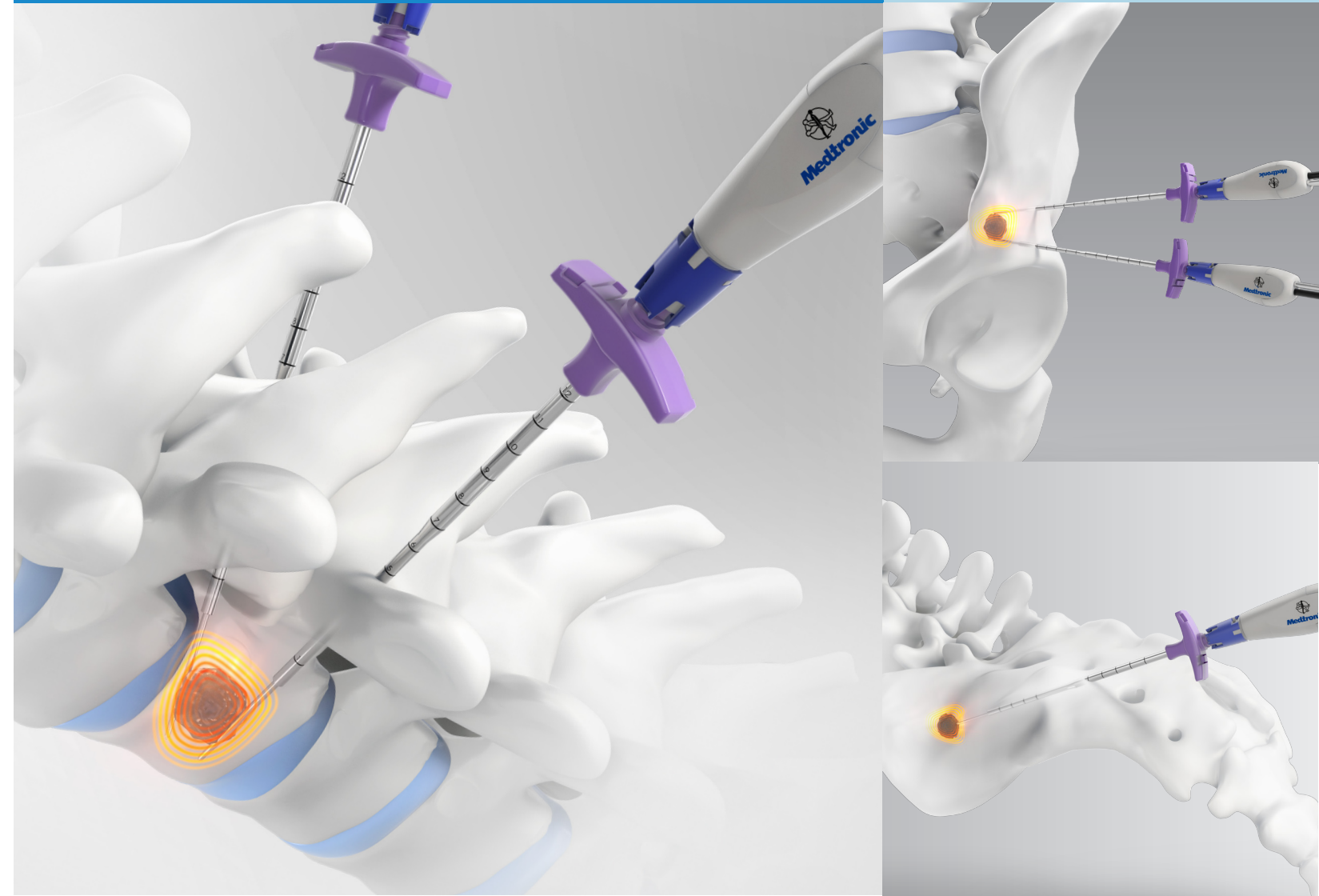


SURGICAL TECHNIQUE

OsteoCool™ RF Ablation System and Bone Access Kits



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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.

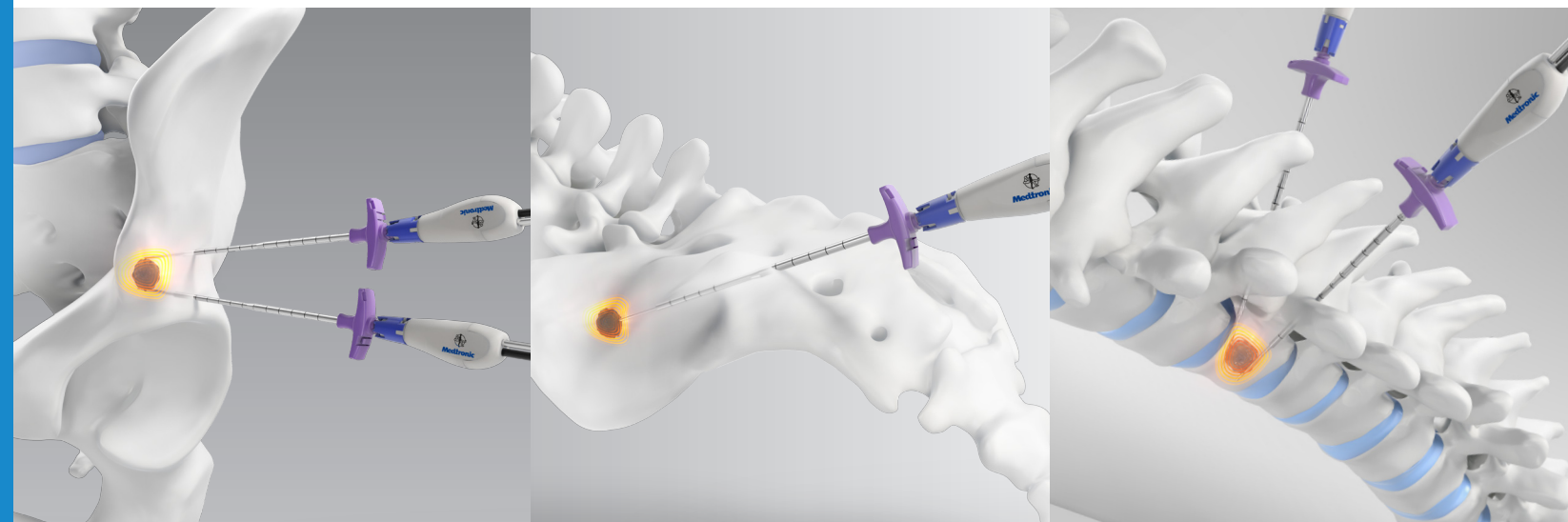
Note: Manuals can be viewed using a current version of any major internet browser. For best results, use Adobe Acrobat™ Reader with the browser.

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The OsteoCool™ RF Ablation System is indicated for palliative treatment in spinal procedures by ablation of metastatic malignant lesions in a vertebral body.

It also is 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.

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 single use.

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 bony anatomy, image-guided procedures, and bone 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.

Please note that the anatomy included in this guide reflects some of the most common locations for metastatic bone tumors — spine, pelvis, and hip — but it is not all inclusive of areas in which the OsteoCool™ system can be used. The OsteoCool™ RF Ablation System is indicated 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.

SYSTEM SETUP

The system may be mounted on a rolling cart or a desk stand (see following instructions).

Desk Stand Assembly and 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.

