

**ReActiv8**<sup>®</sup>  
Restorative Neurostimulation™

Do you have

**LOW BACK PAIN**

that won't  
go away?

**ReActiv8**  
**MAKES**  
**RECOVERY**  
**POSSIBLE**

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# What if you could treat the cause of your **Chronic Low Back Pain (CLBP)** not just the symptoms?

Most people don't know that a **significant amount of low back pain** is caused by muscle dysfunction. This type of pain is often caused by the body's inability to control **the multifidus muscle**, the largest stabilizing muscle in the back. When this muscle doesn't work properly, it can cause uncontrolled stress and mechanical loading of the spine, which can be the source of low back pain.<sup>1</sup>

**ReActiv8®** provides therapy designed to help the body regain control of the multifidus muscle, improving functional lumbar stability and reducing mechanical stress on the spine responsible for pain.



No one should live their lives in constant pain. If you have mechanical CLBP, it's time to address the cause of your pain, not just manage the symptoms.

For many Chronic Low Back Pain patients, none of the available traditional, conservative or palliative treatment options, including medications and injections, provide lasting relief.

**ReActiv8** uses a different type of restorative therapy to address the underlying reasons why the multifidus muscle is not functioning properly. In many patients with CLBP, multifidus dysfunction is responsible for a large part, if not most, of their pain and inability to perform certain exercises and movements.

**ReActiv8** delivers restorative neurostimulation therapy directly to the stabilizing muscles of your lower back, focusing on the root cause of your pain. For many patients, consistent use of the therapy leads to meaningful, long term relief.

**ReActiv8** is a **restorative** option for mechanical chronic low back pain resulting from multifidus muscle dysfunction that makes recovery possible long-term.



# Why does **Multifidus Muscle Dysfunction** cause so much pain?

**A healthy back relies on the deep core muscles for posture and to support the spine during movement.**

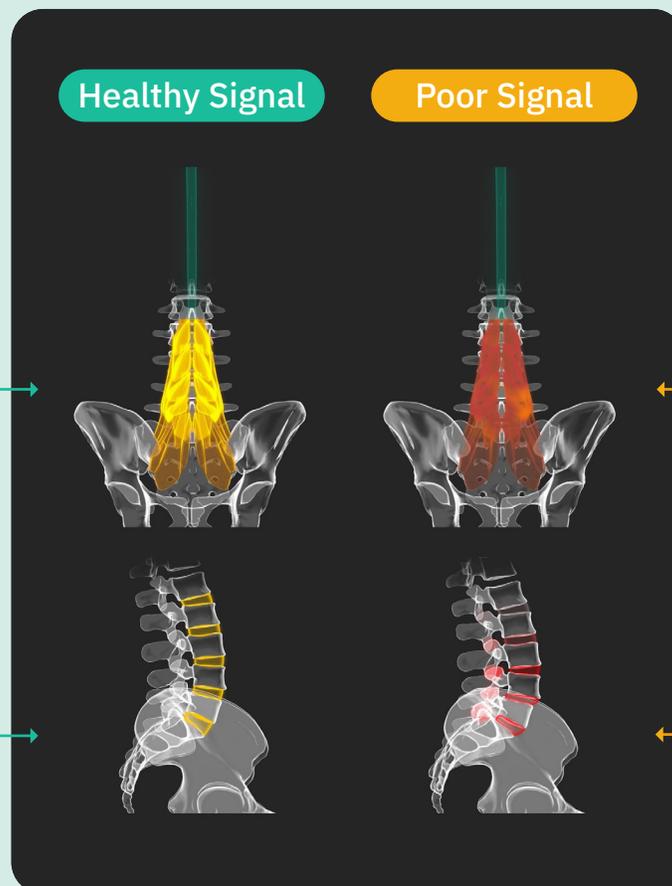
The brain controls these *multifidus muscles* subconsciously, meaning you never have to think about them when they are doing their job.

For a variety of reasons, the brain can lose control of these muscles.

