MEDIA STATEMENT

20 July 2026

Public Trust Demands Facts

For the Medical Technology Association of Australia (MTAA) and our members, our first and absolute priority is, and always will be, the safety, well-being, and peace of mind of the millions of Australians who rely on life-changing and life-saving medical technologies.

We are deeply concerned that the reporting by Nine Publishing and 60 minutes over the weekend will needlessly cause some patients to question or delay the use of medical technologies that may be essential to their health and quality of life. For millions of Australians, medical devices, ranging from pacemakers and joint replacements to insulin pumps, are not abstract concepts; they are essential to living pain-free, active, and healthy lives.

MTAA strongly rejects the underlying premise of this reporting. The conclusions presented are highly predicated on inappropriate interpretation of data, go far beyond what the actual data can demonstrate, and oversimplify highly complex clinical issues.

The reporting appears to rely on raw counts of adverse event reports from the Therapeutic Goods Administration's (TGA) Database of Adverse Event Notifications (DAEN); a dataset that has been fundamentally misused to draw scientifically invalid conclusions. For example, injury and death adverse event data has been used to imply devices are at fault, only for the journalist to acknowledge that *an adverse event report does not necessarily mean a device caused the event*. That distinction is critical and underscores the need for caution when drawing broader conclusions about device safety or regulatory performance.

The DAEN is not an analytical tool designed to measure device failure rates; it is a public repository of raw, unverified, and voluntary reports. A credible assessment of a device's safety or efficacy cannot be made using this database alone.

Adverse event data must be interpreted with extreme care. Reports do not automatically indicate device failure. Instead, they capture a wide range of complex circumstances, including expected wear and tear over time, procedural variables, or patient-specific clinical complications. To conflate a raw notification with a confirmed device failure is scientifically incorrect.

Similarly, the reporting also claims that "*every year there are 150,000 incidents where Australians require hospital treatment because medical devices that are meant to help cause harm instead*", which appears to misinterpret Australian Institute of Health and Welfare (AIHW) data. The AIHW data does

MTAA Media Enquiries
P: (02) 9600 0600 | **E:** media@mtaa.org.au

Medical Technology Association of Australia Ltd
Level 4, 97 Waterloo Rd, Macquarie Park NSW 2113
W: www.mtaa.org.au

not indicate whether a medical device fault caused the patient's condition or whether treatment was required because of a device fault.

The reporting also appears to claim that placebo-controlled trials can readily be undertaken for medical devices and cites a pacemaker study as evidence. However, the study referenced did not compare patients receiving a pacemaker with patients receiving no treatment. Rather, it examined different programming approaches in a small and highly specific patient population. It therefore does not support the broader proposition that placebo-controlled trials are appropriate, practical, or ethical for many implanted medical devices.

Australia has one of the most robust, respected and stringent medical technology regulatory systems in the world overseen by the internationally recognised Therapeutic Goods Administration (TGA).

Contrary to the media's claims, Australia does not operate a system of automatic approval based on overseas registration or device equivalence. Our system is rigorously risk-based, internationally aligned, subject to strict sponsor obligations, and backed by comprehensive post-market monitoring, mandatory recalls, and ongoing regulatory reform.

While the TGA's framework appropriately makes use of evidence from comparable overseas regulators (such as those in the European Union) to avoid unnecessary duplication and prevent delays in patient access, this is not a shortcut.

Crucially, all medical devices supplied in Australia must meet strict Australian safety, quality, and performance requirements. International reliance pathways are a recognised best practice supported by the World Health Organization; they are a tool for efficiency, not a substitute for evidence, manufacturer accountability, or rigorous post-market oversight.

Medical device oversight in Australia is being actively strengthened, not weakened. Over recent years, the TGA has undertaken significant work to bolster its regulatory framework. This includes introducing stronger post-market surveillance, implementing mandatory reporting by healthcare facilities, establishing a Unique Device Identification (UDI) system for improved traceability, reclassifying certain devices into higher-risk categories, and introducing greater transparency and patient information requirements.

Ultimately, patient safety is a continuous, shared commitment. Our industry thrives on rigorous scrutiny, scientific validity, and constant clinical improvement. However, sensationalised reporting that mischaracterises regulatory processes and misinterprets raw data does a profound disservice to the Australian public. Rather than fostering constructive dialogue, it threatens to erode trust in vital medical interventions. This alarmism may dangerously lead patients to delay vital medical procedures or make critical decisions about their healthcare without consulting their clinicians.

MTAA and its members remain steadfast in our collaboration with clinicians, regulators, and government to ensure that Australian patients continue to have safe, timely, and confident access to the world's best medical technologies.

MEDTECH FOR AUSTRALIA

17,000+ direct jobs
51,000+ total jobs
$4.1 bn direct GDP
$5.4 bn total GDP

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For more information, contact:

Justin Foster
Associate Director, Advocacy and Government Relations, MTAA
media@mtaa.org.au

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About MTAA:

The Medical Technology Association of Australia (MTAA) is the peak association representing companies in the medical technology industry. MTAA aims to ensure the benefits of modern, innovative and reliable medical technology are delivered effectively to provide better health outcomes to the Australian community.

MTAA's membership spans Australian start-ups through to global MedTech leaders. Our members develop, manufacture and supply medical technologies used in the diagnosis, prevention, treatment and management of disease and disability. The range of medical technology is diverse, with products ranging from familiar items such as syringes and wound dressings, to high technology implantable devices such as pacemakers, defibrillators, and orthopaedic implants. Products also include hospital and diagnostic imaging equipment such as ultrasounds and magnetic resonance imaging machines, as well as digital health technologies such as remote monitoring devices and digital therapeutics.

MTAA members distribute the majority of non-pharmaceutical products used in the diagnosis and treatment of disease and disability in Australia. Our member companies also play a vital role in providing healthcare professionals with essential education and training to ensure the safe and effective use of medical technology.

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