



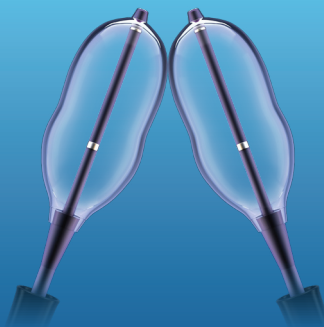
YOUR EXPERTISE **AND OUR INNOVATIONS**

A Streamlined Procedure

Treat painful spinal metastases and stabilize the fractured bone using the same access and instruments.

OsteoCool™ RF
Ablation System

Kyphon™ Balloon
Kyphoplasty



Medtronic
Further. Together



TOGETHER,
WE CAN
**TREAT CANCER
PATIENTS
IN NEW WAYS,**
GIVING YOU
MORE TREATMENT
OPTIONS.

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 (QOL).²

One cause of pain in spinal metastatic lesions is a pathological vertebral compression fracture (VCF).³

SELECT THE PATIENT

Radiographic evaluation and a neurological exam can confirm metastatic malignancies in the spine and VCF.

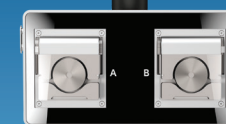
For your patients with painful spinal metastases or VCFs, treatment goals may include pain relief, improved mobility, and restored quality of life.



COMBINE THE SOLUTIONS

Combining OsteoCool™ RF ablation and Kyphon™ Balloon Kyphoplasty (BKP) allows you to predictably ablate the lesion and stabilize the fractured bone during the same procedure.

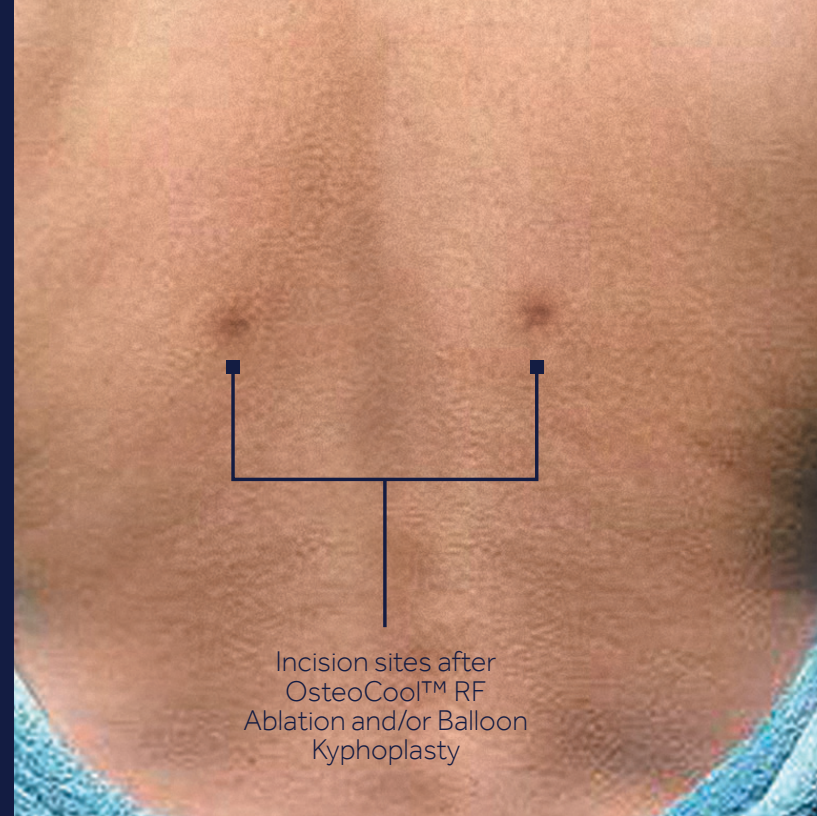
Provide your patients reliable therapy options in one streamlined procedure.



