innoblative®

sira®

RFA Electrosurgical Device

SIRA-1000

℞ ONLY

Caution: Federal Law (USA) restricts this device to sale by or use under the order of a physician.

WARNING

Contents are supplied STERILE using an ethylene oxide (EO) process. Do not use if the sterile barrier is damaged. If damage is suspected or identified, notify your sales representative. Inspect prior to use to verify that no damage has occurred during shipping. Do not use a device that has been damaged.

For single-use only. Do not reuse, reprocess, or resterilize. Reuse, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure which in turn, may result in patient injury, illness, or death. Reuse, reprocessing, or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient. Reprocessing may compromise the integrity of the Device and/or lead to Device failure.

After use, dispose of the device and packaging in accordance with hospital, administrative and/or local government policy.

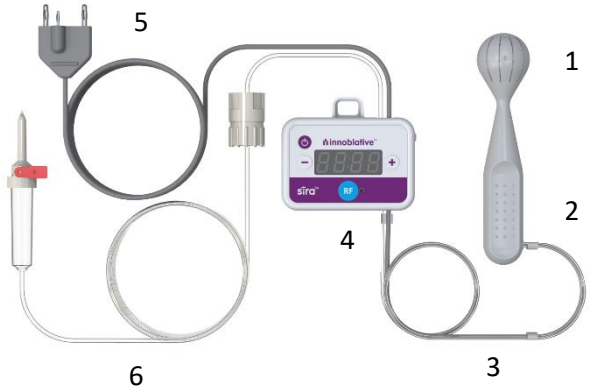
DEVICE DESCRIPTION

The SIRA® RFA Electrosurgical Device, model number SIRA-1000, ("the device") is a radiofrequency ablation device that consists of an electrode array with an internal irrigation chamber, a cable assembly, and an integrated switch and timer. The SIRA® RFA Electrosurgical Device is designed for coagulation and ablation of soft tissue in open abdominal intraoperative procedures and is available with a 4.0 cm diameter electrode array. It has an attached cable assembly/tubing set with an integrated switch and timer that activates the electrical radiofrequency (RF) power.

The Electrosurgical Device is comprised of:

1. a 4cm diameter electrode array (“applied part”),
2. a handle (shaft),
3. a probe cable and saline tubing,
4. an integrated electrical RF switch and timer,
5. a main cable with a connector to interface with standard RF electrosurgical generators for transmitting the radiofrequency energy, and
6. a fluid administration set with a flow regulator for saline infusion.

Figure 1: SIRA® RFA Electrosurgical Device components



INTENDED USE / INDICATIONS FOR USE

The SIRA® RFA Electrosurgical Device supplies energy for use in electrosurgery and is indicated for use in intraoperative coagulation and ablation of soft tissue. The SIRA® RFA Electrosurgical Device is to be used in conjunction with a radiofrequency (RF) electrosurgical generator for use in open abdominal surgical procedures. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

CONTRAINDICATIONS

The Device is contraindicated in patients with implanted cardiac pacemakers, defibrillators, and other electronic device implants. The device is not intended for contraceptive tubal coagulation (permanent female sterilization).

WARNINGS

- If the fluid administration set becomes occluded or the ports on the electrode array are not correctly primed with saline, an improper or unpredictable ablation depth may result.
- Clamps should only be attached to the designated drape clip holder on the integrated switch and timer.
    - Do not attach anything (i.e., clamps) to any other part of the Device. This may damage the Device, which may result in malfunction of the Device and patient injury.
- The Device is not to be reprocessed, reused, or resterilized for use in different patients or in different cases. Reprocessing and reuse of the Device in a different patient creates a potential risk of patient or user infections.
    - Contamination of the Device may lead to injury, illness, or death of the patient.
    - Reprocessing may compromise the integrity of the Device and/or lead to Device failure.
- The Device may be used for multiple ablations on the same patient within the same procedure.
    - If more than one ablation is performed on a patient during an operative procedure, inspect the Device after each ablation for damage. If any damage is observed or suspected, the Device should be discarded and a new Device should be used for the remaining ablation(s).
    - Depths in the IFU are not valid for overlapping ablations.
- The device is single-use. The SIRA-1000 device is limited to 40 minutes of total ablation time. However, this does not imply a 40 minute ablation should be performed on a single site. The suggested durations in Table 1 should be followed, and if further applications beyond 40 minutes are required, a second device should be prepared.
- This Device should not be used in conjunction with MRI image guidance as the Device has not been tested for MRI compatibility.
- DO NOT allow the Device to contact the patient until the electrical cable and tubing of the Device have been properly connected and the tubing primed with saline.
- This device contains Lithium Iron Disulfide batteries. Battery can explode or leak and cause burns if disassembled, charged, or exposed to water, fire, or high temperature. Battery may be removed before disposal. DO NOT replace the battery at any time.

- DO NOT USE electrosurgery in the presence of flammable anesthetics or oxidizing gases (such as nitrous oxide (N2O) and oxygen), near flammable fluids or objects, or in the presence of volatile solvents (such as ether or alcohol) or any other oxidizing agents, as a fire or explosion may occur.DO NOT place Device near or in contact with flammable materials (such as gauze or surgical drapes). Devices that are activated or hot from use may cause a fire.
- The steam and boiling saline produced by the active Device will be hot. Suction and other precautions should be used to avoid unintended burns to the user or patient.
- Electromagnetic disturbances may adversely influence proper operation of the device. Provide as much distance as possible between the Device and generator and other electronic equipment to ensure flow of RF energy from Device is not disturbed. Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) from the device, generator, or cables.
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers.
- When not using Device, place in a clean, highly visible area not in contact with the patient. Inadvertent contact with the patient may result in burns.
- The surface of the active electrode may remain hot enough to cause burns after the RF current is deactivated. Due to concerns about the carcinogenic and infectious potential of electrosurgical byproducts (tissue smoke plume), protective eyewear, filtration masks, and effective smoke evacuation equipment should be used.
- DO NOT energize the Device when not in contact with target tissue, as unintended thermal injury may occur.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

PRECAUTIONS

- Be aware that the device employs RF coupled with saline. This coupling effect may result in a deeper tissue effect than conventional RF and has the potential for hot saline run-off onto delicate structures.

