

Emprint™ ablation system

Value analysis brief



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Emprint™ HP
ablation generator



The Emprint™ HP ablation generator gives you more volume, with a single antenna.

Achieving complete tumor coverage is critical to successful management of patients with non-resectable hepatic tumors¹⁻⁴ – so is preserving healthy liver.^{5,6}

The Emprint™ HP ablation generator achieves complete tumor coverage, maximizing ablative margin while minimizing ablation volume^{7,8} – all with a single antenna.

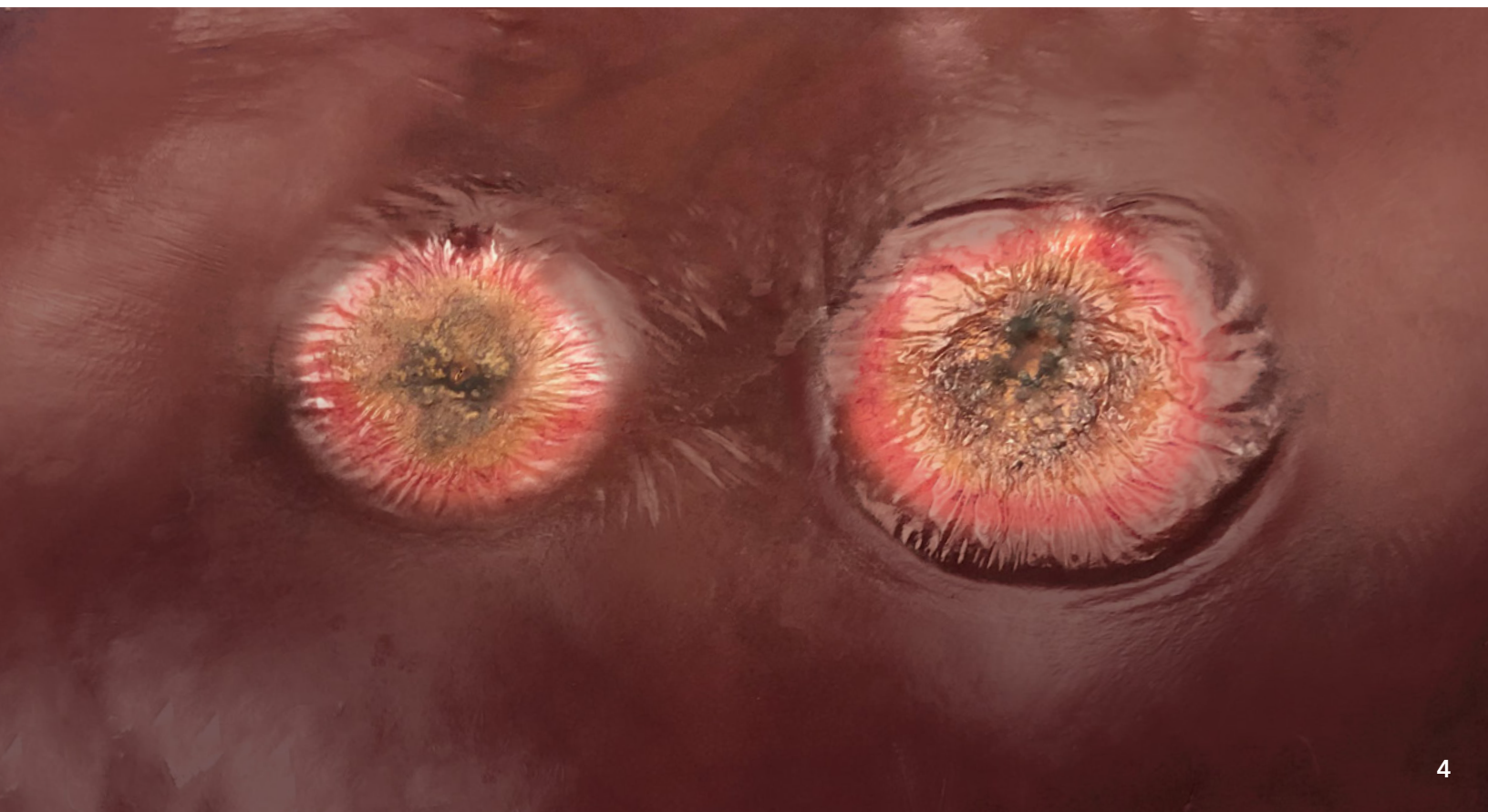


Greater coverage. Fewer antennas. Less collateral damage.