OSTEOCOOL RF ABLATION SYSTEM

THE BENEFITS

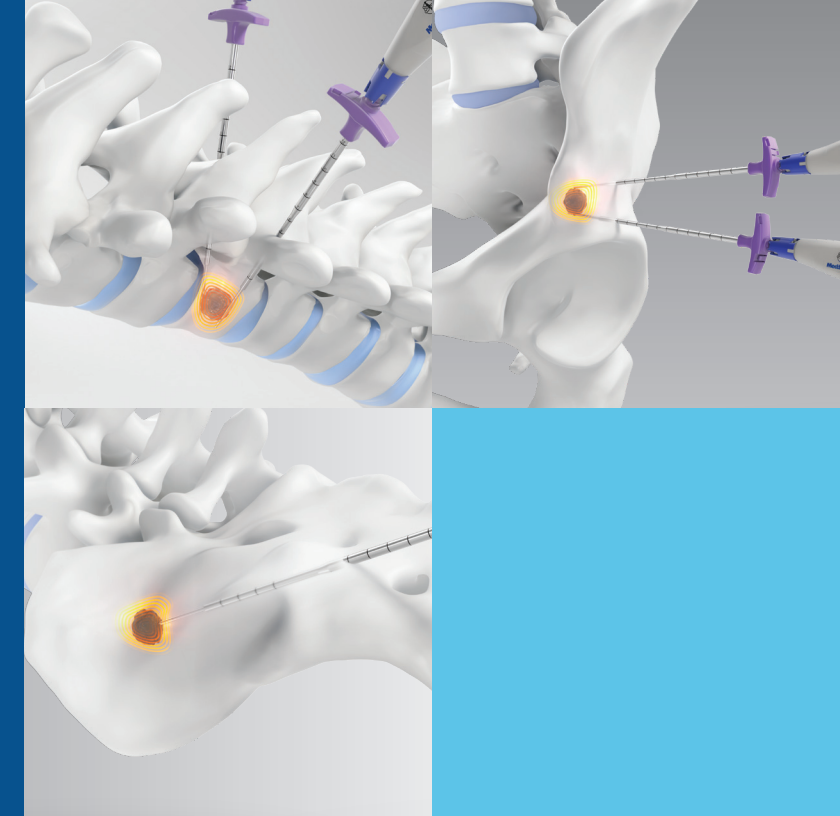
OsteoCool™ RF ablation is for the palliative treatment of spinal metastases with cooled radiofrequency ablation technology. It lets you treat patients confidently and consistently with reproducible precision.



THE PROCEDURE 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

- 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.

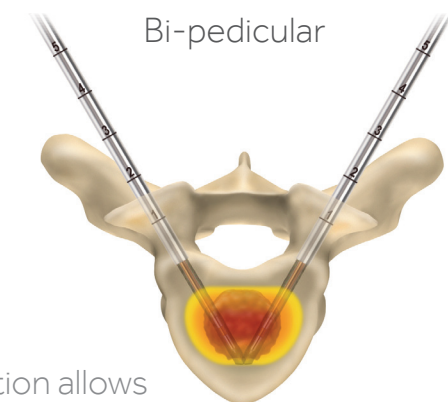
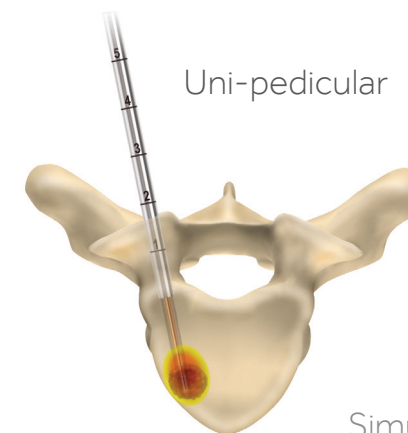
Risks of the system include damage to surrounding tissue through iatrogenic injury as a consequence of electrosurgery; pulmonary embolism; nerve injury including thermal injury, puncture of the spinal cord or nerve roots potentially resulting in radiculopathy, paresis, and paralysis. The OsteoCool™ Bone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

