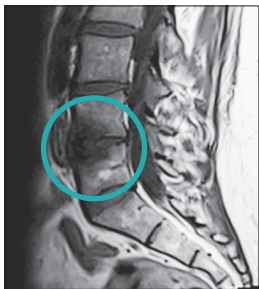


# Modic Type 1 and Type 2 Changes

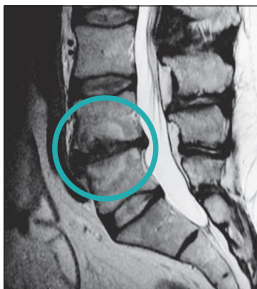


## Modic Type 1

T1 Weighted  
Hypointense

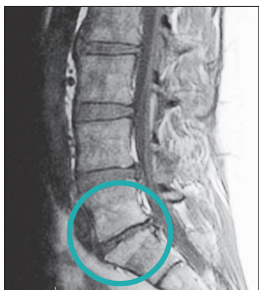


T2 Weighted  
Hyperintense

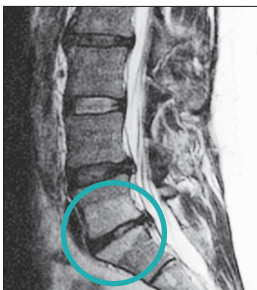


## Modic Type 2

T1 Weighted  
Hyperintense



T2 Weighted  
Hyperintense



# Intrasept™ Procedure Indications

- Chronic low back pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI demonstrated Modic Type 1 or Type 2 changes at one or more vertebrae from L3 to S1 documented by at least one of the following:
  - Modic Type 1 and/or Modic Type 2
  - Endplate changes, inflammation, edema, disruption, and/or fissuring
  - Fibrovascular bone marrow changes (hypointensive signal for Modic Type 1)
  - Fatty bone marrow replacement (hyperintensive signal for Modic Type 2)

Indications for Use: The Intrasept™ Intraosseous Nerve Ablation System is intended to be used in conjunction with radiofrequency (RF) generators for the ablation of basivertebral nerves of the L3 through S1 vertebrae for the relief of chronic low back pain of at least six months duration that has not responded to at least six months of conservative care, and is also accompanied by features consistent with Type 1 or Type 2 Modic changes on an MRI such as inflammation, edema, vertebral endplate changes, disruption and fissuring of the endplate, vascularized fibrous tissues within the adjacent marrow, hypointensive signals (Type 1 Modic change), and changes to the vertebral body marrow including replacement of normal bone marrow by fat, and hyperintensive signals (Type 2 Modic change). Contraindications - Use of the Intrasept Intraosseous Nerve Ablation System is contraindicated in: Patients with severe cardiac or pulmonary compromise, patients with active implantable pulse generators (e.g. pacemakers, defibrillators), patients where the targeted ablation zone is < 10 mm away from a sensitive structure not intended to be ablated, including the vertebral foramen (spinal canal), patients with active systemic infection or local infection in the area to be treated, patients who are pregnant, and/or skeletally immature patients (generally ≤ 18 years of age). Refer to the Instructions for Use provided with the Intrasept Procedure or [www.relevant.com/intrasept/](http://www.relevant.com/intrasept/) for potential adverse effects, warnings, and precautions prior to using this product.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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# Diagnosing Chronic Vertebrogenic Low Back Pain

Patients describe their vertebrogenic pain as worse with activity, sitting and bending forward – characteristics of anterior column pain.<sup>1</sup>



Sitting



Lifting



Activity

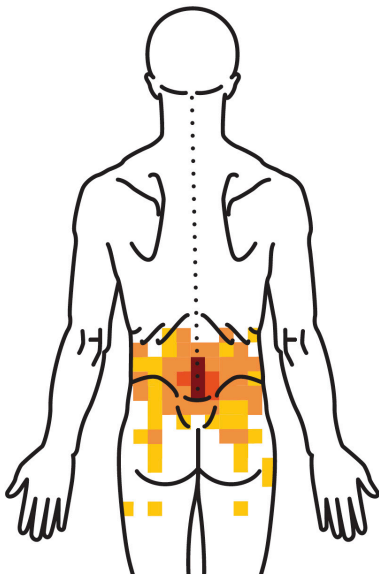


Bending

# Diagnosing Chronic Vertebrogenerenic Low Back Pain

Two-thirds of patients describe their vertebrogenerenic pain as **midline low back pain**.<sup>1</sup>

To confirm vertebrogenerenic pain diagnosis, use MRI to look for Modic changes – specific changes that occur with endplate inflammation and the only known confirmatory indicator of vertebrogenerenic pain.<sup>2</sup>



0%	<1%	1% to <5%
≥5% to <15%	≥15% to <30%	≥30%

1 Zachary L McCormick, MD, Beau P Sperry, BA, Barret S Boody, MD, Joshua A Hirsch, MD, Aaron Conger, Pain Medicine, Volume 23, Issue Supplement\_2, August 2022, Pages S14-S33, <https://doi.org/10.1093/pm/pnac069>

2 Zachary L McCormick, MD, Aaron Conger, DO, Matthew Smuck, MD, Jeffrey C Lotz, PhD, Joshua A Hirsch, MD ...Pain Medicine, Volume 23, Issue Supplement\_2, August 2022, Pages S34-S49, <https://doi.org/10.1093/pm/pnac093>