innoblative®

sira®

RFA Electrosurgical Device
SIRA-1000

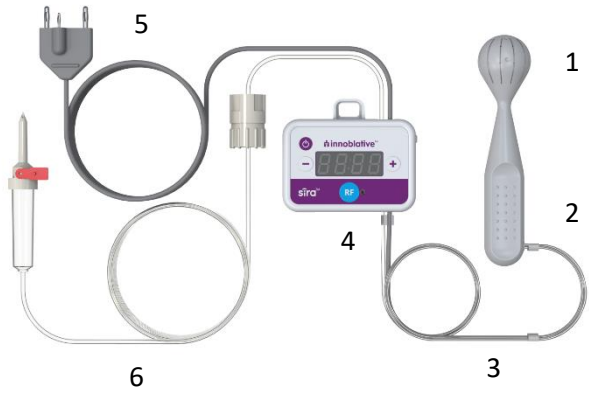
DEVICE DESCRIPTION

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 device is a sterile, single-use electrosurgical device, which is for use in the intraoperative coagulation and ablation of soft tissue, including in subcutaneous tissue and liver surgery.

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 power 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



The SIRA-1000 device handpiece: The handpiece contains an electrode array [1] with saline microinfusion that measures 4 cm in diameter. The bipolar electrodes are made of stainless steel. The device is activated when the following steps are executed: the device is connected to a radiofrequency electrosurgical generator, the power button on the

integrated switch and timer is pressed, a predetermined time is set via (+) and (-) time increment buttons, and the "RF" button on the integrated switch and timer is engaged. The electrode is connected to a handle (shaft, labeled [2] in Figure 1).

Integrated Cable Assembly: The cable assembly includes a main cable [5] with a 3-pin bipolar connector, fluid administration set with an in-line flow regulator and bag spike with drip chamber [6], connected to a probe cable and saline tube [3].

Integrated electrical RF power switch and timer: The integrated switch and timer [4] includes a power button that turns on the switch and timer once the battery pull tab is removed. The power button energizes the switch and timer and cannot be powered off once it is powered on. Time of energy activation is displayed on an LED screen and predetermined prior to activation. The predetermined time is set via (+) and (-) time increment buttons. An RF on/off button activates the RF energy emanating from the RF electrosurgical generator and initiates the timer countdown from the predetermined setting.

Saline Microinfusion system: The electrode array has irrigation ports adjacent to each of the individual bipolar electrodes. Saline is infused by a system consisting of a gravity fed fluid administration set with a flow regulator [6] for manually regulating saline delivery. The saline flows through the system and exits the electrode through irrigation ports along each of the individual bipolar electrodes. The saline flows from the bag, through the tubing of the fluid administration set, the flow regulator, the device handle, the foam inside the electrode array head, and then out the irrigation ports. The foam in the active electrode housing serves to distribute the saline evenly from the device head. The flow regulator allows the user to manually adjust the flow rate of saline from 0 ml/hr to 300 ml/hr.

The following accessories, which are not included with the SIRA-1000 device, are commonly found in operating rooms and are required to be used with the device:

- Electrosurgical Generator: An electrosurgical generator with a bipolar port that has an operating power range including 35-95W is used to supply RF energy to the SIRA-1000 device. The

compatible generators are the Medtronic ForceTriad™ Electrosurgical Generator and the Bovie® OR|Pro 300 Electrosurgical Generator (A3350).

- 0.9% saline bag: The fluid administration set is connected to the sterile saline bag via the bag spike. A minimum volume of 100 ml saline bag is required.
- IV pole: An IV pole which can extend to a height of 2 meters should be used to hang the saline bag while using the device.

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.

MODE OF ACTION OF SIRA® RFA ELECTROSURGICAL DEVICE

The underlying principle of operation of the SIRA-1000 device is the coagulation and ablation of soft tissue via resistive heating due to current flow through the tissue. Bipolar RF energy is supplied by the electrosurgical generator. When the electrode is activated and in contact with tissue, RF energy flows between the bipolar electrodes through the tissue causing vibration of ions, friction, heat, and coagulative necrosis. The addition of a saline medium 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 SIRA-1000 device can produce a range of ablation depths, depending on the chosen power and duration settings. The maximum depth provided in Table 1 is 1.5 cm depth of ablation (see Table 1).

WARNINGS

- 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 local government policy.
- DO NOT USE in patients who have electronic implants such as cardiac pacemakers.
- 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.
- 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.
- Connect adaptors and accessories to the electrosurgical unit only when the energy is off. Failure to do so may result in an injury or electrical shock to the patient or operating room personnel.

