

ReActiv8®



ReActiv8 your life

backspace



ABOUT

BACK PAIN

Around 4 million Australians live with back problems, with low back pain being the most common cause of disability worldwide. There are many causes of back pain, and our understanding continues to improve with ongoing research.

Studies have highlighted the importance of the lumbar muscles in spine health, showing that muscle dysfunction can be the primary cause for low back pain in some people.

Muscle dysfunction can also contribute to the pain from other conditions, as inactivity from pain can lead to muscle weakness and spinal instability.

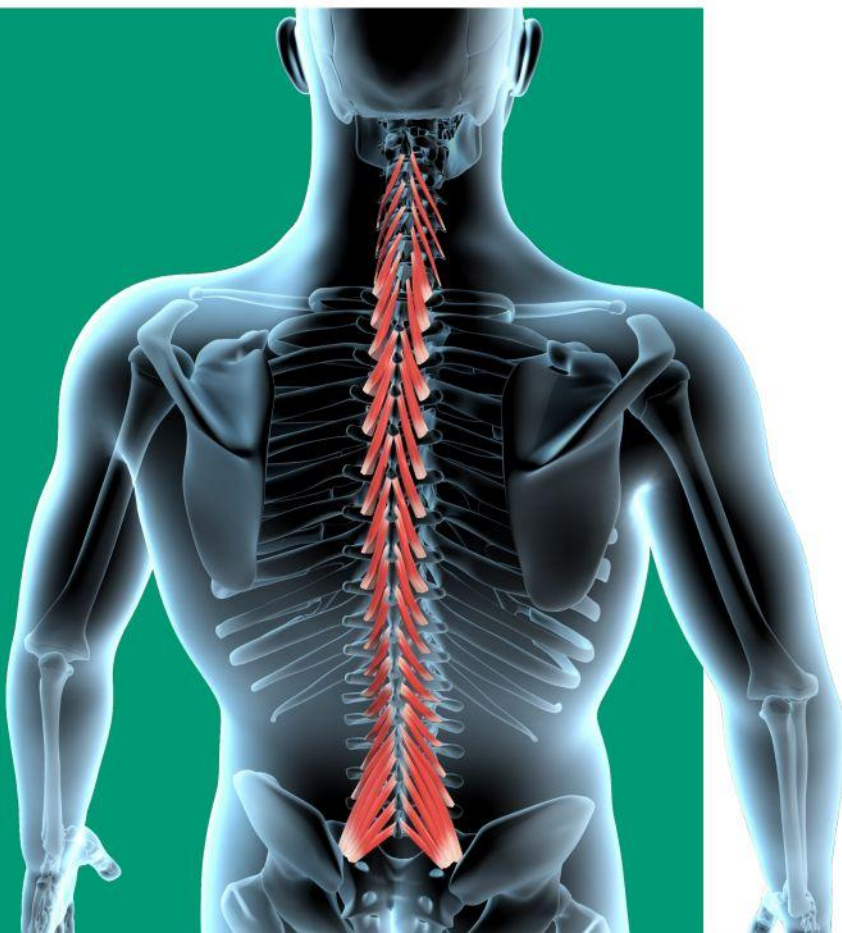
Recent research has shown that reactivating the lumbar spine muscles is an important step in restoring normal spinal function and reducing pain.

THE MULTIFIDUS

The multifidus is a consecutive series of narrow muscles located along either side of the back of the spinal column. These muscles connect from one vertebra to another, and are designed to stabilise the vertebrae and maintain posture rather than move the spine.

It is not entirely clear why multifidus dysfunction causes low back pain. It is proposed that weak multifidus muscles lead to less support for the vertebrae, causing increased pressure on surrounding muscles, ligaments, discs and joints.

Research has shown that restoring neuromuscular control of the multifidus muscle can enhance spinal stability, improve function, and reduce pain.



REHABILITATION

The primary method of restoring multifidus function is rehabilitation. Our physiotherapists and exercise physiologists can provide a comprehensive exercise program that aims to:

- strengthen your lumbar and abdominal muscles, focusing on the multifidus and the core
- increase your spine movement and flexibility
- improve the function of your low back for day-to-day activities
- return you to your active sports and hobbies
- develop a maintenance program for long-term spinal health

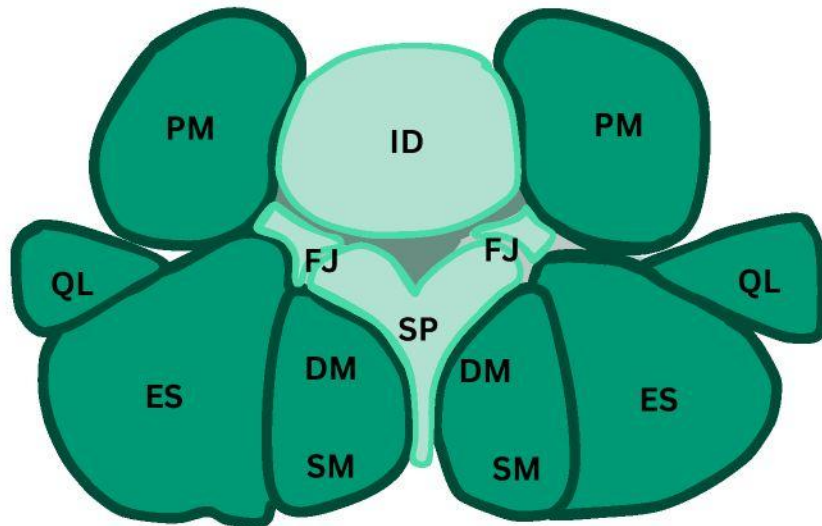
In most people, physical therapy can provide significant improvement in lower back pain and dysfunction.



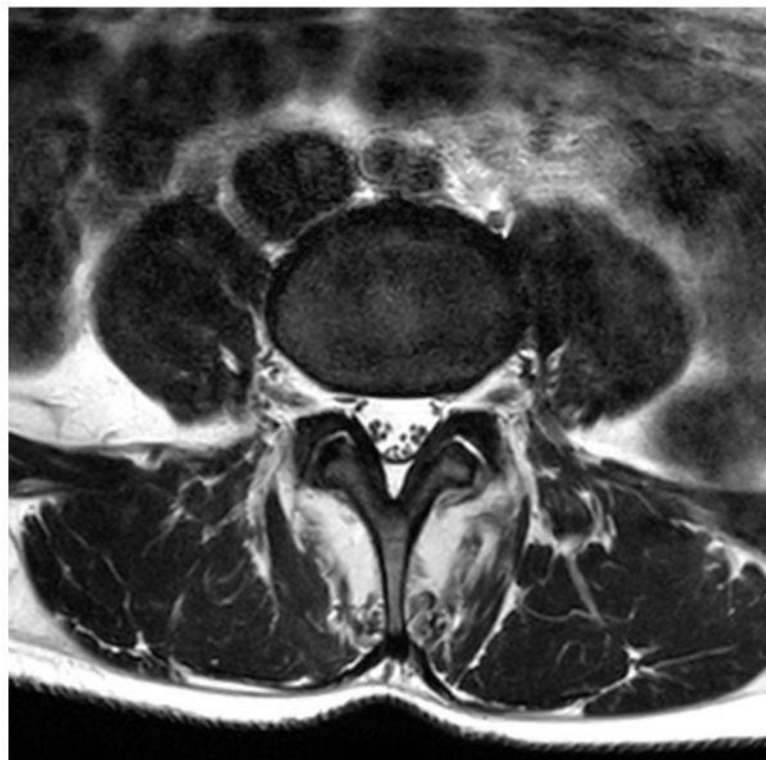
Cross section of healthy lumbar muscles on MRI

