

Solero

Microwave Tissue Ablation System

QUICK REFERENCE GUIDE†



INDICATION FOR USE

The Solero* Microwave Tissue Ablation (MTA) System and Accessories are indicated for the ablation of soft tissue† during open, laparoscopic, or percutaneous procedures. The Solero MTA System is not intended for cardiac use.

*Note Canada Only: Throughout this document, any reference to “soft tissue” means the following tissue types: liver, kidney, and lung (early stage non-small cell lung cancer (NSCLC) and inoperable pulmonary malignancies).

EQUIPMENT

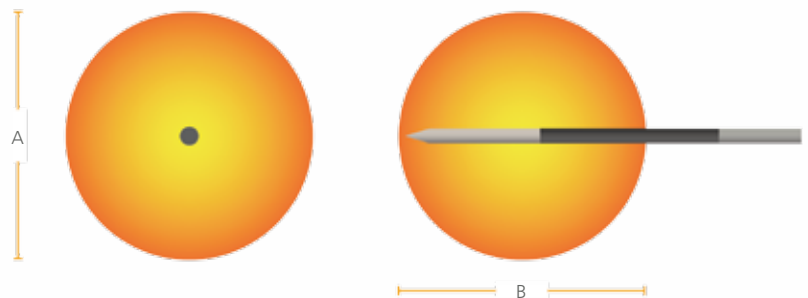
- Solero Generator
- Solero Applicator
- Power cable
- Footswitch (optional)
- Chilled sterile saline (1-3 L)
- IV pole

SETUP

1. Attach the power cable into the back of the Solero Generator.
2. Plug the generator into an electrical outlet.
3. Turn the generator power switch on (located on the back).
4. Connect the Solero Applicator's cartridge to the generator's connection.
5. Spike the applicator tubing into a chilled saline bag (1-3 L) and place the bag above the system with an IV pole.
6. Load the applicator tubing set into the generator pump and pump clip holder.
7. Press the pump button to start the pump.
8. Test the applicator tip at 100 W for 10 seconds with sterile water or saline to ensure device is functional.

DEVICE PLACEMENT


Ablation zone diameter (A) and length (B)




1. Using image guidance such as ultrasound or CT, determine the target location for the ablation.
2. Insert the applicator using the clinician's preferred method.
3. Place the transition of the stainless steel shaft and the ceramic tip at the center of the intended area of the ablation.
 - » When using CT guidance, the transition will show up as a black band in bone windows.
 - » When using ultrasound, the emitting antenna is 1.7 cm from the tip of the device.
4. Make sure that the black shaded area on the shaft of the device is fully inserted into the tissue.

PERFORMING THE ABLATION


EX VIVO BOVINE LIVER

|  | 2 min (A x B) | 4 min (A x B) | 6 min (A x B) |
|---|------------------|------------------|------------------|
| 60 W | 2.4 Ø x 2.8 cm | 3.0 Ø x 3.6 cm | 3.5 Ø x 3.9 cm |
| 100 W | 3.0 Ø x 3.7 cm | 3.5 Ø x 4.4 cm | 4.2 Ø x 4.9 cm |
| 140 W | 3.2 Ø x 4.0 cm | 4.0 Ø x 5.0 cm | 4.4 Ø x 5.4 cm |

EX VIVO PORCINE LUNG

|  | 2 min (A x B) | 4 min (A x B) | 6 min (A x B) |
|---|------------------|------------------|------------------|
| 60 W | 1.3 Ø x 1.9 cm | 1.5 Ø x 2.1 cm | 1.6 Ø x 2.4 cm |
| 100 W | 1.6 Ø x 2.7 cm | 2.0 Ø x 3.2 cm | 2.3 Ø x 3.2 cm |
| 140 W | 1.7 Ø x 3.2 cm | 2.5 Ø x 3.6 cm | 2.6 Ø x 3.6 cm |

EX VIVO PORCINE KIDNEY

|  | 2 min (A x B) | 4 min (A x B) | 6 min (A x B) |
|---|------------------|------------------|------------------|
| 60 W | 2.4 Ø x 3.1 cm | 3.0 Ø x 3.8 cm | 3.2 Ø x 4.0 cm |
| 100 W | 2.6 Ø x 3.7 cm | 3.4 Ø x 4.5 cm | 3.5 Ø x 5.0 cm |
| 140 W | 2.9 Ø x 4.3 cm | 3.5 Ø x 5.0 cm | 3.9 Ø x 5.6 cm |

1. Set the desired ablation power and time using the up and down arrows.
2. Start the ablation by pressing the Microwave Power Button or the footswitch.
3. The timer will begin to countdown to zero as soon as the energy is activated; the delivered power will be displayed to the right of the timer.
4. When the timer reaches zero, the ablation is considered complete. Alternatively, the user may stop the ablation at any time using the Microwave Power Button or the footswitch.

Note: Ablation volumes in perfused tissues may differ from static laboratory results.

ENDING THE PROCEDURE

1. The system will display a window that states "Ablation Complete" when the timer reaches zero.
2. The user may press the "Track" button after the ablation to perform a track ablation as required by the clinician's preference.
3. Once the device is removed from the patient, disconnect the device from the generator and saline source.
4. Dispose of the applicator according to state and hospital policies regarding sharps and biohazard handling procedures.

TROUBLESHOOTING

1. On-screen instructions for failure modes are displayed as pop-up menus or in the top right corner of the screen. Follow the on-screen instructions for use when they arise.
 - » Orange faults are associated with recoverable warnings and the ablation can be restarted/continued.
 - » Yellow faults end the ablation and require that the entire system be rebooted.
2. If rebooting does not clear the fault, contact your AngioDynamics representative.

Consult your AngioDynamics representative for country specific product availability.
Not intended for distribution in the USA.

*Please refer to the Solero Generator Operator's Manual and the Solero Applicator Directions For Use for complete instructions, warnings, and precautions.



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