- Use suction to avoid activating the device in a pool of saline. Activating in pooled saline may reduce the effectiveness of the device or damage unintended tissues.
- Use suction to avoid activating the device in a pool of blood. Activating in a pool of blood may limit the effectiveness of the device or increase the risk of an electrode becoming clogged by coagulated blood.
- During the procedure, monitor the progress of ablation using the "Lift, Assess, and Adapt" technique. To do so, carefully lift the Device to visually observe the ablation zone, assess the progress of the ablation, and, if necessary, adapt the Device placement and/or suction technique.
- Avoid placing lateral forces on the Device. Excessive force on the Device could cause it to break or may cause the saline irrigation ports to become occluded. Adequate saline flow is essential for ablation performance.
- This Device is to be used exclusively in professional healthcare facilities such as hospitals. The Device is not intended to be used outside of clinical settings.
- Surgery should be performed by a board-certified physician with adequate training and preparation. Personnel should fully understand the nature and use of RF before performing electrosurgical procedures to avoid the risks of shock and burn hazards to both the patient and the operator, as well as possible damage to the instrumentation.
- DO NOT use the Device if the expiration date on the packaging has expired or if the seal is broken.
- Use this device only with the Medtronic ForceTriad™ Electrosurgical Generator. Read the warnings, precautions, and instructions provided in the generator user manual before using. Specific instructions may not be included in this manual.
- Use only sterile 0.9% saline for the irrigation.
- DO NOT defibrillate a patient when the Device is in contact with the patient. Completely remove the Device from the patient before defibrillation.
- Use caution when treating areas close to critical structures to prevent damage from thermal ablation (e.g. major vessels, bone, major organs, skin). Critical structures to be spared should be at least 3 cm away from the outer margin of the ablation zone to prevent injury from the RF energy (see Tables 1-3).
- Always use the lowest power and shortest time necessary to achieve the targeted ablation.

- Adequately clean the Device in between ablations using a sterile moist or dry sponge or sterile brush, ensuring no tissue is stuck to the electrodes and all the irrigation ports are clear of obstruction. Care should be taken to avoid inadvertent device activation when cleaning electrodes. It should be visually confirmed that saline is weeping from each port. Do not use a surgical instrument to clean Device.
- Be aware that when the device is energized, all electrodes are active and capable of treating tissue. Use caution to avoid inadvertent treatment of tissue and adjacent structures.
- Interference produced by the operation of the RF surgical equipment may adversely influence the operation of other electronic equipment.
- Place any monitoring electrodes being used as far away as possible from the device to avoid electrical interference with monitoring equipment.
    - Avoid needle-monitoring electrodes.
    - Use monitoring systems incorporating high frequency current limiting devices.
- The cable on the device should be positioned in a way to avoid contact with the patient or other cables.
- Consult the operating and user manuals for additional light sources, other electrosurgical units, and other ancillary devices for operating instructions, warnings, and cautions prior to their use in the same surgical field as the company's device.
- It is recommended that physicians utilize the Company's pre-clinical training, review of pertinent literature and other appropriate educational tools before attempting the surgical procedures outlined in the following instructions.
- DO NOT USE metal tools, such as clamps or metal suction, close to the ablation device. High power settings result in deeper tissue effect than lower power settings.
- The patient should not come into contact with metal parts which are earthed or have an appreciable capacitance to earth (e.g. operating table supports, etc.).
- Skin to skin contact (for example between the arms and body of the patient) should be avoided, for example by insertion of dry gauze.
- For surgical procedures where the RF current could flow through parts of the body having a relatively small cross sectional area, the use of bipolar techniques may be desirable in order to avoid unwanted tissue damage.
- Before using the device, confirm the following:

  - The cable from the device is connected to a qualified generator,
  - All electrical connections are tight, clean, and dry,
  - All fluid connections are secure,
  - The generator is set at the desired power level,
  - The saline delivery tubing and device have been fully primed with sterile saline (0.9% NaCl) solution,
  - The device can be set up in accordance with the user manual, and
  - If device cannot be set up in accordance with user manual, do not use device.
- Any deviation from the instructions outlined in this Instructions for Use manual may alter the path of the electrical energy away from the target tissue resulting in inadequate ablation, unwanted damage to tissue, or injury to the patient.
- Inspect Device and cables for damage prior to each use, and do not use if damaged. Insulation failures may result in burns or other injuries to the patient or operator.
- Users must not touch the active electrode when it is energized.

HOW SUPPLIED

The SIRA® RFA Electrosurgical Device is supplied STERILE using an ethylene oxide (EO) process.

Store in a cool, dry place. Do not use if the package is opened or damaged. Do not use if labeling is incomplete or illegible. Do not use the Device after the expiration date.

