



HORIZON SCANNING

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BRIEF

StimQ peripheral nerve stimulator system for the relief of severe difficult to manage persistent pain

Background

Persistent Pain

The International Association for the Study of Pain defines persistent pain as “pain without apparent biological value that has persisted beyond the normal tissue healing time (usually taken to be three months).”¹ It is typically of sufficient duration and intensity to negatively impact an individual’s well-being, level of function and quality of life.²

It is estimated that 20 per cent of the Australian adult population experience persistent pain, although only a proportion of our population are significantly disabled or distressed by pain.

It is also estimated that approximately 13 per cent of the population experience some degree

of interference with daily activities caused by pain and 2 per cent of the population are significantly disabled and severely limited by their pain. The impact of persistent pain on a large proportion of the population (including people of working age) and its association with markers of social disadvantage make it a significant public health problem in Australia.^{3,4}

Injury is the most common cause of persistent pain (38 per cent), however a third of people who experience persistent pain are unable to identify the original cause.⁵ Other identified causes include arthritis, musculoskeletal conditions, cancer-related pain and post-surgical persistent pain.

Persistent pain is a complex condition associated with changes in the way the brain perceives pain. Physical, social, psychological and genetic factors contribute to an individual’s perception, tolerance and experience of pain.⁶ In addition, people with persistent pain often also have depression, anxiety or other mood disorders which contribute to the burden of pain and complicate its management.

Management of Persistent Pain

The management of persistent pain aims to minimise the impact of pain by restoring physical, psychological and social functioning.⁶ The various factors that contribute to persistent pain often mean that single treatment approaches fail. Effective management of persistent pain

A joint initiative of

requires a coordinated multimodal approach. Multimodal treatment approaches for persistent pain often combine pharmacological, psychological, physical and functional approaches. In some cases, interventional procedures are also utilised.⁷

Interventional pain management approaches include nerve block injections, denervation procedures, implantable drug delivery systems and neurostimulation.⁸ Neurostimulation is a pain management therapy that may be considered when other options have not provided adequate improvements. Neurostimulation involves implanting electrodes to administer electrical stimulation directly to the nervous system (spinal cord, brain or peripheral nerves), in order to interrupt or mask neural signalling that leads to the perception of pain. The precise mechanisms of action of neurostimulation therapy are not fully understood.⁹

Technology Overview

Peripheral Nerve Stimulation

Peripheral nerve stimulation involves electrical stimulation of specific nerve(s) outside of the central nervous system (brain and spinal cord). The aim of peripheral nerve stimulation is to produce paraesthesia (tingling or numbness) around the region supplied by that stimulated nerve to inhibit or minimise the transmission of other signals that lead to the perception of pain in the brain.¹⁰

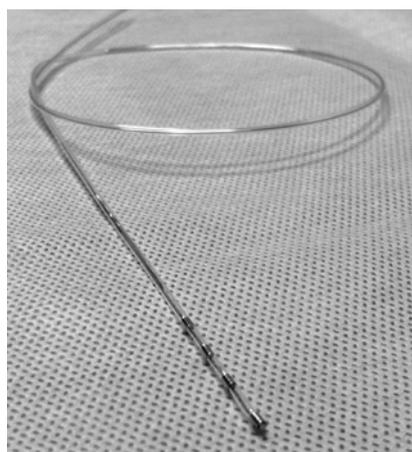
Peripheral nerve stimulation systems typically consist of two components:

1. A small lead or electrode which is surgically implanted alongside the peripheral nerve(s). The electrode delivers electrical pulses that are felt as a tingling sensation.
2. An implanted pulse generator or transmitter to provide electrical power to the electrode.

Recent technical advances making devices smaller and simpler to implant have resulted in increasing interest in peripheral nerve stimulation for the management of persistent pain. It is anticipated that with the development of smaller devices and less invasive approaches to implanting the devices, there will be greater demand and growth in clinical data for the use of peripheral nerve stimulation in managing various persistent pain conditions.¹¹

The StimQ System

The StimQ System is an implantable peripheral nerve stimulation system developed by Stimwave Technologies (stimwave.com) to provide therapeutic relief for persistent pain of peripheral nerve origin. The system can be used alone or in combination with other therapies as part of a multimodal approach.