This breakdown in communication results in improper muscle function and weakened stabilizing forces on the spine, leading to increased mechanical loading. Over time, this accelerates spinal wear and tear and causes chronic low back pain.

A healthy signal between the brain and spine (yellow) allows the multifidus muscles to function properly. Here, the multifidus supports a healthy spine without mechanical pain.

A healthy signal allows for a fully supported spine.

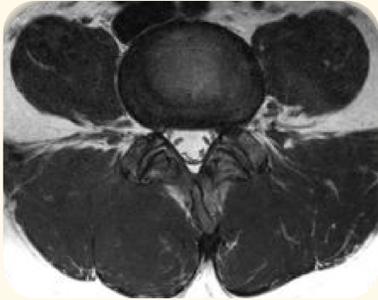


A spine with multifidus muscle dysfunction is not correctly supported, which can lead to overloading and pain.

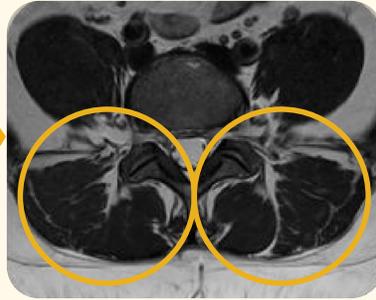
The lack of support leads to altered movement patterns and more stress to the spine.

# MRI Review

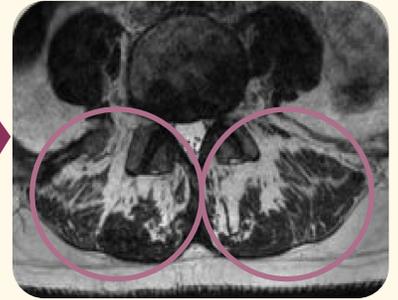
The health of the multifidus muscles can be evaluated on an MRI scan. A normal multifidus muscle appears dark and solid. Muscles with dysfunction can show white marbling where fat has replaced healthy muscle tissue, indicating wasting and atrophy.<sup>1</sup>



Normal Multifidus



Moderate Atrophy



Severe Atrophy



# Is my **Chronic Lower Back Pain (CLBP)** Multifidus Muscle Dysfunction or something else?

Chronic low back pain is one of the most challenging types of pain to deal with. It often doesn't respond to typical treatment.

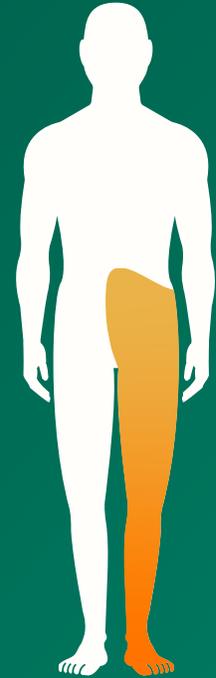
## Two types of Chronic Low Back Pain

### What is nerve pain?

Back pain caused by disease or damage to the spinal nerves - often feels like burning, "electric shock", tingling, numbness or shooting pain.

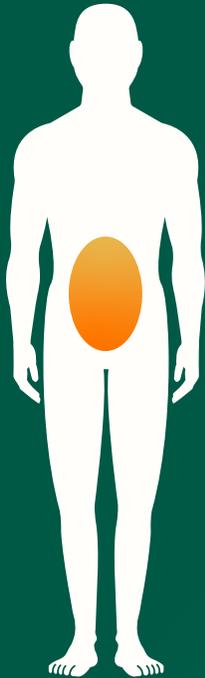
- Includes 'Sciatica', or back pain radiating into the leg(s)
- Often due to ruptured/herniated disc pinching nerve
- Can lead to – or result from – back surgery

Patients with predominantly nerve pain may not be candidates for ReActiv8 but should ask their doctor about another appropriate therapy or surgical intervention.



Approximately **two-thirds** of patients with Chronic Low Back Pain suffer from **mechanical pain**<sup>2,3</sup>.

Mechanical pain may be related to muscle dysfunction.