EQUIPMENT LIST (TO PERFORM PROCEDURE)

- Medtronic ForceTriad™ Electrosurgical Generator
- Sterile 0.9% Saline (at least 100 mL is required)
- IV Pole
- SIRA® RFA Electrosurgical Device
- Suction Device
- Saline Bowl for Priming

OPERATIONAL INSTRUCTIONS

Using the "Lift, Assess, Adapt" Technique for the SIRA-1000

As with all ablation methods, the user should monitor the progress of the ablation throughout the procedure to ensure the desired effect is achieved. The SIRA-1000 should be lifted periodically to observe the target site, and the user should assess the extent of the thermal effect visually. The zone of thermal effect will be evident based on changes in the tissue color. The effect can be adapted by changing the time, power, and saline management as discussed in greater detail in the following instructions. The SIRA-1000 is intended to produce circular ablations of approximately 4-6 cm in height and width, depending on the operating parameters selected. The user should review these instructions and complete the device training prior to initial use.

The following is the recommended procedure for operating the SIRA® RFA Electrosurgical Device.

1. Refer to the Medtronic ForceTriad™ Electrosurgical Generator system User Manual and become familiar with operation of the generator. Do not use the generator if it has been dropped or damaged.
2. Turn on the generator. The generator will run through a self-test.
3. Inspect Device shipping carton, packaging, and sterile barrier for any signs of transit damage. Do not use any Device that is damaged or if the sterile barrier is breached. Do not prematurely remove the device from its packaging. Open only when it is ready for use.
4. Using sterile technique, open the SIRA® RFA Electrosurgical Device packaging and transfer the sterile tray containing the Device onto the sterile field.
5. In the sterile field, open the sterile packaging and inspect the Device's pre-attached cables and tubing prior to use. Do not use the Device if the cables or tubing have any evidence of damage (kinks, cracks, etc.). If there are any shortages, breakage, or apparent damage, do not use the device. Return to manufacturer or use a new device.
6. Remove the battery pull tab from the back of the integrated switch and timer.
7. Place the Device near the operative site and secure the integrated switch and timer to the sterile drapes using a non-perforating clamp and the designated drape clip holder (Figure

2). Do not clamp directly on the integrated switch and timer, fluid administration set, or cable, as this may damage the Device or obstruct saline flow through the system.

Figure 2: Drape clip holder

8. Immerse the electrode array in a reservoir of 0.9% saline until it is used in the procedure to keep it saturated with saline.
9. Pass the free end of the cable off the sterile field for connection to the generator.
10. Check that the pins of the cable connector are aligned and not bent. Insert the cable connector into the bipolar port on the generator.

NOTE: The cable connector can only mate with the bipolar port on the generator in one orientation. Attaching the cable connector to the bipolar port requires minimal force. If more than minimal force is required, the connector may not be aligned correctly with the port or the pins on the connector may be damaged.

NOTE: For generator operation refer to the generator User Manual.

IRRIGATION SYSTEM SET UP

1. Mount an IV bag containing sterile 0.9% saline on an IV pole approximately seven feet high, near the sterile field. Minimum volume required is typically 100 mL.
2. Pass the free end of the irrigation tubing of the Device off the sterile field. Remove the cap on the bag spike and insert the

spike into the appropriate opening in the saline IV bag, being careful not to damage the saline bag or compromise sterility.

3. Prime the tubing and Device by adjusting the flow regulator on the tubing to “OPEN”. Confirm all air bubbles are flushed out of the system and that saline is flowing out of each irrigation port on the surface of the electrode array prior to placing the electrode array onto the target tissue.
    - The goal of priming the device is to fully saturate the foam inside the device housing. Saline should flow through the device long enough during the priming process so that saline not only weeps out of the irrigation ports on the device, but it also fully soaks the foam housed within the device. Keeping the device in a saline reservoir before use allows the foam to remain saturated.
4. If a device is not primed satisfactorily and the foam is not fully soaked, the device may float in the saline reservoir. Check to make sure the device is not floating in the saline reservoir before using it in an ablation.
5. Once priming is complete, turn the flow regulator to the recommended starting flow rate for the procedure or to “OFF” and return the Device to the saline reservoir (see Tables 1-3).

NOTE: The saline flow rates in the ablation depth tables (Tables 1-3) are suggestions for starting flow rates. If during the ablation there is not a visible, thin film of bubbling saline between the device and the tissue, the saline flow rate should be increased. If there is char and/or excessive smoke, increase the flow rate until you see signs of a proper ablation.

NOTE: If saline flow is not observed from all irrigation ports, the Device function may be compromised.

NOTE: Using excessive force during the procedure may block the saline from properly weeping from all ports. Adequate saline delivery is essential for Device performance.

GENERATOR AND DEVICE SET UP

1. Adjust the generator power setting to achieve the desired ablation zone (see Tables 1-3). Refer to the generator User Manual for specific instructions regarding generator settings.

NOTE: Use of the generator adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

2. Select the “Standard” setting on the Bipolar screen.
3. Power on the Device by pressing the power button at the top left of the integrated switch and timer. Powering on prepares the Device for ablation and will not activate the RF electrical energy. The integrated switch and timer will display the setting of 0:00 min.
4. Ensure that critical structures are at least 3 cm away from the perimeter of the ablation zone around the electrode array during placement of the electrode array on the target tissue site.
5. The electrode array should properly contact the target tissue, creating maximum electrode contact with the tissue without compromising saline flow from the irrigation ports.

NOTE: If any critical structure is less than 3 cm away from the perimeter of the ablation zone around the electrode array, the structure may be damaged during the ablation.

NOTE: Ensure the Device is still primed by checking there is no delay in saline flow through the system and saline weeps from all the irrigation ports before starting ablation.

