

ReActiv8[®]
Restorative Neurostimulation™

ReActiv8 Life

Patient information
www.mainstaymedical.com



For too long, you have suffered from Chronic Low Back Pain (CLBP) and nothing has provided you with lasting or meaningful relief.

Approximately two-thirds of adults suffer from low back pain at some point in their lives. In many cases, it goes away, but for some people, back pain becomes a chronic condition that affects every aspect of life.

ReActiv8 is a rehabilitative therapy that addresses the underlying multifidus muscle dysfunction that can lead to mechanical CLBP.

Chronic Low Back Pain (CLBP)

In many cases, low back pain starts as a simple strain or injury to a spinal joint. To avoid pain, the brain automatically limits activation of the most important stabilizing muscle of the low spine, the multifidus muscle. This reduced muscle activation can cause spine segments to move into painful positions from sudden or abnormal movements. If not resolved, this can evolve into a debilitating cycle of pain, poor muscle activation and muscle weakness. If this pain continues for more than three months, it is referred to as Chronic Low Back Pain.

Many studies show that reactivation of the multifidus muscle is an important step in breaking the cycle of CLBP and restoring function to the spine.^{1,2}

1 - MacDonald D, Moseley GL, Hodges PW. Why do some patients keep hurting their back? Evidence of ongoing back muscle dysfunction during remission from recurrent back pain. *Pain* 2009;142:183–8.

2 - Freeman MD, Woodham MA, Woodham AW. The Role of the Lumbar Multifidus in Chronic Low Back Pain: A Review. *PM R* 2010;2:142–6.



ReActiv8 Restorative Neurostimulation Therapy

ReActiv8 is a small electronic device implanted in your low back that activates the key stabilizing muscles of your lumbar spine. You control the therapy sessions by turning it on with a wireless remote two times per day for 30 minutes each, typically in the morning and in the evening. During the treatment, you will feel the muscles in your low back contract and relax.

By activating the multifidus muscle, the restorative nature of the ReActiv8 therapy aims to break the cycle of CLBP and, as a result, alleviate your pain over time.



Image not to scale

Is ReActiv8 right for you?

ReActiv8 is indicated for patients whose daily lives are severely affected by chronic low back pain. To find out if this therapy is a treatment option for you, talk to your doctor or a back pain specialist. You can search for a ReActiv8 certified physician in your area at www.mainstaymedical.com.

If you agree with the following statements, you may be a candidate for ReActiv8. Ask your doctor if this therapy is right for you.

- You are over 21 years old
- In the previous year, you experienced low back pain on half (or more) of the days
- You feel pain primarily in your low back and it is worse than pain in your leg
- You have seen a doctor for your back pain and your doctor did not recommend spine surgery
- You have never had spine surgery in the past
- You have participated in or completed a physical therapy program, but still have pain
- Medications do not relieve your pain or may cause negative and potentially severe side effects

Your doctor may also evaluate other health information related to you.

ReActiv8 is an implantable neurostimulation system that employs a rehabilitative 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, see mainstaymedical.com/safety.

