



**Medical Technology**  
ASSOCIATION OF AUSTRALIA



# ANNUAL REPORT

2018-2019



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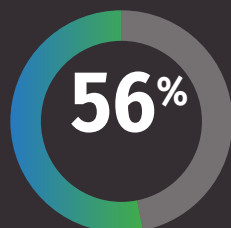
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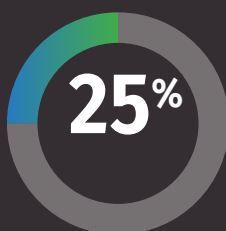
# KEY FACTS AND FIGURES FOR THE YEAR

## MEDICAL TECHNOLOGY ADVANCES

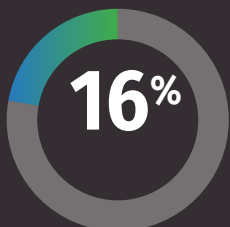
Global advances in medical technology over the past 20 years have resulted in



Reduction in hospital stays



Decline in disability rate



Decline in annual mortality



leading to an approximate

**3.2 year**

increase in life expectancy

## 12 MONTH FINANCIALS

For the 12 months to 30 June 2019 MTAA achieved an operating profit of

**\$129,557**

a decrease in expenditure to

**\$3,452,381**

an increase in net assets of

**8.8%**

with no increase in membership fees.



## MTAA ACHIEVEMENTS

**1<sup>st</sup>**

Women in MedTech  
Mentoring Program

**2<sup>nd</sup>**

anniversary of the  
Women in MedTech Awards

**221**

people attended  
Women in MedTech events

**237**

people attended  
MedTech 2018

**794**

people enrolled in the  
Code of Practice training

MTAA issued

**19**

press releases

**2,199**

participants completed  
MTAA training courses

**829**

individuals enrolled in the online  
Operating Theatre Protocols course

**20**

face-to-face Operating Theatre  
Protocols courses completed by

**171**

enrolled participants

## SOCIAL MEDIA REACH



Twitter followers grew  
by 262 to 1,405



LinkedIn followers grew  
by 1,309 to 3,545





“ Our members play a vital role in providing healthcare professionals with essential education and training in the use of the more complex medical technologies to maximise patient health outcomes

# ABOUT MTAA



MTAA REPRESENTS MANUFACTURERS AND SUPPLIERS OF MEDICAL TECHNOLOGY USED IN THE DIAGNOSIS, PREVENTION, TREATMENT AND MANAGEMENT OF DISEASE AND DISABILITY. MTAA MEMBERS SUPPLY THE MAJORITY OF NON-PHARMACEUTICAL PRODUCTS USED IN THE TREATMENT OF DISEASE AND DISABILITY IN AUSTRALIA.

The range of medical technology (MedTech) is diverse, from familiar items such as syringes, wound dressings and wheelchairs through to more complex technologies such as pacemakers, magnetic resonance imaging (MRI) machines, hip replacements, robotic surgery equipment and remote monitoring devices.

Our members play a vital role in providing healthcare professionals with essential education and training in the use of the more complex medical technologies to maximise patient health outcomes from the use of that technology. Industry-sponsored fellowships and funding for research and development in hospitals, universities and research facilities helps ensure the development and commercialisation of medical technology that meets contemporary healthcare needs and improves patient health and quality of life outcomes.

Associate members of MTAA are supporter or partner organisations and individuals who support the work of the sector along the entire MedTech value chain, all the way from product idea through to patient utilisation. They include legal, logistic and consulting practitioners, compliance agencies, health economists, researchers and universities, as well as industrial designers and product commercialisation specialists. They bring valuable expertise which enables MTAA to support its primary objective – to bring the benefits of technology to patients to ensure patient health outcomes and quality of life are improved.

## Our mission, vision and values

- Our work is to champion medical technology for a healthier Australia
- When our work is done, medical technology will be valued as a key driver of a healthier Australia
- We will work with integrity, collaboration, influence and leadership

## Our People at 30 June 2019

**Ian Burgess** Chief Executive Officer

**Peter Tustin** Director, Business Operations

**Paul Dale** Director, Policy

**Val Theisz** Director, Regulatory Affairs and Clinical Affairs, Code of Practice

**Rachel Fry** Government Relations and Communications Manager

**Louie Radburn** Marketing Manager

**Lee Grow** Professional Development Manager

**Lorraine Hendry** Events Manager

**Ranju Dhungel** Accounts Officer

**Neina Fahey** Code of Practice and Project Coordinator

**Isobel Simpson** Executive Assistant and Office Manager

**Seni Murni** Administration Officer

**David Ross** Policy Advisor

**Katherine Purcell** HR Advisor

# CHAIR REPORT



OVER THE LAST EIGHTEEN MONTHS, WE HAVE FACED MANY CHALLENGES BUT ALSO CELEBRATED MANY ACHIEVEMENTS WITHIN THE AUSTRALIAN MEDICAL TECHNOLOGY INDUSTRY.

We have a world class healthcare system in Australia and our industry is a crucial contributor to this through greater life expectancy, quality of life and early detection. Not only does our industry contribute to Australia through better health outcomes, it brings cutting edge research and innovation, manufacturing employment and education and training to the economy.

Global advances in medical technology over the past 20 years have resulted in a 56% reduction in hospital stays, 25% decline in disability rates, 16% decline in annual mortality and increased life expectancy of approximately 3.2 years.

Australia's health system allows universal access to some of the most up-to-date medical procedures available, enabling great patient outcomes across the country. We are very proud to continue to advocate for greater access to a greater range of technology for patients.







## COMMONWEALTH AGREEMENT

Our Agreement with the Federal Government continues to be a major advocacy focus for MTAA, and we continue to work on ensuring that the Government delivers on its commitments to the industry.

A number of positive outcomes arising from the Prostheses Reform process have been achieved including the move from two to three opportunities to list on the Prostheses List (PL) per year, agreement from the Government to implement an abbreviated pathway for many products to list on the PL and following an intense period of sustained lobbying, the listing of cardiac ablation catheters on the PL as of 1 March.

But there is still work to do. MTAA continues to play a leadership role in the Prostheses Reform Industry Working Groups formed by the Government as a key part of implementing the Agreement, including the Government's acceptance of MTAA's proposal to enable a more pragmatic HTA process for most prostheses.

## HONOURING STEADFAST SUPPORT AND ACHIEVEMENT

It is important to the MTAA Board that our membership base remains strong and diverse and we thank all our members for their contribution to the industry and the support that they provide to the many committees, forums and events throughout the year.

The MedTech Industry Awards Dinner is an important event on our calendar, an event at which we take the opportunity to recognise and thank those who demonstrated their commitment to the industry through continuous membership and participation. This year we recognised:

### 5-YEAR CONTINUOUS MEMBERSHIP

Abbott Vision  
Culpan Medical Australia  
IDE Group  
Wright Medical Australia

### 10-YEAR CONTINUOUS MEMBERSHIP

Paragon Therapeutic Technologies

### 20 YEAR CONTINUOUS MEMBERSHIP

Abbott Medical Australia

### 25 YEAR CONTINUOUS MEMBERSHIP

Australasian Medical & Scientific  
Bard Australia  
Fresenius Kabi Australia



We also believe it is important to recognise outstanding individuals who have dedicated their careers to the Medical Technology Industry in Australia. We do this by honouring such people through life membership of MTAA.

This year we recognised Jamie Stanistreet. Jamie joined Medtronic in 1999 following their acquisition of AVE Inc and was appointed as Managing Director in 2001. He was appointed to the Board of MTAA in October 2006 and elected to the Board of MTAA in January 2008 where he also served as Vice Chair until retiring in August 2013.

Jamie was instrumental in Medtronic's recognition as one of Australia's Best Employers in the 2005, 2006/07 and 2008 Hewitt Best Employers Australia and New Zealand Awards, and again in 2010 when the company received a Highly Commended award.

In 2013, Jamie was awarded the Medical Technology Association of Australia's (MTAA) highest honour - the inaugural Outstanding Individual Achievement Award.

“We believe it is important to recognise outstanding individuals who have dedicated their careers to the Medical Technology Industry in Australia.

This year we recognised Jamie Stanistreet.



### HONOURING GAVIN FOX-SMITH

I would like to thank outgoing MTAA Chair Gavin Fox-Smith. Gavin has worked in the MedTech industry for over three decades, including four years as the Chair of MTAA.

During this time, Gavin oversaw the successful negotiation of the industry's Agreement with the Government and was an active supporter of diversity in the industry through MTAA's Women in MedTech initiative.

Gavin's contribution to the MedTech industry has been significant, both throughout his outstanding career to date and his role as MTAA Chair.

In conclusion, I would like to say thank you to the MTAA Board and the Committee chairs for their support and invaluable counsel throughout this year. I would also like to thank our MTAA team, led by Ian Burgess, who continues to guide MTAA through what has been a challenging few years for the industry. I know that we will continue to grow stronger as we work together towards our mission of championing medical technology for a healthier Australia.

A handwritten signature in black ink, appearing to read 'M Ben-Mayor', written over a light blue horizontal line.

**Maurice Ben-Mayor**  
Chair

# CEO REPORT



2018-19 WAS ONCE AGAIN AN EXTREMELY BUSY AND PRODUCTIVE TIME FOR THE MEDTECH INDUSTRY AND I THANK OUR VALUED MEMBERS FOR THEIR COMMITMENT TO OUR INDUSTRY THROUGH THEIR TIME, SUPPORT AND EXPERTISE.

