RADIOFREQUENCY ABLATION

RITA Medical Systems

Procedure Guide

QUICK REFERENCE

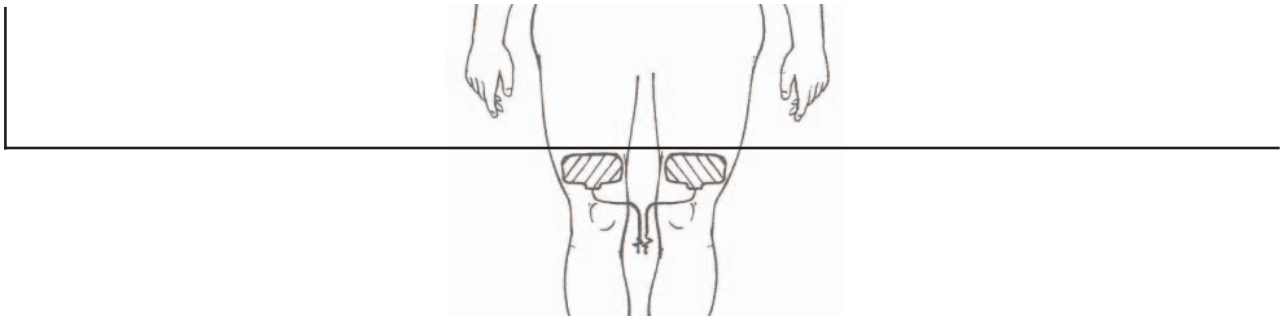
RITA MEDICAL SYSTEMS

Pad Placement

StarBurst™ XL, XL*i enhanced*, SEMI-FLEX, MRI and SDE Dispersive Electrode Instructions

Apply the Dispersive Electrodes according to the package instructions.

- Select a well-vascularized muscular site as close as possible to the knee (so that there is > 25 cm between the ablation zone and the Dispersive Electrodes).
- Pad Level
- **DO NOT** place one pad above the other on a given thigh. They should be at the same level.



- If a portion of the pad wraps around to the posterior of the leg it is recommended that the patient's knees be elevated to eliminate pressure on the pad and to allow for cooling (air flow) at the pad site.
- Avoid placement over scars, bony prominences, metal prostheses, or ECG electrodes.
- Avoid placement in areas where liquid may pool.
- If leg/circulation compressors are used, use calf-length devices.
- It is also recommended that skin-to-skin or pad-to-pad contact, such as between the legs, be avoided by insulating with sheets or another dry material.

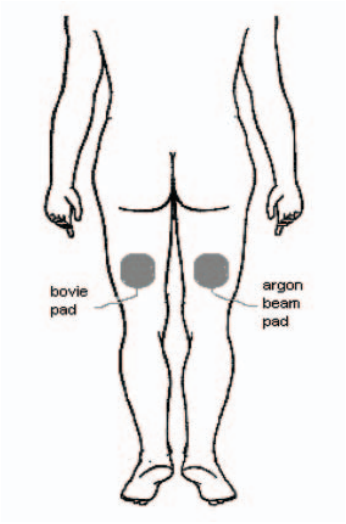
Other Heat Sources

- Avoid placing pads under thermal blankets and in areas where heat may be retained, e.g., under blankets or positioning bags.
- If a Bair Hugger® or another warming device is used, turn it off prior to making ablations to decrease the potential for a pad burn as well as to minimize the elevation of the patient's core temperature.

[1] S. Nahum Godberg, Luigi Solbiati, Elkan F. Halpern, G. Scott Gazelle. "Variables Affecting Proper System Grounding for Radiofrequency Ablation in an Animal Model." JVIR. 11:1069-1075, September 2000.

Note: These instructions are not comprehensive. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. 00188 rev 06

StarBurst™ XL, XL*i enhanced*, SEMI-FLEX, MRI and SDE Dispersive Electrode Instructions (cont.)



Placement of Other Ground Pads (e.g., bovie and argon beam)

- Other pads should not be placed in the path of RF energy (i.e., between the RITA device and the RITA ground pads).
- Place other pads at the same level as the RITA pads, as long as they are not touching. If concerned about posterior thigh placement, the knees could be elevated to eliminate pres sure points on pads and to allow for cooling (air flow) at the pad site

- If it is not possible to place other pads at the same level as the RITA pads, do one of the following:
    - Place distal to the RITA pads (e.g., on the calves), or
    - Place in the opposite direction (e.g., on arms, shoulders, etc.)

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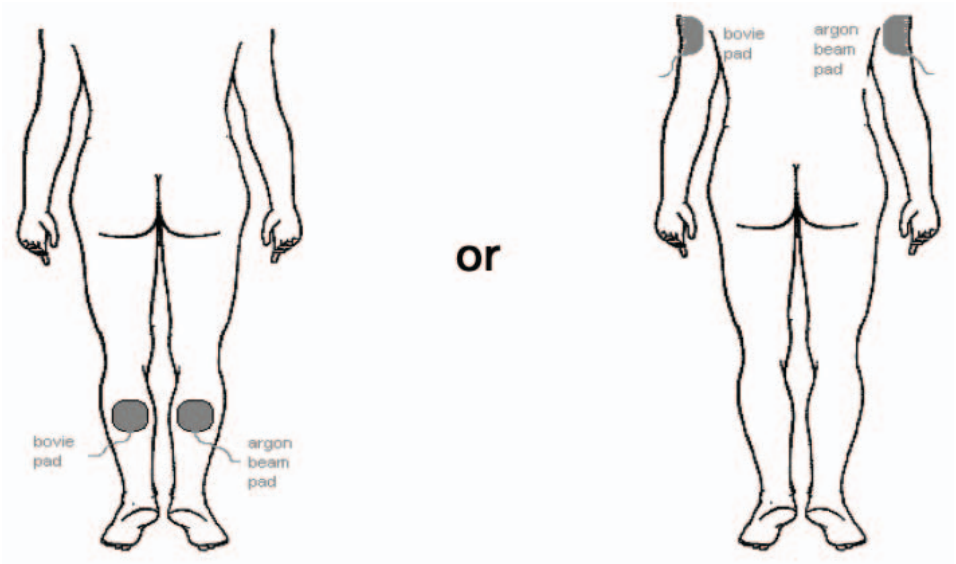

- DO NOT use a whole-body pad for a RITA procedure. With a whole-body pad, the RF energy could go directly to the whole-body pad, travel through the pad, and reenter the body to access the RITA pad. These concentrated points of RF exit / re-entry to the body could potentially heat, causing a skin burn.

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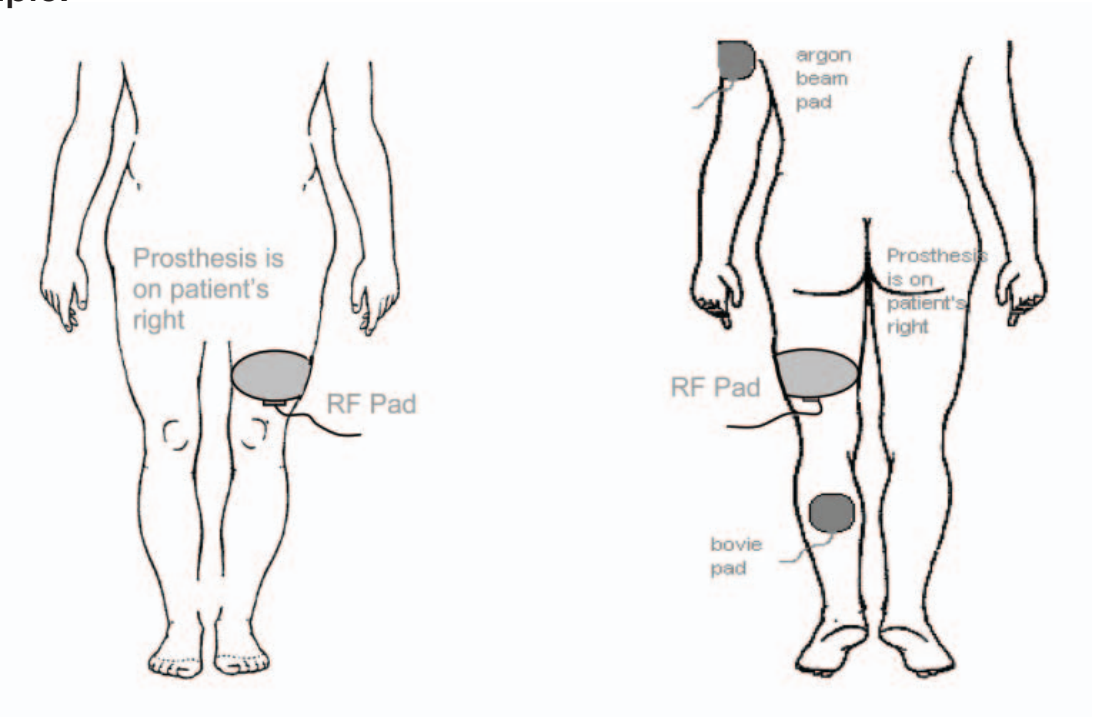
StarBurst™ XL, XL*i enhanced*, SEMI-FLEX, MRI and SDE Dispersive Electrode Instructions (cont.)

Patients with a Metal Prosthesis

- Pads should not be placed over any metal prosthesis (in accordance with AORN guidelines and the package instructions).
- Theoretically, a metal object (i.e., a metal prosthesis) in the path between the active electrode and the dispersive electrodes could heat up, although no studies have proven this. Therefore, if the patient has a hip prosthesis, the pads could be placed on the leg opposite the prosthesis if they will all fit without touching.
- If you have a patient with a prosthesis (or prostheses), for whom all pads cannot be placed according to the instructions above, it is recommended that the patient be informed of the risks and provide their consent prior to doing the procedure.

For Example:



Risk of Pad Burns:

There is a risk of pad burns when using any electrosurgical device. With a monopolar device this risk will always exist. RITA has tried to minimize that risk as much as possible by using dispersive electrodes with approximately twice the surface area of that considered to be safe. RITA has also tried to minimize the risk with the instructions on proper placement and patient preparation.

However, a risk still exists and tends to be greater in cases where ablation times are longer and more power is used.

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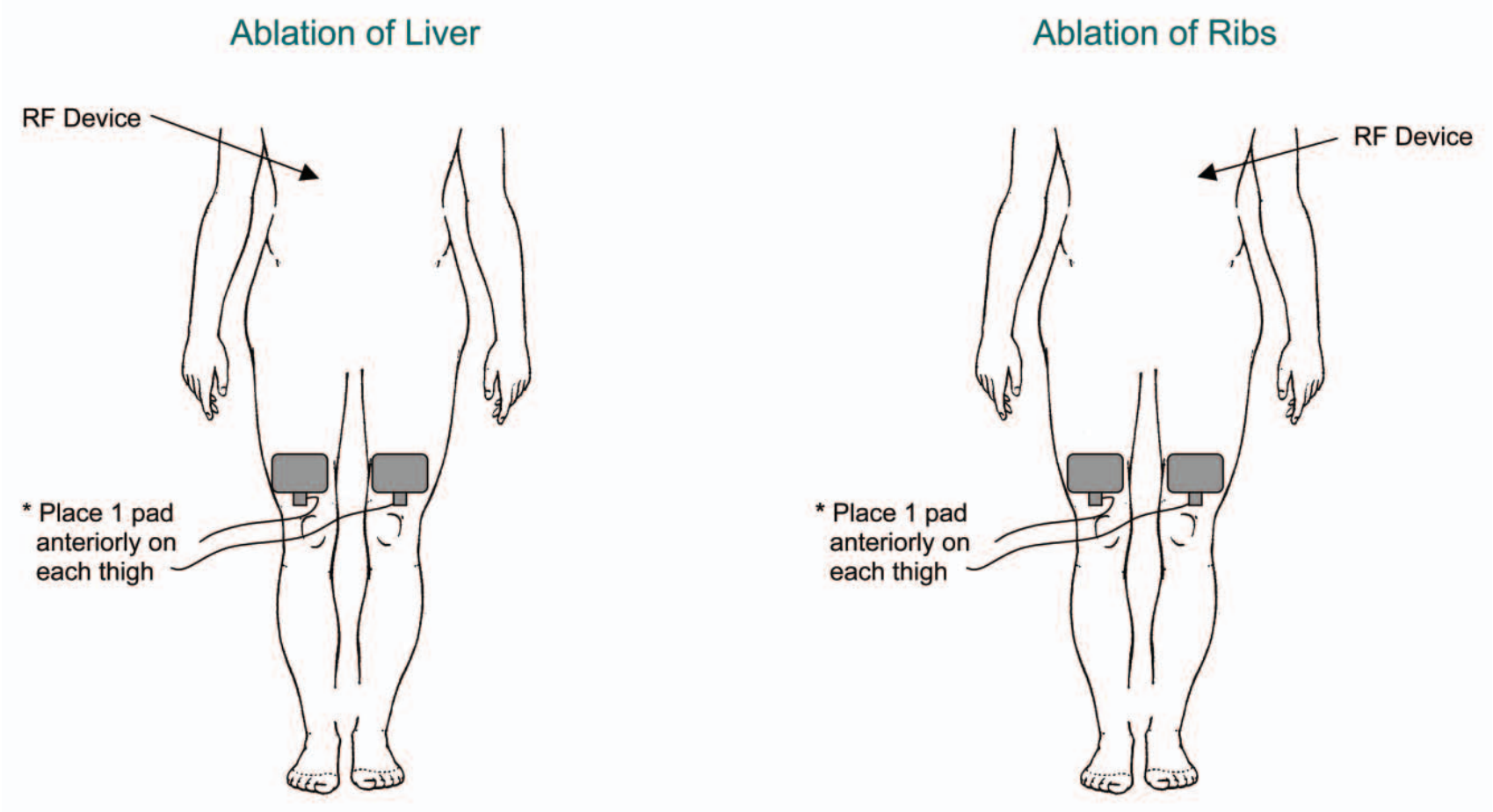
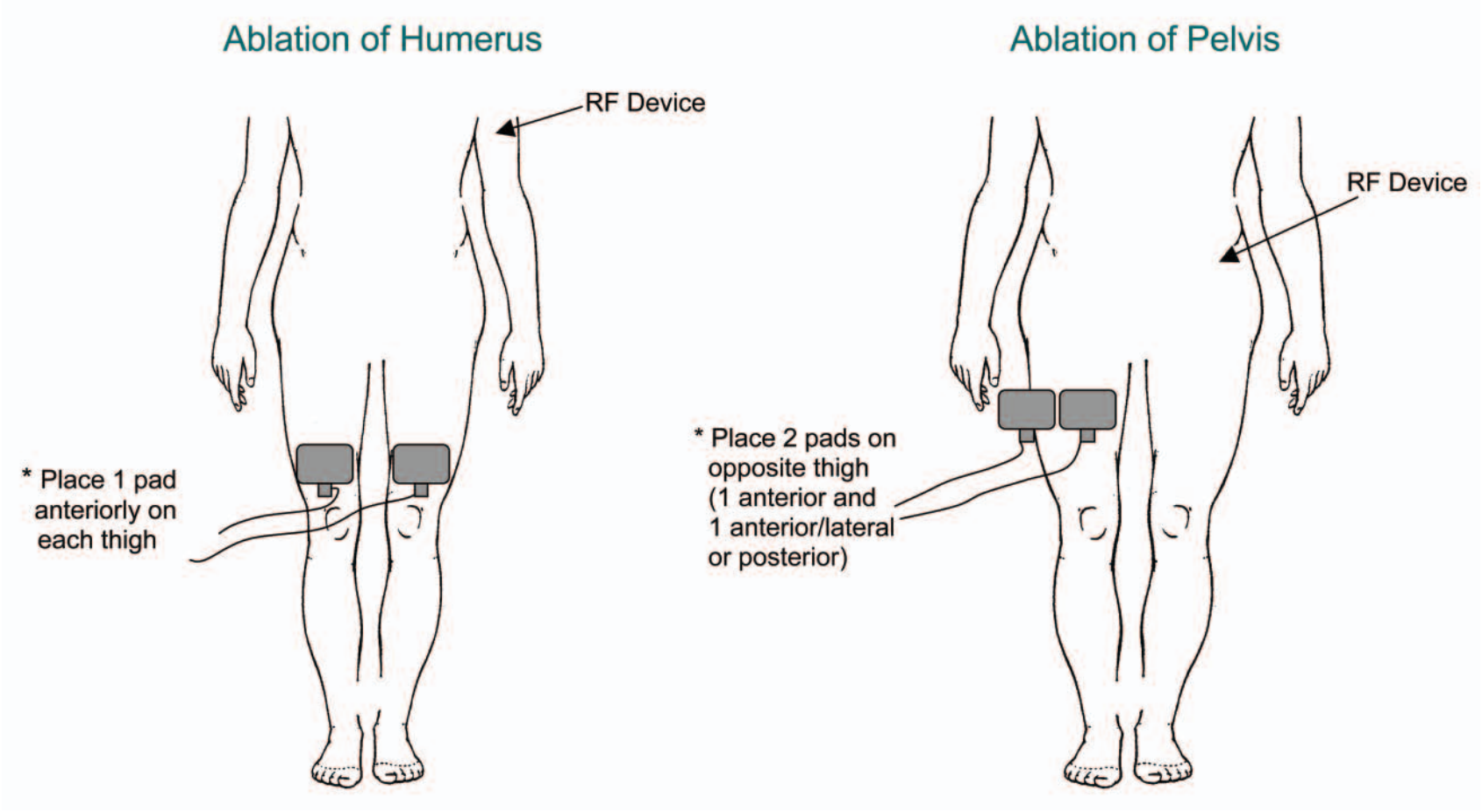
Body Atlas for Dispersive Electrode Placement



* This assumes that the ablation is being done with patient lying supine. If not, pads should be placed posteriorly.