- DO NOT allow the Device to contact the patient until the electrical cable and tubing of the Device have been properly connected and the device primed with saline.
- DO NOT energize the Device when not in contact with target tissue, as unintended thermal injury may occur.
- 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 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 in 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.
- 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). The integrated switch and timer will not allow more than 40 min of ablations to be performed by a single device, to prevent over-use or reprocessing of the Device.
- This Device should not be used in conjunction with MRI image guidance as the Device has not been tested for MRI compatibility.
- The 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.
- 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.

- 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

- DO NOT USE the Device if the expiration date on the packaging has expired or if the seal is broken.
- 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.
- 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.
- 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.
- 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.
- Read the warnings, precautions, and instructions provided in the generator user manual before use. Specific instructions for the generator may not be included in this manual.
- 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.
- 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.
- Interference produced by the operation of the RF surgical equipment may adversely influence the operation of other electronic equipment.
- DO NOT USE metal tools, such as clamps or metal suction, close to the ablation device.
- 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.
- The cable on the device should be positioned in a way to avoid contact with the patient or other cables.
- Always use the lowest power and shortest time necessary to achieve the targeted ablation.
- High power settings result in deeper tissue effect than lower power settings.
- Use only sterile 0.9% saline for the irrigation.
- Use this device only with the Medtronic ForceTriad™ Electrosurgical Generator or the Bovie® OR|Pro 300 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 caution when treating close to critical structures to prevent damage from thermal ablation (e.g. major vessels, bone, major organs, skin). Critical structures should be at least 1 cm away from the outer margin of the ablation zone to prevent injury from the RF energy (see Table 1).
- 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.

- 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.
- Users must not touch the active electrode when it is energized.
- 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 the correct ablation performance.
- DO NOT defibrillate a patient when the Device is in contact with the patient. Completely remove the Device from the patient before defibrillation.
- Adequately clean the Device 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 the Device.
- Before using the Device, confirm the following:
    - The cable from the device is connected to the 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.

INDICATIONS FOR USE

The SIRA® RFA device is indicated for use in the intraoperative coagulation and ablation of soft tissue, including in subcutaneous tissue and liver surgery.

INTENDED USE

The SIRA® RFA Electrosurgical Device is to be used in conjunction with a bipolar electrosurgical generator (e.g., Medtronic ForceTriad™ Generator or Bovie® OR|Pro 300 Generator). It is a single-use device that can be used for multiple applications in one operative site.

A. PATIENT POPULATION

Adult population aged > 18 years undergoing coagulation and ablation of soft tissue including in subcutaneous tissue surgery or liver resection surgery such as excision of hepatocellular cancer or secondary cancer.

B. CONTRAINDICATIONS

Use of the SIRA-1000 device is contraindicated in the following patients due to the presence of an unacceptable risk of harm to the patient or the lack of data supporting the use of the SIRA-1000 device in these specific patient populations:

- With implanted cardiac pacemakers or defibrillators, or any other electronic device
- Who are pregnant
- Who are < 18 years
- Where other critical structures, such as major bile ducts, major blood vessels, the diaphragm, or intestine are less than 1 cm away from the outer margin of the ablation zone to prevent injury from the RF energy

C. POTENTIAL COMPLICATIONS

The following complications have been observed in RFA use in liver surgeries, and may apply to the use of the SIRA-1000 device:

- Improper tissue ablation leading to collateral tissue damage within or near the liver or insufficient tissue coagulation or ablation
- Bile leakage

- Infection of the wound
- Abscess formation near the surface of the liver

D. OPERATIONAL INSTRUCTIONS

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

1. Refer to the 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 and 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 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 the foam 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

11. Mount an IV bag containing sterile 0.9% saline on an IV pole approximately 2 meters high, near the sterile field. Minimum volume required is typically 100 mL.
12. 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.

13. 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.
14. 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.
15. 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 Table 1).

NOTE: The saline flow rates in the liver ablation depth table (Table 1) 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

16. Adjust the generator power setting to achieve the desired ablation zone (see Table 1). 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.

17. If using the ForceTriad™ Generator, select the "Standard" setting on the Bipolar screen. If using the Bovie® OR|Pro 300 Generator, select the "Macro Bipolar" setting.
18. 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 the procedure, and will not activate the RF electrical energy. The integrated switch and timer will display the setting of 0:00 min.

