

TREAT SPINAL METASTASES WITH REPRODUCIBLE PRECISION



OsteoCool™ RF
Ablation System

Medtronic
Further, Together



YOUR EXPERTISE OUR INNOVATION



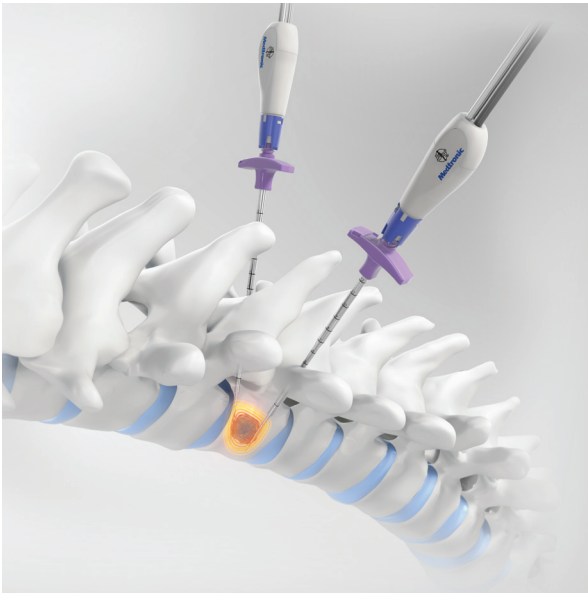
The **OsteoCool™ RF Ablation System** is cooled radiofrequency ablation technology. It offers simultaneous, dual-probe capabilities for the treatment of metastatic malignancies in the spine. OsteoCool lets you treat patients with painful spinal metastases **confidently** and **consistently**.

**TOGETHER, WE CAN
TREAT CANCER PAIN
IN NEW WAYS,
SO PEOPLE
CAN LIVE BETTER**

In 79% of patients with skeletal metastases, the most frequent complaint is pain associated with the disease¹ — a pain that is usually progressive and significantly reduces quality of life.²

Metastatic lesions in the spine become painful due to neural compression, pathologic fracture, or other biochemical mechanisms.³

REPRODUCIBLE PRECISION



KNOW WHERE THE HEAT IS GOING

Coaxial, bipolar technology delivers RF energy to the site consistently

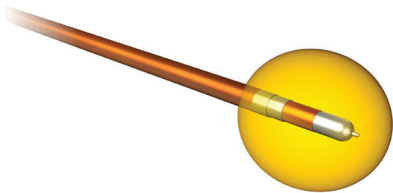
- Algorithms designed to perform optimally in bone
- Bone access kit defines anterior and posterior ablation boundaries
- Confidence in ablation zone mapping

IT'S PREDICTABLE

Create large volume lesions without excessive heating at the active tip

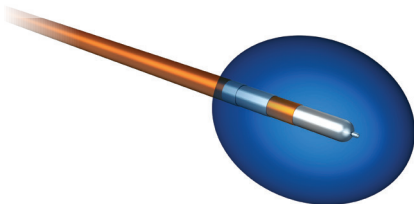
- Minimize potential for char with internally cooled ablation probe
- Thermocouple monitors tissue temperature around the distal tip of the probe

At a target temperature of 70° C at the distal tip, the probes ablate for the pre-set time and yield predictable ablation zones.



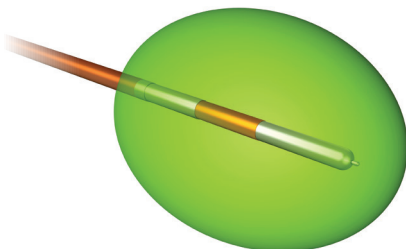
7 mm
PROBE ACTIVE TIP

ABLATION ZONE
SIZE AND DEFAULT TIME
11 x 10 mm
6:30 minutes



10 mm
PROBE ACTIVE TIP

ABLATION ZONE
SIZE AND DEFAULT TIME
17 x 13 mm
7:30 minutes



20 mm
PROBE ACTIVE TIP

ABLATION ZONE
SIZE AND DEFAULT TIME
29 x 21 mm
15:00 minutes

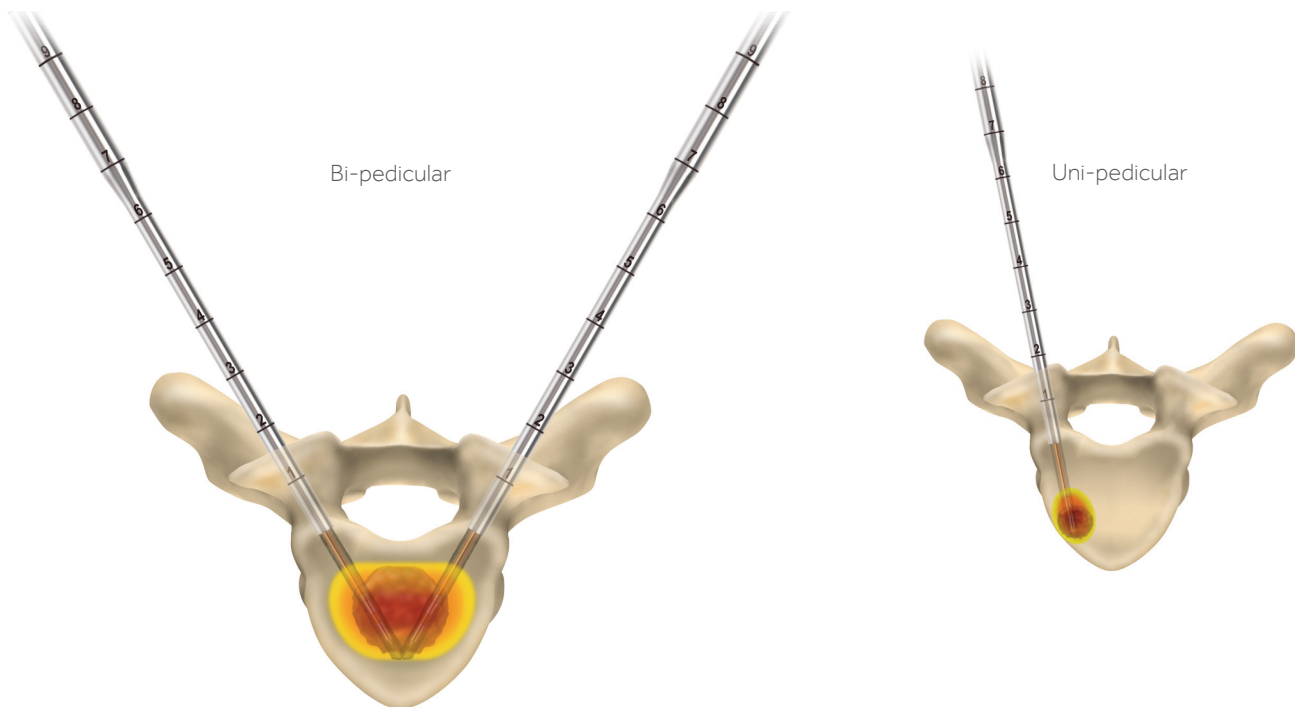


CUSTOMIZE YOUR ABLATION OPTIONS

OsteoCool provides flexibility with a wide range of ablation scenarios for your patient and procedural needs

Treat adjacent or multiple vertebral levels simultaneously:

- Bi-pedicular
- Uni-pedicular
- 7mm, 10mm, and 20mm active tip sizes
- Multiple introducer gauge options
- Track ablation



Simultaneous ablation allows two probes to be positioned closely enough to produce large ablation zones.

DESIGN SIMPLICITY



SIMPLIFY THE PROCEDURE

OsteoCool key design features

- User-friendly touch screen interface
- Recognizes probe size and automatically presets ablation time
- Tracks temperature and power output to reduce risk of thermal damage to adjacent structures
- Generates power levels specific to vertebral lesion sizes
- Monitors impedance and automatically pauses ablation before charring can occur
- Automatically halts RF energy delivery once ablation time is complete

EXPERIENCE EFFICIENCY

- Use two probes at the same time
- Where indicated, use same bone access for subsequent physician-directed procedure such as cementoplasty (i.e., kyphoplasty or vertebroplasty)



Important Safety Information

The OsteoCool™ RF Ablation System is intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. The system is contraindicated in patients with heart pacemakers or other electronic device implants, and contraindicated in vertebral body levels C1-C7. The OsteoCool Bone Access Kits are indicated for percutaneous access to bone.

IMPORTANT SAFETY INFORMATION FOR KYPHON BALLOON KYPHOPLASTY

Kyphon® Xpede™ Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a cementoplasty (i.e., kyphoplasty or vertebroplasty) procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor. Pathologic fracture may include a symptomatic vertebral body microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

Kyphon® HV-R® Bone Cement is indicated for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesions using a kyphoplasty or vertebroplasty procedure. Cancer includes multiple myeloma and metastatic lesions, including those arising from breast or lung cancer, or lymphoma. Benign lesions include hemangioma and giant cell tumor.

The complication rate with Kyphon® Balloon Kyphoplasty has been demonstrated to be low. There are risks associated with the procedure (e.g., cement extravasation), including serious complications, and though rare, some of which may be fatal.

REFERENCES

1. Janjan N, et al. Therapeutic guidelines for the treatment of bone metastasis: a report from the American College of Radiology Appropriateness Criteria Expert Panel on Radiation Oncology. *J Palliat Med.* 2009;12(5):417-426.
2. Nakatsuka A, Yamakado K, Maeda M, et al. Radiofrequency ablation combined with bone cement injection for the treatment of bone malignancies. *J Vasc Interv Radiol.* 2004;15:707-712.
3. Wallace AN, Greenwood TJ, Jennings JW. Radiofrequency ablation and vertebral augmentation for palliation of painful spinal metastases. *J Neurooncol.* 2015;124(1):111-118.

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Please see the package insert for the complete list of indications, warnings, precautions, and other important medical information.



Consult instructions for use at this website www.medtronic.com/manuals.

Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat® Reader with the browser.