Table 1: Liver Expected Ablation Depths from *ex vivo* Testing

	Duration		
Power	**7 min**	**10 min**	**Flow Rate***
35 W	0.9 cm	1.2 cm	75 ml/hour
65 W	1.3 cm	1.4 cm	75 ml/hour

Table 2: Kidney Expected Ablation Depths from *ex vivo* Testing

	Duration		
Power	**7 min**	**10 min**	**Flow Rate***
35 W	0.9 cm	0.9 cm	75 ml/hour
65 W	1.0 cm	1.2 cm	75 ml/hour

Table 3: Muscle Expected Ablation Depths from *ex vivo* Testing

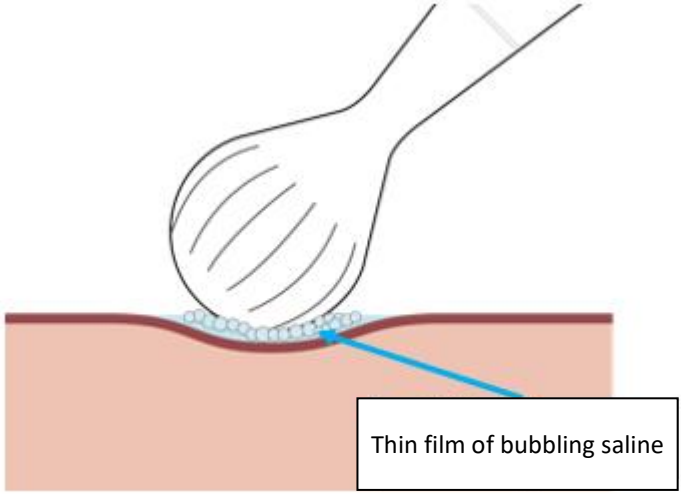
	Duration		
Power	**10 min**	**13 min**	**Flow Rate***
35 W	1.0 cm	1.0 cm	75 ml/hour
65 W	1.1 cm	1.2 cm	75 ml/hour

***NOTE:** The flow rates listed in Tables 1-3 are only recommended starting flow rates. The user should change the flow rate as necessary for each ablation.

NOTE: The tolerance for the depths of ablation is +/- 0.5 cm.

6. Saline has three important functions: it conducts electrical energy from the electrodes to the tissue, it cools the tissue temperature, and it lubricates the electrodes to prevent the tissue from sticking. The appropriate amount of saline is a thin, bubbling film of controlled saline (Figure 3). Sufficient saline flow should be maintained for adequate conductivity and to prevent tissue sticking without excess run-off. The user should follow the "Lift, Assess, Adapt" technique to monitor the thermally affected zone and make the proper saline flow rate adjustments to achieve this thin, bubbling film of controlled saline.

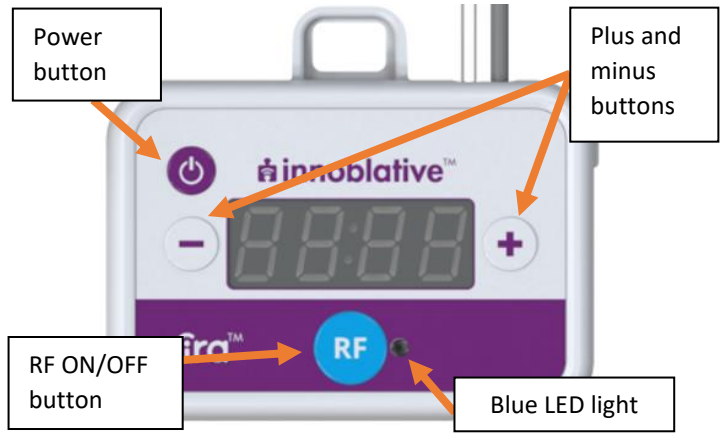
Figure 3: Appropriate amount of saline



7. Using the ablation Tables 1-3:
   a. Select the appropriate table based on tissue type,
   b. Check that the flow rate is set to the appropriate rate,
   c. Check that the wattage on the generator is set to the appropriate setting and the "Standard" Bipolar setting is selected, and
   d. Set the ablation duration time on the integrated switch and timer.
      - The duration is adjusted by selecting the plus or minus buttons on the timer (see Figure 4). If a large adjustment to the duration is necessary, press and

hold the plus or minus button until the numbers start to increase or decrease more rapidly. Press and hold *both* the plus and minus buttons simultaneously, on the integrated switch and timer, and the duration will return to the default time of 15 min.

Figure 4: Integrated Switch and Timer Control



8. The blue LED light next to the RF on/off button will blink when the duration is set and the Device is ready for use.
9. Press the RF on/off button on the integrated switch and timer to begin the procedure. When the RF is activated the blue LED light will stop blinking and turn to a solid blue light, and the timer will start counting down.
10. The ablation will spread outwardly from the device. Monitor the target site during the procedure to observe the extent of this spread. Tissue will change color once ablated.
11. Surface spread depends on saline control, duration of application, and power setting.
12. The saline flow must be carefully managed to achieve the desired effect. Presence of saline is important for a good ablation.
13. To manage saline flow:
    - Increase flow rate when there is no thin, bubbling film of saline, there is excessive steam, or tissue sticks to the device.

- Decrease flow rate when the saline flows outside the desired treatment zone.
- Adapt saline suction technique when the saline flow is spreading beyond the desired treatment zone.

14. Device should be positioned in center of target zone for the duration of the procedure.

NOTE: Duration cannot be adjusted during the ablation. To adjust the duration, turn off the RF power and pause the timer by pressing the RF on/off button, and then adjust the duration on the timer.

---

15. During the ablation, continually monitor the operative site using the Lift, Assess, and Adapt technique by lifting the device to visually observe the ablation zone, assess the progress of the ablation, and if necessary, adapt the technique. You can adapt your technique by adjusting the placement of device, the angle of device, and/or the saline flow rate to account for current progression of the ablation zone. All SIRA-1000 users should use the Lift, Assess, and Adapt technique during the ablation procedure. Each “Lift” should only last a few seconds and will not disrupt the progress of the ablation.
16. The following are characteristics of a normal ablation:
    - Saline bubbling at the surface of the ablation
    - At high powers, saline bubbling from device
    - Steam emitting from ablation site
    - Color of tissue changing
17. The ablation is complete when the time required to achieve the desired target ablation size has elapsed (see Tables 4-6 and Figure 5) and the tissue in the target zone has changed color.
18. If multiple target lesions are to be ablated, relocate the SIRA-1000 to the next target once the ablation is complete. Note that multiple overlapping ablations within a single lesion should not be performed.
19. Remove any excess fluid or steam that may be produced during the ablation with a plastic (nonconductive) suction device.
20. During the ablation, continually monitor the IV saline bag drip chamber to ensure that saline is constantly dripping into the tubing.

NOTE: If excess fluid and steam is not evacuated from the operating site for prolonged durations, unintended tissue injury may result.

NOTE: At any point during the procedure, the ablation can be stopped by pressing the RF on/off button on the integrated switch and timer.

NOTE: During the last minute of ablation, the time will blink once per second to alert the user that the procedure is almost complete.

21. When the ablation time is completed the RF power will automatically turn off. The timer will flash between 0:00 and the total RF time that was delivered, to signal to the user the ablation is complete and to remind the user the total time of ablation. Additionally, the blue LED light will automatically turn off.
22. Remove the Device from the target tissue immediately following the procedure.
23. If additional ablation is desired, reset the parameters to the desired settings and repeat the procedure. Before completing subsequent ablations, the Device must be thoroughly cleaned. For optimum performance, the electrodes must be kept free of debris. The electrodes can be cleaned using a sterile moist or dry sponge or sterile brush. Tissue may adhere to device and must be removed from the electrodes. The irrigation ports must be cleared so that saline is able to weep from each port. It is important to check for proper saline irrigation before continuing to the next ablation.
    - Reduced saline flow can result if one more of the saline openings on the device is clogged by tissue or coagulated blood. If this occurs, clean electrodes with gauze ensuring precautions are taken to avoid inadvertent device activation when cleaning electrodes. Do not attempt to clean electrodes with a scalpel or other surgical instruments. If the above does not correct the problem, discontinue use and obtain a new device and return the used device to Innoblative Designs, Inc.
24. The timer may be reset to the default time setting (15 min) on the integrated switch and timer by pressing the plus and minus buttons simultaneously.

25. The integrated switch and timer will not allow more than 40 min of ablation to be performed by a single device, to prevent over-use or reprocessing of the device.
26. When all ablations are finished, turn the flow regulator to the "OFF" position.
27. Gently remove the Device from the operative site. Tissue may adhere to Device once the ablation is complete. Removal of the Device should be done carefully.
28. Use caution when removing Device from operative site and placing on the surgical field. Device may still be hot. RF energy should be turned off before placing Device on any surface that is not the operative site.
29. If Device use is complete, unplug Device and disconnect from saline bag. The battery may be removed from the back of the integrated switch and timer by tearing the back label along the perforated line. Do not replace the battery.
30. Dispose of the device, battery, and packaging in accordance with hospital, administrative, and/or local government policies.

NOTE: User will be unable to turn off integrated switch and timer once it has been powered on. This ensures the Device is not reused, reprocessed, or resterilized. RF energy can always be turned on and off by the RF button.

EXAMPLES OF ABLATION ZONE SIZE AND TEMPERATURE IN EX-VIVO TISSUE AT 20° C

Figure 5 illustrates the ablation zone dimensions and shape, as well as the recommended angles of application. "A" is the maximum ablation depth into the tissue, and represents the depths listed in Tables 1-3. Figures 6-8 shows a series of graphs depicting ablation shape and temperature with respect to time and power setting. The Device creates circular or oval shaped ablations on the surface of the tissue, with a minimum footprint of 4cm in diameter. Ablation size may vary depending on tissue type and other clinical factors. The thermal spread on the surface of the tissue is dependent on the following factors: the power setting, the duration of the treatment, and management of the saline via suctioning. In *ex vivo* testing performed at 20° C, the following ranges of thermal spreads were achieved for each setting (Tables 4-6). Figures 6-8 shows representative Time vs. Shape, and Time vs. Temperature graphs for all three tissue types.

Table 4: Representative **Liver** Ablation Height and Width, and Temperature from *ex vivo* Testing

Setting	Temperature Range from *ex vivo* Testing	Ablation Dimension Average from ex *vivo* Testing	Ablation Dimension Range from ex *vivo* Testing
35 W, 7 min	20 to 80° C	4.9 cm	4.3 to 5.6 cm
65 W, 10 min	20 to 85° C	5.5 cm	4.9 to 6.2 cm

Table 5: Representative **Kidney** Ablation Height and Width, and Temperature from *ex vivo* Testing

Setting	Temperature Range from *ex vivo* Testing	Ablation Dimension Average from ex *vivo* Testing	Ablation Dimension Range from ex *vivo* Testing
35 W, 7 min	20 to 85° C	4.7 cm	4.2 to 5.5 cm
65 W, 10 min	20 to 85° C	5.5 cm	5.0 to 6.1 cm

Table 6: Representative **Muscle** Ablation Height and Width, and Temperature from *ex vivo* Testing

Setting	Temperature Range from *ex vivo* Testing	Ablation Dimension Average from ex *vivo* Testing	Ablation Dimension Range from ex *vivo* Testing
35 W, 10 min	20 to 85° C	4.9 cm	4.3 to 5.4 cm
65 W, 13 min	20 to 85° C	5.7 cm	5.2 to 6.0 cm

NOTE: The tolerance for the height and width of ablation is +/- 1.0 cm.

The electrode array should properly contact the target tissue for the entire ablation. The angle of application of the device determines the amount of electrode contact between the device and the tissue and may affect the ablation depth. It is recommended to use an angle of application between 0° and 45° (as seen in Figure 5), because this provides the best electrode contact with the tissue. While an exact angle of 45° is not required, angles greater than 45° may result in a less deep ablation, because there is less electrode contact with the tissue. Users may effectively use the ablation Device at any angle between 0° and 45° (Figure 5), and to get results like what is shown in Figures 6-8.

Figure 5: Ablation Zone, 0° to 45° Angle of Application for Best Electrode Contact

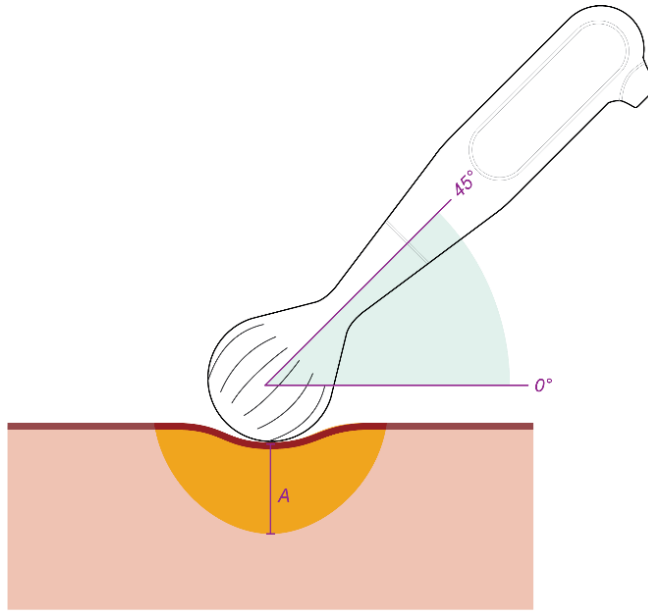
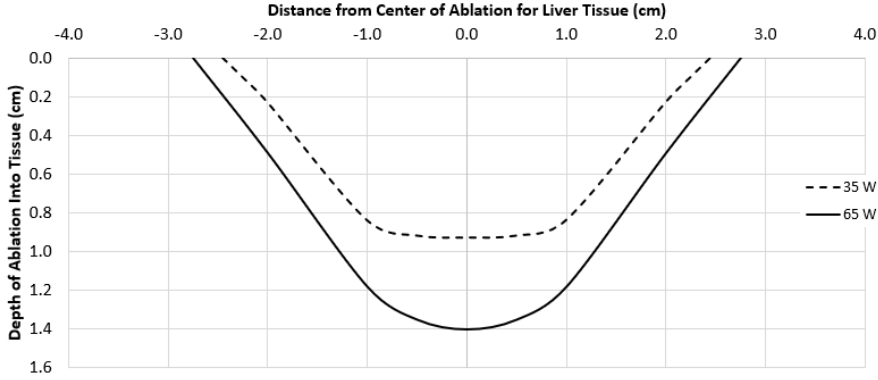


Figure 6: Representative Time vs. Shape vs. Temperature Graphs for Liver (from *ex vivo* testing)

Liver



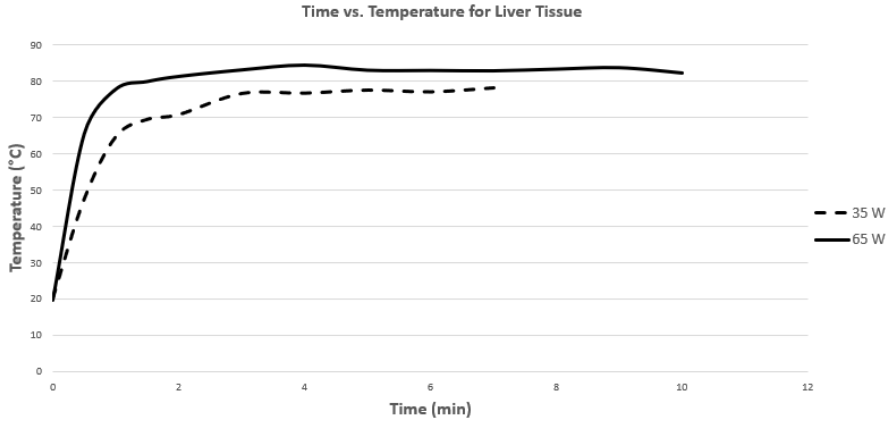


Figure 7: Representative Time vs. Shape vs. Temperature Graphs for Kidney (from *ex vivo* testing)