ABLATION SITE PREPARATION

19. Ensure that critical structures are at least 1 cm away from the perimeter of the ablation zone around the electrode array during placement of the device on the tissue site (Table 1).
20. The electrode array should properly contact the tissue, creating maximum electrode contact with the tissue without compromising saline flow from the irrigation ports.

NOTE: If any critical structure is less than 1 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.

EXAMPLES OF ABLATION ZONE SIZE IN EX-VIVO TISSUE AT 20-25° C

Figure 3 illustrates the ablation zone dimension and the recommended angle of application. "A" is the ablation depth around the Device, and the ablation will be deepest at the location of the arrow. 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 3), 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 shallower 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 3).

Figure 3: Liver Ablation Zone, 45° Angle of Application

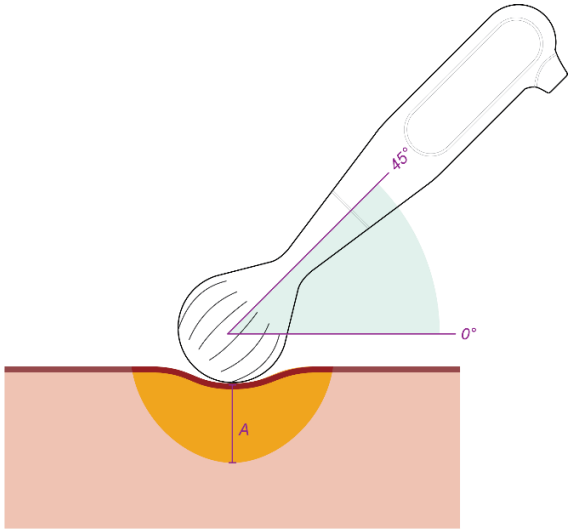


Table 1: Liver Expected Ablation Depths (A)

		Duration			
Generator	**Power**	**7 min**	**10 min**	**13 min**	**Flow Rate***
Medtronic ForceTriad™	**35 W**	0.9 cm	1.2 cm	1.4 cm	75 ml/hour
	65 W	1.3 cm	1.4 cm	1.4 cm	75 ml/hour
	95 W	1.3 cm	1.5 cm	1.5 cm	150 ml/hour
Bovie® OR|Pro 300	**36 W**	0.9 cm	1.2 cm	1.4 cm	75 ml/hour
	66 W	1.3 cm	1.4 cm	1.4 cm	75 ml/hour
	96 W	1.3 cm	1.5 cm	1.5 cm	150 ml/hour

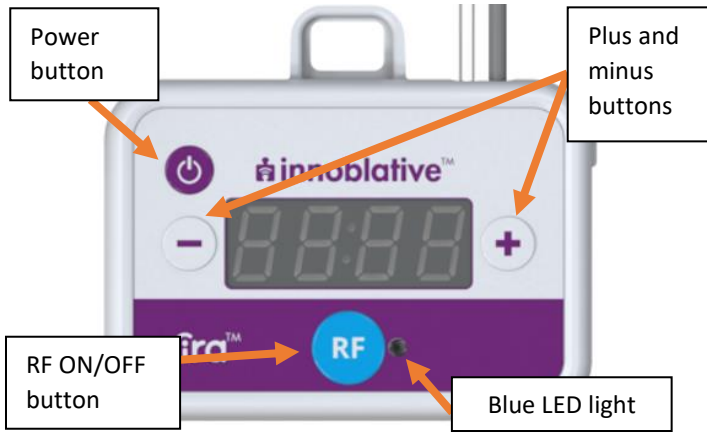
***NOTE:** The flow rates listed in Table 1 are only recommended starting flow rates. The user should change the flow rate as necessary for each ablation.

NOTE: Always use the lowest power and shortest time necessary to achieve the targeted ablation.

ABLATION PROCEDURE

21. Using the ablation settings specified above in the liver tissue table above (Table 1):
    a. Set saline flow rate to appropriate rate,
    b. Check the wattage on the generator is set to the appropriate setting, and
    c. 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 15min.

Figure 4: Integrated Switch and Timer Control



22. 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.
23. 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, turn to a solid blue light, and the timer will start counting down.
24. The ablation will spread outwardly from the device. Monitor the target site during the procedure to observe the extent of this spread.

