Medical Devices Fund

2015



NSW GOVERNMENT Health

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With more than half of Australia's medical device technology businesses based here, NSW leads the way in the development of medical solutions – both now and into the future.

To ensure NSW remains strong in this sector and that our firms have an opportunity to thrive, leadership and commitment is essential. Since 2011 the NSW Government has invested more than $20 million in new competitive programs to support medical device research and commercialisation. This year we announced we would increase funding to these programs by a further $19 million over the next four years.

The Government's support for the commercialisation of emerging medical technology through the Medical Devices Fund will realise the benefits of homegrown innovation faster. Importantly, it will also keep the economic benefits and retain the bright minds behind the developments here in NSW. I strongly believe that programs like the Medical Devices Fund will uncover and nurture more international successes like Cochlear and ResMed.

This year's Medical Devices Fund winners offer an impressive range of pioneering devices. All have the potential to not only transform the delivery of health care, but above all, to deliver life-saving benefits for patients.

I am proud of our medical device commercialisation support programs, and I am delighted that the NSW Government is taking its support of the sector to the next level. The NSW Government is working hard to establish Med Tech City – bringing to the Asia Pacific region an international technology hub similar to renowned global centres like Roosevelt Island in New York and London's Tech City. NSW's Med Tech City will be a global hub of excellence and a leading force in the translation of medical research into practical health outcomes.

I offer my most sincere thanks to Professor Mary O'Kane, NSW Chief Scientist and Engineer, the members of the Expert Panel and the Office for Health and Medical Research for their outstanding commitment throughout the evaluation process for the NSW Medical Devices Fund 2015. To the many individuals and organisations who submitted applications this year as well as the grant recipients from previous years, I thank you for your innovative ideas and persistence. Your efforts provide hope for future medical breakthroughs in NSW.

Hon Jillian Skinner MP
Minister for Health

A Message from the Chair

November 2015

The Medical Devices Fund, established by the Minister for Health, is now in its third year and is proving to be a very valuable program. The program provides critical support for the development of devices and related technologies into the health system and market.

The Expert Panel was delighted with the number and the quality of the applications this year. In this round we encouraged applicants to utilise NSW's clinical experts, to ensure that there are clear linkages between the medical devices they are developing and the problems they are trying to solve.

Once again, the task of assessing these high quality applications was not an easy job and I want to thank the wonderful members of the Expert Panel: Neville Mitchell, Dr Bob Frater AO, Michael Still and Dr Greg Keogh. I also wish to thank the sub-committee, who assisted with the shortlisting and the assessment of the applicants and the MDF Secretariat, led by Dr Antonio Penna.

Above all, I congratulate the recipients of the Medical Devices Fund 2015 whose innovative and inspiring work will have a lasting and meaningful impact on both the health system and the wider community.

Mary O'Kane
NSW Chief Scientist & Engineer

PAFtec Australia Pty Ltd

CleanSpace™
wearable protective masks

PAFtec Australia specialises in innovative and quality respiratory protection device design and manufacturing.

Founded by a world class medical device engineering team with a vision to make respiratory protection wearable and easy to use. The team has previously designed medical products from concept to manufacturing that are currently being used by millions of people around the world. Their expertise is the reason our products (CleanSpace™ Respirators) are safe, robust and high performing even in the harshest environments. These award winning respirators are used by companies all around the world from mine sites in the Pilbara to manufacturers and specialists in transportation, infrastructure and energy. Sold in over 20 countries around the world, CleanSpace™ deliver significant safety and compliance benefits over traditional masks.

CleanSpace™

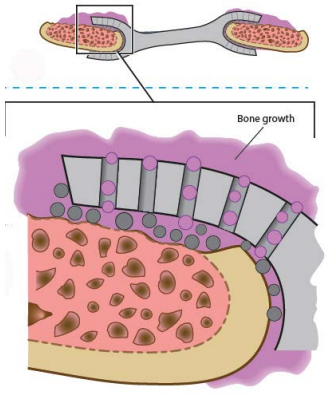
CleanSpace™ Respirators are the world's smallest and lightest powered respirators and a game changer for respiratory protection. CleanSpace™ Respirators are certified to the high P3 protection (99.98% filtration efficiency for particles 0.3 micron and above) have patented, breath-responsive algorithm and a powerful, efficient micro-turbine motor which permits the airflow to be adjusted in situ to match the wearer's breathing. The powered airflow offers both protection and comfort for long periods (up to 8 hours) – ideal for primary healthcare, screening, triage or treatment by first response in the field operations where traditional powered masks fail.

