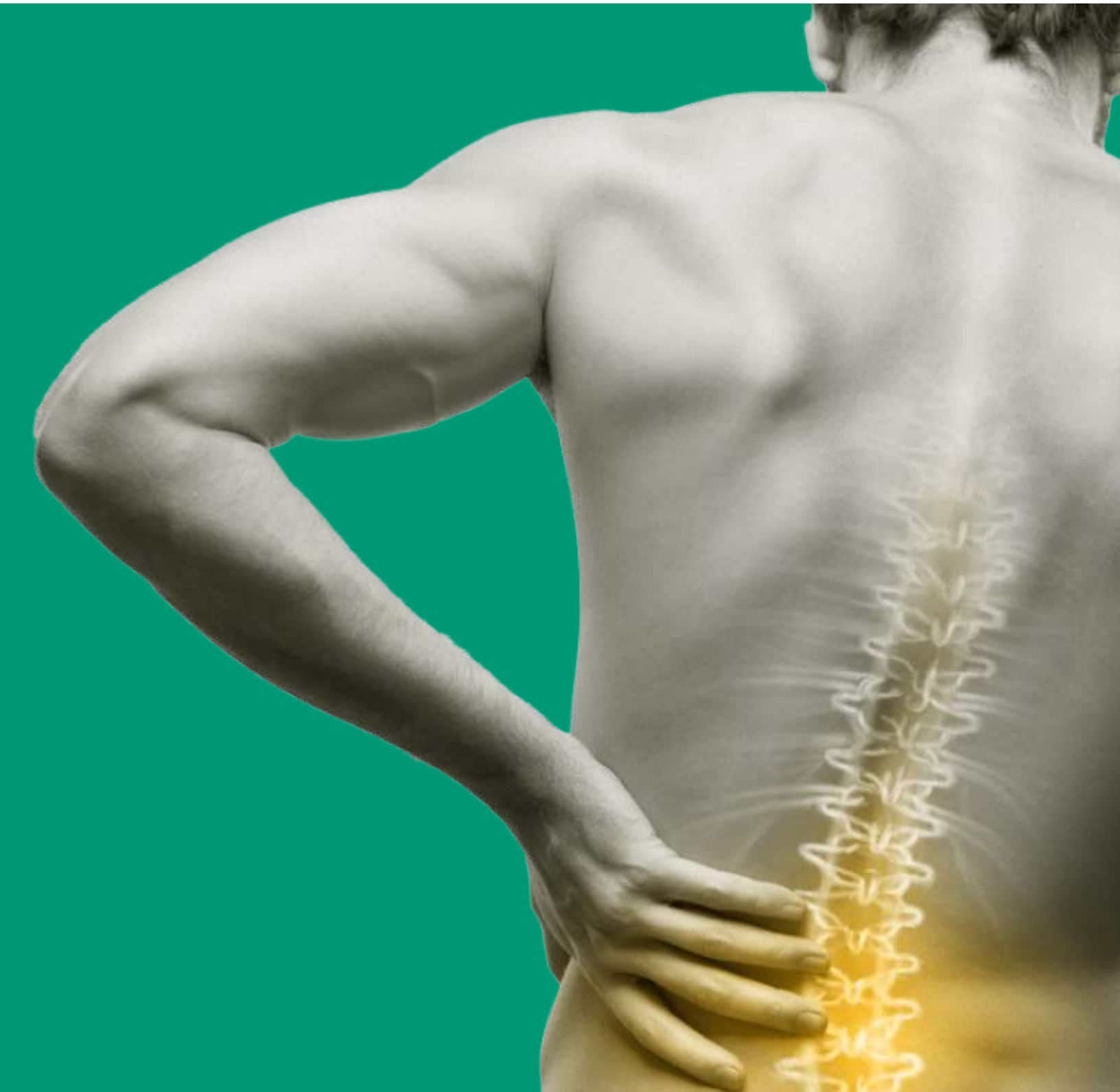
ReActiv8®

Restorative Therapy for CLBP



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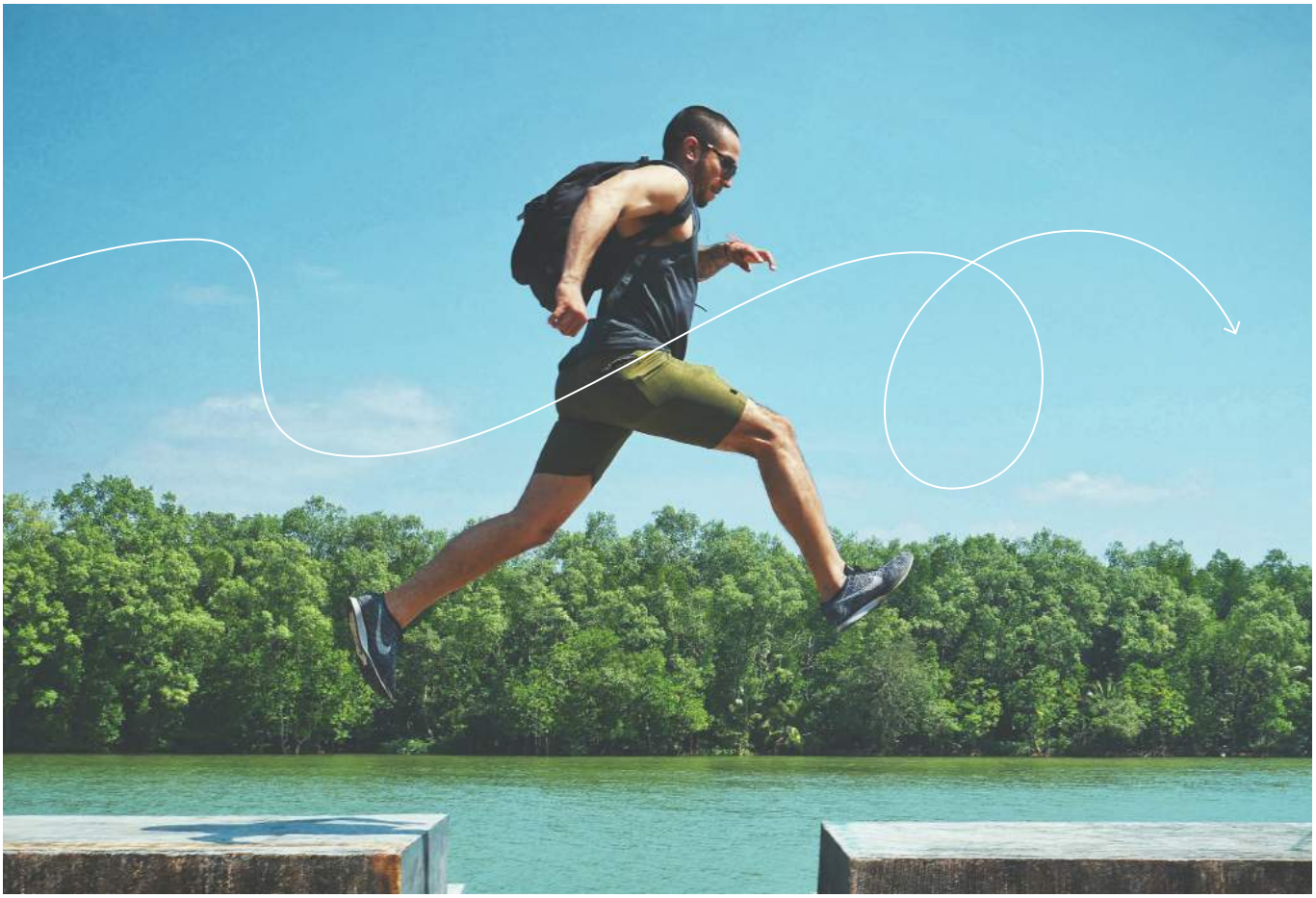


The ReActiv8 procedure is the first restorative neuromodulation therapy that is **clinically proven to provide long-term relief for chronic low back pain.**

Low back pain is the leading cause of patients living with disability and missing work, and these patients often endure impaired quality of life, depression, anxiety, and sleep disturbance.

Two thirds of patients suffering from CLBP are deficient in correct functional stability and proper mechanics of the spine, which are the root causes of mechanical low back pain (it's in the name!). Many of these patients, through past injuries or improper loading due to spine degeneration, have a dysfunction of the body's stability control system. This is caused by neuromotor inhibition, evidenced by atrophy and poor function in spinal stability muscles such as the multifidus.