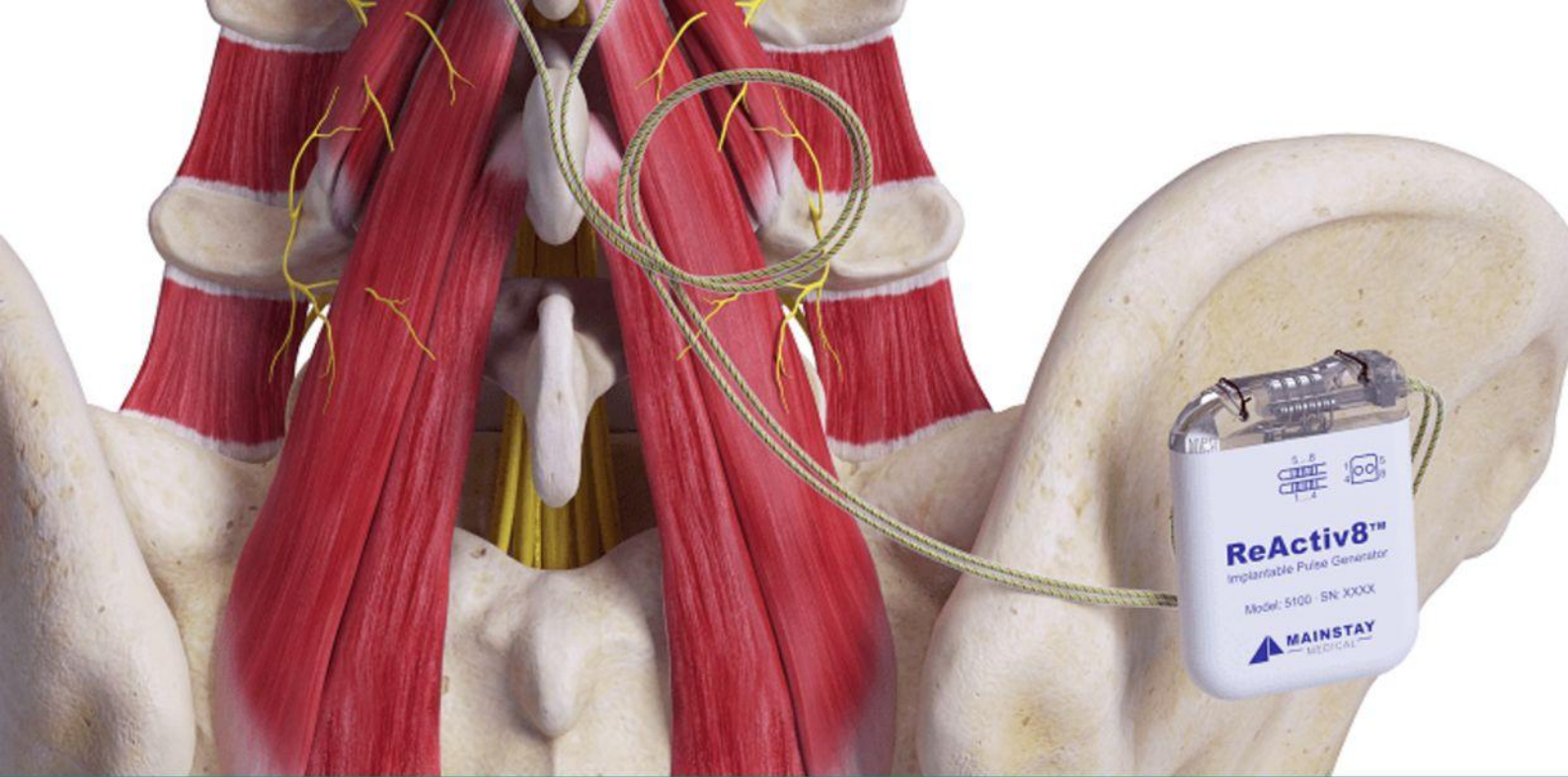


PM - Psoas Major
ID - Intervertebral Disc
FJ - Facet Joint
QL - Quadratus Lumborum
SP - Spinous Process
ES - Erector Spinae
DM - Deep Multifidus
SM - Superior Multifidus



Cross section of unhealthy lumbar muscles on MRI





ReActiv8[®]

If you completed a comprehensive rehabilitation program but did not improve, you may be a suitable candidate for an implant that can help reactivate your lumbar multifidus muscle.

ReActiv8 is a neurostimulation device that aims to restore multifidus function by electrically stimulating the muscles.

The device comprises a battery about the size of a matchbox connected to two electrical leads. The battery is surgically implanted in the buttock region and the leads are passed under the skin and anchored close to the nerves that control the multifidus.

This is a relatively simple procedure that is done as an inpatient with an overnight stay in hospital, and you are able to return to gentle activities in a few days.