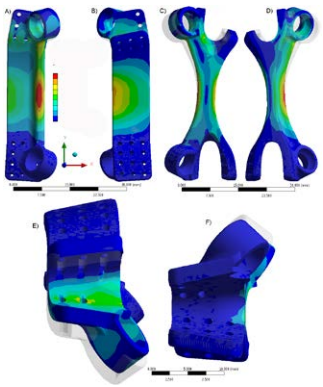
Every CleanSpace™ respirator is individually tested for quality and performance in our facility in NSW, Australia. The Company's Quality Management System is accredited to the globally recognised ISO 9001 standard. An important element of using a CleanSpace respirator is our training. PAFtec was one of the first respirator manufacturers to develop an online training system with compliance tool enabling rapid high volume deployment in remote locations. The Training Program has been developed with our customers' in mind and is augmented by our product specialists and distribution partners.

There is an opportunity to extend the patented CleanSpace Technology to develop a respirator to meet the specific needs of healthcare workers. The device will be tested and used for protection of healthcare workers at high risk of airborne infectious disease (ie Ebola, Viral Haemorrhagic Fever, Tuberculosis). In conjunction with world class researchers in NSW in the areas of respiratory protection and infectious disease, PAFtec plans to clinically evaluate the performance and staff acceptance of the CleanSpace PAPR with full face mask in hospital and remote field operations.

Public/Private Company	Private
Stage/Category	Pre-clinical Respiratory Protection device with Revenues in adjacent applications
Website	www.cleanspacetechnology.com
Contact	Dr Alex Birrell CEO
	Email: alex.birrell@paftec.com
	Phone: +61 2 8436 4000

University of New South Wales





Thru-Fuze Orthopaedics Pty Ltd is an early stage NSW Biotech company formed to bring this development from UNSW Australia to benefit the people of NSW, Australia and the world.

Thru Fuze has received seed funding (AUD$2.3 million + IP costs) from Intellectual Ventures, this has provided Professor Walsh and UNSW Australia assistance in the research and development phase of this project and in protecting the related intellectual property.

Thru Fuze will use the support provided by the NSW Medical Devices Fund to more forward with clinical trials.

Thru-Fuze

The Thru-Fuze™ device is a new orthopaedic device for the treatment of spinal disorders. The device is positioned between the transverse processes of adjacent vertebrae and facilitates rapid fusion of bone both on and through the device.

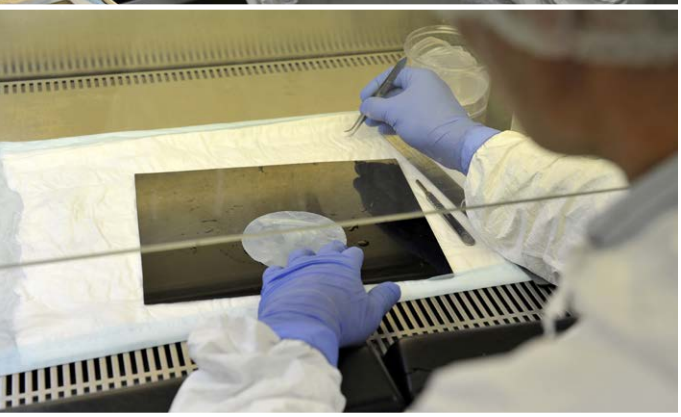
The Thru-Fuze™ device was conceived and invented at UNSW Australia by Professor Bill Walsh and Dr Matt Pelletier. Initial funding provided by Intellectual Ventures ($2.3 million) allowed a team of global industrial experts (Dr Andy Carter and Orchid Design (USA)) to assist in product development. The NSW MDF funding will allow this work to be taken into the clinical arena and assist this Australian innovation to realise its global healthcare potential.

