

VALUE ANALYSIS BRIEF

Emprint™ ablation system



Poz 7 - Abliacijos kateteriai

Medtronic
Further, Together

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Emprint™ HP
ablation generator



PRESERVE THEIR FUTURE

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

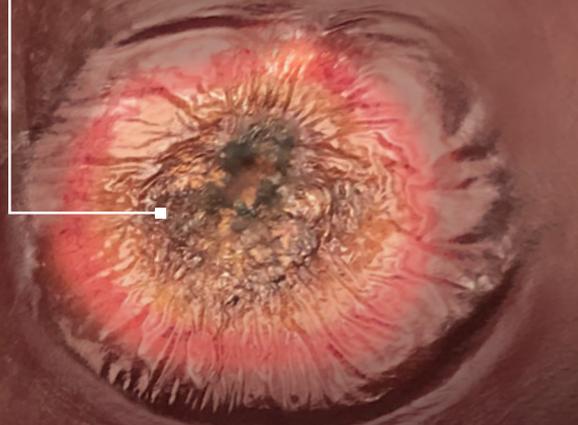
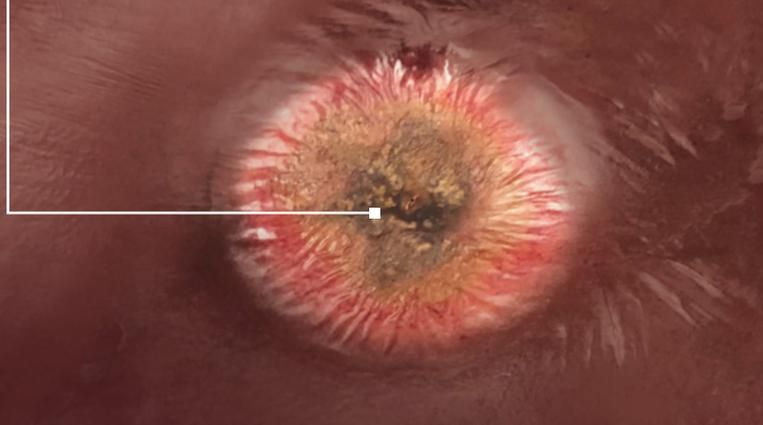
†Independent study was performed using the 100 W Emprint™ ablation generator. A total of 56 tumors ablated with the Emprint™ ablation system had a median size of 1.4 cm (range 0.4 to 3.7 cm).



Emprint™ ablation generator
100 W, 10 min – 4.2 cm x 4.2 cm

Emprint™ HP ablation generator
150 W, 10 min – 4.7 cm x 4.8 cm

**Maksimalus darbinis galingumas i 150W.
Su viena kateteriu pasiekiami abliacijos zona iki 4.7x4.8cm.**



Ablations created in a bovine liver model chilled to 17 degrees Celsius to model tissue perfusion. See pages 8–9 for details.

SYSTEM OVERVIEW

Ablation cart

An all in one system designed with a 17" x 19" footprint to save space in crowded procedural suites.

Order code: CARTHP



Ablation reusable cable

Order code: CA190RC1



Emprint™ HP ablation generator

150 W high-frequency (2.45 GHz) generator

Order code: CAGENHP



Footswitch (Optional accessory)

Order code: RFASW



Emprint™ percutaneous antenna with Thermosphere™ technology

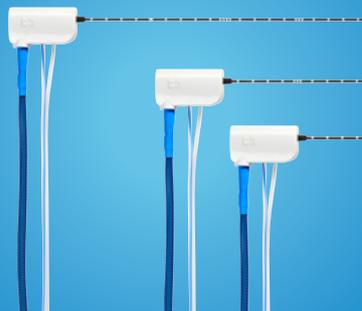
Igis pasirinktinai 15, 20, 30cm

Order codes:

Short (15 cm): CA15L2

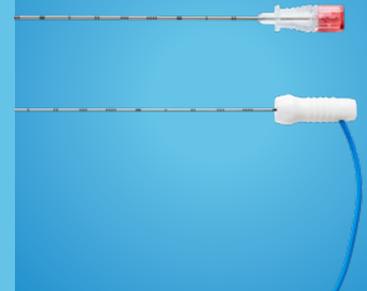
Standard (20 cm): CA20L2

Long (30 cm): CA30L2



Remote temperature probe (Optional accessory)

Order code: RTP20



Ablation pump

Order code: CAPUMP1



THE POWER OF THERMOSPHERE™ TECHNOLOGY

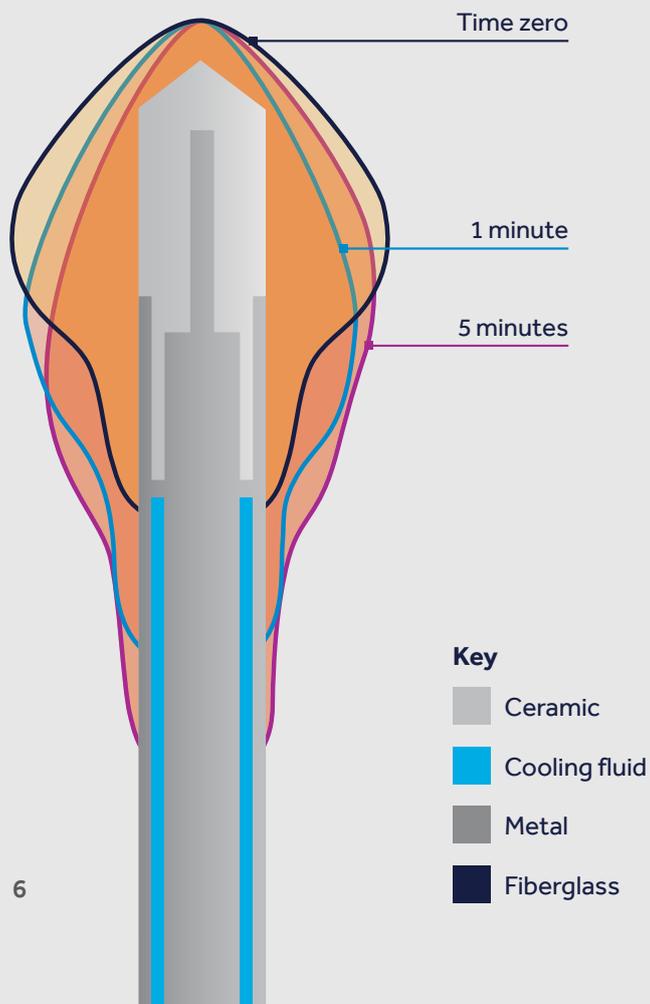
The Emprint™ ablation system with Thermosphere™ technology leverages three types of energy control to deliver a predictable, repeatable ablation zone — thermal control, field control, and wavelength control.