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

25. During the ablation, continually monitor the operative site. Remove any excess fluid or steam that may be produced during the ablation with a plastic (nonconductive) suction device.
26. During the ablation, continually monitor the IV saline bag drip chamber to ensure that saline is constantly dripping into the tubing.
27. The saline flow must be carefully managed to achieve the desired effect. Presence of saline is important for a good ablation.
28. To manage saline flow for surface procedures:
    - Increase flow rate when there is no thin, bubbling film of saline, when there is excessive steam, or when tissue sticks to the device.
    - Decrease the 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.

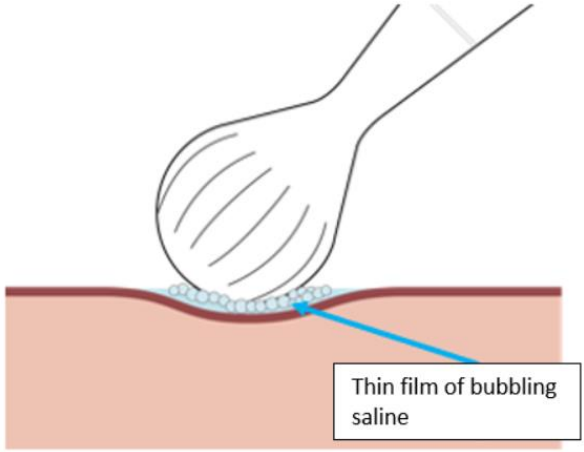
NOTE: If excess fluid and steam is not evacuated from the operating site for prolonged durations, unintended tissue injury may result.

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.

29. During the procedure, continually monitor the operative site using the Lift, Assess, and Adapt technique by **lifting** the device to visually observe the ablation zone, **assessing** the progress of the ablation, and if necessary, **adapting** the technique. You can adapt your technique by adjusting the placement of device, the angle of device, suction placement, 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 a surface procedure. Each "Lift" should only last a few seconds and will not disrupt the progress of the ablation.
30. 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 5)**.** 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, and 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 5: Appropriate amount of saline



31. The following are characteristics of a normal surface ablation procedure:
    - Saline bubbling at the surface of the ablation,
    - At high powers, saline bubbling from the device,
    - Steam emitting from the ablation site, and
    - Color of tissue changing
32. 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.
33. Remove the Device from the target tissue immediately following the procedure.
34. If an 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.
35. 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.
36. 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 in 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.

37. Relocate the SIRA-1000 to the next target once the Device has been cleaned and the parameters have been reset. Note that multiple overlapping ablations within a single lesion should not be performed.
38. When all ablations are finished, turn the flow regulator to the "OFF" position.
39. Caution must be used when removing device from operative site to avoid unintended thermal injury. Tissue may adhere to Device once the ablation is complete. Removal of the Device should be done carefully.
40. Use caution when placing Device 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.
41. 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.
42. 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.

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 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:**

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

- **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 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 that 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 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 sources:	Medtronic ForceTriad™ Generator (472 kHz, 350 Vpp) Bovie® OR|Pro 300 Generator (490 kHz, 800 Vpp)
Generator settings:	Bipolar RF Power: 5 – 96 watts
Saline flow rate:	0 – 300 ml/hr

GENERAL INFORMATION:

Sterile, EO

Multiple-use in single patient disposable, Do Not Reuse

Caution: Read Instructions for Use (IFU) before using this device.

PHYSICAL DESCRIPTION (typical):

Probe Height: 6.75 in (17.1 cm)

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

Length of Main Cable: 10.5 ft (3.2 m)

Length of Fluid Administration Set: 11.75 ft (3.6 m)

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

HF DIELECTRICT RATING: 800 Vpp

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, 8m, 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

AUTHORIZED REPRESENTATIVE (EC REP)

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MANUFACTURER

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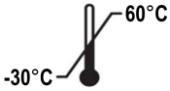
GLOSSARY OF SYMBOLS

	Consult Instructions for Use		Do Not Reuse
	Caution		Do Not Resterilize
	Separate Collection		Temperature Limitation Store at -30°C to 60°C
	Do Not Use if Package is Damaged		Humidity Limitation Store at 15% - 90% Non-condensing Humidity
	Package Contents		Use by Date
	Keep Dry		Catalogue Number
	Sterilized by Ethylene Oxide		Batch Code
	Legal Manufacturer		Prescription Only (USA)
	IEC 60601-1 Safety Test Symbol		Type BF Applied Part
	Non-ionizing Electromagnetic Radiation		Dangerous Voltage
	Double Sterile Barrier System		Medical Device
	Authorized Representative	 0459	CE Marking