The Thru-Fuze™ device helps alleviate chronic back pain, such as that caused by degenerative disc disease. During spinal fusion surgery, the device is fixed between transverse processes of adjacent vertebrae to hold them in place and thus stabilise the spine and alleviate pain. The geometry of the device encourages bone growth through the device providing rapid biomechanical fixation. Over time, the device then acts as a bridge between the adjacent vertebrae for additional bone to grow across thus fusing the adjacent vertebrae together, bone to bone.

Comparable devices include pedicle screw and rod systems with bone graft material. These systems are costly and difficult and time consuming to implant. They also have relatively low rates of fusion success. The Thru-Fuze™ device is simpler, cheaper, and allows faster surgery with less, or no, radiation exposure, and a faster biomechanical fusion.

Public/Private Company	Private
Stage/Category	Early stage biotech
Website	powcs.med.unsw.edu.au/research/groups/surgical-and-orthopaedic-research-laboratory
Contact	Professor W.R. Walsh Surgical & Orthopaedic Research Laboratories, Prince of Wales Clinical School, Prince of Wales Hospital, Randwick NSW 2013
	Email: w.walsh@unsw.edu.au

Maverick Biomaterials Pty Ltd



Maverick Biomaterials (MBM) has established itself as a key provider of product & service into the emerging transcatheter device arena.

Strong skillsets and IP around materials selection, production and global Quality & Regulatory needs surrounding the use of animal derived biological (ADB) materials in medical products, has MBM working alongside numerous global partners optimising their business and product outcomes.

Over the next 2 years 3-4 of MBM clients will likely attain regulatory approvals for their product and commence market launch, 2 of these in developed markets and 2 in emerging economies. Behind these organisations is the next wave of development targeting mitral valve disease with world 1st products expecting to be on market in 2020.

MAVERICK

BIOMATERIALS PTY LTD

MBM has been in long term collaboration with these entities, often since their benchtop R&D began, and have co-developed optimum material for product success, and eloquent pathways for Quality & Regulatory approvals being obtained.

MBM utilises its extensive IP developed in the ADB sector to meet the needs of global product developers. The market for aortic valve focussed products is about to experience a wave of new product approvals, and mitral focussed products will launch 2020-2025. The tricuspid arena is now the focus of very early stage R&D.

MBM has developed innovative bovine materials used in the manufacture of heart valves implanted via keyhole surgery techniques. This reduces the patient's time in intensive care facilities (therefore reducing hospital costs) and allows for valve implantation into frail patients. The Maverick material supports client needs for optimising catheter loading and device performance.

MBM is investing in cleanroom facilities that will be operational Q3 2016 and given growth forecasts will be working diligently to strengthen and enhance the manufacturing process and overarching organisational capabilities. Over the next 10 years significant growth will occur and MBM will be on the front foot in having the requisite facilities and human resources available to quickly respond to the need of the global market and our dynamic, innovative and entrepreneurial clientele.

Public/Private Company	Private
Stage/Category	Commercialisation / Medical Device / Cardiovasculars
Website	www.maverickbio.com
Contact	Cameron Crowley Business Development Manager
	Phone: +61 2 6885 1200

Atomo Diagnostics Pty Ltd

atomo diagnostics

Atomo Diagnostics is a leading innovator in the point-of-care test (POCT) market. The company is focused on addressing unmet user needs in diagnostics and delivers solutions that materially improve usability, accuracy and safety for both professional and self-test users.

Atomo's first product to market, AtomoRapid HIV, was launched in 2014 in Southern Africa. AtomoRapid HIV was developed to significantly reduce diagnostic errors common with existing 'bits in a box' HIV test kits used in the field.

The AtomoRapid platform integrates standard test kit components into an all-in-one convenient device that is easy to use and simplifies user steps. AtomoRapid materially improves the usability of rapid diagnostic tests and addresses common user errors that are known to lead to excessive misdiagnosis. This is particularly important in resource limited settings and developing countries where rapid diagnostic tests are relied upon for both screening and confirming HIV infection. Since launch of solutions for HIV and malaria, the AtomoRapid platform has also been selected by a leading UK based diagnostics company for launch of a rapid Ebola test that also utilises the UK MOD's Ebola reagents.