Using our patented Thermosphere™ technology, the Emprint™ HP ablation generator enables a minimally invasive procedure with:

- Large ablations, with up to 40 percent more volume compared to the original Emprint™ ablation system⁹
- Proven spherical shape,¹⁰⁻¹⁶ giving you flexibility in antenna placement approach⁷
- Consistent ablative margins greater than 5 mm^{7,†}
- Scalability, allowing you to create both small and large ablation zones⁹

†Independent study was performed using the 100 W Emprint™ ablation generator. A total of 56 tumors ablated with the Emprint™ ablation system had a median size of 1.4 cm (range 0.4 to 3.7 cm).

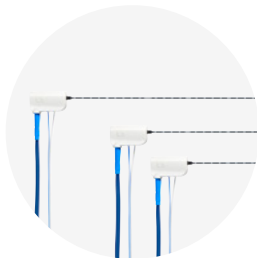


System overview

**Emprint™ HP
ablation generator**
150 W high-frequency
(2.45 GHz) generator
Order code: CAGENHP



Ablation cart
An all in one system designed with a
17" x 19" footprint to save space in
crowded procedural suites.
Order code: CARTHP



**Emprint™ percutaneous antenna
with Thermosphere™ technology**
Order codes:
Short (15 cm): CA15L2
Standard (20 cm): CA20L2
Long (30 cm): CA30L2



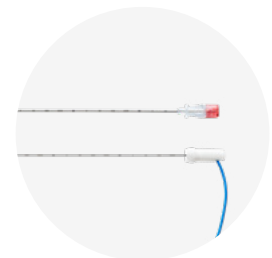
Ablation pump
Order code: CAPUMP1



**Ablation
reusable cable**
Order code: CA190RC1



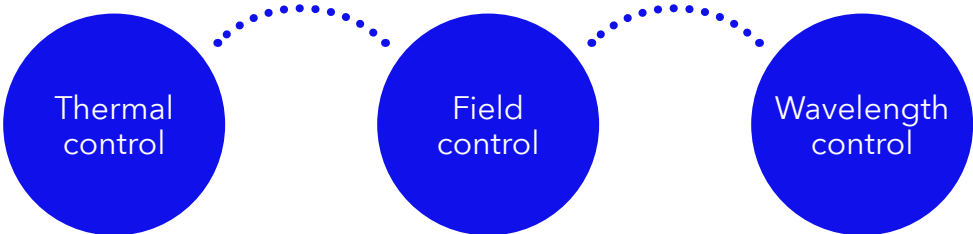
Footswitch
(Optional accessory)
Order code: RFAW



**Remote
temperature probe**
(Optional accessory)
Order code: RTP20

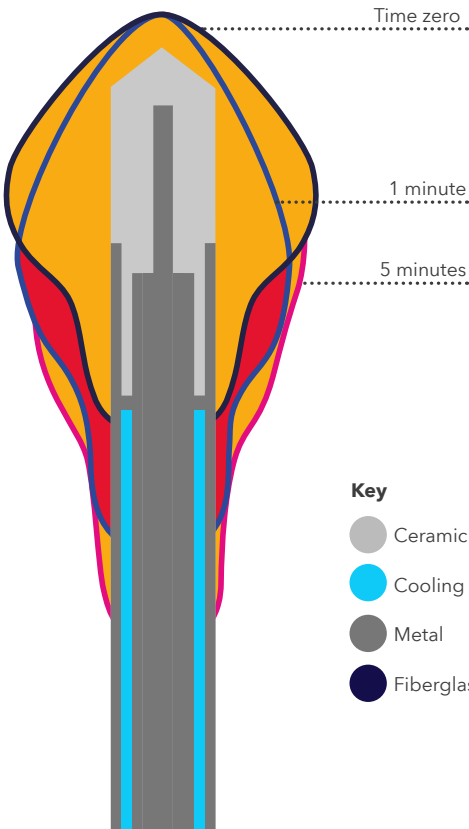
The power of Thermosphere™ technology

The Emprint™ ablation system with Thermosphere™ technology leverages three types of energy control to deliver a predictable, repeatable ablation zone.