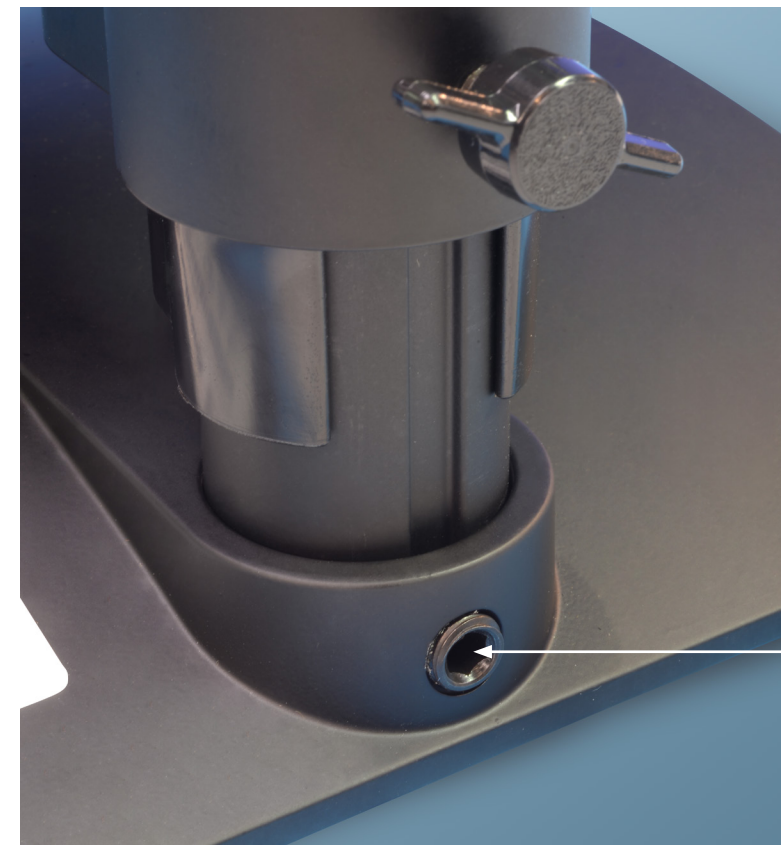
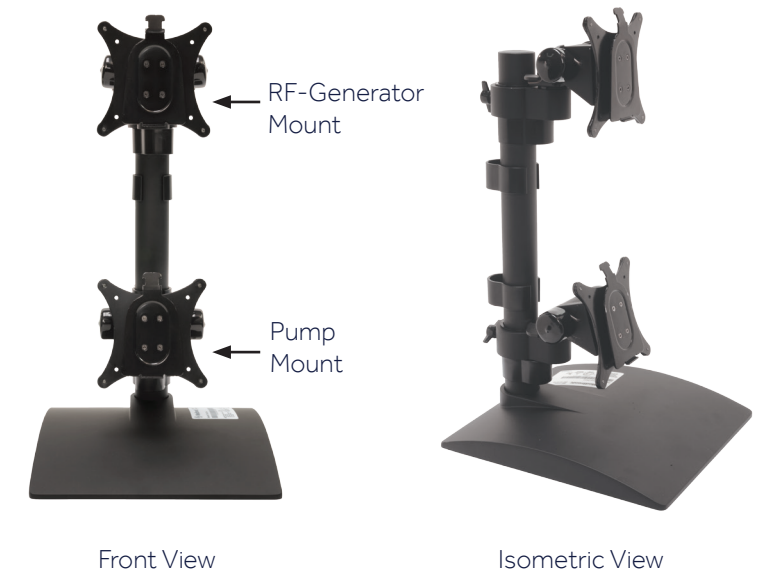
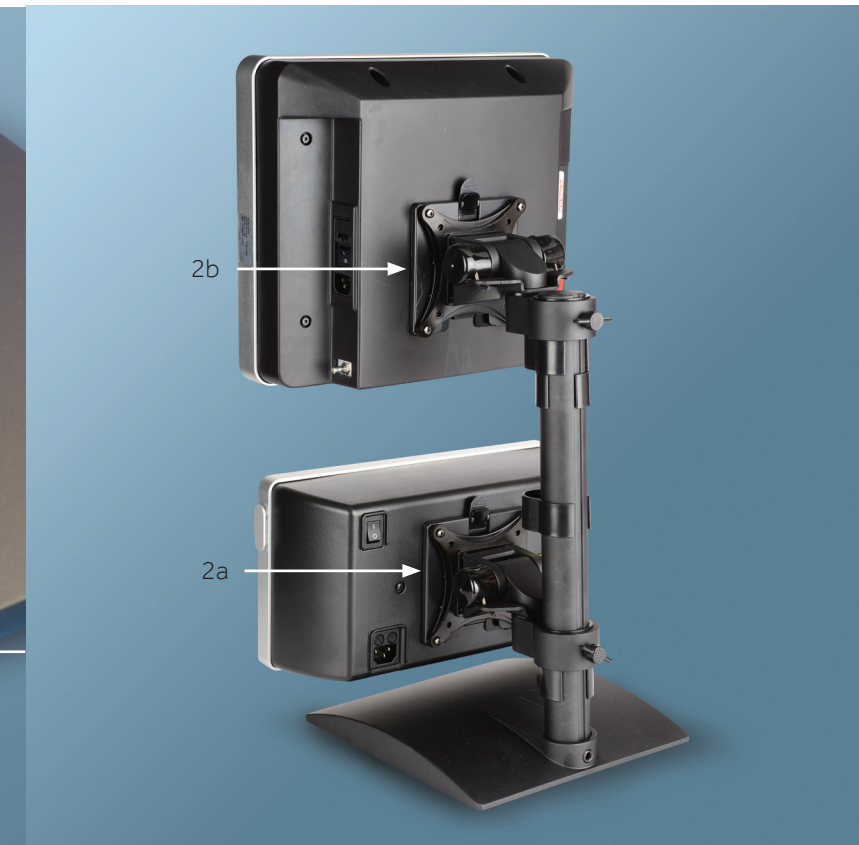


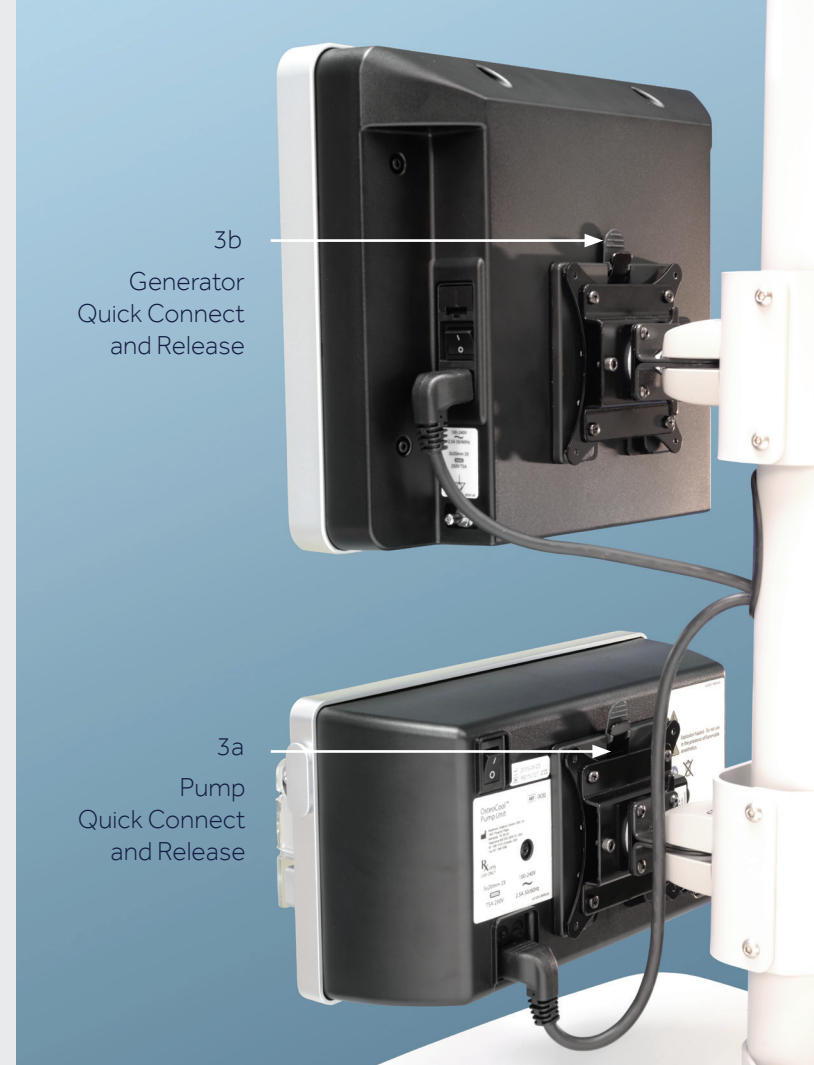
Figure 1



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.

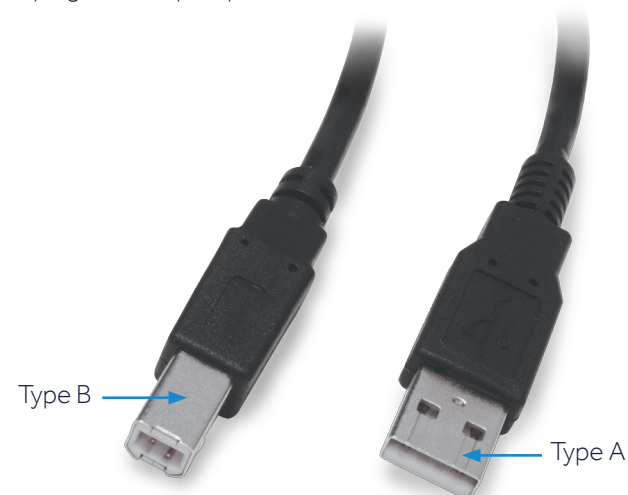


Figure 4a



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 a surge protector/power strip.
4. Turn on the generator using the power switch located on the back of the device (**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 turning on the generator, turn on the pump using the power switch located on the back of the device.

Note
Turning on the pump before turning 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 5a

Power Switch

Figure 5b



Figure 6

PATIENT POSITIONING

1. Place the patient in the prone position for access to the spine.

Note: For access to other areas of bone, a supine or lateral patient positioning may be more effective for gaining appropriate access.

2. Using appropriate image guidance, confirm the target location for treatment and proceed with the necessary skin incision(s).



OSTEOMAP TECHNIQUE USING BONE ACCESS KITS — SPINE

1. Insert the stylet into the cannula to form the osteointroducer.

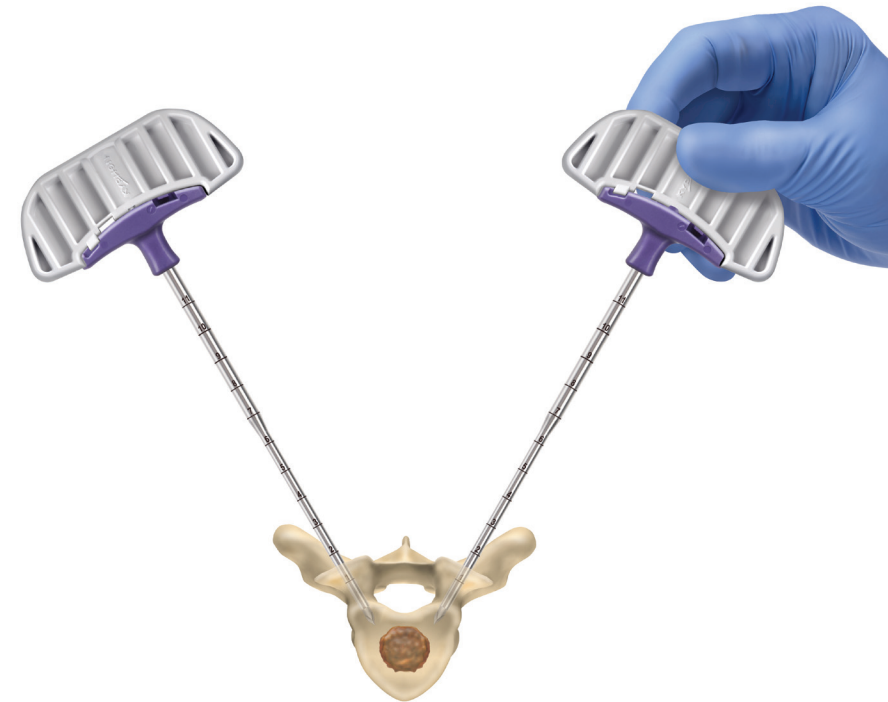
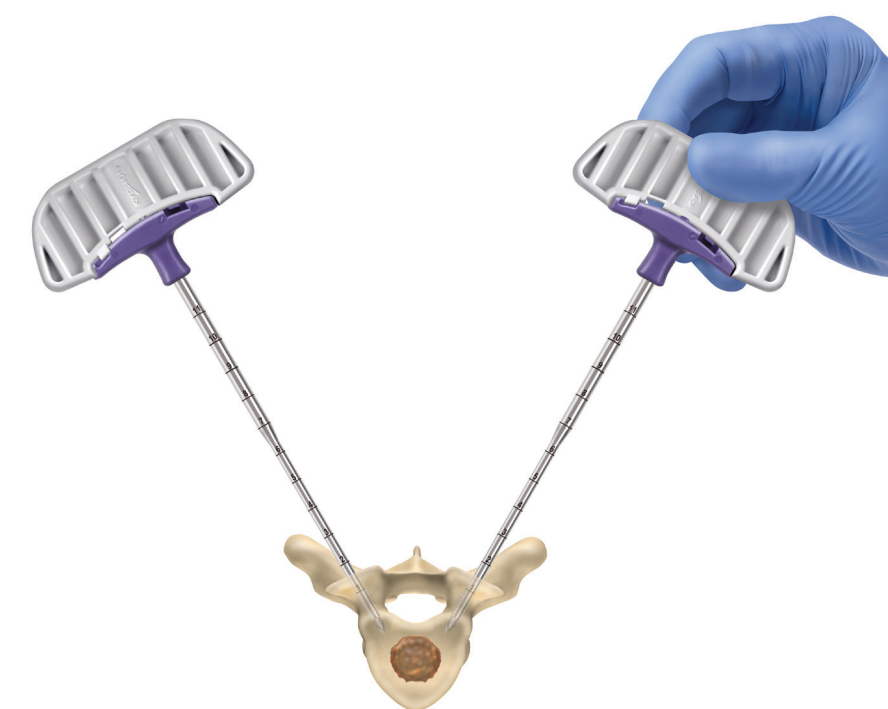
2. Using fluoroscopic image guidance, insert the osteointroducer at the desired site.

3. Using manual control and appropriate image 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.

5. While holding the cannula, rotate the handle 180 degrees counter-clockwise to remove the stylet. Proceed with the OsteoCool™ precision drill.

For bi-pedicular ablation, repeat the steps above.



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 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.

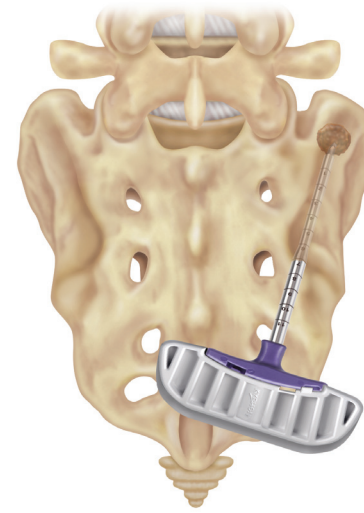
OSTEOMAP TECHNIQUE USING BONE ACCESS KITS — SACRUM, ILIAC, AND ACETABULUM

1. Insert the stylet into the cannula to form the osteointroducer.
2. Using CT or fluoroscopic image guidance, insert the osteointroducer at the desired site.
3. Using manual control and appropriate image 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.
5. While holding the cannula, rotate the handle 180 degrees counterclockwise to remove the stylet. Proceed with the OsteoCool™ precision drill.

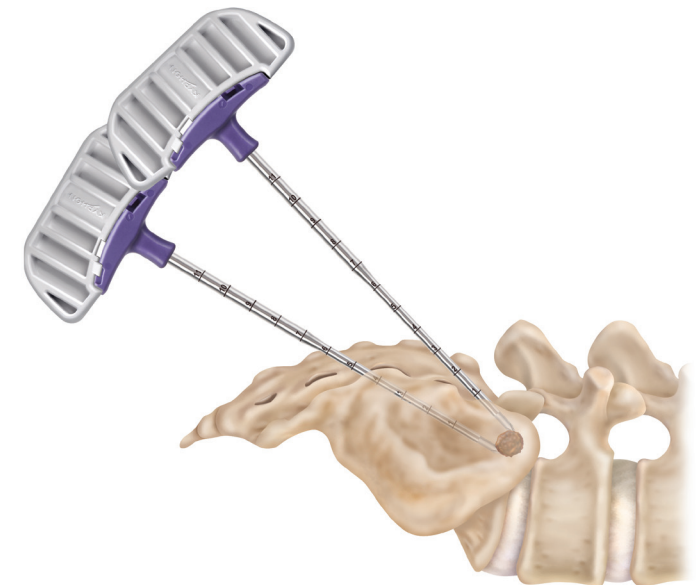
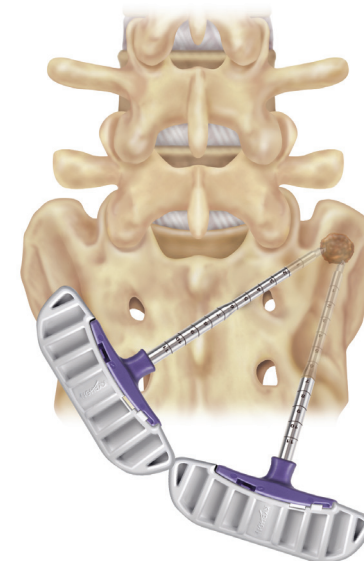
For ablation using two probes, repeat these steps.