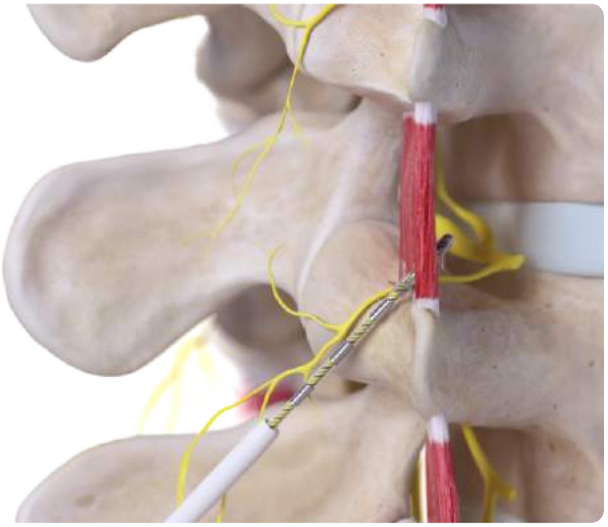
By restoring this natural stabilizing system, patients can improve their function, allowing them to confidently do the activities they want to do without pain.

ReActiv8 is a **minimally invasive procedure that restores the body's natural ability to control spine stability,** improving your functionality and decreasing your CLBP. Following a small incision, minimally invasive instruments and X-ray guidance are used to place leads next to nerves outside your spine. These leads are connected to an implanted pulse generator which controls the therapy. Patients control sessions of therapy that retrain the brain and body to restore its ability to control spinal stability. ReActiv8 is an outpatient procedure, which does not alter or change the structure of the spine and is reversable. A 204-patient clinical trial demonstrated the safety and effectiveness of the ReActiv8 Procedure, proving long-term relief of chronic low back pain.

