

ReActiv8[®] LIFE

RESTORE **CONTROL**
RESTORE **FUNCTION**
RESTORE **STABILITY**

The **ReActiv8** system is now
full body MRI conditional



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Questions?

Scan here to sign up
to connect with a real
ReActiv8 Patient Mentor

TREAT THE CAUSE...



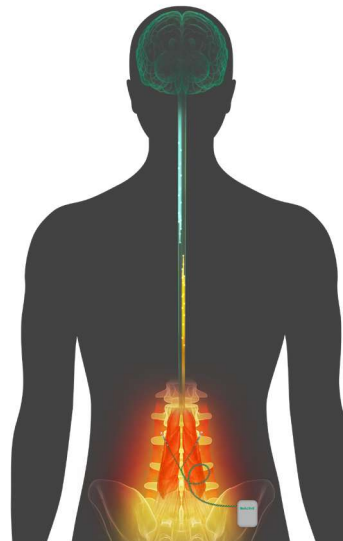
Restorative treatments focus on improving function for patients by addressing the underlying cause.

...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 reduce pain and disability



Mechanical Chronic Low Back Pain¹



Have experienced
back pain for more than
3 months



Back pain is worse
than leg pain



Physical Therapy and
medications have not
provided relief



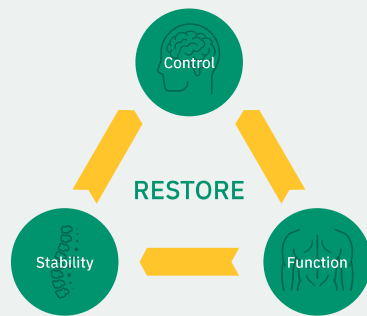
Ask your doctor if
you have multifidus
dysfunction

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 a result of the body being unable to control the multifidus muscle, which is the largest stabilizing muscle in your back. When this stabilizer doesn't work properly, it can cause uncontrolled loading of sensitive parts of your spine. This can be the source of low back pain.

ReActiv8 is designed to address the loss of neuromuscular control in order to allow the body to regain control of the multifidus, thereby providing functional lumbar stability and a reduction in mechanically-based pain.

ReActiv8®



CONTROL

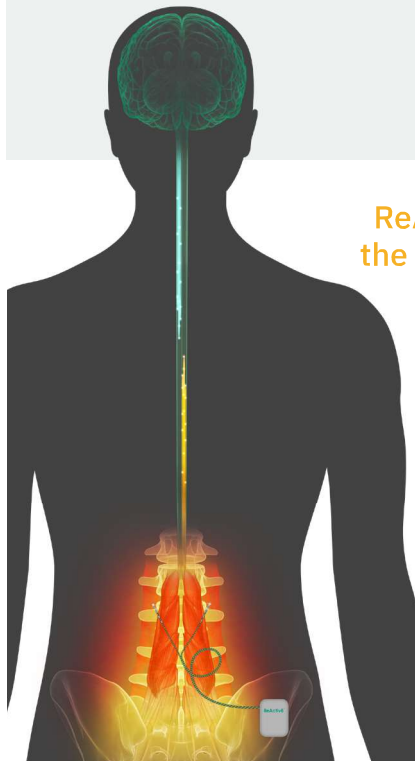
of neural signals activating
your multifidus muscle

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.

- An implantable pulse 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.

2025 | ReActiv8 Patient Brochure (US)
RX only. For use in US Only.

Long-Term Clinical Outcomes¹

Pain and Function Improvements



~9 out of 10 patients were “Definitely satisfied” with ReActiv8

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

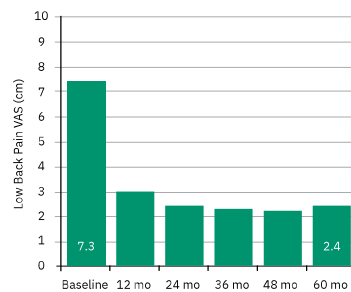
Opioid Reduction



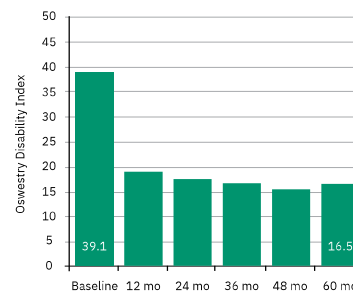
~7 out of 10 patients voluntarily eliminated or reduced their opioid intake*

*Percent of patients that were on opioids at baseline:
(5-Year=36/52).