The MedTech industry continues to face challenges but we have faced them as a united front over the past year. Our position as a key player in the ongoing healthcare debate has been strengthened through our ongoing advocacy on behalf of the industry.

Reform of the Prostheses List and holding the Government to account on the Agreement signed with them in October 2017 has continued to be a major activity for MTAA, however we have maintained significant broader advocacy and policy development, including regulatory reform, and member services such as our annual conference and events, professional development program and our Women in MedTech initiative and regular provision of information and analysis of industry and healthcare issues.

## STRATEGIC PLAN

MTAA's Strategic Plan was launched in November 2017, with a core objective to: "communicate to the Government the economic value and benefits of the industry for Australia". This means more than the economic value and benefit the industry brings, but also how patients have benefited from the industry. This message is a great way to humanise our industry, which will play an important role in our advocacy and engagement work.

The Strategic Plan draws on extensive quantitative and qualitative research conducted with MTAA members in 2017 and identifies that the best path to growth is in collaboration with a broad-based alliance that includes researchers, manufacturers, distributors, clinicians, providers, funders and consumers.

Collaboration is at the heart of the plan. It widens engagement, expands a base for representation and advocacy, and brings benefits to members. The plan was developed at an important time. Healthcare policy and funding is in flux in Australia and the MedTech industry needs to ensure that it has a strong voice in policy debates that affect the future. The industry needs to continue to engage with the Government to move forward on a long list of issues.

The MTAA Strategic Plan 2017–2020 prioritises work in five strategic areas of activity:

- Advocacy
- Engagement
- Collaboration
- Integrity
- Member focus





## ADVOCACY

Advocacy is an essential and growing part of MTAA's work and our engagement with the Minister for Health and his department, our focus on data-based advocacy and the work of individual companies have combined to ensure that we are driving better outcomes for the industry. Our profile and reputation has been strengthened in Canberra through the ongoing Prostheses List reform process and we look forward to continuing to help deliver better access to medical technology for patients as a result.

MTAA has continued to engage with the Federal Government on the Agreement signed in October 2017 to ensure continued certainty and stability regarding the Prostheses List (PL), securing a number of positive outcomes, including the listing of cardiac ablation catheters on the PL as of 1 March.

We are engaging on an increasing range of issues, including cybersecurity, the MBS reviews and proposed changes to the Research & Development Tax Incentive, and MTAA was once again present at this year's health budget lock-up.

We have continued to build the industry's presence as a voice in the national health debate, as we actively remind the media and stakeholders that lower-than-expected private health insurance premiums were the direct result of the Agreement between MTAA and the Government. In December 2018, as part of our role in the ongoing conversation around how to arrest the decline in private health insurance, MTAA

commissioned economic consultancy AlphaBeta to prepare an analysis of ways to keep private health insurance premiums lower.

MTAA's Ophthalmic Forum undertook an analysis of the value of accessing ophthalmic devices through the Prostheses List, another piece of work that will be key to highlighting the importance of medical technology to the value proposition of private health insurance.

Building on our successful advocacy in 2017-18 to allow for the data from the MyHR system to be used by researchers and industry to better help them target research and development activities, MTAA is working with the Therapeutic Goods Administration (TGA) and the Australian Digital Health Agency (ADHA) to progress this through the MyHealth Record future work-plan.

MTAA has provided submissions on the National Clinical Quality Registry strategy and informed work by the Independent Hospital Pricing Authority in updating coding and classification of hospital services and advocated for the provision of more transparent information about the MBS Reviews.

We have worked closely with the TGA in progressing regulatory reforms and, in particular, ensuring that the new and revised regulations and guidelines are workable for the MedTech industry and maintain alignment with the EU Medical Device Regulations.



## COLLABORATION

MTAA has collaborated with a number of other associations throughout the year resulting in a number of successful outcomes. We have signed a new and extended Memorandum of Understanding with MTPConnect to help create more opportunities for collaboration between MTPConnect and our member organisations and continued oversight of the \$30m BioMedTech Horizons Program established under MTAA's Agreement with the Government to support development of new and innovative device technologies, clinical trials and associated registries, support researcher exchanges and workforce development.

In the lead-up to the 2019 federal election, MTAA also worked closely with Research Australia and other peak bodies to develop a Pre-Election Statement to advocate for greater awareness of the needs of the health and medical research sector.

Our involvement with the BridgeTech Program in collaboration with Queensland University of Technology, MTPConnect and 20 university and industry partners and organisations in the medical-biotechnology sector has helped to deliver an exciting and innovative education program that will provide the necessary training to enable the successful commercialisation of Australian medical technology research.

Our collaboration has also included joint advocacy in relation to the Research & Development Tax Incentive, Skilled Migration and support for MTPConnect.

## ENGAGEMENT

Our Committee structure, as part of the Strategic Plan at the start of 2018, has included the introduction of a number of new Forums, established at the request of members, to progress initiatives directly relevant to those groups. The Forums established as part of that process include Clinical Investigations, Ophthalmic, Orthopaedic, Regulatory and also the Radiation Therapy Advisory Group (RTAG). Major bodies of work progressed by those forums include an analysis undertaken by the Ophthalmic Forum of the value to patients and Government of accessing ophthalmic devices through the Prostheses List and obtaining significant funding commitments from both Government and the Opposition at the 2019 election for radiation therapy for regional Australia, which was driven by RTAG.

Our online digital platform, PulseLine, continues to be a key distribution channel for the Association and members to communicate and advocate to a wide range of stakeholders and decision makers. We have significantly increased our engagement with members and stakeholders through this platform and its objectives of showcasing the value of medical technology and communicating key advocacy messages on behalf of the industry.



## MTAA continues to build the industry's presence as a voice in the national health debate.

### MEMBER FOCUS

Total membership numbers have held steady this year with 104 members, this includes 69 corporate members and 35 associate members. We welcomed 8 new corporate members and 4 new associate members this year. There are 9 committees currently operating and there are 104 positions. The 2019 committees are Public Affairs, Industry Policy, Reimbursement, Regulatory Affairs, Code Authority, Code Monitoring, Finance, Women in MedTech and the MedTech Conference Committee. Our sincere thanks to our members for their ongoing contribution to our committees, which is critical to our success.

### FINANCIAL PERFORMANCE

MTAA achieved a net profit of \$129,557 for the twelve months to 30 June 2019. The result compared to the prior year profit of \$497,189, which included a substantial payroll tax refund.

Strong financial management enabled member subscription rates to be frozen for 2018-19. Historically, subscription rates have been increased by more than CPI, however the Board recognised the tougher operating environment that all members face, including those members incurring Prostheses List cuts.

Total revenue in 2018-19 was \$3,581,938, a decrease of 3.6% on the previous year after normalising for the payroll tax refund received in 2017-18. Operating revenue excluding special levies, Code of Practice and grant income was stable in 2018-19 at \$3,270,441, 0.8% less than the prior year.

Total operating expenditure to 30 June 2019 was \$3,452,381, a decrease of 2.2% from the previous year. The balance sheet reflects a strong financial position with net assets increasing by 9% over the prior year to \$1,597,107.

### MTAA TEAM

Finally, I would like to acknowledge the outstanding efforts of the entire MTAA staff team during what was a busy and challenging year. MTAA has a small but dedicated and talented team that continue to go above and beyond to meet the needs of our members.

**Ian Burgess**  
Chief Executive Officer

# ADVOCACY





## ADVOCACY

ADVOCACY IS AND WILL REMAIN A KEY FOCUS OF MTAA. WE WILL CONTINUE TO CONTRIBUTE TO CURRENT REVIEWS AND CONSULTATIONS WITH A KEY FOCUS OF NEGOTIATING WITH THE AUSTRALIAN GOVERNMENT. AS A COLLABORATIVE ALLIANCE, WE WILL COMMUNICATE TO THE GOVERNMENT THE ECONOMIC VALUE AND BENEFITS OF THE INDUSTRY FOR AUSTRALIA.

MTAA has continued to engage with the Federal Government on the Agreement signed in October 2017 to ensure continued certainty and stability regarding the Prostheses List (PL), securing a number of positive outcomes, including the listing of cardiac ablation catheters on the PL as of 1 March.

MTAA was again present at this year's health budget lock-up and has continued to engage on an increasing range of issues, including cybersecurity, the MBS reviews and proposed changes to the Research & Development Tax Incentive.

It is important for the industry to continue to build its presence as a voice in the national health debate. In December 2018 MTAA commissioned economic consultancy AlphaBeta to prepare a report on ways to keep private health insurance premiums lower as part of our contribution to the ongoing conversation around how to arrest the decline in private health insurance participation.

## PROTHESES LIST REFORM AND AGREEMENT IMPLEMENTATION

The historic Agreement signed between MTAA and the Government on 11 October 2017, negotiated on behalf of the MedTech sector following a period of continued pressure on the industry is now well underway. Under this Agreement, cuts to benefits on the PL were limited to \$303 million (compared to the \$1 billion Government had put on the table). MTAA committed to work with Government on a range of reforms to the Prostheses List Framework which will have significant ramifications for the sector.