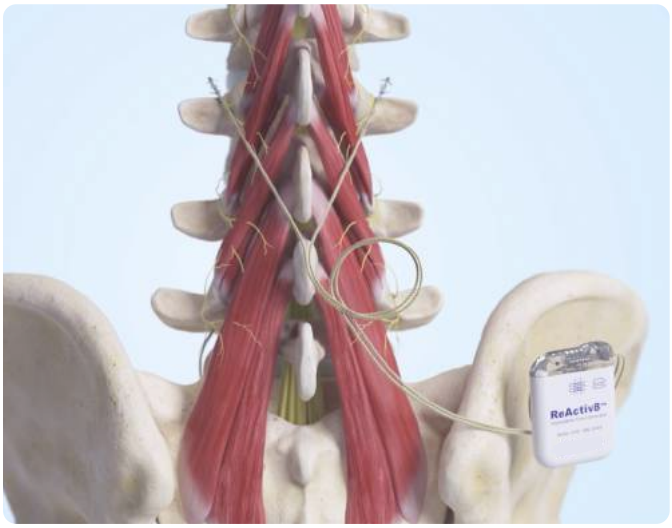
Multifidus Dysfunction and Chronic Low Back Pain (CLBP)

Low back pain is the biggest musculoskeletal issue affecting the world today. Back pain can range in intensity from a dull and constant ache to a sudden, sharp or shooting pain. It can begin suddenly as a result of an accident or injury, or it can develop over time as we get older.

There are two basic types of back pain: neuropathic and nociceptive (i.e., mechanical). Back pain caused by disease or damage to the nerve tissue itself is called neuropathic pain. Back pain caused by injury or stress on the tissues in the spine (bones, joints, etc.) is called nociceptive (or mechanical) pain. Two thirds of axial CLBP is predominantly nociceptive (i.e. mechanical), and therefore needs to be addressed as such. These two types of back pain require very different approaches. ReActiv8® is a therapy designed for nociceptive, mechanical low back pain.



ReActiv8 leads are positioned outside your spine next to the nerves that control your spine's stabilizing muscles.



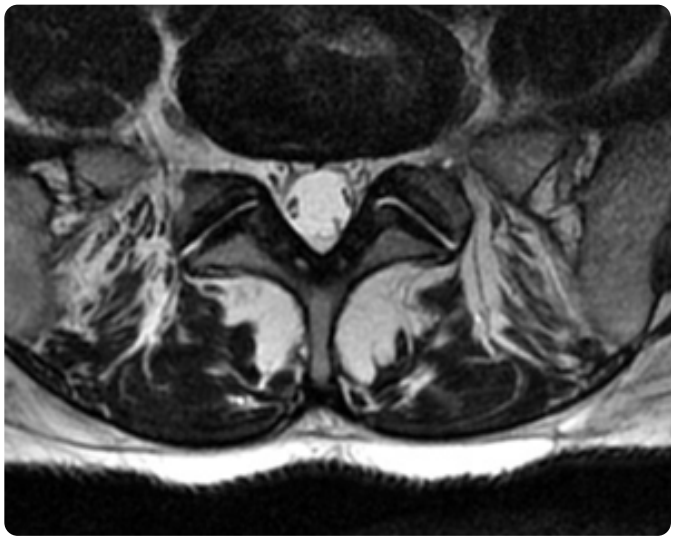
The deep, stabilizing muscles of the lumbar spine and placement of the ReActiv8 System

Nociceptive or mechanical pain is caused by uncontrolled loading, which is often due to impaired muscle control and neural inhibition. This impaired muscle control can arise after even a single incidence of low back injury or pain. 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. This lack of muscle control and neural inhibition decreases functional stability of the spine, which can leave the spine susceptible to further injury and overloading.

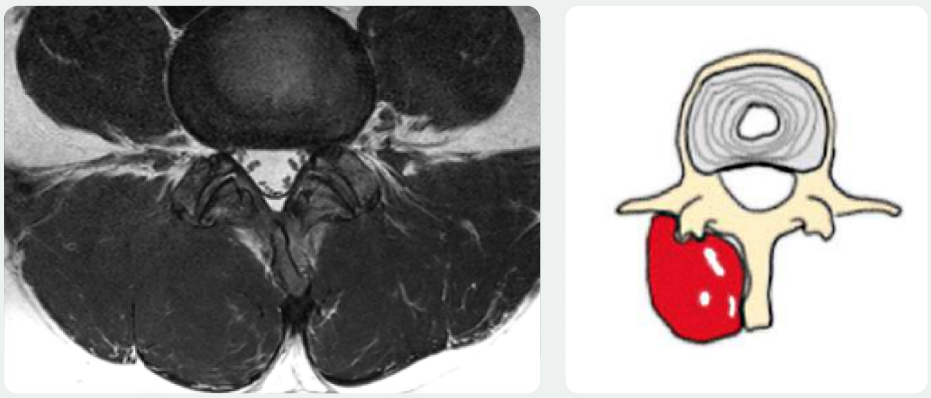
Unfortunately, patients with chronic low back pain of mechanical origin are usually not well served with available treatment methods, especially if surgical or reconstructive options are not well indicated for treatment. The patients that suffer from non-surgically indicated mechanical back pain often have been suffering for a long time and have tried all sorts of different therapies with little to no effect.