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

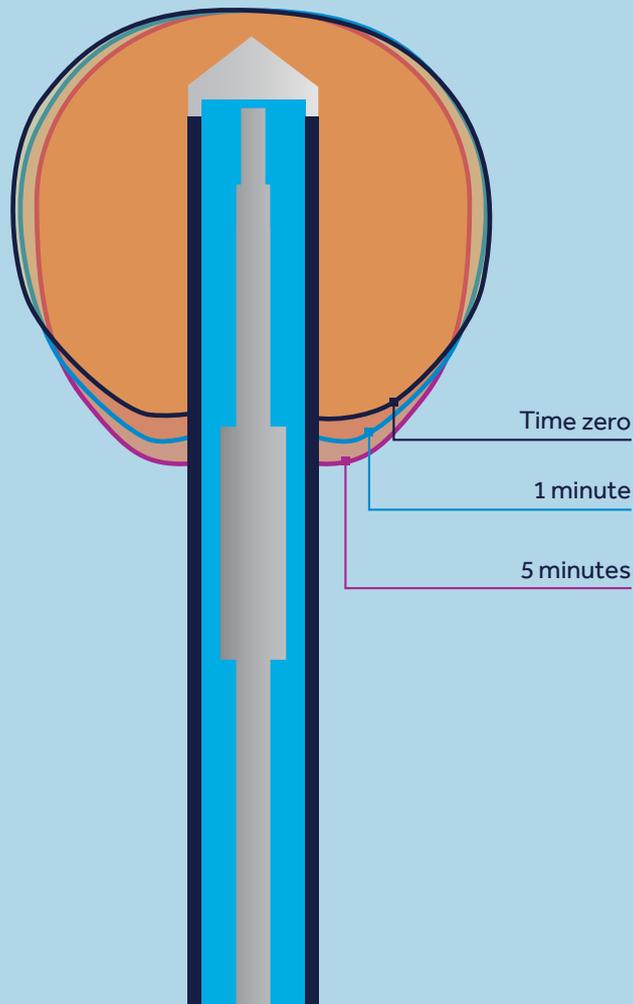


Kateteriai su aušinimu, aušinimo skystis cirkuliuoja per visą abliacijos adatos

Conventional MWA technology without wavelength control



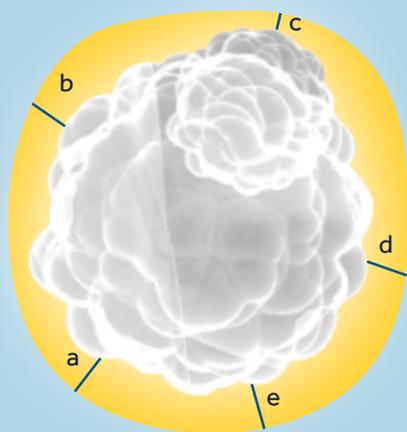
Thermosphere™ technology with wavelength control



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.

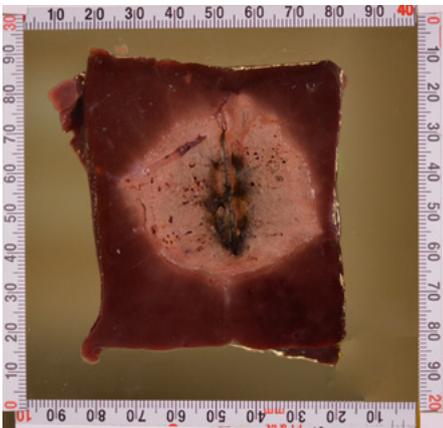
At Medtronic, we've studied the effect of tissue model temperature on ablation zone reference data.¹⁸

CURRENT MWA MANUFACTURER MODEL TEMPERATURES^{19,20}

	17 °C	25 °C	35 °C
Medtronic	■		
J&J		■	
Angiodynamics			■
HS Hospital Service		■	

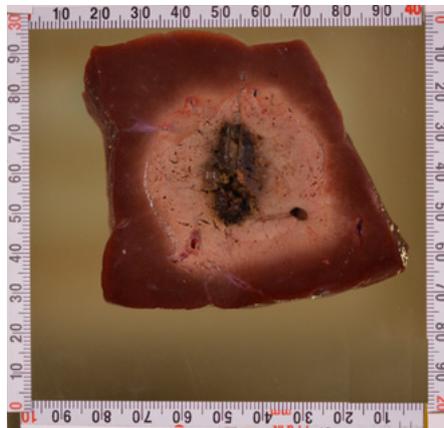
Emprint™ ablation system performance across varied tissue model temperatures (100 W, 10 min in bovine liver model)¹⁸

