

STAR™

TUMOR ABLATION SYSTEM



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.

Source: KurupAN and CallstromMR. J VascIntervRadiol. 2010;21:S242-S250. National Comprehensive Cancer Network. Adult Cancer Pain (Version 2.2014).

Expanding your range of treatment options

While any patient with focalized 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**.

Intelligent Energy Delivery

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

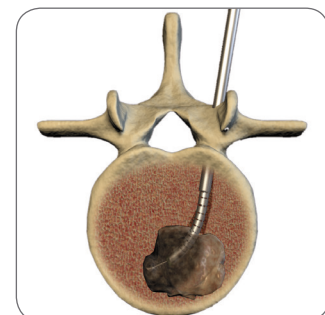
- real-time temperatures at multiple locations within and at the periphery of the ablation zone.
- active impedance measurements.



Real-time temperature information is displayed to assist physicians in assessing ablation zone size.

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

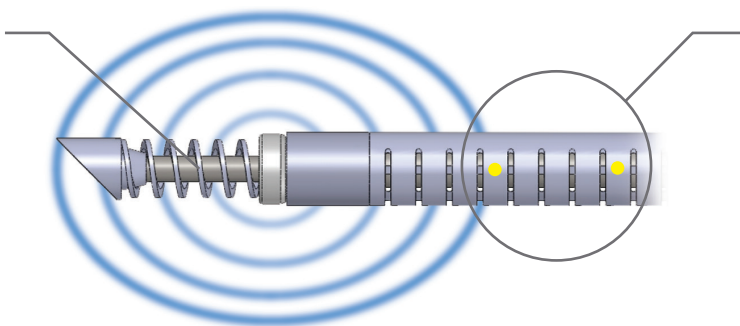
The STAR Tumor Ablation System provides controlled thermal distribution to produce a consistent and predictable ablation zone.

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



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

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

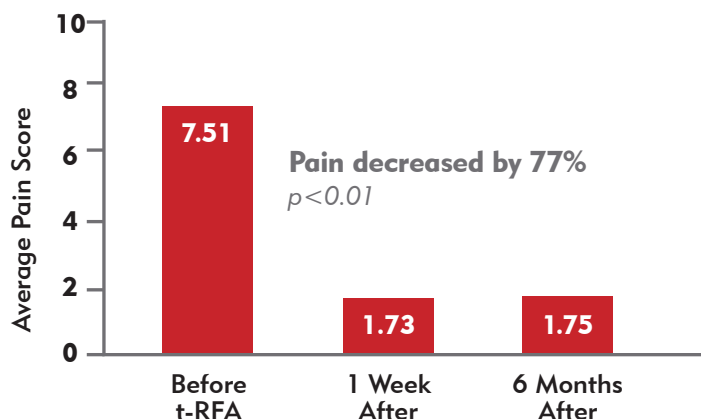





Unlike other conventional ablation instruments, the SpineSTAR thermocouples are located at the periphery of the ablation zone in order to monitor thermal spread.

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.



Catalog No.	PRODUCT DESCRIPTIONS/SPECIFICATIONS
3544 (5/10 short) 3192 (10/15 short) STR-0510L (5/10 long) STR-1015L (10/15 long)	<p>SpineSTAR® Ablation Instrument</p> <p>Specifications:</p> <ul style="list-style-type: none"> 11 gauge 15.5 cm maximum reach (short instrument) 17.5 cm maximum reach (long instrument) 3192 and STR-1015L Thermocouple configuration: 10 & 15 mm 3544 and STR-0510L Thermocouple configuration: 5 & 10 mm 
RF-0510S-01 (5/10 short) RF-1015S-01 (10/15 short) RF-0510L-01 (5/10 long) RF-1015L-01 (10/15 long)	<p>STAR™ Tumor Ablation Kit</p> <p>Includes:</p> <ul style="list-style-type: none"> 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) 
3195	<p>MetaSTAR® RF Generator</p> <p>Specifications:</p> <ul style="list-style-type: none"> 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) 

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



Understand. Innovate. Deliver.™

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