Fortunately, research has shown that the multifidus is the main muscle that controls the functional stability of the lumbar spine at a segmental level, and that if multifidus control (via the brain's neuromotor system) can be rehabilitated, it can again create functional stability in the spine and decrease low back pain.



Dysfunctional multifidus muscle showing atrophy and fatty infiltration.

Normal multifidus
Healthy Grade MRI (Grade 0)
(0-10 %)



Severe Atrophy
Unhealthy Grade MRI (Grade 2)
(>50 %)

How ReActiv8 Works

Therefore, the ReActiv8 therapy was developed to address the need for a clinically useful treatment.
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. By stimulating the innervating nerves (e.g. the medial branch) of the multifidus directly, an efficient, effective therapy can be delivered with minimal effort by the patient and provider.

The therapy program ReActiv8 uses is simple: the patient starts a 30-minute therapy session twice a day, which allows the system to contract and relax the muscle via the stimulation of the medial branch nerve. This presents a comfortable (and sometimes pleasing!) sensation that the patient can perform while resting in bed or on the couch. Treatment sessions last for 30-minutes and are activated twice per day by the patient with a remote control.

During the session, ReActiv8 bilaterally stimulates the L2 medial branch nerve of the dorsal ramus, and the patient will experience repetitive multifidus muscle contractions. While any implant is an invasive procedure, the important concept behind ReActiv8 is that it is a minor procedure that is completely reversible and does not change the patient's anatomy, so all other options are available to the patient and physician in the future. This is in stark contrast to other surgical procedures, which alter the structure of the spinal column to increase stability.

For mechanical CLBP patients who have attempted and failed conservative therapy, and who are not indicated for a major surgical procedure, ReActiv8 offers a highly effective solution that restores functional stability and reduces pain.

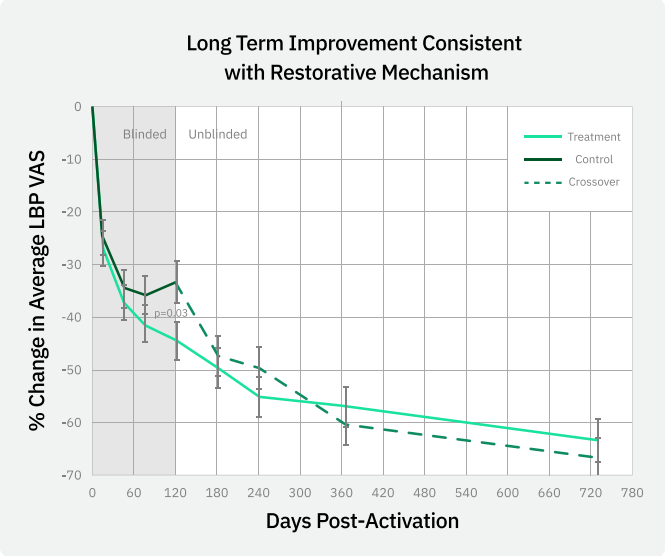
Who is ReActiv8 For?

ReActiv8 is for patients with disabling, musculoskeletal, chronic low back pain who don't have indications for lumbar spine surgery and have not had spine surgery in the past. Typically, patients have had primarily disabling low back pain for at least a year during which they have tried most available treatment options. These patients have demonstrated an insufficient response to physical therapy and medical management and are not satisfied with pain medication. Finally, patients display multifidus neuromuscular impairment as evidenced by imaging or physiological testing. Ask your doctor if this therapy is right for you.

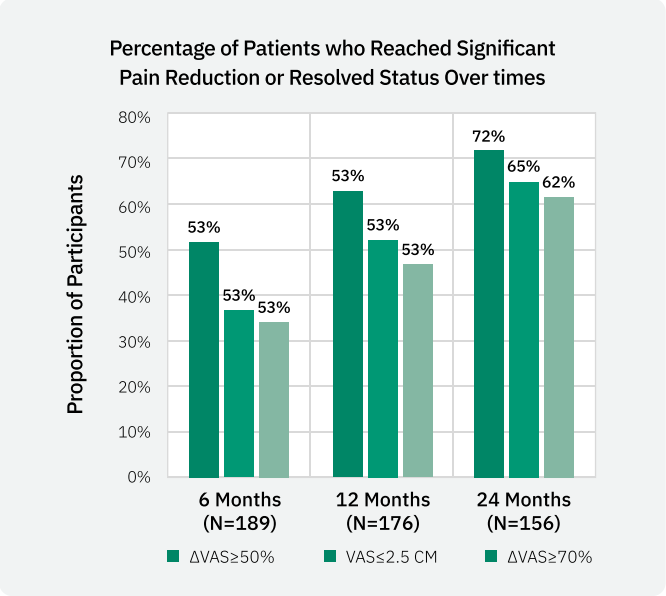
ReActiv8 Clinical Data

The ReActiv8-B trial is an international, multi-center, prospective, randomized, active sham controlled, blinded trial. At 24 sites in the US, Australia, and Europe, a total of 204 patients were implanted with the ReActiv8 system and randomized (1:1) to a Treatment or Control group.

