

AveCure ® Coagulation-Ablation System





Key Components and Features

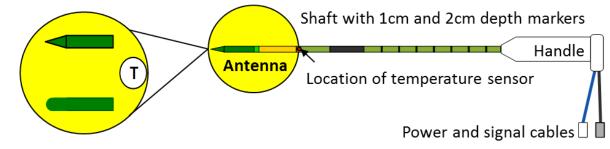
Coagulation-Ablation System

Generator:

- Active Temperature-controlled Power Output: user selectable set-point (60-130°C) and real-time temperature feedback from antenna control power output for optimum safety, predictability and prevents complications from runaway temperature, such as, thrombosis, charring and cavitation.
- Active Wavelength (Frequency) control: real-time active wavelength (902 -928 MHz) tuning to optimize antenna performance in changing tissue condition and management of antenna ecosystem.
- Antenna selection menu: eases setup and use.
- Ablation information: temperature (°C), energy (k-joules), forward and reverse (reflected) powers (watts), elapsed and remaining times (mm:ss). Automatic detection of unsafe system conditions, such as overtemperature, power output error, etc.
- Multiple Generators can be used simultaneously to coagulate-ablate very large or multiple lesions to save time.

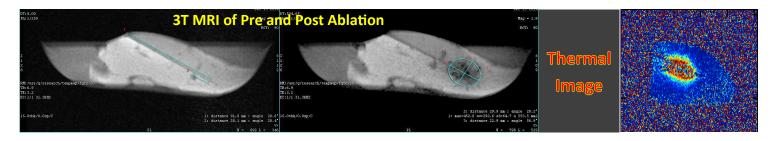


Antennas:



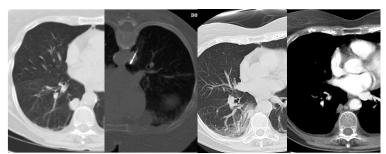
- Integrated temperature sensor for active real-time temperature feedback-control
- Full antenna spectrum (1, 2, 3, and 4cm) for predictable focused ablation zones
- Wide range of shaft lengths for reach, convenience and comfort: 10 to 158cm
- Robust design with sharp or round tip: no ceramic parts to chip or break
- Flexible-catheter and Rigid-probe configurations: 16 and 14G
- MRI Safe: CT, Fluoro, MR and Ultrasound imaging
- Detachable extension cables to 7.2 meters
- Easy Plug-n-play; No cooling hookup











Lung Tumor next to the aorta MW Ablation: Successfully treated lung carcinoids next to the aorta. From left to right: pre ablation image of tumors next to aorta growing front to back and top to bottom, pre ablation image of one of the antenna placements, post ablation image of ground-glass effect of coagulation around the tumors; 12-month follow-up of scar-tissue shrinkage, and no enhancements.



Liver Tumor next to hepatic veins MW Ablation: Successfully treated colorectal metastasis next to hepatic veins in the liver. From left to right: pre ablation image of tumor next to the hepatic veins, post ablation image of the ablation zone between the veins. Onemonth follow-up of shrinkage, and no enhancements.

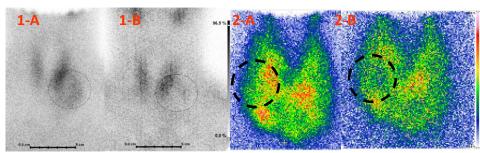


Kidney Tumor next to a renal pelvis MW Ablation: Successfully treated renal carcinoma next to the pelvis. From left to right: pre ablation image of 3x4 cm tumor next to the pelvis, a large antenna positioned from posterior entry, and post ablation image of substantial tissue contraction, no hemorrhage; 12-month follow-up of no enhancements.