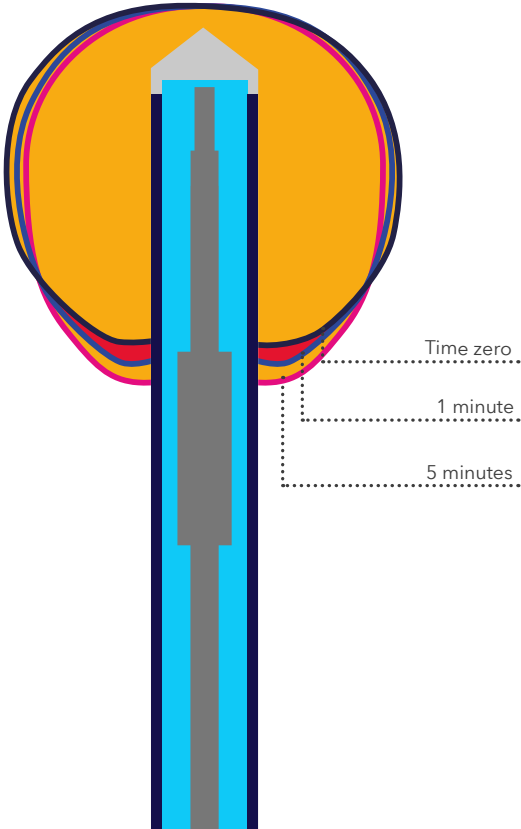


Wavelength control is unique to Thermosphere™ technology. With wavelength control, cooling fluid circulates around the antenna, ensuring a spherical ablation zone is maintained over time.¹⁷

Conventional MWA technology without wavelength control



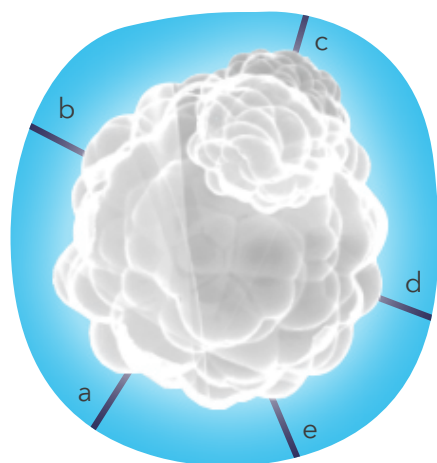
Thermosphere™ technology wavelength control



The clinical impact of Thermosphere™ technology



Defining minimum ablative margin



● Tumor ● Ablation zone

In the image above, a-d represent discrete measurements of ablative margin at different locations around a tumor.

Minimum ablative margin is defined as the smallest distance from the tumor to edge of the ablation zone. In this case, the minimum ablative margin = c.

Ablative margin of >5 mm is associated with better local tumor control upon follow-up imaging.¹⁻⁴

Delivering clinically relevant ablation margin

Evaluation of microwave ablation of liver malignancy with enabled constant spatial energy control to achieve a predictable spherical ablation zone

Thomas J Vogl et al. *Int J Hyperthermia*. 2018 Jun;34(4):492-500.

Compared to other commercially available microwave ablation technologies, spherical ablation zones created with the Emprint™ ablation system result in **clinically relevant (>5 mm) ablative margins.**⁷

The Emprint™ ablation system delivers energy efficiently, **maximizing ablative margin** while **minimizing collateral tissue damage.**⁷

3.57%

local tumor progression (LTP) at 12 months⁷

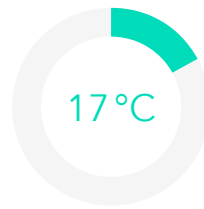
Information you can count on

We believe sharing clinically relevant ablation information will lead to better care for patients.

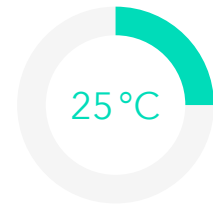
Standards do not exist to align manufacturers on ablation performance modeling for thermal ablation devices. With no common standard, it's challenging to compare reported performance between manufacturers.

