Medtronic

Value analysis packet

OsteoCool™ 2.0 radio frequency (RF) ablation
for the treatment of painful bone tumors

CONTENTS

PRODUCT INTRODUCTION

A minimally invasive treatment for painful bone tumors

OsteoCool™ 2.0 radio frequency (RF) ablation

About cancer pain

When cancer metastasizes, or moves into surrounding bone, it can affect patients' quality of life, producing complications such as pain, fractures, and decreased mobility[1] – making every day a challenge. Bone metastases can also cause mood changes such as depression and anxiety.[2]

Patients may feel cancer pain from:

- Cancer treatment such as surgery, radiation, and chemotherapy[3]
- Tumor growth that invades or presses on bones, nerves, the spinal cord, or body organs[3]

Patients with metastatic bone cancer may be treated with conventional therapies such as opioids, chemotherapy, or radiation therapy for pain palliation.

However, many cancer patients are left with inadequate treatment or undermanaged pain control because these conventional therapies didn't work for them,[4] are too slow acting, or cause unacceptable side effects.[5]

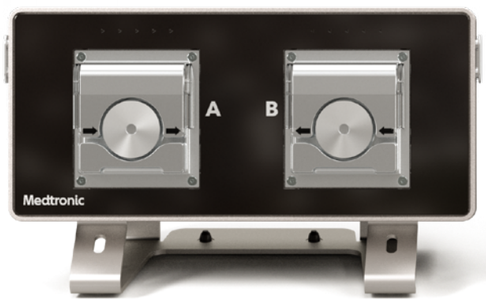
In these cases, physicians may use radiofrequency ablation to help treat painful bone tumors.

About OsteoCool™ 2.0 radiofrequency ablation (RF)

Medtronic offers OsteoCool™ 2.0 RF ablation to **help treat painful bone tumors**. RF ablation uses alternating, low-power current to generate heat during the procedure. The heat is delivered by a probe to the tumor to intentionally dry out and kill cancerous cells.

Accelerated results.
Dependable outcomes.

OsteoCool™ 2.0 RF ablation system delivers the same proven outcomes – faster. Featuring the same patented internally cooled probe design that reduces the risk of charring, the OsteoCool™ 2.0 system delivers **powerful, predictable, and proven pain relief.**



Powerful

- **Allows the use of four probes simultaneously**, enabling ablation of two vertebral bodies at once or overlap ablation zones to create larger lesions in extraspinal applications.
- Features 100W system – **the most ablative power** on the market.[6-8]

Ablate lesions up to

30%

faster than the OsteoCool™ 1.0 system[9†]

†Bench testing may not be indicative of clinical results.

Predictable

- **Independent channel control** adds the convenient ability to stop and start channels individually.
- Internally cooled probes **reduces the risk of charring** without introducing ionic solutions into the ablation zone.
- Four available sizes to tailor the ablation size to **individual patient needs**.

Proven

- **Backed by OPuS One**, the largest study on RF ablation in bone metastases.[10]
- Time-tested with over 18,000 patients receiving OsteoCool™ procedures over the last six years.
- **Trusted** – more than 1,400 hospitals use OsteoCool™ technology to treat patients with bone metastases.

Radiofrequency Ablation Provides Rapid and Durable Pain Relief for the Palliative Treatment of Lytic Bone Metastases Independent of Radiation Therapy: Final Results from the OsteoCool Tumor Ablation Post-Market Study.

Levy J, David E, Hopkins T, et al. Cardiovasc Intervent Radiol. 2023;46(5):600-609. doi:10.1007/s00270-023-03417-x

OBJECTIVE

To evaluate the effectiveness of radiofrequency (RF) ablation as measured by change in worst pain score from baseline to 3 mo after RF ablation for the palliative treatment of painful bone metastases.

