

# HEALTHY PROSPECTS

*Australian enterprises specialising in innovative medical devices are showing the world what our technology and design have to offer. By Carole Goldsmith.*

Australia's medical technology industry is growing fast, with turnover of around \$11.8bn in 2012-13 (including in-vitro diagnostics (IVDs) and dental), up from \$10bn in the previous year. Med tech was responsible for 43,952 medical device entries on the Australian Register of Therapeutic Goods (ARTG) in 2014, estimated to represent between 500,000 and one million different devices, according to the Medical Technology Association of Australia (MTAA). The MTAA's 2014 Fact Book, Medical Technology in Australia: Key Facts and Figures, reveals that over 500 med tech companies had products listed on the ARTG.

## **MiniFAB – Sustained success**

A world-leading provider of custom-designed medical and diagnostic devices, MiniFAB is one of Australia's great manufacturing success stories. In just 13 years the company has completed 900 projects globally and exported millions of units, specialising in contract product development and manufacturing of polymer micro-engineered systems (including microfluidics, biosensors, cell and tissue devices) for the health, biotech, agri-food and aerospace industries.

Located at the Small Technologies Cluster (STC) in Scoresby, east of Melbourne, MiniFAB's production facilities are certified to ISO 9001 and ISO 13485 (medical devices quality standard), with the bulk of its manufacturing undertaken in Class 1,000 and 10,000 cleanrooms. MiniFAB Chairman Mike Wilkinson explains that the STC assists in the uptake of small technologies in industry, with office and laboratory space available for people starting up businesses, and a number of innovative technology firms in residence.

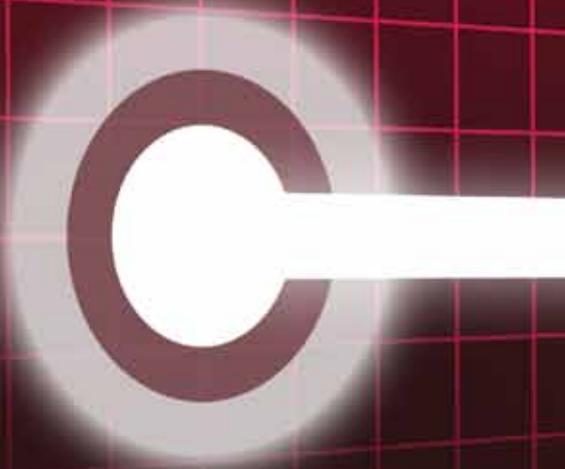
Wilkinson gives AMT magazine a tour of MiniFAB's development and manufacturing laboratories, which take up much of the STC's premises. Staff move about fully gowned from head to foot; one employee is preparing medical devices' plastic substrates, which will then be cut to a pattern in the Excimer laser machine nearby. MiniFAB employs 120 people across a wide range of disciplines including physics, chemistry, biology, engineering, material science and commercialisation.

An engineer by profession, Wilkinson established MiniFAB in 2002 with co-founder Dr Erol Harvey. He speaks excitedly about two of the many projects MiniFAB has been working on.

"We are developing a Bionic Eye with Monash University," says Wilkinson. "The Monash Vision direct-to-brain bionic eye project is a four-year Australian Research Council (ARC)-funded development program. MiniFAB's role is to design and fabricate an implant and a surgical tool, to assist implant surgery. We are also providing guidance to Monash on the regulatory framework for ISO13485 compliance.

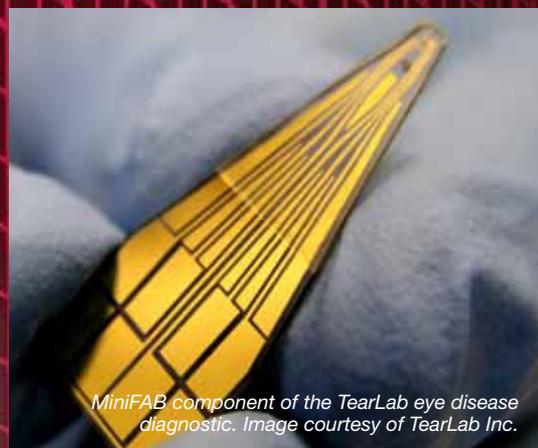
"Another one, the Monarch Project, is for global medical technology company Becton Dickinson, USA. We designed the disposable cartridge used to detect AIDS and these are now being sold into Third World countries."