Kidney

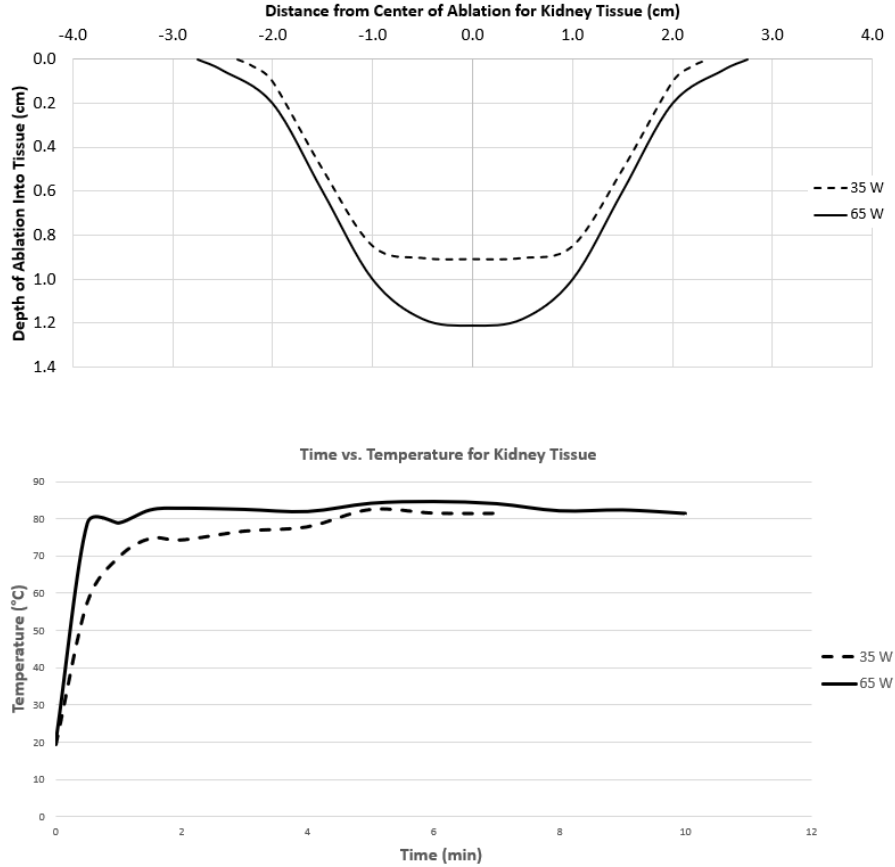
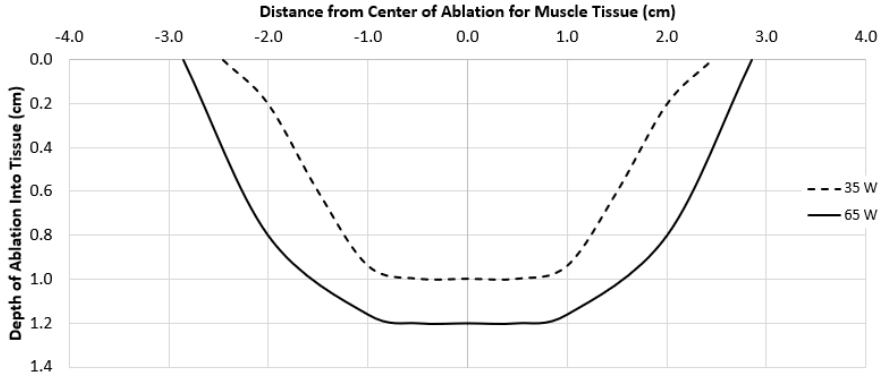
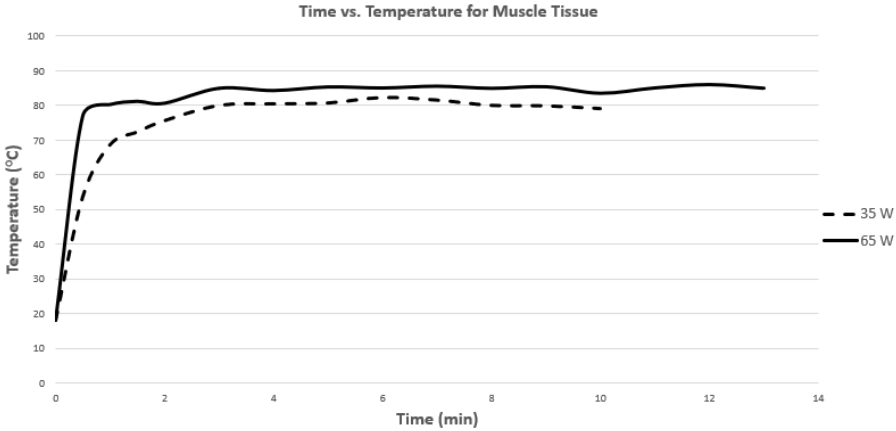


Figure 8: Representative Time vs. Shape vs. Temperature Graphs for Muscle (from *ex vivo* testing)

Muscle





TROUBLESHOOTING

- **If the irrigation system becomes blocked and saline isn't flowing appropriately:**

  Turn off the RF energy and check that the irrigation system has not become kinked, pinched, or clamped.

  AND check for loose connections.

  AND check for blockages in the saline irrigation ports.

  AND make sure tubing is properly purged (i.e. there are no large bubbles or air gaps inside the tubing).

- **If the tissue sticks to the Device:**

  Gently rotate the Device periodically throughout the procedure, to allow for different electrodes in the electrode array to contact the tissue.

  AND increase the saline flow rate on the flow regulator.

  AND gently rotate the Device while removing it from the tissue.

  AND gently remove any accumulated tissue from the Device by wiping off the Device with a coarse sponge or gauze.

- **If integrated switch and timer does not power on:**

  Check for loose connections.

  AND ensure the battery tab has been removed. Do not attempt to open the integrated switch and timer for any reason.

- **If the ablation produces too much smoke:**

  Increase the saline flow rate on the flow regulator (i.e. more saline will result in less smoke).

- **If the integrated switch and timer creates a pull on the Device:**

  Move and secure the integrated switch and timer closer to the ablation site to decrease tension in the cable.

- **If nothing is displayed on the timer:**

  Check the battery tab has been removed.

  AND press the power button on the timer.

  AND check to make sure the Device is plugged into the generator and the generator is turned on.

  IF there is still no display on timer, discard Device and retrieve a new one.