SACRUM

One-probe approach:

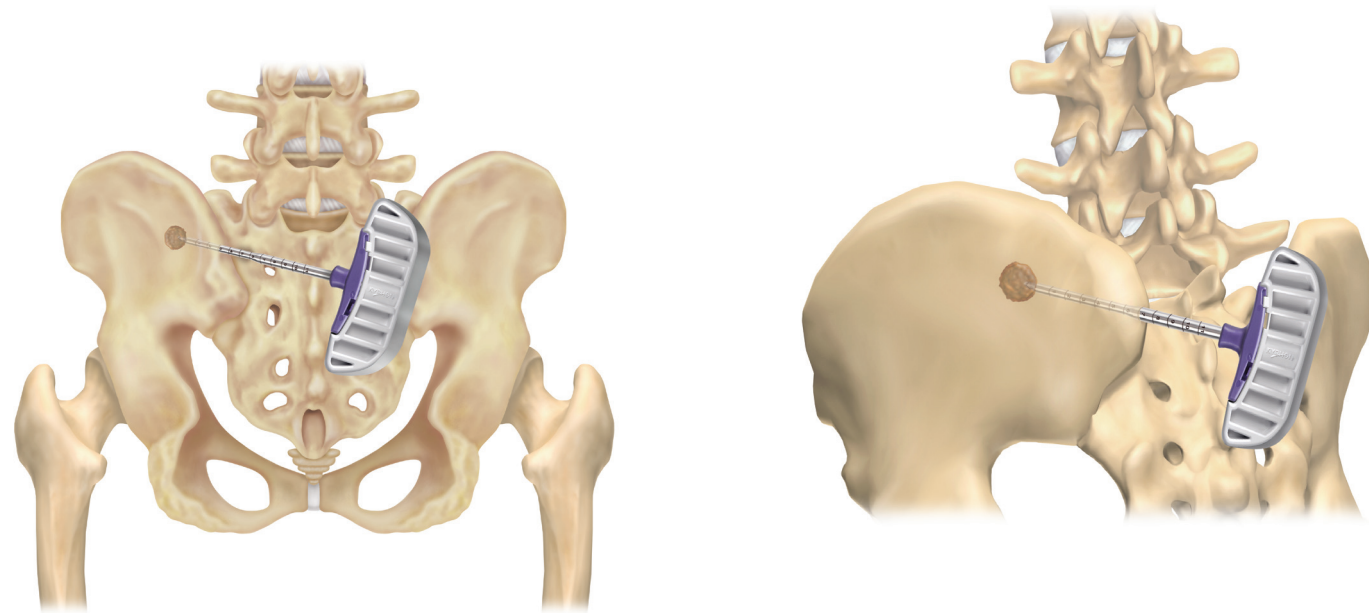


Two-probe approach:

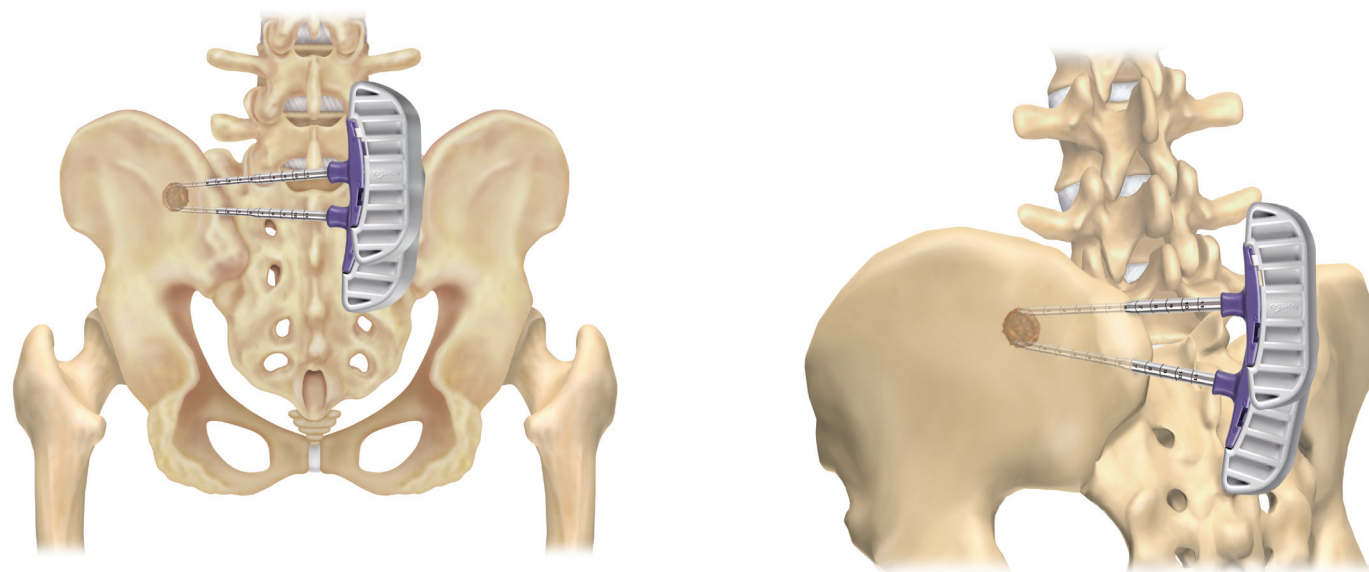


ILIAC

One-probe approach:



Two-probe approach:

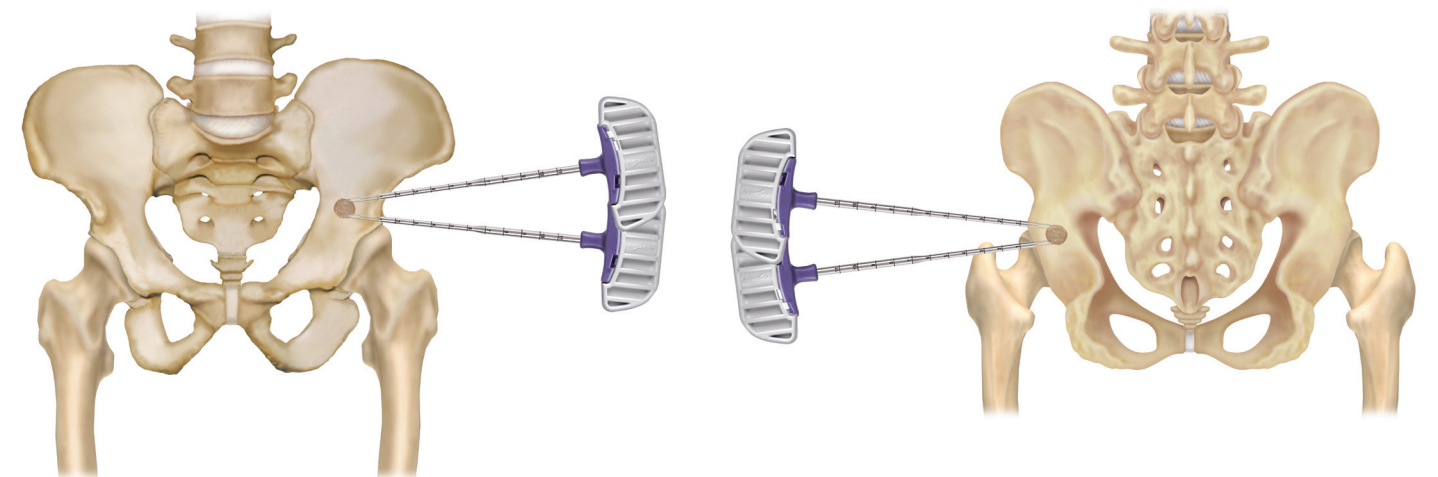


ACETABULUM

One-probe approach:



Two-probe approach:



Note

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

Note

The OsteoCool™ osteointroducer offers an internal stylet that extends beyond the distal end of the cannula. The 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