MTAA has secured a number of positive outcomes arising from the Prostheses Reform process to date, including moving from two to three opportunities to list on the (PL) per year, the listing of cardiac ablation catheters on the PL as of 1 March 2019 and the agreement from the Government to implement an abbreviated pathway for many products to list on the PL.

A key deliverable of the Agreement was the Government's commitment to list life-saving non-implantable medical devices to support private health insurance reimbursement for clinically effective and cost-effective medical devices. Cardiac ablation catheters for atrial fibrillation was the first initiative in this area and listing means that privately insured patients now have access to this life-changing technology.

“ It is important for the industry to continue to build its presence as a voice in the national health debate.

As the catheter is removed from the body following surgery, it is classified as non-implantable technology, previously not requiring private health insurers to pay for it, limiting private patient access to this technology and pushing patients into an already over-crowded public system.

MTAA has also played a key leadership role in the Prostheses Reform Industry Working Groups set up by the Government as part of implementation of the Agreement. In particular, MTAA's proposal to enable a more pragmatic HTA process for most prostheses was accepted by Government and is under development.

MTAA's work has included highlighting issues with current PL processes and identifying ways to improve these going forward. MTAA has also identified issues with proposals for Prostheses Reform that have the potential to undermine patient access to devices through their private health insurance.

As an advisory member of the Prostheses List Advisory Committee (PLAC) and Clinical Advisory Groups (CAGs), MTAA continues to inform quality decision making on the Prostheses List. MTAA has provided feedback and produced improvements to new Guidelines or announcements of targeted reviews of PL items and provided a fully developed proposal for expanding the PL criteria to include some non-implanted devices, key components of which have been accepted by the Government.

## PRIVATE HEALTH INSURANCE

In 2018-19, MTAA has continued to actively advocate on behalf of the sector in relation to private health insurance and the Government's ongoing reform process, actively reminding the media and stakeholders that lower-than-expected private health insurance premium increases were the direct result of the Agreement struck between the Government and MTAA members, and that the medical devices industry has been the sole contributor to keeping premiums lower.

MTAA supports the intent of the Government's reforms to deliver greater transparency for consumers and to make private health insurance more attractive and valuable to policyholders, however there are ongoing concerns around the categorisation of insurance policies into gold, silver, bronze and basic and MTAA will continue to raise these.

In late 2018 MTAA engaged economic consultancy AlphaBeta to prepare a report on reducing costs in the private health insurance system and what role medical technology can play, to be released in the second half of 2019.

The AlphaBeta report will be an invaluable resource as MTAA continues to highlight to Government that the medical devices industry has made the only significant contribution to keeping premiums low, with another round of cuts yet to come.

MTAA's Ophthalmic Forum, established by the Board at the request of member companies in 2018, undertook an analysis of the value of accessing ophthalmic devices through the Prostheses List, another piece of work that will be key to highlighting the importance of medical technology to the value proposition of private health insurance.

## WOMEN IN MEDTECH

The Women in MedTech (WiMT) committee continued to promote the WiMT initiative to the MedTech industry. In 2018-19, WiMT hosted a number of events, including panel sessions and workshops covering key issues around diversity, inclusion and opportunity.

For the first time, university students with an interest in the industry were invited to attend WiMT events through the introduction of the Ignite Program. The program allows member organisations to sponsor students looking to connect with healthcare professionals and raises the profile of the MedTech sector as an industry for career consideration, an opportunity to receive tangible tools and resources in a practical environment and encourages future leaders in the MedTech Industry.

The WiMT Committee also launched the pilot MTAA Mentoring Program, an initiative to assist women in their career, professional and personal development by connecting them with mentors within the MedTech industry.



## HEALTHCARE POLICY

In 2017-18 MTAA successfully advocated with Government to allow for the data from the MyHR system to be used by researchers and industry to better help them target research and development activities as well as identify areas requiring improvement. Building on this significant win, MTAA has continued to work with the Therapeutic Goods Administration (TGA) and the Australian Digital Health Agency (ADHA) to progress this through the MyHealth Record future work-plan.

MTAA is continuing to advocate for a move towards more value-based healthcare for the procurement of devices within the states and territories and is identifying what this would mean for the MedTech sector in a range of areas, including the impact on company business models, marketing approval and reimbursement decisions.

MTAA has provided submissions on the National Clinical Quality Registry strategy and informed work by the Independent Hospital Pricing Authority in updating coding and classification of hospital services. MTAA has also advocated for the provision of more transparent information about the MBS Reviews.

## BUDGET

MTAA monitors the health budget and advocates on areas of interest for our members. The current budget has a significant focus on health, with a record spend of \$104 billion in 2019-20, with the emphasis on the 'four pillars' of the Government's long-term health plan: guaranteeing Medicare and the PBS; supporting hospitals; prioritising mental health, preventive health and sport; and investing in research.

MTAA believes that Government should continue to prioritise health expenditure, however, the current service delivery system in Australia provides fragmented care and Australia needs to transform its healthcare system to be fit for the 21st century. Unfortunately, the budget did not provide any further commitments to reforming our healthcare system to align with a shift away from volume to value. This will be something that MTAA will continue to pursue with decision-makers.

The Government will deliver ongoing funding for Australia's health and medical research sector, with \$5 billion invested in the Medical Research Future Fund (MRFF) over 10 years to complement \$3.5 billion for the National Health and Medical Research Council and \$0.5 billion for the Biotechnology Translation Fund.

This budget also delivered \$45.5 million to be spent on radiation therapy for regional Australia for which the medical technology industry had campaigned hard.

## REGULATORY AND CLINICAL ISSUES

During 2018-19, MTAA continued to work closely with the TGA in progressing regulatory reforms and ensuring that the new and revised regulations and guidelines are workable for the MedTech industry and maintain alignment with the EU Medical Device Regulations.

In response to the International Consortium of Investigative Journalists investigation into medical devices in late 2018, the TGA announced an Action Plan for Medical Devices. MTAA will continue to actively engage with the TGA in the development and implementation of the Action Plan.

MTAA has successfully argued for the inclusion of obsoleted orthopaedic implant (whose ARTG inclusion lapsed in 2015 when joint replacements were up-classified from Class IIb to Class III) in the Category C list of the Special Access Scheme to enable patient access to parts needed for revision surgery.

MTAA has contributed to the CT:IQ project Early Phase Best Practice for clinical trials. The project delivered a checklist and toolkit that provides a summary of recommendations, considerations and resources for clinical research sites in the conduct of clinical trials, particularly those sites conducting early phase studies.



## RESEARCH & DEVELOPMENT TAX INCENTIVE

MTAA has continued to work in collaboration with industry peak bodies such as AusBiotech and a wide range of stakeholders, including Cochlear, ResMed, CSL, Cook Medical and Deloitte to advocate for a better R&D tax system in Australia.

Collaborative advocacy with other peak bodies successfully prevented the implementation of R&D Tax Incentive changes in the Senate.

## SUBMISSIONS

MTAA submitted the following formal responses to Commonwealth consultations:

### Advertising

- MAR 2019 Follow-up Submission to TGA consultation #2 Proposed Therapeutic Goods Advertising Code Guidance
- NOV 2018 Follow-up Submission to TGA Consultation #1 Proposed Therapeutic Goods Advertising Code Guidance
- OCT 2018 TGA Advertising Code Guidance

### Annual TGA Performance Stats

- APR 2019 Proposed content for the annual TGA performance statistics report

### Cybersecurity

- FEB 2019 Medical device cyber security

### Medical Company Representatives

- MAR 2019 Joint AOA and MTAA position statement on orthopaedic MedTech company representatives (OMCRs) in operating rooms

### Personalised including 3D printed medical devices

- MAR 2019 Proposed regulatory scheme for personalised medical devices, including 3D-printed devices

### Private Health Insurance

- JUL 2018 Private Health Insurance Legislation Amendment Bill 2018

### Prostheses List

- FEB 2019 HTA Pathway Proposal to the Prostheses Reform Benefit Setting Industry Working Group February 2019
- OCT 2018 Comparison of prostheses pricing across different markets

### Regulatory Reform

- APR 2019 Proposed changes to the classification of active implantable medical devices and their accessories
- MAR 2019 Proposed reclassification of spinal implantable medical devices
- MAR 2019 Regulation of software, including Software as a Medical Device (SaMD)

### Research & Development

- JUL 2018 Draft Treasury Laws Amendment (Research and Development Incentive) Bill 2018

### Standards

- JULY 2019 In-house service and refurbishment of medical equipment - understanding regulatory risk

### UDI

- FEB 2019 TGA consultation: Proposal to introduce a Unique Device Identification system for medical devices in Australia



# ENGAGEMENT

## ENGAGEMENT

INCREASING ENGAGEMENT IS A WAY FOR MTAA TO BENEFIT FROM THE BEST TALENT THE INDUSTRY HAS TO OFFER NOW AND IN THE FUTURE. MTAA ENGAGES WITH CURRENT AND POTENTIAL MEMBERS AND KEY STAKEHOLDERS, INVOLVING INDUSTRY LEADERS AND CREATING OPPORTUNITIES FOR FUTURE INDUSTRY LEADERS. FOCUSING ON ISSUES OF SPECIAL INTEREST TO MEMBER COMPANIES AND COMPANY REPRESENTATIVES INCREASES ENGAGEMENT AND HENCE MEMBERSHIP LOYALTY AND RETENTION.

### MTAA Annual Conference

7 and 8 November 2018

#### *The Future of MedTech gets Personal*

Over 200 people attended MedTech18 at Luna Park in Sydney, bringing the industry together to network, exchange ideas and hear the latest industry news.

MedTech Europe's Diana Kanecka joined the Department of Health's John Skerritt to discuss alignments between policy in Australia and Europe, and Technologist Futurist, Shara Evans presented the latest innovations in the Future of medical devices. In a heartwarming reminder of why we work in the industry, Marina Te Maro shared the amazing work the Children First Foundation is doing to change the lives of disadvantaged children from developing countries.

The Cross-Political panel provided great insights and practical tips about our political system and how we engage with politicians.

Innovation through Physician Collaboration opened day 2, revealing the importance of primary users of equipment driving innovation and the role



physicians play in manufacturing tools today. The cybersecurity session gripped the audience with AustCyber's Michelle Price and other panellists delivering a powerful message on the rising risks of cyber-attacks on devices.

Let's Commercialise your Idea host Jennell Robinson from MedTech Innovator and others discussed the support networks for successful product market entry and infrastructure development and the factors for going global.

The Actuator played host to MedTech's Got Talent – Rapid Fire Round in search of young entrepreneurs to mentor and sponsor.

Closing the conference saw Dr. Norman Swan facilitate an entertaining and refreshing 1.5-hour session. Through re-enactment, panellists were put on the spot to respond to commonly misunderstood scenarios facing the industry.







## 2018 MEDTECH INDUSTRY AWARDS

7 November 2018

Once again, the annual MedTech industry awards dinner brought together industry leaders to celebrate and pay tribute to a year of innovation and leadership. Held at the end of day one of MedTech 2018, MTAA was proud to announce the winners in three awards categories, chosen from a record number of high-quality entries, a testament to an industry that is developing and providing the Australian healthcare system with innovative solutions for patients.

The Kerrin Rennie Award was established in 2007 to recognise and profile the innovative and extraordinary contribution of medical technology in improving health outcomes of patients. This year's award was won by Boston Scientific's HeartLogic Heart Failure Diagnostic, which is a heart failure diagnostic tool available to patients with certain Boston Scientific implantable cardiac devices and remote monitoring system. This multi-sensor approach allows physicians to detect early warning signs of worsening heart failure symptoms and adjusting treatment to avoid potential hospitalisations.

The Outstanding Achievement Award is open to individuals who have contributed in a significant way to the development of the medical technology industry through improvement to patient outcomes or excellence in leadership and innovation. This year's winner, Gavin Fox-Smith, with more than 30 years' experience in the industry, including 21 years at Johnson & Johnson, has an extensive background as a senior executive in the Asia Pacific region. Mr Fox-

Smith is well known for his track record of developing and exporting outstanding leaders and ensuring a truly diverse and inclusive workforce. He is a passionate advocate for efforts that improve health, literacy and education, particularly for Indigenous communities.

Women in MedTech is a Board led initiative which started in July 2015 in response to the gap of women in leadership positions across the industry. The support and engagement on this issue from members of our industry has been overwhelming, making it a clear issue of importance for MTAA to support.

The Women in MedTech Champion is awarded to an individual or a company who has contributed to advancing the mission and goals just mentioned, and this year was awarded to Yolanda Mallouhi. Yolanda has been with Edwards Lifesciences for nearly 11 years as Senior Manager, HR, responsible for identifying, attracting, retaining and building the talent capabilities of Edwards to meet the needs of business today and into the future.

The Women in MedTech Company Champion was awarded to Baxter Healthcare. Baxter was once again named among the top 100 companies in Australia for gender equality (Australian Government – Employer of Choice for Gender Equality: 2017, 2016, 2015). With its 16-person Senior Leadership Team for ANZ equally represented by women and men, in line with the industry's benchmark metrics, Baxter has put gender equality and diversity at the core of its business in Australia.

[www.mtaa.org.au](http://www.mtaa.org.au)





The Six Signature Traits of Inclusive Leadership



International Women's Day Lunch

## HARNESSING THE POWER OF DIVERSITY AND FLEXIBILITY IN THE WORKPLACE

26 July 2018

Attended by around 110 people, this event was an opportunity for networking, learning and taking action on gender diversity. The keynote speaker was Amanda MacLean, Co-Founder of the Gravitas Project. Joining Amanda on the panel discussion was Steven Flynn, Baxter Healthcare, Patrick Gaynor, Medical Specialties Australasia and Mandi Jacobson, Dentons.

## MTAA DIGITAL MEDIA WORKSHOP

12 November 2018

This workshop, conducted for MTAA members and the wider MedTech industry, was designed to provide attendees with foundational knowledge of how they can best leverage digital channels. For example, demonstrating effective use of LinkedIn to promote the economic and social benefits the MedTech industry provides in Australia.

The workshop sessions provided real examples and practical insights for attendees to take back to their companies and begin implementing right away.

## THE SIX SIGNATURE TRAITS OF INCLUSIVE LEADERSHIP

22 November 2018

This Women in MedTech breakfast, attended by around 60 people, was addressed by Juliet Bourke, co-author of the Deloitte paper, *The Six Signature Traits of Inclusive Leadership – Thriving in a diverse new world*.

The event was aimed at professionals at all stages of their careers, providing an opportunity for attendees to explore their individual leadership differences and learn how to leverage their qualities in an adaptive working environment.

## INTERNATIONAL WOMEN'S DAY LUNCH

8 March 2018

The topic for this year's International Women's Day was Balance for Better. Over 120 people gathered in the Sydney CBD to hear from great innovators in their industry who have pioneered gender balance for their organisations. Speakers included Natalie Turmine, CEO, Australia Campbell Page, Yolanda Mallouhi, HR Director, Edwards Lifesciences and Steven Flynn, General Manager ANZ, Baxter Healthcare.

## ADVERTISING REGULATION UPDATE WORKSHOP

3 April 2019

Featuring speakers from the TGA and Dentons Australia, this workshop was an opportunity to become familiar with how the new Advertising Code impacts on individual organisations. The workshop was attended by around 80 people and covered a high-level overview of the legislative requirements, the Advertising Code and complaints handling.

## EU MEDICAL DEVICE REGULATION TRANSITION UPDATE

27 June 2018

The transition to the new regulatory framework for medical devices in the European Union has been slow and challenging. As of June 2019, only two notified bodies, BSI UK and Germany's TÜV SÜD, have been designated to the new EU MDR. A number of important implementation milestones are yet to be met and time is running out. Diana Kanecka, MedTech Europe Manager International Affairs, provided an update on the transition status.

## PWC BRIEFING ON ATO TRANSFER PRICING GUIDANCE

10 December 2018

MTAA hosted this briefing in conjunction with PwC to discuss the key elements of the release of the Practical Compliance Guidelines on transfer pricing from the ATO towards the end of November 2018. This session was targeted at medical device distributors who are part of a multinational group and have related cross-border transactions and dealings.

## MTAA ORTHOPAEDIC MARKET SURVEY

Following preparatory work by an MTAA Orthopaedic Working Group and KPMG, the new MTAA Orthopaedic Market Survey provided its first report to contributing companies on 1 March 2019. Fourteen MTAA member companies, who meet the cost of the survey, provided their sales data for 2017 and 2018 to KPMG covering the categories of hips, knees, shoulders, spinal, trauma and sports.

MTAA has spent several years without an orthopaedic survey after the previous survey ceased. With the submission of six-monthly data, survey results will be updated biannually.

## WORKPLACE INVESTIGATIONS WEBINAR

31 July 2018

Conducted by Caitlin Watson of Atkinson Vinden Lawyers, this webinar was tailored to HR managers and management and focused on how to handle allegations of inappropriate behaviour in the workplace. The webinar investigated how to conduct an effective workplace investigation when allegations of misconduct are raised and how to best reach the right conclusions whilst protecting the company's position.

## PROFESSIONAL DEVELOPMENT

Professional development is an essential way for healthcare professionals to stay up to date on the latest standards, reduce risk and advance better practices in the healthcare environment. The skills and engagement of our workforce is reflected in better medical outcomes for patients, longer staff retention, and greater stability for our industry. The Operating Theatre Protocols (OTP) course was the most attended facilitated face-to-face training course by MTAA with 182 registrations in the 2018–19 financial year.

## CHANGE IN ACORN STANDARDS

Every two years the ACORN Standards for Perioperative Nursing are reviewed and updated to reflect the evidenced-based practices that result from extensive research. All Company Representatives entering the Operating Theatre must comply with and obtain current accreditation of the ACORN Standards.

Some hospitals are now asking for the MTAA OTP card as part of their vendor credentialing process for visitor identification and standards verification.

- 2,199 professionals participated in MTAA training courses
- 829 professionals enrolled in the online Operating Theatre Protocols course
- 171 new attendees took part in the Introduction to Operating Theatre Protocols course
- 794 people enrolled in Introduction to Code of Practice training

## COMMUNICATIONS

MTAA continues to engage and develop strong networks and relationships with key journalists. These relationships have enabled MTAA to be made aware of media stories before they are printed and have allowed MTAA to respond to them proactively, increasing public and stakeholder awareness of the issues that matter to our industry.

In 2018–19, MTAA issued 19 press releases and was mentioned in many mainstream media avenues. In 2018 MTAA successfully defended the industry against spurious claims made by the International Consortium of Investigative Journalists and also through the Netflix film 'The Bleeding Edge'.

Our social media reach has continued to grow with the number of LinkedIn followers increasing by 1,309 to 3,545, and our Twitter followers growing by 262 to 1,405 followers. MTAA continues to communicate directly to members through the Members Update newsletter and direct emails.



## PULSELINE

In March 2018, MTAA launched PulseLine, a digital-first publication dedicated to providing news, commentary and insights on the Australian MedTech and healthcare landscape. PulseLine continues to grow in readership and is now a key distribution channel used by MTAA and members to communicate to the wider Australian MedTech community and decision-makers. MTAA also secured funding from the NSW Department of Industry under its Knowledge Hub Program to support the development of PulseLine content and provide opportunities to showcase the NSW medical device industry to the public. Under this initiative, we developed 10 separate pieces of digital video content from an animated infographic showcasing the NSW MedTech landscape.

## PULSELINE ADVISORY GROUP

A PulseLine Advisory Group has been established to help coordinate member company content and develop a positive messaging content stream for patient stories and industry news. MTAA will continue working with the advisory group members to ensure a proactive approach is taken to the planning and delivery of the industry's public messaging and content development.





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MTAA  
ANNUAL REPORT 2019

# COLLABORATION



## COLLABORATION

### MTPCONNECT

MTPConnect CEO Dr Dan Grant joined MTAA CEO Ian Burgess to sign a new and extended Memorandum of Understanding (MoU) at MTAA's MedTech 18 Annual Conference in Sydney. Dr Grant said the agreement would create more opportunities for collaboration for MTAA's member organisations in Australia. "MTAA has been significant in engaging and promoting Australian medical technology companies, large and small, the agreement will see our two organisations working together to continue providing in-market support and introductions to potential investors and customers, exchanging information on key issues and trends, supporting inbound and outbound missions and the delivery of joint projects," Dr Grant said.

As part of the October 2017 Agreement between MTAA and the Federal Government, a provision was included for a \$30m Grants Fund to be established under the Medical Research Futures Fund (MRFF) to support Australian MedTech innovation. The BioMedTech Horizons Program is open to small-to-medium size enterprises (SMEs) and researchers who partner with SMEs for conducting activities that support development of new and innovative device technologies, clinical trials and associated registries, support researcher exchanges and workforce development.



The BioMedTech Horizons Grants Program is being administered by MTPConnect and is required to align with the principles of the Medical Research Futures Fund.

### RESEARCH AUSTRALIA PRE-ELECTION STATEMENT

Research Australia has released its Healthy Australians, Healthy Economy publication reporting recommendations on the policy settings needed to position health and medical research as a significant driver of a healthy population and contributor to a healthy economy.

With a Federal election held in May this year, Research Australia worked closely with MTAA and other peak bodies to track movements in health and medical research policy and the needs of the health and medical research sector. This process kicked off last year with a Pre-Election Summit and continued over the course of 2018.

## “ A \$30m Grants Fund to be established under the Medical Research Futures Fund (MRFF) to support Australian MedTech innovation.

### BRIDGETECH PROGRAM

MTAA, in collaboration with Queensland University of Technology, MTPConnect and 20 university and industry partners and organisations in the medical-biotechnology sector, is delivering an exciting and innovative education program that will provide the necessary training to enable the successful commercialisation of Australian medical technology research.

The 2019 offering of the BridgeTech Program selected 100 participants from across Australia to take part in face-to-face and online training in the scientific, legal, financial, clinical, regulatory and reimbursement disciplines that contribute to research translation and the commercialisation of medical devices and diagnostics.

### PEAK BODIES

The CEOs of several health sector associations meet as a group to ensure effective communication and identify issues of common interest and potential collaboration.

Along with MTAA, this group includes Research Australia, Medicines Australia, Consumer Healthcare Products Australia, Complementary Medicines Australia, Pathology Technology Australia, Generic and Biosimilar Medicines Association, AusBiotech and ARCS Australia.

Collaboration has included joint advocacy in relation to the Research & Development Tax Incentive, Skilled Migration and support for MTPConnect.

### NSW KNOWLEDGE HUB

MTAA has been collaborating and co-funding projects with the NSW Department of Industry on an annual basis to promote business development in the MedTech sector. The Department of Industry provides a maximum amount of \$50,000 and MTAA provides in-kind funding of up to \$150,000.

NSW Knowledge Hub funds have been used to develop a range of content demonstrated the value of medical technology and its positive impact on the everyday lives of Australians that depend on it. All the content



developed in collaboration with the NSW Government has been deployed through MTAA's online digital platform, PulseLine.

## AUSTRALIAN CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION IN THE HEALTHCARE SECTOR

MTAA was one of five organisations that led the development of the Australian Consensus Framework, which aims to increase ethical behaviour characterised by values and principles such as honesty, integrity, transparency, accountability and oversight. That work was led by MTAA, the Australian Orthopaedic Association, Medicines Australia, the Royal Australasian College of Surgeons and the Australian Healthcare & Hospitals Association.

On 20 July 2018, an Australian delegation that included MTAA member representation attended the launch of the ACF Initiative at the APEC Business Ethics for SME Forum in Tokyo. The group, with the support of almost all of the Australian federal, state and territory health ministers, launched its primary document, The Australian Consensus Framework for Ethical Collaboration in the Healthcare Sector.

In recognition of the considerable effort involved in developing the ACF, Australia was acknowledged at the meeting for its ethical leadership and awarded the 'APEC Business Ethics for SMEs 2018 Lighthouse Award' by the U.S Deputy Assistant Secretary of Commerce for Asia, who publicly recognised the ACF as the largest initiative in the world of its type.

The group has subsequently changed its name to the Australian Ethical Health Alliance (AEHA) and there are currently 71 member organisations who are signatories to the Australian Consensus Framework, including professional health bodies, industry organisations, hospital and health services associations, universities, regulators, patient and advocacy groups, and other related organisations.

The 71 member organisations represent approximately:

- 200,00 Australian health professionals, employees and trainees
- 3.2 million consumers/patients.



# INTEGRITY

## INTEGRITY

### THE CODE AUTHORITY – CODE REVIEW

The Code Authority (CA) meets six times per year and is responsible for the oversight and effective administration of the Code including complaints and monitoring.

During 2018-19, the CA allocated two of its independent members to form part of the Code Review Working Group (CRWG). The Code Review Working Group was managed by the Code of Practice and Project Manager at MTAA and was comprised of the independent members from the CA and a document drafter with appropriate legal background. The substantial revision of the MTAA Code will be presented for approval by MTAA members at the 2019 Annual General Meeting.

### THE CODE MONITORING COMMITTEE

The Code Monitoring Committee (CMC) meets five times per year and is responsible for reviewing company monitoring reports to determine compliance with the Code.

Each year the CMC will review approximately 70 monitoring reports from companies who are members of MTAA. The reports provide transparency between MTAA and its members and allow recognition of opportunities to provide education on the Code and support where it is required.

In 2019, the CM Committee reviewed companies' responses to how they ensure they are meeting the provisions relating to claims and endorsements (clause 8.3) related to advertisements.





# FINANCES

## FINANCES

The financial operating results reflect that MTAA achieved an operating profit of \$129k for the twelve months to 30 June 2019.

The favourable result achieved was ahead of Budget and the FY19 Forecast primarily due to increased revenue from Professional Development courses, reduced expenditure through strong financial management and cost control, offset by reduced Membership, Annual Conference income (due to lower than expected sponsorship income) and Other Event income.

The Balance Sheet reflects a strong financial position with Net Assets of \$1,597k reflecting an increase of 8.8% since the prior year. This is due to the increased levels of cash from operating profit and reductions in Current Liabilities, in particular, Deferred Income relating to PL Levy and RTAG.



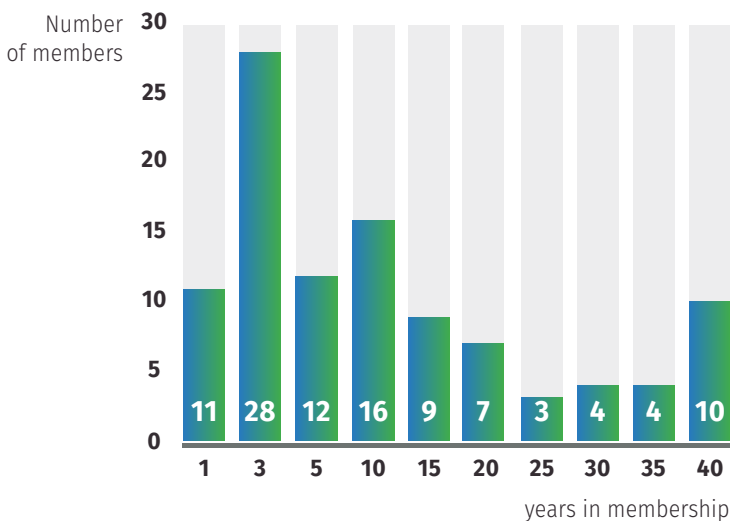
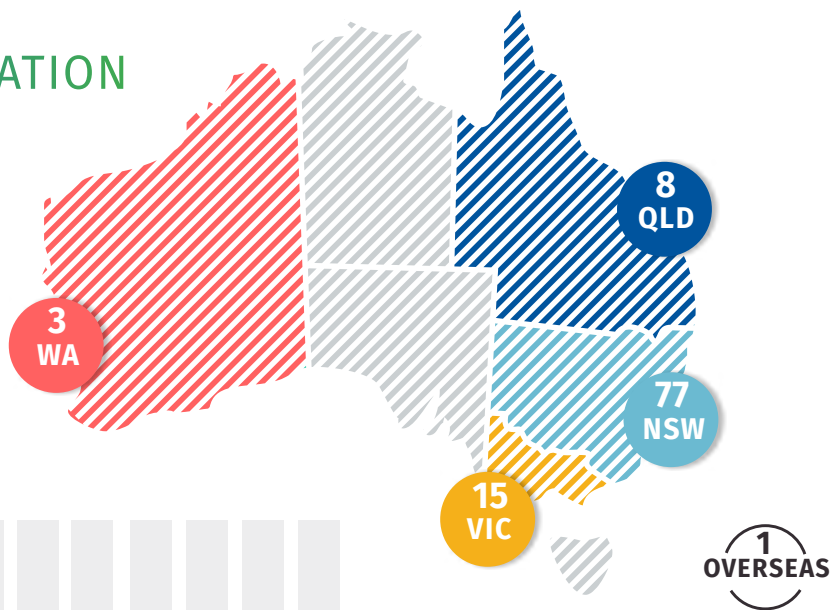
# MEMBERSHIP

## MEMBERSHIP

MTAA remained focused on the needs of members and its value offering as an organisation. The organisation’s service lines continued to develop with advocacy remaining a priority for most members, along with professional development and event networking opportunities.

In 2018-19, membership numbers held steady with 104 members; 69 corporate members and 35 associate members. Seventy-seven MTAA members host their head office in NSW, followed by 15 in Victoria, 8 in QLD, 3 in WA and 1 based overseas.

## MEMBERSHIP LOCATION



## LIFETIME OF MEMBER

## MTAA MEMBERS

### Corporate Members

3M Healthcare Pty Ltd
3DMEDiTech
Abbott (Vascular) Australasia Pty Ltd
Abbott Medical Australia (previously St Jude)
Admedus (Australia) Pty Ltd
Alcon Laboratories (Australia) Pty Ltd
Allergan Australia Pty Ltd
AlphaXRT
Analytica Ltd
APNE Surgical Pty Ltd
Australian Dermatology Equipment P/L
Australasian Medical & Scientific Ltd
Avanos (previously Halyard Australia)
B Braun Australia Pty Ltd
Bard Australia Pty Ltd
Bausch & Lomb (previously iNova Pharmaceuticals)
Baxter Healthcare Pty Ltd
Biotronik Australia Pty Ltd
Boston Scientific Pty Ltd
Brainlab Australia Pty Ltd
ConMed Australia
Cook Australia
Corin (Australia) Pty Ltd

### Corporate Members

Culpan Medical Australia Pty Ltd
Device Technologies Australia Pty Ltd
Edwards Lifesciences Pty Ltd
Elekta
Exactech Australia Pty Ltd
Fresenius Kabi Australia Pty Ltd
Gamma Gurus Pty Ltd
Gel Works Pty Ltd
Global Orthopaedic Technology Pty Ltd
Grey Innovation
Hill-Rom Pty Ltd
Hologic (Australia) Pty Ltd
Horten Medical
Johnson & Johnson Medical Pty Ltd
Laminar Air Flow Pty Ltd
LifeHealthcare Pty Ltd
LivaNova Australia Pty Ltd
Materialise Australia P/L
Medacta
Medical Specialties Australia Pty Ltd
Medigroup Australia Pty Ltd
Medtronic Australasia Pty Ltd
Med-El



### Corporate Members

Molnlycke Healthcare
NeedleCalm Pty Ltd
Nevro Medical Pty Ltd
NL-Tech
O&M Halyard Australia
Olympus Australia Pty Ltd
Paragon Therapeutic Technologies
Powervision Inc
Prism Surgical Designs Pty Ltd
Smith & Nephew Pty Ltd
Smiths Medical Australasia Pty Ltd
Spectrum Surgical Pty Ltd
Stryker Australia Pty Ltd
Surgical Specialties Pty Ltd
Teleflex Medical Australia Pty Ltd
Terumo Australia Pty Ltd
Tomi Australia Pty Ltd
Tunstall Australasia Pty Ltd
Varian Medical Systems Australasia Pty Ltd
Vision RT
W. L. Gore and Associates (Aust) Pty Ltd
Wright Medical Australia
Zimmer Biomet

### Associate Members

Atkinson Vinden Lawyers
Brandwood CKC
Cancer Care Associates
Caretech Services Pty Ltd
Certification Body Australia
Circuitwise Electronics
Clinical Research Corporation
Covance Pty Ltd
Cutlass Pharmed Regulatory Services
Dentons (previously Gadens)
DHL Supply Chain (Australia) Pty Ltd
Elementum Advisory
Evolution Clinical
Five Corners Pty Ltd
GenesisCare
Prospitalia hTrak Pty Ltd
ICON Cancer Care
IDE Group
Illuminate Health Consulting Pty Ltd
Insight Strategy
KD&A
Lucid Health Consulting
Mainfreight Distribution Pty Ltd
Master Control Pty Ltd
Medtechnique
MTP Connect (Affiliate)
Oliver Healthcare Packaging
Open Sesame Consulting
Regulatory Concepts Pty Ltd
SJ Alder Pty Ltd
Smartways Logistics
Sue Akeroyd & Associates
The SPD Company Pty Ltd
The University of Newcastle
University of NSW

# BOARD OF DIRECTORS

## BOARD OF DIRECTORS



**Maurice Ben-Mayor** (Chair)

*B.SC (UNSW), Exec MBA (AGSM)*

President, Stryker South Pacific.

Maurice has over 20 years of experience in the MedTech industry across senior roles in sales, management, marketing and market access.

Maurice has been at Stryker for 15 years and is currently the President of Stryker's South Pacific division.

*Maurice joined the board in December 2016 and was elected Chair in November 2018.*



**Rebecca Cortiula** (Vice-Chair)

*B.Sc (UTS), MBA (AGSM), GAICD*

Managing Director, Terumo Australia Pty Ltd.

Rebecca has been working within the Australian Healthcare system for more than 20 years. Rebecca joined Terumo in 1998 and has held multiple leadership roles within Sales, Marketing and General Management before taking up the Managing Director role in 2013. Prior to joining Terumo, she worked within the Australian hospital system as a scientist and also worked for the Australian Red Cross Blood Service. Rebecca is passionate about healthcare and ensuring that Australia has a sustainable healthcare system that can be readily accessed by all. She is also a strong advocate of supporting women to aspire to senior organisational roles.

*Rebecca joined the board in November 2015, was elected Vice-Chair in December*



**Steve Flynn** (Vice-Chair)

*BEng, Mech, Grad Dip Management, MEI (Swinburne)*

General Manager, Australia/New Zealand, Baxter Healthcare.

Steven has responsibility of over 1,100 employees and oversees a significant commercial, manufacturing and compounding pharmacy footprint across Australia and New Zealand. As the current Vice Chair of the MTAA board, Steven has ensured that Baxter is active in advocating directly for MTAA policy platform to deliver benefits to the entire membership. Since 2006, Steven has held senior executive roles in Baxter Australia, New Zealand and Asia Pacific. Prior to joining Healthcare, Steven worked at TNT and GM Holden Limited.

*Steven joined the board in November 2015 and was elected Vice-Chair in November 2017.*

## BOARD OF DIRECTORS



### Lyn Davies

*Dip Bus Mgt, PERSA, AMACs, MAICD*

Managing Director, Tunstall Australasia Pty Ltd

Lyn commenced with Tunstall in October 2004. A seasoned executive with over 25 years in senior leadership roles across the private and public sectors. Prior to Tunstall, Lyn has worked with well-known organisations such as Logan City Council, Mater Hospitals QLD and CITEC Queensland State Government. Lyn has presented both nationally and internationally on assistive technology and Connected Healthcare solutions and is experienced in the implementation and building of 24/7 operations centres within Australia and parts of the Asia Pacific regions. A high level of commercial acumen with extensive experience in leading and growing mid to large scale business. Able to lead multiple teams towards attaining high quality with a focus on exceptional customer service. Extensive government, community and not for profit service delivery experience. Proven track record driving innovation and change to achieve results.



### Andrew Fox-Smith

*B.Bus (Charles Sturt), AMP (Harvard), AICD*

Chief Executive Officer & Director, Global Orthopaedic Technology Pty Ltd

Andrew has over 25 years' experience in the Medical Technology Industry and brings a broad range of skills from working in both MNC's and Australian SME's. Andrew was most recently CEO of Global Orthopaedic Technology up until their successful acquisition by Corin. Prior to that he was Chairman at Optimized Ortho and before that he was Group President International for Stryker where he also sat on the Executive Committee. He joined Global Orthopaedic in July 2014 when he led a MBI with other investors.

*Andrew joined the board in April 2017.*



### Mark Taffa

*B.Bus (CSU)*

Managing Director, Horten Medical Pty Ltd

Mark is the founder and Managing Director of Horten Medical a company distributing medical devices, established 2005. Actively involved in the healthcare industry for over 22 years, Mark has worked with both large multinationals and small business. At GE Medical, Mark had product responsibility for all of Asia in digital imaging which included living in Singapore and consulting to the Brunei government on e-health. Mark has experience in running small scale local manufacturing of complex medical equipment for local and export sales.

He is the Secretary of the charity Doctors Assisting in the South Pacific Islands (DAISI). His charity work involves multiple trips to the region each year, with a particular focus on Papua New Guinea.

*Mark joined the board in December 2013 and was elected Vice-Chair in December 2014 to November 2017.*





### **Matt Muscio**

*Queensland University of Technology, Bachelor of Business (International Business). Melbourne Business School, Post Graduate Degree in Management.*

Chief Executive Office, LifeHealthcare

Matthew has 20 years' experience in the medical device industry across sales, marketing and management functions. Matthew joined LifeHealthcare as Chief Operating Officer in 2013, playing a key role in LifeHealthcare's IPO in December 2013. He was appointed Chief Executive Officer in September 2015, leading LifeHealthcare through its delisting under Pacific Equity Partners (PEP) in May 2018.

*Matthew joined the board in November 2017.*



### **Samih Nabulsi**

*University of Queensland, Doctor of Philosophy (PhD), Mechanical Engineering/Material Science, 1997. University of Queensland, MESC Research, Mechanical Engineering - compressible gas dynamics, 1993. University of Sussex, Bachelor of Science (BSc), Mechanical Engineering, 1997.*

General Manager – Cook Medical Australia

Samih has worked in the medical devices industry for 20 years, both internationally and in Australia, and has led the development of innovative medical solutions through in-house R&D, the growth of domestic and international partnerships, collaborations with research partners and the development of new technologies with industry leaders. An engineer and scientist by training and holds a PhD in engineering combined with an extensive and practical background in the medical devices industry.

*Samih joined the board in November 2017.*



### **Craig Stamp**

*University of NSW, Bachelor of Optometry (Hons Class 1) and a Graduate Diploma in Marketing. Adjunct Associate Professor at the SOVS, Faculty of Science, University of NSW. Active member of the SOVS Visiting Committee.*

General Manager, Device Technologies

Craig has over 25 years of experience in healthcare, pharmaceuticals and medical devices in Australia and Asia. He has held senior leadership positions at Allergan and Bausch & Lomb where he was Managing Director and VP Commercial Operations, Asia-Pacific. Has also served as CEO and Managing Director at a publicly listed company Vision Group Holdings Ltd, a former ASX listed company (now privately held).

*Craig joined the board in November 2017.*

## BOARD OF DIRECTORS



### Andrew Wiltshire

RN (Qld), BA (Media Studies) Griffith, MBA (UNE), GAICD

Senior Director, Market Access, Public Affairs and Policy, Medtronic Australasia Pty Ltd

Andrew has over 25 years' experience in the Australian medical technology and pharmaceutical sectors. As Senior Director, Market Access, Andrew is actively engaged in efforts to positively promote industry to government, healthcare providers and the community for appropriate access to medical technologies.

He oversees Medtronic's government affairs, healthcare economics policy and reimbursement initiatives in Australia and New Zealand.

*Andrew joined the board in October 2013, resigned in November 2017 and joined the Board in November 2018.*



### Anne-Louise Arnett

B.SC (ANU), Master of Business (Marketing) (UTS)

Vice President and General Manager, Hologic (Australia) Pty Ltd

Anne-Louise's career has spanned over two decades in the healthcare-consumer industry holding sales, marketing and leadership roles at Stryker in ANZ and the USA. Anne-Louise started her career in Australia with Kimberley-Clark Healthcare where she spent more than 8 years in various sales and marketing roles around the country.

Anne-Louise is passionate about the Medical Device Industry in ANZ and the patients it serves.

*Anne-Louise joined the board in July 2018.*



### Susan Martin

Monash University, Bachelor of Nursing, GAICD.

Managing Director, Johnson & Johnson Medical Devices ANZ

Susan Martin has taken increasingly senior commercial and leadership roles culminating in her current appointment as Managing Director (MD) of Johnson & Johnson Medical Devices (JJMD) for Australia and New Zealand in January 2018. She was recently the Asia Pacific Lead for JJMD's Cardiovascular Specialty Solutions business and responsible for providing regional insights to drive global franchise strategy and technology pipeline.

She is a champion of, and role model for, women in the medical devices sector. Susan is the Executive Sponsor of the Asia Pacific Women Leadership & Inclusion initiative for the Johnson & Johnson Family of Companies and a passionate supporter of the diversity and inclusion agenda for the medical devices and broader healthcare sector.

*Susan joined the board in November 2018.*

## FORMER BOARD OF DIRECTORS

### Gavin Fox-Smith

*B.Sci (USyd), Grad Cert Mktg (CSU), MBA (Deakin) AFAMI, CPM, GAICD*

Vice President – Global Education Solutions | Johnson & Johnson Medical Devices, Asia Pacific

With more than 30 years' experience in the Medical Devices industry, including 21 years at Johnson & Johnson, Gavin has an extensive background as a senior executive in the Asia Pacific region. Gavin was recently appointed Vice President for Johnson & Johnson Medical Devices Asia Pacific, leading Global Education Solutions. Prior to this, he was Managing Director of Johnson & Johnson Medical Devices for Australia and New Zealand, a role he held for 6 years. He is a member of the Johnson & Johnson Medical Devices Asia Pacific Regional Leadership Team. Gavin has a strong record of leading organisational growth, change and transformation; and is well known for his track record of developing and exporting outstanding leaders, and ensuring a truly diverse and inclusive workforce.

As former Chair of the Medical Devices industry body – the Medical Technology Association of Australia (MTAA) – Gavin has helped to shape industry dialogue with Government and ensure stable and beneficial policy settings for the industry, customers and patients into the future.

Gavin's philosophy of collaboration and service extends to community. He is a passionate advocate for efforts that improve health, literacy and education, particularly for Indigenous communities. Gavin is a Governor of the American Chamber of Commerce, a member of the Male Champions of Change (MCC) in STEM and an ambassador for Bowel Cancer Australia and Rotary Oceania Medical Aid for Children (ROMAC).

*Gavin joined the board in April 2012, was elected Chair in December 2014 and retired in November 2018.*

### Vassie Ponsamy

*Bachelor of Commerce – Economics. Honours Degree – Marketing. Diploma in Engineering.*

Managing Director, Smith & Nephew ANZ

Appointed Managing Director of Smith & Nephew Pty Ltd, Australia and New Zealand (ANZ) in September 2016. Vassie joined Smith & Nephew in July 2014 as Regional Managing Director for Sub-Saharan.

Prior to joining Smith & Nephew, he was Managing Director, Middle East and Africa for Getinge Healthcare and before this, Executive Director, International Business for AECL and Managing Director, Africa Region for GE Healthcare.

Vassie has extensive experience across many industries in several geographies, including Africa, the Middle East, South America, South East Asia and Australia.

*Vassie joined the board in January 2018 and resigned in November 2018.*



# COMMITTEES & MEMBER FORUMS



## COMMITTEES

### PUBLIC AFFAIRS COMMITTEE

The Public Affairs Committee (PAC) is the most senior MTAA Committee and provides oversight of the Reimbursement, Regulatory and Industry Policy Committees to ensure a coordinated and aligned strategy and communications approach.

PAC sets the advocacy direction for the MedTech industry with relevant stakeholders across key areas in healthcare policy, reimbursement, regulatory and industry development.

The objective for the past financial year has been to build on the comprehensive advocacy strategy developed in 2017-18 that included key priorities, messaging and implementation plans. It has also been involved in providing direction to the industry on private health insurance reform and has provided guidance on the development of the AlphaBeta report and MTAA's response to the International Consortium of Investigative Journalists investigation into medical devices in late 2018.

### REGULATORY AFFAIRS COMMITTEE

The Regulatory Affairs Committee (RAC) meets eight times per year, before and after each of the four TGA RegTech meetings each calendar year. RAC is responsible for formulating MTAA positions and the strategic direction of MTAA on regulatory matters within the scope of the Therapeutic Goods Act, the Medical Devices Regulations and the Advertising Code. RAC drives MTAA advocacy on all regulatory reform issues. During 2018-19, the advocacy work of RAC included:

- Progressing the regulatory framework for personalised medical devices including 3D-printed medical devices to ensure a level playing field between the MedTech industry and other entities engaging in mass production of patient-specific devices such as 3D-printed orthopaedic implants.
- Ensuring that patient information leaflets for implants, required to be handed out to patients as part of informed consent, can be provided in electronic format on a company's website.
- Contributing to TGA guidance documents on electronic instructions for use (eIFU), on designation of Australian conformity assessment bodies, and on wider use of market authorisation evidence from comparable overseas regulatory bodies, advertising, cybersecurity, implementation of an UDI system for medical devices in Australia, reclassification of spinal implants and accessories of active implantables, SaMD, changes to the Essential Principles and requirements for systems and procedure packs.
- Coordinating membership feedback to the revision of the Therapeutic Goods Advertising Code and related guidelines and the annual TGA performance statistics report content.

## REIMBURSEMENT COMMITTEE

The role of the Reimbursement Committee is to promote funding and reimbursement pathways for medical devices to enable timely access to these technologies in the public and private markets.

The committee met four times in 2018–19 with its work primarily focused on supporting the implementation of the MTAA-Government Agreement. The committee's achievements include:

- Assessment of Prostheses List (PL) benefit setting and review options being considered by the Industry Working Groups established through the MTAA Agreement with Government
- Developing proposed options for expanding the criteria for listing on the PL
- Provided feedback on updates to the Prostheses List Guide and Prostheses List Management System (PLMS)
- Supported feedback to targeted reviews of PL categories
- Provided input on Clinical Quality Registries and implications for medical device reimbursement
- Developed information demonstrating the value of medical technology in response to private health insurance reforms

## INDUSTRY POLICY COMMITTEE

The role of the Industry Policy Committee (IPC) is to promote initiatives which impact on the development and sustainability of the industry and health care.

The committee met three times to 30 June 2018 and identified an ambitious workplan to enable the industry to be well-placed to engage in shaping policy on emerging issues such as digital healthcare and cybersecurity, state-based procurement, as well as in initiatives to support SMEs such as through the reforms to the R&D Tax Incentive.

The IPC also provided guidance on the industry environment to enable the Public Affairs Committee to develop its advocacy strategy.

## MEMBER FORUMS/WORKING GROUPS

### REGULATORY FORUM

The Regulatory Forum (RF) meets at least four times per year, with additional ad hoc meetings as requested. The RF raises awareness on regulatory issues that members face in their day-to-day work. The RF represents an opportunity for members to interact and exchange ideas, discuss specific topics of interest, and provide an opportunity for learning and development for professionals starting in regulatory roles.

### CLINICAL INVESTIGATIONS FORUM

The Clinical Investigations Forum (CIF) meets four times per year with additional ad hoc meetings as requested. The CIF provides an opportunity to members who share an interest in advancing clinical investigations in Australia to discuss, share information, network and consult, and to progress relevant issues.

The CIF reports directly to the Industry Policy Committee (IPC) and is responsible for policy development in relation to clinical trials. The CIF participated in various initiatives activities during 2018–19, including monitoring of and engaging with national initiatives in the clinical trials space, and participating in and contributing to relevant state initiatives.

### OPHTHALMIC FORUM

The Ophthalmic Forum was established by the Board at the request of member companies in April 2018. The Forum progresses issues of common interest and has undertaken an analysis of the value to patients and Government of accessing ophthalmic devices through the Protheses List. The Forum will also undertake advocacy to communicate with and educate the Government on the economic and health benefits generated by the ophthalmic device industry.

### ORTHOPAEDIC FORUM

The Orthopaedic Forum offers MTAA orthopaedic members the opportunity to discuss and address issues of mutual interest and concern.

The orthopaedic sector is vibrant and innovative, and the forum provides members with a medium to address the dynamics of their environment. The forum meets quarterly and is open to membership by all MTAA orthopaedic companies.

The MTAA Orthopaedic Forum meetings are attended by representatives of up to 14 member companies. Activities this year included meeting with the Australian Orthopaedic Association (AOA) Presidential Line, the AOA CEO and the Director of the National Joint Replacement Registry, commencement of the newly formed MTAA Orthopaedic Market Survey and development of a joint proposal to the Department of Health for coverage with evidence development for listing of hips, knees and shoulders on the Protheses List.

### RADIATION THERAPY ADVISORY GROUP (RTAG)

The Radiation Therapy Advisory Group is an alliance of cancer patient advocates, healthcare providers, medical technology vendors and oncology professionals who are aligned in their desire to raise the profile of radiation therapy and ensure it is adequately funded by Government by providing highly informed and expert advice.

Radiation therapy and the many different specialised treatments it involves are not always simple to understand. RTAG achieved significant success through its advocacy highlighting the lack of access to radiation therapy in regional and rural Australia at the 2018 Federal election, obtaining commitments from both the Government and the Opposition to provide funding for regional radiation centres.

## COMMITTEE MEMBERS

### Code Authority Committee

Paul Gibbeson (Chair)	Independent
Steven Flynn (Board Director)	Baxter Healthcare
Andrew Fox-Smith (Board Director)	Global Orthopaedic
Carol Mazzella	Stryker
Michelle Wagner	Johnson & Johnson
Jason Neal	W.L. Gore
Paul Braico	Boston Scientific
Dawn DeCruz	Allergan
Henry Ko	Consumer Health Forum
John Quin	Royal Australasian College of Surgeons
Pam Davis	Independent

#### Resigned committee member

Dean Taylor LifeHealthcare | Hugh Cameron Becton Dickson

### Women in MedTech Committee

Rebecca Cortiula (Chair / Board Director)	Terumo Australia
Lyn Davies (Board Director)	Tunstall Australasia
Andy Hansen	Device Technologies
Katrina Symons	Johnson & Johnson Medical
Lauren Johnston	Zimmer Biomet
Nicki Walsh	Tunstall Australasia
Sauming Ho	Varian
Naeema Mohamed	Zimmer Biomet
Eleni Spiridonos	Stryker Australia
Michael Keenan	Medtronic Australasia

#### Resigned committee member

Lauren Goodridge Zimmer Biomet | Nicki Luther Stryker  
Belinda Ramirez Medtronic | Samantha Russell 3M  
Glenn Whittaker Device Technologies

### Code Monitoring Committee

Paul Gibbeson (Chair)	Independent
Leonardo Cevallos	Cook Medical
Nadine Crimston	Alcon
Mark Flynn	University of Newcastle
Megan Guy	Healthcare Professional
Chloe Meyer	Smith & Nephew
Jennifer Mew-Sum	Medtronic
Glen Mason	Johnson & Johnson
Pam Davis	Independent

#### Resigned committee member

Trent Enright Terumo

### Finance Committee

Craig Stamp (Chair / Board Director)	Device Technologies
Joel Stuhler	LifeHealthcare
Sue Martin (Board Director)	Johnson & Johnson Medical

### Reimbursement

Michael Simmonds (Chair)	Boston Scientific
Doug Symonds	Medtronic
Kieran Murphy	Nevro
Laurence Fong	Smith & Nephew
Sarah Botros	Stryker
Sheryl Dunlop	Zimmer Biomet
Georgia Psarros	Baxter Healthcare
Rebecca Schnabel	Allergan
Sarah Griffin	Medtechnique Consulting
Rachael Todd	LivaNova
Michael Reynolds	Biotronik
Joel Parrish	Elekta
Sebnem (Shebnem) Erdol	Abbott Medical
Natasha Diasinos	J & J Medical

#### Resigned committee member

Michelle Costa Johnson & Johnson Medical | Kevin Guinee Bard  
Peggy McBride Abbott/St Jude Medical



### Public Affairs Committee

Andrew Wiltshire (Chair and Board Director)	Medtronic
Mark Taffa (Board Director)	Horten Medical
Paul Davies (Chair of Industry Policy Committee)	Abbott Medical
George Faithfull (Chair of Regulatory Committee)	Stryker
Michael Simmonds (Chair of Reimbursement Committee)	Boston Scientific
Carolyn Cameron	Allergan
Emily Williams	Cook Medical
Will Knox	Device Technologies
Laurence Fong	Smith & Nephew
Robyn Chu	Alcon
Michael Reynolds	Biotronik
Fraser Cleave	LifeHealthcare
Natalie Lawandi	Medtronic
Jane McMillan	Johnson & Johnson Medical
James Doyle	Stryker
Clinton Lubcke	Baxter Healthcare
Polo Guilbert-Wright	Edwards Lifesciences

**Resigned committee member**

Maurice Ben-Mayor (PAC Chair) Stryker | Libby Day Baxter Healthcare  
Carey Jackson Johnson & Johnson Medical | David Cain Varian

### Regulatory Affairs

George Faithfull (Chair)	Stryker
Jason Aldworth	3DMEDTech
Mahesh Datar	Medtronic
Cheryl Davey	Alcon
Kea Dent	KD&A
Falko Thiele	Biotronik
Elizabeth Van Den Akker	Abbott Vascular
Renee Cotta	Boston Scientific
Ruth Shennan	Device Technologies
Laleetha Devi	O & M Halyard Australia
Rebecca Gaudin	Johnson & Johnson
Sue Hunter	Abbott Medical
Fleur Winslade	Terumo
Rachel Patrick	Mölnlycke Health Care
Juliana William	Baxter Healthcare
Minta Chen	Smith & Nephew
Maneesha Pillay	Edwards Lifesciences
Ramon Ippolito	Surgical Specialties
Joanne Daniels	Cook Medical
Naeema Mohamed	Zimmer Biomet

**Resigned committee member**

Katie-Lou Buscher Cook Medical | Hugh Cameron BD  
Suhayl Khan AMSL | Meryl Musson Edwards Lifesciences  
Samantha Tham Smith & Nephew

### Industry Policy

Paul Davies (Chair)	Abbott Medical
Matthew Malone	Stryker
Alex Best	Johnson & Johnson
Ross Lane	Cook Medical
Michael Reynolds	Biotronik
Geoff Feakes	Tunstall Healthcare
Kirk Kikirekov	Prospitalia h-trak

**Resigned committee member**

Juliet Spencer 3M

### MedTech Conference

Samih Nabulsi (Chair / Board Director)	Cook Medical
Annie Arnett (Board Director)	Hologic
Emily Williams	Cook Medical
Donna McCann	Medtronic
James Boyce	Johnson & Johnson
Lucille Vong	Fresenius Kabi
Charlotte Hart	Nervo



# WHAT WE DO

champion medical technology  
for a healthier Australia





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