ReActiv8[®]

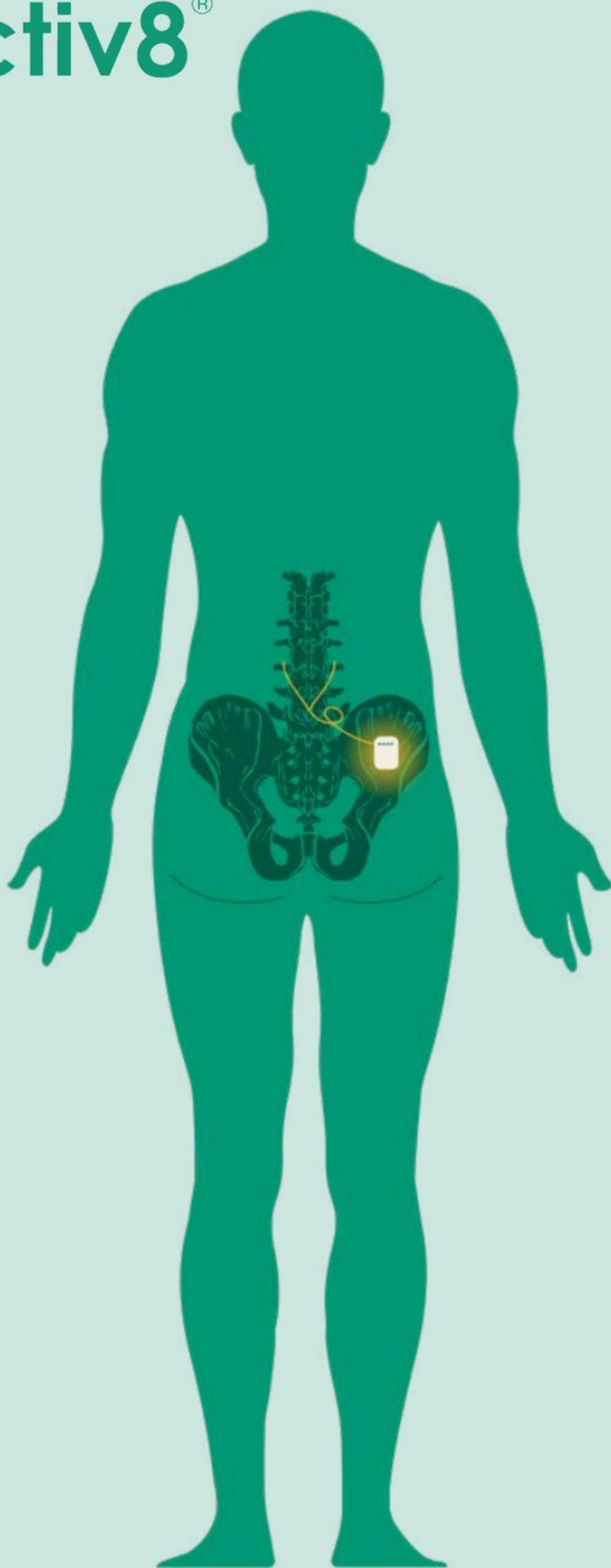


Image not to scale



After Implantation

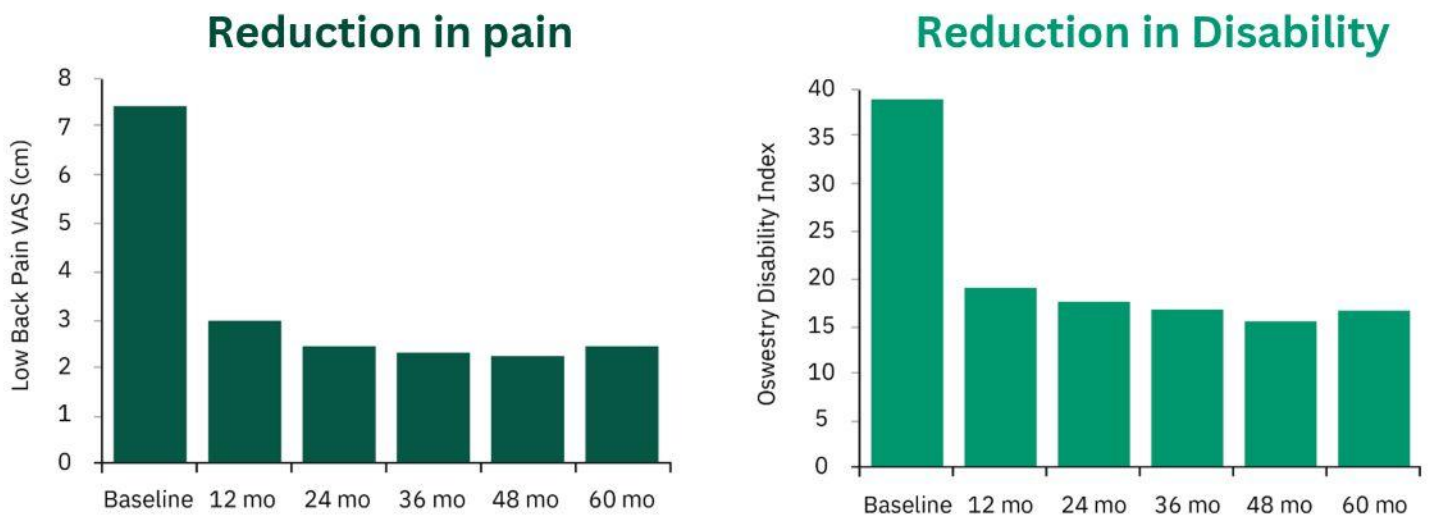
After 2 weeks the wounds have healed and your implant is activated by the ReActiv8 team. You will then start your treatment with two 30 minute sessions a day. You will get into a comfortable position on the bed or couch and turn on the ReActiv8 stimulator with the supplied remote control. You will feel the multifidus muscle contracting and relaxing, which is not painful.