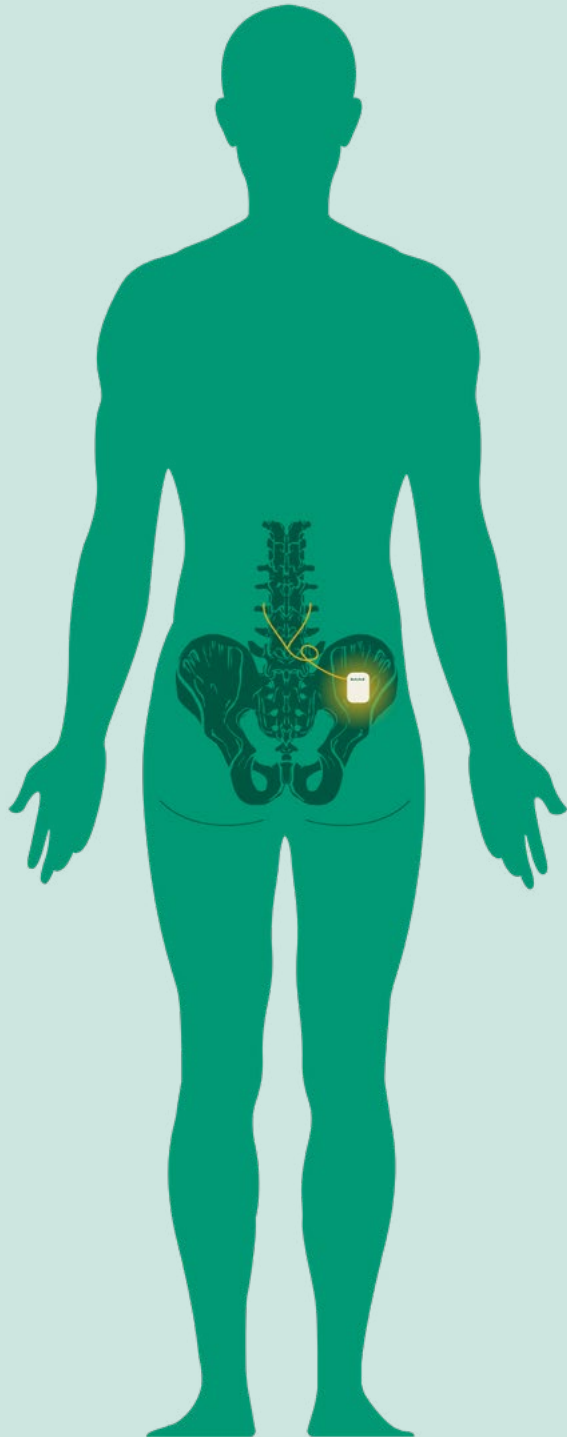


Image not to scale

ReActiv8 placement

The ReActiv8 system is implanted in your low back during a minimally invasive surgical procedure, typically performed on an outpatient basis. In limited cases, a brief hospital stay may be required.

Using a needle, your doctor will guide two electrical leads to both sides of your low spine, anchoring them close to the nerves that control the stabilizing muscles in your low back. The leads are connected to a small pulse generator (about the size of a matchbox) which is implanted under the skin in the upper buttock or low back area.

As with any surgical procedure, there are risks associated with implanting ReActiv8. Talk to your doctor to make sure you fully understand the risks. For detailed product safety information, see www.mainstaymedical.com/safety.

ReActiv8[®]

Treat the cause,
not just the symptoms.



Not actual patient



Not actual patient

Living with ReActiv8 therapy

About two weeks after the implant procedure, your ReActiv8 system is activated and you will receive instructions on how to turn on the therapy using a hand-held remote. After that, your doctor may only need to check your ReActiv8 system a few times per year or when you feel it may require an adjustment.

Most patients start their twice daily, 30-minute therapy sessions in the morning before they get out of bed and at night when they go to sleep.

Based on patient data from the clinical trials, many patients experience a noticeable reduction in their low back pain after several months of therapy³. And even after their back pain improved significantly, most patients keep using their device. If you and your doctor decide you no longer need ReActiv8, the system can be removed by your doctor.

3 - Gilligan C, Volschenk W, Russo M, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain 2021; Article in Press. doi: 10.1097/j.pain.0000000000002258



ReActiv8 is effective with lasting results

The international multi-center ReActiv8-B clinical trial demonstrated compelling improvements in pain and disability after one year⁴:

73%

of patients reported a substantial improvement (50% or greater) in their pain and/or disability.*

78%

of patients reported that they were “Definitely Satisfied” with their ReActiv8 therapy.

The success of any therapy differs from patient to patient. ReActiv8 therapy is intended to help you return to your normal level of physical activity. It is not an alternative for daily exercise. Discuss the importance of physical activity and exercise in managing your back pain as well as the benefits and potential risks of ReActiv8 with your doctor.

