

# 1. ReActiv8 Patient Identification

## Ideal ReActiv8 Candidate:

- ✓ Mechanical Chronic Low Back Pain
- ✓ Virgin Back - No prior spine surgery / not a candidate for spine surgery
- ✓ Multifidus Dysfunction determined through imaging and / or physical assessment

## 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](http://www.mainstaymedical.com).

## Step 1: Patient History

- |   |   |  |
|---|---|--|
| <input type="checkbox"/> Adult (21 years or older)            | <input type="checkbox"/> Non-responder to conservative management | <input type="checkbox"/> Appropriate BMI for implant surgery |
| <input type="checkbox"/> No previous spine surgery            | <input type="checkbox"/> No active implantable medical device     | <input type="checkbox"/> Appropriate cognitive/psych state   |
| <input type="checkbox"/> No indication for surgical treatment | <input type="checkbox"/> No comorbid pain conditions              |  |

## Step 2: Clinical Pain Assessment

- |   |   |
|---|---|
| <input type="checkbox"/> Pain frequency: >50% of days in past year                            | <input type="checkbox"/> Predominantly nociceptive pain |
| <input type="checkbox"/> Low back pain worse than leg pain, pain not radiating below the knee | <input type="checkbox"/> Pain is moderate to severe     |

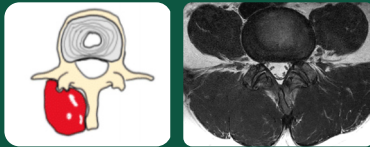
## Step 3: Imaging and Physical Assessments to Detect Multifidus Atrophy and Dysfunction

### Targeted MRI Review

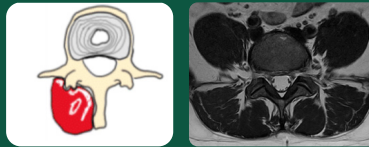
Extent of fatty infiltration of multifidus in radiographic imaging

**Rule In:** Multifidus atrophy with Grade 1 or 2 fatty infiltration

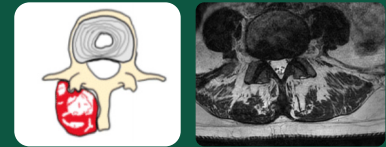
**Rule Out:** Surgical indications (i.e. unstable spondylolisthesis, vertebral compression fracture, etc.)



Normal multifidus  
**Fat Grade 0**  
(0-10 %)



Slight atrophy and fatty infiltration  
**Fat Grade 1**  
(10-50 %)



Severe atrophy and fatty infiltration  
**Fat Grade 2**  
(>50 %)

### Physical Examinations of Lumbar Functional Instability

At least one positive test for dynamic instability, inhibition, or motor control dysfunction



**Prone Instability Test**  
Recommended test for painful dynamic instability



**Multifidus Lift Test**  
Optional test for multifidus activation



**Aberrant Movement Patterns**  
Optional test for motor control dysfunction

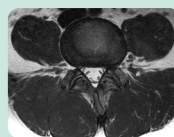
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## Review MRI of the Lumbar Spine without contrast

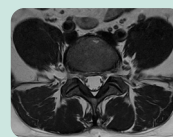
**DX:** Intractable mechanical low back pain. Please comment on multifidus muscle atrophy and % fatty infiltration on the reverse and return to the ordering physician.

## Guidance on MRI Examination of the Multifidus for Atrophy & Dysfunction

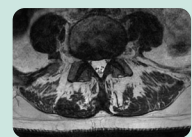
Visit [www.mainstaymedical.com/patientselection](http://www.mainstaymedical.com/patientselection) for helpful videos and other educational materials regarding identifying atrophy and/or fatty infiltration of the multifidus muscle.



Normal multifidus  
Grade 0 fatty infiltration  
(0-10%)



Slight atrophy  
Grade 1 fatty infiltration  
(10-50%)



Severe atrophy  
Grade 2 fatty infiltration  
(>50%)

# 2. Patient Identification Additional Details

Visit [www.mainstaymedical.com/patientselection](http://www.mainstaymedical.com/patientselection) or scan the QR code.