17 °C



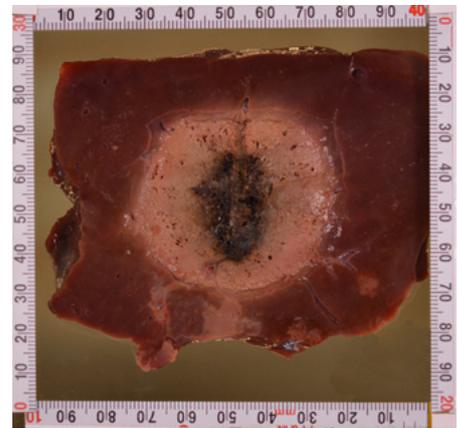
**W = 4.2 cm
H = 4.2 cm**

25 °C



**W = 4.7 cm
H = 4.5 cm**

35 °C



**W = 5.0 cm
H = 4.8 cm**

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

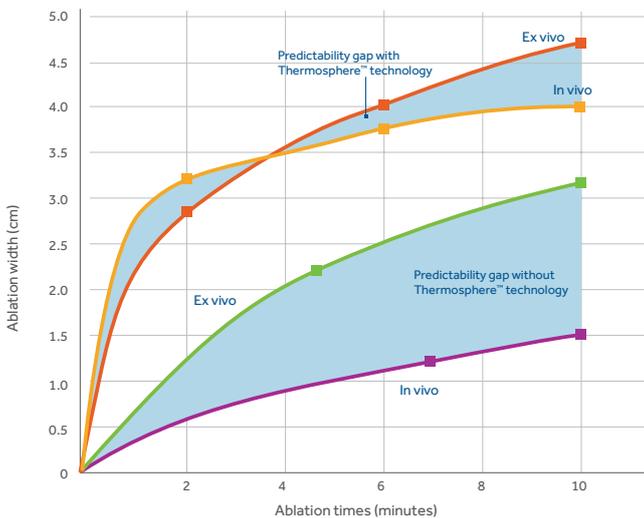
VALIDATED BY INDEPENDENT INVESTIGATION



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



- Ex vivo with Thermosphere™ technology
- Ex vivo without Thermosphere™ technology
- In vivo with Thermosphere™ technology
- In vivo without Thermosphere™ technology

Further, Emprint™ ablation system results have been validated by independent investigations of ablation zone predictability.^{16,22}

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.

skirti minimaliai invazinei minkštųjų audinių mikrobangų abliacijai

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

Maksimalus darbinis galingumas 150W

dydis- 13G, ilgis pasirinktinai 15, 20, 30cm.

Ablation Zone Reference Information

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

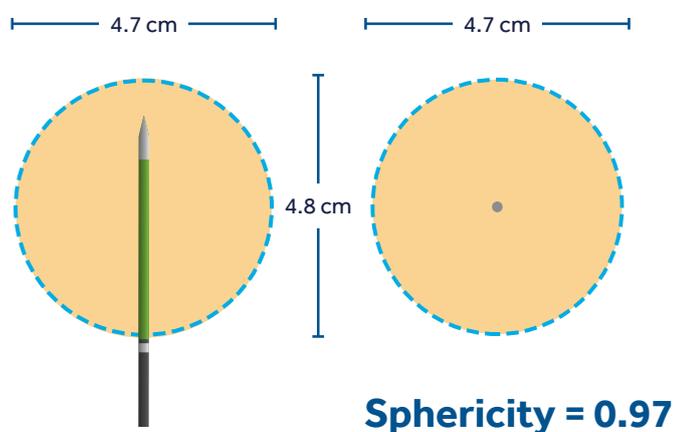
	Test tissue	Height (cm)	Width (cm)	Sphericity Ratio
150 W	Liver	4.8	4.7	0.97
	Lung	4.9	4.4	0.90
	Kidney	4.9	4.6	0.94

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.