Passing the packaging room, Wilkinson points to a large consignment of TearLab biosensors, which are being packed for export to the USA. This is one of the company's top selling products, with the bulk of the TearLab customers in the USA.





Disposable cartridges for point-of-care medical diagnostics. Image courtesy of The McDevitt Lab.



MiniFAB component of the TearLab eye disease diagnostic. Image courtesy of TearLab Inc.

“The TearLab detects a disease called dry eye, by looking at the osmolality of the tear fluid,” Wilkinson explains. “This project came from product development that we did for [US company] TearLab initially. Then we transferred the TearLab manufacturing to our premises and we have been making the product here for the past five years.”

MiniFAB does product development and manufacturing for many global clients. The US and Europe are its main export markets, and the company has satellite offices in Rochester, New York state in the US, and Bristol in the UK.

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MiniFAB's Headquarters



Manufacture of medical products in MiniFAB's cleanroom facilities.

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"A company may contract us to develop an assay or a new method to detect a disease state and ask us to develop it into a point-of-care application," says Wilkinson. "With that in mind, our R&D team use its knowledge and expertise to design and develop it for the customer."

Wilkinson believes that tax incentives are needed for Australian manufacturers. There should be expanding accelerated depreciation rules to encourage Australian manufacturers to invest in automation and efficient processes.

According to Wilkinson, MiniFAB's future plans are to keep growing the manufacturing business, especially in the medical technology area.

"Traditionally we were seen as an engineering company," he says. "But we are a manufacturer first, developing and making products with high resolution and fine features that enable state-of-the-art medical devices and diagnostics."

### Analytica – Pioneering e-health

Brisbane-based Analytica's lead product is the PeriCoach™ system, an e-health treatment system for women who suffer Stress Urinary Incontinence. The PeriCoach system's electronics are manufactured in Dandenong, east of Melbourne, and the plastics are made, assembled and tested at Villawood in western Sydney, using ISO 13485-qualified contract manufacturers.



PeriCoach devices being charged prior to shipping.

Analytica CEO Geoff Daly explains how the system works: "The PeriCoach system comprises a sensor device, web portal and smartphone app. The wireless device has biosensor technology to monitor the squeeze and lift of a woman's pelvic floor muscles. Development of strong clamping force enables a female to stop urine leaking through the urethra, thus preventing incontinence.

"The clamping force measurement is transmitted to a smartphone app, which can then be loaded to the PeriCoach portal or PeriCloud, where physicians can monitor the female patient via the web portal. This enables physicians to remotely determine if a woman is performing her pelvic floor exercises correctly, and so prevent or improve her incontinence condition. We are trying to get people talking about incontinence and our job is to prevent and fix women's incontinence."

Daly, who has been at Analytica since 2005, is a chartered biomedical and mechanical engineer with almost 20 years' experience in the medical devices industry. The company's employees are scattered along Australia's east coast, with global marketing managers in Denver, USA, and Lyon, France. Analytica's registered office is in Brisbane.

"The entire design team works in Brisbane and all 10 employees, as well as myself, work from home," he adds. "The advantage of this is that we can hire the best people regardless of where they live. We also use expert consultants and suppliers when the product development and commercialisation lifecycle requires."

The PeriCoach system can be purchased on Analytica's website for around \$300, which includes the sensor device, the smartphone app, and a 12-month fee for the PeriCoach portal. Analytica is currently selling the PeriCoach system in Australia and New Zealand, the UK, Ireland and the US.

"Eventually, we want to sell everywhere," says Daly. "We have patents (pending), trademarks and design registrations in the US, Canada, Brazil, Australia, Japan, China, India and Europe. Japan has the highest per-capita spend in continence products and double the expenditure in the US, so Japan could be a future market."

### SomnoMed – tackling sleep disorders

A global leader in Continuous Open Airway Therapy (COAT), SomnoMed® provides clinically proven diagnostic and treatment options for sleep-related breathing disorders such as obstructive sleep apnoea (OSA) and sleep bruxism (teeth grinding). SomnoMed's innovative custom-made medical devices have helped treat thousands of OSA sufferers globally.

"Severe OSA sufferers have 50, 60 or even more sleep interruptions per hour," says Dr Peter Neustadt, SomnoMed's Executive Chairman and CEO. "They will get up in the morning and think they have slept, but they have not. This can result in headaches and falling asleep at work, plus it can also contribute to diabetes, high blood pressure and obesity. Severe cases are life-threatening – breathing can stop for minutes and prevent the brain from receiving oxygen."