StimQ System: Stimwave Technologies, Inc.

The system includes a small implantable stimulator (Freedom-8A/Freedom-4A Stimulator) which consists of a set of thin wires and a micro-receiver, covered by a protective casing. The neurostimulator has small metal electrodes near the tip that create an electrical field of energy when power is applied. The stimulator is 45cm in length and 1.35mm in diameter and can be cut down to 16cm following insertion. The neurostimulator receives energy wirelessly from a small, flexible, wearable external fabric patch

transmitter unit. The small pulses of energy create an energy field that alters the transmission of signals that lead to the perception of pain. The transmitter can be programmed with specific stimulation parameters.^{12,13}

Before the device is implanted permanently, there is a mandatory trial implant (usually a 3–7 day period but no longer than 30 days) to determine if stimulation with the StimQ System provides an adequate and sustained level of pain relief during the trial period. After the trial device is removed and the results of the trial determined to be successful, the permanent implant is scheduled.¹⁴

According to the manufacturer, the StimQ System is the world's first miniature, wireless, fully programmable peripheral nerve stimulator device. The device is powered by an external component and is injectable, therefore eliminating the need for surgery, extensive tunnelling and placement of large implanted generators and batteries within the body. The stimulator can be implanted through a standard needle-sized insert or small incision in a procedure that can be conducted in a procedure room. The stimulator is less than 5 per cent of the size of other standard implanted options.¹⁵

Clinical Indication

Peripheral nerve stimulation may offer an alternative or additional/additive treatment option for patients who do not experience sufficient pain relief or who have intolerable side effects from conventional treatments.¹¹

The StimQ System may be indicated for severe intractable persistent pain in the limbs and torso. The StimQ System is not intended to treat pain in the craniofacial region.¹⁶

Clinical Effectiveness Safety

No completed or ongoing studies assessing the effectiveness of the StimQ Peripheral Nerve Stimulator System could be identified.

An ISCRH evidence review conducted in 2015 concluded that, due to a lack of high-quality, controlled primary studies, there is insufficient evidence to support the use of peripheral nerve stimulation for the treatment of persistent pain.¹⁷

Potential for Impact

Wireless neurostimulation with the StimQ System claims to provide clinical advantages relating to a reduction in the complexity and time required for surgical implantation. This will reduce patient exposure to post-operative infections, surgical complications and the anaesthesia required for the implantation process.¹⁹

If peripheral nerve stimulation technologies are shown to be effective, the StimQ System may provide a minimally invasive option for the management of persistent pain of peripheral nerve origin. The wireless neurostimulation approach has the potential to reduce the lifetime cost of care for patients with persistent pain and may provide an alternative to pain medications, specifically opioids.

No completed or ongoing studies assessing the safety of the StimQ Peripheral Nerve Stimulator System could be identified.

Safety considerations that have been associated with peripheral nerve stimulation include: infection, haemorrhage, injury of nervous tissue, placing the device into wrong compartment, hardware migration, erosion and malfunction, including equipment fractures and disconnections.¹⁸

Setting for Technology Use

The StimQ System is intended for hospital and home use and to be provided by orthopaedic surgeons, neurosurgeons, interventional pain physicians and anaesthetists.¹⁶

Regulatory Approval

The StimQ System received United States Food and Drug Administration 510(k) clearance in March 2016 and is being marketed in the United States.¹⁶ 510(k) clearance is based on a determination of being substantially equivalent to a device that is already legally marketed for the same use.

The StimQ System is not currently available in Australia. An application

for Therapeutic Goods Administration registration is anticipated to be made in the first half of 2017.²⁰

At the time of publication, the regulatory status of the StimQ System in Australia, Canada, the United Kingdom and the United States is summarised in the table below.

Country	Regulatory Approval
Australia	No
Canada	No
United Kingdom	Yes
United States	Yes

Cost

No information was available on the cost of the StimQ System.

There are current Medicare Benefit Schedule items that relate to the surgical placement of components used in spinal cord stimulation and peripheral nerve stimulation. The cost of the neurostimulation system is separate to the medical costs associated with device implantation.^{21,22}

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