CUSTOMIZE YOUR ABLATION OPTIONS

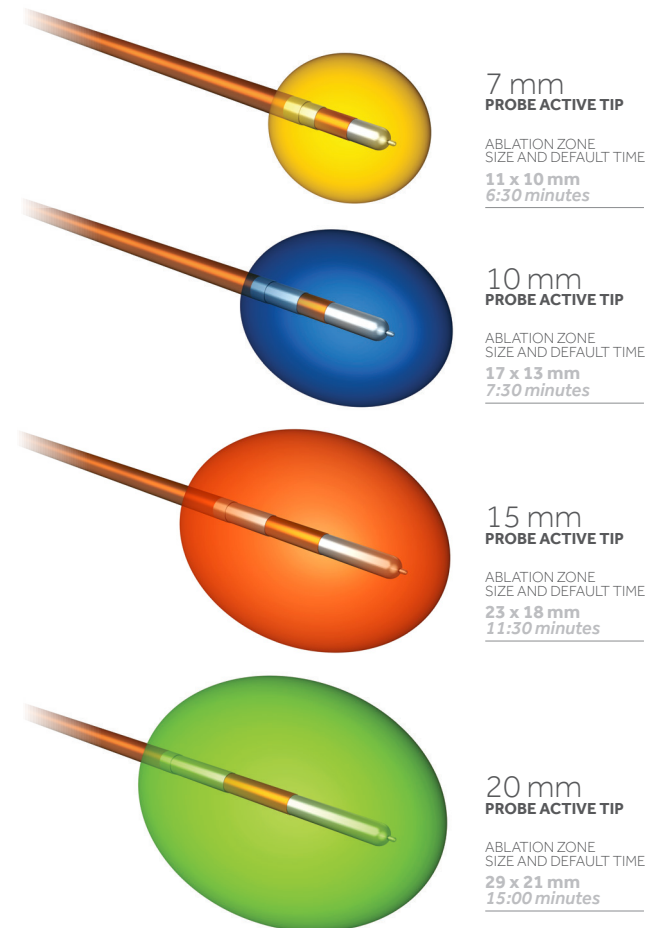
Flexibility with a wide range of ablation scenarios for your patient and procedural needs

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



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



KYPHON BALLOON KYPHOPLASTY

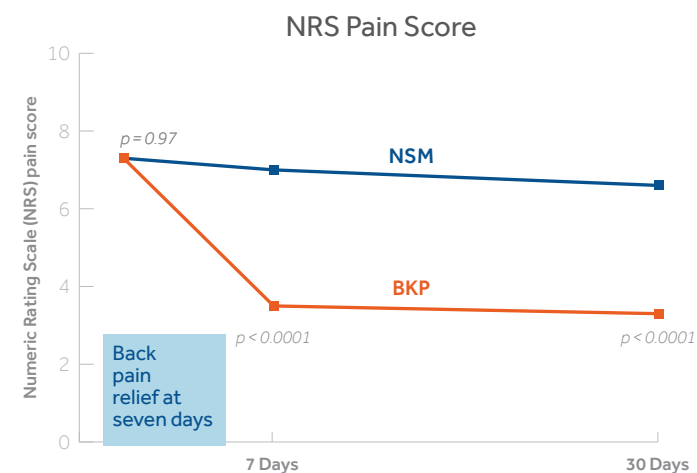
THE BENEFITS

For patients with VCF due to osteoporosis or cancer, studies show that BKP, a minimally invasive treatment, provides significant benefits compared with non-surgical management (NSM) such as bed rest and pain medication. See important outcomes, below.

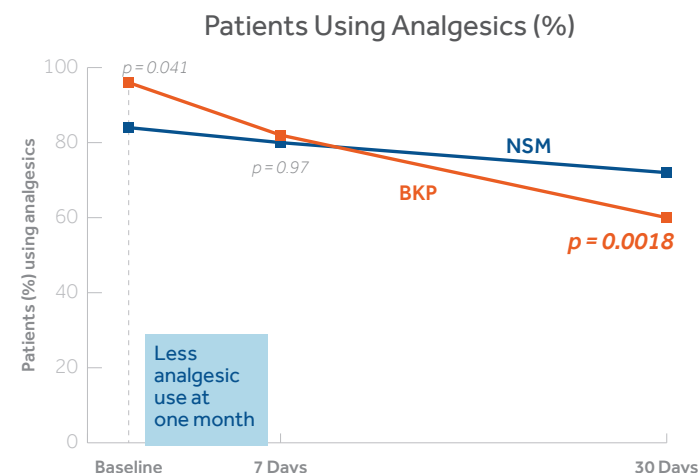


RAPID AND SUSTAINED BACK PAIN RELIEF⁴

Kyphon™ Balloon Kyphoplasty (BKP) provided clinically and statistically significant back pain relief compared with non-surgical management (NSM) for cancer patients with painful spinal fractures at one month.