The percent change in average LBP between the control and treatment groups was statistically significant at the 120 day end point, and when the control group crossed over to receiving treatment, they followed the same pattern of improvement.



ReActiv8 therapy was significantly better than control, and when all groups were finally given therapy, their pain improved and continued to decrease over time.



Patients continue to improve over time, demonstrating that the therapy is truly restorative for patients with neuromuscular instability and dysfunctional lumbar motor control.*

Long term follow-up of these patients over two years demonstrated the restorative nature of the therapy, as the patients revealed continued improvement over time.

These long term results of the ReActiv8-B trial show durable, statistically significant, and clinically substantial benefits in a cohort of patients with severe, disabling CLBP and multifidus muscle dysfunction who were not satisfied with conservative care outcomes including physical therapy and medications. Patients demonstrated improvements in pain and disability that increased the longer they were treated. This recovery trajectory is consistent with restoration of neuromuscular control and structural muscle changes.

* The ReActiv8-B Trial demonstrated a strong safety profile for the ReActiv8 system (particularly when compared to spinal cord stimulator devices). Among the 204 randomized patients, 8 serious adverse events (SAEs) related to the device/procedure were reported (4% overall) at the 120-day mark. There were no unanticipated SAEs related to the device/procedure, and notably no instances of lead migration. (Among all adverse events (serious and non-serious), 53% occurred within the first 30 days; 83% of all related adverse events were resolved.) For more information on safety, efficacy, and risk, see https://mainstay-medical.com/safety/ and https://www.accessdata.fda.gov/cdrh_docs/pdf19/P190021B.pdf.

Preparing for Implantation

Your doctor will order laboratory tests and a visit with your primary care physician for clearance for surgery. This will help the anesthesia team determine the safest type of anesthesia, as well as catch any brewing infections or health issues that may preclude you from surgery.

We recommend a “wearability” trial to determine where to put the stimulator battery. This is best done by taping a provided example battery or package of dental floss in several different locations in your back, buttocks, and flanks. Although the battery pack will be under the skin, this helps decide where it is most comfortable for you to have it placed. This way you won’t be constantly feeling it while sitting down on top of the battery pack or leaning against it while sitting in a chair once it has been implanted.

Most right-handed patients prefer it on the left, and vice versa. Most commonly, patients prefer it in the flank between the lowest rib and the top of the pelvis bone in the back. But this is entirely up to you! Once you have found the most comfortable location, mark it for the day of the procedure and that is where it will be placed!

The Day of Surgery

There will be nothing to eat or drink starting at midnight the night before the procedure. You can take your routine morning medications with sips of water, but nothing besides that.

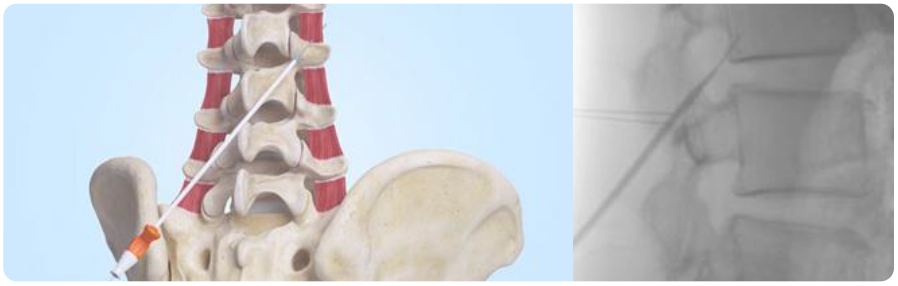
The ReActiv8 procedure is performed in an outpatient surgical center.

The ReActiv8 procedure may be performed under general or conscious sedation, and is usually determined based on the anesthesia team and the patient’s preference. The procedure time is 45-60 minutes. The patient will spend 1-2 hours in post-op care unit and then will the same day to go home.