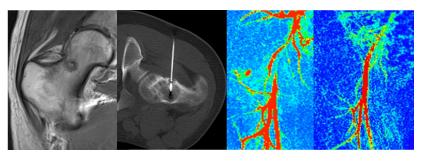


Clivus Tumor next to spine and brain MW Ablation:

Successfully treated recurring Clivus tumor, from left to right: pre ablation image of tumor; post ablation image of coagulation behind the uvula, significant tissue shrinkage after 2-week, 8-mos and 48-mos; patient received immediate relief of breathing and swallowing; a second ablation was performed after 8-mos and the 48-mos follow-up of no tumor enhancements and symptom



Thyroid Tumor MW Ablation: Successfully evaluated of MW ablation of hot and cold thyroid nodules by method-1: scintigraphic Tc-99m-MIBI imaging, method-2: functional imaging with Tc-99-M-pertechnetate. The MW ablation is effective and safe, and can be verified with both methods.



Bone Tumor, Osteoid Osteoma MW Ablation: Successfully treated a patient with pain for several months with sclerotic-rimmed osteoid in the right hip. Ablated with Mini antenna (80°C, 1-minute). From left to right: pre ablation MRI T1W image of tumor in the right femoral head; pre and post dynamic MRI images of change tumor and vascularization in the ablation zone. Complete pain relief achieved post ablation.

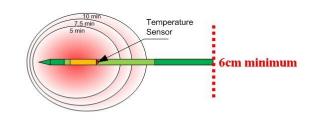




Large Antenna: 14 Gauge						
Time (minutes)	Tempera- ture (°C)	Ablation coverage short x long axis (cm)		Energy delivered (K-Joule)		
5	120	3.0 x 5.0	3	10 kJ		
10	120	4.0 x 5.5	4	18 kJ		
1.5	120	50 60	- C	2.4.1-T		

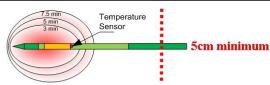
15 min 10 min 5 min	Temperature sensor	
		8cm minimum

Medium Antenna: 14 Gauge Tempera-Ablation coverage Beyond the tip of the Energy delivered (minutes) ture (°C) short x long axis (cm) antenna (mm) (K-Joule) 120 2.5 x 3.0 6 kJ 120 3.0 x 3.5 120 3.5 x 4.0 11 kJ



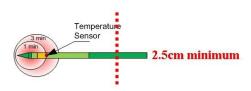
Small Antenna: 16 Gauge

Time (minutes)	Tempera- ture (°C)	Ablation coverage short x long axis (cm)	Beyond the tip of the antenna (mm)	Energy delivered (K-Joule)
3	110	1.5 x 2.5	1	4 KJ
5	110	2.0 x 2.7	2	6 kJ
7.5	110	2.5 x 3.0	3	8.5 kJ



Mini Antenna: 16 Gauge

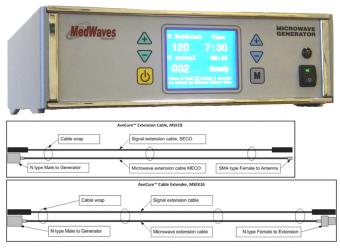
Time (minutes)		Ablation coverage short x long axis (cm)	Beyond the tip of the antenna (mm)	Energy delivered (K-Joule)
1	80	1.0 x 1.0	1	0.8 kJ
3	80	1.5 x 1.5	2	2 kJ

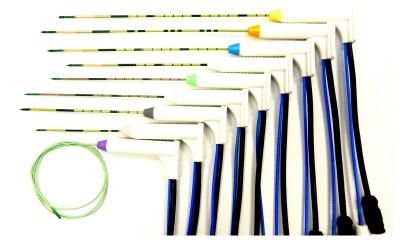


Disclaimer: Images are not to scale. Ablation zones displayed above serve as guidelines only and based on situations with low reverse-power (0-1w). Actual ablation zones need to be verified using normally accepted techniques by the clinician.

To avoid potential surface injuries, the minimum insertion depths must be adhered. To avoid unintended surface injuries while treating sub-capsular lesions for longer than 10minutes in the same insertion, apply sterile gauze pads wetted with cool sterile water or saline at the insertion site. Please refer to IFUs.

This system has been cleared for soft-tissue ablation/coagulation, and not intended for cardiac applications. The above ablation zone dimensions do not account for tissue contractions following ablation.





Manufacturer:

MedWaves Incorporated

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Website: www.medwaves.com

Brand: AveCure®

FDA Cleared and CE Mark Certified Not cleared for cardiac applications

Local Representative: