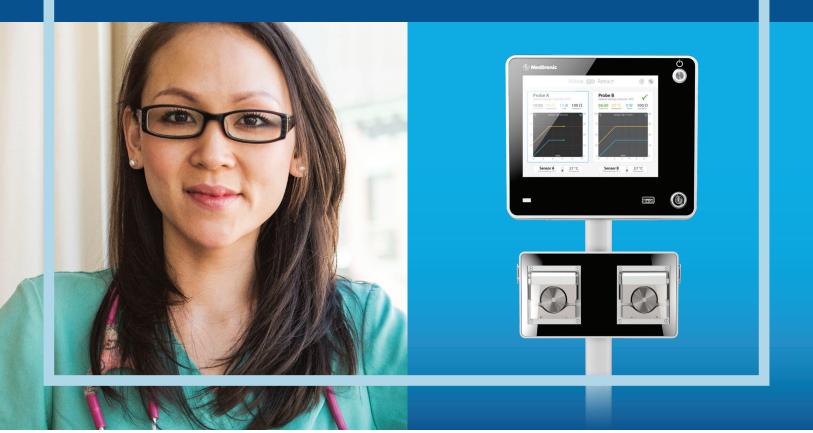
TREAT BONE TUMORS WITH REPRODUCIBLE PRECISION

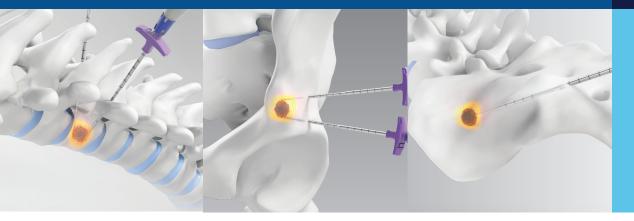


OsteoCool™ RF Ablation System Medtronic Further, Together



REPRODUCIBLE PRECISION

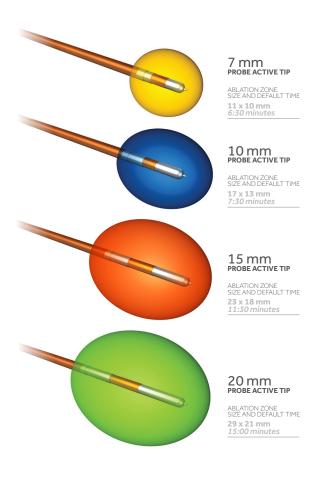




KNOW WHERE THE HEAT IS GOING

Coaxial, bipolar technology delivers RF energy to the site consistently

- Algorithms designed to perform optimally in bone
- OsteoMAPSM Technique 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

- Minimizes 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.

PROCEDURAL FLEXIBILITY



CUSTOMIZE YOUR ABLATION OPTIONS

Flexibility with a wide range of ablation scenarios for your patient and procedural needs

OsteoCool™ RF ablation probes can be used simultaneously:

- Simultaneous ablation of adjacent or multiple levels in the spine
- Simultaneous ablation using two probes, such as bipedicular spine tumor ablation
- Ablation using one probe
- 7 mm, 10 mm, 15 mm, and 20 mm active tip sizes
- Multiple introducer gauge options
- Track ablation

ONE PROBE













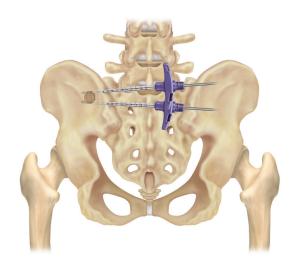


Simultaneous ablation allows two probes to be positioned closely enough to produce large ablation zones.

DESIGN SIMPLICITY







SIMPLIFY THE PROCEDURE

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 bone 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, sacroplasty, or vertebroplasty).

Indications and Risks

The OsteoCool™ RF Ablation System is intended for ablation of benign bone tumors such as osteoid osteoma and for the palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. It is also intended for coagulation and ablation of tissue in bone during surgical procedures, including palliation of pain associated with metastatic lesions involving bone in patients who have failed or are not candidates for standard therapy.

Risks of the system include damage to surrounding tissue through iatrogenic injury as a consequence of electrosurgery; pulmonary embolism; nerve injury including thermal injury, puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis, and paralysis. The OsteoCool™ bone access kits are indicated for percutaneous access to bone.

YOUR EXPERTISE OUR INNOVATION



The OsteoCool™
RF Ablation
System is cooled
radiofrequency
ablation technology.

It offers simultaneous, dual-probe capabilities for the treatment of bone tumors.

And, it lets you treat patients confidently and consistently.

TOGETHER, WE CAN TREAT CANCER PAIN

IN NEW WAYS, SO PEOPLE CAN LIVE BETTER

Bone is invaded in 60-80% of patients with metastatic disease¹ — most frequently among patients with primary malignancies of the breast, prostate, and lung.²

More than 80% of bone metastases are found in the axial skeleton, and the spine, pelvis, and ribs are often the earliest sites of disease.³

Bone metastases can impact quality of life with pain, fractures, and decreased mobility. In addition to these symptoms, they can cause mood changes such as depression⁴ and anxiety.⁵

IMPORTANT SAFETY INFORMATION FOR KYPHON BALLOON KYPHOPLASTY

Kyphon XpedeTM Bone Cement and Kyphon HV-RTM Bone Cement are 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. It is also indicated for the fixation of pathological fractures of the sacral vertebral body or ala using sacral vertebroplasty or sacroplasty. 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.

The complication rate with KyphonTM 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. Schulman, et al. Economic Burden of Metastatic Bone Disease. American Cancer Society 2007.
- 2. Kurup AN, Callstrom MR. J Vasc Interv Radiol. 2010;21 (8 Suppl);S242-50.
- 3. Nielsen OS, Munro AJ, Tannock IF. Bone Metastases: Pathophysiology and Management Policy. *J Clin Oncol.* 1991;9(3):509-524.
- 4. Spiegel D, et al. Pain and depression in patients with cancer. Cancer. 1994;74:2570-2578.
- 5. Goetz et al. Percutaneous Image-Guided Radiofrequency Ablation of Painful Metastases Involving Bone: A Multicenter Study. *J Clin Oncol*. 2004;22(2):300-306.

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Spinal and Biologics Business Worldwide Headquarters

2600 Sofamor Danek Drive Memphis, TN 38132 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 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.



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