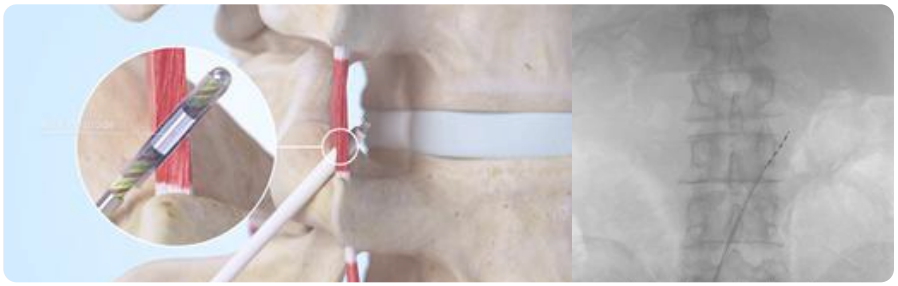
ReActiv8 Procedure Steps

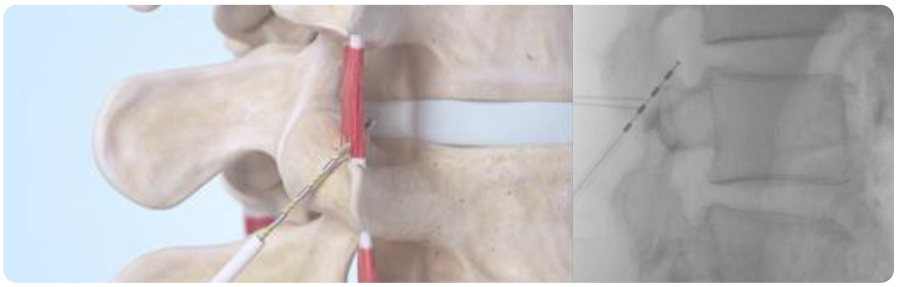
Determine lead trajectory:
A small central incision is made and a needle is used to create the path of the lead. This path is held by a small wire.

Introduce Sheath:
A sheath is placed down the path of the wire to prepare the way for the lead.

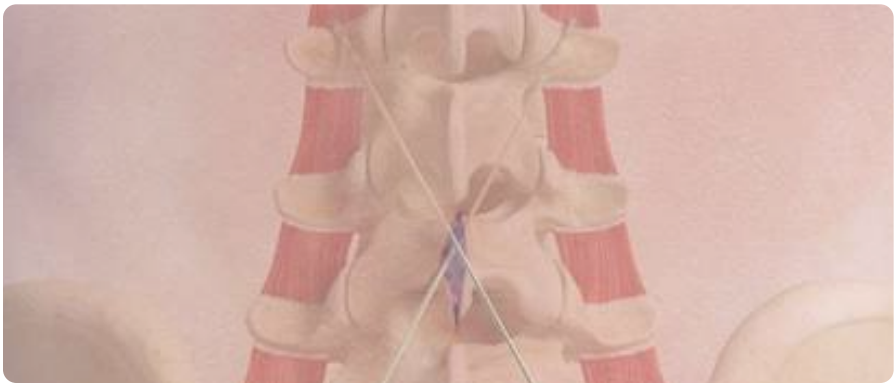


Insert the ReActiv8 Lead:
The lead is placed down the sheath until it is positioned through the intertransversarii muscle. The sheath is retracted and the specialized anchors hold the lead in place.



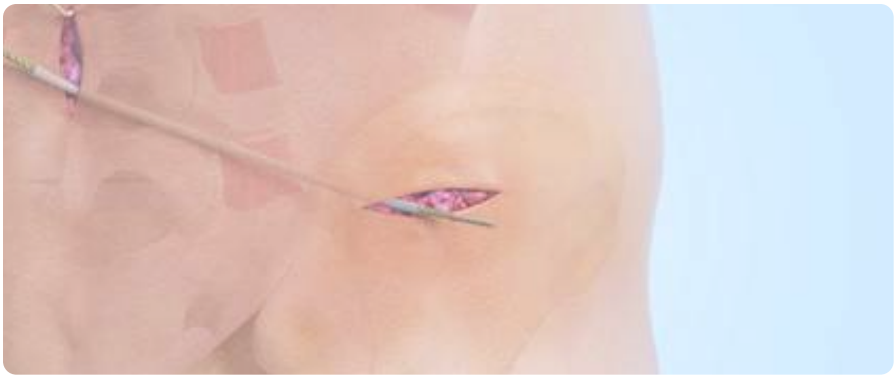


The process is repeated for the other side.

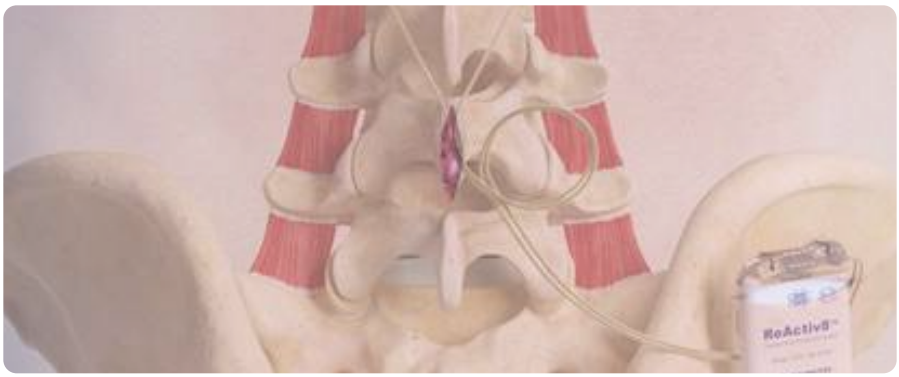


IPG pocket:
A pocket is made (either in the flank or upper buttock) where the ReActiv8 IPG or Battery will be placed

Tunneling:
The leads are tunneled under the skin to the IPG pocket using a special tunneling tool.