## What is muscle dysfunction pain?

- Impaired/weak core muscles (Multifidus) lead to mechanical pain and aberrant movement.
- Patients often experience a sense of instability, deep aches, muscle spasms, throbbing or sharp pain.
- There are few therapeutic options, and surgery is rarely indicated.

Patients experiencing pain from muscle dysfunction may be candidates for **ReActiv8** Restorative Neurostimulation, which activates the multifidus to help restore core muscle function.

### Ask your doctor about Multifidus Muscle Dysfunction.

Your healthcare provider can confirm the presence of dysfunction in your lower back muscles via a simple, non-invasive physical exam and muscle atrophy or fatty infiltration on an MRI scan.



# Real Results from Recovered ReActiv8 Patients



**Susi, Patient in her 80s, NYC**

After suffering from debilitating back pain for over a decade and getting no lasting results from physical therapy, muscle relaxers, pain medications, steroid injections, and even ablations, Susi felt results from ReActiv8 “almost immediately.”

*“ReActiv8 definitely improved my quality of life and got me back to doing the things I love – I can stand long enough to paint again, sit long enough to go to the theater, and walk long enough to enjoy museums.”*

Mack’s back pain first started bothering him during his time in the US Navy, but continued to worsen as he transitioned to other jobs in civilian life. His back pain became unbearable after being injured doing deliveries. Mack received ReActiv8 and has credited it with being able to stop using his cane and getting back to his passion for hosting cookouts with his friends.

*“For anyone considering ReActiv8, I’d say the question is: do you want your life back? It’s really incredible the difference it’s made.”*



**Mack, Patient in his 30s, Indiana**

Scan here to  
view **ReActiv8**  
Patient Stories



\* Patient testimonials represent experiences that are unique to the individual, and may not be representative of other cases.



**Ruby, 86,**  
Maryland

A back spasm after standing up to put a load of clothes in the washing machine led to over 30 years of severe low back pain while trying to do normal daily activities. The pain also caused her neck to stiffen up, making it difficult to drive. Prior to ReActiv8, Ruby was having so much trouble completing daily tasks that she was having to consider entering an assisted living facility.

*“The recuperation time was very short, and it has given me significant relief from the pain I’ve been feeling for the last 30 years.”*

John experienced back pain for the last 50 years. He tried different medications, physical therapy, injections, ablations, and even surgery, but none of them provided lasting relief until ReActiv8. He even credits ReActiv8 with allowing him to maintain enough physical fitness to mitigate his heart issues.

*“The frequency and duration of the pain is diminished. I’m able to do activities that, in the past, would have created significant pain, and now they don’t.”*



**John, 76,**  
Florida



**Henry,**  
Patient in his  
70s, Georgia

An auto accident where he was t-boned by another driver caused an injury that would affect Henry’s life for decades. He asked about ReActiv8 after seeing a poster in the exam room during a follow-up visit for an ablation. After 15 years of treatments for low back pain, he was shocked that he’d never even heard of the multifidus muscle, but when his MRI showed atrophy, he was hopeful he had finally found what had been the problem all along.

*“I’d tell anyone thinking about ReActiv8 to go for it. I struggled with low back pain for over 15 years, and I think I tried almost everything to make it better. It was really frustrating – but ReActiv8 actually worked because it doesn’t just mask the pain, it actually solved the problem for me.”*

# Quiz Time: Is **ReActiv8** right for me?

## Does any of this sound familiar?

Check all that apply

You have back pain, muscle spasms, or feelings of instability often.

They are getting worse with time.

Your pain flares or worsens if you stay in one position for an extended period, such as sitting, standing, driving, etc.

You often have to shift positions or support yourself with your arms because of this pain.

You experience back pain or spasms when doing small tasks like brushing your teeth over a sink, washing dishes, or reaching for an item.

You have had pain for more than one year.

Your back pain is worse than your leg pain.

You have failed to find long-term relief from (check all that apply):

Time and rest

Physical therapy

Chiropractic

Acupuncture/massage

Medications (anti-inflammatories, muscle relaxers, narcotics)

Steroid injections

Radiofrequency ablations

You have had no prior lumbar spine fusion surgery and are not a current surgical candidate.