DESIGN

The OsteoCool™ tumor ablation post-market study (OPuS One) was a prospective, multi-national, single-arm study to investigate safety and effectiveness of radiofrequency ablation (RFA) for palliation of painful lytic bone metastases with 12 months of follow-up. RFA has demonstrated effective palliation of osseous metastases in small clinical studies with short-term follow-up; however, a long-term assessment with robust subject numbers is lacking.

RESULTS

206 subjects were treated with RFA at 15 institutions in OPuS One. Worst pain, average pain, pain interference and quality of life significantly improved at all visits starting 3 days post-RFA and sustained to 12 months ($P < 0.0001$). Post hoc analysis found neither systemic chemotherapy nor local radiation therapy at the index site of RFA influenced worst pain, average pain, or pain interference. Six subjects had device/procedure-related adverse events.

CONCLUSIONS

RFA for lytic metastases provides rapid (within 3 days) and statistically significant pain and quality of life improvements with sustained long-term relief through 12 months and a high degree of safety, independent of radiation.

https://pubmed.ncbi.nlm.nih.gov/37012392/

†"Clinically meaningful" indicates that there was at least a 2-point change in worst pain from one follow-up visit to the next.

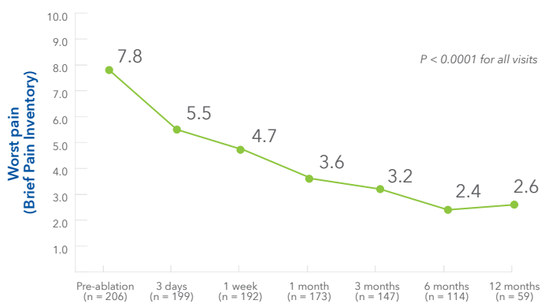
Clinical data: OPuS One study

OPuS One is the largest prospective study to date in RF ablation for bone metastases.

It is important to highlight that the original OsteoCool™ system was the only RF ablation technology evaluated in the OPuS One study.

Key takeaways

OsteoCool™ RF ablation provides pain relief that is swift, significant, and sustained.

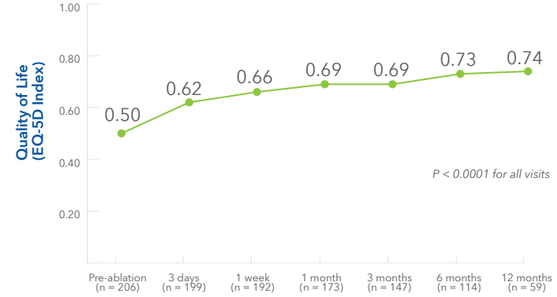


Swift

- **Pain relief was as quick** as 3 days post-procedure
- **60% of patients had clinically meaningful pain relief** at 3 days post-procedure
- Beneficial for patients who are considered end of life given their advanced stage of disease.

Significant

- **Improvement in worst pain at all visits**
- **Improvement in QOL** - a key additional measurement given the fact that cancer patients are living longer with their disease.[11]