Disclaimer: There is always a potential for a pad burn when using electrosurgical devices. While these placement recommendations are intended to help prevent burns, there is no guarantee that burns will not occur. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects.

Body Atlas for Dispersive Electrode Placement (cont.)



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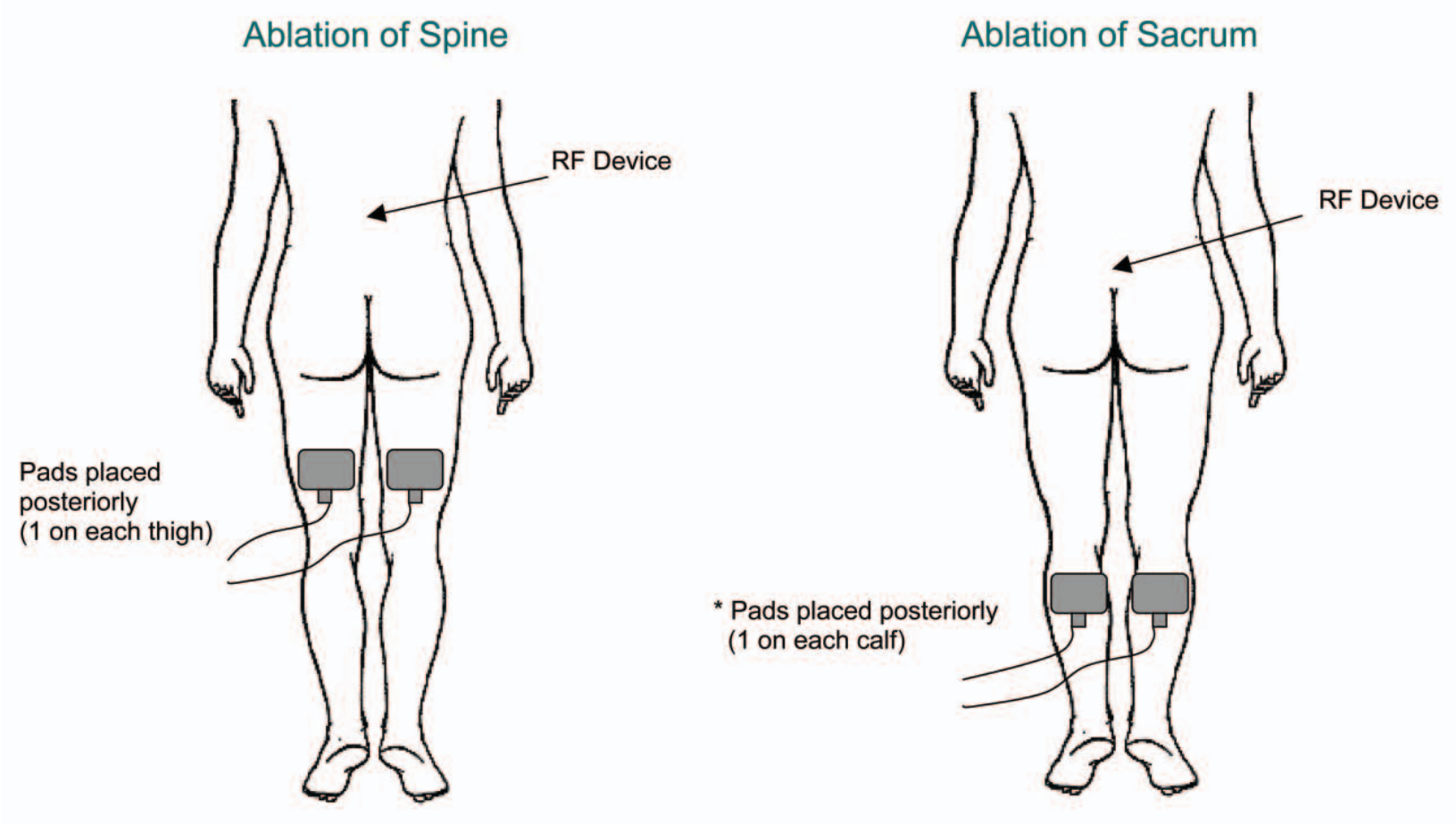
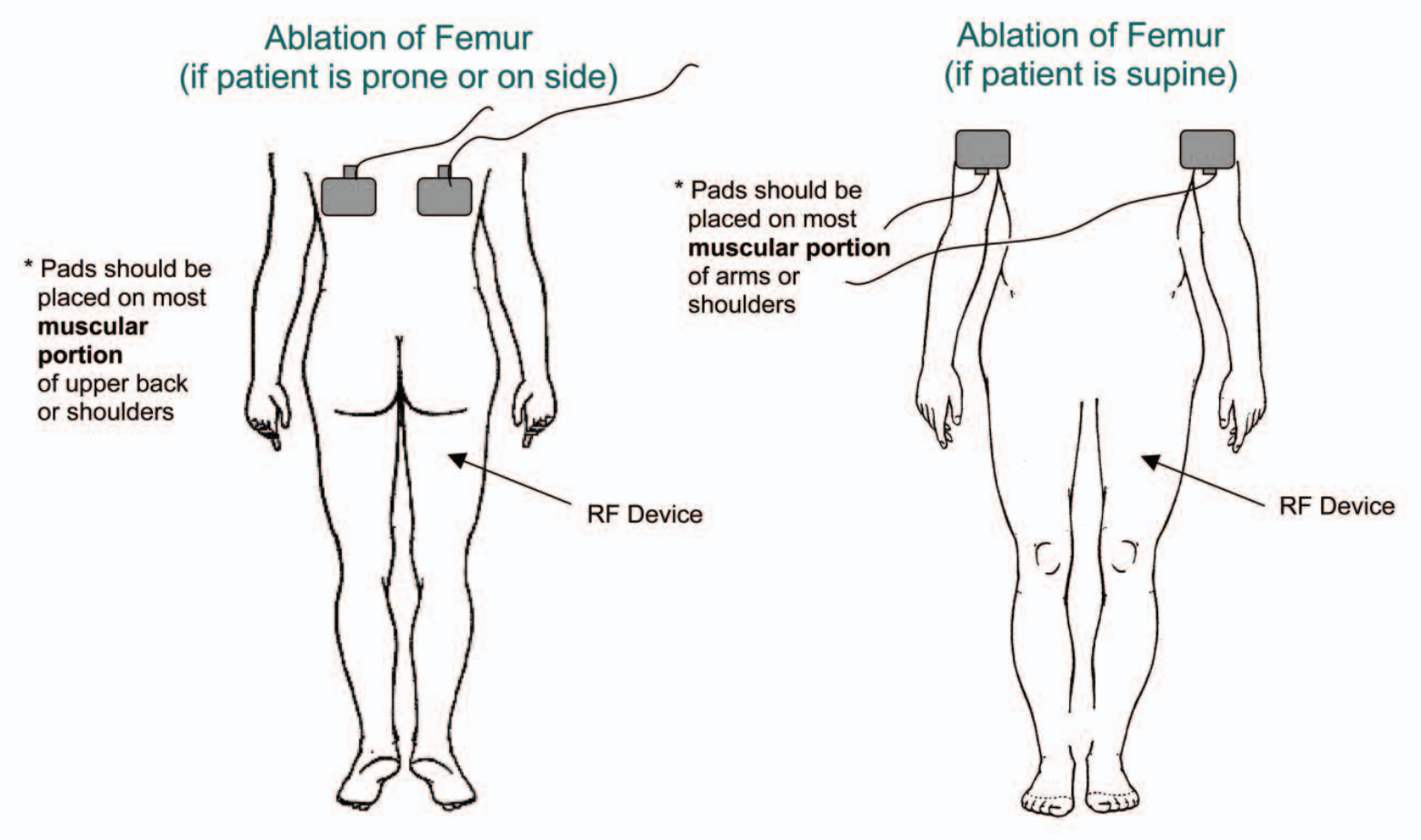
Body Atlas for Dispersive Electrode Placement (cont.)



* When pads are placed on the calves ensure that no other pads are placed in the path of RF energy (between the RF Device and the dispersive electrodes for the RF Device).

Disclaimer: There is always a potential for a pad burn when using electrosurgical devices. While these placement recommendations are intended to help prevent burns, there is no guarantee that burns will not occur. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects.

Body Atlas for Dispersive Electrode Placement (cont.)



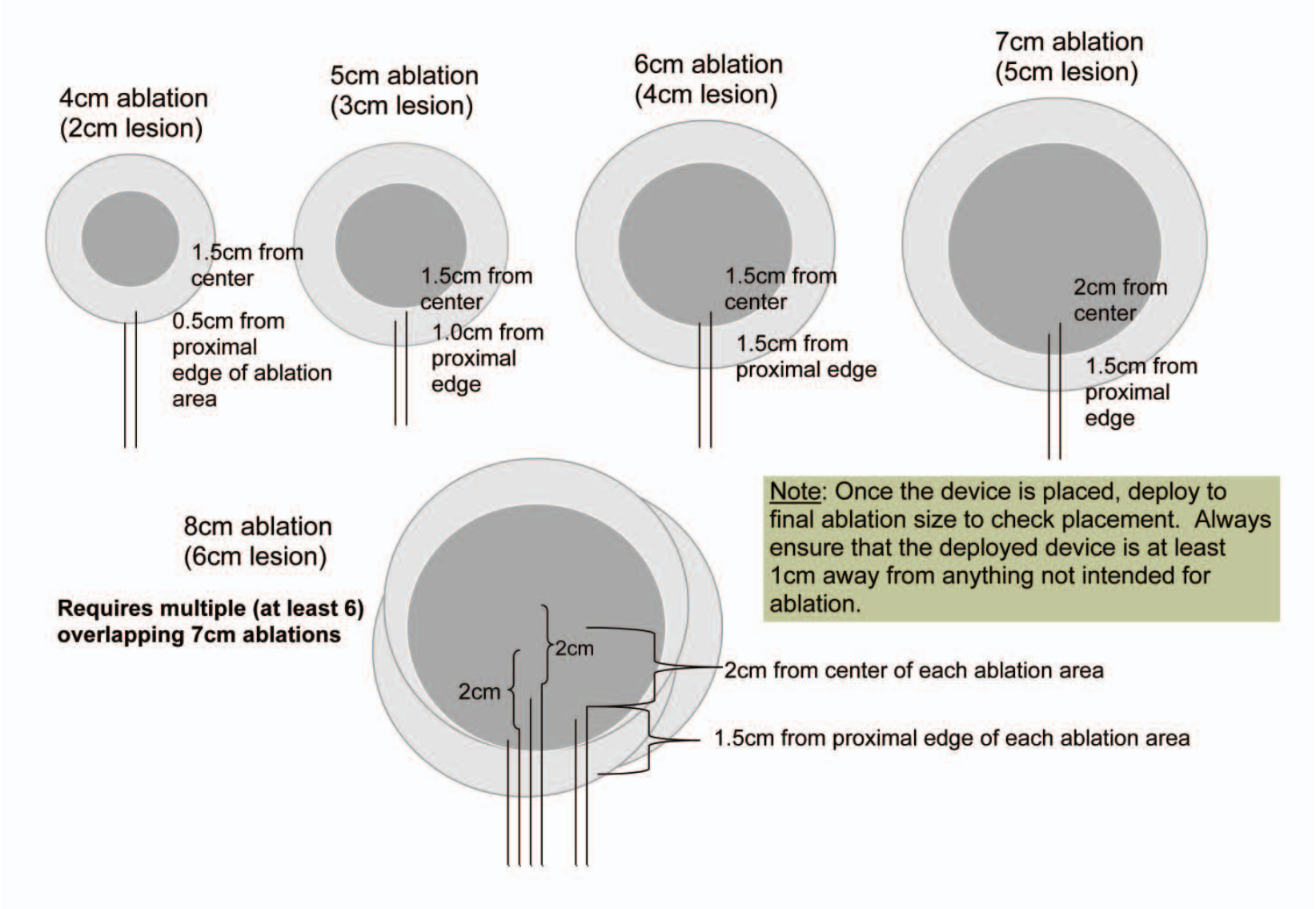
* Care should be taken not to place pads over bony prominences.

Disclaimer: There is always a potential for a pad burn when using electrosurgical devices. While these placement recommendations are intended to help prevent burns, there is no guarantee that burns will not occur. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects.

RITA MEDICAL SYSTEMS

Device Placement

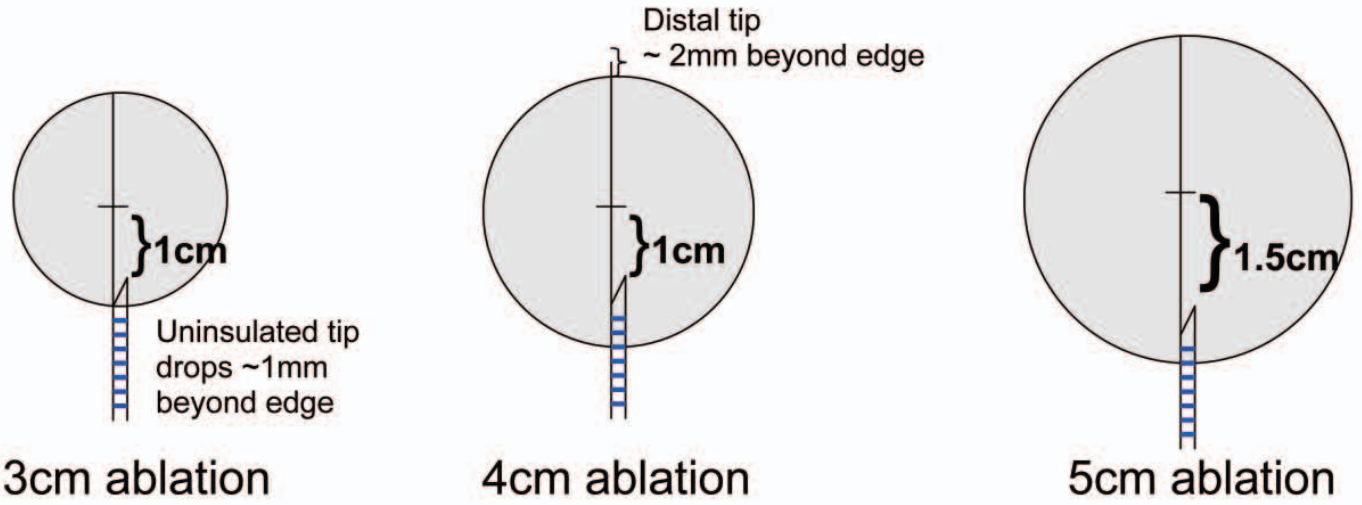
XL*i enhanced* Device Placement Diagram

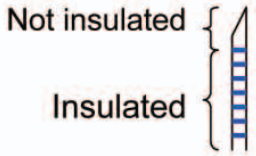


Note: These instructions are not comprehensive. The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA Medical Systems, Inc., 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102955 rev 02

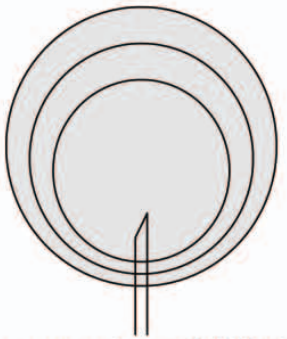
STARBURST™ XL, SEMI-FLEX AND MRI Device Placement Diagram

The tip of the trocar should be placed 1cm from the center of the intended ablation area for a 3cm or 4cm ablation, and 1.5cm for a 5cm ablation, as shown below:





Note: The larger surface area at the tip of the trocar and longer ablation time will help to propagate the ablation to the proximal edge for the 4cm and 5cm ablations. Similarly, the 3cm ablation will likely grow beyond the proximal edge. The smaller surface area at the distal tip will prevent the lesion from growing too far beyond the distal edge in a 4cm or 5cm ablation.



Progression of Ablation Over Time

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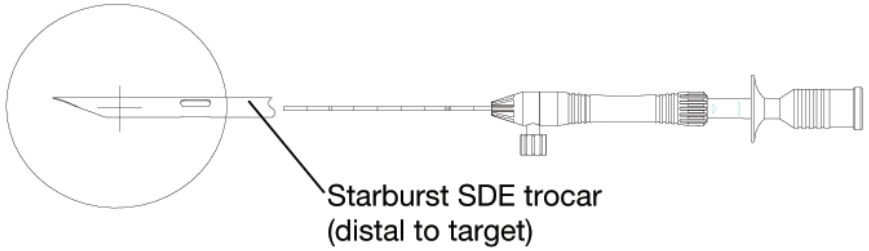
StarBurst™ SDE Device Placement Diagram

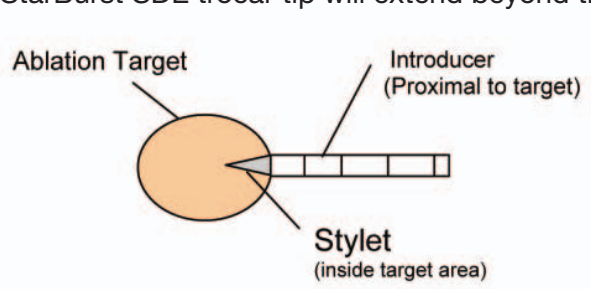
- The tip of the trocar should be placed approximately 6 millimeters distal to the center of the target area.
- The uninsulated portion of the trocar tip is 1.4cm.

