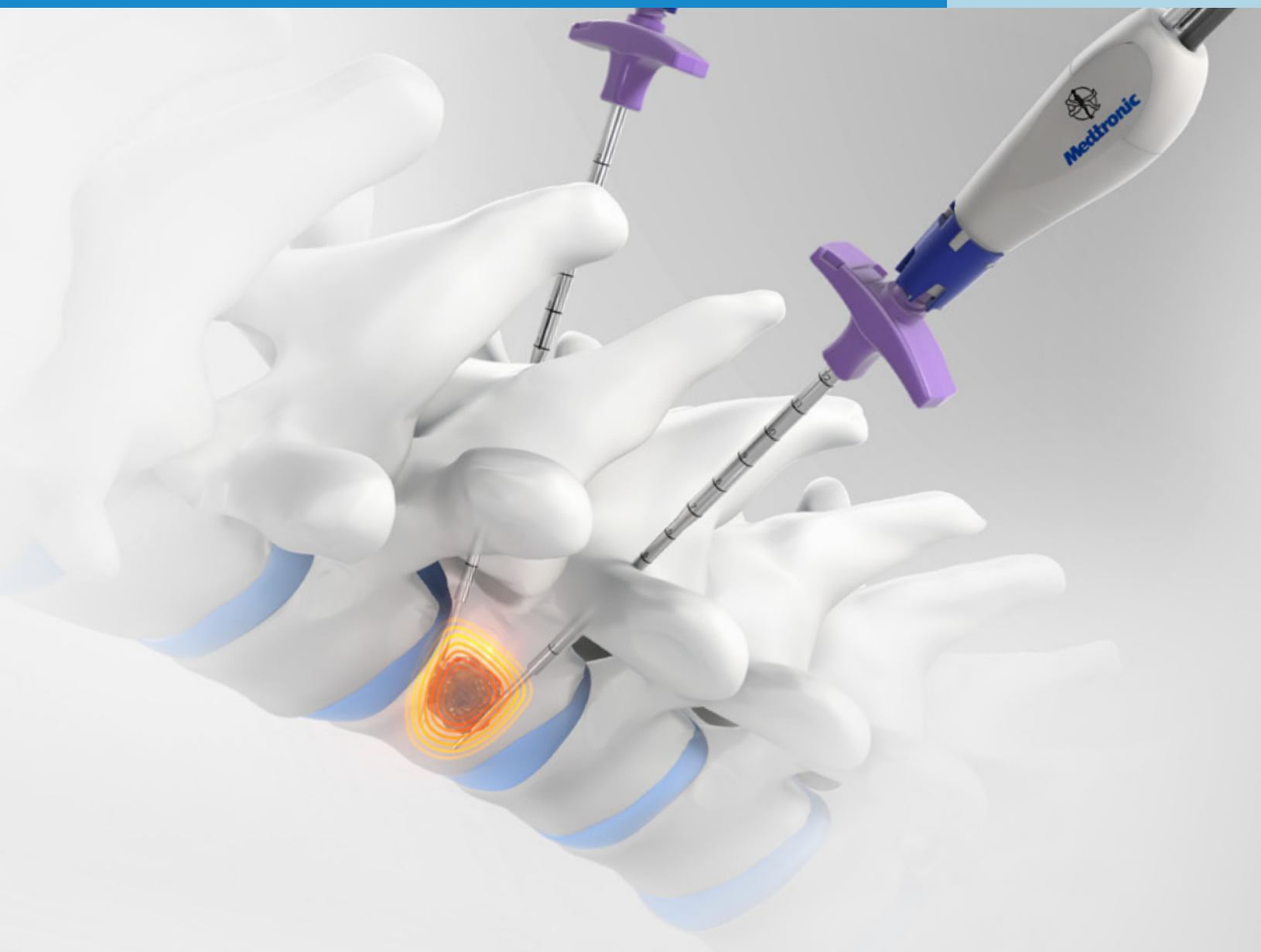


**SURGICAL
TECHNIQUE**

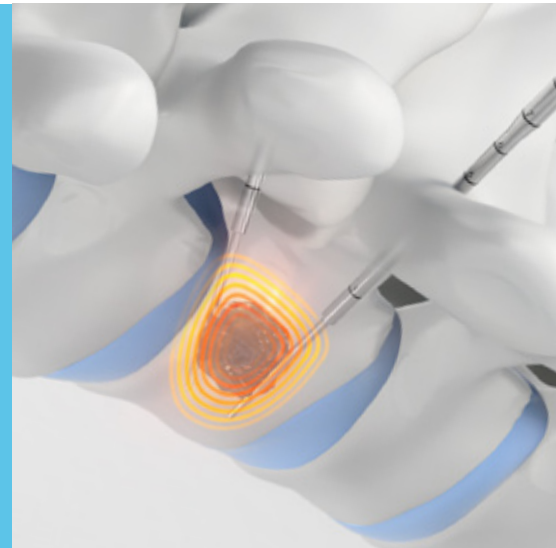
OsteoCool™

RF Ablation System and Bone Access Kits



Medtronic





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The OsteoCool RF Ablation System is indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body. The System contains an RF Generator, Peristaltic Pump and the Connector hub, which provides two channels for the use of the OsteoCool RF Ablation Probes and two channels for use of the OsteoCool Independent Thermocouples.

The OsteoCool RF Ablation Probe uses a coaxial, bipolar technology that delivers localized tumor ablation and automatically moderates power to keep RF heating within the desired treatment range, reducing risks of potential thermal damage to adjacent structures. The active tip of the RF Ablation Probe is internally-cooled with circulating water. RF energy heats the tissue while circulating water moderates the temperature in close proximity to the active tip. This combination creates large volume lesions without excessive heating at the active tip. The OsteoCool RF Ablation Probes are sterile and intended for use within a single vertebral body.

The OsteoCool Bone Access Kit is a single use device intended to contact body tissues. Do not reuse, reprocess, or resterilize.

The OsteoCool Independent Thermocouple is for optional temperature monitoring at or near the site of ablation.

A physician using this equipment must be familiar with spine anatomy, image-guided spine procedures and vertebral body access techniques.

Refer to the OsteoCool Instructions for Use for Complete Generator and Pump Setup.

Important

This guide does not replace the information in the Instructions for Use provided with the components of the OsteoCool RF Ablation System, OsteoCool RF Ablation Probes, OsteoCool Bone Access Kits and the OsteoCool Independent Thermocouple. The Instructions for Use includes important information such as warnings, precautions, contraindications, and troubleshooting. It is important to read the Instructions For Use and these precautions carefully prior to device operation. Additional help information can be accessed through the "help" button located on the generator screen.

OSTEOCOOL SYSTEM SET-UP

The OsteoCool System may be mounted to either a rolling Cart or a Table Top Desk Stand. For mounting the device on a desk stand, proceed to the Desk Stand Assembly and Mounting. For mounting on the Cart, proceed to Cart Mounting Instructions.

Desk Stand Assembly & Equipment Mounting

1. Assemble the desk stand by sliding the pole into the base and tightening the set screw with the provided Allen wrench (**Figure 1**).
2. Position the desk stand on a stable surface and in close proximity to an electrical source.
3. Mount the pump by sliding the quick connect bracket on the back of the pump down the opposite mounting bracket located on the bottom of the desk stand (**Figure 2a**). Mount the generator by sliding the quick connect bracket on the back of the generator down the opposite mounting bracket located on the top of the desk stand (**Figure 2b**).
4. Proceed to cable connection.

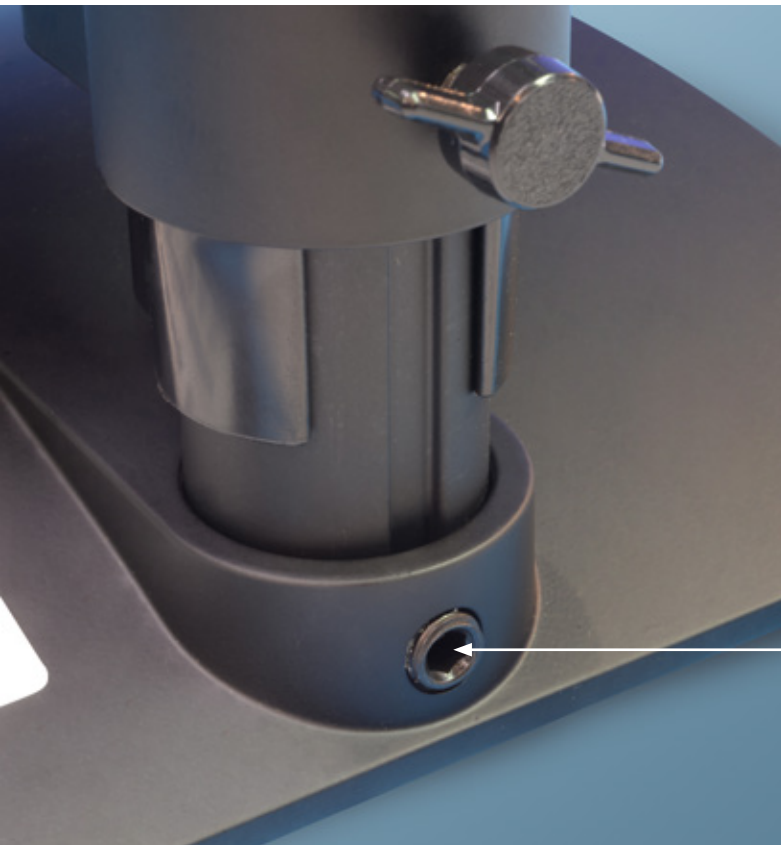
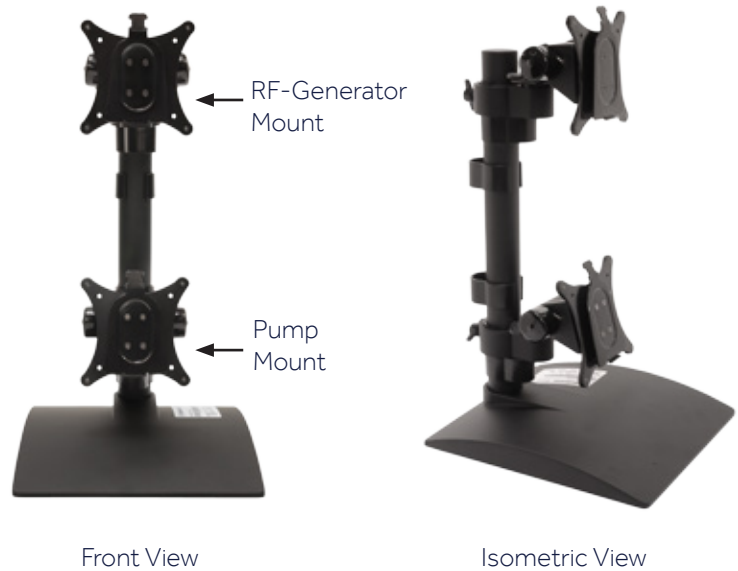


Figure 1



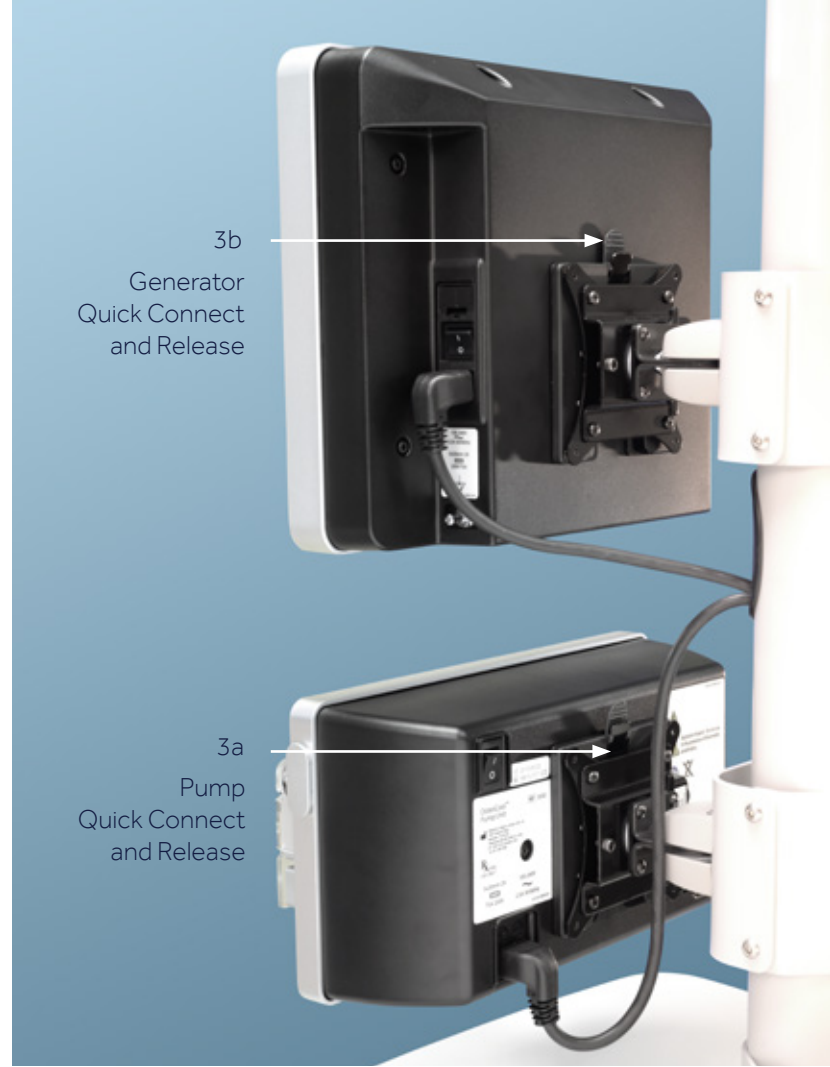
Figures 2a (Pump Bracket) and
2b (Generator Bracket)

Cart Mounting

1. Position the cart in proximity to an electrical source.
2. Lock the wheels on the cart before mounting the devices.
3. Mount the pump by sliding the quick connect bracket on the back of the pump down the opposite mounting bracket located on the bottom of the cart (**Figure 3a**).