You will be reviewed regularly by the ReActiv8 team to check and fine tune the device, and by the BackSpace rehabilitation team to optimise the results with a specific exercise program.



IS IT EFFECTIVE? TRIAL RESULTS

Result of the Clinical Trial conducted by Mainstay Medical



Clinical study data show that patients experience progressive long-term improvements in pain and function, over time, demonstrating a durable, consistent, and restorative result.*

*Gilligan et al. Five-Year Longitudinal Follow-up of Restorative Neurostimulation Demonstrates Durability of Effectiveness in Patients with Refractory Chronic Low Back Pain associated with Multifidus Muscle Dysfunction

8 out of 10 people reported substantial (>50%) improvements in pain and/or function.

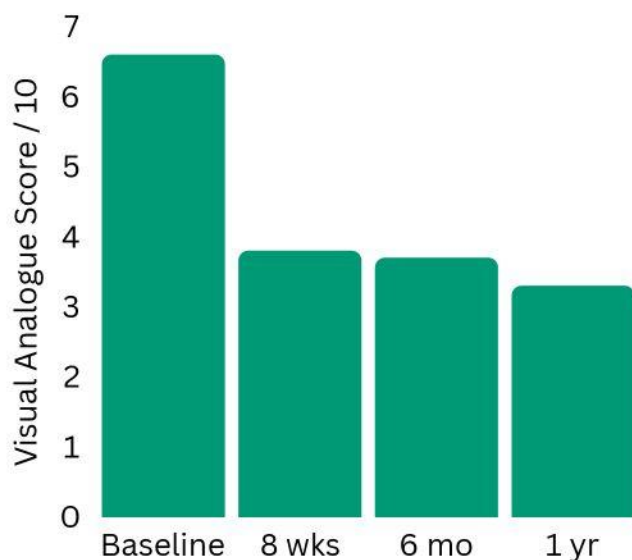
9 out of 10 people were “Definitely Satisfied” with ReActiv8.

IS IT EFFECTIVE? OUR RESULTS

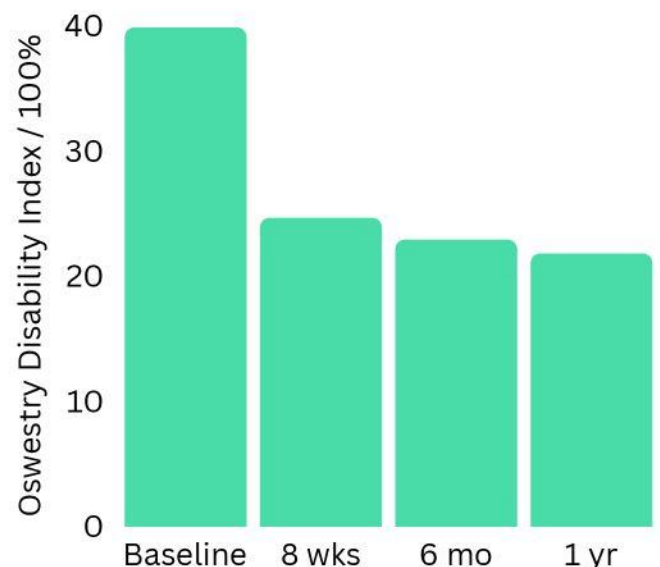
Result of the real world study conducted through

backspace

Reduction in back pain



Reduction in Disability



Results from our real-world study conducted through the BackSpace clinic indicate that 1-year post-implant:

6 out of 10 people reported substantial ($\geq 50\%$) improvements in pain and/or disability.