Rapid diagnostic device for HIV

Atomo and its technology have been disruptive to the POCT industry, with both the company and technology receiving numerous awards including 'Best in Show' at the 2014 Medical Design Excellence Awards in New York as well as receiving the Johnson & Johnson Innovation's Australian Emerging Company of the Year 2014.

As well as improving diagnostics in clinical settings, Atomo is now working on commercialising self-test products for a range of consumer applications. In particular, Atomo is focused on launching an HIV self-test product to increase access to and frequency of HIV testing. Self-testing for HIV is set to play an increasingly important role in reducing transmission rates and achieving global goals in improving HIV diagnosis and treatment. This is an area where ease of use, safety and reliability are critical.

Public/Private Company	Private
Stage/Category	Early stage commercialisation
Website	www.atomodiagnostics.com
Contact	John Kelly CEO
	Email: john.kelly@atomodiagnostics.com
	Phone: +61 2 9099 4750

Kleer-i

Kleer-i Pty Ltd is a start-up delivering innovative eye repair.

Kleer-i® replaces sutures. It seals wounds and delivers drugs directly to the wound site; promoting rapid healing with less infection and scarring at low cost. Trials on animals have been successful and the Kleer-i® system will be evaluated in humans.

Kleer- i® aim to obtain regulatory approval and launch in the market by 2017. Kleer-i Pty Ltd will target the global need for safe, easy to apply wound sealants that promote better functional tissue repair. Its easy application will alleviate the strains on public healthcare systems.

Kleer-i

Ophthalmic surgery has the longest waiting list of all specialities in NSW with a current median waiting time of 232 days. Kleer-i® can be applied 3 to 4 times faster than current practice with sutures, saving 60% to 70% of operating time.

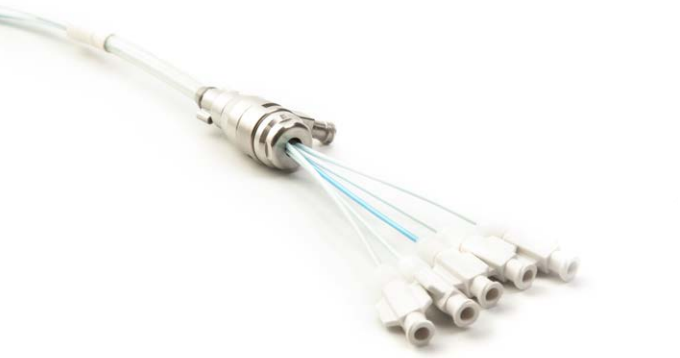
Cataract surgery is the most common elective procedure in NSW. Current practice is to leave cataract wounds unsealed or apply sutures. But wound leak occurs in 1 in 20 cases and the risk of infection persists with devastating vision loss. Patients are also left to deliver their own post-operative therapy, yet compliance can be poor. Increased post-operative care follows a wound leak and treatment for infection from cataract surgery can cost over $8,000 per infected patient.

Kleer-i® can also be used for corneal transplantation, the most common transplant procedure, and following corneal trauma, an important cause of vision loss. Hospitalised eye injuries are more common in Indigenous Australians and corneal trauma is a 'silent epidemic' in the developing world. In these settings, Kleer-i® will allow faster surgery, as well as reliable wound closure and delivery of post-operative therapy preventing vision loss and distortion from complications.

Kleer-i is smart eye repair, a fundamental leap in the field, saving sight and costs in a growing healthcare market.

Public/Private Company	Private
Stage/Category	Early stage ophthalmology medical device
Website	Under construction
Contact	Professor Stephanie Watson Co-founder
	Email: **Phone:**

AllVascular Holdings Pty Ltd



AllVascular is a Sydney based medical device company that has developed a novel vascular access platform to improve the delivery and effectiveness of anti-cancer agents to solid organs.

The pharmacological advancement of anti-cancer agents in the past several decades has led to the introduction of new treatment regimens for treating advanced solid organ cancers. While these regimens have brought about improved patient outcomes, a significant portion of the treated population still show only limited or no response. For many patients, a major treatment limiting factor is the side effects these anti-cancer agents induce on the whole body. These side effects dramatically impact patient quality of life and often cause treatment to be discontinued without eliminating all tumour cell activity.