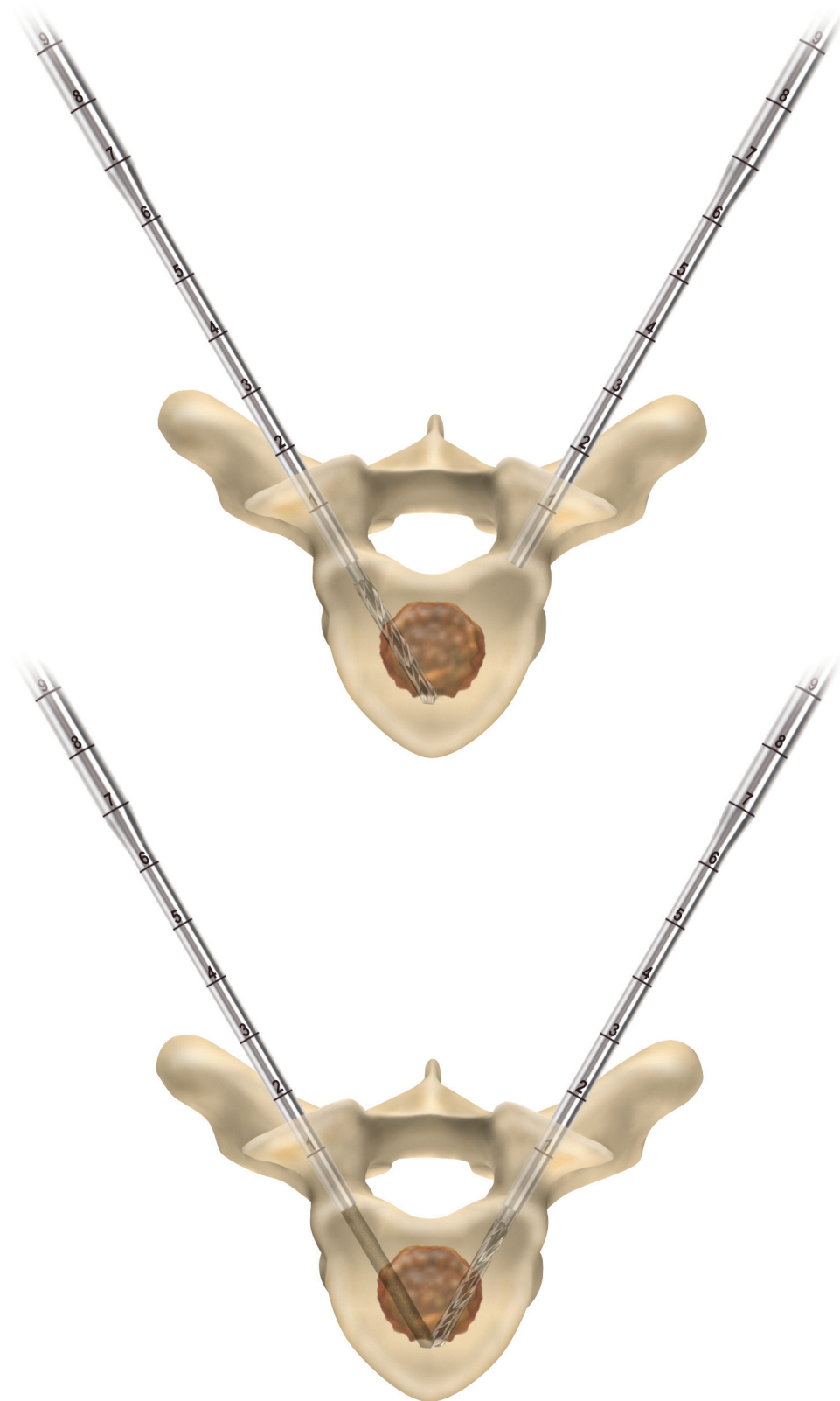
To maintain structural integrity, do not advance the cannula without the stylet fully inserted.

USE OF THE PRECISION DRILL — SPINE

1. After gaining access to the vertebral body using the osteoinducer, advance the precision drill down the cannula lumen into the vertebral body.
2. Using manual control and image 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.



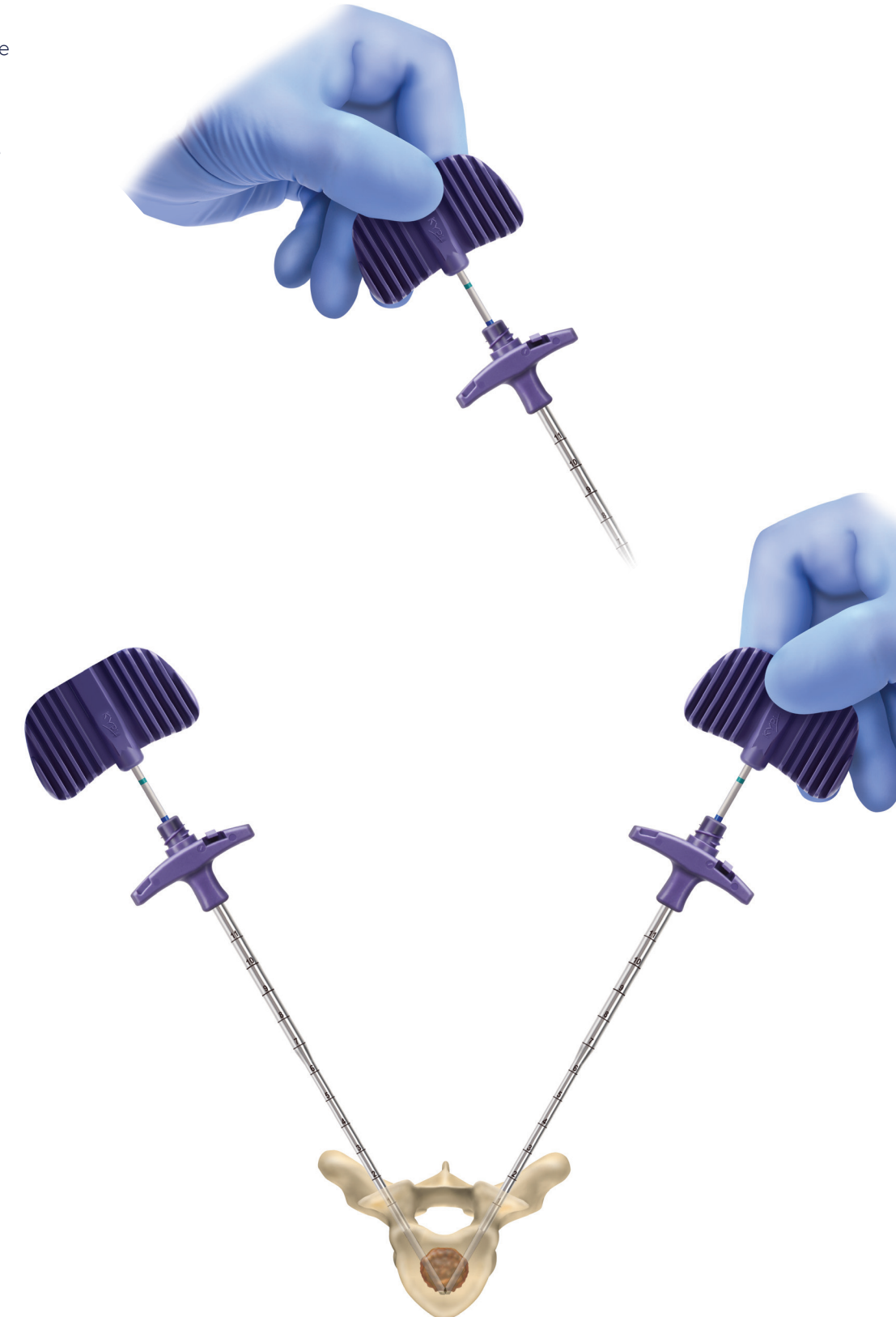
3. Read the color marking on the proximal end of the drill to aid in probe selection. If the drill positioning is in between color markings, advance or retreat to a color marking. Select the probe size that corresponds with the color marking.

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 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 8–10 mm between the distal tips of the probes to yield the largest ablation zone.



USE OF THE PRECISION DRILL — SACRUM, ILIAC, AND ACETABULUM

1. After gaining access into bone using the osteointroducer, advance the precision drill down the cannula lumen into the tissue.
2. Using manual control and image 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, advance or retreat to a color marking. Select the probe size that corresponds with the color marking.

Note

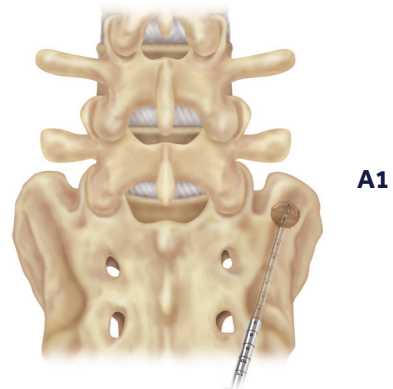
Markings on the drill should be used as reference marks only. They are not intended to replace the use of CT or fluoroscopic observation.

4. Remove the precision drill from the cannula lumen using clockwise rotation. The target site is now ready for ablation probe placement.

For ablation using two probes, repeat the steps above.

