ReActiv8® LIFE

REDUCE **PAIN**

IMPROVE **FUNCTION**

REACTIV8 **LIFE**

Mainstay Medical

TREAT THE CAUSE...

Restorative treatments focus on improving function for patients by addressing a primary underlying cause of chronic low back pain.

...NOT THE SYMPTOMS

Palliative treatments focus on blocking pain through Spinal Cord Stimulation, oral medication, injections, or burning nerves.

ReActiv8 is designed to treat chronic low back pain in patients diagnosed with dysfunction of the multifidus, which is the primary muscle responsible for lumbar spinal stability. ReActiv8 aims to reduce pain and improve related disability and quality of life.

Mechanical Chronic Low Back Pain

Have experienced back pain for more than 6 months

Back pain is worse than leg pain

Physical Therapy and medications have not provided relief

Ask your doctor if you have multifidus dysfunction

Mechanical chronic low back pain results from an injury or stress on the tissues surrounding the spine, including soft tissues, muscles, bones, and joints.

Often times, this type of pain is due to impaired muscle control and neural inhibition of the **multifidus**, which is the largest stabilizing muscle in your back. When this neuromuscular inhibition occurs, there can be misalignment of the spine, causing uncontrolled loading and pain.

ReActiv8® FAQs

What are the key differences between ReActiv8 and Spinal Cord Stimulation (SCS)?

ReActiv8 and SCS are different in almost every way. Most importantly, they each target different CLBP patient populations:

- ReActiv8 addresses predominantly musculoskeletal/mechanical/axial nociceptive CLBP
- SCS addresses predominantly neuropathic CLBP and radiculopathy

They have a completely different delivery schedule:

- ReActiv8 delivers stimulation to cause repetitive multifidus contractions during two 30-minute sessions daily.
- SCS typically delivers stimulation 24/7 to cover the pain.

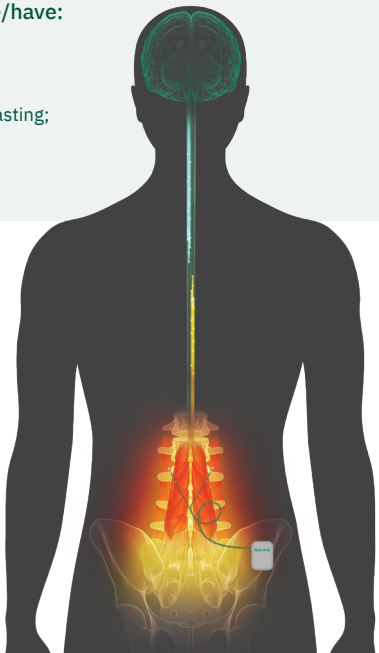
Is ReActiv8 right for me?

Talk to your doctor to see if you are a candidate. ReActiv8 is for patients who have mechanical chronic low back pain, but have not found relief through medical management or physical therapy.

ReActiv8 is indicated as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing.

ReActiv8 is contraindicated for patients who are/have:

- Unable to operate the system;
- Unsuitable for ReActiv8 implant surgery;
- Current or planned pregnancy;
- Current condition associated with muscle wasting;
- Current neurological disease; or
- A Body Mass Index (BMI) greater than 35.



How does ReActiv8 work?

ReActiv8 is implanted in the lower back or upper buttocks area during a minimally-invasive outpatient procedure.

- A generator is connected to two electrical leads, which stimulate the nerves that control your multifidus muscle.
- You control your 30-minute therapy sessions, twice-daily, which can feel like a deep tissue massage.

Long-Term Clinical Outcomes[1,2,3]

Pain and Function Improvements

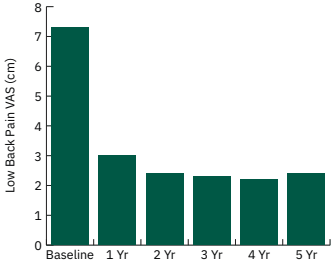
~8 out of 10[**] patients reported substantial improvements[***] in pain and/or function

Opioid Reduction

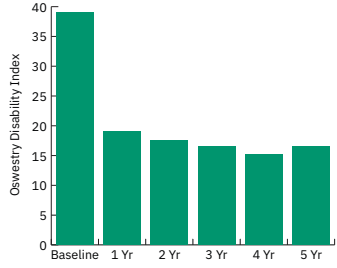
~7 out of 10 patients voluntarily eliminated or reduced their opioid intake[*]

* Of the 52 subjects who were on an opioid-containing medication at baseline and had a 5-year visit, 69% either decreased (23%) or discontinued (46%) opioids. In addition, of the 74 patients who were not on opioids at baseline, 72 (97%) remained off opioids at the 5-year visit. Therefore, the efficacy results observed at 5-years are in addition to significant reductions in opioid use.

Reduction in Pain



Reduction in Disability (Improvement in Function)



[**]78.2% (97/124) had a 50% improvement in VAS and / or 20 point at 5 years. 69% of the 52 patients that at baseline were using opioids and were followed to 5 years.