- BKP patients experienced more than 50% pain reduction on average.
- NSM patients did not significantly change on average.
- BKP n = 68, 63, and 64 at three time points
- NSM n = 60, 54, and 50 at three time points



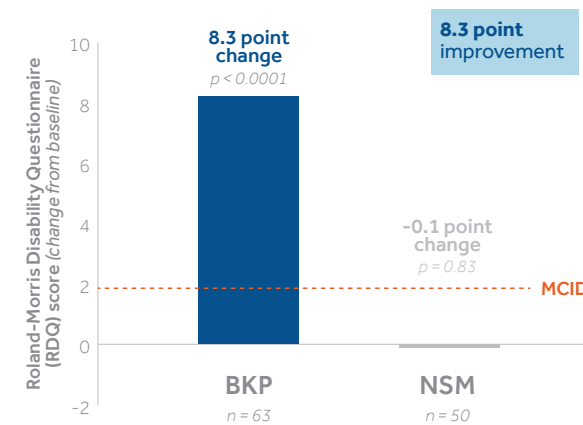
- Significantly fewer BKP patients used pain medication at one month.
- BKP n = 68, 63, and 64 at three time points
- NSM n = 60, 55, and 49 at three time points

For BKP patients, back pain improvement observed at one month post-procedure was generally maintained until the final 12-month assessment.

Study limitations: A limitation of the CAFE study¹ is that randomization of treatment lasted for one month. After the first month, patients were allowed to cross over from NSM to BKP, creating a non-randomized population for the long-term analysis. For patients randomly assigned to BKP, improvement in functional status and quality of life, and reduction of pain continued until the end of the study (12 months).

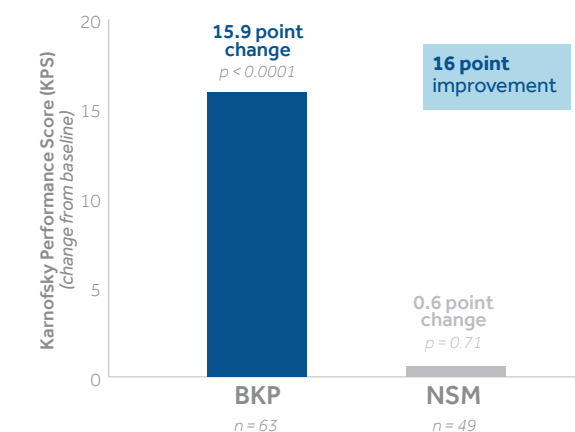
IMPROVED QUALITY OF LIFE ACROSS MULTIPLE MEASURES⁴

Back Function as Measured by Roland-Morris Disability Questionnaire (RDQ) at ONE MONTH



- BKP patients significantly improved from baseline (mean 8.3 points). NSM patients showed no significant change.
- Significantly more BKP patients (81%, 51/63) had clinical improvement (2-point MCID*) compared with NSM patients (28%, 14/50) (p < 0.0001).

Karnofsky Performance Score (KPS) at ONE MONTH

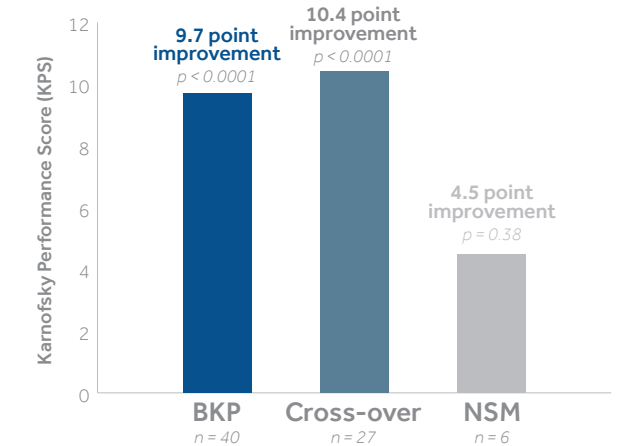


- BKP patients increased 15.9 points from baseline, whereas NSM patients showed no significant change.
- More BKP patients (75%) had a KPS Score of ≥ 70 compared with only 39% of patients who received NSM. Note: 70 is a clinically meaningful threshold score for the ability to care for oneself.

More BKP patients were more independent one month after the procedure.

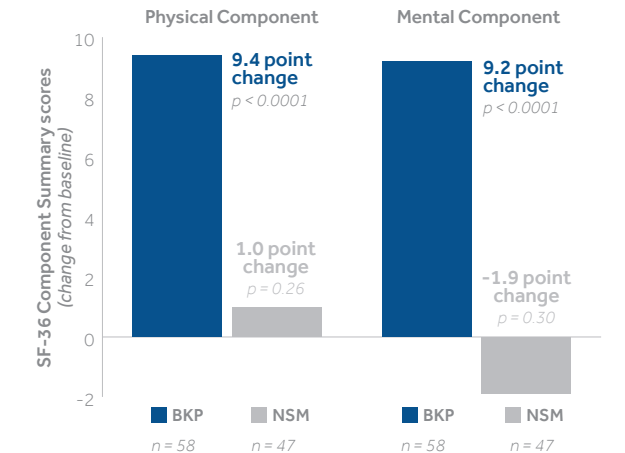
*Note MCID - minimal clinically important difference

Back Function as Measured by Roland-Morris Disability Questionnaire (RDQ) at 12 MONTHS



- At 12 months, baseline RDQ scores in BKP patients and crossover control patients significantly improved 9.7 points and 10.4 points respectively; NSM patients had less improvement at 4.5 points.

