

# SWIFT SIGNIFICANT **SUSTAINED** PAIN RELIEF

Treating cancer patients with painful bone metastases in new ways — together.



**Medtronic**

# CANCER PAIN RELIEF IN AS FEW AS 3 DAYS

In 79% of patients with skeletal metastases, the most frequent complaint is pain associated with the disease<sup>1</sup> — a pain that significantly reduces quality of life (QOL).<sup>2</sup>

**Pain is multifaceted and can derive from two potential causes: the biological source such as cytokine release or the pathological vertebral compression fracture (VCF).**<sup>3-4</sup>

For patients with painful spinal metastases or VCFs, consider treatment with the OsteoCool™ RF Ablation (RFA) System and Kyphon™ Balloon Kyphoplasty (BKP).



SIR 2021  
ABSTRACT  
OF THE  
YEAR

## PROCEDURAL DETAILS

- 89% of subjects were treated for lesions in the thoracolumbar spine
- 9% of subjects were treated for lesions involving the pelvis and/or sacrum
- 95% of subjects were radiation therapy naïve prior to RFA

# 97%

of RFA procedures were followed by **cementoplasty**



The OPuS One clinical study found patients with bone metastases treated with the OsteoCool™ RFA System followed by cementoplasty demonstrated improvements in pain relief and QOL<sup>5-7</sup>:

### 3 DAYS POST-PROCEDURE

( $P < 0.0001$ )

### SIGNIFICANT IMPROVEMENT AT ALL VISITS

( $P < 0.0001$  for all visits)

### LONG-TERM IMPROVEMENTS FOR UP TO 12 MONTHS

( $P < 0.0001$  for all visits)

## CLINICAL STUDY BACKGROUND

- **Largest prospective study on the performance and safety of RFA for the treatment of palliative bone metastases to date** (206 patients treated)
- Global multicenter post-market single arm study
- This abstract reports patients with bone metastases treated with the OsteoCool™ RFA System, followed by cementoplasty at operator's discretion, followed up for 12 months.

## KEY TAKEAWAYS

**No post-procedure fractures** reported at the ablation site

**Clinically meaningful pain relief** ( $\geq 2$ -point change in worst pain) experienced by **60% and 83% of patients** 3 days and 12 months post procedure, respectively

## ADVERSE EVENTS

- Six adverse events related to device, therapy, and/or procedure with three considered serious: intra-abdominal fluid collection, pneumonia, respiratory failure
- All deaths (n=82) attributed to not be related to study device, therapy, or procedure

COMBINE COMPLEMENTARY SOLUTIONS:

RFA +  
BKP +  
RADIATION

You may have patients who **cannot wait up to six weeks for radiation therapy (RT) to provide pain relief. RFA plus cementoplasty offers the possibility of pain relief in as few as 3 days.**<sup>5</sup> It is not intended to replace RT. The National Comprehensive Cancer Network (NCCN) Bone Health Task Force proposes radiation after augmentation.<sup>8</sup>

**OsteoCool™ RF Ablation** is for the palliative treatment of bone metastases with cooled radiofrequency ablation technology. As a stand-alone or complementary option to radiation, RFA is an option for your patients with painful bone metastases.

**Kyphon™ Balloon Kyphoplasty** commonly follows the OsteoCool™ RF ablation procedure for patients with VCF to stabilize the fracture.

Expand your treatment options to include RFA and BKP therapies. **Combining the RFA and BKP procedures** allows you to predictably ablate the lesion and stabilize the fractured bone during the same procedure using the same access tools.