At Medtronic, we've studied the effect of tissue model temperature on ablation zone reference data.¹⁸

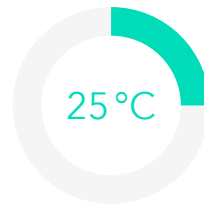
Current MWA manufacturer model temperatures^{19,20}



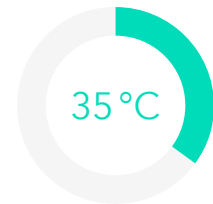
Medtronic



J&J

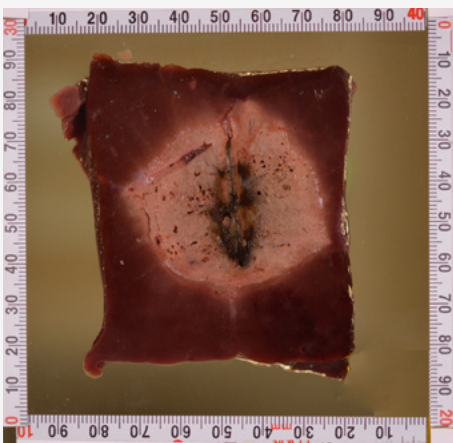


HS Hospital Service



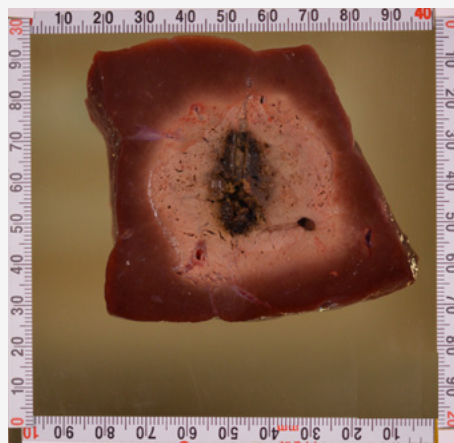
Angiodynamics

Emprint™ ablation system performance across varied tissue model temperatures (100 W, 10 min in bovine liver model)¹⁸



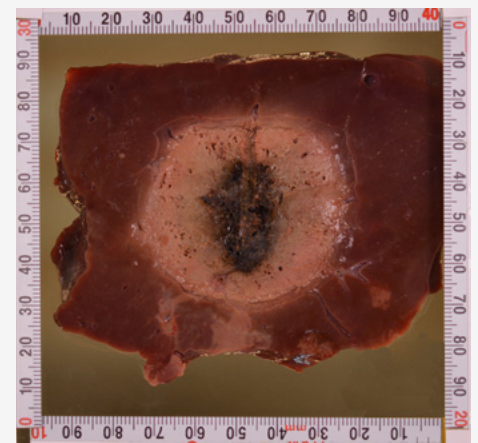
W = 4.2 cm H = 4.2 cm

17°C



W = 4.7 cm H = 4.5 cm

25°C



W = 5.0 cm H = 4.8 cm

35°C

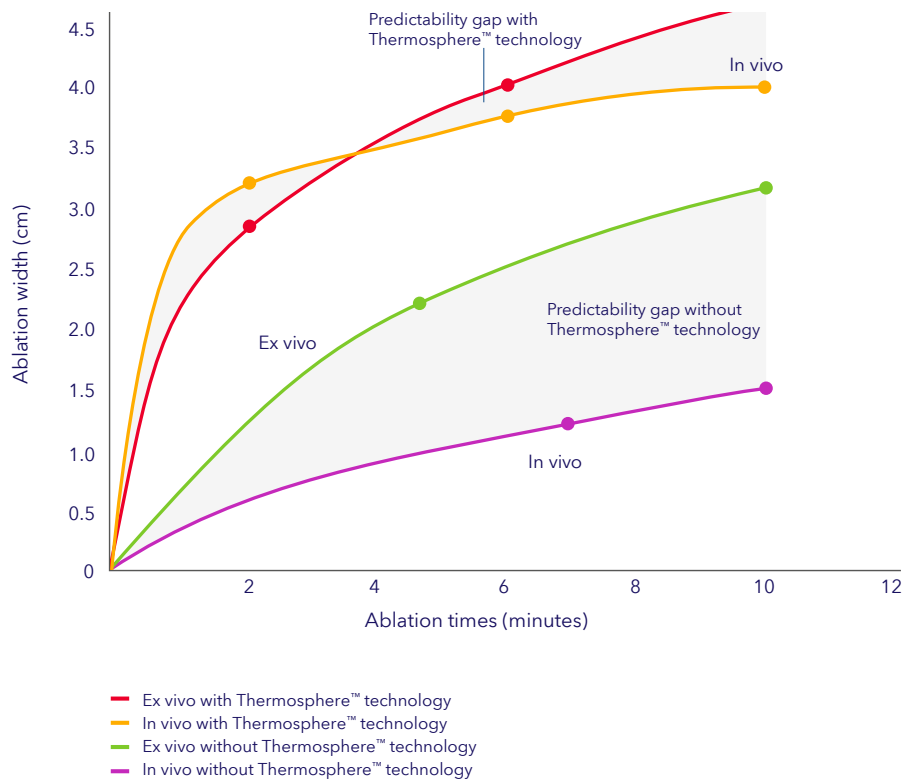
Model temperature has a significant effect on the size of ablation zone created.¹⁸

Validated by independent investigation

When evaluating performance of the Emprint™ ablation system, we use an ex vivo ablation model temperature of 17°C.