Reduction in Pain



Reduction in Disability (Improvement in Function)



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

Do you have back pain that won't go away?



Do you have back pain, muscle spasms, or feelings of instability often?

Do they seem to be getting worse with time?



If you stay in a position for an extended period (sitting, standing, driving, etc.) does your back become increasingly painful?

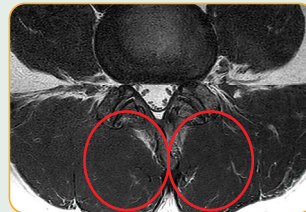
Do you have to shift positions or support yourself with your arms because of this pain?



Do you experience back pain or spasms when doing small tasks like brushing teeth over a sink, washing dishes, or reaching for an item?

Is ReActiv8® Right For you?

ReActiv8 is the first and only **restorative** therapy option for mechanical chronic low back pain resulting from multifidus muscle dysfunction - the therapy aims to reduce pain and restore function long-term.



Healthy Multifidus



Unhealthy Multifidus Atrophy

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.

What are the outcomes for patients with ReActiv8?¹

Patients experience progressive long-term improvements in pain and function, over time, demonstrating a durable and consistent result. This has been demonstrated through multiple clinical studies, with the largest randomized controlled trial demonstrating first of its kind results out to five years.

- ~**9/10** patients were “Definitely satisfied” with ReActiv8.
- ~**8/10** patients report substantial (> 50%) improvements in pain and/or function.
- ~**7/10** patients voluntarily eliminated or reduced their opioid intake.
- ReActiv8 demonstrated favorable safety profiles compared to other neurostimulators.

*Patients that were on opioids at baseline: (5-Year=36/52).

Can I have an MRI (Magnetic Resonance Imaging)?

ReActiv8 patients can receive an MRI. The ReActiv8 Implantable Pulse Generator (device) and 45 cm implantable leads (Model 8145) are MR Conditional devices with demonstrated safety in the MR environment only within specified conditions. Refer to the document ReActiv8 System Magnetic Resonance Imaging (MRI) Guidelines for an up-to-date list of approved MR Conditional components, model numbers, and required conditions. Consult with your healthcare provider prior to an MR exam and inform MRI site personnel that you have an MR Conditional medical device during MR screening prior to the MR exam. Carry your device identification card with you at all times.

Does ReActiv8 work for older patients?

Yes, ReActiv8 has been shown to provide significant and clinically meaningful benefits in disability, health-related quality of life, and pain in well-selected patients, irrespective of age².

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!





1. Gilligan C., Volschenk W., Russo M., et al (2025) Five-Year Longitudinal Follow-up of Restorative Neurostimulation Shows Durability of Effectiveness in Patients With Refractory Chronic Low Back Pain Associated With Multifidus Muscle Dysfunction. *Neuromodulation*, Article in Press, doi.org/10.1016/j.neurom.2025.01.006

2. Ardeshiri A., Amann M., Thomson S. and Gilligan C., (2025) Application of Restorative Neurostimulation for Chronic Mechanical Low Back Pain in an Older Population with 2-Year Follow Up. *Reg. Anesth. Pain. Med.* Article in Press, doi.org/rapm-2023-105032

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.)

Refer to The ReActiv8 System MRI Guidelines at www.mainstaymedical.com/resources for complete conditions information.

Magnetic resonance imaging – The ReActiv8 Implantable Pulse Generator (IPG) and implantable leads are MR Conditional devices with demonstrated safety in the MR environment only within specified conditions. Refer to the document ReActiv8 System Magnetic Resonance Imaging (MRI) Guidelines for an up-to-date list of approved MR Conditional components, model numbers and required conditions for safe use in the MR Environment.

Direct the patient to consult with their healthcare provider prior to an MR exam and inform MRI site personnel that they have an MR Conditional medical device during MR screening prior to the MR exam.

Failure to follow these guidelines for MRI scans may result in severe patient injury and/or device malfunction.