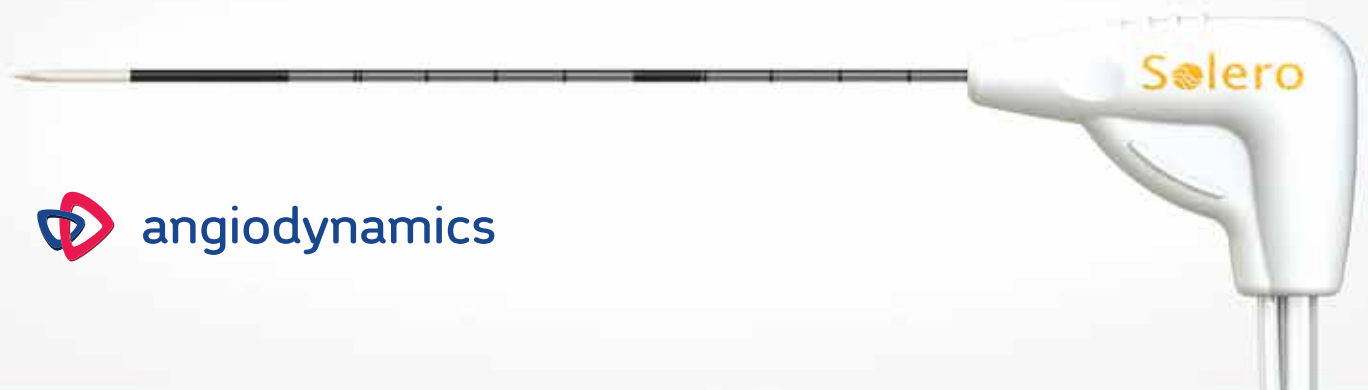


Solero

Microwave Tissue Ablation System



VALUE ANALYSIS BRIEF



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SOLERO VALUE ANALYSIS SUMMARY

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).

The Solero MTA System is a software-controlled, microwave generator which surgically ablates soft tissue through sterile applicators that are saline cooled. The Solero Applicator is designed to fit into a CT gantry with visibility under ultrasound. The applicator is available in 14, 19, and 29 cm lengths with an integrated microwave power delivery cable and coolant tubing set that is 2.86 m in length.

Features of the Solero MTA System include:

- A single applicator system with the ability to create up to a 5 cm ablation in 6 minutes[†]
- 2.45 GHz operating frequency
- Generator output power up to 140 W
- Integrated peristaltic pump
- Intuitive touch screen user interface with power and time settings
- Real-time output power display
- Applicator coolant temperature monitoring
- Reflected energy monitoring
- No grounding/ dispersive/ neutral electrode required
- Applicator for ablation in soft tissues

SOLERO MICROWAVE TISSUE ABLATION SYSTEM

The Solero MTA System is unique because it is specially designed to complete up to a 5 cm ablation in 6 minutes at max power output using a single applicator.[†] The Solero MTA System is able to accomplish this through the innovative solid state generator and specially designed applicator.

Power:

The Solero MTA System is specifically designed to deliver an optimized power to the tissue, maximizing the ablation volume in the shortest period of time. Reflected power is monitored and visualized in the delivered power window on the generator throughout the procedure to ensure maximum efficiency.

Frequency:

Microwave energy at 2.45 GHz is deposited nearly spherically into the tissue, utilizing a dielectric antenna and optimized ceramic tip. The tip to shaft transition is reinforced with a stainless steel, copper coated outer conductor for percutaneous placement.

Temperature:

As microwave energy is transmitted, it creates heat along the cable and length of the shaft. The Solero MTA System utilizes patented cooling channel technology which includes a thermocouple for continuous temperature monitoring. The system will alert the user if overheating occurs, minimizing the risk to surrounding tissues while maintaining nearly spherical ablations.

[†]Ex vivo bovine liver – actual clinical results in perfused tissues may differ

SOLERO MICROWAVE GENERATOR FEATURES AND BENEFITS

The Solero Microwave (MW) Generator with a 2.45 GHz operating frequency is a solid state generator that can power up to 140 W. It has an intuitive touch screen interface and integrated peristaltic pump for continuous device cooling with having the capability to monitor both coolant temperature and reflected energy.