- **If the switch and timer powers on, but the RF power does not turn on:**

  Check the cable is plugged into and seated in the generator all the way and the generator is turned on.

  AND check the limit of 40 total minutes of ablation has not been surpassed.

  IF there is still no power being delivered to the Device, discard Device and retrieve a new one.

- **If the RF power does not turn off:**
  Ensure the active end of the device is safely away from patient and user.
  AND power off the generator.
- **If the switch and timer powers on, but the desired duration cannot be set:**
  Check the limit of 40 total minutes of ablation has not been surpassed.
  IF user still cannot set desired time, discard Device and retrieve a new one.

RETURNS

Defective Devices should be returned to Innoblative Designs Inc. Contact Customer Service for all returns.

DISPOSAL

Dispose of the SIRA® RFA Electrosurgical Device using the hospital's standard operating procedure pertaining to handling of contaminated sharps, biohazard material, and electrical waste. The battery may be removed prior to disposal.

TECHNICAL DESCRIPTION

GENERAL DESCRIPTION:

Bipolar electrosurgical instrument.
Employs RF energy and saline irrigation for ablation and coagulation of soft tissue.

RF energy source:	Medtronic ForceTriad™ Generator
Generator settings:	Bipolar RF power: 5 – 95 watts
Saline flow rate:	0 – 300ml/hour

GENERAL INFORMATION:

Sterile, EO
Multiple-use in single patient disposable,
Do Not Reuse.
No modification of this equipment is allowed.
Caution: Read Instructions for Use (IFU) before using this device.

PHYSICAL DESCRIPTION (typical):

Probe Height: 6.8 in (17.3 cm)

Length of Probe Cable and Saline Tubing: 2 ft (61 cm)

Length of Main Cable: 7.8 ft (2.4 m)

Length of Fluid Administration Set from saline bag to Integrated Switch and Timer: 9.2 ft (2.8 m)

Weight (with cables): 0.6 lbs (0.26 kg)

OPERATING CONDITIONS:

Temperature:	55°F to 80°F (13°C to 27°C)
Humidity:	30% – 75%, non-condensing

STORAGE CONDITIONS:

Temperature:	-22°F to 140°F (-30°C to 60°C)
Humidity:	15% – 90%, non-condensing

EXPECTED SERVICE LIFE:

The maximum period of useful life of the SIRA® RFA Electrosurgical Device is no more than 3 years.

ELECTROMAGNETIC COMPATIBILITY:

The SIRA® RFA Electrosurgical Device complies with the appropriate IEC 60601-1-2:2014+A1:2020 and EN IEC 60601-2-2:2018 specifications regarding electromagnetic compatibility. The SIRA-1000 Device meets the following requirements:

Emissions/Immunity Test	**IEC 60601-1-2:2014+A1:2020 Test Level**
Radiated Emissions *CISPR 11 Class A Group 1*	30 – 1000 MHz
Conducted Emissions *CISPR 11 Class A Group 1*	150 kHz – 30 MHz
Electrostatic Discharge (ESD) Immunity *IEC 61000-4-2*	±8 kV contact discharge ±2, 4, 8, 15 kV air discharge
Radiated Immunity *IEC 61000-4-3*	3 V/m, 80 – 2700 MHz 80% AM at 1kHz
Immunity to Proximity Fields from RF Wireless Comm. Equip. *IEC 61000-4-3*	IEC 60601-1-2:2014+A1:2020, Clause 8.10
Proximity Magnetic Fields Immunity Test *IEC 61000-4-39*	134.2 kHz @ 65 A/m, 2.1kHz PM 13.56 MHz @ 7.5 A/m 50kHz PM
Electrical Fast Transient/Burst *IEC 61000-4-4*	±2 kV AC Mains
Surge Immunity *IEC 61000-4-5*	±1 kV differential mode ±2 kV common mode
Conducted Disturbances Immunity *IEC 61000-4-6*	3Vrms 150 kHz – 80 MHz 6Vrms in ISM Bands 80% AM at 1kHz
Power Frequency Magnetic Field Immunity *IEC 61000-4-8*	30 A/m 60 Hz
Voltage Dips, Short Interruptions and Variations *IEC 61000-4-11*	0%, 0.5 cycles 0%, 1 cycle 70%, 25 cycles 0%, 250 cycles
NOTE: The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.	

WARRANTY

Innoblative Designs, Inc. warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, recleaning, and resterilization of this device as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond Innoblative's control may directly affect device function, safety, and results obtained from its use. Innoblative's obligation under this warranty is limited to the repair or replacement of this instrument and Innoblative shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Innoblative neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument**. Innoblative assumes no liability with respect to instruments reused, reprocessed, resterilized, modified or altered in any way and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such.**

PATENTS

www.innoblative.com/Patents

MANUFACTURER

Innoblative Designs, Inc.
1623 W Fulton St.
Chicago, IL 60612 USA
www.innoblative.com
Customer Service: +1 (833) 920-4660

GLOSSARY OF SYMBOLS

Consult Instructions for Use

Caution

Separate Collection

Do Not Use if Package is Damaged

Package Contents

Keep Dry

Sterilized by Ethylene Oxide

Legal Manufacturer

IEC 60601-1 Safety Test Symbol

Non-ionizing Electromagnetic Radiation

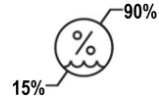
Double Sterile Barrier System

Authorized Representative

Do Not Reuse

Do Not Resterilize

Temperature Limitation
Store at -30°C to 60°C



Humidity Limitation
Store at 15% - 90%
Non-condensing Humidity

Use by Date

Catalogue Number

Batch Code

Prescription Only (USA)

Type BF Applied Part

Dangerous Voltage

Medical Device

CE Marking