

Medtech takes on pain



[Elizabeth Cairns](#)



Attempts to treat pain with non-opioid drugs have ended in repeated failures - but device makers have met with greater success.

Despite strenuous efforts to meet an enormous and potentially highly lucrative unmet need, few novel painkilling drugs have been approved over the past decade or so. On that front, it seems medtech has biopharma beat: last month Abbott's Proclaim Plus spinal cord stimulator became the sixth medical device to be approved for pain since 2015.

All but one of those systems are spinal cord stimulators. But a look at devices in development for pain reveals a few novel strategies, including infrared therapy and an ambitious attempt to retrain the brain to regulate oversensitive pain responses. Next in line at the FDA, however, is a more conventional system from Medtronic.

Medtronic's Inceptiv is conventional in that it is a spinal cord stimulator. However, it has a novel twist: it is intended to be a closed-loop system, capable of detecting and adjusting the strength of the impulses. This should enable different levels of stimulation for different patients, avoiding under- or overstimulation.

Inceptiv is filed with the FDA, but is in a separate study in Australia in back and limb pain subjects to assess its performance with the closed-loop technology on versus with it off.

Sanofi is one of the many pharma companies giving the pain space a wide berth, *Evaluate Vantage's* [recent analysis](#) found. Intriguingly it appears to be looking at a device instead. The group is sponsoring a large phase 3 study of an infrared therapy patch in back pain patients. Sanofi's website makes no mention of this study; perhaps its intentions will become clear when the trial concludes later this year.

Selected ongoing trials of medical devices for pain

Company	Device	Type	Details	PCD
<i>Filed</i>				
Medtronic	Inceptiv	Spinal cord stimulator	90 pts w low-back, leg and/or upper limb pain (NCT05177354)	Nov 2022
<i>Phase 3</i>				
Sanofi	Firtech	Infrared therapy patch	Irpach: ph3 trial in 200 pts w acute low back pain (NCT05137041)	Nov 2022
Redo Neurosystems	Relearn Neurofeedback	Brain retraining system	Relearn: ph2/3 trial in 36 pts w knee OA pain (NCT05335486)	Dec 2023
<i>Phase 2</i>				
Boston Scientific	Unknown DBS system	Deep brain stimulation	Ph1/2 trial of deep brain neuromodulation in 12 pts w chronic neuropathic pain (NCT05404581)	Jun 2026
<i>DBS=deep brain stimulation; OA=osteoarthritis; PCD=primary completion date. Source: Evaluate Medtech, clinicaltrials.gov.</i>				

The approach taken by the Danish start-up Redo Neurosystems is somewhat off the wall – perhaps a reflection of how difficult it is to treat knee osteoarthritis pain. Redo’s Relearn software was initially designed as a way to measure pain objectively, by looking at patients’ brainwaves, but the group now believes that by manipulating alpha-waves in particular, patients’ brains can be “rewired” to reduce the perceived intensity of chronic pain.

The first indication of whether this might hold water will come with data from an ongoing single-site phase 2/3 trial. According to its website Redo has only raised \$600,000, so if the trial is a washout the company’s future looks dicey.

Another slightly off-kilter notion is being investigated by Boston Scientific. The group is sponsoring a trial of a deep brain stimulation system – technology usually used in motion disorders including Parkinson's disease, as well as obsessive-compulsive disorder and epilepsy.

Boston is using a DBS device to stimulate the insula, a region of the brain believed to be involved in consciousness, emotion, perception, and awareness of hunger, fatigue and pain.

The first part of the study will identify responders – those who have positive analgesic effects from acute insular stimulation. These will go on to the second stage, a randomised, sham-controlled, double-blind study in which subjects will receive both active and sham stimulation. Data are far from imminent, however.