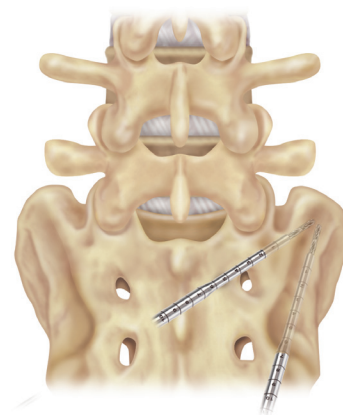


A. Sacrum



A1

A2

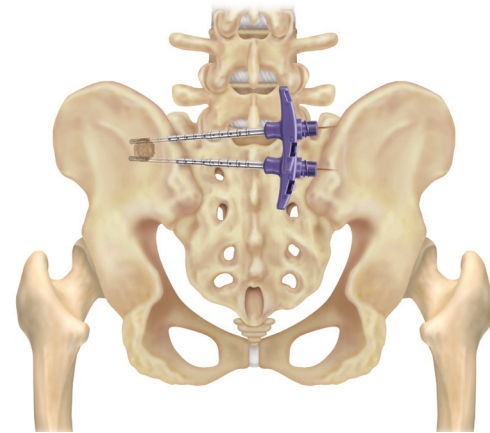


B. Iliac

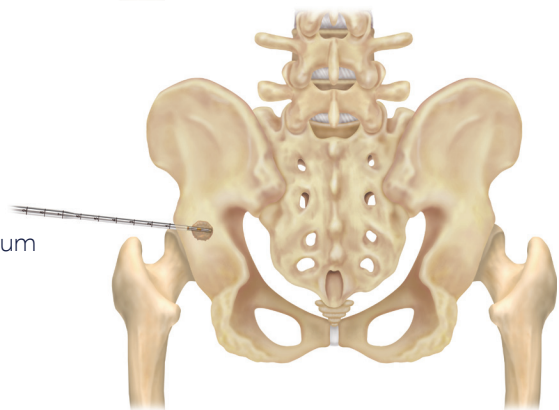


B1

B2

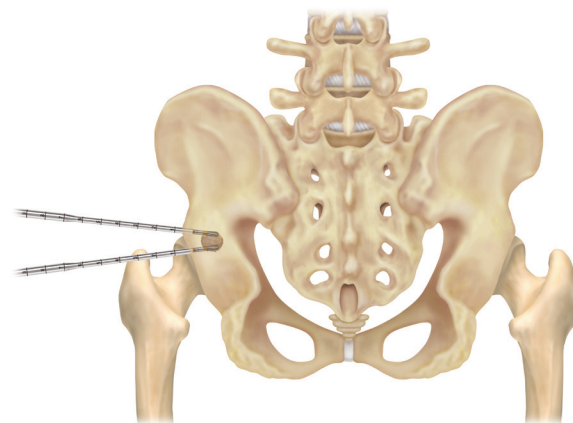


C. Acetabulum



C1

C2

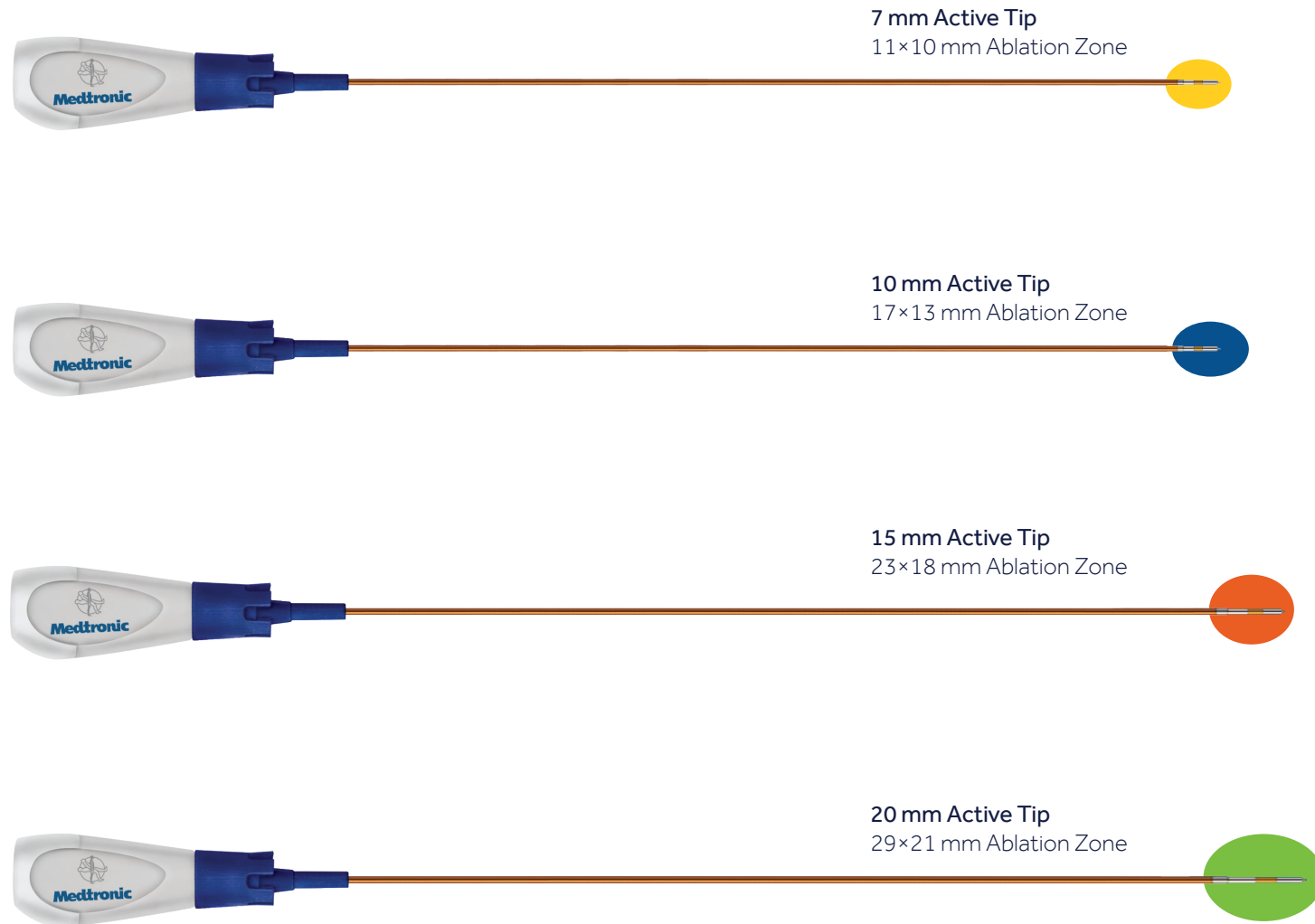


PROBE SELECTION AND TUBE KIT PREPARATION

Select the OsteoCool™ RF ablation probe size for the procedure.

Note

If the OsteoCool™ precision drill was used, select the probe size that coordinates with the color marking on the drill shaft.



FILLING THE OSTEOCOOL TUBE KIT INSERTING IT INTO THE PUMP UNIT

Once a 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, using one of the following options:

Option 1 – Inject water through the port in the lid.

Option 2 – Remove the lid and pour the water directly into the burette.

Option 1 — Injecting sterile water using the lid port

a. Place sterile syringe in the port.

b. Inject 70 mL of sterile water at room temperature into the burette.

Option 2 — Removing the lid and pouring sterile water directly into the burette

a. Open the lid by pressing in and up with your thumbs around one of the three petals.

b. Observe proper sterile handling technique while filling the burette; do not place the lid of the burette on a non-sterile surface.

c. The fill lines on the burette represent 70 mL and 80 mL respectively.

d. After filling to between the lines, snap the lid back into place on the burette.

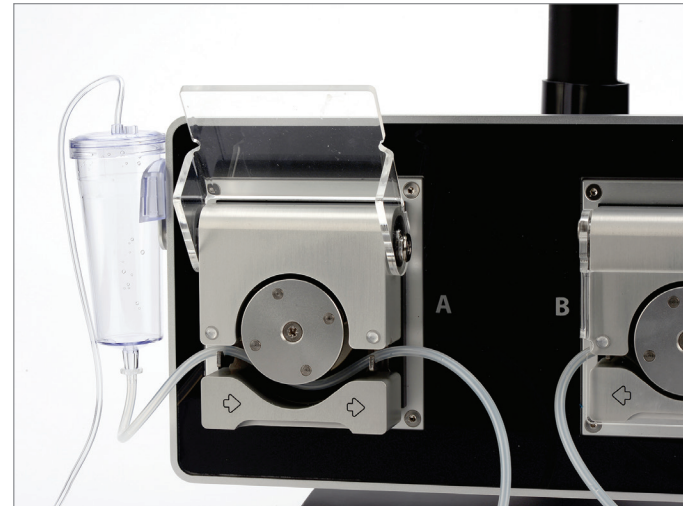


2. Put the burette into the pump unit's burette holder.
3. Open the pump head lid and thread the thicker tubing from the bottom of the burette into the pump head tube holder.
4. Ensure that the tubing is properly placed between the notches and along the center channel beneath the pump head.