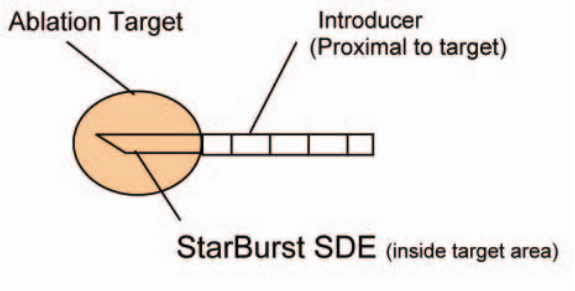
  CAUTION: Do not bend or kink the trocar or electrodes/needles during placement or once they are placed inside tissue. This may cause damage and result in a non-functional device.



Use Of a RITA Hard Introducer

- StarBurst SDE is only compatible with a 6cm hard introducer (RITA part # 700-102330).
- Before deploying arrays, insert the StarBurst SDE device into the introducer until the 11cm (minimum) mark on the StarBurst SDE trocar is at the top of the introducer before deploying arrays.
  - When using the introducer, the tip of the stylet should be placed approximately 6 millimeters proximal to the center of the target area. When the StarBurst SDE device is inserted into the introducer to the 11cm mark on the trocar, approximately 1.7cm of StarBurst SDE trocar tip will extend beyond the introducer tip.





- While the StarBurst SDE trocar is inside the hard introducer, do not push or bend the device against the hard introducer. This may cause damage to StarBurst SDE trocar.
- The uninsulated portion of the trocar on the StarBurst SDE device should be outside/distal to the hard introducer prior to deployment or starting an ablation.
- Do not push out (deploy) arrays inside the hard introducer. Arrays can bend and damage.

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RITA MEDICAL SYSTEMS

Pump

Tips for Set-up of Harvard Pump

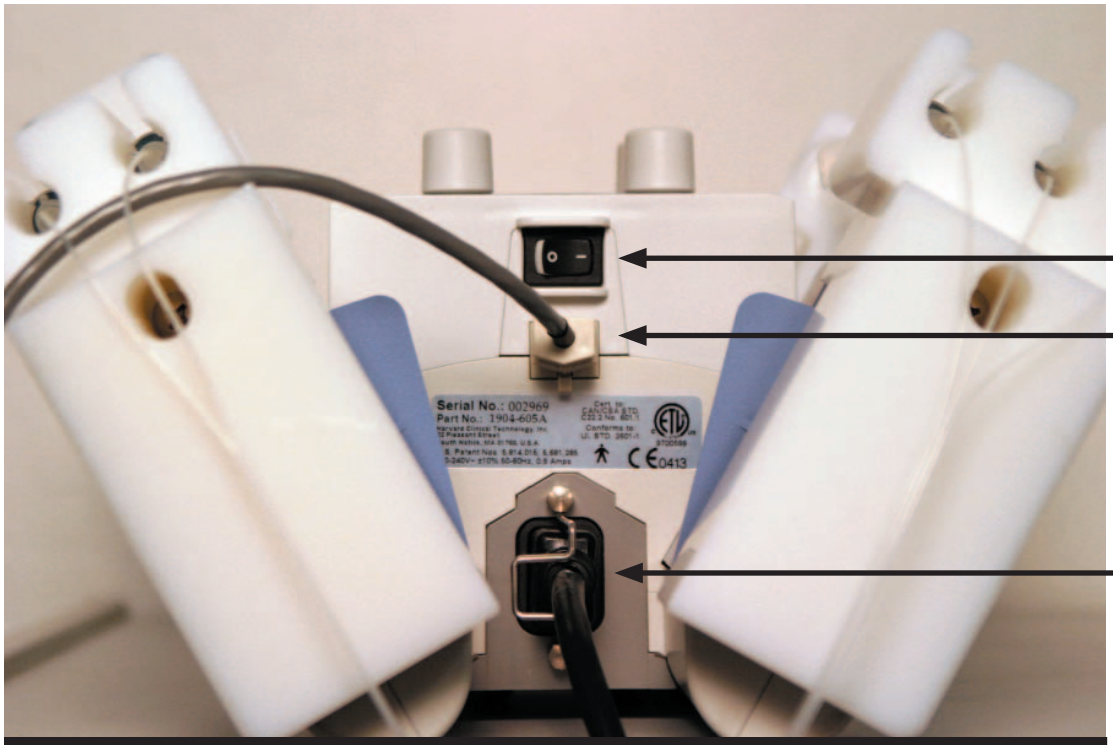

Figure 1: Bottom of Pump

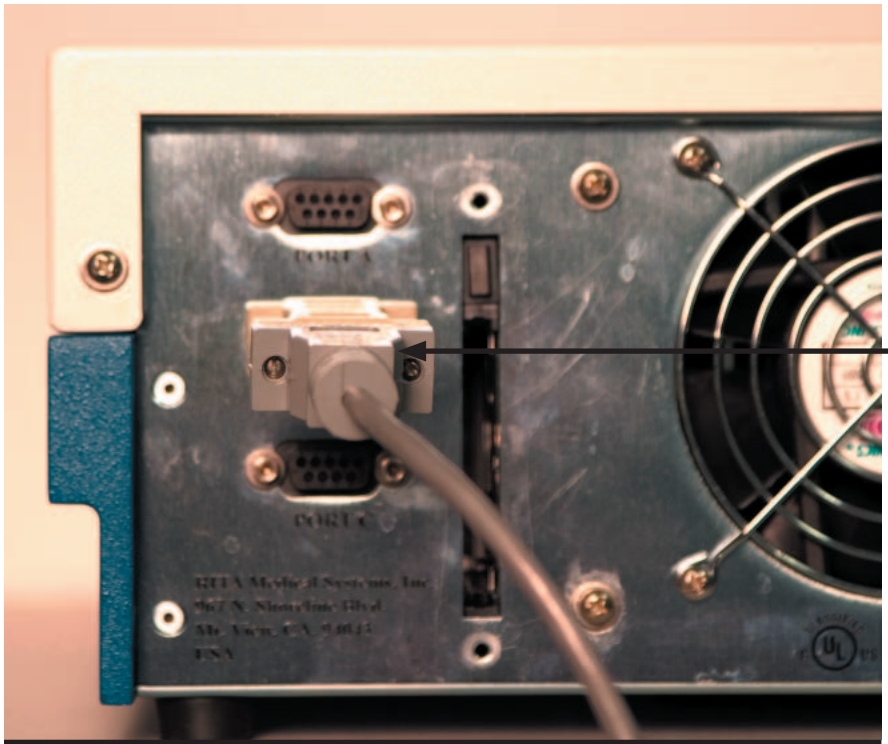

Figure 2: Back of Generator

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA and StarBurst are trademarks of RITA Medical Systems, Inc. RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102978 Rev 01.

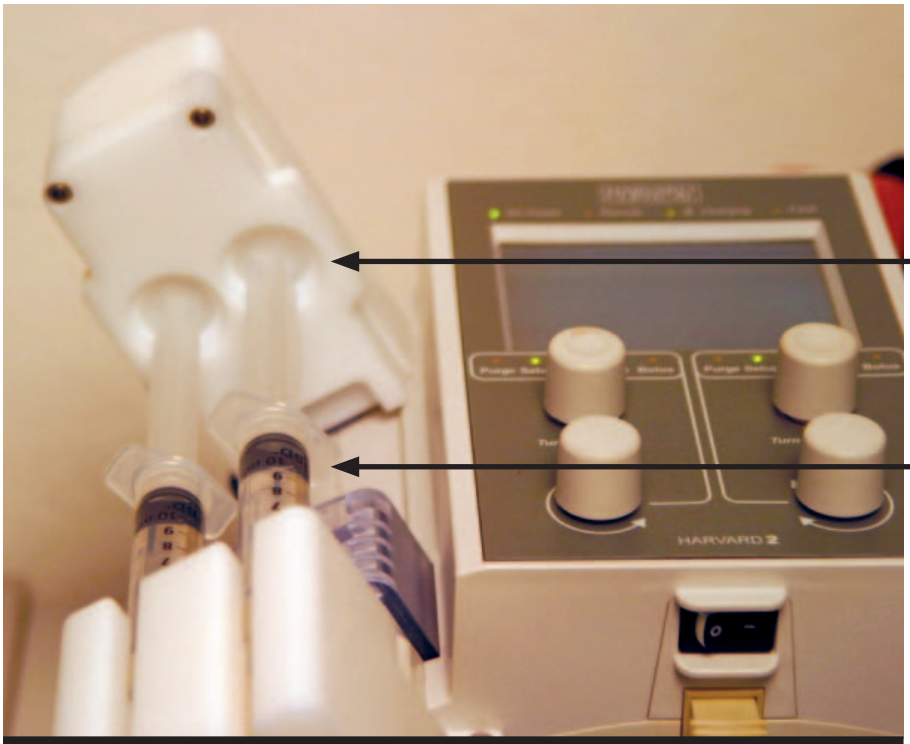

Figure 3: Syringe plunger

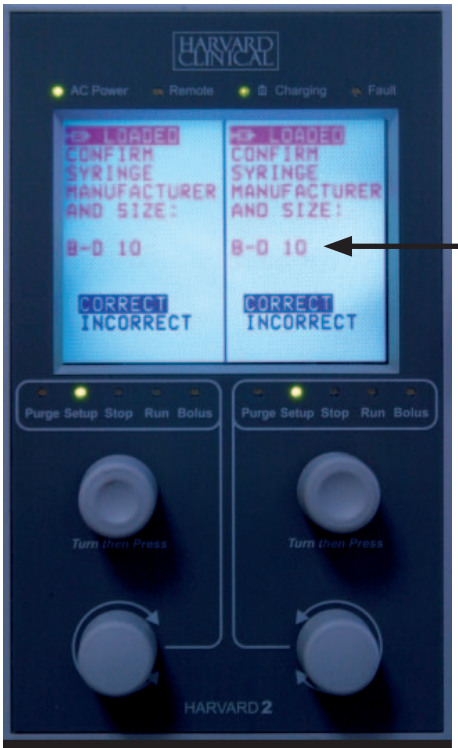

Figure 4: Pump Interface

Figure 5: Pump Interface

Figure 6: Pump Interface

Press A button on generator to begin purge mode; the pump will automatically change from .05 ml/min to 1.5 ml/min.

Figure 7: Pump Interface

After visually confirming saline flowing out of all 5 lines, hit B on the generator, and flow rate will change automatically and lock to .05 ml/min.

Figure 8: Pump Interface

How to correct wrong mode settings?

Rotate top knobs to highlight mode setting

Figure 9: Pump Interface

1. Press top knob to view drop down box

2. Rotate top knob to correct setting

3. Press top knob in again to select correct setting

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Figure 10: Pump Interface

Change to correct mode by rotating the top knob.

Figure 11: Pump Interface

Once correct mode is highlighted, press top knob in to confirm.

RITA MEDICAL SYSTEMS

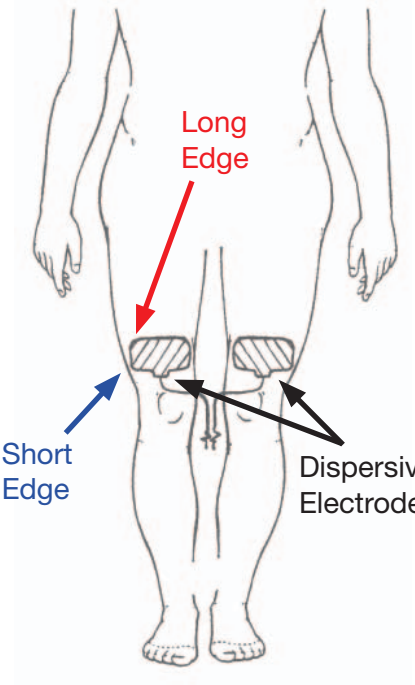
Liver Infusion

Infusion Based RFA Liver Tumor Protocol

Compatible Devices: StarBurst™ XL*i enhanced*

EQUIPMENT LIST:

- RITA Model 1500X RF Generator with V7.03 or higher software, Foot Switch and Power Cord
- StarBurst XLi enhanced Electrosurgical Device 700-102669 (4- 7cm, 25cm) or 700-102664 (4-7 cm, 12cm) with Main Cable PN 700-101972 (14 to 14 pin BLUE connector)
- RITA ThermoPad Dispersive Electrodes PN 700-102649 with adaptor cable PN 700- 102648 (Package includes 2 dispersive electrodes)
- Harvard 2 Infusion Pump and Power Cord
- Communication Cable PN 700-102801
- B-D 10cc syringes (reference #309604) (5 each required per case
- Sterile injectable normal (0.9%) saline (minimum 100cc required)
- Bowl (or similar container)



SETUP

1. Sterilize BLUE (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
    - The two dispersive electrodes should be placed on clean, dry surface over large well-perfused muscle mass.
    - Hair should be removed before applying the dispersive electrodes.
    - Electrodes should be oriented with the longest edge toward the target ablation site with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
    - Electrodes should not be place over bony prominences, scar tissue, skin over an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
    - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
    - Other dispersive electrodes (electrosurgical cutting device) shall not be placed between the ablation location than the dispersive electrodes used with the RITA RF Generator.
    - Insulate patient's leg by placing a towel between the patient's thighs.
    - ThermoPad Dispersive Electrodes should not be placed under compression socks or leg compressors.

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Infusion Based RFA Liver Tumor Protocol (cont).

PREPARATION:

1. Connect Power Cord to Generator and plug into appropriate outlet.
2. Connect Power Cord to Pump and plug into appropriate outlet.
3. Connect Pump Communication Cable to Pump. Connect the other end to port B on the Generator.
4. Apply ThermoPad Dispersive Electrodes according to package instructions.
   a. Place 1 Dispersive Electrode anteriorally on each thigh (Please see Figure on page 1).
5. Connect ThermoPad Dispersive Electrode connectors into the ThermoPad adaptor cable. Connect the other end to any 2 of the 4 “Return” ports and connect the remaining plug to the “Aux” port on the Generator.
6. Connect Foot pedal to the Generator.
7. Using sterile technique, place the injectable 0.9% normal saline in a bowl (or similar container) on the sterile field.
8. Within the sterile field, completely fill 5 B-D 10cc syringes to the mechanical stop (≈12 cc).
9. Using sterile technique, open the Device and pass it into the sterile field.
10. Attach a sterile Main Cable to the connector on the Device. Connect the other end to the Generator.
11. Turn Generator on with the switch on the back.
12. Within the sterile field, attach a filled syringe to each Device fluid port.
13. Hand off syringes from sterile field to circulating nurse.
14. Load syringes into the Pump.
    a. Raise pusher block to highest position by rotating the blue lever on the side of pump forward.
    b. Load all five saline filled syringes into pump. Ensure that both hubs and plungers are within the wells of the pump clips.
    c. Lower pusher block by rotating lever on the side of pump forward. This locks syringes in place.
15. Turn Pump on with the switch underneath the pump.
16. Purge the system.
    a. Confirm purge mode on Generator.
    b. Within the sterile field, fully deploy the device out to the 7 cm mark.
    c. Start the purge of saline through the device by pushing the “A” button on the Generator.
    d. As soon as saline flows out of all 5 tines, push the “B” button on the Generator to stop the purge mode.

Infusion Based RFA Liver Tumor Protocol (cont).

e. Push the “Control” button on the Generator to set the Generator to the “XLi enhanced” mode (pump will automatically switch back to 0.05 ml/min).

PLACEMENT:

1. Using image guidance (e.g., ultrasound, CT), place the Device into the tissue. Remember to begin your deployment 1.5 cm proximal to the center of your target for a 4 cm, 5 cm or 6 cm ablation and 2.0 cm proximal to the center for a 7 cm ablation. Please refer to the Xl*i enhanced* device placement diagram (procedure binder’s liver section).
2. Deploy the Device to the desired final deployment size.
3. Verify position and deployment of the device with imaging (e.g., ultrasound, CT).
4. Retract to 2 cm deployment.
5. Confirm Xl*i enhanced* mode with a maximum Power of 250 W and Target Temperature of 105ºC
6. Depress the RF ON/OFF button.

Caution: If the patient has a pacemaker, consult the patient’s cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are/are not in the field of energy (not in the field between the target tumor and the dispersive electrodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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Infusion Based RFA Liver Tumor Protocol (cont).

ABLATION

1. Start the RF power using the foot pedal or RF ON/OFF button.

Table: Guidelines for Time at Target Temperature*

Protocol: Ablation	Deployment	Target Temperature	Hold at Target Temperature
For a 4-cm ablation:	2cm	105°	
	3cm	105°	
	4cm	105°	6 min.
For a 5-cm ablation:	2cm	105°	
	3cm	105°	
	4cm	105°	6 min.
	5cm	105°	6 min.
For a 6-cm ablation:	2cm	105°	
	3cm	105°	
	4cm	105°	
	5cm	105°	6 min.
	6cm	105°	6 min.
For a 7-cm ablation:	2cm	105°	
	3cm	105°	
	4cm	105°	
	5cm	105°	
	6cm	105°	6 min.
	7cm	105°	6 min.