In order to address this issue, AllVascular has developed a vascular access platform that allows clinicians to repeatedly access a cancerous organ such as the liver or pancreas through a minimally invasive approach. The platform allows catheters to isolate the blood flow to the organ. This setup allows for high concentration anti-cancer agents to be administered directly to the target organ without spilling into the systemic circulation, in order to maximise potency while minimising side effects. The reduced toxicity and ease of access afforded by the platform, allows the treatment to be administered up to twice a week for one month. Ultimately, the aim of the treatment is to improve the effectiveness of anti cancer agents and thereby increase patient quality of life and clinical response.

Arterial & Venous Access System

The technology's intellectual property was developed by Sydney based vascular surgeon and biomedical engineer Prof. Rodney Lane. The device has TGA and EU marketing approval and is currently being used successfully in Sydney hospitals to treat end stage patients suffering with liver metastases that have spread from the colon. The initial pilot study was recognised at the Royal Australia and New Zealand College of Radiologists where Prof. John Magnussun (Macquarie University) was awarded the Best Scientific Presentation and subsequently presented results at the largest European interventional radiology conference – CIRSE.

The NSW Medical Devices Fund will play a pivotal role to further the commercialisation of the technology by supporting a large clinical study at Sydney hospitals including, North Shore Hospital, Sydney Adventist Hospital and Macquarie University Hospital for treating patients with liver cancer that has spread from the colon. The platform and treatment method is also being trialled in a pilot study for patients with locally advanced unresectable pancreatic cancer with early results expected to be published late next year.

Public/Private Company	Private
Stage/Category	Early Stage Medical Device
Website	www.allvascular.com
Contact	David Lane General Manager
	Email: **Phone:**

cmee4 Productions Pty Ltd

cmee4 productions is a content creation company focused on harnessing the power of mobile games to help address global health issues.

With over twenty-five years experience in medical and corporate content production cmee4 Productions Founder, Carolyn Mee, has applied her knowledge of creative engagement to the increasingly powerful medium of games with the belief that games can deliver and capture vital health information.

The company's flagship project, Sound Scouts, offers a revolutionary solution to screen children's hearing. Developed in collaboration with the National Acoustic Laboratories, led by Dr Harvey Dillon, Sound Scouts looks and feels like a game however it incorporates advanced scientific principles that enable it to detect and identify a range of hearing issues.

Statistics from Australian Hearing show that the second, third and fourth most common ages for children to be fitted with hearing aids are six, seven and eight years of age. Their hearing issues are being detected when they experience learning and social difficulties at school. The need to identify these children before or during their first year of school, to ensure they are not disadvantaged by two, three or more years of not coping, has been a major driver throughout the project's development phase.

Sound Scouts' release meets the need in the hearing healthcare system for a low-cost, easily administered, reliable test of hearing that can be widely accessed. The game is played on a mobile tablet utilising headphones. Parents/caregivers input some details including their child's age, as results are age dependent, and oversee their children playing, but otherwise the game is completely self-contained.

The game comprises three interleaved tests of hearing; two based on perceiving speech (one in noise and one in quiet), and one based on perceiving tones against a noise background. Each of these constantly adapts so that the child is always listening at the edge of his or her hearing capability. Algorithms within the game check that the child is responding reliably, as well as measuring the child's actual ability. The results from the three tests are combined to automatically display a test result as soon as the game is completed.

Sound Scouts was recently presented at the International Collegium for Rehabilitative Audiology in San Francisco attracting international development partners.

The Medical Devices Fund Grant will help Sound Scouts hearing screening solution to become a routine part of every Australian child's preschool or kindergarten health check.

Public/Private Company	Private
Stage/Category	Commercialisation Stage and Continued Development
Website	www.soundscouts.com.au
Contact	Carolyn Mee Founder
	Email: carolyn@cmee4.com.au **Phone:** +61 414 400 114

Medical Devices Fund Expert Panel

Professor Mary O'Kane

Professor Mary O'Kane is the NSW Chief Scientist and Engineer and also a company director and Executive Chairman of Mary O'Kane & Associates Pty Ltd, a Sydney-based consulting practice.

