ReActiv8 Patient Identification

Visit www.mainstaymedical.com/patientselection or scan the QR code.





To Health Care Professionals:

This form contains general guidance to help with identifying patient candidates for Mainstay Medical's ReActiv8 neurostimulation therapy. Please note it is not intended to replace your independent medical judgment or decision-making regarding patients and treating low back pain. To find out more, visit www.mainstaymedical.com.

ReActiv8 is for patients with:

- ✓ Mechanical Chronic Low Back Pain
- ✓ No prior spine surgery / not a candidate for spine surgery
- ✓ Multifidus Dysfunction as evidenced by clinical/functional cues questionnaire, physical assessment, and/or imaging.

Candidates for ReActiv8 typically present with higher prevalence of the following clinical assessment parameters.

Step 1: Patient History and Clinical Pain Assessment (check all that apply) ☐ No previous spine surgery ☐ No indication for surgical treatment ☐ No active implantable spinal medical device (SCS/PNS, etc.) ☐ Predominantly nociceptive mechanical CLBP

Step 2: Clinical Cues Questionnaire (check all that apply)







☐ Does your bac	k ever feel l	like it is un	stable?
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- ☐ Do you get surprised by sudden pain or spasms when you do mild trunk movements or light tasks?
- ☐ Do you have problems with activities such as brushing teeth over the sink, washing dishes, or unloading the dishwasher, etc.?
- □ Does it feel like your back is getting tired or painful the longer you maintain a position (e.g., standing, sitting, etc.)?
- ☐ Do you tend to support yourself with your arms while standing, sitting, or performing light, small movement tasks?
- ☐ Do backrests and back braces help when sitting or standing for long periods?
- ☐ What does your back pain keep you from doing? (look for activities that require bending, lifting, twisting, or prolonged postures like sitting, standing, walking, etc.)

Step 3: Physical Assessments

(check which physical assessments patient tests positive for)



■ Multifidus Toe Touch Test (MT3)

Test for motor control dysfunction

- Tests for pain or weakness during simple forward bending
- Patient tries to touch toes and come back up
- Pain or trouble coming back up = motor control problems in back



□ Prone Instability Test (PIT)

Test for painful dynamic instability

- Tests for low back pain when muscles are "off"
- Simulates muscles being turned "on" with leg lifts
- Pain Reduction = Spinal Muscle Inhibition



■ Multifidus Lift Test (MLT)

Test for multifidus activation

- Tests for specific multifidus muscle automatic function
- Arm lift should active multifidus
- Doctor feels for muscle contraction and grades as either "on" or "off"

Step 4: MRI Review

(check level of multifidus muscle atrophy present on MRI)

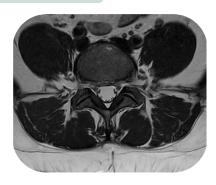
□ **Normal** Multifidus





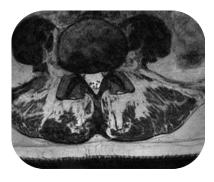
■ Moderate Atrophy





□ **Severe** Atrophy





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