Warning

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

5. Close the lid 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.



Open lid



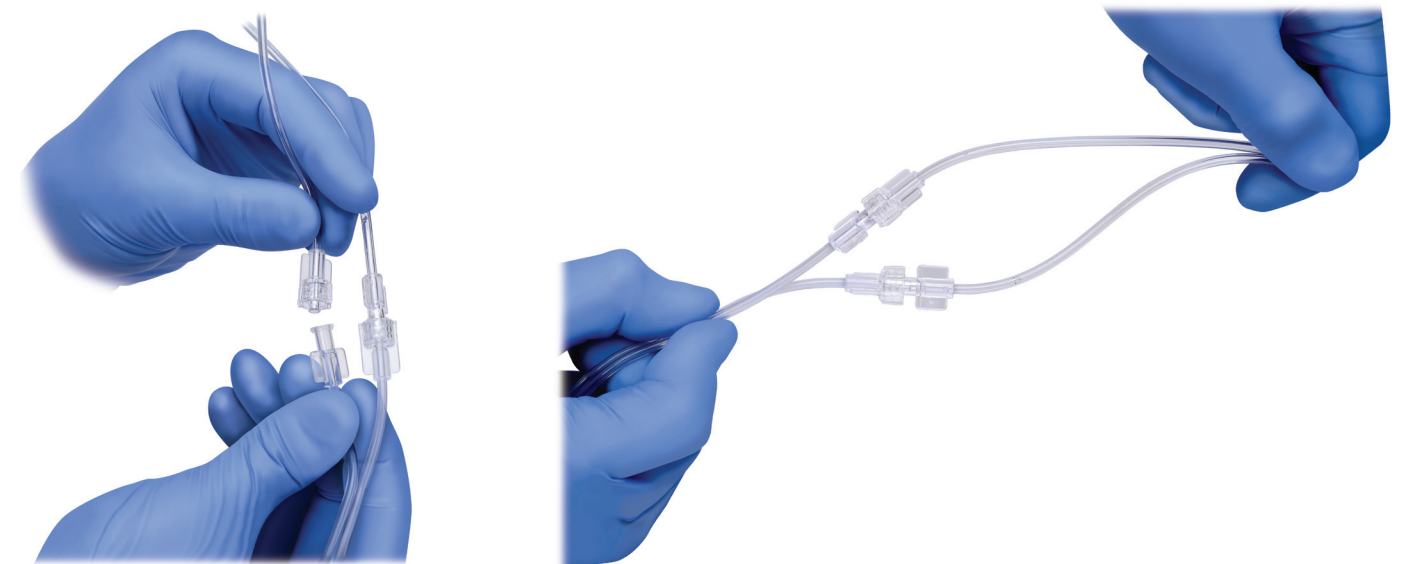
Closed lid holds tubing in place

CONNECTING 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 if water is spilled in the sterile field, sterility will not be compromised.



CONNECTING TO THE CONNECTOR HUB

The connector hub provides two channels for the use of the ablation probes and two channels for use of the independent thermocouples.

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

1. Connect the male connector on the ablation probe to the female connector on the connector hub.
2. Confirm via on-screen information that the probe has been detected and is ready for use.

Note

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



PERFORMING RF ABLATION — SPINE

1. The ablation probes come with a pre-assembled spacer. Discard or keep the spacer, based on the bone access tool used. Reference chart below:
2. Place the ablation probe through the bone access cannula, ensuring it is fully seated in the cannula.

Warning

Never force the probe if you feel significant resistance.

3. Under image guidance, confirm the proximal radiopaque marker has fully surpassed the distal end of the cannula.

Warning

Incorrect use of the spacer may result in inadequate 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 10G 095	OCN004	Discard Spacer
OsteoCool™ Bone Access Kit 13G 100	OCN005	Discard Spacer



Remove spacer for use with OCN004 and OCN005.



Use spacer with OCN002 and OCN003.



PERFORMING RF ABLATION — SACRUM, ILIAC, AND ACETABULUM

4. When the screen shows "Ready," press 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

Modifications to standard 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 for error signs 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. 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.

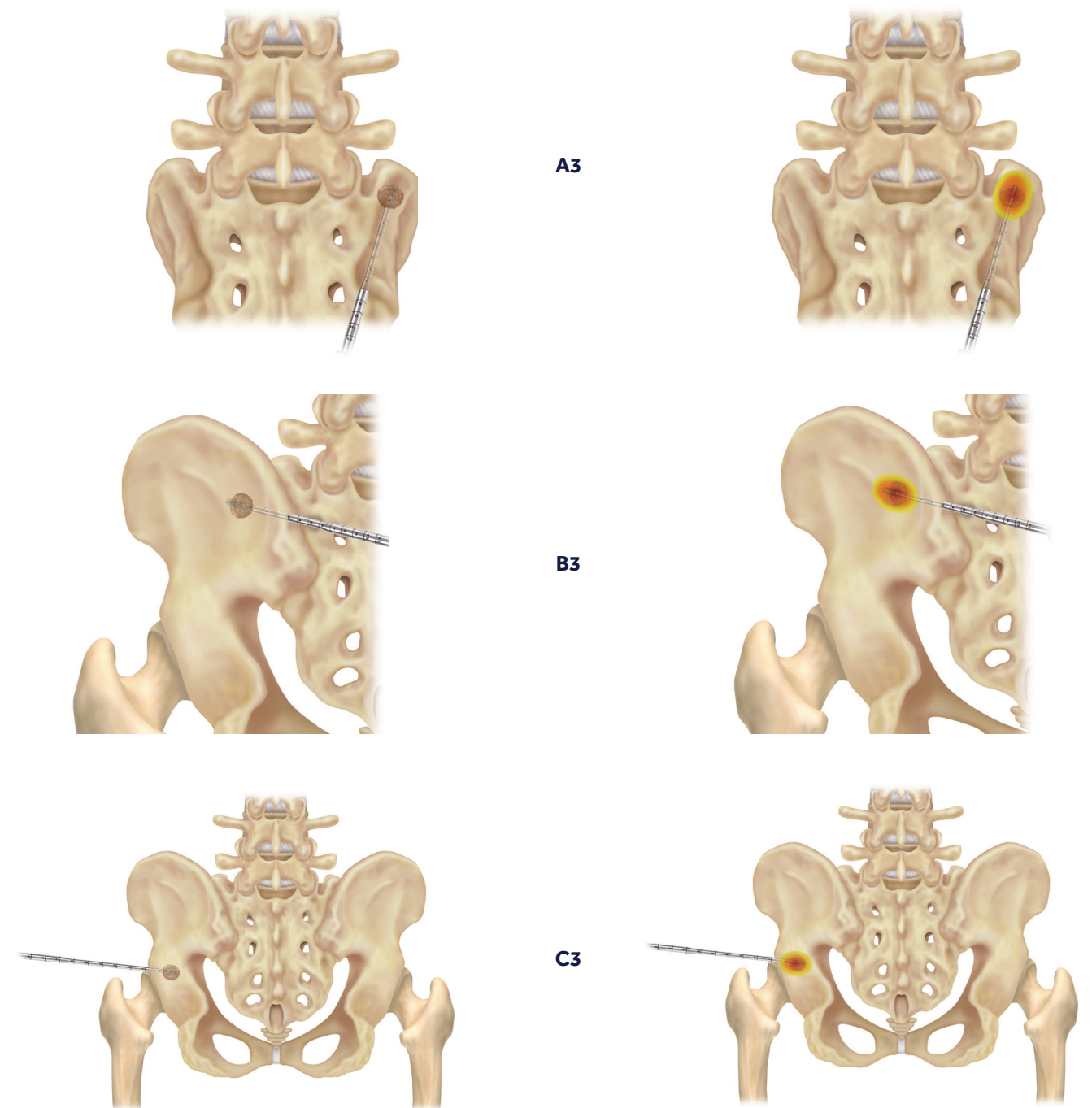
Label Color	Product Code	Active Tip	Lesion Size	Ablation Time
Yellow	OCP107 and OCP207	7 mm	11 × 10 mm	6:30 min
Blue	OCP110 and OCP210	10 mm	17 × 13 mm	7:30 min
Orange	OCP115 and OCP215	15 mm	23 × 18 mm	11:30 min
Green	OCP120 and OCP220	20 mm	29 × 21 mm	15:00 min



