

MEDIA STATEMENT

27 MARCH 2024

Every year, over 1,200 privately insured Australian patients with guidance and support from their healthcare professionals carefully consider Spinal Cord Stimulation (SCS) to target their chronic pain. Their safety is our highest priority.

As a nation, we must acknowledge Australia is in a chronic pain crisis.

One in five Australians over the age of 45¹ are living with chronic persistent pain, yet according to Pain Australia, up to 80% of people living with chronic pain are missing out on treatment that could manage their pain effectively including access to pain specialists and interdisciplinary care.

Pain often infiltrates every element of a patient's life. Pain affects their ability to sleep, work, engage with their family, and participate in their community. Before they turn to SCS, patients have shared with our members that they've tried almost everything to relieve their pain, including physiotherapy and medication such as opioids.

SCS has demonstrated the ability to produce clinically meaningful pain relief, improve quality of life, and significantly reduce the need for medication usage in individuals suffering from chronic pain. Today's SCS devices offer the opportunity to tailor the pain management therapy to each patients' circumstances. Importantly, technology is undergoing continual improvement through global clinical trials with therapy development and connected healthcare support.

Evidence Supporting Spinal Cord Stimulation

We firmly stand behind the evidence that supports the availability of SCS for Australians with chronic pain and share the concerns from pain experts and leading pain clinical and patient organisations on the limitations of the Cochrane Review led by researchers at the University of Sydney.

The methodology of this meta-analysis provides a limited view of the evidence landscape for SCS and ignores several other data sources such as long-term multi-centre comparative trials, more pragmatic studies and real-world evidence (RWE). In order to truly assess long-term safety and effectiveness of a therapy the totality of the evidence must be considered.

While double-blinded randomised controlled trials (RCTs) are ideal for building an evidence base to demonstrate the efficacy of new technologies, there are significant challenges in delivering these. While taking a placebo medication is relatively simple, there are practical and ethical reasons why researchers may not conduct such a trial for certain implantable devices,

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17,000+
direct jobs



51,000+
total jobs



\$4.1 bn
direct GDP



\$5.1 bn
total GDP

including ethical challenges of offering a placebo surgery, and procedural risks. In addition, there is also significant complexity in assessing and managing chronic pain, which is best brought to life by considering RWE, which captures real-world outcomes that are meaningful for patients.

Importantly, MTAA members have actively participated in the TGA's post-market review of spinal cord stimulation (SCS) devices. The purpose of the review was to reassess the safety and performance of these devices taking into consideration the additional real-world evidence associated with the use of SCS devices for Australian patients with chronic pain. We will continue to support the process to ensure these patients and their clinicians continue to have this clinical option available.

Reporting of Adverse Events

The TGA is internationally well regarded as a trustworthy regulator with a strong interest in tough safeguards that protect Australians. Medical devices are subject to robust regulatory approval and legal frameworks. Our companies are required to evaluate and report adverse events to the TGA in accordance with the regulations. Adverse events are carefully reviewed through our members' internal compliance processes and by TGA. The current guidelines and process is clear, simple to follow, and effective in ensuring devices continue to be safe and perform as intended.

The Value of Medical Technology

We're committed to ensure the benefits of modern, innovative and reliable medical technology are available to Australian patients.

Since 2017, the MTAA and our members have partnered with the Australian Government to ensure the affordability of private health insurance for Australians. As a result, the average benefit paid for a medical device has fallen 14% since 2017. Our partnership has generated \$2.3 billion in savings during this time, including \$126 million in savings since July 2022.

Importantly, access to these technologies has grown as the clinical demands of health change and grow. As a result, Australians benefit from early access to safe and effective medical device technologies that deliver significant health and economic gains.

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