FEATURE	BENEFIT
2.45 GHz solid state generator	Reliable operation with no need for annual calibration
Powers up to 140 W	Optimized power delivery for speedy ablations up to 5 cm [†]
Integrated peristaltic pump	Continuous cooling capacity
Single action cartridge connection	Simple and intuitive device setup
Continuous temperature monitoring	Minimizes risk to non-targeted tissues along the cable and the length of the applicator
Real-time reflected energy monitoring	Provides user feedback on the efficiency of the ablation
Touch screen user interface	Simple to operate
Countdown timer and delivered power monitoring	Easy to understand setup and operation
Time and wattage settings	Simple procedure parameters

SOLERO MICROWAVE TISSUE ABLATION SYSTEM—

The single applicator system with the ability to complete up to a **5 cm ablation in 6 minutes[‡]**

[‡]Ex vivo bovine liver- actual clinical results in perfused tissues may differ

SOLERO MICROWAVE APPLICATOR FEATURES AND BENEFITS

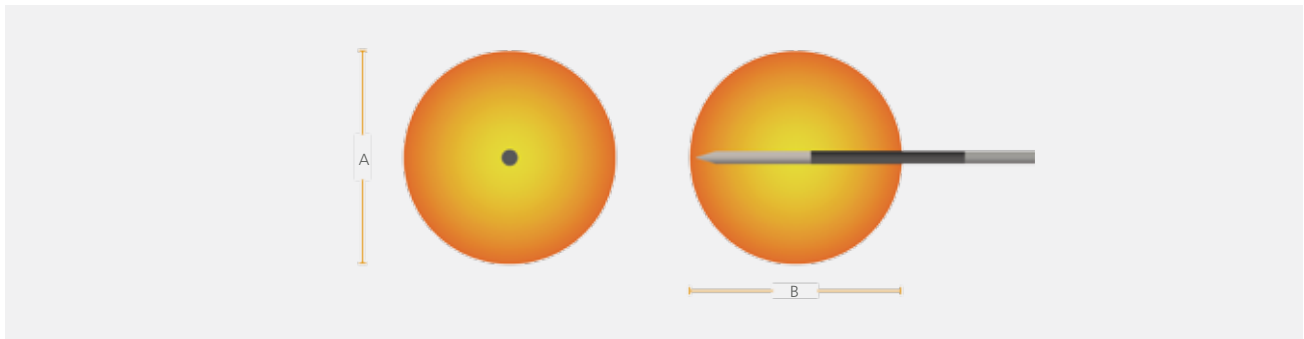
The Solero MTA System offers scalability with a single applicator designed for multiple predictable ablation zones. The Solero MW Applicator is available in 14, 19, and 29 cm lengths. The Solero MTA System is easy to setup and only requires a single applicator to reduce MW applicator placement time. The low profile handle and rigid 15 g stainless steel applicator includes centimeter markings to aid in device positioning, and the 2.86 m power delivery cable is fully cooled by the integrated coolant tubing set.

FEATURE	BENEFIT
15 g stainless steel applicator	Rigid enough to provide trackability and small enough to support minimally invasive procedures
Available in 14, 19, and 29 cm lengths	Variety of lengths available for open, percutaneous, and laparoscopic procedures
Molded ergonomic handle	Fits easily through the CT gantry
Patented coolant channel with thermocouple	Provides real-time feedback on the device coolant temperature, minimizing the risk to tissues not intended for ablation
Centimeter markings along the shaft	Visibility of placement depth during procedures
Optimized ceramic tip	Diffuses MW energy nearly spherically around the dielectric antenna
Dielectric antenna with a stainless steel, copper coated outer conductor	Optimized power delivery into the tissue while providing reliable percutaneous placement
2.86 m flexible, fully cooled cable	Easy placement while minimizing the risk of non-targeted tissue burns
Integrated single piece coolant tubing with molded bag spike	Simple setup and reliable operation




SOLERO MTA SYSTEM RESULTS


The Solero MTA System, which features the Solero MW Applicator, delivers focused microwave energy to generate lethal heat levels, greater than 70°C, in order to destroy tissue. Microwave energy generates heat in soft tissue through the rapid oscillation of water dipoles, which causes frictional heat within the target zone of ablation. The active zone of microwave energy radiates approximately 2 cm around the device's energy emitting antenna. The remaining heat generation is considered conduction heat transference, where core heated tissue delivers heat to adjacent tissue over time, increasing the overall size of the ablation. The size of the ablation is repeatable and predictable based on pre-established protocols using ex vivo bench testing in bovine liver and porcine kidney and lung.