4 - Gilligan C, Volschenk W, Russo M, et al. An implantable restorative-neurostimulator for refractory mechanical chronic low back pain: a randomized sham-controlled clinical trial. Pain 2021; Article in Press. doi: 10.1097/j.pain.0000000000002258

* Pain was measured using a low back pain visual analogue scale from 0 to 10 where 0 indicates “no pain” and 10 “worst imaginable pain”. Disability was measured using a questionnaire which produced a score between 0 and 100 where 0 indicates “no restrictions” and 100 “worst imaginable disability”.

Not actual patient

Frequently asked questions:

Is ReActiv8 right for me?

Talk to your doctor to see if ReActiv8 is right for you.

Why is this therapy different?

ReActiv8 is designed to address the cause of low back pain by activating the muscles that control stability of your low back.

Will the therapy work long-term?

On average, people with CLBP who were treated with ReActiv8 had substantial improvements in pain, disability and quality of life after one year. Learn more about the clinical outcomes at www.mainstaymedical.com.

Is ReActiv8 covered by my insurance?

To assist you in obtaining coverage from your health insurer, we offer the ReActiv8 Support and Verification Program (R.S.V.P.) by partnering with experts specialized in working with health insurance companies. To learn more about enrollment, talk to your doctor or visit www.mainstaymedical.com.

FDA Approved, CE Marked, TGA Approved.

By prescription only.

Let's get started

Take the first step to determine if
ReActiv8 is right for you.
Visit www.mainstaymedical.com
for more information.

ReActiv8®

Treat the cause, not just the symptoms.

Rx Only

CAUTION: Federal law (USA) restricts this device to sale, distribution and use by or on the order of a physician. Refer to user manuals for a complete listing of indications, contraindications, warnings, precautions, potential adverse events and directions for use.

Indications for Use: The ReActiv8 System is indicated for bilateral stimulation of the L2 medial branch of the dorsal ramus as it crosses the L3 transverse process 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 have failed therapy including pain medications and physical therapy and are not candidates for spine surgery.

Contraindications: ReActiv8 is contraindicated for patients who are :Unable to operate the system or Unsuitable for ReActiv8 implant surgery.

Warnings: ReActiv8 therapy has not been evaluated in patients with evidence on an MRI scan of a pathology that may be amenable to surgery (e.g., severe stenosis, moderate to severe scoliosis). It is very important that you inform your physician or other healthcare professional (e.g. physical therapist, chiropractor, dentist, etc.) that you are implanted with the ReActiv8.

Magnetic Resonance Imaging (MRI): Safety of MRI with an implanted ReActiv8 has not been evaluated. Do not use MRI on patients who have been implanted with the ReActiv8 system. You SHOULD NOT have an MRI scan, as it may be hazardous for you.

Diathermy: Safety of diathermy with an implanted ReActiv8 has not been evaluated. Do not use short - wave diathermy, microwave diathermy, or therapeutic ultrasound diathermy (all now referred to as diathermy) on patients implanted with a ReActiv8. You SHOULD NOT receive diathermy therapy, as it may be hazardous for you.

Strangulation by cable: When operating the Activator, keep the antenna cable away from your neck to avoid strangulation. Do not allow children to handle or play with the Activator.

Case damage: If the case that the Activator is pierced or ruptured, burns could result from exposure to battery chemicals.

Electromagnetic interference from electrical or magnetic fields generated by equipment found in the home, work, medical or public environments may interact with or disrupt the function and operation of ReActiv8.

Defibrillation/cardioversion: When a patient is in ventricular or atrial fibrillation, the first consideration is patient survival. External defibrillation or cardioversion can damage the ReActiv8 IPG. It may also cause induced currents in the leads that can injure the patient.

USA Rx Only
C € – 2797

ReActiv8® is a registered trademark
of Mainstay Medical Limited.
Copyright © 2021 Mainstay Medical
Limited. All rights reserved.



610023 Rev. C