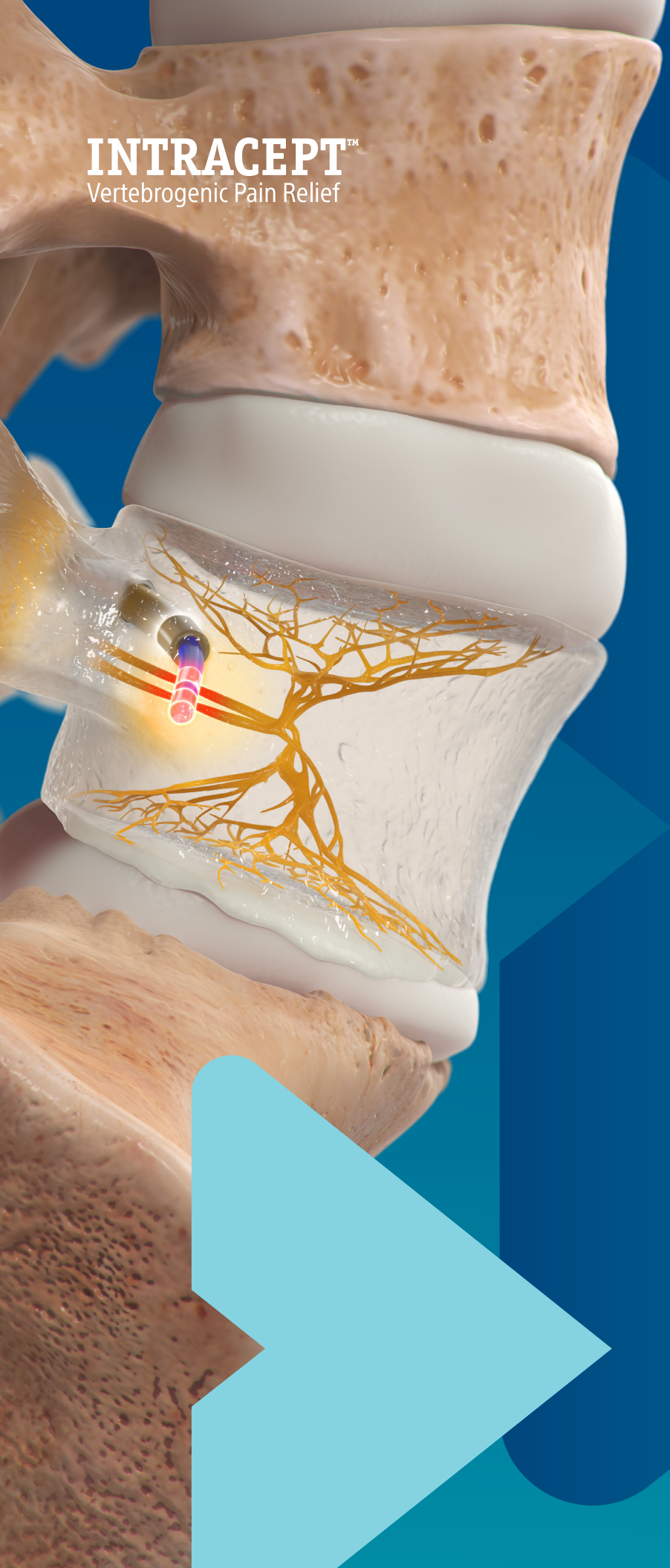


Boston Scientific
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Intracept™ Radiology **Clinical Education**

Clinical Update from Boston Scientific

Modic Matters: What Radiologists Need to Know About This Objective Biomarker for Low Back Pain

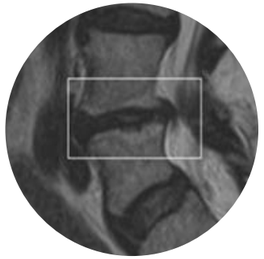
The Intracept Procedure has been commercially available since 2018. The radiographic biomarker for the Intracept Procedure is the presence of Modic changes and/or degenerative endplate changes as seen on MRI (in clinical correlation with axial, vertebrogenic low back pain [LBP]).

Insurance prior authorization frequently is denied if the formal radiology report does not document Modic type 1 or 2 changes or the descriptive terms associated with Modic changes. Documentation must include specific vertebral bodies with Modic changes.