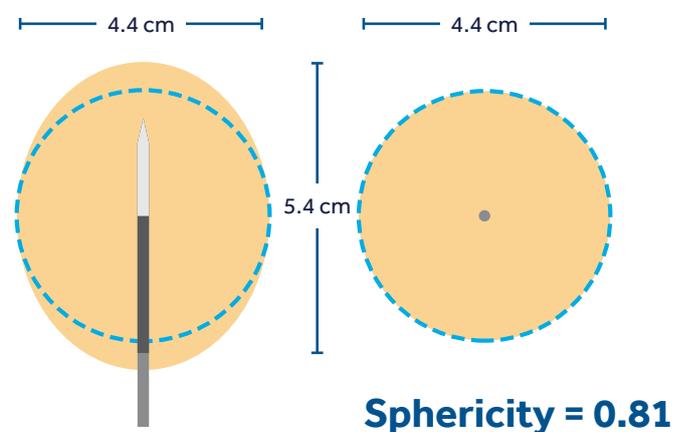
Emprint™ ablation system

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



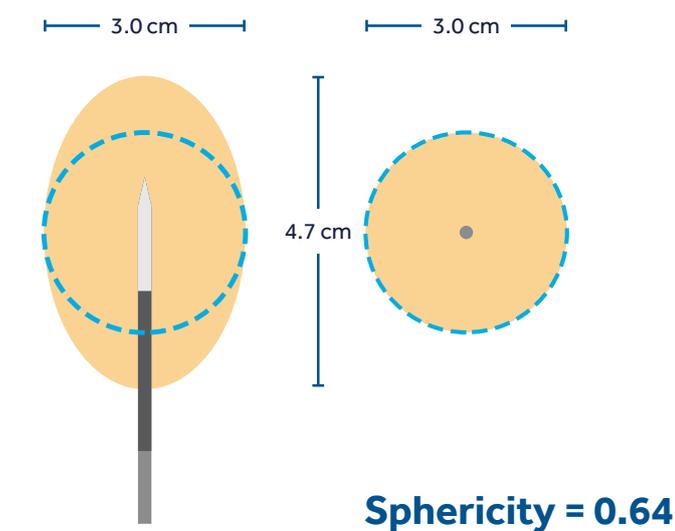
Solero ablation system²³

140 W, 6 min

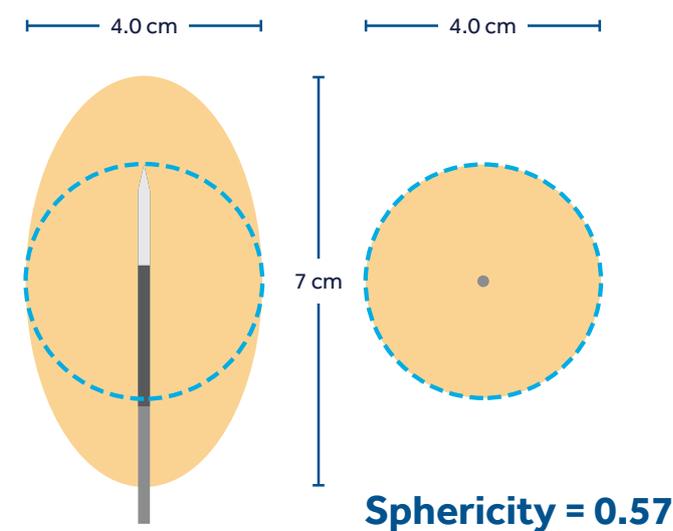


Neuwave™ microwave ablation system^{24,25}

PR Probe, 65 W, 10 min



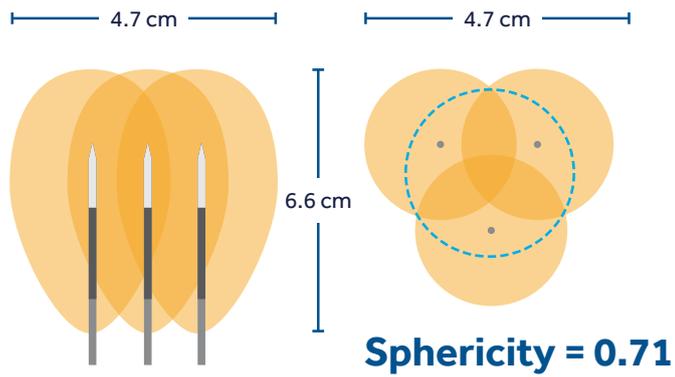
LK Probe, 140 W, 10 min



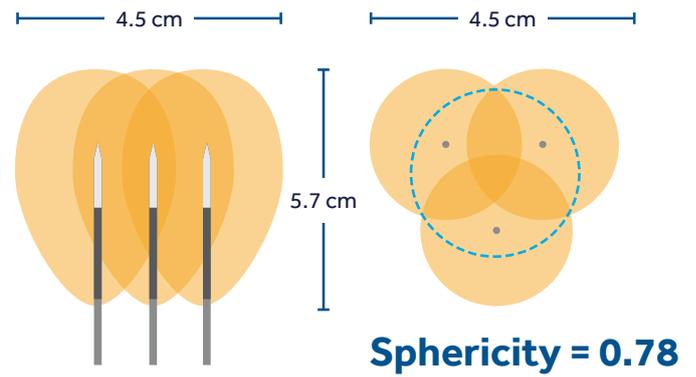
PRODUCT CROSS REFERENCES

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 Dydis- 13G	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 Ilgai	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 Maksimali galia	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.

Prekės kodai

44 pirkimo dalis

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

**Thank you for reviewing this information.
Please feel free to contact me if you have any questions.**

Sincerely,

REFERENCES

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2. Wang X, Sofocious 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.
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8. RE00181406 Emprint™ Ablation Zone Equivalence Verification Report, dated March 2019 (Data on file).
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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.
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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.
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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.



Medtronic

IMPORTANT: Please refer to the package insert for complete instructions, contraindications, warnings and precautions.

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[medtronic.com/covidien/uk](https://www.medtronic.com/covidien/uk)

EMPRINT™ HP ABLATION GENERATOR

In-service



Medtronic
Further, Together

EMPRINT™ HP
ABLATION
GENERATOR
OVERVIEW

EMPRINT™ HP ABLATION GENERATOR

OVERVIEW

Greater coverage. Fewer antennas. Less collateral damage.

Achieving complete tumor coverage is critical to successful management of patients with non-resectable hepatic tumors¹⁻⁴ – so is preserving healthy liver. The Emprint™ HP ablation generator achieves complete tumor coverage, while minimizing collateral tissue damage⁵ — all with a single antenna.

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

- Large ablations, with up to 40% more volume compared to the original Emprint™ ablation system⁶
- Proven spherical shape,⁷⁻¹³ giving you flexibility in antenna placement approach⁵
- Consistent ablative margins greater than 5mm⁵
- Scalability, allowing you to create both small and large ablation zones⁶



EMPRINT™ HP ABLATION GENERATOR OVERVIEW

Su viena kateteriu pasiekama
abliacijos zona iki 4.7x4.8cm

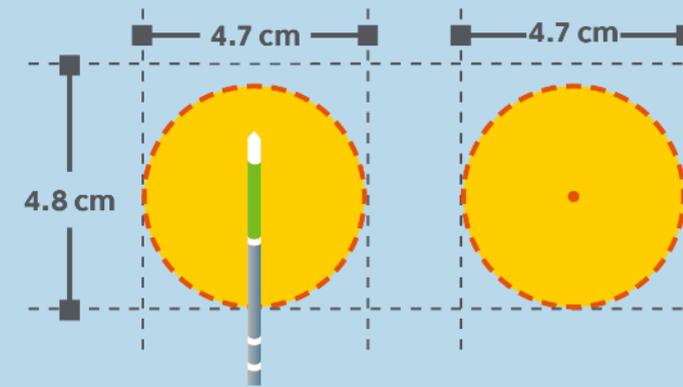
Complete tumor coverage. Simplified.

150W generator creates a large ablation zone –
4.7 cm by 4.8cm – with a single antenna⁶.