SF-36 at ONE MONTH



- BKP patients significantly improved in QOL from baseline (9.4 points). NSM patients showed no significant change.

- BKP patients significantly improved from baseline (9.2 points). NSM patients showed no significant change.

Following an OsteoCool™ procedure, a kyphoplasty procedure may be completed, where indicated, through the same access instruments to stabilize the vertebral body.



THE PROCEDURE

BKP IS A MINIMALLY INVASIVE PROCEDURE THAT TYPICALLY LASTS ABOUT AN HOUR.

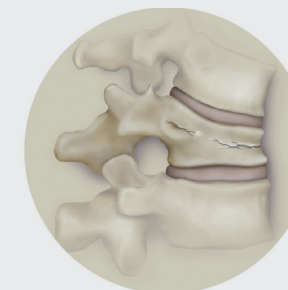
- Orthopedic balloons elevate fractured vertebra to return it to correct position
- Cavity is filled with bone cement, creating internal cast
- Can be performed under general or local anesthesia, either in hospital or physician office setting
- Has been shown in clinical studies to stabilize painful VCFs, reduce back pain, and restore vertebral body height⁴

BKP is backed by:

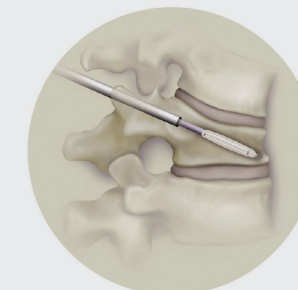
- Level 1 clinical evidence⁴
- A 20-year history
- More than 1 million VCFs treated*

Risks of acrylic bone cements include cement leakage, which may cause tissue damage, nerve or circulatory problems, and other serious adverse events, such as: cardiac arrest, cerebrovascular accident, myocardial infarction, pulmonary embolism, or cardiac embolism.