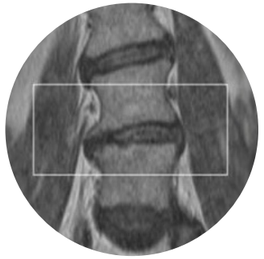
Evidence regarding treatment of vertebrogenic LBP with the Intracept Procedure suggests that Modic changes are binary—and the presence of Modic changes is the key radiologic finding, not the severity of the endplate disease.[1]

Indications for the **Intracept Procedure are:**

- Chronic LBP 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)



Modic Type 1



Modic Type 2

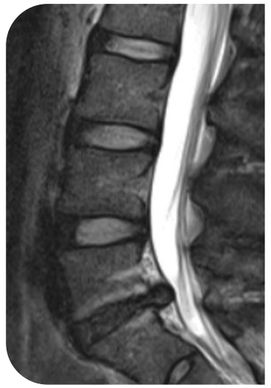
On post-ablation MRI scans, a radiofrequency ablation zone will be evident. The appearance of the ablation zone will vary based on bone healing and time since procedure.



Post-ablation MRI scans

Modic is Binary

Vertebrogenic back pain patients with smaller volume Modic, non-centrally located Modic, and those with <25% involvement of the endplate responded similarly to the Intracept Procedure as patients with large volume Modic.[2]



Intracept Procedure performed at L5 & S1



Intracept Procedure performed at L4 & L5



Intracept Procedure performed at L4 & L5



Intracept Procedure performed at L3, L4, L5 & S1



Intracept Procedure performed at L3, L4, L5 & S1

These MRIs are from real patients who had the Intracept Procedure. Actual results after the procedure may vary. The Intracept Procedure, as with any procedure, has risks that should be discussed between the patient and medical provider. To learn more about the Intracept Procedure and important safety information, visit www.Intracept.com.

Intracept Imaging **Recommendations**

Background

The FDA cleared the use of the Intracept procedure when a patient demonstrates radiographically Modic Type 1 and/or 2 changes at L3, L4, L5 or S1.

Many radiologists do not document Modic changes or will only use the word Modic if there is a “hamburger sign” in a mid-sagittal cut. For 30+ years, Modic changes had no clinical correlation to identify a treatment.

The amount of Modic does not correlate with the amount of pain a patient feels or the response following BVN ablation.

Modic significance

- In the early 2000s, Modic changes were identified as the radiographic biomarker for a patient with axial LBP to be diagnosed with vertebrogenic LBP.
- In 2021, the CDC added a code for vertebrogenic LBP, M54.51 to the ICD-10 code set.
- In May 2019, the FDA clearance was amended to include the descriptive terms that are synonymous with Modic.
  - Endplate changes, inflammation, edema, disruption and/or fissuring
  - Fibrovascular bone marrow changes (hypointense signal for Modic Type 1)
  - Fatty bone marrow changes (hyperintense signal for Modic Type 2)

Recommendations

The clinical research has demonstrated that for patients with vertebrogenic LBP, the radiographic indicator of Modic is binary—its presence or absence is what is important for diagnosing this type of pain. The amount of Modic changes, the type of Modic (1 or 2), and the location do not impact the diagnosis. A slight blush of endplate edema laterally can cause as much pain as a "hamburger sign" mid-sagittal.

- Terms such as disc desiccation, subtle mixed endplate changes, and chronic T2 hyperintense zones at multiple levels are appropriate descriptors.
- It is important to call out the specific vertebral bodies. In most cases, degeneration of a disc leading to disc desiccation is the precursor to the development of Modic changes.
- Schmorl's nodes may be an indication for the Intracept Procedure. These are changes where there is an invagination of the endplate and nucleus into the vertebral body. If the nucleus has the ability to interact with the bone marrow of the vertebral body, it creates cross-talk, the release of inflammatory mediators, and the development of Modic changes.
  - Schmorl's nodes can be described as ACTIVE—meaning there is edema and are indicated for the Intracept Procedure—or INACTIVE, whereby there hasn't been any cross-talk and although there is a Schmorl's node, the patient doesn't have a diagnosis of vertebrogenic LBP.
- Coronal images are an excellent way to uncover the far-lateral changes that would cause a patient to develop vertebrogenic LBP.
- STIR images may show early Modic 1 changes and assist in making the diagnosis.
- The best way to fully evaluate these patients is with the following sequences:
  1. STIR sagittal
  2. T2 sagittal
  3. T1 sagittal
  4. T2 axial
  5. T1 axial
  6. T2 coronal