The more boxes you check, the better fit **ReActiv8** might be for you.

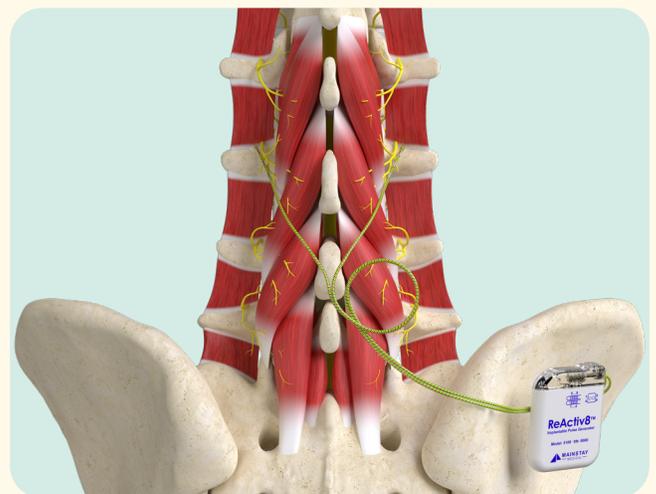
# What is ReActiv8?

ReActiv8 is a surgical implant that delivers restorative therapy directly to the areas affecting the source of CLBP. Patients using ReActiv8 saw a much higher likelihood of significant improvement in their CLBP when compared with other common palliative interventions, or Optimal Medical Management.<sup>5</sup>

- The ReActiv8 system is implanted in your lower back by your physician during a minimally invasive outpatient procedure.
- Two electrical leads are positioned to stimulate the nerves that control your multifidus muscle.
- The leads are connected to an Implantable Pulse Generator (IPG) and placed in the under the skin in your upper buttock or lower back.

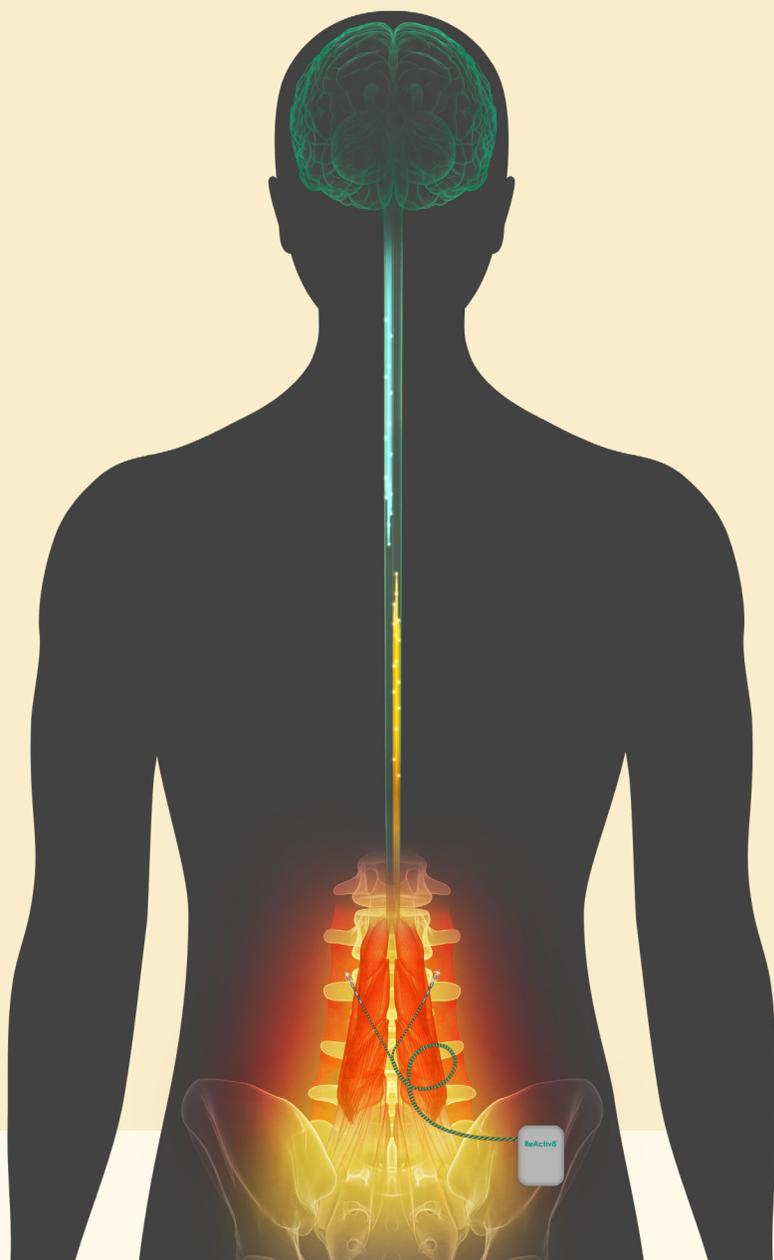
## How does the therapy work?