Chilled ex vivo tissue simulates ablation performance in live models.^{12,21} We've proven this by comparing ablations conducted in vivo in live porcine tissue to ex vivo bench-top results.

Enhancing predictability of MWA ablation with Thermosphere™ technology



Predictable ablation zones

Microwave ablation of liver malignancies: comparison of effects and early outcomes of percutaneous and intraoperative approaches with different liver conditions.

Francesco De Cobelli et al. *Med Oncol.* 2017 Apr;34(4):49.

Ablation zones produced clinically by the Emprint™ ablation system in non-resectable liver malignancies **match the predicted ablation zone** based on manufacturer provided ex vivo reference charts.¹⁶

Microwave ablation with Thermosphere™ technology is **minimally influenced by different pathophysiologic, hemodynamic, and operative conditions** when used clinically.¹⁶

93%

tumor control at one month¹⁶

Product specifications

Indication for use

The Emprint™ ablation system is intended for use in percutaneous, laparoscopic and intraoperative coagulation (ablation) of soft tissue, including partial or complete ablation of non-resectable liver tumors.

The Emprint™ ablation system is not intended for use in cardiac procedures.

The Emprint™ ablation system products include:

SKU	Product
CARTHP	Emprint™ HP ablation cart
CAGENHP	Emprint™ HP ablation generator with Thermosphere™ technology
CAPUMP1	Emprint™ ablation pump
CA190RC1	Emprint™ ablation reusable cable
RFASW	Ablation footswitch
CA15L2	Emprint™ short percutaneous antenna with Thermosphere™ technology
CA20L2	Emprint™ standard percutaneous antenna with Thermosphere™ technology
CA30L2	Emprint™ long percutaneous antenna with Thermosphere™ technology

Product specifications:

Specification	Details
Microwave output frequency	2450 MHz
Output power	0-150 Watts maximum adjustable in 5-watt increments
Time setting	Adjustable in 30 second increments up to 10 minutes maximum for single activation
Antenna compatibility	Emprint™ percutaneous ablation antenna with Thermosphere™ technology
Antenna lengths	15 cm, 20 cm, 30 cm
Antenna gauge	13 G

Ablation zone reference information

Emprint™ ex vivo size and shape comparison at 10:00 min and a maximum power output of 150 W.

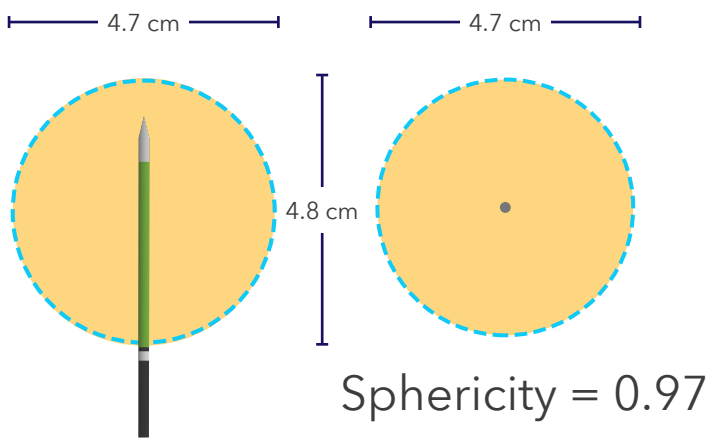
	Test tissue	Height (cm)	Width (cm)	Sphericity Ratio
150 W	Liver	4.8	4.7	0.97
	Lung	4.9	4.4	0.90
	Kidney	4.9	4.6	0.94

Product cross references

The Emprint™ HP ablation generator provides the largest cross-axis ablation with a single antenna, based on manufacturer provided ex vivo reference charts.