Intracept Procedure:
The only clinically proven treatment for vertebrogenic LBP

Multiple studies, including two Level I RCTs, have proven that the Intracept Procedure is a safe, effective and durable treatment for vertebrogenic LBP.[3,5]

Multi-Study Post-BVNA Oswestry Disability Index (ODI) Results[3-8]

* All BVNA treated cohort (N=249) years from consent to 60-month visit was 5.6 years
** Standard arm re-baselined and offered active treatment at a median of 5.8 months

Multi-Study Post-BVNA Numeric Pain Scale (NPS) Results[3-8]

* All BVNA treated cohort (N=249) years from consent to 60-month visit was 5.6 years
** Standard arm re-baselined and offered active treatment at a median of 5.8 months

Case Study #1

Patient History and Presentation

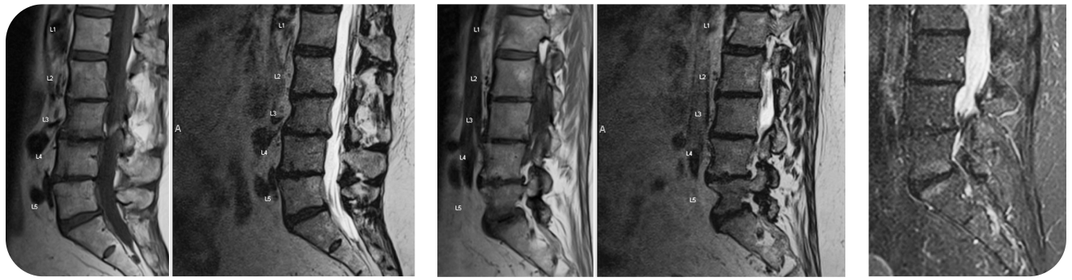
- 78-year-old female
- Age-related multilevel degeneration
- Multilevel spondylolisthesis
- Varying degrees of stenosis
- Axial low back pain and bilateral LE radicular pain
- Orthopedic surgeon offered decompression and fusion targeting spondylolisthesis
- Upon further questioning, the back pain is the predominant issue
- Pain at the lumbosacral junction
- Pain worst first thing in the morning and when bending and lifting grandchildren

Prior Treatment

- Modest improvement with ESI (~6 months)
- Received second ESI but only helped for a couple of months

Imaging

- Modic Type 3 changes (mixed with Modic Type 2) at L3-L4
- Modic Type 2 changes toward the right side at L4-L5
- Some Modic Type 1 changes at L5-S1, which were toward the left



Treatment Plan and Outcomes

- Insurance coverage limited to two vertebral bodies/session – performed the Intracept Procedure
- 100 percent improvement in pain, including leg symptoms
- Measured at 2-week and 3-month timepoints
- Patient reports feeling better than she has felt in years

Post-Procedure Correspondence from Patient

Dear Dr. Barrette,

I wanted to send you a note to thank you so much for the wonderful, rather immediate result I have had from my procedure yesterday.

I had no pain or even discomfort upon discharge or arrival home. This morning, I woke up and for the first time in decades, felt zero pain in my lower back. I wasn't counting on such quick results, so I was especially thrilled.

For me, this is life changing. (My visiting son informed me this morning that I no longer walk like an old lady so I guess that sums it up pretty well!)

Your impressive skill and positive attitude regarding what is possible, is so appreciated. My challenge now is to behave and follow the excellent advice to not overdo. I will do that, of course, but it is such a luxury to have that as my problem!

Words can't adequately express my gratitude, but I wanted to give it a try and wish you an excellent weekend.

Warm Regards.

Images provided courtesy of Dr. Kevin Barrette

Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

Case Study #2

Patient History and Presentation

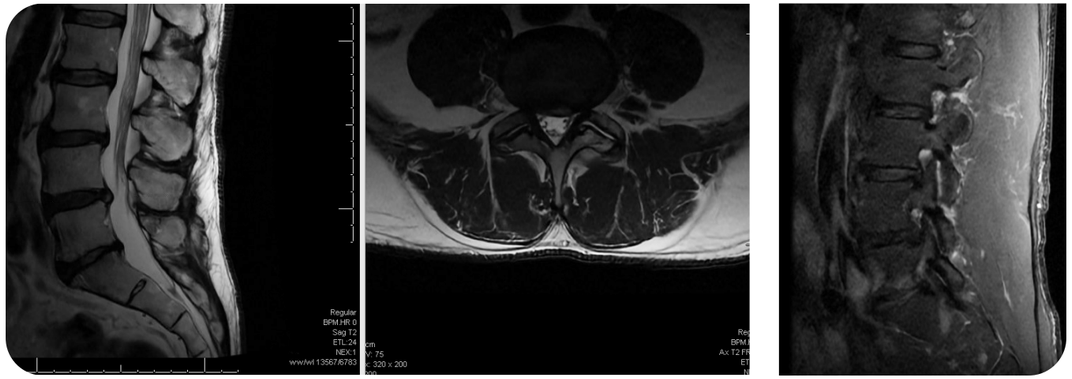
- 61-year-old male
- Classic posterior column symptoms – biggest issues were extension and twisting
- Challenges with golf
- Intermittent radiating lower extremity pain that gets worse with ambulation, improves with rest in an L5 distribution