- By stimulating the nerves that activate the multifidus muscle, ReActiv8 encourages the body to regain control of the multifidus, improving spine stability and reducing mechanically-based pain.
- Using a remote control, the patient activates a 30-minute therapy session twice a day. This allows the system to contract and relax the multifidus muscle via the stimulation of the medial branch nerve, presenting a comfortable sensation that the patient can perform while resting in bed or on the couch.
- Once the patient obtains their goals of improved functionality and reduced pain, they can tailor the therapy usage to fit their needs. Some patients use the therapy twice daily, while others use it as needed.



# ReActiv8 generates comfortable electrical pulses that cause your multifidus muscle to contract and relax.

- Fully Patient Controlled - your ReActiv8 device will be fully controlled by YOU. Therapy sessions must be started and stopped by the ReActiv8 Activator, which is similar to a remote control. The Activator ensures that the device does not deliver therapy unless you start a session, and allows you to end the session early, if needed. Please refer to the **ReActiv8** user manual for additional instructions.
- For maximum benefit, patients should perform two 30-minute therapy sessions per day. Many patients find that performing a session right when they wake up and right when they get into bed at night is the best way to work their therapy sessions into their daily routine.
- Most patients report that their therapy sessions feel “like a pleasant series of deep muscle contractions,” similar to flexing a muscle in an arm or leg, but in the their lower back. Some even compare the sensation to a deep tissue massage.
- Patients will have the opportunity to adjust the programming of their device at each of their follow-up appointments to ensure that it is as comfortable and enjoyable as possible to perform their daily therapy sessions.



# Long-term Clinical Outcomes<sup>4</sup>

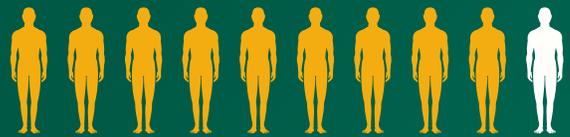
## What are the outcomes for patients with ReActiv8?

- Multiple clinical trials have demonstrated that a significant amount of ReActiv8 patients experience progressive, long-term improvements in pain and function over time, demonstrating a durable and consistent result.
- ReActiv8 demonstrated favorable safety profiles compared to other neurostimulators.
- ReActiv8 is **superior** to Optimal Medical Management for the treatment of mechanical chronic low back pain associated with multifidus muscle dysfunction.<sup>5</sup>