Sustained

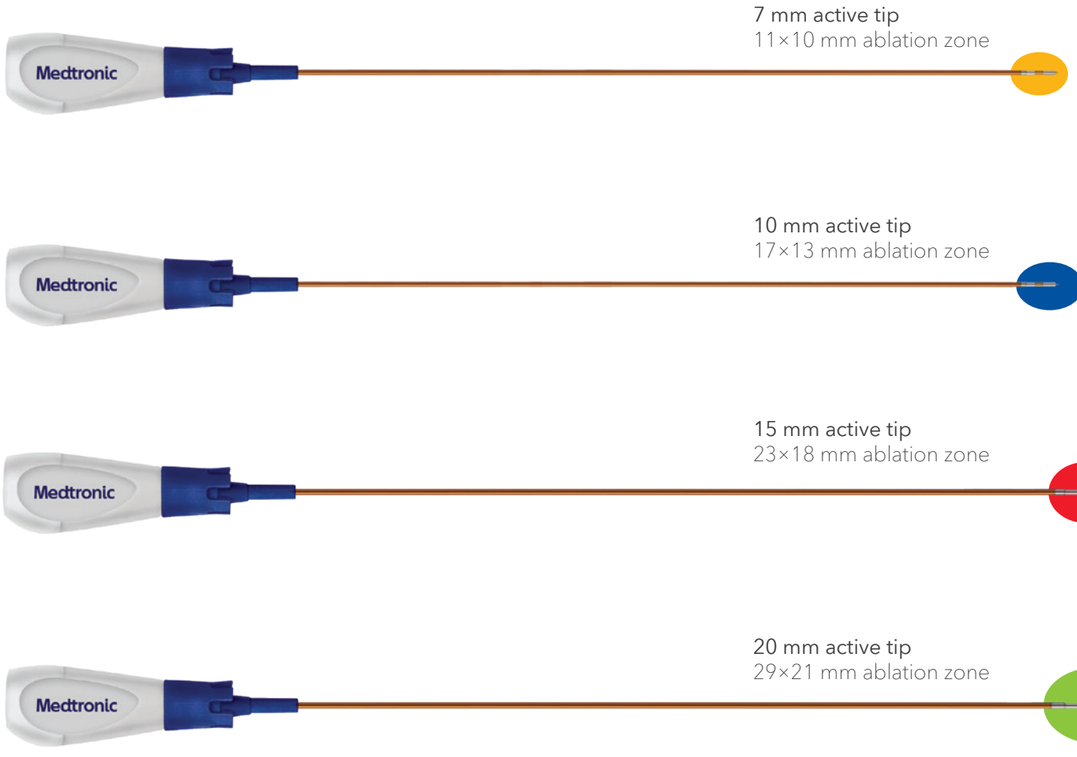
83% of patients had clinically meaningful pain relief at 12 months post-procedure.

ABLATION ZONES

The OsteoCool™ RF ablation probes are bipolar and cooled internally with water. Probes are 17 G, available with 7 mm, 10 mm, 15 mm, and 20 mm active ablation tips, and may be used with a variety of cannula sizes. A thermocouple monitors the temperature around the distal tip of the probe. The ablation time for each size probe varies. When a probe is plugged into the connector hub, the time is automatically set on the generator.

At a target temperature of 70 C at the distal thermocouple, a probe will ablate for a standardized time and yields the following ablation zone sizes:

Ablation tips	OsteoCool 1.0	OsteoCool 2.0	Dimensions
7 mm	6:30 minutes	5:30 minutes	11 mm long × 10 mm wide
10 mm	7:30 minutes	6:00 minutes	17 mm long × 13 mm wide
15 mm	11:30 minutes	8:00 minutes	23 mm long × 18 mm wide
20 mm	15:00 minutes	11:30 minutes	29 mm long × 21 mm wide



The OsteoCool™ independent thermocouple monitors surrounding tissue temperature. The 28 G thermocouple comes with a 20 G spinal needle.

The OsteoMAP℠ technique relies on an OsteoCool™ bone access kit to access bone percutaneously. Access kits are available in 8 G, 10 G, and 13 G, and include an introducer (cannula plus trocar tip stylet) and a bone access drill. The drill is color-coded to correspond with different ablation probe sizes.

BILLING AND CODING INFORMATION

Hospital outpatient coding and payment

Effective January 1, 2024 – December 31, 2024

RFA

A single CPT code identifies RFA of bone tumor, metastatic or benign, regardless of the site.

CPT code[a]	Description	APC[f]	APC level	Status indicator[f,8]	Relative weight[f]	Medicare national average[f,g]
20982	20982 Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis), including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed, radiofrequency[4]	5115	Level 5	J1	143.6551	$12,553

RFA with Vertebroplasty

Note: Although codes for vertebroplasty may be assigned, relative weight and payment are not shown below because RFA code 20982 is assigned to a higher ranked C-APC. Any VP/BKP performed during the same encounter is considered adjunctive and no separate payment is made.

