ReActiv8® LIFE

RESTORE **CONTROL**

RESTORE **FUNCTION**

RESTORE **STABILITY**

Mainstay Medical

Restoring Function. Restoring Life.

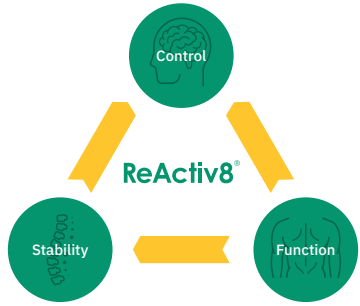
TREAT THE CAUSE...

Restorative treatments focus on improving function for patients by addressing the underlying cause.

...NOT THE SYMPTOMS

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

ReActiv8 aims to restore neuromuscular control of the lumbar spine to increase function and stability, leading to a reduction of pain.



Mechanical Chronic Low Back Pain

Have experienced back pain for more than 3 months

Back pain is worse than leg pain

Physical Therapy and medications have not provided relief

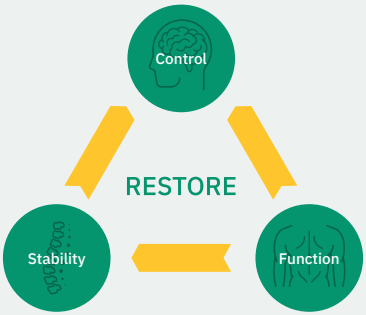
Ask your doctor if you have multifidus dysfunction

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 overcomes neural inhibition and allows the body to regain control of the multifidus, allowing it to provide functional lumbar stability and reduce mechanically based pain.

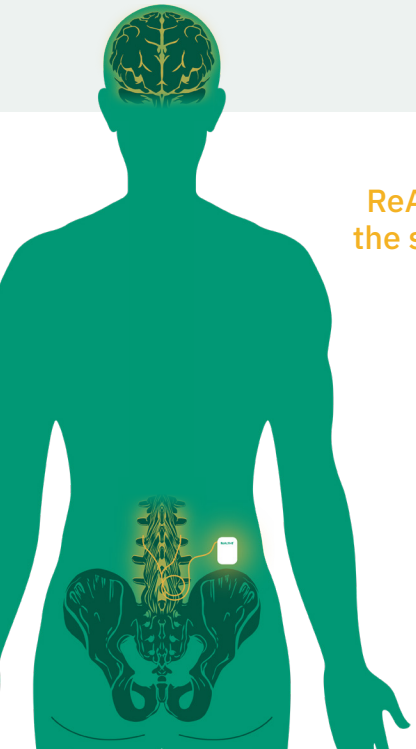
ReActiv8®



CONTROL
of neural signals activating your multifidus muscle

FUNCTION
of the multifidus muscle to provide stability to the spine

STABILITY
of the spine to reduce pain



ReActiv8 is implanted underneath the skin during a minimally-invasive outpatient procedure.

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

Long-Term Clinical Outcomes

Pain and Function Improvements

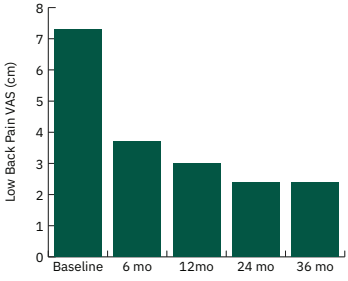
8 out of 10 patients reported substantial improvements in pain and/or function

Opioid Reduction

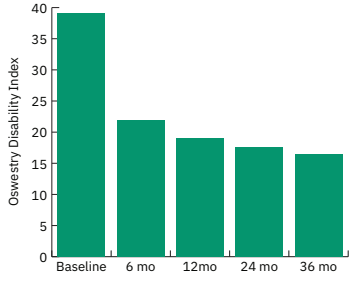
7 out of 10 patients voluntarily eliminated or reduced their opioid intake*

*Percent of patients that were on opioids at baseline: (1-year=31/65), (2-Year= 34/57), (3-Year= 36/51).

Reduction in Pain



Reduction in Disability (Improvement in Function)



Patients experience **progressive long-term improvements** in pain and function, over time, demonstrating a durable, consistent, and restorative result.

FAQs

What makes ReActiv8 unique?

ReActiv8 is designed to address the underlying cause of mechanical low back pain by helping patients restore neuromuscular control of the multifidus muscle.

Why is the multifidus muscle important?

The multifidus muscle is the key stabilizing muscle in the lower back. A single injury to the back can cause impaired muscle control of the multifidus. This lack of muscle control can decrease the spine's functional stability, leaving the spine susceptible to further injury and overloading. Restoring the neuromuscular control of the multifidus muscle can stabilize the spine, thereby increasing function and decreasing pain.

Is ReActiv8 covered by my insurance?

By enrolling in the RSVP Program, you may be able to increase your access to ReActiv8 through the submission of prior authorization and patient-based appeals.

Is ReActiv8 right for me?

Talk to your doctor to see if you are a candidate.

Scan the QR code
to start your ReActiv8 journey today!

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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.

The ReActiv8 System is an implantable neurostimulation system that employs a restorative therapy designed to restore muscle control of the lumbar spine for improved low back pain management. More specifically, ReActiv8 is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the transverse process at L3 as an aid in the management of intractable chronic low back pain associated with multifidus muscle dysfunction, as evidenced by imaging or physiological testing in adults who (i) have failed therapy including pain medications and physical therapy and (ii) are not candidates for spine surgery. ReActiv8 is a prescription device implanted by certified physicians in an outpatient setting. Patients should talk to their health care provider to discuss whether ReActiv8 is right for them. For important safety and product information, visit www.mainstaymedical.com/safety

The ReActiv8-B Trial demonstrated a strong safety profile for ReActiv8 (particularly compared to spinal cord stimulators). Among the 204 randomized patients, 8 serious adverse events (SAEs) related to the device/procedure were reported (4 percent overall) at the 120-day mark. There were no unanticipated device/process SAEs and no instances of lead migration. (Among all adverse events, 53 percent occurred within the first 30 days, and 83 percent were resolved.)

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