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.

Step 1: Patient History

- ☐ Adult (21 years or older)
- ☐ No previous spine surgery
- ☐ No indication for surgical treatment
- ☐ Non-responder to conservative management
- ☐ No active implantable medical device
- ☐ No comorbid pain conditions
- ☐ Appropriate BMI for implant surgery
- ☐ Appropriate cognitive/psych state

Step 2: Clinical Pain Assessment

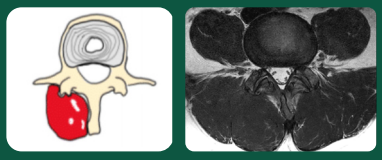
- ☐ Pain frequency: >50% of days in past year
- ☐ Low back pain worse than leg pain, pain not radiating below the knee
- ☐ Predominantly nociceptive pain
- ☐ Pain is moderate to severe

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

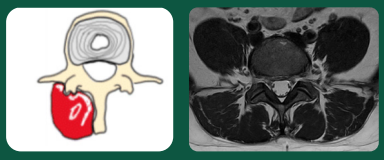
Targeted MRI Review
Extent of fatty infiltration of multifidus in radiographic imaging

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

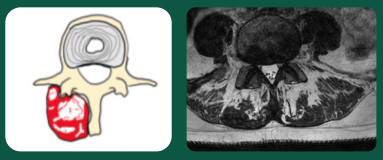
Rule Out: Surgical indications (i.e. unstable spondylolisthesis, vertebral compression fracture, etc.)



Normal multifidus
Fat Grade 0
(0-10 %)

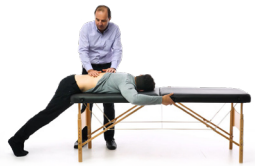


Slight atrophy and fatty infiltration
Fat Grade 1
(10-50 %)



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

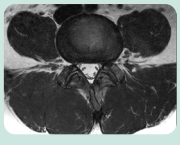
Aberrant Movement Patterns
Optional test for motor control dysfunction

610031 Rev. C

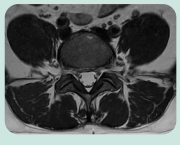
Review MRI of the Lumbar Spine without contrast
DX: Intractable mechanical low back pain. Please comment on multifidus muscle atrophy and % fatty infiltration on the reverse and return to the ordering physician.

Guidance on MRI Examination of the Multifidus for Atrophy & Dysfunction

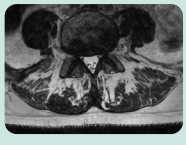
Visit **www.mainstaymedical.com/patientselection** for helpful videos and other educational materials regarding identifying atrophy and/or fatty infiltration of the multifidus muscle.



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 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

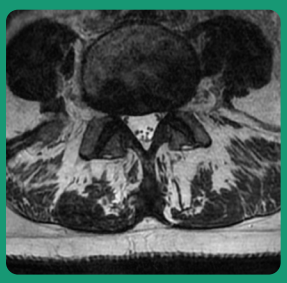
Imaging and Physical Assessments to Detect Multifidus Atrophy and Dysfunction

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[4] and reduced contractility and inhibition of the multifidus.[5]

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.[4]

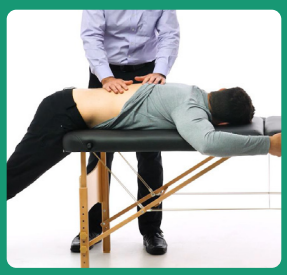


Prone Instability Test (PIT)

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 (MLT²)

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[3]

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.

1. 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,
2. Hebert JJ, Koppenhaver SL, Teyhen DS, et al. Palpation : Reliability and Validity of a New Clinical Test. Spine J 2015;15:1196–202.
3. Biely 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.
4. 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.
5. 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.

610031 Rev. C

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	☐	☐	☐
L2-L3	☐	☐	☐
L3-L4	☐	☐	☐
L4-L5	☐	☐	☐
L5-S1	☐	☐	☐