Mount the generator by sliding the quick connect bracket on the back of the generator down the opposite mounting bracket located on the top of the cart (**Figure 3b**).

4. Do not adjust the position of the mounting brackets.
5. Proceed to cable connection.



Figures 3a and 3b

Connect Cables and Power on the Generator and Pump

1. After assembly, Connect pump and the generator with the connector cable to USB ports on the back of both pump and generator (**Figures 4a and 4b**).

Plug the USB Type A plug to the Generator, and the USB Type B plug into the Pump.

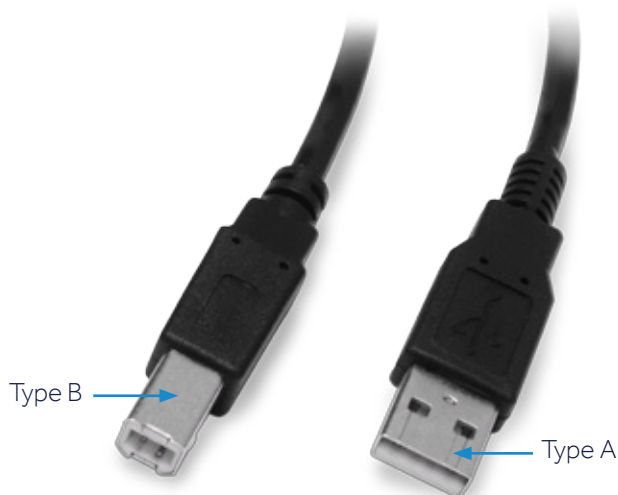


Figure 4a



Figure 4b

Connect Cables and Power on the Generator and Pump

2. Connect power cables to the back of both the generator and pump
 - a. **Connecting Power Cables with the Desk Stand:**
Route the cable to the backside of the pole and use the clips on the desk stand to manage the power and USB cables (**Figure 5a**).
 - b. **Connecting Power Cables with the Cart:**
The Cart is provided with cables that are fed through the cart pole. Attach the connections located near the mounting brackets to the back of the generator and pump. The socket end of the cables, which come out near the bottom of the cart pole, should be connected directly to the power cables provided with the generator and pump.
3. Plug both power cables into surge protector/power strip.
4. Power on the generator using the Power Switch located on back of device (**Figure 5b**).



Figure 5a



Power Switch

Figure 5b

- Note**
The circular power button located on the front (top right corner) of the device is to initiate radiofrequency ablation, not to turn on power to the generator.
5. After powering on Generator, power on the pump using the Power Switch located on the back of the device.
- Note**
Powering on the Pump before Powering on the Generator is not recommended as it could lead to system error.
6. Following the on-screen setup instructions, connect the Connector Hub to the front of the generator. (**Figure 6**)



Figure 6

PATIENT POSITIONING

1. The patient should be placed in the prone position for access to the spine.
2. Using appropriate image guidance confirm the target location for treatment and proceed with the necessary skin incision.



USE OF OSTEOCOOL BONE ACCESS KITS

1. Insert the Stylet into the Cannula to form the OsteoCool osteointroducer.
2. Using fluoroscopic image guidance, insert the osteointroducer at the desired site.
3. Using manual control and appropriate imaging guidance, advance the osteointroducer through the soft tissues into the selected bone to the desired depth.
4. A surgical mallet may be used to augment the insertion of the osteointroducer.



Note

Markings on the Cannulas should be used as reference marks only. They are not intended to replace the use of fluoroscopic observation.

Note

The design of the OsteoCool osteointroducer offers an internal stylet that extends beyond the distal end of the cannula. This design is intended to provide a visual indication under image guidance of where the posterior margin of the ablation zone with the OsteoCool RF Ablation probe will stop.

Caution

To maintain structural integrity, do not advance the Cannula without the Stylet fully inserted.

5. While holding the Cannula, rotate the handle 180° counter-clockwise to remove the Stylet. Proceed to use of OsteoCool Precision Drill.

For bi-pedicular ablation, repeat the steps above.



USE OF OSTEOCOOL PRECISION DRILL

1. After gaining access into the vertebral body using the OsteoCool Osteoinducer, advance the OsteoCool Precision Drill down the Cannula lumen into the vertebral body.
2. Using manual control and imaging guidance, rotate clockwise and advance the Precision Drill to the desired depth. This depth will serve as the anterior boundary for the ablation zone.

Note

The color markings on the proximal shaft of the OsteoCool Precision Drill correlate with sizes of the OsteoCool RF Ablation Probes.



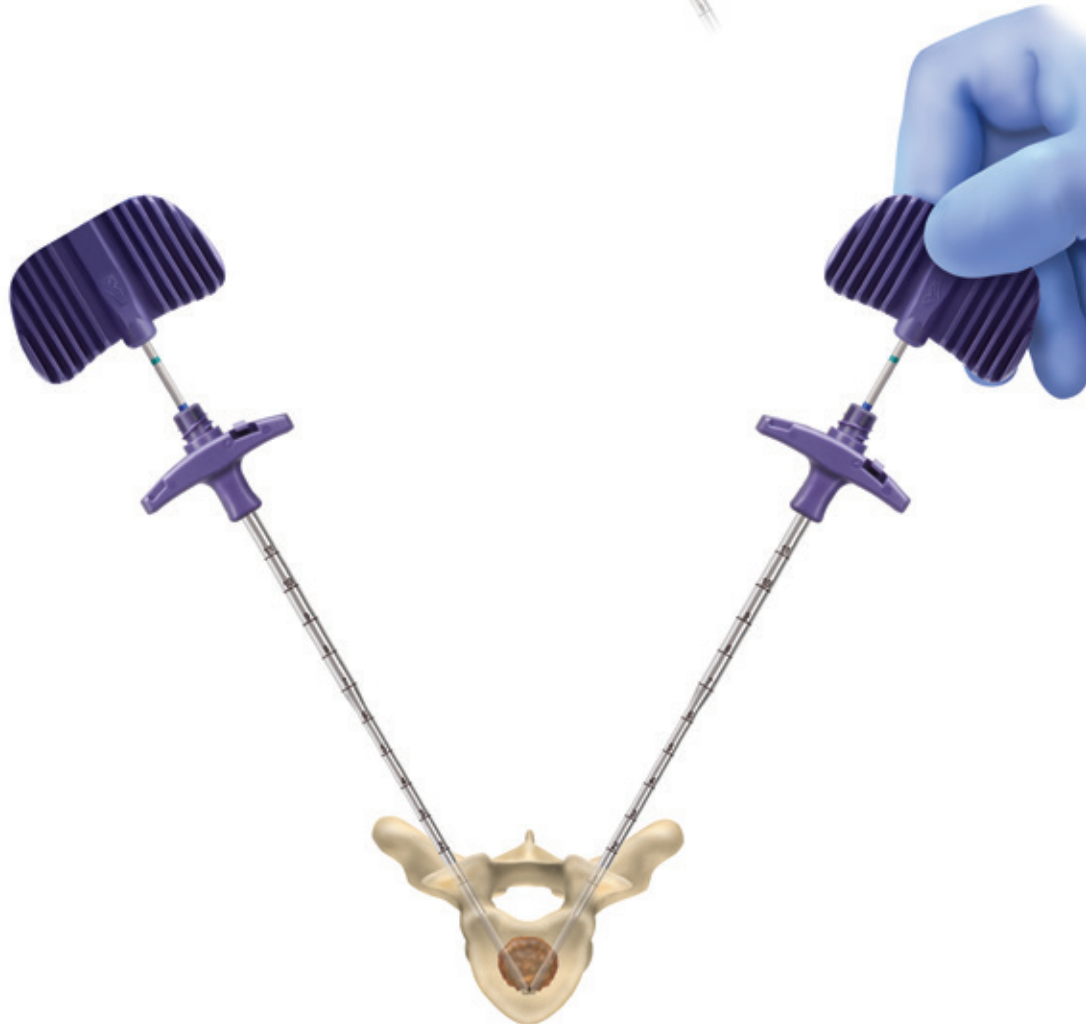
3. Read the color marking on the proximal end of the drill to aid in probe selection. If the drill positioning is in between color markings, the user should advance or retreat to a color marking. Select the probe size which corresponds with the color marking.

Note

Markings on the Drill should be used as reference marks only. They are not intended to replace the use of fluoroscopic observation.

4. Remove the OsteoCool Precision Drill from the Cannula lumen using clockwise rotation. The target site is now ready for ablation probe placement.

For bi-pedicular ablation, repeat the steps above. Product testing recommends a distance of 8-10mm between the distal tips of the probes to yield the largest ablation zone.

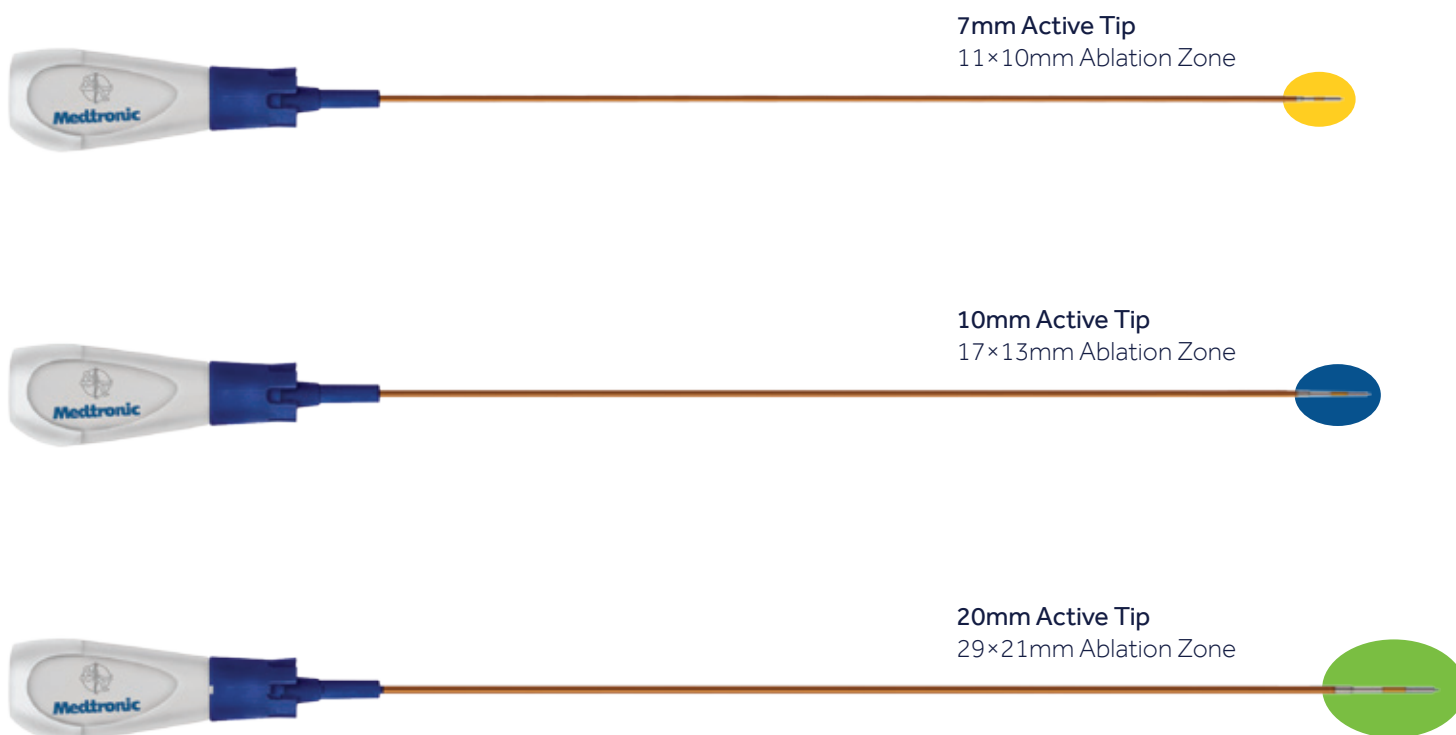


OSTEOCOOL RF ABLATION PROBE SELECTION AND TUBE KIT PREPARATION

1. Select the OsteoCool RF ablation probe size of choice for the procedure.

Note

If the OsteoCool Precision Drill was used, select the probe size which coordinates with the color marking on the drill shaft.



FILL OSTEOCOOL TUBE KIT AND INSERT INTO PUMP UNIT

1. Once an OsteoCool RF Ablation Probe Kit has been chosen, remove the Tube Kit and probe from the sterile package and place in the sterile field

Fill the burette with sterile water

1. Fill the burette to the 70 mL mark with room temperature sterile water by one of the following options:
Option 1: injecting through the port in the lid or Option 2: removing the lid and pouring directly into the burette.

Burette Fill—Option 1

- a. Inject sterile water through the port in the lid
 - a1. Place sterile syringe in the port.
 - a2. Inject 70 mL of sterile water at room temperature into the burette.

Burette Fill—Option 2

- a. Remove the lid and pour sterile water into the burette
 - a1. Open the lid by pressing in and up with your thumbs around one of the three petals.
 - a2. Observe proper sterile handling technique while filling the burette; do not place the lid of the burette down on a non sterile surface.
 - a3. The fill lines on the burette represent 70 mL and 80 mL respectively.
 - a4. After filling to between the lines, snap the lid back into place on the burette.



2. Put the burette into the Pump Unit's burette holder.
3. Open the pump head lid and thread the thicker tubing from the bottom of the burette into the pump head tube holder.
4. Ensure that the tubing is properly placed between the notches and along the center channel beneath the pump head.

Warning

Improper positioning of the tubing can pinch the tube and restrict the water flow.

5. Close the lid in order to hold the tubing in place. Leave the luer lock caps on the tubing until you are ready to connect the probes so the inner pathway of the tube kit remains sterile.



CONNECT THE PROBE TO THE TUBE KIT

1. Pass the tubing and electrical connections on the probe out of the sterile field.
2. Remove the caps on the male and female luer locks for both the Tube Kit and the chosen probe. Connect the appropriate luer lock on the Tube Kit to the corresponding luer lock on the probe.

Warning

DO NOT over tighten the connection. Maintain sterility of the tubing's inner pathway so in case water is accidentally spilled in the sterile field, sterility will not be compromised.



CONNECT TO THE OSTEOCOOL CONNECTOR HUB

The OsteoCool Connector hub provides two channels for the use of the OsteoCool RF Ablation Probes and two channels for use of OsteoCool Independent Thermocouples (ITC).

The white ports (top) accept the RF ablation probes. The black ports (bottom) accept the independent thermocouples.

1. Connect the male connector on the OsteoCool RF Ablation Probe to the female connector on the OsteoCoolConnector Hub.
2. Confirm via on-screen information that the OsteoCool probe has been detected and is ready for use.

Note

The Generator will quickly detect the probe then indicate a "High Impedance" error while the probe is outside of tissue. When probe is placed in tissue, the "High Impedance" error will automatically disappear.



PERFORM RF ABLATION WITH OSTEOCOOL SYSTEM

1. The RF Ablation probes are provided with a pre-assembled spacer. Discard or Keep the spacer based on the bone access tool used. Reference chart below:

2. Place the OsteoCool RF Ablation probe through the bone access cannula, ensuring it is fully seated in the cannula.

Warning

Never force the probe in if significant resistance is felt.

3. Confirm under image guidance that the proximal radiopaque marker has fully surpassed the distal end of the cannula.

Warning

Incorrect use of the spacer may result in improper probe clearance from the cannula.

Description/Size	Part Number	Directions
OsteoCool Bone Access Kit 10G 090	OCN002	Use with Spacer
OsteoCool Bone Access Kit 8G 090	OCN003	Use with Spacer
OsteoCool Bone Access Kit 13G 100	OCN005	Discard Spacer



Remove for use with OCN005.



Proper use with OCN002 and OCN003.



4. When the screen shows "Ready," press on the RF Power button. Ablation time is pre-set based on the active tip size of the probe(s) being used.
 - a. Pre-set ablation times are shown at right.

Note

Additional modifications to procedure settings can be adjusted on the RF Generator User Interface. Refer to the User Manual for instruction on changing these settings.

5. Allow the generator to complete the ablation, monitoring intermittently for any signs of error on the generator screen.
 - a. The ablation will terminate automatically as soon as the set ablation time is reached.
6. After the ablation is complete, remove the probe from the cannula and detach from the tube kit and discard as biohazardous waste. Detach the tube kit from the generator and discard as biohazardous waste.
7. The OsteoCool Bone Access Cannula is still in place and ready to accept other instrumentation.

Label Color	Product Code	Active Tip	Lesion Size	Ablation Time
Yellow	OCP107 and OCP207	7 mm	11 × 10 mm	6:30 min
Blue	OCP110 and OCP210	10 mm	17 × 13 mm	7:30 min
Green	OCP120 and OCP220	20 mm	29 × 21 mm	15:00 min

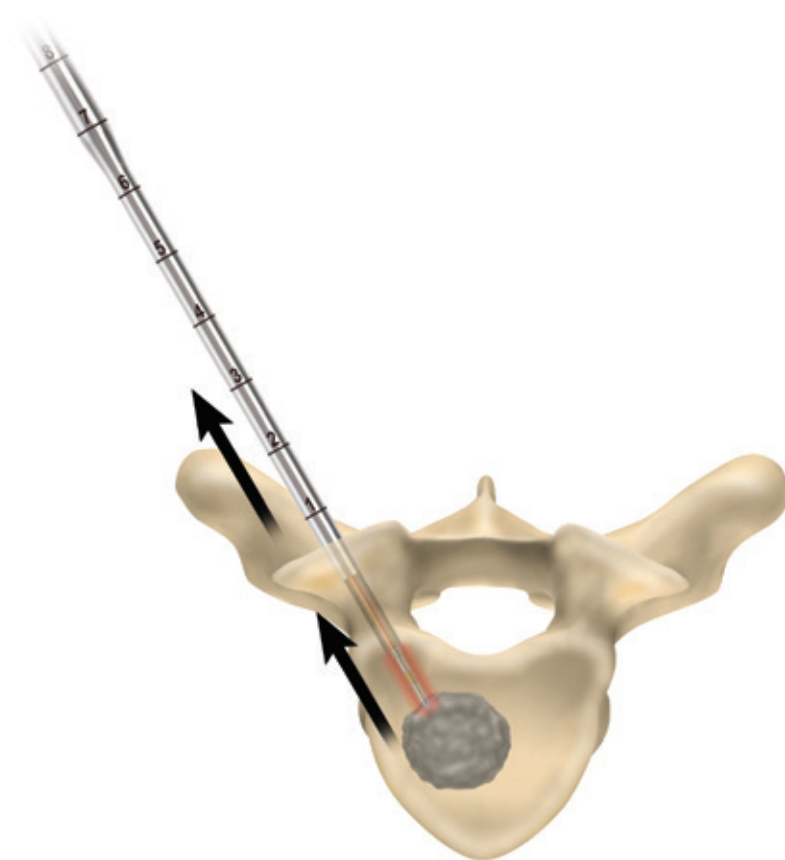


OPTIONAL TRACK ABLATION WITH OSTEOCOOL RF ABLATION SYSTEM

1. To burn the track with the OsteoCool RF Ablation system, select "Retract" on the Generator screen.
2. Press the RF power button.
3. The screen will signal when the RF ablation track burn has initiated.
4. Slowly pull back on the RF ablation probe and cannula simultaneously. When the desired end point for track ablation is reached, press the RF power button to stop RF delivery.

Warning

Burning the track all the way to the skin can result in skin burns. It is recommended to end track burn prior to this point.



OPTIONAL TEMPERATURE MONITORING WITH THE INDEPENDENT THERMOCOUPLE

The OsteoCool Independent Thermocouple provides real-time temperature information to the user to assist in gauging ablation zone margins to ensure there is no inadvertent thermal damage to adjacent critical structures. The temperature detected by the OsteoCool Independent Thermocouple is displayed by the OsteoCool RF Generator.

1. Insert the Thermocouple into the provided introducer.
2. Connect the male connector on the thermocouple to the female connector on the OsteoCool Connector Hub.
3. Confirm via on-screen information that the OsteoCool Thermocouple (Sensor) has been detected.
4. Access site and place thermocouple in tissue to be monitored

BONE ACCESS FOR SUBSEQUENT PROCEDURES

Bone access can be used for a subsequent physician directed procedure such as cementoplasty, vertebroplasty or Kyphoplasty. Check to make sure that such procedures are compatible with the OsteoCool Bone Access Introducer length and gauge.



Indications for Use

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.

GENERAL SAFETY GUIDELINES

For desired tissue heating and anatomical access abide by the following guidelines:

Avoid advancing the probe into bone tissue without first using the introducer and drill to create a clear channel for the probe. Forcing the probe through bone tissue may cause damage to the probe.

PRODUCT ORDERING INFORMATION

OsteoCool RF Ablation Probes

OsteoCool RF Generator	OC01
OsteoCool RF Pump	OC02
OsteoCool RF Pump Cable	OC03
OsteoCool Connector Hub	OC04

OsteoCool RF Ablation Probes

Probe Kit OsteoCool RF 17G 7mm	OCP107
Probe Kit OsteoCool RF 17G 10mm	OCP110
Probe Kit OsteoCool RF 17G 20mm	OCP120
Dual Probe Kit OsteoCool RF 17G 7mm	OCP207
Dual Probe Kit OsteoCool RF 17G 10mm	OCP210
Dual Probe Kit OsteoCool RF 17G 20mm	OCP220

OsteoCool Bone Access Kits

OsteoCool Bone Access Kit 10G 090	OCN002
OsteoCool Bone Access Kit 8G 090	OCN003
OsteoCool Bone Access Kit 13G 100	OCN005

OsteoCool Carts and Stands

OsteoCool Cart Stand	OCA01
OsteoCool Desk Stand	OCA02

Temperature Monitoring

Thermocouple OsteoCool ITC 180mm	OCN001
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IMPORTANT PRODUCT INFORMATION

- OsteoCool RF Ablation System: Intended for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.
- OsteoCool Bone Access Kits: Indicated for percutaneous access to bone.
- OsteoCool Independent Thermocouple: Intended for measuring tissue in temperature throughout an RF ablation procedure.

The OsteoCool RF Ablation System is contraindicated for use in the cervical spine and for use in patients with pacemakers or other electronic implants.

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The surgical technique shown is for illustrative purposes only. The technique(s) actually employed in each case will always depend upon the medical judgment of the surgeon exercised before and during surgery as to the best mode of treatment for each patient.

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.

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