

Intrasept[®] Procedure Indications

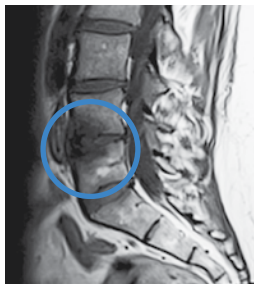
- Chronic low back pain of at least 6 months duration; and
- Failure to respond to at least 6 months of conservative care; and
- MRI demonstrated Modic Type 1 or Type 2 changes at one or more vertebrae from L3 to S1 documented by at least one of the following:
 - Modic Type 1 and/or Modic Type 2
 - Endplate 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).

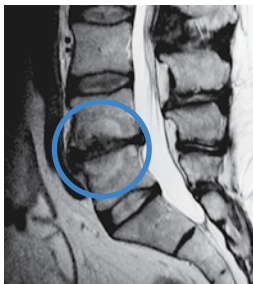
Modic Type 1 and Type 2 Changes

Modic Type 1

T1 Weighted
Hypointense



T2 Weighted
Hyperintense



Modic Type 2

T1 Weighted
Hyperintense



T2 Weighted
Hyperintense