7 out of 10 people noted improved physical function on the sit-to-stand test.

THE SPECIFICS OF SURGERY

The procedure

You are admitted to hospital and given a general anaesthetic. You are placed face-down on the operating table. A 6cm horizontal incision is made over the left or right buttock and a pocket is created where the battery will be inserted. The leads are then passed under the skin and a second 3cm vertical incision is made in the middle of the back to guide the leads to either side of the L3 vertebra. Image guidance is used to accurately place the leads into the multifidus muscle adjacent to the nerves that supply the muscle and the leads are anchored in place. The leads are connected to the battery and the device is tested. The surgical procedure should take between 40 and 60 minutes. You will stay in hospital overnight.

Getting back to normal activity

8 weeks after the implantation you can expect to be back to normal daily activities and lifting moderately heavy objects. By 3 months you can expect to be back in the gym and playing sports. The only ongoing restriction involves manual therapy (e.g., massage) directly over the implanted leads. You can still receive manual therapy in other areas, however it should be delivered by a clinician familiar with the device.

Risks and complications of the implant

Some patients describe discomfort or pain around the battery site but this usually settles. There is a risk of infection of the implant which may require antibiotics, further surgery or removal of the implant. More serious complications such as nerve damage during wire insertion are rare.

YOUR TREATMENT JOURNEY

1

Receive a specialist spine opinion

You will see one of the doctors at SpinePlus to assess your suitability for the ReActiv8 device.

2

Meet the treating team

You will be referred to an implanting specialist clinician who will discuss the ReActiv8 implantation surgery with you. The BackSpace rehabilitation team will undertake a comprehensive functional assessment of your spine.

3

Have the ReActiv8 device implanted

You will be admitted to hospital, have the device implanted under general anaesthetic and be discharged the next day.

4

2 weeks after the implantation

You will return to see the ReActiv8 team at BackSpace to have your device activated. You will be instructed on how to use the device.

5

4 weeks after implantation

You will return to see the BackSpace rehabilitation team. They will begin a gentle mobility program with specific multifidus activation exercises.

6

8 weeks after implantation

You will return to BackSpace to see the ReActiv8 team who will fine tune the device. You will progress your exercises with the BackSpace rehabilitation team. You will have an x-ray and a check-up with the implanting specialist.

7

3 months after implantation

You will see the BackSpace rehabilitation team with the goal of returning to your normal activity level.

8

6 months after implantation

You will return to see the ReActiv8 team to check the device function. The rehabilitation team will check your progress and develop a long-term maintenance program.

9

1 year after implantation

You will return to see the ReActiv8 team to check and fine tune the device. The BackSpace team will repeat the functional assessment to measure the improvements in your spine function.

10

2 years after implantation

This is your final planned visit, where the ReActiv8 team will review the function of the device and the outcome of your treatment.

WHAT ELSE CAN I DO?

STRUCTURED REHABILITATION

In addition to ReActiv8 therapy it is also recommended to undergo a structured rehabilitation program designed around your goals, while also addressing the neuromuscular recovery of the multifidus muscle. This can begin as early as 2 weeks post implantation.

It is important that this is delivered by qualified professionals who have experience in treating patients with implanted devices.





FREQUENTLY ASKED QUESTIONS

How is Reactiv8 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 reactiv8 help with my nerve pain?

ReActiv8 is for mechanical chronic low back pain and is not indicated for predominantly neuropathic pain such as radiculopathy or complex regional pain syndrome.

Do Specialists recommend getting in shape before the implantation?

Maintaining a healthy lifestyle is always important, however it is understandable that CLBP may prevent you from doing the amount of activity that you would like.

For a full list of FAQs please refer to

<https://lowbackpainrecovery.com/faq/>



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