She is also Chair of the CRC for Spatial Information and the Space Environment Management CRC and is a Director of Capital Markets CRC and Business Events Sydney.

Professor O'Kane was Vice-Chancellor of the University of Adelaide from 1995-2001. 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 Co-operative Research Centres (CRC) Committee, the board of FH Faulding & Co Ltd and the board of CSIRO. She is a Fellow of the Academy of Technological Sciences and Engineering and an Honorary Fellow of Engineers Australia.

Mr 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 broad range banking and business roles including M&A, reconstruction and corporate advisory, he has been responsible for the leadership of infrastructure and property companies and for projects of many types. These have included Public Private Partnerships, social infrastructures as well as major economic infrastructures. He has significant experience in project and long term financing and direct ownership.

Over a long period Michael has advised governments, offshore corporates and investment funds on strategic matters and 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, board member of the New South Wales Cancer Institute and is a Committee Member of the Medical Devices Fund Expert Panel (NSW Govt). 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 surgical director of the Prince of Wales Hospital Operating Theatres. He also currently fills the role of Clinical Stream Director for Surgery, Anaesthetics and Peri-operative Medicine for the South East Sydney Area Health Service.

His other roles include National Director of the CPMEC Australian Curriculum Framework for Junior Doctors Project, and a senior medical adviser to HETI (Health Education Training Institute). He is a member of the NSW Surgical Services Taskforce, and the NSW Acute Care Taskforce.

He has been a former Director of Clinical Training at the Prince of Wales Hospital, chair of the Postgraduate Medical Council of NSW and state director of basic skills courses for RACS.

Mr Neville Mitchell

Neville is Chief Financial Officer and Company Secretary at Cochlear Limited (1995 – present). His responsibilities include;

- Part of Senior Management Team charged with the setting of Cochlear's global strategic development and its implementation.
- Responsible for financial management for Cochlear Limited world-wide including revenue, working capital control and disclosure reporting.
- Principal role in evaluation and subsequent acquisitions by Cochlear Limited.
- Risk Management and Treasury functions including FX strategy and execution.
- Company Secretarial duties including ASX and statutory requirements in Australia and overseas. Attendance at all Cochlear Limited Board meetings with direct input on financial and operational matters, also attendance and participation at all Board Committee meetings.
- Investor Relations management including formulation and execution of IR strategy for Cochlear Limited. This includes direct contact with fund managers/ investors, analysts and financial press in Australia and abroad.
- Government Relations strategy and relationships.

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-acoustics and biomedical devices. In 1996, he was made an Officer of the Order of Australia for his contributions to science in Australia and internationally.

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 now ResMed as VP Innovation. He also serves as Chief Technology Officer for Innovation Capital and 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 University of Sydney. He is a Fellow of the Australian Academy of Science and a Fellow of the Australian Academy of Technological Sciences & Engineering.

NSW Office for Health and Medical Research

Health and medical research play a vital role in the continued growth and better health of our community and economy. From increased life expectancy and new treatments for disease, and technologies that change the way we live and work, to addressing environmental challenges - scientific research and the knowledge it generates affects us all.

The Office for Health and Medical Research (OHMR) plays a crucial role in supporting the State's leading health and medical research efforts. OHMR helps support the broad range of outstanding health and medical research effort being carried out in NSW.

OHMR works with the health and medical research communities, the higher education sector and business to promote growth and innovation in research to achieve better health and environmental and economic outcomes for the people of NSW.

Medical Devices Fund

The NSW Health and Medical Research Strategic Review recommended that NSW be enabled to contribute to the discovery and application of new treatments and diagnostic techniques and devices that will be major contributors to health reform into the future. The NSW Government established the Medical Devices Fund (MDF) to help encourage and support investment in the development and commercialisation of medical devices and related technologies in NSW.

The key objective of the MDF is to promote new and innovative medical devices and technologies within NSW that may have a global benefit. Broadly, the MDF aims to:

- provide support to individuals, companies, public and private hospitals, medical research institutes, universities, other public sector research organisations, and the medical devices industry, to take local innovation to market; and
- increase the uptake of NSW medical devices by the health system where they are cost effective and contribute to improved patient outcomes.

(OHMR) 150650