Treating Metastatic Spinal Tumors

with targeted radiofrequency ablation (t-RFA)

using the STAR™ Tumor Ablation System
A Known Solution

Up to 85% of late stage cancer patients face localized bone pain due to metastatic skeletal tumors. The National Comprehensive Cancer Network (NCCN) Clinical Practice Guidelines indicate that radiofrequency ablation should be a considered treatment option in these cases.

Targeted radiofrequency ablation (t-RFA) using the STAR Tumor Ablation System can offer patients with painful metastatic spinal tumors fast, durable pain relief and localized tumor destruction in a single, minimally invasive treatment.

Additionally, t-RFA is compatible with adjuvant therapies such as radiation therapy and systemic therapy.


Intelligent Energy Delivery

The MetaSTAR® RF Generator displays direct feedback to the physician including:

- real-time temperatures at multiple locations within and at the periphery of the ablation zone.
- active impedance measurements.

Expanding your range of treatment options

While any patient with localized pain from a metastatic spinal tumor may be a candidate for t-RFA, several specific patient groups will likely benefit most.

These include patients

- with radio-resistant tumors.
- with recurrent pain after radiation therapy.
- with posterior vertebral body metastatic tumors.
- who have reached their radiation dose limit.
- with focal pain and symptoms that are preventing palliative radiation.
- who cannot undergo other palliative treatments due to current systemic therapies.

Access and Navigation in 3 dimensions

The SpineSTAR® Ablation Instrument’s active steering capabilities enables physicians to create site-specific ablation zones throughout the vertebral body from a unipediculate approach.
**Controlled Ablation Zone**

The STAR Tumor Ablation System provides controlled thermal distribution to produce a consistent and predictable ablation zone.

The SpineSTAR Ablation Instrument’s steep thermal gradient is designed to minimize impact to vital structures adjacent to the ablation zone.

The unique bipolar design of SpineSTAR’s beveled extendable electrode tip allows the instrument to serve as both an osteotome and an ablation electrode.

The electrode tip is designed to maximize edge effects and RF energy delivery to the targeted tissue while minimizing charring and impedance shut-offs.

Unlike other conventional ablation instruments, the SpineSTAR thermocouples are located at the periphery of the ablation zone in order to monitor thermal spread.

**Meaningful Clinical Outcomes**

Clinical data show that rapid and lasting pain relief from metastatic spinal tumors is a reality for patients who choose t-RFA using the STAR System.

This multicenter retrospective study included 128 treated lesions in 92 patients, many of whom had failed radiation therapy. 54% of patients were able to reduce pain medication usage after t-RFA.

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**Figure:** Pain decrease over time after t-RFA.

<table>
<thead>
<tr>
<th>Average Pain Score</th>
<th>Before t-RFA</th>
<th>1 Week After</th>
<th>6 Months After</th>
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<tbody>
<tr>
<td></td>
<td>7.51</td>
<td>1.73</td>
<td>1.75</td>
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</table>

Pain decreased by 77% **p<0.01**

Source: Anchala et al. Pain Physician 2014; 17:317-327 • ISSN 1533-3159
<table>
<thead>
<tr>
<th>Catalog No.</th>
<th>PRODUCT DESCRIPTIONS/SPECIFICATIONS</th>
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<tbody>
<tr>
<td>3544 (5/10 short) 3192 (10/15 short) STR-0510L (5/10 long) STR-1015L (10/15 long)</td>
<td>SpineSTAR® Ablation Instrument  Specifications:  11 gauge  15.5 cm maximum reach (short instrument)  17.5 cm maximum reach (long instrument)  3192 and STR-1015L Thermocouple configuration: 10 &amp; 15 mm  3544 and STR-0510L Thermocouple configuration: 5 &amp; 10 mm</td>
</tr>
<tr>
<td>RF-0510S-01 (5/10 short) RF-1015S-01 (10/15 short) RF-0510L-01 (5/10 long) RF-1015L-01 (10/15 long)</td>
<td>STAR™ Tumor Ablation Kit  Includes:  SpineSTAR® Ablation Instrument  5/10mm or 10/15mm (Thermocouple configuration)  StabilIT® Introducer (Bevel tip and Diamond tip)  VertecoR® Straightline Cement Staging Osteotome  PowerCURVE® Navigational Osteotome  AE Cable (approx. 10 feet)  Hand Switch Cable (approx. 10 feet)</td>
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<tr>
<td>3195</td>
<td>MetaSTAR® RF Generator  Specifications:  Power Input: Universal 100/240V AC 50/60Hz  Power Outputs: 3W, 5W, 7.5W and 10W  Frequency of 480kHz  20Ω-1000Ω impedance load  Weight: 10 lbs  Dimensions: 18”(L) x 11”(W) x 6”(H)</td>
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**RISKS AND INDICATIONS**
The STAR™ Tumor Ablation System is indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. Like all surgical procedures, radiofrequency ablation procedures using the STAR System involve risks, and some patients are not candidates for the procedure. For detailed description of risks and contraindications, please review the product Instructions for Use.

**IOS**
Interventional Oncology & Spine