Aikenhead Centre for Medical Discovery in the Melbourne Biomedical Precinct are in planning for 2021. Aikenhead is the first hospital-based interdisciplinary biomedical engineering research and education centre in Australia. It could also serve an incubator function by attracting start-up medical technology companies and facilitating better collaboration, commercialisation and investment within Victoria.

Future opportunities

Growth of new disciplines

There is a need to educate and train a new type of researcher, the 'clinician-engineer', who can drive the development of advanced medical devices. This will be further supported by the increased focus on the Melbourne Biomedical Precinct as an innovation precinct which encourages networking and serendipitous meetings from researchers and clinicians across multiple fields.

Addressing unmet medical needs and translating ideas to the clinic

Development of successful medical devices will hinge on the ability to identify a real need and a suitable target population. Growing demand in Asia for the latest medical technology represents a tremendous opportunity for Australian businesses and advanced manufacturers.

Manufacturing growth

There is opportunity to increase the advanced manufacturing capacity within Victoria to support the production of prototypes that are needed to prove the viability of new medical devices and gain regulatory approval.