*These ablation parameters have been developed from RITA Medical Systems' experience in liver tissue (i.e., explanted beef liver and unresectable liver lesion patients). Shorter ablation times may result in a smaller ablation size.

Note: Temperature array 4 (only passive array) will automatically be removed from the Generatortemperature algorithm at every deployment. Target temperatures will automatically be set at 105 degrees at each deployment. The infusion rate will automatically be set at 0.05 ml/min and will automatically be adjusted as necessary throughout the ablation.

Infusion Based RFA Liver Tumor Protocol (cont).

COOL DOWN

1. When the timer runs out, the Generator automatically goes into “Cool Down” mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).

TRACK ABLATION

1. For Track Ablation, retract the arrays fully and depress the Track Ablation ON/OFF button. When ready depress the RF ON/OFF button to start track ablation.

   Note: watch only temperature #4. When it reaches 60°C, retract approximately 1 cm. Repeat until entire track is ablated.

Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms)or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase, bringing the other temperatures up.
- If temperatures have not risen for 2 minutes, increase the power.
- If temperatures have not risen for 2 minutes, retract the needles ½ cm. Once the desired target temperature is reached, deploy the needles ½ cm to the previous setting.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

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Infusion Based RFA Liver Tumor Protocol (cont).

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out at the end of an ablation, check cool down temperatures to determine if continued ablation is necessary.

Micro-infusion needle is blocked:

- If a needle becomes blocked (e.g., Pump will alarm), turn off the RF energy and check that the fluid tubing has not become kinked, pinched or clamped.
- Alternatively, turn off the RF energy and remove all non-occluded syringes from the pump and manually purge with hand. Note: Using a tuberculin syringe may help purge the occlusion. Once cleared, replace with 10 cc syringe and insert in pump.

If having difficulty retracting array:

- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

In instances during procedures where the pad temperatures are high:

- Decrease pad temperature by cooling the pad. (See note below)
- Decrease the delivered power.
- Interrupt the ablation until the skin temperature cools.

  Note: Cool pads to 38ºC or below. One technique for decreasing pad temperatures is to apply chemical cool packs or ice pack(s) on the entire leading edge of the pad (refer to pad placement graphic). Ensure that there is a barrier between the chemical cool pack and skin. If using ice packs, ensure a barrier between ice pack and skin and that the area remains dry.

  DO NOT USE DRY ICE. Once temperature is below 38ºC, the software is automatically reset.

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

RITA MEDICAL SYSTEMS

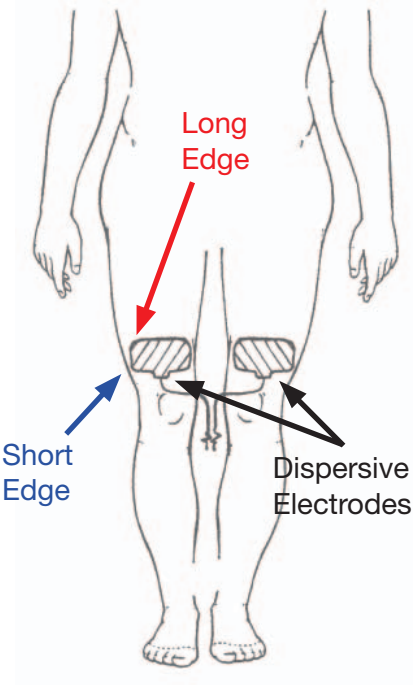
Liver

RITA Medical Systems

RFA for Liver Tumor Protocol

Compatible Devices: StarBurst™ XL, SEMI-FLEX, MRI & SDE

SETUP



1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site and at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be place over bony prominences, scar tissue, skin over an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patients' leg by placing a towel between the patient thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.
3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below. (Always start with the parameters for a 2 cm deployment.)

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive electrodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

RFA for Liver Tumor Protocol (cont.)

PLACEMENT: StarBurst™ XL, SEMI-FLEX & MRI

1. Place Device and deploy array to desired ablation size. Use forward pressure and monitor for tissue displacement or Device "push-back". Once deployed, apply forward pressure to seat the Device. Then retract array to 2 cm starting position for a 3 cm, 4 cm, or 5 cm ablation. Remember to begin your deployment 1 cm proximal to the center of your target for a 3 or 4 cm ablation, 1.5 cm proximal to the center for a 5 cm ablation. **Please refer to the StarBurst™ XL, SEMI-FLEX and MRI placement diagram (procedure binder's Liver section).**
2. Connect Device to Main Cable and Main Cable to Generator. Verify temperature display and impedance reading.
3. Set to Control Mode A.

ABLATION

1. Start the RF power using the foot pedal or RF ON/OFF button.

For a 5 cm ablation:

Deploy to: (always 1st step)	Set Target Temp at:	Set Power at:	Set Timer at:	For a Duration of:
2 cm	105°	150 W	15.0	Until Target Temp is reached (you will hear a beep) then deploy to 3 cm
3 cm	105°	150W	14.5	Until Target Temp is reached (you will hear a beep) then deploy to 4 cm
4 cm	105°	150W	14.0*	7 minutes at Target Temp (after hearing the beep wait 7 min.) then deploy to 5
5 cm	105°	150W	7.0**	7 minutes at Target Temp (after hearing the beep wait 7 min.) then go to Cool Down

* Ensure that there is at least 14 minutes on the timer after deploying to 4 cm. If it is less than 14, increase to 14.

** Ensure that there is at least 7 minutes on the timer after deploying to 5 cm. If it is less than 7, increase to 7.

Note: when deploying from 2 cm to 3 cm, 3 cm to 4 cm, and from 4 cm to 5 cm, there should be a drop in temperatures and a rise in power output. If this does not occur, Device may not be deployed properly. In this case, retract and redeploy to achieve these changes.

RFA for Liver Tumor Protocol (cont.)

For a 4 cm ablation:

Deploy to:	Set Target Temp at:	Set Power at:	Set Timer at:	For a Duration of:
2 cm	105°	150 W	8.0	Until Target Temp is reached (you will hear a beep) then deploy to 3 cm
3 cm	105°	150 W	7.5	Until Target Temp is reached (you will hear a beep) then deploy to 4 cm
4 cm	105°	150 W	7.0**	7 minutes at Target Temp

** Ensure that there is at least 7 minutes on the timer after deploying to 4 cm. If it is less than 7, increase to 7.

For a 3 cm ablation:

Deploy to:	Set Target Temp at:	Set Power at:	Set Timer at:	For a Duration of:
2 cm	105°	150 W	5.5	Until Target Temp is reached (you will hear a beep) then deploy to 3 cm
3 cm	105°	150 W	5.0+	5 minutes at Target Temp

+ Ensure that there is at least 5 minutes on the timer after deploying to 3 cm. If it is less than 5, increase to 5.

*These ablation parameters have been developed from RITA Medical Systems' experience in liver tissue (i.e., explanted beef liver and unresectable liver lesion patients). Shorter ablation times may result in a smaller ablation size.

Note: When deploying from 2 cm to 3 cm, 3 cm to 4 cm, and from 4 cm to 5 cm, there should be a drop in temperatures and a rise in power output.

Note: A successful deployment causes temperatures to fall ≈20ºC as the electrode advances into cool tissue. If the temperatures do not drop, Device may not be deployed properly. Either retract and redeploy the arrays or push the handle distally to flair the array.

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102874 Rev 02.

RFA for Liver Tumor Protocol (cont.)

COOL DOWN

1. When the timer runs out, the Generator automatically goes into “Cool Down” mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 70°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).
3. If cool down temps are low, consider ablating for an additional 5 minutes.

PLACEMENT StarBurst™ SDE (for lesion up to 2 cm)

1. The tip of the trocar should be placed approximately 6 millimeters distal to the center of the target area. **Please refer to the SDE placement diagram (Liver section).**
2. The uninsulated portion of the trocar tip is 1.4cm.

CAUTION: Do not bend or kink the trocar or electrodes/needles during placement or once they are placed inside tissue. This may cause damage and result in a non-functional device.

ABLATION using StarBurstTM SDE

1. Connect Device to Main Cable and Main Cable to Generator. Verify temperature display and impedance reading.
2. Set to control Mode A with maximum power 150 W and target temperature 105ºC.
3. Start the RF power using the foot pedal or RF ON/OFF button.

For a 2 cm ablation:

Deploy to:	Set Target Temp at:	Set Power at:	Set Timer at:	For a Duration of:
2 cm	105°	150 W	5	Until Target Temp is reached (you will hear a beep) 5 minutes at target temperature

* These ablation parameters have been developed from RITA Medical Systems’ experience in liver tissue (i.e., explanted beef liver and unresectable liver lesion patients). Shorter ablation times may result in a smaller ablation size.

COOL DOWN

1. When the timer runs out, the Generator automatically goes into “Cool Down” mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).

RFA for Liver Tumor Protocol (cont.)

TRACK ABLATION

1. For Track Ablation, retract the array fully and depress the Track Ablation ON/OFF button. When ready depress the RF ON/OFF button to start track ablation.

   Note: for XL, SEMI-FLEX, and MRI watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat until entire track is ablated.

   Note: for SDE watch only temperature #3. When it reaches 70°C, retract approximately 1 cm.

   Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance was gradually increasing, consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.
- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.

If having difficulty retracting array:

- Consider infusing normal saline and working shaft back and forth to loosen cooked tissue.
- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102874 Rev 02.

Bone Metastatic

RITA MEDICAL SYSTEMS

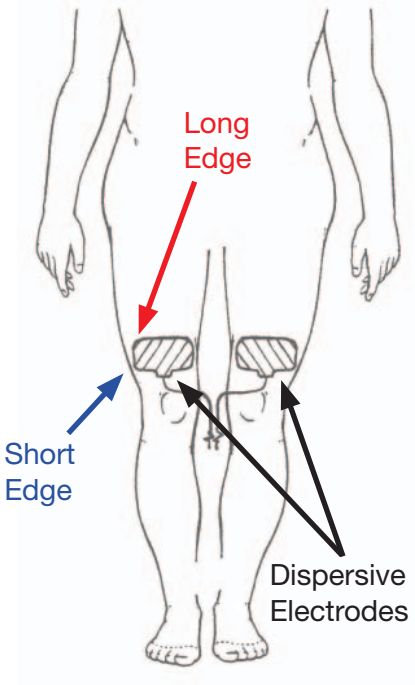
BONE METASTATIC

RITA Medical Systems

RFA of Painful Metastases Involving Bone Protocol

Compatible Devices: StarBurst™ XL, SEMI-FLEX, MRI & SDE

SETUP



1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large, well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be place over bony prominences, scar tissue, skin over an implanted metal prosthesis, hairy sur faces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patient's leg by placing a towel between the patient's thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.
3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below. (Always start with the parameters for a 2 cm deployment.)

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive electrodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

RFA of Painful Metastases Involving Bone Protocol (cont.)

PLACEMENT: StarBurst™ XL, SEMI-FLEX & MRI Devices for Painful Metastases Involving Bone

1. Connect the Device to the Main Cable and the Main Cable to the RF Generator. Verify the temperature display and the impedance reading. Test the temperature response of the Device by holding each array tip and observing a temperature increase on the RF Generator display.
2. Using imaging guidance, place the Device by holding along the main body. **Note: For SEMI-FLEX device, hold the main body with one hand and the trocar (at the point of insertion) with the other hand.** Do not hold the deployment shaft handle during placement, as this could inadvertently cause deployment of the array. The tip of the trocar should be placed approximately 1 cm (for a 3-cm ablation) to 1.5 cm (for a 5-cm ablation) proximal to the center of the target area. **PLEASE REFER TO THE STARBURST™ XL, SEMI-FLEX AND MRI PLACEMENT DIAGRAM (PROCEDURE BINDER'S LIVER SECTION).**
3. After Device placement is complete, deploy the array electrodes slowly by holding the main body in place (with light forward pressure) and pushing on the deployment shaft disk. Use forward pressure and monitor for tissue displacement or Device "push-back". Once deployed, apply forward pressure to seat the Device. Deploy array electrodes as indicated in the table below based on desired deployment size.
4. Monitor the deployment with imaging to ensure that it is deployed properly into the intended area. This intended area should be at least 1 cm from tissue not intended for ablation.
5. If the area targeted for ablation is encased in cortical bone, it may be necessary to use the RITA StarBurst Hard Tissue Access System to achieve entry. Use only an insulated or conductive trocar/introducer to prevent RF current from traveling to the biopsy system and causing unintended tissue damage.

PLACEMENT StarBurst™ SDE (for lesion up to 2 cm)

- The tip of the trocar should be placed approximately 6 millimeters distal to the center of the target area. **Please refer to the SDE placement diagram (procedure binder's Liver " section).**
- The uninsulated portion of the trocar tip is 1.4cm.

CAUTION: Do not bend or kink the trocar or electrodes/needles during placement or once they are placed inside tissue. This may cause damage and result in a non-functional device.

RFA of Painful Metastases Involving Bone Protocol (cont.)

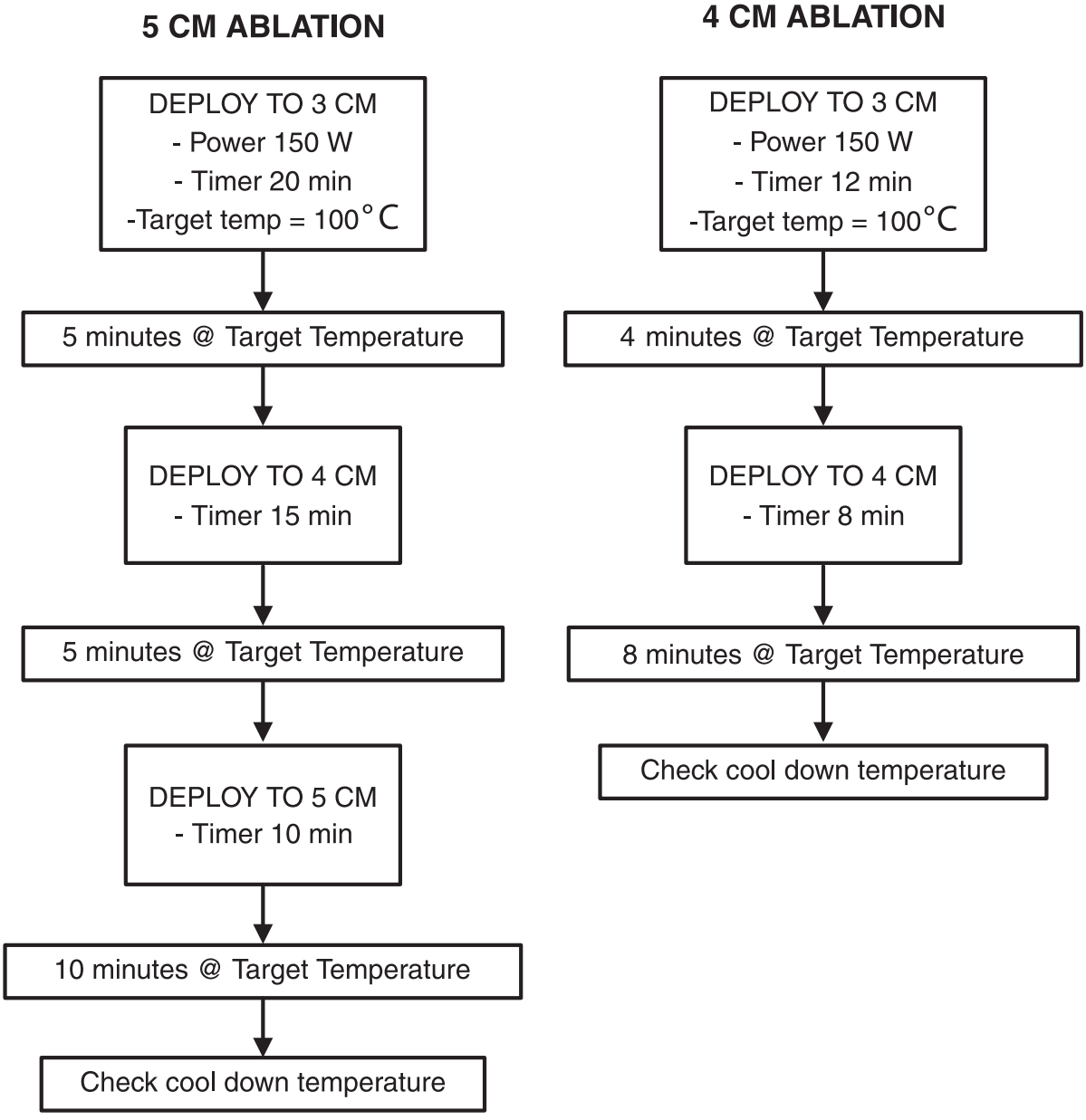
ABLATION

1. Set the parameters on the RF Generator using the following as a guideline.
2. Set to Control Mode A.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

Table: Guidelines for Time at Target Temperature*

Array Electrode Deployment Protocol – Metastases w/ Extensive Bone Destruction



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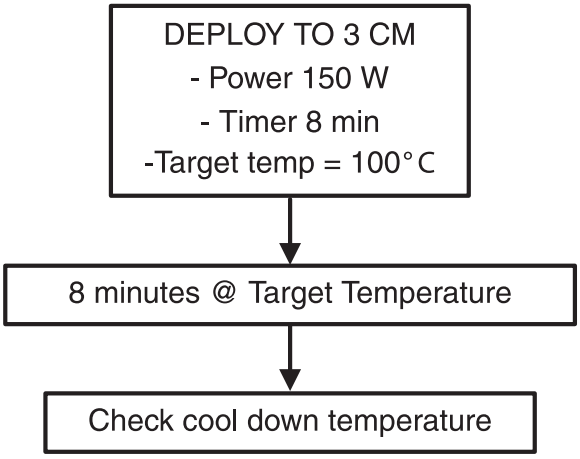
RFA of Painful Metastases Involving Bone Protocol (cont.)