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 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

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

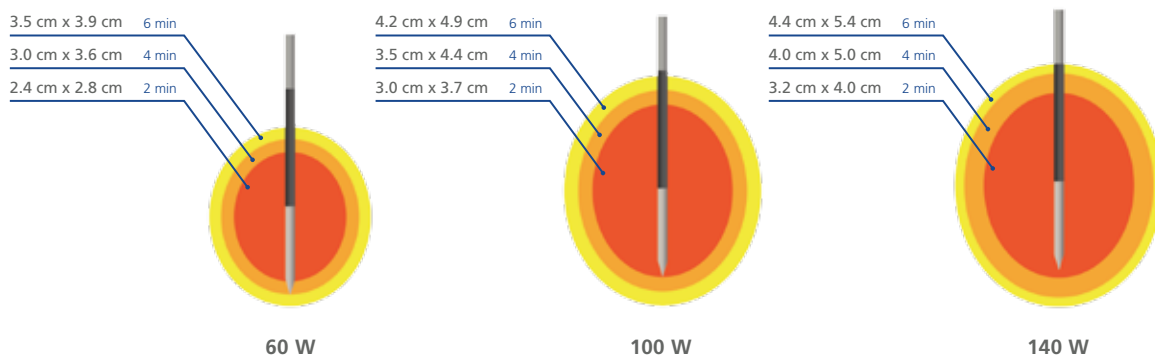
Note: Ablation volumes in perfused tissues may differ from static laboratory results.

SPEEDY AND SCALABLE ABLATION VOLUMES

To evaluate the performance of the Solero MTA System's speedy, predictable, and scalable ablation volumes, time (2, 4, and 6 min) and wattage (60, 100, and 140 W) were varied and ablation volumes were assayed by diameter and length measurements. The Solero MTA System is unique because it is specially designed to complete a 5 cm ablation in 6 minutes at max power output using a single applicator.* The Solero MTA System is specifically designed to deliver optimized power to the tissue to maximize the ablation volume in the shortest period of time. Furthermore, the data demonstrates the additional benefit of the Solero MTA System's ability to generate predictable and scalable volumes by simply varying time and wattage.

Ex Vivo Bovine Liver (diameter x length)

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



*Ex vivo bovine liver- actual clinical results in perfused tissues may differ

SOLERO MTA SYSTEM COMPETITIVE COMPARISON

Brand Name	Company	Frequency	Applicator Size	Number of Applicators	Single Applicator Ablation	Time to Max Ablation	Cooling Mechanism
Solero	AngioDynamics	2.45 GHz	15 g	Single	4.4 x 5.4 cm [‡]	6 min [‡]	Saline
Emprint	Medtronic	2.45 GHz	13 g	Single	3.5 x 4 cm	10 min	Water
Certus140	Ethicon	2.45 GHz	17 g	Up to 3	4 x 7 cm	10 min	CO2
Amica	HS Amica	2.45 GHz	11, 14, 16 g	Single	5 x 4 cm	10 min	Saline
MicroThermX	Perseon	915 MHz	14 g	Up to 3	3.8 x 6.3 cm	15 min	Saline
Avecure	MedWaves	908–928MHz	12, 14, 16 g	Single	6 x 9 cm	30 min	None

Brand Name	Company	Frequency 2.45 GHz	15 g or Smaller Applicator	Single Applicator 5 cm Ablation	Up to a 5cm Ablation in 6 min
Solero	AngioDynamics	Yes	Yes	Yes [‡]	Yes [‡]
Emprint	Medtronic	Yes	No	No	No
Certus140	Ethicon	Yes	Yes	No	No
Amica	HS Amica	Yes	Yes	Yes	No
MicroThermX	Perseon	No	No	No	No
Avecure	MedWaves	No	Yes	No	No

Competition information derived from publicly available product literature.

ORDER INFORMATION

SKU	Description
H787127400000	Solero MW Generator
H7877001060010	Solero MW Applicator 14 cm
H7877001060020	Solero MW Applicator 19 cm
H7877001060030	Solero MW Applicator 29 cm

[‡]Ex vivo bovine liver- actual clinical results in perfused tissues may differ





REFERENCES

1. Solero MTA System Generator Operator's Manual; 16750970-21C.
2. Solero MTA Applicator Directions For Use; 16600970-01B.

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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