YOUR PATIENT MAY BENEFIT  
FROM COMBINING SOLUTIONS

- RT alone provides potential pain relief but can take **4–6 weeks to realize** and does not prevent vertebral collapse<sup>5,9</sup>
- Recurrent pain, previously irradiated, usually cannot be treated with additional RT<sup>10</sup>

OsteoCool™ RFA System



- Minimally invasive procedure for the treatment of metastatic bone tumors
- Internally cooled ablation probes can create large-volume lesions without excessive heating at the active tip
- Simultaneous ablation allows two probes to be positioned closely enough to produce large ablation zones

Kyphon™ BKP



- 3 times more pain reduction at 1 week vs. non-surgical management (NSM)<sup>11</sup>
- 4 times more improvement in quality of life at 1 month vs. NSM<sup>11</sup>
- 5 fewer days of restricted activity at 1 month vs. NSM<sup>11</sup>

AN IMPROVED  
RESPONSE USING  
RADIATION WITH RFA

When treating patients with RFA in conjunction with RT — versus RT alone — for bone metastases palliation, Di Staso, et al. showed<sup>10</sup>:

**6 WEEKS**  
faster pain response  
( $p < 0.0001$ )

**33% INCREASE**  
in overall pain  
response ( $p = 0.048$ )

**93% OF PATIENTS**  
who received RT and  
RFA achieved overall  
pain relief (versus 59%  
of patients who received  
RT alone)

**Study Limitations:** 1) Small, non-randomized and non-current comparison. 2) Cohort not well matched for sites treated. 3) Interpret comparative effectiveness with caution.

\* RFA therapy used: Leveen Needle Electrode ( Boston Scientific Corp)

# MEET PROCEDURAL GOALS WITH AN INTEGRATED SYSTEM

Once you have confirmed metastatic malignancies in the spine and VCF with radiologic evaluation and a neurological exam, you can ablate the tumor and stabilize the bone with the same access.



# FURTHER, TOGETHER

Since 1998, Medtronic Interventional Pain has been discovering novel approaches to safe and effective, minimally invasive pain relief. You can feel confident knowing our therapies are tried, tested, and proven. When you choose Medtronic, you're supported by a long-term investor in advancing the therapy.

- **A comprehensive portfolio.** We offer expertise in a comprehensive portfolio, including balloon kyphoplasty market originator, vertebral augmentation therapy innovator and market leader, and metastatic bone tumor and nerve ablation market expanders
- **Clinically demonstrated swift pain relief.** Medtronic is distinctive in its evidence-based therapies.
  - Clinically demonstrated swift pain relief for patients with VCF and painful metastatic lesions in the bone
  - Better VCF outcomes than NSM
  - Treating cancer patients by combining solutions because pain is multifaceted

## OsteoCool™ RFA

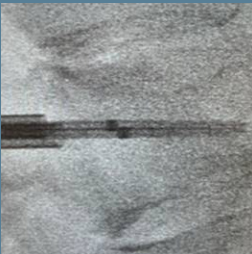


*Internally cooled ablation probes can create large-volume lesions without excessive heating /charring at the active tip*

AP View



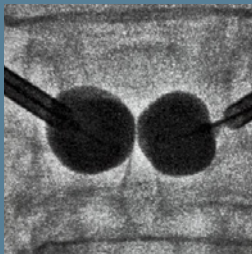
Lateral View



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

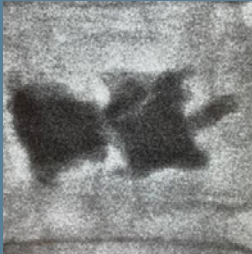
Kyphon™ BKP can follow an OsteoCool™ procedure through the same access instruments to stabilize the vertebral body.

## Kyphon™ BKP

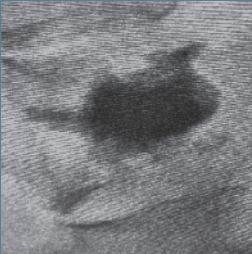


*Orthopedic balloons elevate fractured vertebra to return it to correct anatomical position*

AP View



Lateral View



*Cavity is filled with bone cement, creating internal cast*

## SUPPORT AT EVERY STEP

Your Medtronic team is committed to:

- Improved patient access
- Cost-effective solutions
- Research and innovation
- Reimbursement advocacy

## LEARN MORE AT:

[medtronic.com/oncologypartnership](https://www.medtronic.com/oncologypartnership)

[medtronic.com/VCFcarepathway](https://www.medtronic.com/VCFcarepathway)

Together, we continue to advance our Mission to **alleviate pain, restore health, and extend life.**