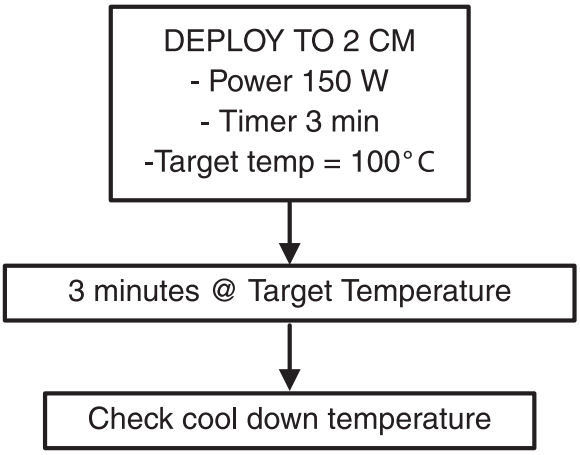
Table: Guidelines for Time at Target Temperature (cont.)*

Array Electrode Deployment Protocol – Metastases w/ Extensive Bone Destruction (cont.)

3 CM ABLATION

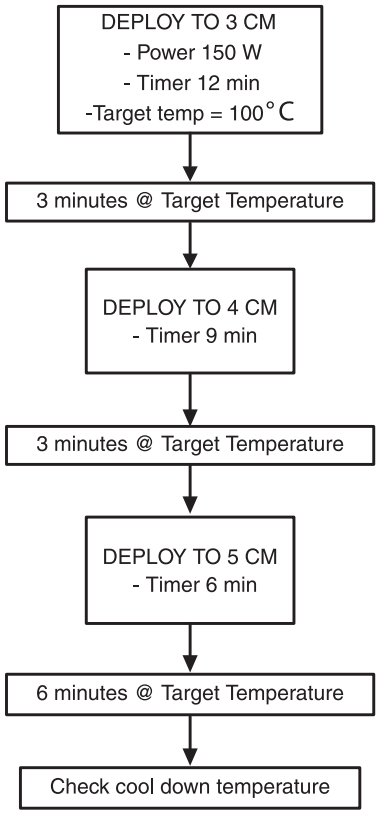


2 CM ABLATION

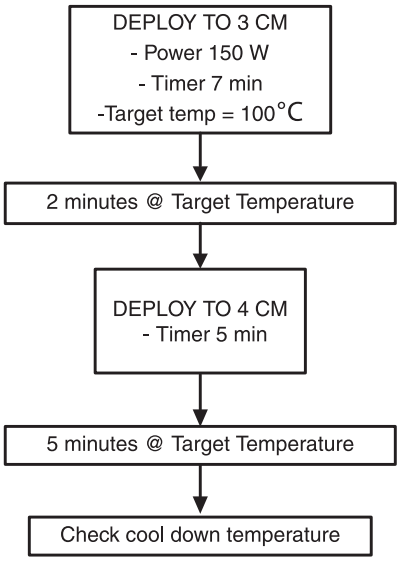


Array Electrode Deployment Protocol – Metastases Encased in/Surrounded by Bone †

5 CM ABLATION



4 CM ABLATION

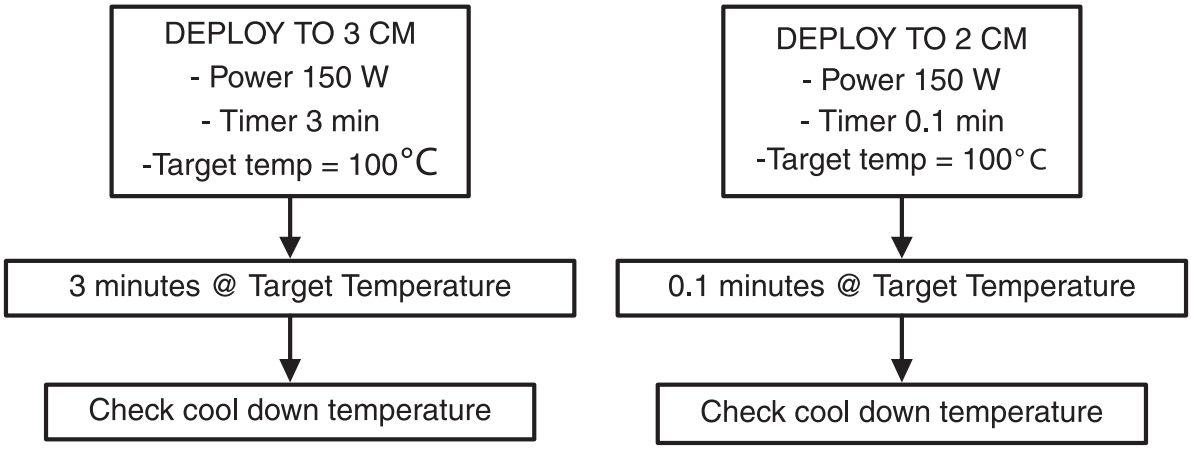


The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA and StarBurst are trademarks of RITA Medical Systems, Inc. RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102871 Rev 02.

RFA of Painful Metastases Involving Bone Protocol (cont.)

Table: Guidelines for Time at Target Temperature (cont.)*

Array Electrode Deployment Protocol – Metastases Encased in/Surrounded by Bone (cont.)



* These ablation parameters have been developed from a multi-center clinical study of painful metastases involving bone. Shorter ablation times may result in a smaller ablation size. Goetz MP, Callstrom MR, Charboneau JW, et al. Percutaneous Image-Guided Radio-frequency Ablation of Painful Metastases Involving Bone: A Multicenter Study. *J Clin Oncol*. January 2004;22(2):300-306.

† At 2-cm deployment, ablation lesions, using these parameters and performed in metastases encased in or surrounded by bone, may be larger than 2 cm.

Note: A successful deployment causes temperatures to fall ≈20ºC as the electrode advances into cool tissue. If the temperatures do not drop, either retract and redeploy the arrays or push the handle distally to flair the arrays.

COOL DOWN

1. When the timer runs out, the Generator automatically goes into “Cool Down” mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).
   Note: Cool down temperatures < 60ºC may require additional ablation time.

TRACK ABLATION

1. For Track Ablation, retract the arrays fully, and depress the Track Ablation ON/OFF button. When ready depress the RF ON/OFF button to start track ablation.

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User’s Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102871 Rev 02.

RFA of Painful Metastases Involving Bone Protocol (cont.)

Note: For XL, SEMI-FLEX, and MRI watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat until entire track is ablated.

Note: For SDE watch only temperature #3. When it reaches 70°C, retract.

Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING (Metastatic tumors only)

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance was gradually increasing, consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.
- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.

If having difficulty retracting array:

- Consider infusing normal saline and working shaft back and forth to loosen cooked tissue.
- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for detailed instructions, warnings, precautions and possible adverse effects. RITA Medical Systems, Inc. 967 N. Shoreline Blvd. Mountain View, CA 94043 1-800-472-5221 150-102871 Rev 02.

RITA MEDICAL SYSTEMS

IntelliFlow

Tips for IntelliFlow Pump

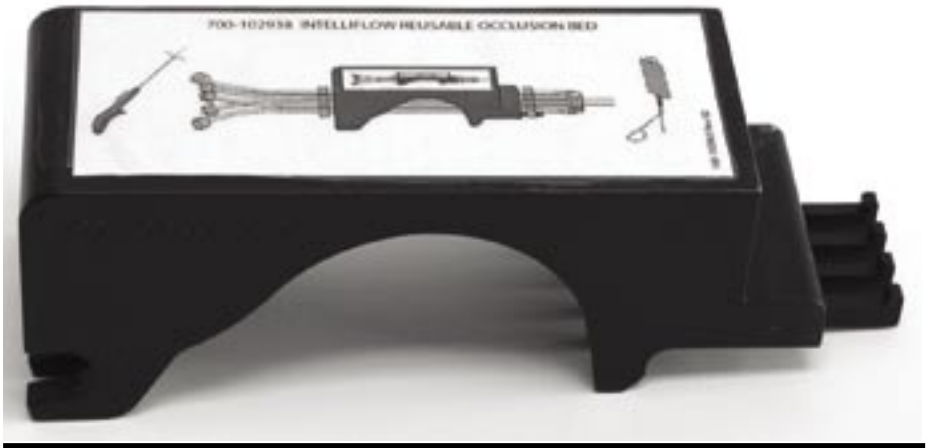


Figure 1: Reuseable Occlusion Bed

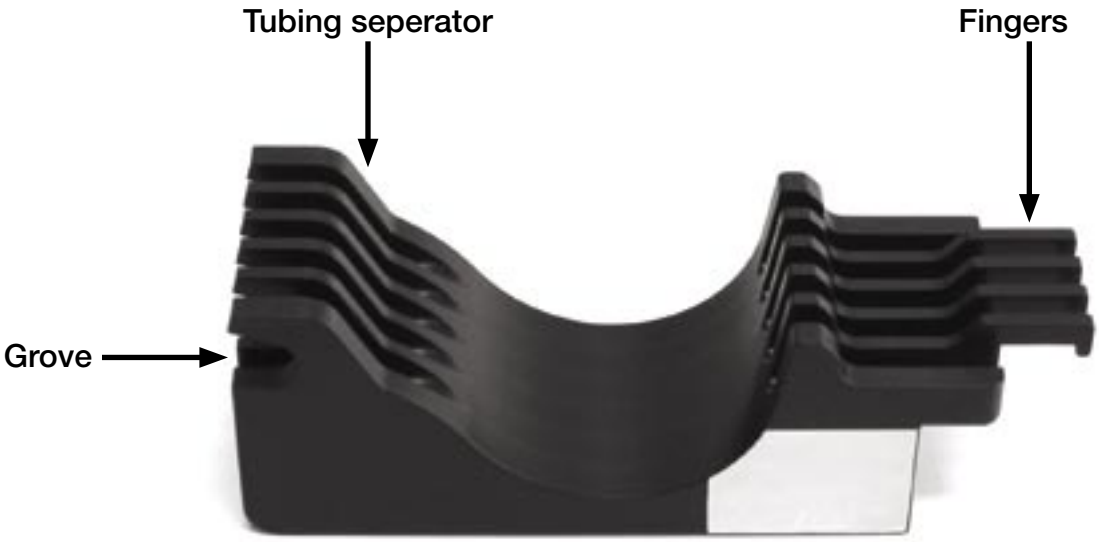


Figure 2: Inverted Occlusion Bed

Tips for IntelliFlow Pump (cont.)

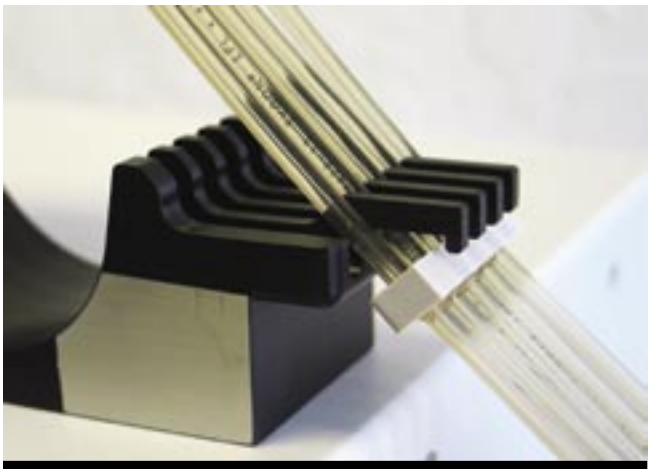


Figure 3:
- Bed Inverted (flat side down)
- Feed the tubing thru the tubing seperator

Figure 4: Stretch the tubing thru the tubing seperator on the other side of the bed

Figure 5: Verify the tube cassette is on the outside of the tubing seperator.

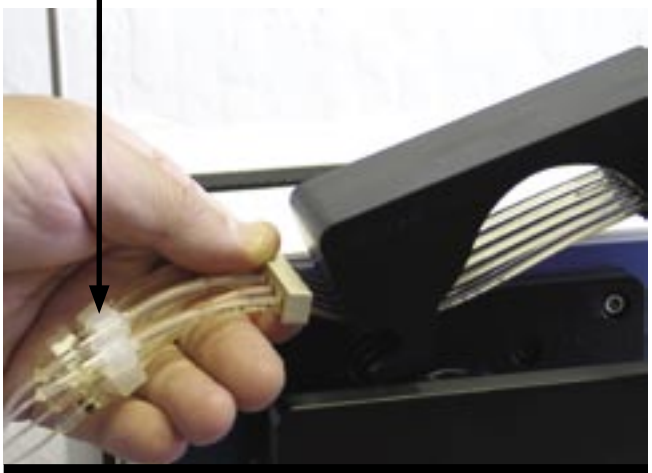


Figure 6:
- Invert occlusion bed
- Maintain tension on the tubing

Tips for IntelliFlow Pump (cont.)

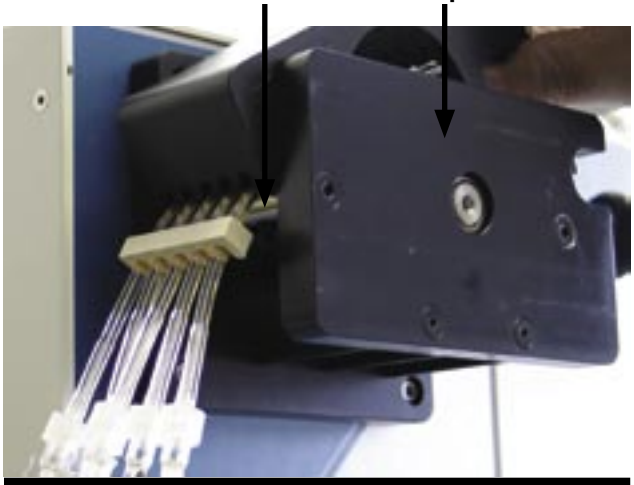


Figure 7: • Place the semi-circle of the bed onto the cross bar

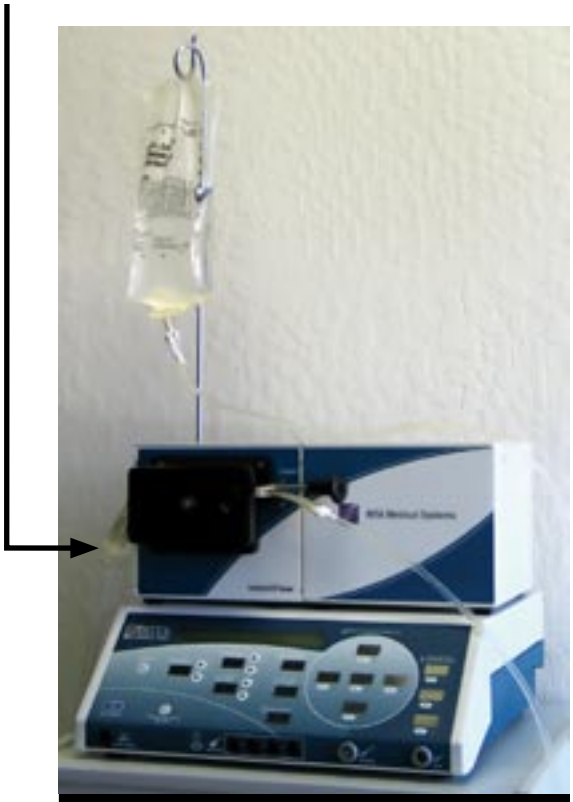


Figure 8: • Spike saline bag
• Allow saline to run completely thru tubing until it flows past luer lock connectors

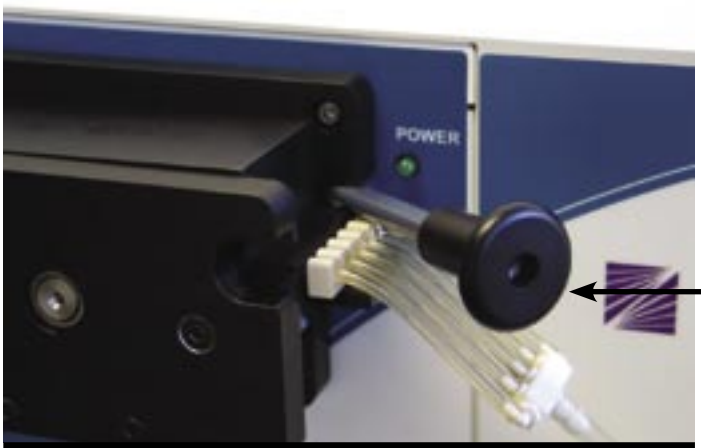


Figure 9: • Tubing to saline bag on right side of bed
• Cassette is snug against the bed

Tips for IntelliFlow Pump (cont.)

Figure 10: Pull latch out and over tubing.