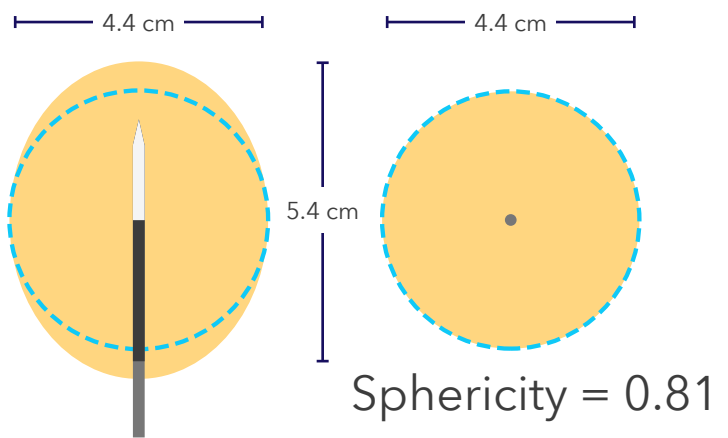
Emprint™ ablation system

150 W, 10 min
(17 °C ex vivo bovine model)



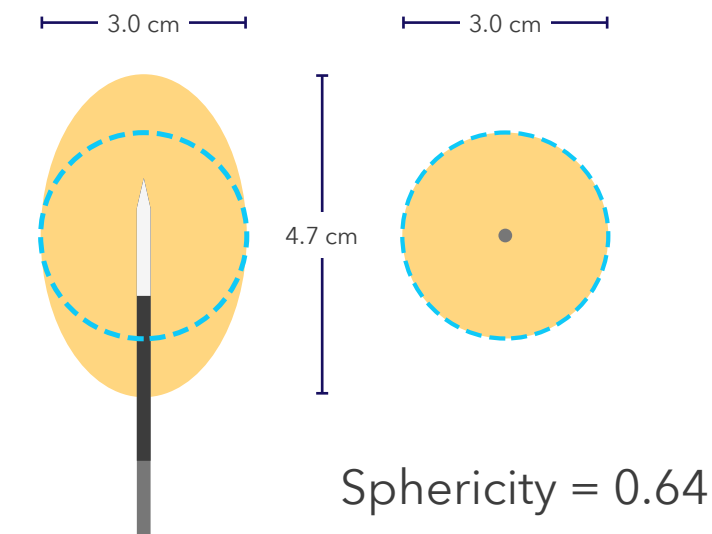
Solero ablation system²³

140 W, 6 min

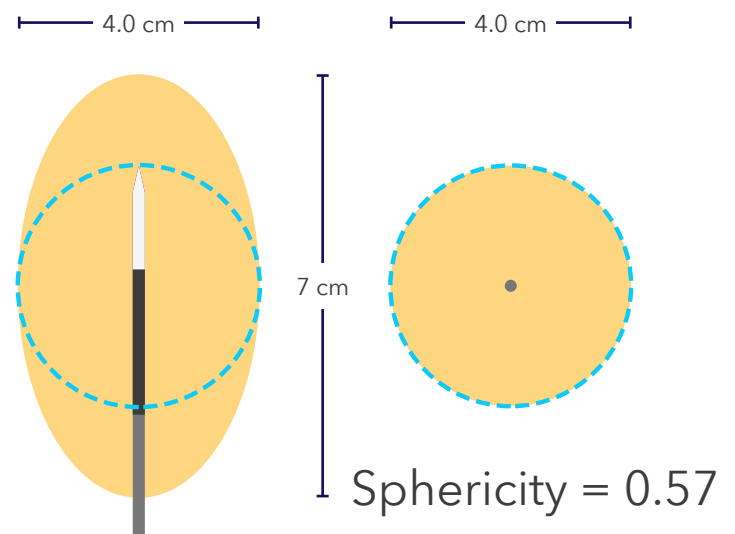


Neuwave™ microwave ablation system^{24,25}

PR Probe, 65 W, 10 min



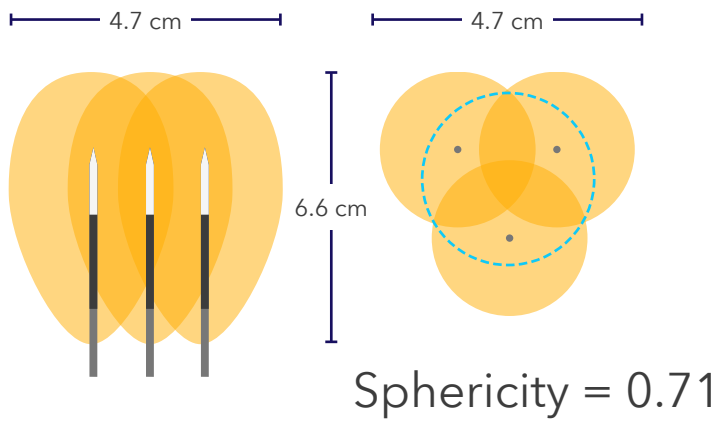
LK Probe, 140 W, 10 min



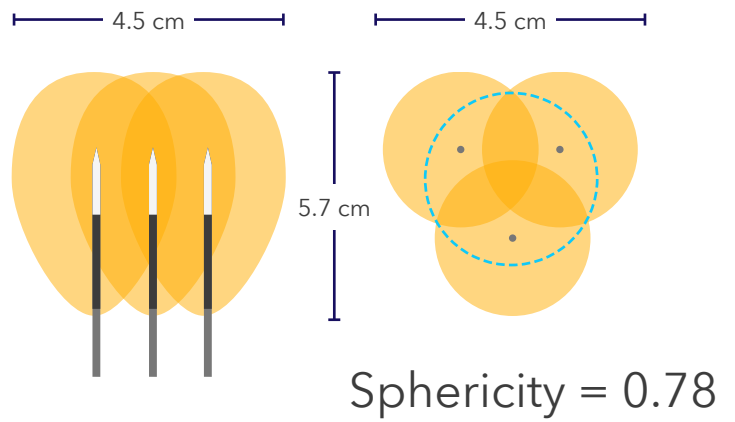
Product cross references

Neuwave™ ablation system^{24,25}

PR Probe, 65 W, 10 min



LK Probe, 65 W, 10 min



Product cross references

Product	Emprint™ ablation system	Solero ablation system ²³	Neuwave ablation system ²⁶	Amica ²⁷
Manufacturer	Medtronic	Angiodynamics	Johnson & Johnson - Ethicon	HS Hospital Service
Proprietary technology	Thermosphere™ technology	N/A	CO ₂ cooling system	MINI-CHOKE™ technology
Ablation antennas	Emprint™ percutaneous ablation antenna with Thermosphere™ technology	Solero MW applicator	Neuwave™ PR probe Neuwave™ LK probe Neuwave™ LN probe Neuwave™ PRXT probe Neuwave™ LKXT probe Neuwave™ SR probe	Amica™ probe
Available gauges	13 G	15 G	15 G, 17 G	11 G, 14 G, 16 G
Available lengths	15 cm 20 cm 30 cm	14 cm 19 cm 29 cm	15 cm 20 cm	15 cm 20 cm 27 cm
Generator power Maximum power to a single antenna	Up to 150 W	Up to 140 W	Up to 140 W	Up to 140 W
Cooling fluid	Saline	Saline	CO ₂	Saline
Temperature monitoring	Built in continuous temperature monitoring Remote temperature probe monitors tissue temperature at the tip	Built in continuous temperature monitoring	Built in temperature monitoring system	Built in thermocouple for probe temperature monitoring

Product request form

I would like to request the Emprint™ ablation system with Thermosphere™ technology for our facility so that I have consistent access to this system for my cases.

The Emprint™ ablation system products include:

SKU	Product
CARTHP	Emprint™ HP ablation cart
CAGENHP	Emprint™ HP ablation generator with Thermosphere™ technology
CAPUMP1	Emprint™ ablation pump
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CA20L2	Emprint™ standard percutaneous antenna with Thermosphere™ technology
CA30L2	Emprint™ long percutaneous antenna with Thermosphere™ technology

Thank you for reviewing this information.

Please feel free to contact me if you have any questions.