[***]Substantial improvement is 50% reduction in Pain measured on visual analogue score and / or a 20 point reduction in Oswestry disability index compared to baseline.

Patients experience **long-term improvements** in pain and function over time, demonstrating long-term, durable outcomes.

Risk & Adverse Event Summary

The implantation of ReActiv8 involves risks similar to those of peripheral nerve stimulators. In addition to risks commonly associated with surgery, implantation or use of ReActiv8 includes, but is not limited to, the following risks (some of which were observed in clinical studies):

- Adverse Events (AEs) associated with the surgical procedure, including implant, revision, replacement and removal
- Acute or persistent pain including more pain than anticipated after surgery or worsened low back pain
- Accidental injury to adjacent tissues, e.g. piercing structures such as muscle, blood vessels or organs
- Infection, including local infection of the surgical site, systemic infection and sepsis
- Slow, abnormal or inadequate wound healing including wound dehiscence (slow healing), which may require surgical repair
- Tissue reaction to the presence of the implanted device or materials in/on the implanted device such as response to residual material on device or an allergic response, e.g. previously unknown nickel or titanium allergy. Reaction may be local or systemic.
- Nerve irritation, impingement or damage, including that resulting from mechanical presence of device, exposure to electricity including electrical stimulation, or migration of the leads, suture sleeve or IPG. This may lead to pain, paralysis, sensory deficits or changes to bowel, bladder or reproductive function.
- Device extrusion
- Erosion, threatened erosion or fistula formation in skin overlying device components
- Excessive fibrotic tissue growth
- Hematoma, seroma, cyst or swelling
- Acute or persistent pain including worsened low back pain and/or pain and discomfort due to presence of the device
- Undesired sensations such as uncomfortable paraesthesia, numbness, vibration, pressure, prickling, or uncomfortable contraction of the multifidus
- Overstimulation of tissue, resulting in symptoms such as painful muscle contraction, paraesthesia, jolts or shocks. In addition, injuries that occur as a consequence of stimulation, e.g. accidents that occur as a result of being startled.
- Tissue damage due to mechanical presence of device, or exposure to electricity including electrical stimulation
- Contraction of muscles other than the target muscle(s)
- Muscle fatigue, spasm or injury
- Stiffness, including restricted motion due to adhesions to the device
- Inability to deliver stimulation, including inadequate doses of stimulation. Causes include lead migration, device malfunction or exposure to electromagnetic fields, e.g. security screening devices
- Undesired electrical stimulation
- Inability to stop therapy, with possible sequelae such as anxiety, restriction of movement, pain, muscle fatigue, postural changes, difficulty in walking, sitting or physical activity
- Accidents, injuries, body movements, body positions or biological processes which lead to device complications. Examples include a fall which may cause damage to the IPG; sit-ups or severe coughing leading to migration of the lead; or fracture of bones leading to device migration or damage

You may need medical and/or surgical intervention (such as revision or explant) to treat the issues identified above.

1. Gilligan C, Volschenk W, Russo M, Green M, Gilmore C, Mehta V, et al. Long-term outcomes of restorative neurostimulation in patients with refractory chronic low back pain secondary to multifidus dysfunction: two-year results of the ReActiv8-B pivotal trial. Neuromodulation Technol Neural Interface. 2023;26:87–97.
2. Gilligan C., Volschenk W., Russo M., Green M., Gilmore C., Mehta V., Deckers K., De Smedt K., Latif U., Sayed D., Georgius P., Gentile J., Mitchell B., Langhorst M., Huygen F., Baranidharan G., Patel V., Mironer E., Ross E., Carayannopoulos A., Hayek S., Gulve A., Van Buyten J.-P., Tohmeh A., Fischgrund J., Lad S., Ahadian F., Deer T., Klemme W., Rauck R., Rathmell J., Schwab F., Maislin G., Heemels J.P., Eldabe S. 2022. Three-Year Durability of Restorative Neurostimulation Effectiveness in Patients With Chronic Low Back Pain and Multifidus Muscle Dysfunction. Neuromodulation 2022; -: 1–11.
3. 5-year data on file.

The ReActiv8-B Trial demonstrated a strong safety profile for ReActiv8 (particularly compared to spinal cord stimulators). Among the 204 randomized patients through 5 years of follow-up, there were a reported 8 patients (4%) who experienced serious adverse events (SAEs) related to the device/procedure, with 6 of those having pocket infection requiring explant prior to the 120-day visit. There were no unanticipated device/procedure related AEs and no instances of lead migration reported during this study. Key adverse events included implant pocket pain in 21% of patients with 83% resolved, device overstimulation in 15% of patients with 88% resolved, and lead fracture in 5% of patients which all were resolved with intervention.

For more information on safety, efficacy, and risk, see **https://mainstaymedical.com/safety/** and **https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf**

Scan the QR code to start your ReActiv8 journey today!

FIXMYLOWERBACK.COM.AU

Mainstay Medical

2159 India St, Suite 200, San Diego, CA 92101

610021 Rev. D