Note

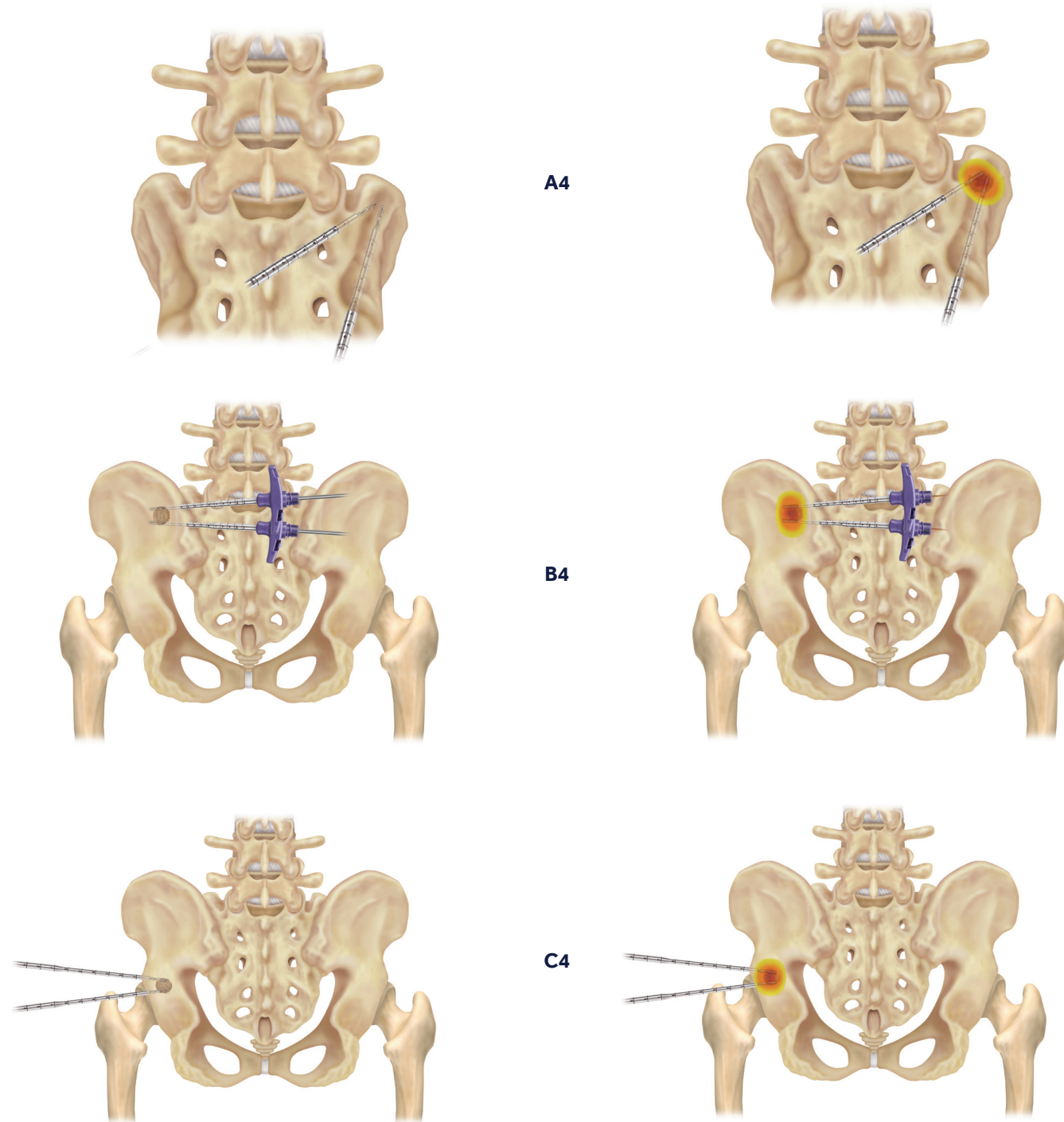
The ablation process will remain the same for all bony anatomy. Follow steps 1–7 under "PERFORMING RF ABLATION — SPINE" for detailed instructions regarding this process.

One-probe approaches:



OPTIONAL TRACK RF ABLATION

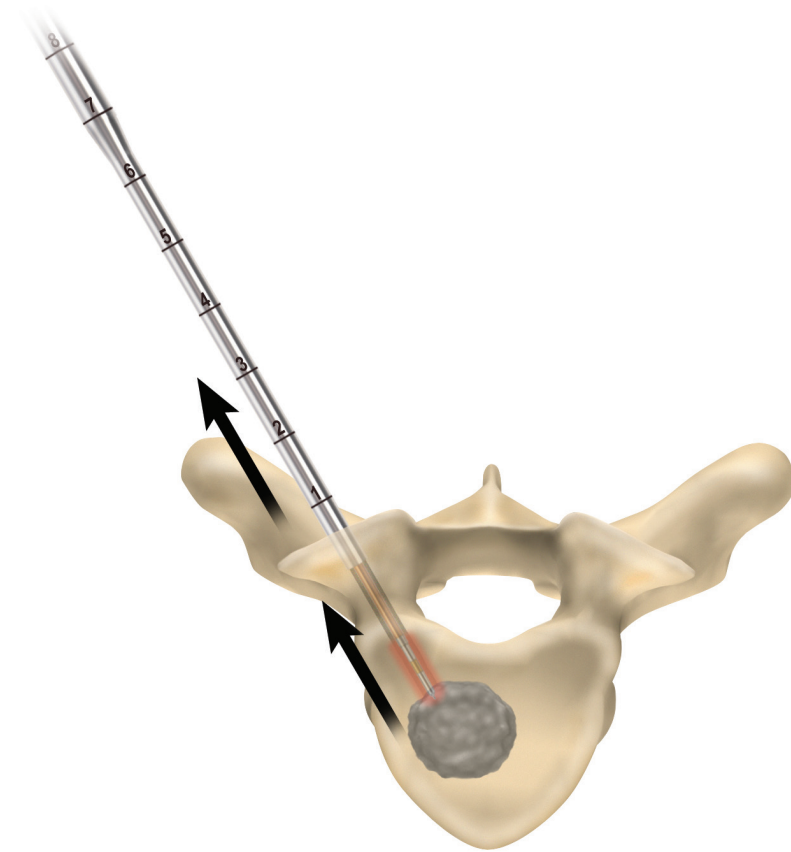
Two-probe approaches:



1. To ablate the track, select "Retract" on the generator screen.
2. Press the RF power button.
3. The screen will signal when the track ablation starts.
4. Slowly pull back on the RF ablation probe and cannula simultaneously (approximately 1–2 mm/second) or pull back and track ablate while stationary. When the desired end point for track ablation is reached, press the RF power button to stop RF delivery.

Warning

Track ablation is the use of uncooled RF ablation during which time the peristaltic pump is not circulating water. Ablating the track all the way to the skin can result in skin burns. It is recommended to end the track ablation prior to this point.



OPTIONAL TEMPERATURE MONITORING WITH THE INDEPENDENT THERMOCOUPLE

The independent thermocouple provides real-time temperature information to gauge ablation zone margins and help prevent thermal damage to adjacent critical structures. The temperature detected by the independent thermocouple is displayed on the generator screen.

1. Insert the thermocouple into the provided introducer.
2. Connect the male connector on the thermocouple to the female connector on the connector hub.
3. Confirm via on-screen information that the thermocouple (sensor) has been detected.
4. Access the site. Place the thermocouple in the tissue to be monitored.

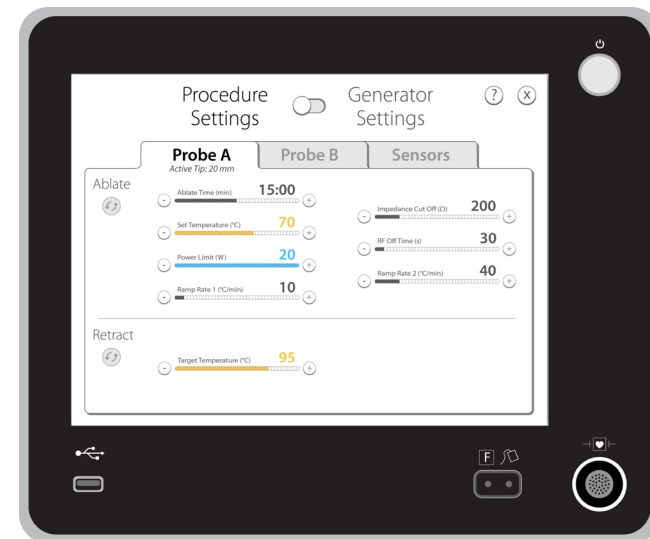
PERFORMING RF ABLATION USING CUSTOM SETTINGS

The OsteoCool™ system generator screen includes the ability to change procedure settings. These settings should only be adjusted by physician experts in RF ablation. To access the custom settings on the generator, complete the following steps:

1. Press the "Settings" button.
2. Select "Procedure Settings."
3. Edit settings based on procedural need. Each probe can be individually adjusted by time, temperature, power limit, ramp rate, and impedance cut off. Additionally, each independent thermocouple sensor can be individually adjusted by temperature.
4. Once desired settings have been achieved, press the "X" button to return to the generator's home screen user interface.
5. Proceed with the RF ablation procedure.

Note

All ablation zone sizing is based on default settings. Using custom settings by manipulating the procedure settings will change the ablation zone sizing. To reset the generator settings to default settings, select the "Refresh" button.



BONE ACCESS FOR SUBSEQUENT PROCEDURES

The bone access can be used for subsequent physician-directed procedures such as cementoplasty, sacroplasty, vertebroplasty, or kyphoplasty. Confirm 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. 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.

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 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 microfracture (as documented by appropriate imaging and/or presence of a lytic lesion) without obvious loss of vertebral body height.

GENERAL SAFETY GUIDELINES

For desired tissue heating and anatomical access:

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.