Final system placement:
A strain relief loop is placed next to where the leads enter the muscle in order to insure smooth motion of the leads during movement. The system is tested, the incisions are sutured closed and bandages are placed on the incision sites.



Post Implantation Guidelines

There are two incision sites, one central on the back about 1-2 inches and another at the location of the battery pack about 2 inches. The incisions will be closed using sutures with either a glue, steri-strips, or a plastic incision closing device, then covered with a gauze dressing.

Do not submerge in water until you have been cleared to by your doctor. You may shower 48 hours after your procedure, and the dressing should be changed with gauze and tape at that time. If the dressing gets saturated with blood within the first 24 hours, give us a call. Some bleeding on the dressing is expected. The dressing may be changed each day as needed after that first dressing change.

For activity, we recommend to be out of bed as much as you can without exhausting yourself or worsening your pain. Walking is encouraged. Do not bend or twist to extremes. Do not lift anything heavier than a gallon of milk (about 10 pounds).

Talk to your physician about pain control post surgery. Many patients use Tylenol or NSAIDS along with ice for pain control, but your physician may have a specific plan for you.

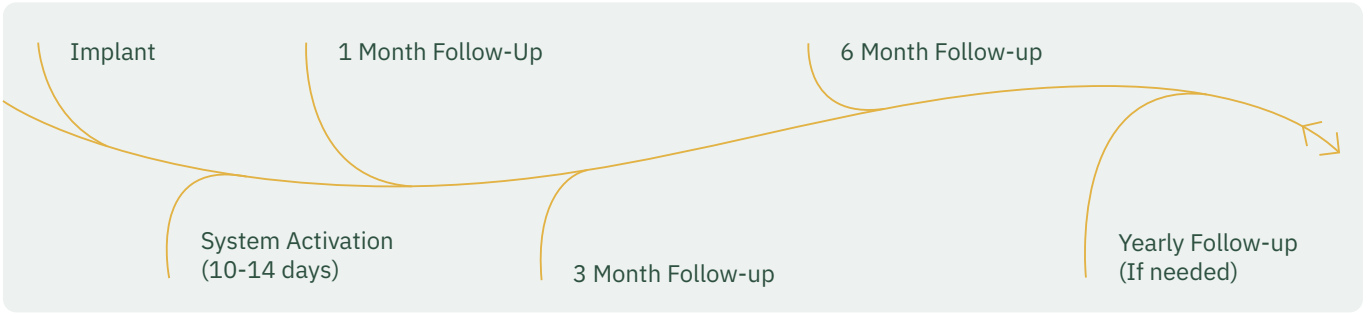
If using ice, ice for no more than 15 minutes at a time, and wait for 15 minutes before reapplying ice to allow the skin to recover so it doesn’t get a freezing burn. DO NOT use heat until follow up.

The steri-strips or glue will fall off on its own, so do not take them off yourself. Your doctor will remove anything needed at follow up and inspect the incision for proper healing.

Activation Day

The ReActiv8 device won't be turned on until the activation follow-up, about 10-14 days after surgery. At that time, the device stimulation will be programmed and individualized to your therapy needs. You will also be shown how to use your activator remote and perform your therapy sessions.

The therapy starts with patients performing two, 30 minute sessions twice a day whenever they choose, typically in the morning before they get out of bed and when going to sleep or watching television.



The ReActiv8 follow-up schedule is tailored to customize the therapy to your body as it begins to restore control over the supporting muscles of your spine. It is an opportunity to gauge your progress and celebrate your journey toward improved functionality and reduced pain.

Long Term Expectations

Further follow-ups at 1, 3, and 6 months (or as needed) will be performed to tune your programming as your body heals and begins to restore proprioception and spinal stability.

The majority of patients begin to feel improvement in their ability to function and perform activities with improved confidence by 6 weeks, but can take up to 12 weeks in some patients, and some patients may take longer. Patients report their back pain beginning to decrease shortly after they feel an improvement in function. The data from the trials suggests that improvements seen in function and pain continue to accrue over time and are durable.

To maximize the benefit of the therapy, patients are prescribed to do two therapy sessions a day for the first 12 months or until improvement is made. When significant improvement is made, most patients choose to tailor their therapy to fit their treatment needs and lifestyle.

While some patients enjoy their therapy session every day in the long term, most tend to use their system when needed. A few patients elect to have their system removed in a few years because they feel they have recovered. We may start a physical therapy prescription within the first 6 weeks as well.

This helps jump start the reactivation, improves healing, and addresses kinesiophobia—the fear of moving, which is common for patients who have been in pain for so long! Ask your doctor about what options may be available for you as your therapy progresses.

If the patient has increased pain or any concerns please contact the office.

