

Medical Devices Fund 2018





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A Message from the Minister

Leadership and commitment from the NSW Government is essential to ensure NSW's medical technology sector remains strong and our firms have every opportunity to thrive. The support that the Medical Devices Fund provides will ensure we see the benefits of new medical technology in NSW and beyond.

Past recipients have made remarkable advancements. Elastagen Pty Ltd, who received grants in the first and fourth rounds of the Medical Devices Fund. has developed elastin technology for medical repair and regeneration of the skin. They have since expanded from their Australian base to include production in Europe and clinical operations in the United Kingdom. The company was recently acquired by Dublin-headquartered Allergan for A\$330 million. Through this sale, Elastagen Ptv Ltd will be the first Medical Devices Fund recipient to pavback NSW's investment.

SpeeDx Pty Ltd, who received grants in the second and fifth rounds of the Medical Devices Fund, has commercialised the first diagnostics test worldwide which detects both sexually transmitted infections and antibiotic resistance in a single test. The Australian STI Management guidelines have now been updated to include recommendations to test for antibiotic resistance in mycoplasma genitalium infections, with resistance NSW has always been a leader in the development of medical technology. The sector is made up of highly innovative and nimble firms that are improving patient outcomes and creating real benefits to our economy through innovation.

guided therapy offering significantly increased cure rates. SpeeDx now provides ResistancePlus MG to the majority of clinical laboratories across Australia. Internationally, guidelines in the United Kingdom are set to mirror those in Australia, and clinical trials in the United States are on track for a 2019 product launch.

This year's grant recipients offer a wide range of innovative solutions to real world problems. Every one of these companies has the potential to be instrumental in improving the way health care is delivered and save lives. I am hopeful that our grant recipients will ultimately develop world changing technologies.

I offer my sincere thanks to Professor Mary O'Kane, the members of the Expert Panel, and staff in the Office for Health and Medical Research who provided outstanding leadership throughout the evaluation process for this year's Medical Devices Fund.

Thank you to all that applied to this and past rounds of the Fund. The ideas presented over the years have been outstanding. Your efforts, enthusiasm and commitment are creating real change and improving the lives of patients not just in NSW, but world-wide.

Hon Brad Hazzard MP

Minister for Health Minister for Medical Research



A Message from the Chair

The Medical Devices Fund would not have happened without the leadership and foresight of the NSW Government. Now in its sixth round, it has proved to be an invaluable program.

The Medical Devices Fund provides NSW organisations with the necessary support to quickly move their medical devices innovations up the Technology Readiness Levels, benefiting the health system and improving patient outcomes within NSW and abroad. A priority for the Fund is that applicants work closely with clinical experts across NSW to ensure the medical devices developed actually address contemporary NSW problems.

I want to thank my colleagues on the expert panel: Dr Bob Frater AO, Professor John Mattick, Neville Mitchell, Dr Greg Keogh and Michael Still. I also wish to thank the sub-committee who assisted with shortlisting and assessing the applicants, and the Fund secretariat led by Dr Antonio Penna. It has been a great joy working with you all!

The task of assessing applications is never an easy job. The expert panel was very impressed with the high number of quality grant applications this year, awarding over \$9 million dollars in funding support for this round.

Finally, congratulations to the 2018

Medical Devices Fund grant recipients, whose inspiring and innovative work will have an important and long-lasting impact on the State's health system and the wider community!

Professor Mary O'Kane

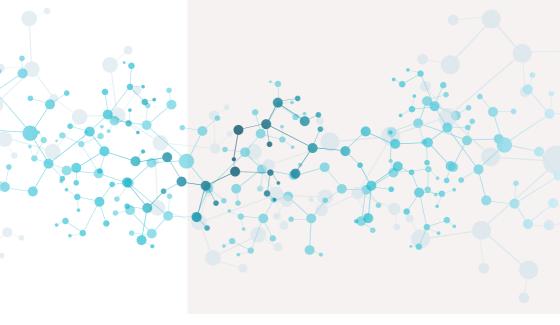
Chair of the Expert Panel



Kico

Kico Knee Innovation Company Pty Ltd

Kico is currently bringing a customised total knee replacement technology platform to market. The platform has software and hardware components that provide orthopaedic surgeons and patients with dynamic, functional and patient specific solutions. It is primarily aimed at Australian and US markets.





The existing software platform helps orthopaedic surgeons personalise the positioning of the knee implant hardware components. It has been effectively used more than 4000 times in Australia and the US and is playing an important role in the current international debate surrounding alignment strategy selection and patient specific optimisation.