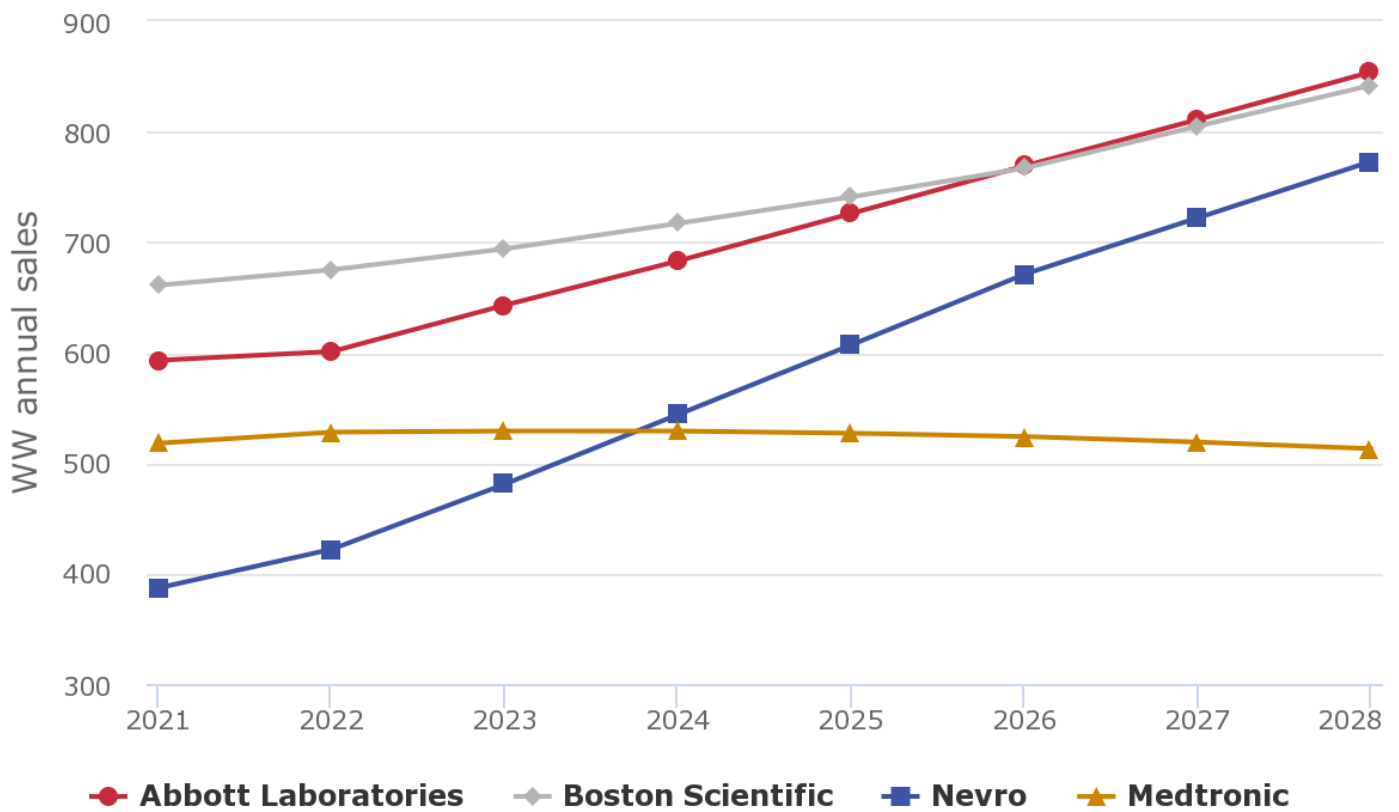
For now the market belongs to four public companies and three private concerns. Of the former, the sellside sees Abbott leading the spinal cord stimulator market in 2028, data compiled by *Evaluate Medtech* show. Should the FDA approve Medtronic’s Inceptiv, however, this could change.

Selected novel devices approved in the US for pain

Approval date	Company	Device	Type	Indication
Aug 2022	Abbott Laboratories	Proclaim Plus	Spinal cord stimulator	Pain of the trunk and/or limbs
Feb 2022	Saluda Medical	Evoke	Spinal cord stimulator	Pain of the trunk and/or limbs
Jun 2020	Mainstay Medical	ReActiv8	Neuromuscular stimulator	Low back pain
Feb 2016	Abbott Laboratories	Axium	Spinal cord stimulator	Low back pain
Nov 2015	Nuvectora	Algovita	Spinal cord stimulator	Pain of the trunk and/or limbs
May 2015	Nevro	Senza	Spinal cord stimulator	Pain of the trunk and/or limbs

All pain conditions are chronic and intractable. Approvals are all first-time PMAs awarded over the past decade. Source: FDA.

The spinal cord stimulator market



Private companies excluded. Source: Evaluate

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