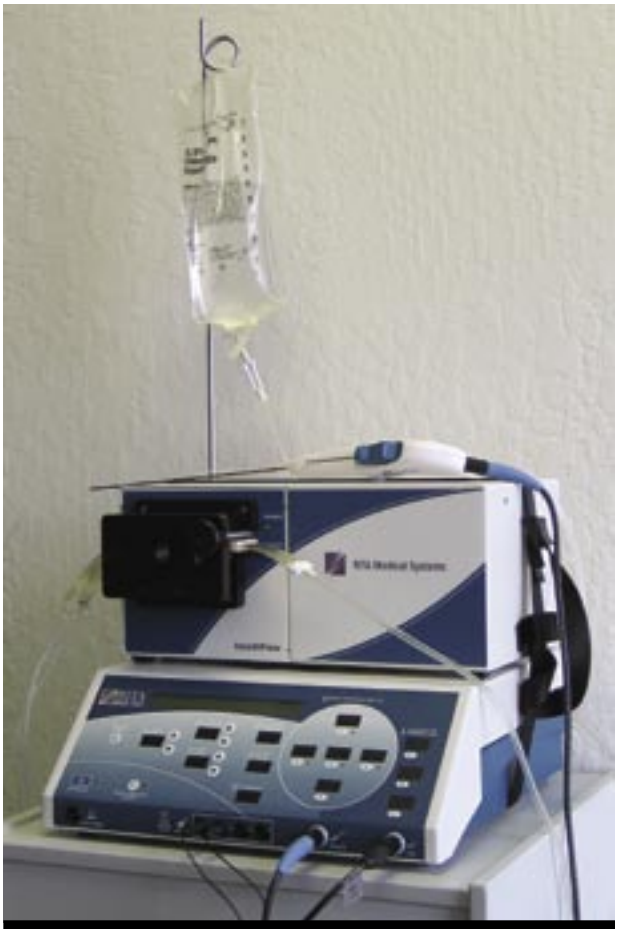


Figure 11: Complete set-up

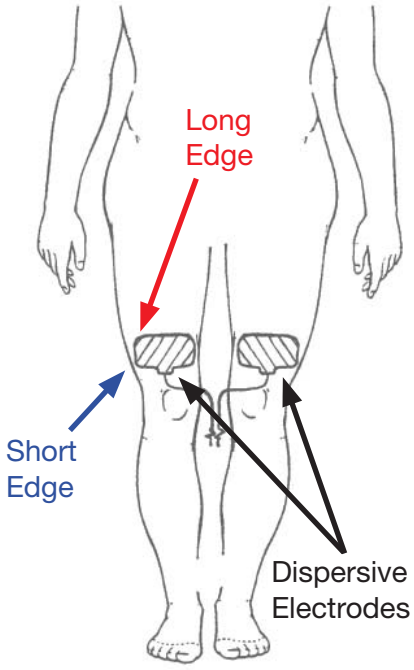
RITA MEDICAL SYSTEMS

Osteoid Osteoma

RFA of Osteoid Osteoma Protocol

Compatible Devices: StarBurst™ XL, SEMI-FLEX, MRI & SDE

SETUP



1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large, well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be placed over bony prominences, scar tissue, skin covering an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patients' leg by placing a towel between the patient thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.
3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below. (Always start with the parameters for a 2 cm deployment.)

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive elec trodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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RFA of Osteoid Osteoma Protocol (cont.)

PLACEMENT: Using Starburst™ XL, SEMI-FLEX, MRI and SDE Devices for Osteoid Osteoma

1. Connect the Device to the Main Cable and the Main Cable to the RF Generator. Verify the temperature display and the impedance reading. Test the temperature response of the Device by holding each array tip and observing a temperature increase on the RF Generator display.
2. Using imaging guidance, place the Device by holding along the main body. Note: For SEMI-FLEX device, hold the main body with one hand and the trocar (at the point of insertion) with the other hand. Do not hold the deployment shaft handle during placement, as this could inadvertently cause deployment of the array. The device should be positioned such that the un-insulated tip (for XL, SemiFlex and MRI device equals 0.5 cm and SDE equals 1.4 cm) of the trocar is in the nidus of the tumor. (Note: RITA StarBurst Hard Tissue Access System should be used.)
3. Monitor the ablation with imaging to ensure that it is positioned in the proper area. This intended ablation area should be at least 1 cm from tissue not intended for ablation.

Caution: If the area targeted for ablation is superficial, i.e., in close proximity to the skin surface, monitor the temperature of the superficial tissues for excessive heating. If the area becomes too warm, consider applying a chemical cool pack (isolated from the skin with dry cloth) to prevent tissue damage.

ABLATION

1. Connect Device to Main Cable and Main Cable to Generator. Verify temperature display and impedance reading.
2. Start the RF power using the foot pedal or RF ON/OFF button.
3. Set the parameters on the RF Generator using the following as a guideline.

Table: Guidelines for Time at Target Temperature*

Target Temp (Average, °C)	90
Wattage	35-60**
Time at Target Temp (min)	5

** Start with lower setting. If the system is slow to reach target temperature, increase Power as necessary.

* These ablation parameters have been developed from published experience RFA in Osteoid Ostemoma's. Rosenthal DI, Hornicek FJ, Torriani M, Gebhardt MC, Mankin HJ. Osteoid osteoma: Percutaneous treatment with radiofrequency energy. *Radiology* 2003; 229(1): 171-5.

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RFA of Osteoid Osteoma Protocol (cont.)

TRACK ABLATION

1. For Track Ablation, retract the arrays fully, and depress the Track Ablation ON/OFF button. When ready depress the RF ON/OFF button to start track ablation.

Note: for XL, SEMI-FLEX, and MRI watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat until entire track is ablated.

Note: for SDE watch only temperature #3. When it reaches 70°C, retract.

Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- **If it is high at the beginning of the case, check the dispersive electrode for proper placement.**
- **If it is high during the case, consider lowering the target temperature, taking out the lowest temperature.**
- **If power is also high, consider decreasing the power.**

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.
- If it impedes out at the end of an ablation, check cool down temperatures to determine if continued ablation is necessary.

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

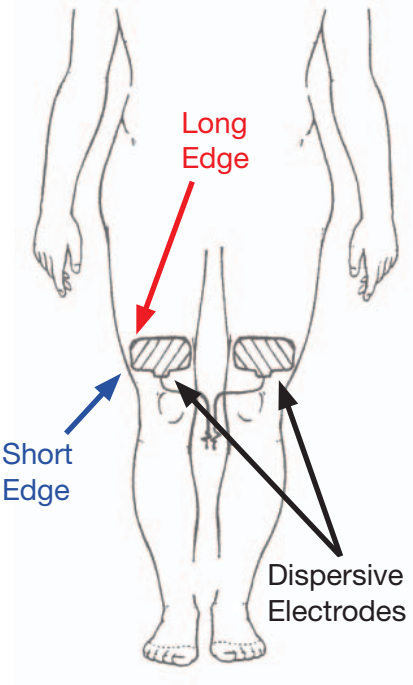
RITA MEDICAL SYSTEMS

Lung

RFA of Malignant Lung Tumor Protocol

Compatible Devices: StarBurst™ XL, SEMI-FLEX, MRI & SDE

SETUP



1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be place over bony prominences, scar tissue, skin over an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patient's leg by placing a towel between the patient's thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.
3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below. (Always start with the parameters for a 2 cm deployment.)

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive elec trodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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RFA of Malignant Lung Tumor Protocol (cont.)

PLACEMENT: StarBurst™ XL, Semi-Flex & MRI

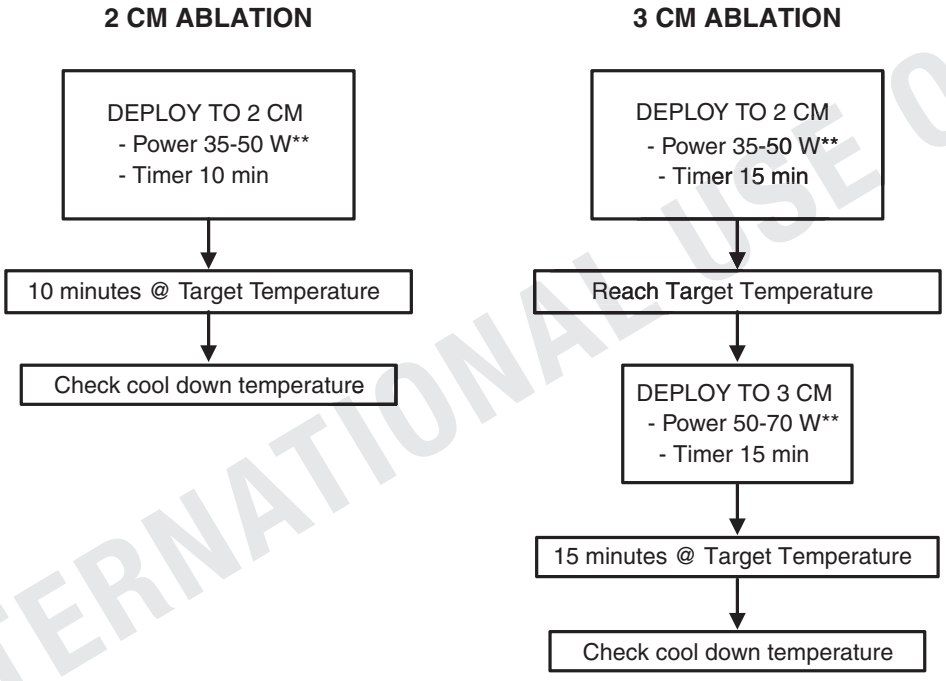
1. Place Device and deploy array to desired ablation size. Use forward pressure and monitor for tissue displacement or Device "push-back". Once deployed, apply forward pressure to seat the device. Then retract array to 2 cm starting position for a 3 cm, 4 cm, or 5 cm ablation. Remember to begin your deployment 1 cm proximal to the center of your target for a 3 or 4 cm ablation, 1.5 cm proximal to the center for a 5 cm ablation. **Please refer to the StarBurst™ XL, SEMI-FLEX and MRI placement diagram (Liver section).**
2. Connect Device to Main Cable and Main Cable to Generator. Verify temperature display and impedance reading.

ABLATION

1. Set the parameters on the RF Generator using the following as a guideline.
2. Set to Control Mode A with target temperature 90ºC.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

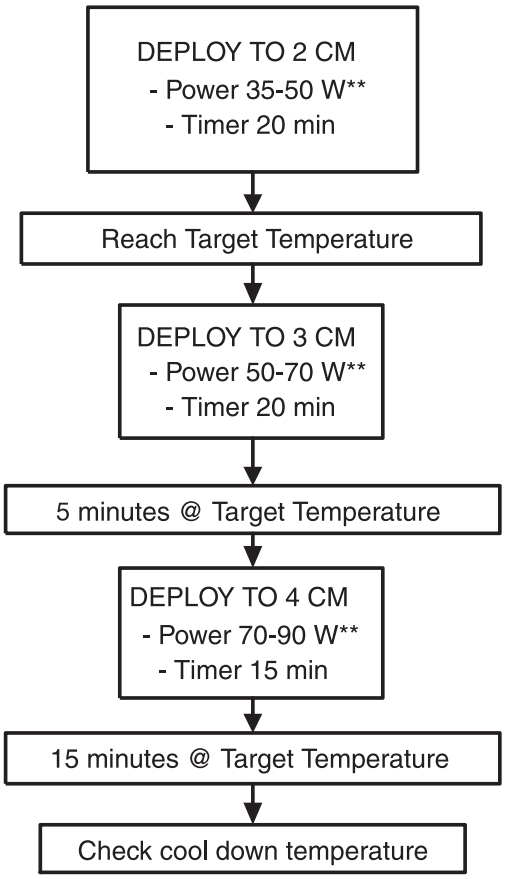
Table: Guidelines for Time at Target Temperature*



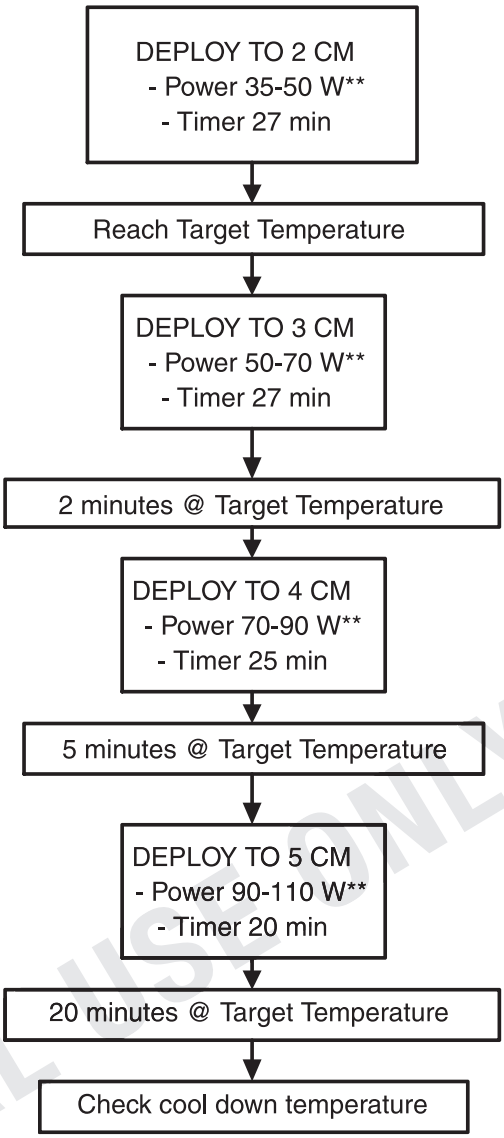
** Start ablation with lower Power setting. If system is slow to reach target temperature and impedance is low (less than 100 ohms), increase Power as needed to reach target temperature.

RFA of Malignant Lung Tumor Protocol (cont.)

4 CM ABLATION



5 CM ABLATION



* These ablation parameters have been developed from RITA Medical Systems' experience in a prospective multi-center Clinical trial. Shorter ablation times may result in a smaller ablation size. Lencioni RA, Crocetti L, Cioni R, Ambrogi M, Mussi A, Angeletti C, Wallace A, Suh R, Bartolozzi C. Percutaneous radiofrequency ablation of stage I non-small cell lung cancer: a prospective multicenter clinical trial. In: *American Society of Clinical Oncology* [ASCO]; June 5-8, 2004; New Orleans, LA.

** Start ablation with lower Power setting. If system is slow to reach target temperature and impedance is low (less than 100 ohms), increase Power as needed to reach target temperature.

Note: when deploying from 2 cm to 3 cm, 3 cm to 4 cm, and from 4 cm to 5 cm, there should be a drop in temperatures and a rise in power output. If this does not occur, device may not be deployed properly. In this case, retract and redeploy to achieve these changes.

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RFA of Malignant Lung Tumor Protocol (cont.)

Note: A successful deployment causes temperatures to fall ≈20ºC as the electrode advances into cool tissue. If the temperatures do not drop, either retract and redeploy the arrays or push the handle distally to flair the arrays.

COOL DOWN

1. When the timer runs out, the Generator automatically goes into "Cool Down" mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary.)

PLACEMENT StarBurst™ SDE (for lesion up to 2 cm)

1. The tip of the trocar should be placed approximately 6 millimeters distal to the center of the target area. **Please refer to the SDE placement diagram (procedure binder's Liver section).**
2. The uninsulated portion of the trocar tip is 1.4cm.

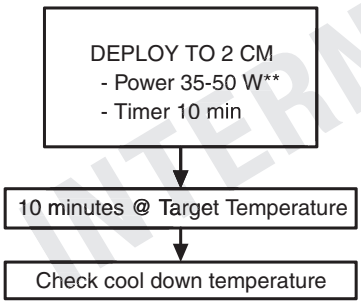
CAUTION: Do not bend or kink the trocar or electrodes/needles during placement or once they are placed inside tissue. This may cause damage and result in a non-functional device.

ABLATION using StarBurst™ SDE

1. Set the parameters on the RF Generator using the following as a guideline.
2. Set to Control Mode A with target temperature 90ºC.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

2 CM ABLATION



** Start ablation with lower Power setting. If system is slow to reach target temperature and impedance is low (less than 100 ohms), increase Power as needed to reach target temperature.

RFA of Malignant Lung Tumor Protocol (cont.)

COOL DOWN

1. When the timer runs out, the Generator automatically goes into “Cool Down” mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).

TRACK ABLATION

1. For Track Ablation, retract the arrays fully and depress the Track Ablation ON/OFF button. When ready depress the RF ON/OFF button to start track ablation.

   Note: For XL, SEMI-FLEX, and MRI watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat until entire track is ablated.
   Note: For SDE watch only temperature #3. When it reaches 70°C, retract approximately 1 cm.

   Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance was gradually increasing, consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.
- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.

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RFA of Malignant Lung Tumor Protocol (cont.)

If having difficulty retracting array:

- Consider infusing normal saline and working shaft back and forth to loosen cooked tissue.
- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

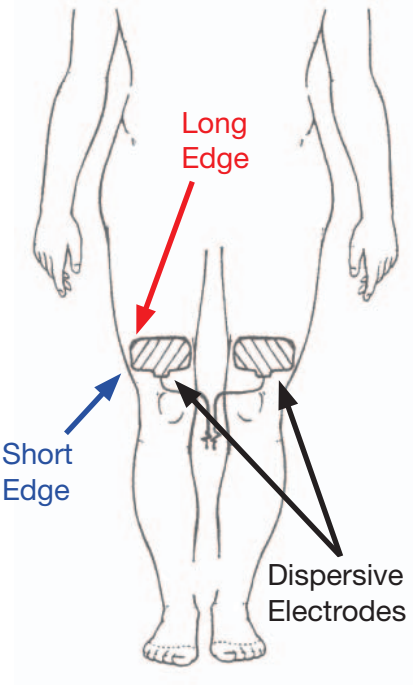
RITA MEDICAL SYSTEMS

Kidney

RFA for Kidney Protocol

Compatible Devices: StarBurst™ XL, SEMI-FLEX, MRI & SDE

SETUP



1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large, well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be placed over bony prominences, scar tissue, skin covering an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patient's leg by placing a towel between the patient's thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.
3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below.