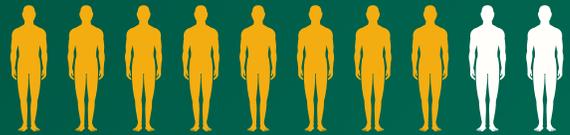
### Take a look at the results below

#### Pain and Function Improvements:

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

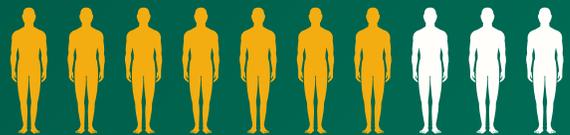


~8 out of 10 patients reported substantial improvements in pain and/or function

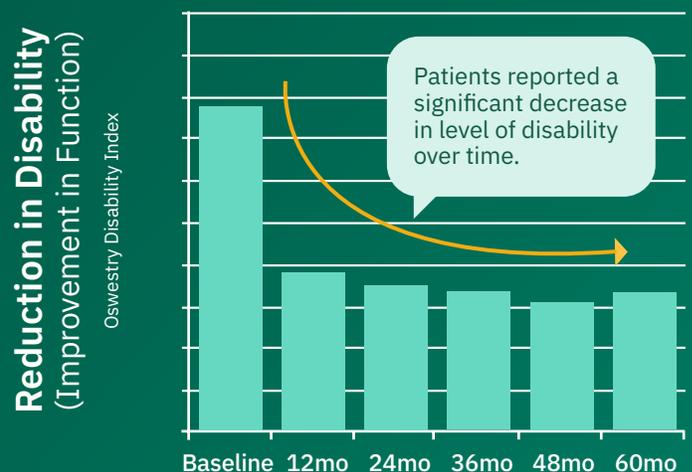
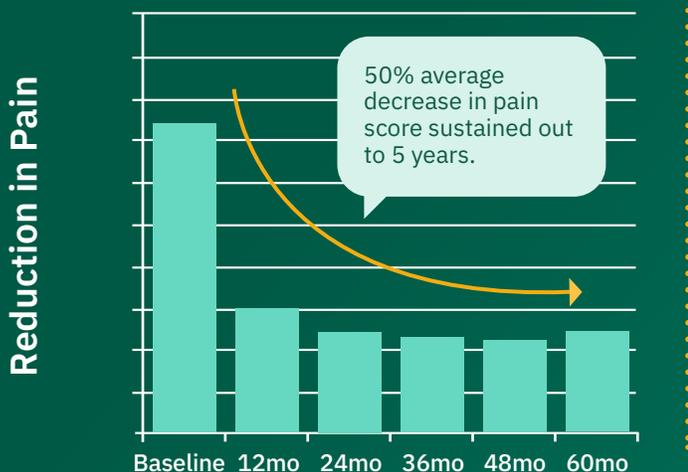


#### Opioid Reduction:

~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)



# FAQs - Life with ReActiv8

## How often do I have to come back in for appointments?

The ReActiv8 follow-up schedule is tailored to customize the therapy to the patient's body as it begins to restore control over the multifidus muscle. It is an opportunity to gauge progress and celebrate the journey toward improved functionality and reduced pain. After the activation appointment, further follow-ups at 1, 3, and 6 months (or as needed) will be performed to fine-tune your programming as your body heals and begins to restore function and stability.



## When will I start seeing results?

Most patients begin to feel improvement in their ability to function and perform activities with improved confidence between 6 and 16 weeks. Still, results can take longer than the average range in some patients. Patients report their back pain beginning to decrease shortly after they feel an improvement in function. Data from clinical trials suggest that unlike traditional palliative treatments such as medications and injections, ReActiv8 patients maintain their improvement over time.

- Patients who are most consistent with their twice-per-day therapy sessions are most likely to see the most noticeable improvement. Once feeling significantly better, patients can adjust their therapy usage to their needs or lifestyle. Some patients even choose to have their system removed after a few years because they felt that they had fully recovered.
- Your healthcare provider may also encourage you to complete physical therapy in conjunction with ReActiv8, as studies show it may enhance the results.

## Can I go swimming or use a hot tub with ReActiv8?

Yes, assuming that your doctor has cleared you and your incisions are fully healed.

### **How long does the ReActiv8 battery last? Do I have to charge it?**

The ReActiv8 battery does not need to be charged. The system is tested to have enough battery life to last a minimum of 5 years with continuous use (two 30-minute sessions per day). However, in practice, ReActiv8 systems have been shown to last much longer. If the battery ever needs replacement, a straightforward procedure to switch it out can be performed without having to replace the implanted leads.