The next step is to accelerate implant hardware developments. The critical differentiated feature of the 360KS hardware program is the mass customisation of the tibial insert component. This allows for optimisation of the articular response between the tibial and femoral components.

Surgeons will be empowered to customise the care regime for every patient with a focus on improving post-operative functional performance. This feature will be unique in the world and is heavily protected by a series of awarded patents.





Company/Organisation Name Public/Private Company Contact

Kico Knee Innovation Company Pty Ltd Private

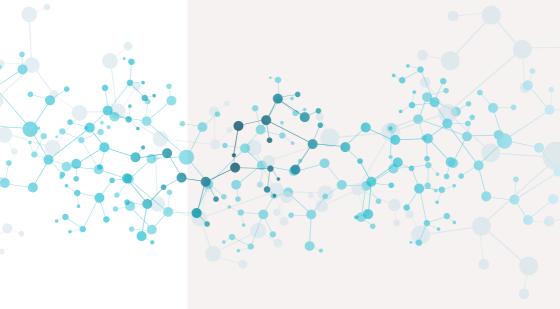
Bede O'Connor Email: bede@kneesystems.com Phone: 0420 688 139



Indee Labs Pty Ltd

Indee Labs is developing hardware for gene delivery. The hardware is uniquely positioned for the efficient development and scalable manufacturing of gene-modified cell therapies (gene therapies).

The impact of gene therapies will be similar to that of antibiotics seen during the last century. In the near term, gene therapies will provide cures for most cancer cases that would otherwise be terminal, with minimal side effects. In the long term, gene therapies will be applied to other indications such as rare disease and autoimmune disorders.





Current price tags for a cure are higher than the average house in Sydney, and lead times may be too long for patients with an aggressive condition.

For a patient, a typical treatment will involve having blood taken, sent to a facility where immune cells are reprogrammed, before they are reinfused weeks or months later. At this facility, engineered viruses are typically used to deliver new genetic material into a few cells before they are cultured to obtain a quantity suitable to treat a patient. This is a lengthy process and risks associated with it mean that the patient will need to be monitored for up to 15 years after treatment.



Indee Labs technology uses a mechanical method to deliver genetic material (constructs) into cells as an alternative to viruses. Cells and constructs are passed through a microfluidic chip, which uses microfluidic vortex shedding (μ VS) to disrupt the cell membrane allowing new genes to enter. The process is fast, efficient and very gentle on cells. Importantly, it is the only manufacturing technology that has the scale to meet demand for patients who will need a gene therapy in the future.

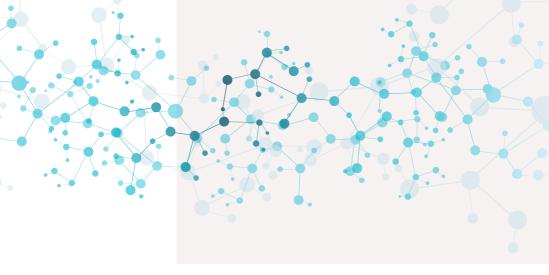
Ultimately, the technology will make gene-modified cell therapies accessible to the masses.

Company/Organisation Name		Indee Pty Ltd
Public/Private Company		Private
Website		http://indeelabs.com/about-us/
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Ellen Medical Devices Pty Ltd

Ellen Medical Devices is building a breakthrough dialysis system which will provide millions of kidney patients around the world access to this life-saving treatment for the first time. This transformation is achieved through a radical reduction in cost.





The George Institute for Global Health



Dialysis is a safe and effective treatment for kidney failure, 'but it is expensive, costing \$50,000-100,000 per patient annually in Australia. In Australia, dialysis is provided by health care systems. But each year in the developing world, up to 7 million people die because dialysis is too expensive for them to access.

The system employs peritoneal dialysis. It is pain free, portable and solar powered, using water from any source, it meets all safety standards. This costs just \$1,000 to build and \$5 a day to run.

Traditional peritoneal dialysis requires manufacturing bags of fluid at a central sterile manufacturing site, then transport across long distances at high cost. This system fills the bag at the



point of care, eliminating manufacturing and transport costs, creating a new low-cost business model.

The machine can be used at home or by rural health workers in remote settings. It will save lives, create a new global business for NSW, and reduce costs - wherever dialysis is needed.

Company/Organisation Name		Ellen Medical Devices Pty Ltd.
Public/Private Company		Private
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<u>Trimph Technology</u> <u>Pty Ltd</u>

Trimph Technology Pty Ltd is an Australian biomedical company that has developed a platform technology to repair bone, cartilage and connective tissues. The properties of this material can be tuned to treat a number of pathologies including osteoarthritis, bone injuries and soft tissue defects.

Since Trimph's incorporation in August 2015, the company has established its own ISO13485 accredited production facility, received granted patents in the US and Europe and completed a first-in-man trial for a dental application. TrimphDent is the company's first product to be used to accelerate hard and soft tissue healing post tooth extraction.





Tooth extraction is an inherently traumatic procedure that damages the underlying tissue and leads to inevitable jaw bone shrinkage. Clinically, loss of alveolar ridge bone results in aesthetic and functional complications as well as the need for a secondary invasive operation prior to prosthetic placement.

TrimphDent is a ready to use, injectable scaffold that is applied immediately after tooth extraction and has been shown to preserve the socket in a pilot clinical trial. Unlike all other bone substitutes, TrimphDent is delivered to the extraction socket as a liquid, and quickly forms an elastic matrix at the site to provide a predictable platform for bone regeneration. TrimphDent requires no specialised preparation, socket packing



or additional surgical expertise. These unique properties save time for surgeons and allow more general dentists to perform the procedure.

Improving access to dental services is aligned with the vision of both State and Federal health Governments. Boneanchored prosthetics improve quality of life by allowing better mastication and speech and improving general health outcomes. However, economic barriers and poor access to specialist oral surgeons are recognised limitations to the widespread use of implant secured prosthetics.

With the aid of NSW's Medical Devices Fund, Trimph will run a clinical trial and complete the requirements for European and Australian registration.

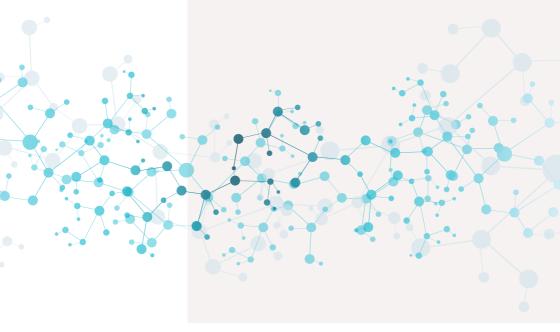
Company/Organisation Name
Public/Private Company
Contact

Trimph Technology Pty Ltd Private Dr Ali Fathi Email: ali.fathi@trimph.com.au Phone: 0413 721 939



iFix Medical Pty Ltd

iFix Medical, a NSW consortium of researchers, surgeons and industry have developed a novel medical treatment technology that incorporates 3D printing for corneal diseases and injuries.

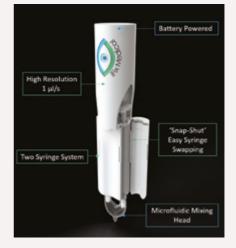






The cornea is the clear window at the front of the eye, and corneal disease is the third most common cause of blindness worldwide. Corneal ulceration is extremely painful and accounts for 55,000 presentations to hospitals each year across Australia. Current medical treatments do not adequately address issues of pain relief, infection or the development of scar tissue. Infection and scarring may necessitate lengthy hospital stays and further treatment.

The iFix system can be used to deliver a 3D-printed structure directly onto the eye to treat defects. It comprises of two components: iFixInk[™] and its delivery device, the iFixPen[®]. The system involves the printing of a transparent structure that seals the wound and prevents pathogen infiltration. It



relieves pain, accelerates healing and is biodegradable. The ink formulation can be tailored to clinical need and can contain antibiotics and or other active regenerative agents.

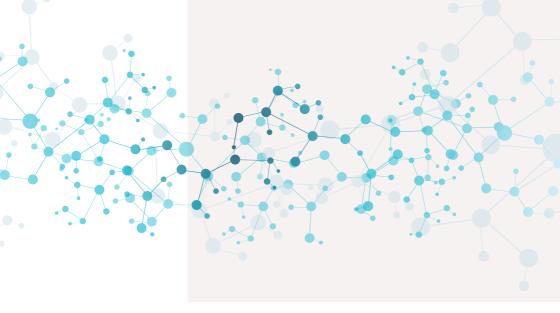
The iFixPen is a handheld 3D-printing device, which can deliver the "ink" to the defect with high accuracy in a smooth and effective manner. The delivery process takes less than two minutes.

Company/Organisation Name		iFix Medical Pty Ltd
Public/Private Company		Private
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Eudaemon Technologies

Eudaemon Technologies is creating the next-gen condom made from innovative materials called tough hydrogels. These tissue-like materials perform like latex rubber but with enhanced feel, self-lubrication, have no adverse odours or tastes, and do not cause allergic reactions.