CPT code[a]	Description	APC[f]	APC level	Status indicator[f,8]	Relative weight[f]	Medicare national average[f,g]
20982	20982 Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis), including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed, radiofrequency[4]	5115	Level 5	J1	143.6551	$12,553
Plus						
22510	Percutaneous vertebroplasty (bone biopsy included when performed), 1 vertebral body, unilateral or bilateral injection, inclusive of all imaging guidance; cervicothoracic	5113	Level 3	J1	-	-
22511	Lumbosacral[5]	5113	Level 3	J1	-	-
+22512	each additional cervicothoracic or lumbosacral vertebral body[6]	-	-	N	-	-

RFA with Kyphoplasty

Note: Although codes for Kyphoplasty may be assigned, relative weight and payment are not shown below because RFA code 20982 is assigned to a higher ranked C-APC. Any VP/BKP performed during the same encounter is considered adjunctive and no separate payment is made.

CPT code[a]	Description	APC[f]	APC level	Status indicator[f,8]	Relative weight[f]	Medicare national average[f,g]
20982	20982 Ablation therapy for reduction or eradication of 1 or more bone tumors (eg, metastasis), including adjacent soft tissue when involved by tumor extension, percutaneous, including imaging guidance when performed, radiofrequency[4]	5115	Level 5	J1	143.6551	$12,553
Plus						
22513	Percutaneous vertebral augmentation, including cavity creation (fracture reduction and bone biopsy included when performed) using mechanical device (eg, kyphoplasty), 1 vertebral body, unilateral or bilateral cannulation, inclusive of all imaging guidance; thoracic	5114	Level 4	J1	-	-
22514	Lumbar	5114	Level 4	J1	-	-
+22515	each additional thoracic or lumbar vertebral body[6]	-	-	N	-	-

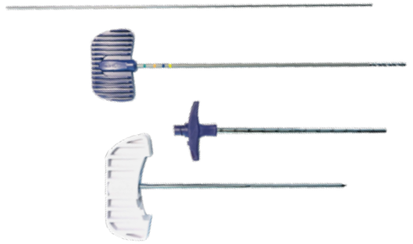
Note: In CPT, the kyphoplasty codes involve a separate and distinct mechanical device, eg, an inflatable balloon or tamp, used in an intentional manner to further develop the defect into a purposeful cavity prior to cement injection.[7]

OsteoCool™ bone access kits

OsteoCool™ hard bone access kit
10 ga, 090mm, BKP

Compatible with Kyphon Express™ I, Express™ II, and Kurve™

OCN002HB



OsteoCool™ bone access
10 ga, 090 mm, BKP

Compatible with Kyphon Express™ I, Express™ II, and Kurve™

OCN002

OsteoCool™ bone access
8 ga, 090 mm, BKP

Compatible with Kyphon Xpander™, Xpander™ II, and Kurve™

OCN003

OsteoCool™ bone access
10 ga, 095 mm, VP

Compatible with Kyphon V™

OCN004

OsteoCool™ bone access
13 ga, 100 mm, VP

Compatible with Kyphon V™

OCN005

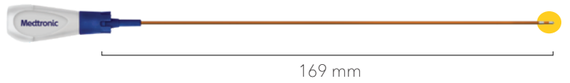
Each kit contains: (1) cannula, (1) stylet with trocar tip and (1) precision drill