Prior Treatment

- Tried an ESI for radicular pain: about 25% improvement in radicular pain, no improvement in axial pain
- Tried medial branch block at L4-L5, L5-S1: 80% improvement for expected duration of anesthetic first medial branch block
- No improvement with second medial branch block
- Still convinced he has some posterior column pain, tried a medial branch block at L3-L4
- Tried an SI joint injection; nothing helped

Imaging

- MRI with some age-related degenerative changes
- Facet arthrosis, facet edema, some subarticular and lateral recess stenosis L4-L5, all correlate with his symptoms
- On review of MRI, on the STIR sequence at very far lateral aspect of L5-S1 with some Modic Type 1 changes



Treatment Plan and Outcomes

- Explained that we could potentially try BVNA at L5-S1 but that symptoms were not very consistent with what we know of vertebrogenic pain
- Other options were limited and wanted to avoid a surgical intervention
- Ultimately performed the Intracept Procedure at L5 and S1
- 75 percent improvement in axial pain and the residual radicular pain
- No pain now while playing golf

Images provided courtesy of Dr. Kevin Barrette

Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

EXAM: Lumbar spine MRI without contrast

Indications: _____

Comparison: _____

Technique: Sequences include STIR sagittal, T2 sagittal, T1 sagittal, T2 axial, T1 axial and T2 coronal

Findings:

- **Bone marrow:** No suspicious bone marrow lesions are noted. Hyperintense and hypointense changes are noted at the endplates of L3-L4 and L4-L5 consistent with Modic 1 and 2 changes
- **Discs:** narrowing and degenerative disc signal is noted at L3-L4, L4-L5 and L5-S1

Evaluation of individual disc levels:

L1-L2:
L2-L3:
L3-L4:
L4-L5:
L5-S1:

Impression:

- Modic 1 changes noted adjacent to L3-L4 disc space
- Modic 2 changes noted adjacent to L4-L5 disc space

Descriptive terms that are synonymous with radiographic diagnosis of Modic:

- Discogenic endplate edema
- Endplate changes with inflammatory signal
- Edematous changes at the endplate
- Disruption and fissuring at the endplate with associated signal changes
- Fibrovascular bone marrow changes adjacent to the endplate with hypointense signal (Modic 1)
- Fatty bone marrow changes adjacent to the endplate with hyperintense signal (Modic 2)

Include other findings noted while reading the MRI such as spondylolisthesis, disc herniations/bulges, spondylolysis and spinal stenosis.

Radiology **Template**

EXAM: Lumbar spine MRI without contrast (short version)

Build the following simple multi-pick drop down list:

Options shown below as A) and B):

A. Multi-pick drop down:

- Edematous changes at the endplates (Modic 1)
- Fatty bone marrow changes at the endplates (Modic 2)

B. Multi-pick drop down:

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

Consider inserting into the template as follows:

Findings:

Optional sentence pulling picklists as below:

A. "seen at" **B.**

Examples:

- Edematous changes at the endplates (Modic 1) seen at L4-L5, L5-S1
- Edematous changes at the endplates (Modic 1), Fatty bone marrow changes at the endplates (Modic 2) seen at L3-L4, L4-L5, L5,S1

Include area to identify at each motion segment:

Picklist:

L2-L3 A.
L3-L4 A.
L4-L5 A.
L5-S1 A.

Impression:

Same optional sentence as in the findings section:

A. "seen at" **B.**

Notes

Notes

INTRACEPT™
Vertebrogenic Pain Relief

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References

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View Boston Scientific Intracept Intraosseous Nerve Ablation System Indications, Safety, and Warnings at bostonscientific.com/intracept-indications

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

Results from clinical studies are not predictive of results in other studies. Results in other studies may vary.

Images provided by Boston Scientific.

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