Condoms are the only medical device that can simultaneously prevent pregnancy and sexually transmitted infections (STIs). However, condoms are often avoided because of the stigma of reduced sensation during sex. What if instead there was a condom that people couldn't wait to try? Producing a condom that people actually want to use would revolutionise the definition of safe sex, enhance family planning (reducing the 85 million unintended pregnancies per year), support sexual health strategies (reduce STI rates), save healthcare agencies millions worldwide, and disrupt a growing \$8 billion global market.

The project will establish the manufacturing and clinical validation





to create a market ready product for consumers. Through investment from NSW's Medical Devices Fund, Eudaemon Technologies will demonstrate the ability to on-shore condom manufacturing in Australia and provide these superior condoms to address sexual health needs in NSW. Australia, and the world.

Company/Organisation Name

Public/Private Company

Contact

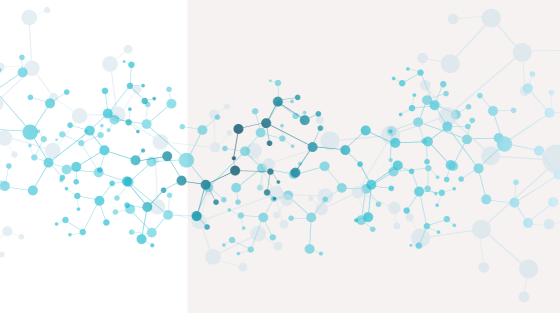
Eudaemon Technologies Private Dr Robert Gorkin info@geldom.org Phone: 0401 071 021

Email:



<u>Cenofex</u> Innovations

Cenofex Innovations is an early stage medical device company that uses a novel, proprietary ultrasound technology to move fluids within the body. By controlling the output of the individual ultrasonic transducers in the device's flexible array, acoustic forces are generated and used to move subcutaneous fluid. Using this technology, Cenofex Innovations aims to treat lymphoedema.













Lymphoedema is a chronic and painful disease affecting millions of people. Linked to a poorly functioning lymphatic system, it is characterised by a painful

swelling of a limb or body region. Along with pain and discomfort, it can also lead to dangerous infections, restricted movement, depression, poor selfesteem, and an overall poorer quality of life.

Patients therefore, are forced into a lifetime of symptom management. This is made more challenging because existing solutions to symptom management can be painful, taxing, difficult, or overly burdensome. This limits the access most patients have to regular, effective lymphoedema treatment and can lead to even more significant health risks if left unmanaged. There is currently no treatment device that is capable of providing personalised lymphoedema treatment wherever and whenever the patient needs it.

Designed with input from over 200 patients and clinicians, the Active Lymphoedema Device delivers customisable, pain-free treatment using novel, proprietary ultrasound technology, empowering the user to control and monitor their lymphoedema.

In partnership with NSW Health, Cenofex Innovations will bring to market the only device capable of actively moving lymphatic fluid while incorporating a patient's need for comfort, portability, and ease. This unique, innovative technology will transform lymphoedema treatment and return freedom, dignity, and functionality to the millions of patients living with this debilitating condition.

Company/Organisation Name		Cenofex Innovations
Public/Private Company		Private
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Medical Devices Fund <u>Expert Panel</u>



Professor Mary O'Kane

Professor Mary O'Kane AC is the Chair of the Independent Planning Commission of NSW, a company director and Executive Chair of Mary O'Kane & Associates Pty Ltd, a Sydney based consulting practice. She is Chair of the CRC for Digital Health, the Space Environment Management CRC and Chair of the Institute of Marine and Antarctic Studies board at the University of Tasmania.

Professor O'Kane was NSW Chief Scientist & Engineer from 2009 to 2018, and Vice-Chancellor of the University of Adelaide from 1995 to 2001 She is a former Chair of the board of the Australian Centre for Renewable Energy, a former member of the Commonwealth's Review of the National Innovation System, the Australian Research Council, the Cooperative Research Centres (CRC) Committee, the board of FH Faulding & Co Ltd and the board of CSIRO. She is a Fellow of the Academy of Technology and Engineering and an Honorary Fellow of Engineers Australia.



Neville Mitchell

Neville Mitchell has had a 30 year career in medical devices and accounting. He was Chief Financial Officer & Company Secretary of Cochlear Limited for over 25 years before retiring in 2017. Cochlear Limited is the world leading cochlea hearing implant company and is headquartered in Sydney Australia. Cochlear grew from a listing valuation of \$125 million in 1995 to an international company with a market capitalisation of over \$8 billion at his time of leaving.