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive elec trodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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RFA for Kidney Protocol (cont.)

PLACEMENT: StarBurst™ XL, Semi-Flex & MRI

1. Connect the Device to the Main Cable (**Black** Model 1500) or (**GREEN** Model 1500X) and the Main Cable to the RF Generator. Verify the temperature display and the impedance reading. Test the temperature response of the Device by holding each array tip and observing a temperature increase on the RF Generator display.
2. Insert device percutaneously (after a small nick is made in the skin using a scalpel) under real-time ultrasound guidance through the tumor.
3. Place the Device by holding along the main body. Note: For Semi-Flex device, hold the main body with one hand and the trocar (at the point of insertion) with the other hand. Do not hold the deployment shaft handle during placement, as this could inadvertently cause deployment of the array. The tip of the trocar should be placed approximately 1 cm (for a 3-cm ablation) proximal to the center of the target area. **PLEASE REFER TO THE STARBURST™ XL, SEMI-FLEX AND MRI PLACEMENT DIAGRAM (PROCEDURE BINDER'S LIVER SECTION).**
4. After Device placement is complete, deploy the array electrodes slowly by holding the main body in place (with light forward pressure) and pushing on the deployment shaft disk. Use forward pressure and monitor for tissue displacement or Device "push-back". Once deployed, apply forward pressure to seat the device. Deploy array electrodes as indicated in the flowchart below based on desired deployment size.
5. Monitor the deployment with imaging (real-time ultrasound) to ensure that it is deployed properly into the intended area. This intended area should be at least 1 cm from tissue not intended for ablation.

ABLATION

1. Set the parameters on the RF Generator using the following as a guideline.
2. Set to Control Mode A with maximum power 150 W and target temperature 105ºC.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

International Use Only

RFA for Kidney Protocol (cont.)

Table: Guidelines for Time at Target Temperature*

2 cm Ablation	3 cm Ablation	4 cm Ablation	5 cm Ablation
Deploy to 2 cm Timer at 5 minutes	Deploy to 3 cm Timer at 7 minutes	Deploy to 4 cm Timer at 8 minutes	Deploy to 5 cm Timer at 10 minutes
5 minutes @ Target Temperature (TT) (cycle 1)	7 minutes @ Target Temperature (TT) (cycle 1)	8 minutes @ Target Temperature (TT) (cycle 1)	10 minutes @ Target Temperature (TT) (cycle 1)
Reset Time 5 minutes	Reset Time 7 minutes	Reset Time 8 minutes	Reset Time 10 minutes
Start RF energy 5 minutes at TT (cycle 2)	Start RF energy 7 minutes at TT (cycle 2)	Start RF energy 8 minutes at TT (cycle 2)	Start RF energy 10 minutes at TT (cycle 2)
If any of these conditions - slow reaching target temperature - visual or radiographic evidence of incomplete ablation - cool down temp <60 °C then consider retracting, rotating, redeploying, and ablating for an additional 5 minutes at TT	If any of these conditions - slow reaching target temperature - visual or radiographic evidence of incomplete ablation - cool down temp <60 °C then consider retracting, rotating, redeploying, and ablating for an additional 5 minutes at TT	If any of these conditions - slow reaching target temperature - visual or radiographic evidence of incomplete ablation - cool down temp <60 °C then consider retracting, rotating, redeploying, and ablating for an additional 5 minutes at TT	If any of these conditions - slow reaching target temperature - visual or radiographic evidence of incomplete ablation - cool down temp <60 °C then consider retracting, rotating, redeploying, and ablating for an additional 5 minutes at TT

*** These ablation parameters have been developed from personal communication with Dr. Jeffrey Cadeddu and his recently published study: Matsumoto ED, Watumull L, Johnson BD, Ogan K, Taylor GD, Josephs S, Cadeddu JA. The radiographic evolution of radio frequency ablated renal tumors. *J Urol*. 2004;172:45-48.**

PLACEMENT StarBurst™ SDE (for lesion up to 2 cm)

1. The tip of the trocar should be placed approximately 6 millimeters distal to the center of the target area. **Please refer to the SDE placement diagram (liver section).**
2. The uninsulated portion of the trocar tip is 1.4cm.

CAUTION: Do not bend or kink the trocar or electrodes/needles during placement or once they are placed inside tissue. This may cause damage and result in a non-functional device.

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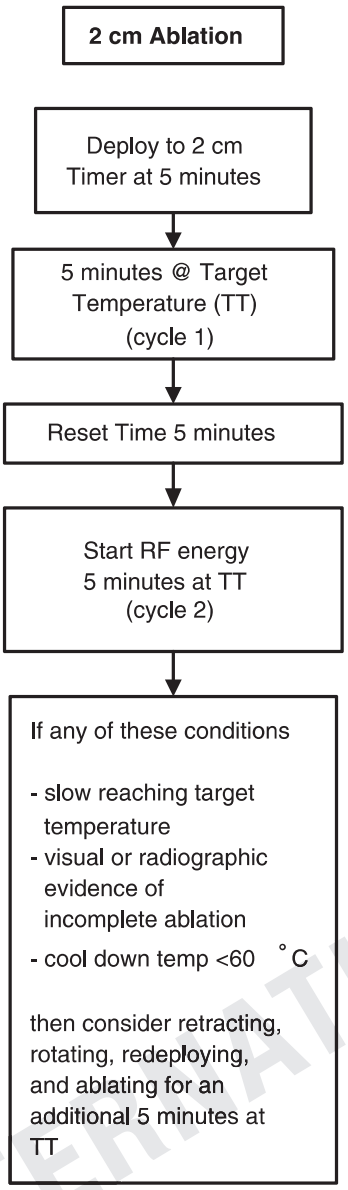
RFA for Kidney Protocol (cont.)

ABLATION using StarBurst™ SDE

1. Connect Device to Main Cable and Main Cable to Generator. Verify temperature display and impedance reading.
2. Set Control Mode A with maximum power 150 W and Target Temperature 105°C.
3. Start the RF power using the foot pedal or RF ON/OFF button.



COOL DOWN

1. When the timer runs out, the Generator automatically goes into **"Cool Down"** mode for 30 seconds (0.5 minutes on the Generator).

RFA for Kidney Protocol (cont.)

2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).

TRACK ABLATION

1. For Track Ablation, retract the arrays fully and depress the Track Ablation ON/OFF button. When ready, depress the RF ON/OFF button to start track ablation.

   Note: For XL, SEMI-FLEX, and MRI watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat until entire track is ablated.

   Note: For SDE watch only temperature #3. When it reaches 70°C, retract approximately 1 cm.

   Caution: To prevent unintended skin tissue following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance was gradually increasing,

RFA for Kidney Protocol (cont.)

consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.

- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.
- If it impedes out at the end of an ablation, check cool down temperatures to determine if continued ablation is necessary.

If not able to reach target temperature:

- If one tine not heating up (near vessel), consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.
- Consider stage deployments from 3 cm to 4 cm to 5 cm. Note: A successful deployment causes temperatures to fall ≈20ºC as the electrode advances into cool tissue. If the temperatures do not drop, either retract and redeploy the arrays or push the handle distally to flair the arrays.

If having difficulty retracting array:

- Consider infusing normal saline and working shaft back and forth to loosen cooked tissue.
- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

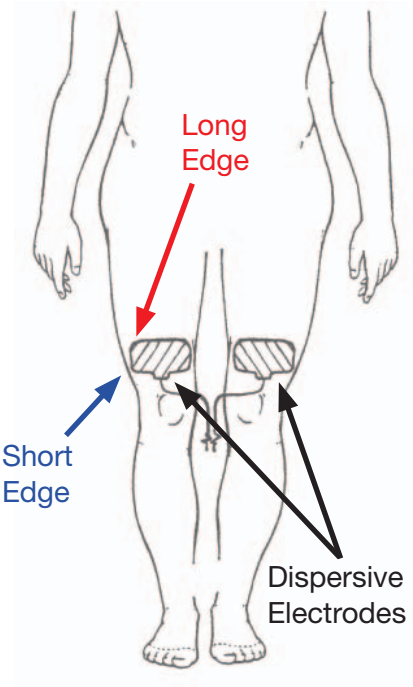
RITA MEDICAL SYSTEMS

Breast

RFA for Local Treatment of Small (≤ 2.0 cm) Breast Carcinoma Protocol

Compatible Devices: StarBurst™ XL, SEMI-FLEX & MRI

SETUP



1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be placed over bony prominences, scar tissue, skin covering an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patient's leg by placing a towel between the patient's thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.
3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below.

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive elec trodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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RFA for Local Treatment of Small (≤ 2.0 cm) Breast Carcinoma Protocol (cont.)

PLACEMENT: StarBurst™ XL, SEMI-FLEX & MRI

1. Connect the Device to the Main Cable (**Black** Model 1500) or (**GREEN** Model 1500X) and the Main Cable to the RF Generator. Verify the temperature display and the impedance reading. Test the temperature response of the Device by holding each array tip and observing a temperature increase on the RF Generator display.
2. Insert device percutaneously (after a small nick is made in the skin using a scalpel) under real-time ultrasound guidance through the tumor.
3. Place the Device by holding along the main body. Note: For Semi-Flex device, hold the main body with one hand and the trocar (at the point of insertion) with the other hand. Do not hold the deployment shaft handle during placement, as this could inadvertently cause deployment of the array. The tip of the trocar should be placed approximately 1 cm (for a 3-cm ablation) proximal to the center of the target area. **PLEASE REFER TO THE STARBURST™ XL, SEMI-FLEX AND MRI PLACEMENT DIAGRAM (PROCEDURE BINDER'S LIVER SECTION).**
4. After Device placement is complete, deploy the array electrodes slowly by holding the main body in place (with light forward pressure) and pushing on the deployment shaft disk. Use forward pressure and monitor for tissue displacement or Device "push-back". Once deployed, apply forward pressure to seat the device. Deploy array electrodes as indicated in the table below based on desired deployment size.
5. Monitor the deployment with imaging (real-time ultrasound) to ensure that it is deployed properly into the intended area. This intended area should be at least 1 cm from tissue not intended for ablation.

ABLATION

1. Set the parameters on the RF Generator using the following as a guideline.
2. Set to Control Mode A.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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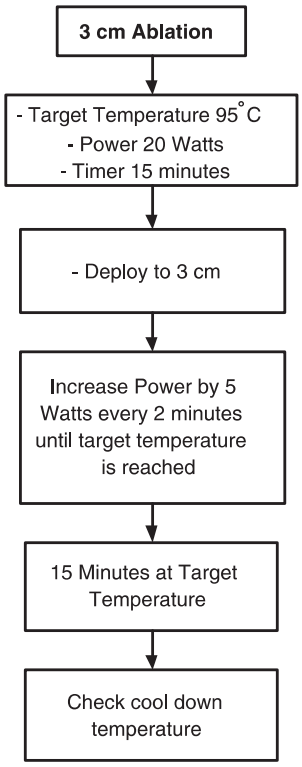
RFA for Local Treatment of Small (≤ 2.0 cm) Breast Carcinoma Protocol (cont.)

Table: Guidelines for Time at Target Temperature*



* These ablation parameters have been developed from a phase I IDE ablate and resect study in breast tissue. Fornage BD, Sneige N, Ross MI, et al. Small (≤2 cm) Breast Cancer Treated with US-guided Radiofrequency Ablation: Feasibility Study. *Radiology*. April 2004;231(1):215-224. Clinical safety and effectiveness in a treatment protocol has not been evaluated.

COOL DOWN

1. When the timer runs out, the Generator automatically goes into “Cool Down” mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).

   Note: Cool down temperatures < 60ºC may require additional ablation time.

TRACK ABLATION

1. For Track Ablation, retract the array and depress the Track Ablation ON/OFF button. When ready depress the RF ON/OFF button to start track ablation.
   Note: watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat untilentire track is ablated.

   Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from insertion site.

RFA for Local Treatment of Small (≤ 2.0 cm) Breast Carcinoma Protocol (cont.)

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance was gradually increasing, consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.
- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.

If having difficulty retracting array:

- Consider infusing normal saline and working shaft back and forth to loosen cooked tissue.
- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

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RITA MEDICAL SYSTEMS

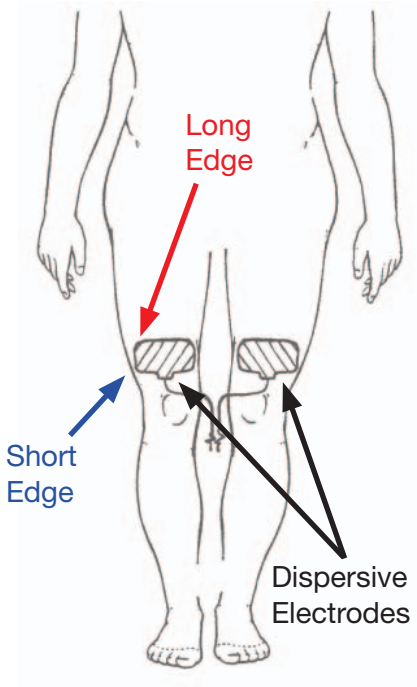
Uterine Fibroid

RFA of Uterine Fibroids Protocol

Compatible Devices: StarBurst™ XL & MRI

SETUP

1. Sterilize **BLACK** (Model 1500) or **GREEN** (Model 1500X) Main Cable according to instructions for use.
2. Place one Dispersive Electrode (Pad) anteriorly on each thigh.
   - The two dispersive electrodes should be placed on clean, dry surface over large, well-perfused muscle mass.
   - Hair should be removed before applying the dispersive electrodes.
   - Electrodes should be oriented with the longest edge toward the target ablation site, with at least 25cm distance between the ablation site and dispersive electrodes. Dispersive electrodes should be equivalent distances from the active electrode.
   - Electrodes should not be placed over bony prominences, scar tissue, skin over an implanted metal prosthesis, hairy surfaces, pressure points, or areas distal to tourniquets.
   - Avoid placement in areas where liquid may pool, under thermal blankets, and in areas where heat may be retained, e.g., under blankets or positioning bags.
   - Other dispersive electrodes (electrosurgical cutting device) shall not be placed further away from the ablation location and the dispersive electrodes used with the RITA RF Generator.
   - Insulate patient's leg by placing a towel between the patient's thighs.
   - Dispersive Electrodes should not be placed under compression socks or leg compressors.



3. Flush the Device with NORMAL (0.9%) saline, through infusion port, prior to use.
4. Connect Power Cord to Generator and plug into appropriate outlet.
5. Connect Foot Pedal and Dispersive Electrodes to Generator.
6. Turn Generator on with the switch on the back.
7. After self-test is complete, depress RF ON/OFF button.
8. Default control mode is "A" – "Average of all".
9. Set Power, Temperature, and Time according to the parameters in the table below.

Caution: If the patient has a pacemaker, consult the patient's cardiologist prior to doing this procedure. Using the RF Generator in the presence of an internal or external pacemaker may require special considerations.

Caution: If the patient has metal implants, the RF current may pass through the metal implant and cause an unintended burn at the implant site. Orientating the dispersal electrodes in such a manner that the metal implants are not in the field of energy (not in the field between the target tumor and the dispersive elec trodes) may reduce this risk.

Caution: If an introducer is desired for use with the RITA devices, use only the RITA tissue access system. Do not use an introducer made of an electrically conductive material.

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Radiofrequency Ablation of Uterine Fibroids Protocol (cont.)

PLACEMENT: StarBurst™ XL & MRI

1. Place Device and deploy array to desired ablation size. Use forward pressure and monitor for tissue displacement or Device "push-back". Once deployed, apply forward pressure to seat the device.
2. Remember to begin your deployment 1 cm proximal to the center of your target for a 3 or 4 cm ablation, 1.5 cm proximal to the center for a 5 cm ablation. **Please refer to the StarBurst™ XL and MRI placement diagram (procedure binder's liver section).**
3. Connect Device to Main Cable and Main Cable to Generator. Verify temperature display and impedance reading.

ABLATION

1. Start the RF power using the foot pedal or RF ON/OFF button.

Table 1: Guidelines for Time at Target Temperature*

Set Power (W): 150	Set Temp (°C): 100	CONTROL MODE: A

Size of Final Deployment:	Set timer at: (Minutes)
5 cm	14
4 cm	7
3 cm	5
2 cm	2

* These ablation parameters have been developed from the ACOG 2002 presentation and personal commutation with Bruce Lee, M.D. Shorter ablation times may result in a smaller ablation size.

COOL DOWN

1. When the timer runs out, the Generator automatically goes into "Cool Down" mode for 30 seconds (0.5 minutes on the Generator).
2. When the Cool Down is complete, check the temperatures to ensure that all are above 60°C. If not, continue ablation for 5 more minutes at target temperature. (Alternatively, the Device can be rotated 45 degrees to check temps and continue ablation, if necessary).

Radiofrequency Ablation of Uterine Fibroids Protocol (cont.)