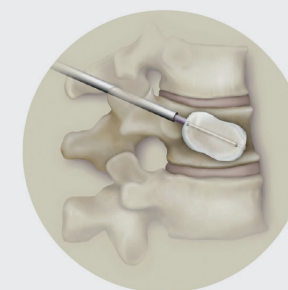
* Internal data on file



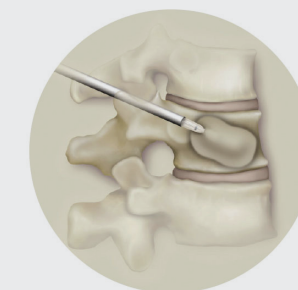
1. Fractured vertebra



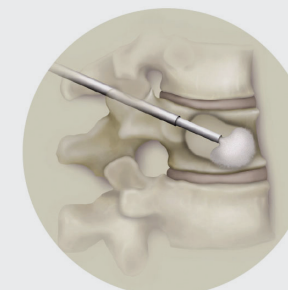
2. Balloon inserted into vertebra



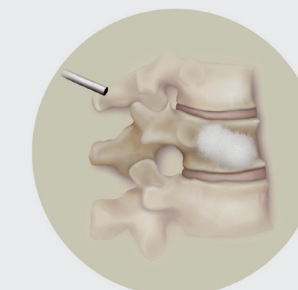
3. Balloon inflated to lift endplates



4. Balloon removed leaving cavity



5. Bone cement injected into cavity



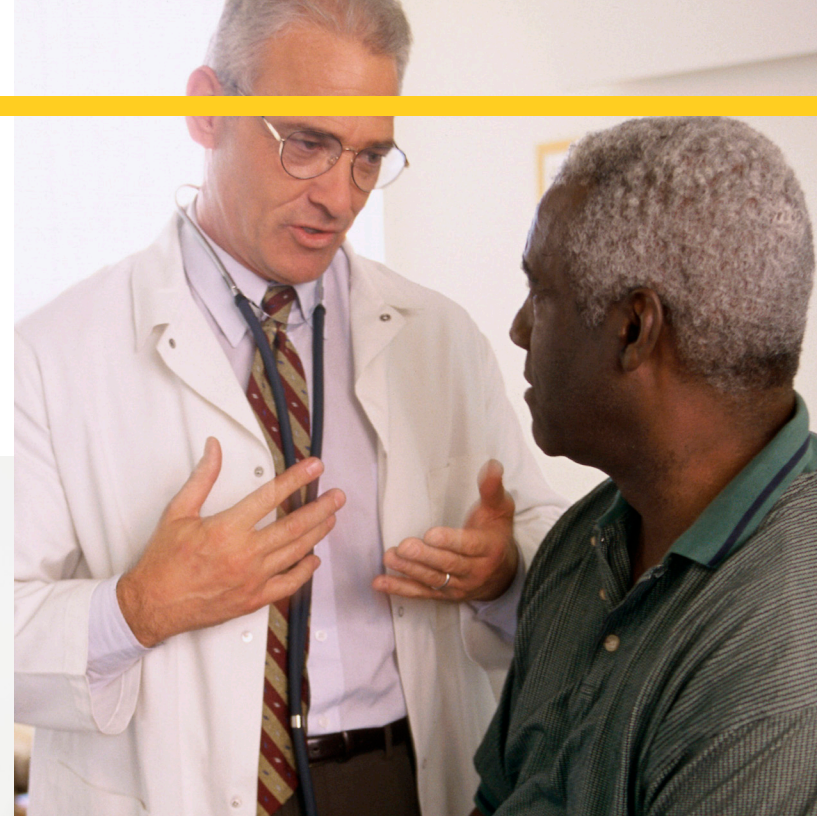
6. Internal cast to stabilize

A LEGACY OF LEADERSHIP

MEDTRONIC — SUPPORT AT EVERY STEP

- Procedural and case support
- Technical support
- Reimbursement support
- Patient education
- Coverage and authorization
- Training and medical education

[medtronic.com/OsteoCool](https://www.medtronic.com/OsteoCool)
[medtronic.com/Kyphoplasty](https://www.medtronic.com/Kyphoplasty)



"Patients with metastatic bone cancer may be treated with conventional therapies such as opioids, chemotherapy, or radiation therapy for pain palliation. With OsteoCool™ RF Ablation, I can treat patients' bone tumors when conventional therapies aren't effective, are too slow acting, or cause unacceptable side effects."⁵

Sandeep Bagla, MD
Interventional Radiologist
Vascular Institute of Virginia,
Woodbridge, VA

"Right away, it was a technique that I thought was dramatic in its results, and I have since worked hard to educate other physicians about the distinct clinical results I have seen by treating fractures promptly. Because of the often immediate improvement after the procedure I have observed, I strongly advocate balloon kyphoplasty to my patients."

Van Boggus, MD
Orthopedic Surgeon
The Toledo Clinic
Toledo, OH



MEDTRONIC — COMMITMENT TO PATIENTS

In the time it took you to read this sentence,

SIX MORE LIVES WERE IMPROVED
by a Medtronic therapy.

Treat your patients' spinal metastases and VCF with therapy options in a streamlined procedure.

PRODUCT INDICATIONS

The OsteoCool™ RF Ablation System is intended for ablation of benign bone tumors such as osteoid osteoma and for 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.

Kyphon™ Balloon Kyphoplasty is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion.

For complete information regarding indications for use, contraindications, warnings, precautions, adverse events, and methods of use, please reference the devices' Instructions for Use included with the product.

REFERENCES

1. Janjan, Lutz ST, Bedwinek JM, 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.
4. Berenson J, Pflugmacher R, Jarzem P, et al. Balloon kyphoplasty versus non-surgical fracture management for treatment of painful vertebral body compression fractures in patients with cancer: a multicentre, randomised controlled trial. *Lancet Oncol.* 2011;12:225-235.
5. Sabharwal T, Katsanos K, Buy X, Gangi A. Image-guided ablation therapy of bone tumors. *Semin Ultrasound CT MR.* 2009;(2):78-90.

Medtronic

Medtronic
Spinal and Biologics Business
Worldwide Headquarters

2600 Sofamor Danek Drive
Memphis, TN 38132

Medtronic Sofamor Danek USA, Inc.
1800 Pyramid Place
Memphis, TN 38132

(901) 396-3133
(800) 876-3133
Customer Service: (800) 933-2635

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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.