Neville is a Non-executive Director of Sirtex Medical Limited (ASX:SRX) Osprey Medical (ASX:OSP) and a Director of the Board of Tax and the South Eastern Sydney Local Health District.



Michael Still

Michael Still has enjoyed a 30 year career in investment banking, corporate finance, equity investment and infrastructure in Australia and globally.

As well as being engaged in a broad range of banking and business roles including mergers and aquisitions, reconstruction and corporate advisory, he has been responsible for the leadership infrastructure and property companies for many projects. These have included public-private partnerships, and major social and economic infrastructures. He has significant experience in project management, long term financing and direct ownership.

Throughout his career, Michael has advised governments, offshore corporates and investment funds on strategic matters, ownership, and financing issues across many industries and asset types. He brings to bear significant experience in dealing with equity investors and debt financiers globally.

Michael is Chairman of the South Eastern Sydney Local Health District, and a board member the Cancer Institute NSW. He is also a director of the Silverchain Group and the Silverchain Foundation. He holds a Masters in Business Administration from the Macquarie Graduate School of Management.



Dr Greg Keogh

Dr Keogh is a Senior Staff Specialist Surgeon at Sydney's Prince of Wales Hospital and a Fellow of the Royal Australasian College of Surgeons (FRACS). His clinical interests include the management and treatment of gastrointestinal cancer, particularly in the upper gastro-intestinal tract.

He is currently the Head of General Surgery, Prince of Wales Hospital, and was until recently the surgical head of Operating Theatres. He also fills the role of Clinical Stream Director for Surgery, Anaesthetics and Perioperative Medicine for South Eastern Sydney Local Health District. He is also an examiner for the Fellowship Exam of Royal Australasian College of Surgeons.

He is a member of the Surgical Services Taskforce (under the Agency for Clinical Innovation), and has recently assumed the role of Surgical Champion of NSQIP at Prince of Wales Hospital (the Quality and Safety Program of the American College of Surgeons).

He has been a former Director of Clinical Training at the Prince of Wales Hospital, Chair of the Postgraduate Medical Council of New South Wales, a member of the State Committee and State director of Basic Surgical Skills for the Royal Australasian College of Surgeons.



Dr Bob Frater AO

Dr Bob Frater AO is one of Australia's most respected scientists. He has researched electronics, telecommunications, radio astronomy instrumentation, electro-acoustic and biomedical devices.

In 1996 he was made an Officer of the Order of Australia for his contributions to science in Australia and internationally. Other honours include the IREE Norman W.V. Hayes Medal in 1980, Pawsey Lecturer in 1983, IEEE (USA) Centennial Medal in 1984 and the Australian Centenary Medal in 2001.

His career went from industry (AWA, OTC, Ducon) to academia (Electrical Engineering at Sydney University), then to CSIRO from Chief of Radiophysics Division to Deputy Chief Executive, and then to ResMed as VP Innovation.

He is currently Chief Technology Officer for Innovation Capital and an Adjunct Professor at Macquarie University. He is a member of a number of advisory committees.

His CSIRO achievements included construction of the highly successful \$50 million Australia Telescope at Narrabri and sponsorship of the WLAN developments by his former students from the University of Sydney.

He is a Fellow of the Australian Academy of Science and a Fellow of the Australian Academy of Technological Sciences & Engineering.



Professor John Mattick

AO FAA FAHMS FRSN HonFRCPA

Professor John Mattick, until recently, was the Executive Director of the Garvan Institute of Medical Research. He is currently the Chief Executive of Genomics England. He spent much of his career at the University of Queensland, where he was Foundation Director of the Institute for Molecular Bioscience and the Australian Genome Research Facility.

He is best known for showing that most of the human genome is not junk, and was recently named by the National Health and Medical Research Council as one of the alltime high achievers in Australian health and medical research.

His honours and awards include the inaugural Gutenberg Professorship of the University of Strasbourg, the Order of Australia and Australian Government Centenary Medal. Fellowship of the Australian Academy of Science and the Australian Academy of Health & Medical Sciences. Honorary Fellowship of the Roval College of Pathologists of Australasia, the International Union of Biochemistry & Molecular Biology Medal, the Human Genome Organisation Chen Award for Distinguished Achievement in Human Genetic & Genomic Research. and the MD Anderson Cancer Center Bertner Memorial Award for Distinguished Contributions to Cancer Research.

John has overseen the development of a number of startup enterprises, including most recently one of the world's first clinical genomics companies.