### Confirm Patient Selection Checklist:

- ✓ Mechanical Chronic Low Back Pain
- ✓ Virgin Back - No prior spine surgery / not a candidate for spine surgery
- ✓ Multifidus Dysfunction determined through imaging and / or physical assessment

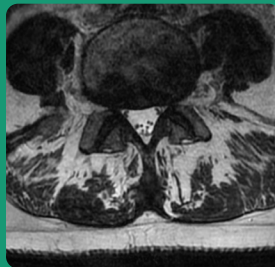
## Imaging and Physical Assessments to Detect Multifidus Atrophy and Dysfunction

### MRI Signs of Fatty Infiltration & Atrophy

MRI is a useful diagnostic tool to assess fatty infiltration and atrophy of the multifidus. These signs have been correlated with the presence of low back pain<sup>4</sup> and reduced contractility and inhibition of the multifidus.<sup>5</sup>

**What it Measures:** MRI can quantify the fatty and connective tissue infiltration in the multifidus at each motion segment.

**What to look for:** Slight or Severe (Grade 1 or 2) fatty infiltration of the multifidus cross-section.<sup>4</sup>



### Prone Instability Test (PIT)

The recommended test to detect for painful dynamic instability.

**What it Measures:** Spinal segmental instability and the ability of muscle activation to provide stability.

**What to look for:** A positive test, where patient demonstrates a reduction in pain upon leg lift, indicates impaired motor control or inhibition of the multifidus muscle.



## Other Physical Examinations

### Multifidus Lift Test (MLT<sup>3</sup>)

**What it Measures:** Subjective changes in lumbar multifidus thickness between resting state and submaximal contraction as an indirect assessment of the muscle's automatic function.

**Positive Test:** Absence of multifidus contraction or compensatory activation of longissimus.

**Negative Test:** Firm contraction of the multifidus.



### Aberrant Movement Patterns<sup>3</sup>

**What it Measures:** Specific deviations from normal patterns of trunk movement during flexion.

**What to look for:** One or more of altered lumbopelvic rhythm, Gower's Sign, Sagittal Plane Deviation, Instability Catch or Painful Arc of Motion.



- Ferrari S, Manni T, Bonetti F, et al. A literature review of clinical tests for lumbar instability in low back pain: Validity and applicability in clinical practice. *Chiropr Man Ther*; 2015;23:14.
- Hebert JJ, Koppenhaver SL, Teyhen DS, et al. Palpation : Reliability and Validity of a New Clinical Test. *Spine J* 2015;15:1196–202.
- Bielý SA, Silfies SP, Smith SS, et al. Clinical observation of standing trunk movements: What do the aberrant movement patterns tell us? *J Orthop Sports Phys Ther* 2014;44:262–72.
- Kjaer P, Bendix T, Sorensen JS, et al. Are MRI-defined fat infiltrations in the multifidus muscles associated with low back pain? *BMC Med* 2007;5:1–10.
- 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.

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.

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### MRI Addendum

Date: \_\_\_\_\_

Please review the MRI for \_\_\_\_\_, date of birth \_\_\_\_\_  
 Medical Record # \_\_\_\_\_, that was performed on \_\_\_\_\_ (date).

Please, quantify the presence of multifidus atrophy and/or fatty infiltration as per the grading described overleaf. MRI evidence of lumbar multifidus atrophy and/or fatty infiltration can corroborate clinical findings of dysfunction. Please, check the applicable boxes below and return the signed form to the physician rather than an addendum to the formal report.

Notes: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Signature: \_\_\_\_\_

Level	Normal <10% Fatty infiltration	Grade 1 10-50% Fatty Infiltration	Grade 2 >50% Fatty Infiltration
L1-L2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L2-L3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L3-L4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L4-L5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
L5-S1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>