A dentist fitting a SomnoMed device.

Founded in 2004., SomnoMed today employs 300 people globally, including 30 in in Australia. The company has achieved record earnings in recent years, with revenue jumping from \$10.7m in FY2010 to \$34.4m in FY 2015. Over the same period unit sales jumped from 19,543 to 51,355. Today SomnoMed's head office and product development centre is in Crows Nest, Sydney, but it has 16 global logistic hubs and service centres across the US, Europe, Japan and South Korea.

"Very early in the development of the company, it was obvious that we would be a global business," explains Dr Peter Neustadt, SomnoMed's Executive Chairman and CEO. "We have patents for our devices in every country they are sold. One difficulty we've experienced in selling medical devices globally is that in Europe, every country has its own regulation and insurance system, plus there are many different languages to deal with. That is why we have local people in every country that we sell in, responsible for device registration, fulfilment, service, marketing and sales."

SomnoMed makes a wide range of patented products. The company's principal product is the SomnoDent device, which is custom-made for each patient to holds the lower jaw in a slightly forward position, helping to prevent OSA.

"The SomnoDent device is a very sophisticated mouthguard, made with special proprietary materials under the ISO 13485 medical devices manufacturing regulations," says Neustadt. "It is certified and contains a microchip, which measures its compliance on a nightly basis. We are reaching 85%-90% compliance on treatment on an all-night, every-night basis, compared to alternative treatments with CPAP masks of 60%-70% compliance only, on a minimum of four hours per night on a 21 nights-per-month basis."

Neustadt explains that when a patient is diagnosed with OSA, their sleep specialist or GP will refer them to a dentist who takes an impression of

the patient's upper and lower teeth as well as a bite record, which is sent to SomnoMed. The device is then custom-made for the patient, before being fitted and adjusted by the patient's dentist, in a process that typically takes 15-30 minutes. Patients are then referred back to their medical practitioner.

In June, the company received US Food and Drug Administration (FDA) approval for its DentiTrac compliance control system. It is the only device in the US with an FDA-approved insertion of a micro-recorder that objectively records compliance data that can be assessed by sleep specialists. Collected minute-by-minute throughout the night, it records the number of hours the device is worn and whether the patient adopts a supine or non-supine head position.

"We operate successfully across 27 countries, with 55% of our sales in the US, 35% in Europe and 10% in the Asia Pacific," says Neustadt. "US unit sales increased by 35% from 2013 and our European sales climbed by 65% over the same time. Within the next few months we will reach the milestone of having fitted 250,000 patients around the world."

**Bolstering innovation**

"The vibrant med tech industry is expanding in this country," says Glenn Cross, Chief Operating Officer of AusBiotech. "[That's] according to the figures, plus the interest of 396 delegates at our AusMed-tech conference this May, with increasing numbers every year. However the industry needs end-to-end tax incentives."



Glenn Cross, Chief Operating Officer of AusBiotech.

AusBiotech, along with the MTA, Cook Medical and the Export Council of Australia, submitted a joint report to the Federal Department of Industry and Science in April. Entitled 'Australian Innovation and Manufacturing (AIM) Incentive – Who Cares about Australia? We do.', the report urges the government to implement a patent box-style tax incentive that would offer a reduced tax rate on qualifying profit from IP.

The AIM report says that, though Australia supports the R&D phase of innovation via the R&D Tax Incentive, the resultant IP is vulnerable to being sold, managed or manufactured overseas, due to a lack of supportive manufacturing tax incentives in Australia. Subsequently the economic benefits of the IP creation, such as jobs, exports, manufacturing and clinical trials, head overseas to countries that are providing patent box tax incentives, like the UK and several EU countries.

"Obviously the R&D tax incentives need to continue," says Cross. "But to increase Australia's global competitiveness in innovation and manufacturing, we need a patent box-style tax incentive to keep manufacturing in this country."

Cross advises that as a result of the AIM report: "Treasury came back to us expressing interest in a manufacturing tax policy. To complete the tax reform story, we are currently producing a white paper on an investor incentive to encourage investors to 'park' their funds in pre-revenue companies for lengthy periods."

Cross is positive about the Medical Research Future Fund, passed by the Federal Government on 12 August. There is currently \$10bn in the fund, potentially rising to \$20bn in the future.

"This is a great nation-building program," Cross says. "But there is a risk that all the money in the fund will go into early research, and we believe that a proportion of it should be dedicated to the commercialisation of this research." **AMT**

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A SomnoMed Classic device.