TRACK ABLATION

1. For Track Ablation, retract the arrays fully and depress the Track Ablation ON/OFF button. When ready, depress the RF ON/OFF button to start track ablation.

   Note: watch only temperature #5. When it reaches 70°C, retract approximately 1 cm. Repeat untilentire track is ablated.

   Caution: To prevent unintended tissue damage following Track Ablation, discontinue RF power prior to withdrawing device from target organ.

TROUBLESHOOTING

If one temp is very different from the others:

- If one temp is very low, but impedance is okay (35-100 ohms), then consider leaving it as is.
- If one temp is very low and impedance is very high (>100 ohms) or very low (<35 ohms), consider removing the low temp from the algorithm.
- If one temp is very high and impedance is okay (35-100 ohms), consider taking it out of the algorithm to allow the power to increase bringing the other temperatures up.

If impedance is high (>100 ohms):

- If it is high at the beginning of the case, check the dispersive electrode for proper placement and ensure that the Device is fully deployed to desired ablation size.
- If it is high during the case, consider lowering the target temperature temporarily, taking out the lowest temperature, or retracting the array and rotating the device.
- If power is also high, consider decreasing the power.

If it impedes out:

- If it impedes out at the start of the ablation, check all connections and restart.
- If it impedes out in the middle of an ablation, and the impedance was gradually increasing, consider retracting the array, rotating 45 degrees, redeploying, and continuing the ablation.
- If it impedes out in the middle of an ablation, and the impedance increased sharply, check all connections and consider rotating and continuing the ablation.

If having difficulty retracting array:

- Consider infusing normal saline and working shaft back and forth to loosen cooked tissue.
- Cleaning the array in between ablations can help prevent difficulty in retraction (use a soft bristle brush).

Cleaning arrays due to tissue build-up:

- Soak in hydrogen peroxide and wipe.

RITA MEDICAL SYSTEMS

Habib 4X Procedures

Open Liver Surgery Resection Protocol

Compatible Devices: 1500 Generator; HABIB™ 4X Resection Device; 1500 Adapter Cable

EQUIPMENT LIST:

To perform open liver surgery with the HABIB 4X device, confirm availability of the following compatible Devices: 1500 Adapter Cable (5200), HABIB 4X Resection device and Generator 1500.

SETUP

1. HABIB 4X kit contains HABIB 4X Device C (long needles), Device B (short needles) and a “push-off” plate.

2. ATTENTION: NO Dispersive Electrodes (Pads) are required when using the Habib 4X!

3. Connect the foot pedal to the generator (if available).

4. Plug the adapter cable into the generator as indicated by the illustration on the adapter cable.

5. Turn on the generator. The “ON&OFF” switch is located on the back of the generator. Press the “RF ON” button on the front of the generator to activate “RF READY” mode.

6. Press control mode button until a “P” is displayed in the window and “Power Control” is displayed on the LCD.

7. Set the power to 100W and increase “Timer” to 30 min (this ensures adequate total ablation time).

8. Using sterile technique, open the product inner blister pack by peeling back the lid and place contents of the kit in a sterile instrument tray. The device to be used first is usually the long needle - Device C.

9. Pass the HABIB 4X cable connector out of the sterile field and connect to the adapter cable.

10. The HABIB 4X device is now ready for use.

PLACEMENT AND RESECTION:

1. *Expose the organ using standard surgical techniques and mark the intended resection line.*

   Introduce the needle array of the device approximately 2-3cm into the anterior of the organ at a point along the determined line of resection. Take care that the needles do not pierce the surgeon's gloves. (Care should be taken when the needles are introduced to avoid contact with surrounding vital structures. The ablation should not be attempted within 1 centimeter of adjacent vital structures in direct contact with the target ablation zone.) Activate the power by pressing the foot pedal once (do not press and hold the pedal down!). Once the foot pedal is pressed and released, energy is automatically applied by the generator to the HABIB™ 4X device to produce heating to cause tissue coagulation. The energy applied in this manner is sufficient to create coagulation to a depth of approximately 4cm along the needle path and with a cross-section of approximately 7mm x 7mm.

2. Enable the power with foot pedal. Press briefly once - do not press and hold the pedal down! (If foot pedal is not available, activate the device by pressing the "RF ON/OFF" button. To deactivate the device, press the "RF ON/OFF" button again.)

3. As the ablation starts and proceeds, look at the impedance level. First, the impedance will decrease and plateau, then the impedance will increase. Allow the impedance to rise 30% higher than plateau value (lowest), then stop the power with the foot pedal (or with the "RF ON/OFF" button).

4. Once the foot pedal is pressed and released (or the "RF ON/OFF" button is pressed and released), energy is automatically applied by the generator to the HABIB™ 4X device to produce heating to cause tissue coagulation. The energy applied in this manner is sufficient to create coagulation to a depth of approximately 4cm along the electrode path and with a cross-section of approximately 7mm x 7mm.

5. Remove and replace the device further along the line of resection moving from front to back and thus, repeating the previous step.

6. *The proper positioning of the needles during a continuing surgical parenchyma transaction:*

   Place the two back needles/electrodes of the following ablation right next to the two front holes made by the previous ablation.

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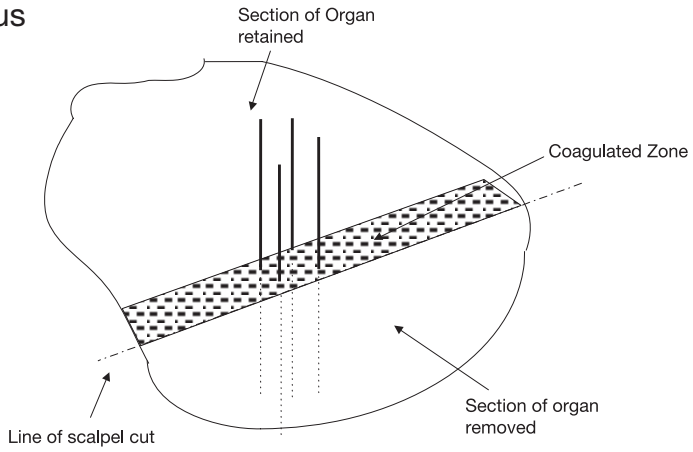
7. Continue this process to produce a contiguous band of tissue coagulation at least 7mm wide. At this point a partial resection can be performed by a scalpel. Resect the appropriate part of the organ by cutting along the resection line of the coagulated tissue using a conventional scalpel. The cut should be along the coagulation band nearest to the portion of tissue to be resected. A band of coagulated tissue at least 6mm wide should be left proximal to the remaining organ.



8. If there is any remaining bleeding on the cut surface, using sterile technique, disconnect Habib Device C from the Adapter Cable and connect Habib Device B. Insert the needles of Habib Device B into the cut surface with any uncoagulated tissue between the needles. Apply power to coagulate tissue as described in previous steps.

9. Once all the required sections of the organ have been coagulated and resected, the operation can continue using standard surgical techniques, and the abdomen closed.

TROUBLESHOOTING

1. CLEANING THE ELECTRODES. If tissue collects on the needles, clean the needles using a sterile wet wipe or the supplied “push-off” plate to remove any residue. If tissue residue cannot be removed or is carbonized, the device should be disposed of, and a new kit opened and used. (Do not clean electrodes using sharp objects as this will damage the electrodes and render them unusable!) Damaging the needle coating can induce tissue charring and tissue adhesion to the tips of the electrodes.)

2. USING “PUSH-OFF” PLATE. If the device is difficult to remove from the ablated tissue (organ), place the “push-off plate” (long plastic plate) between the needles of the device, and push down until it is against the tissue surface. Pull the device handle up to remove the device from the organ, holding down the “push-off plate” during this removal. This technique can be used to prevent the device from adhering to the tissue which can cause tissue tearing and additional bleeding.

3. UNDER ABLATION / EXCESSIVE BLEEDING. If the tissue appears to be under-ablated or excessive bleeding persists, lower the power on the generator. Repeat the resection using the same procedure steps. (Please, note that lower output power will result in longer ablation times per each application.)

4. OVERLAPPING. If excessive bleeding is noticed, overlap the ablations by placing the two back electrodes of the following ablation before the two front holes made by the previous ablation. Continue the resection using overlapping positioning until bleeding stops.

5. NOT RECOMMENDED! Placing electrodes in the same ablation holes twice or more times is not recommended. This may cause tissue charring and, therefore tissue adhesion to the electrodes and tearing of the parenchyma during the withdrawal of the electrodes.

6. BLEEDING AREAS. For any remaining bleeding areas, it is recommended to place the electrodes into the bleeding porting of the organ and ablate the area using slightly varying angles until the bleeding is controlled. Several successive ablations may be required to seal areas with vessels.

NOTE: Refer to the User Guide and Instructions for Use packaged with the 1500 Generator, Adapter Cable and Habib 4X for a complete list of Warnings, Precautions, Contraindications, and Possible Side Effects.

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User's Guide and package inserts for the HABIB™ 4X and 1500 Generator for detailed instructions, warnings, precautions and possible adverse effects. RITA and HABIB™ 4X are trademarks of RITA Medical Systems, Inc. RITA Medical Systems, Inc. One Horizon Way, Manchester, GA 31816 1-800-472-5221 160-103412 Rev.: 01.

Open Liver Surgery Resection Protocol

Compatible Devices: 1500X Generator; HABIB™ 4X Resection Device ; Adapter Cable and Software Module (version 8.30 BUILD 8)

EQUIPMENT LIST:

To perform open liver surgery with the HABIB 4X device, confirm availability of the following compatible Devices: 1500X Adapter Cable (700-103285), HABIB 4X Resection device, Software Module (version 8.30) and Generator 1500X.

SETUP

1. HABIB 4X kit contains HABIB 4X Device C (long needles), Device B (short needles) and a "push-off" plate.

2. ATTENTION: NO Dispersive Electrodes (Pads) are required when using the Habib 4X!

3. Connect foot pedal to the generator.

4. Turn on generator (Note: the LCD display will eventually display "8.30 BUILD 008").
   NOTE: The "ON&OFF" switch is located on the back of the generator. Press the "RF ON" button on the front of the generator to activate "RF READY" mode.

5. Plug the adapter cable into the generator as indicated by the illustration on the adapter cable ("HABIB MODE" will automatically appear on the generator's display).

6. Using sterile technique, open the product inner blister pack by peeling back the lid and place contents of the kit in a sterile instrument tray. The device to be used first is usually the long needle - Device C.

7. Pass the HABIB 4X cable connector out of the sterile field and connect to the adapter cable.

8. The HABIB 4X device is now ready for use.

PLACEMENT AND RESECTION:

1. *Expose the organ using standard surgical techniques and mark the intended resection line.*
   Introduce the needle array of the device approximately 2-3cm into the anterior of the organ at a point along the determined line of resection. Take care that the needles do not pierce the surgeon's gloves. (Care should be taken when the needles are introduced to avoid contact with surrounding vital structures. The ablation should not be attempted within 1 centimeter

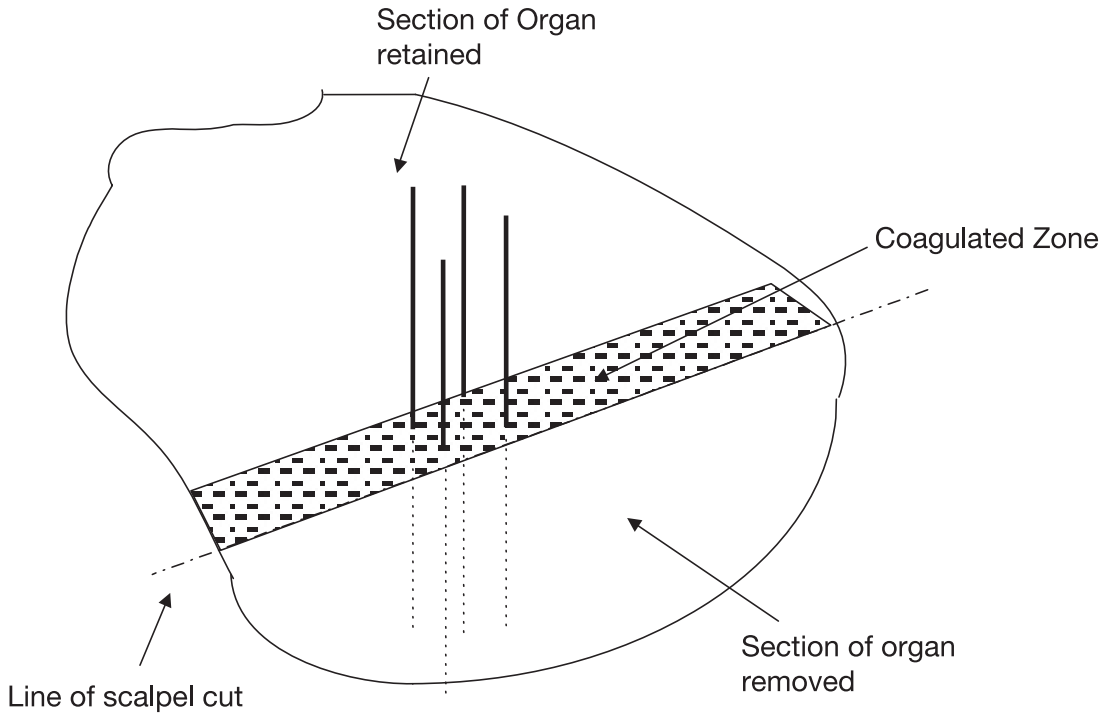
of adjacent vital structures in direct contact with the target ablation zone.) Activate the power by pressing the foot pedal once (do not press and hold the pedal down!). Once the foot pedal is pressed and released, energy is automatically applied by the generator to the HABIB™ 4X device to produce heating to cause tissue coagulation. The energy applied in this manner is sufficient to create coagulation to a depth of approximately 4cm along the needle path and with a cross-section of approximately 7mm x 7mm.

2. Remove and replace the device further along the line of resection moving from front to back and thus, repeating the previous step.

3. *The proper positioning of the needles during a continuing surgical parenchyma transaction:*

   Place the two back needles/electrodes of the following ablation right next to the two front holes made by the previous ablation.

4. Continue this process to produce a contiguous band of tissue coagulation at least 7mm wide. At this point a partial resection can be performed by a scalpel. Resect the appropriate part of the organ by cutting along the resection line of the coagulated tissue using a conventional scalpel. The cut should be along the coagulation band nearest to the portion of tissue to be resected. A band of coagulated tissue at least 6mm wide should be left proximal to the remaining organ.



5. The cut depth should be limited to the depth of the coagulation. Separate the tissue and re-insert the needles to coagulate deeper regions of the organ until the coagulation region penetrates the entire depth of the organ. The liver parenchyma should be supported with the fingers on both sides of the device in order to avoid pulling suddenly with force which might lead to parenchymal fracture and bleeding. Excessive coagulated tissue should be trimmed back to reduce the potential of abscess formation.

6. If there is any remaining bleeding on the cut surface, using sterile technique, disconnect Habib Device C from the Adapter Cable and connect Habib Device B. Insert the needles of Habib Device B into the cut surface with any uncoagulated tissue between the needles. Apply power to coagulate tissue as described in previous steps.

7. Once all the required sections of the organ have been coagulated and resected, the operation can continue using standard surgical techniques, and the abdomen closed.

TROUBLESHOOTING

1. CLEANING THE NEEDLES. If tissue collects on the needles, clean the needles using a sterile wet wipe or the supplied “push-off” plate to remove any residue. If tissue residue cannot be removed or is carbonized, the device should be disposed of, and a new kit opened and used. (Do not clean needles using sharp objects as this will damage the needles and render them unusable!) Damaging the needle coating can induce tissue charring and tissue adhesion to the tips of the needles.)

2. USING “PUSH-OFF” PLATE. If the device is difficult to remove from the ablated tissue (organ), place the “push-off plate” (long plastic plate) between the needles of the device, and push down until it is against the tissue surface. Pull the device handle up to remove the device from the organ, holding down the “push-off plate” during this removal. This technique can be used to prevent the device from adhering to the tissue which can cause tissue tearing and additional bleeding.

3. EXCESSIVE BLEEDING. If the tissue appears to be under-ablated or excessive bleeding persists, lower the power on the generator. Repeat the ablation using the same procedure steps. (Please note that lower output power will result in longer ablation times per each application.)

4. OVERLAPPING. If excessive bleeding is noticed, overlap the ablations by placing the two back needles of the following ablation before the two front holes made by the previous ablation. Continue the resection using overlapping positioning until bleeding stops.

5. NOT RECOMMENDED! Placing needles in the same ablation holes twice or more times is not recommended. This may cause tissue charring and, therefore tissue adhesion to the needles and tearing of the parenchyma during the withdrawal of the needles.

The above steps are abbreviated from the complete instructions for use for the RITA System. Refer to the User’s Guide and package inserts for the HABIB™ 4X, HABIB/1500X Adapter Cable and 1500X Generator for detailed instructions, warnings, precautions and possible adverse effects. RITA Medical Systems, Inc. One Horizon Way, Manchester, GA 31816 1-800-472-5221
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6. BLEEDING AREAS. For any remaining bleeding areas, it is recommended to place the needles into the bleeding portion of the organ and ablate the area using slightly varying angles until the bleeding is controlled. Several successive ablations may be required.

NOTE: Refer to the User Guide and Instructions for Use packaged with the 1500X Generator, Adapter Cable and Habib 4X for a complete list of Warnings, Precautions, Contraindications, and Possible Side Effects.

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