Precision drill
17 ga, OC, BKP, and VP

OsteoCool™ single probe kits

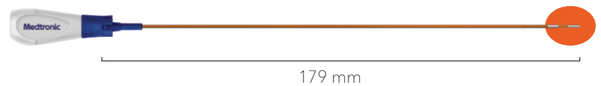
Single probe ablation sizing

OCP107
7 mm
Probe active tip
5:30 minutes
Accelerated timings

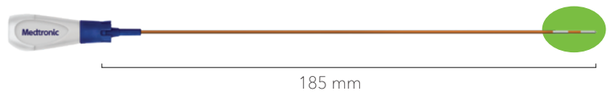


OCP110
10 mm
Probe active tip
6:00 minutes
Accelerated timings

OCP115
15 mm
Probe active tip
8:00 minutes
Accelerated timings

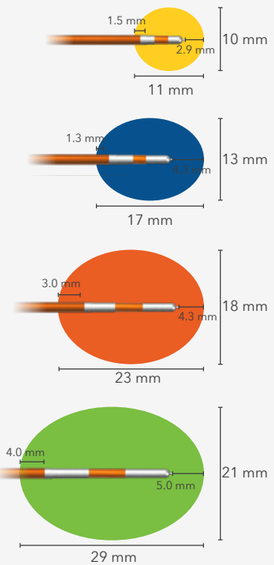


OCP120
20 mm
Probe active tip
11:30 minutes
Accelerated timings



Illustrations above show measurement from top of cannula to tip of probe.

Proportionate, but not actual size



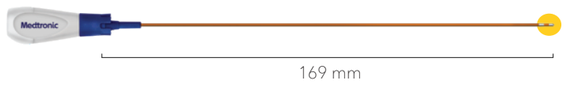
OsteoCool™ burette

Each kit contains: (1) OsteoCool™ RF ablation probe and (1) OsteoCool™ RF ablation burette

OsteoCool™ independent thermocouple
28 ga, 180 mm

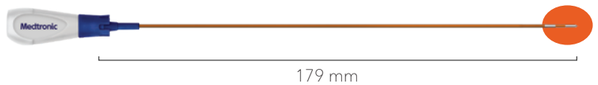
OsteoCool™ 2-probe kits

OCP207
7 mm
Probe active tip
5:30 minutes
Accelerated timings



OCP210
10 mm
Probe active tip
6:00 minutes
Accelerated timings

OCP215
15 mm
Probe active tip
8:00 minutes
Accelerated timings

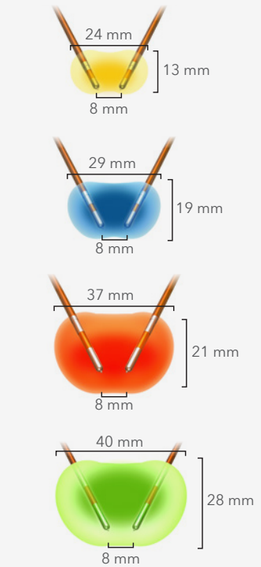


OCP220
20 mm
Probe active tip
11:30 minutes
Accelerated timings

Illustrations above show measurement from top of cannula to tip of probe.

Dual-probe ablation zones

Proportionate, but not actual size



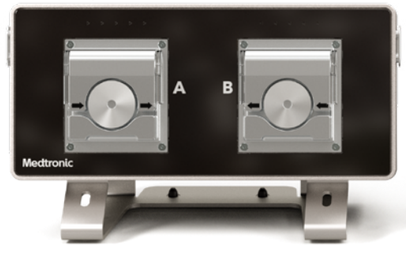
OsteoCool™ burette

Each kit contains: (2) OsteoCool™ RF ablation probes and (2) OsteoCool™ RF ablation burette

OsteoCool™ independent thermocouple 28 ga, 180 mm

Capital equipment

OsteoCool™ pump
OC02-100



OsteoCool™ RF generator
OC01-100

OsteoCool™ probe connector hub
OC04-100

NOTES

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11. https://www.cancer.gov/about-cancer/understanding/statistics

SAFETY INFORMATION

- Intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body
- 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
- Ablation of benign bone tumors such as osteoid osteoma

Risks

- As a consequence of electrosurgery, damage to surrounding tissue through iatrogenic injury could occur
- Pulmonary embolism

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