Frequently Asked Questions

Which 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 patient populations both with disabling CLBP:

- ReActiv8 addresses musculoskeletal/mechani cal/axial predominantly nociceptive CLBP.
- SCS addresses predominantly neuropathic CLBP and radiculopathy.

The employ different mechanisms of action:

- ReActiv8 aims to restore multifidus motor control and functional segmental stability.
- SCS aims to interfere with the perception of pain with a palliative objective.

They have a completely different delivery schedule:

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

Can I go through metal detectors with a ReActiv8 stimulator?

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 that 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 not to hold the wand near your neurostimulator any longer than needed.

What sort of imaging can I get with a ReActiv8 stimulator?

CT scans, fluoroscopy, and X-Ray are all compatible with the ReActiv8 device. Special considerations need to be made for MRI, please refer to your physician and the ReActiv8 manual.

Can I have chiropractic manipulation or deep tissue massage after surgery?

Ask your physician first. It's possible that chiropractic manipulation or deep tissue massage could damage your neurostimulator or dislodge the lead, which would cause you to need additional surgery to repair the system.

Is the ReActiv8 system like a TENS (Transcutaneous Electrical Nerve Stimulation) unit?

No. The ReActiv8 system is specially implanted to stimulate the nerves that control the muscles that stabilize your lumbar spine. This results in comfortable therapy that cycles deep muscular contractions, allowing restoration of your neuromotor control of the lumbar spine. In contrast, TENS units attempt to block painful signals by transmitting electrical signals through your skin. This results in a completely different sensation and does not address the root cause of mechanical back pain.

How long with my ReActiv8 System last?

The ReActiv8 system is tested to have enough battery life to last a minimum of 5 years with continuous, 60 min per day use. However in practice patient's systems are lasting much longer. In the case of needing to replace the battery, a straightforward procedure switching out the battery can be performed using the same implanted leads.

How does the doctor decide where to place the lead and generator?

While everyone's body is a little different, the nerve that is stimulated by the ReActiv8 leads runs in the same place in almost everyone. Your doctor will use x-ray images of your spine to obtain the best position of the leads to stimulate the nerve. The implantable pulse generator (which also contains the battery pack) is generally implanted in the upper part of the buttock, below the belt line and above the seat line, or in the flank between the hips and the ribs, to make it as comfortable as possible. You should discuss the location of the generator with your doctor before surgery.

Will I be able to see or feel my Implant?

While you will typically be able to feel where the battery is located with your hands, after 60-90 days the body will heal around the battery to the point where it is not as perceptible. You may be able to see the locations of the incisions, but you won't typically be able to see the battery outline through your skin when standing naturally, and definitely not under clothing.

What do the therapy sessions feel like?

Most patients say the sessions feel like a pleasant series of deep muscle contractions, like flexing a muscle in an arm or leg, only in the low back region. Your system is programmed to be as comfortable as possible, so that it is easy and even enjoyable to perform your daily therapy sessions.

Indications and Risks

The ReActiv8 System is indicated for patients who have intractable chronic low back pain associated with multifidus muscle dysfunction. This is evidenced by multifidus atrophy on MRI or physiological testing. The ReActiv8 therapy is for adults who have failed conservative therapy including pain medications and physical therapy and are not candidates for lumbar spine surgery.

As an implanted device and reversible treatment, it is important that the procedure and system have a high safety profile. ReActiv8 was able to demonstrate a safety profile equivalent or better than current standard neuromodulation therapies.

ReActiv8 is contraindicated for patients who are unable to operate the system or unsuitable for ReActiv8 implant surgery. 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 important that you inform your physician or other healthcare professional (e.g. physical therapist, chiropractor, dentist, etc.) that you are implanted with the ReActiv8.

Safety of the ReActiv8 system has not been evaluated when used in combination with active implantable devices (e.g. pacemaker, defibrillator, spinal cord stimulation). There may be undesirable interactions between the stimulation pulses of the ReActiv8 system and the other active implantable device.

Talk with your doctor about if you are a candidate for **ReActiv8.**

Additional Information

For more information on patients and to hear their experiences with ReActiv8, scan the QR code below.

USA 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 manual 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. **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. **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:** In the case that the Activator is pierced or ruptured, burns could result from exposure to battery chemicals. **Electromagnetic Interference:** 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. **Electrocautery and radio frequency (RF) ablation:** Electro-surgery devices should not be used in close proximity to the ReActiv8 IPG or Lead(s). Contact between a lead and the electrosurgical instrument can cause direct stimulation of a nerve and can result in severe injury to the patient. **ReActiv8 interaction with other active implantable devices:** Safety of the ReActiv8 system has not been evaluated when used in combination with active implantable devices (e.g. pacemaker, defibrillator, spinal cord stimulation). There may be undesirable interactions between the stimulation pulses of the ReActiv8 system and the other active implantable device.

ReActiv8®

77 Sir John Rogerson's Quay
Block C, Grand Canal Docklands
Dublin 2, Ireland
www.mainstaymedical.com

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