## KEY TAKEAWAYS

- **Pain is multifaceted and can derive from two potential causes:** the biological source such as cytokine release or the pathological vertebral compression fracture (VCF).
- RT alone provides potential pain relief but can take 4–6 weeks in only 60% of patients.
- The OPUS One clinical study **demonstrated improvement in pain relief and QOL in as little as 3 days.**
- RT does not prevent (*increase risk of*) vertebral collapse (*or skeletal events*).
- Recurrent pain, previously irradiated, usually cannot be treated with additional RT, leaving the need for further interventions to treat the pain and stabilize the bone.
- Because radiation affects bone and increases risk of skeletal events (*fractures*), the National Comprehensive Cancer Center Network (NCCN) bone task force proposes radiation after augmentation.
- The OPuS One clinical study reported no post-procedure fractures at the ablation site and 97% of RFA procedures were followed by cementoplasty.
- In the Di Staso study, treatment with both RFA and RT showed better overall pain relief in 93% of the study subjects compared to only 59% in the RT group alone.
- Cementoplasty stabilizes the bone and reduces the risk of future skeletal events caused by the tumor or radiation therapy.

### OSTEOCOOL™ RF ABLATION INDICATIONS AND RISKS

The OsteoCool™ RF Ablation System is intended for the palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body and for ablation of benign bone tumors such as osteoid osteoma. 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.

### BKP RISKS

Kyphon™ BKP is a minimally invasive procedure for the treatment of pathological fractures of the vertebral body due to osteoporosis, cancer, or benign lesion. The complication rate with Kyphon™ BKP 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.

1. Janjan N, 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(7):707–712.
3. Rybak LD. Fire and ice: thermal ablation of musculoskeletal tumors. *Radiol Clin N Am.* 2009;47(3):455–469.
4. Callstrom M, Charboneau J, Maus T, et al. Image-guided ablation of painful metastatic bone tumors: a new and effective approach to a difficult problem. *Skeletal Radiology.* 2006;35(1):1–15.
5. Levy J, Hopkins T, Morris J, et al. Radiofrequency ablation for the palliative treatment of bone metastases: outcomes from the multicenter OsteoCool™ tumor ablation post-market study (OPuS One study) in 100 patients. *J Vasc Interv Radiol.* 2020;31(11):1745–1752.
6. Levy J, David E, Hopkins T, et al. Radiofrequency ablation for the palliative treatment of osseous metastases: final results from a multicenter study (OPuS One). Abstract presented at the Society for Interventional Radiology Annual Scientific Meeting. Virtual. 2021.
7. Levy J, David E, Hopkins T, et al. Improvement in quality of life in patients treated for painful osseous metastases with radiofrequency ablation: the OPuS One study. Abstract presented at the Society for Interventional Radiology Annual Scientific Meeting. Virtual. 2021.
8. Adapted with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Central Nervous System V.5.2020. © National Comprehensive Cancer Network, Inc. 2021. All rights reserved. Accessed April 24, 2021. To view the most recent and complete version of the guideline, go online to NCCN.org. The National Comprehensive Cancer Network makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, NCCN GUIDELINES®, and all other NCCN content are trademarks owned by the National Comprehensive Cancer Network, Inc.
9. Cazzato RL, Garnon J, Caudrelier J, Rao P, Koch G, Gangi A. Low-power bipolar radiofrequency ablation and vertebral augmentation for the palliative treatment of spinal malignancies. *Int J Hyperthermia.* 2018;34(8):1282–1288.
10. Di Staso M, Zugaro L, Gravina GL, et al. A feasibility study of percutaneous radiofrequency ablation followed by radiotherapy in the management of painful osteolytic bone metastases. *Eur Radiol.* 2011;21(9):2004–2010.
11. Tillman J, Shabe P, Rose M, Elson P, Wülfert E, Ashraf T. Fracture reduction evaluation study 24-month final clinical study report. August 27, 2010. *Medtronic Spinal and Biologics Europe BVBA.*

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[medtronic.com/manuals](http://medtronic.com/manuals).

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