### **Have you seen improvement in the quality of life of patients post-procedure?**

Yes. Quality of life has been measured in multiple clinical studies and shows patients still enjoying dramatic improvements as long as 5 years after surgery.

### **Are these positive results only seen in controlled clinical studies?**

No. Patients participating in real-world studies have reported results consistent with those found in the controlled clinical studies out to 5 years.

### **What sort of imaging can patients receive with a ReActiv8 system?**

CT scans, fluoroscopy, ultrasound, and X-ray are all compatible with the ReActiv8 device. The ReActiv8 Device is also full body MRI conditional. Review the ReActiv8 Manual and MRI guidelines for specific considerations.

### **Can I have an MRI (Magnetic Resonance Imaging)?**

Yes, but you must consult with your healthcare provider before an MR exam, and inform MRI site personnel that you have an MR Conditional medical device during MR screening before the MR exam. Carry your device identification card with you at all times. Since the ReActiv8 device must be turned “off” before the MRI, you will need to have an appointment with a ReActiv8 representative before your MRI appointment.

### **Can I have chiropractic manipulation or deep tissue massage with ReActiv8?**

Ask your physician first. Chiropractic manipulation or deep tissue massage could damage your neurostimulator or dislodge a lead, requiring additional surgery to repair the system. It is generally advised not to attempt anything new or strenuous for the first three months after receiving ReActiv8.

### **Can I go through metal detectors or airport security with ReActiv8?**

Yes, you can walk through metal detectors or screening devices with an implanted neurostimulator. Do not linger inside, and try not to touch the sides of the screening device. Tell the security personnel you have a “pacemaker for pain” and show your ReActiv8 Patient Identification Card. You may also request a hand search. If the search involves a hand-held security wand, ask them to only hold it near your neurostimulator for as long as needed.

1. Chakravarthy K. et al. Restorative Neurostimulation: A Clinical Guide for Therapy Adoption. J Pain Res. 2022 Jun 20;15:1759-1774
2. Deyo, R. A., & Weinstein, J. N. (2001). Low back pain. The New England Journal of Medicine, 344(5), 363–370. <https://doi.org/10.1056/NEJM200102013440508>
3. Will, J. S., Bury, D. C., & Miller, J. A. (2018). Mechanical Low Back Pain. American Family Physician, 98(7), 421–428. [https://doi.org/10.1007/978-3-642-28753-4\\_101227](https://doi.org/10.1007/978-3-642-28753-4_101227)
4. Gilligan C., Volschenk W., Russo M., et al (2024) 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, [doi.org/10.1016/j.neurom.2024.01.006](https://doi.org/10.1016/j.neurom.2024.01.006)
5. Schwab, F., Mekhail, N., Patel, K.V. et al. Restorative Neurostimulation Therapy Compared to Optimal Medical Management: A Randomized Evaluation (RESTORE) for the Treatment of Chronic Mechanical Low Back Pain due to Multifidus Dysfunction. Pain Ther (2025). <https://doi.org/10.1007/s40122-024-00689-0>

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.

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. ReActiv8 is a prescription device implanted by certified physicians in an outpatient setting. Patients should talk to their healthcare provider to discuss whether ReActiv8 is right for them.

The implantation of ReActiv8 involves risks associated with the surgery, implantation and use of ReActiv8 and may include pain at implant site, undesirable sensations or uncomfortable contractions of the muscles, muscle fatigue or spasms, scar tissue and stiffness, erosion, device malfunction or migration, lack of pain relief, hematoma, seroma, infection, and other surgical risks. For additional safety and product information, visit [www.mainstaymedical.com/safety](http://www.mainstaymedical.com/safety).

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 ReActiv8 System MRI Guidelines at [mainstaymedical.com/resources](http://mainstaymedical.com/resources) for complete conditions information. Failure to follow these guidelines for MRI scans may result in severe patient injury and/or device malfunction.