Sincerely,

References

1. Shady W, Petre EN, Gonen M, et al. Percutaneous radiofrequency ablation of colorectal cancer liver metastases: factors affecting outcomes – A 10-year experience at a single center. *Radiology*. 2016;278(2):601-611.
2. Wang X, Sofocleous CT, Erinjeri JP, et al. Margin size is an independent predictor of local tumor progression after ablation of colon cancer liver metastases. *Cardiovasc Intervent Radiol*. 2013;36(1):166-175.
3. Liu CH, Arellano RS, Uppot RN, et al. Radiofrequency ablation of hepatic tumours: effect of post-ablation margin on local tumour progression. *Eur Radiol*. 2010;20(4):877-885.
4. Nakazawa T, Kokubu S, Sibuya A, et al. Radiofrequency ablation of hepatocellular carcinoma: correlation between local tumor progression after ablation and ablative margin. *AJR Am J Roentgenol*. 2007;188:480-488.
5. Ruers T, Van Coevorden F, Punt C, Pierie JP, Borel-Rinkes I, et al. Local treatment of unresectable colorectal liver metastases: Results of a randomized phase II trial. *JNCI J Natl Cancer Inst*. 2017;109(9):dix015.
6. Thomas M, Drake, Ewen M, Harrison. Malignant liver tumours. *Surgery*. 2017;35(12):707-714.
7. Vogl TJ, Basten LM, Nour-Eldin NA, et al. Evaluation of microwave ablation of liver malignancy with enabled constant spatial energy control to achieve a predictable spherical ablation zone. *Int J Hyperthermia*. 2018;34(4):492-500.
8. RE00181406 Emprint™ Ablation Zone Equivalence Verification Report, dated March 2019 (Data on file).
9. Versus the Emprint™ ablation generator. Based on internal testing data RE00205202 Emprint™ Performance Report, dated Jan 2020.
10. Imajo K, Tomeno W, Kanezaki M, et al. New microwave ablation system for unresectable liver tumors that forms large, spherical ablation zones. *J Gastroenterol Hepatol*. 2018;33(12):2007-2014.
11. Zaidi N, Okoh A, Yigitbas H, et al. Laparoscopic microwave thermosphere ablation of malignant liver tumors: An analysis of 53 cases. *J Surg Oncol*. 2016;113(2):130-134.
12. Based on internal testing report R0043973, In vivo performance testing of the Emprint™ microwave ablation system in a porcine model. March 2014.
13. Based on internal testing report R0054596, Emprint™ MWA System with CT Imaging in a porcine model. April 2016.
14. Howk K L C, Peterson D, Cafaro A. Consistent and predictable spherical ablation shape in both liver and lung: performance of the Emprint™ ablation system with Thermosphere™ technology in an in vivo porcine model [Poster 129]. *Journal of Vascular*. 2015.
15. Ierardi AM, Mangano A, Floridi C, et al. A new system of microwave ablation at 2450 MHz: preliminary experience. *Updates Surg*. 2015;67(1):39-45.
16. De Cobelli F, Marra P, Ratti F, et al. Microwave ablation of liver malignancies: comparison of effects and early outcomes of percutaneous and intraoperative approaches with different liver conditions. *Med Oncol*. 2017;34(4):49.
17. Details from public white paper, US140714(2) Thermosphere White Paper, dated Jul 2018.
18. Based on internal testing RE00100439_A, Emprint™ variable temperature ex vivo ablation performance evaluation report. June 2017.
19. Neimeyer D, Simo K, McMillan M, Seshadri R, Hanna E, et al. Optimal ablation volumes are achieved at submaximal power settings in a 2.45-GHz microwave ablation system. *Surgical Innovation*. 2015;22(1):41-45.
20. Winokur R, Du J, Pua B, Talenfeld A, Sista A, et al. Characterization of in vivo ablation zones following percutaneous microwave ablation of the liver with two commercially available devices: are manufacturer published reference values useful? *J Vasc Interv Radiol*. 2014;25:1939-1946.
21. Based on internal test report R0048333, Emprint™ ablation size test report, dated December 2013.
22. Young S, Rivard M, Kimyon R, Sanghvi T. Accuracy of liver ablation zone prediction in a single 2450 MHz 100 Watt generator model microwave ablation system: An in human study. *Diagn Interv Imaging*. 2020 Apr;101(4):225-233.
23. Solero ablation system value analysis brief, ANGM 354 GL Rev 01 12/16. Accessed online at <https://www.angiodynamics.com/products/17/Solero-Microwave-Tissue-Ablation-System/>, May 2020.
24. Neuwave™ LK ablation probes instructions for use, PL-000006 Rev E.
25. Neuwave™ PR ablation probes instructions for use, PL-000026 Rev C.
26. Neuwave™ ablation system information, accessed online at <https://www.jnjmedicaldevices.com/en-US/product/neuwave-microwave-ablation-system>, May 2020.
27. K182605 HS Amica devices family 510k clearance summary, dated Oct 28, 2019.