With the Emprint™ HP generator, you can reduce the need for bracketing and sequential ablation techniques. Our revolutionary Thermosphere™ technology allows you to create ablation zones equal or greater in size to other systems requiring multiple antennas or sequential ablations.^{6, 14-16}

Emprint™ ablation system

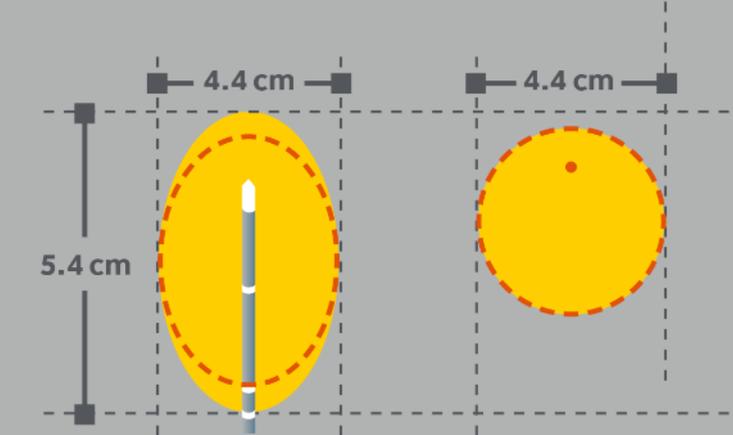
150W, 10 min | Sphericity = 0.97



17°C ex vivo bovine model

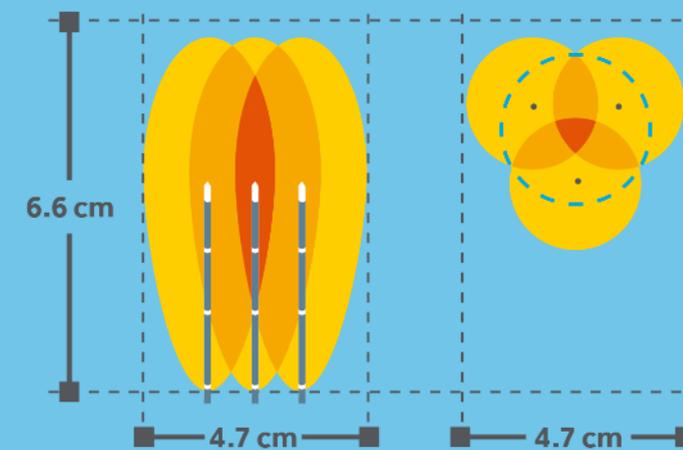
Solero ablation system¹⁴

140W, 6 min | Sphericity = 0.81

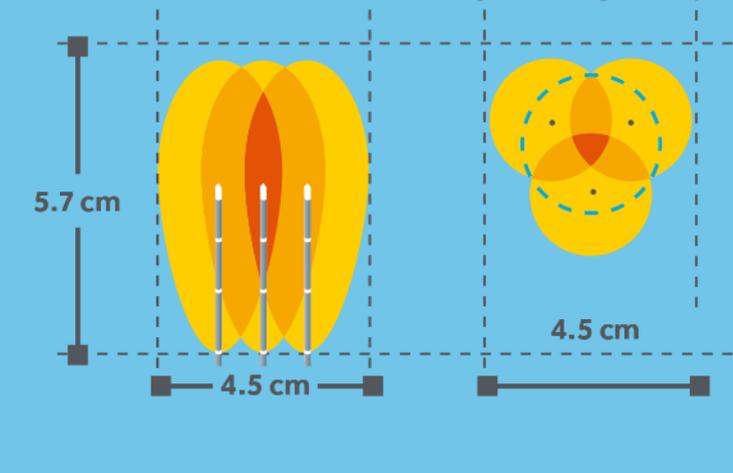


Neuwave™* ablation system^{15,16}

PR Probe, 65W, 10 min | Sphericity = 0.71



LK Probe, 65W, 10 min | Sphericity = 0.78



THERMOSPHERE™ TECHNOLOGY **OVERVIEW**

Click to watch the Emprint™ ablation system product overview video



THERMOSPHERE™ TECHNOLOGY & THE EMPRINT™ ABLATION SYSTEM

KEY POINTS

Thermosphere™ technology:

- Is a patented, proprietary technology
- Is minimally impacted by varying tissue conditions¹³
- Maintains ablation shape over the course of ablation^{8,11-13}

The Emprint™ ablation system:

- Creates large, spherical ablation volumes⁶
- Helps to lower the chance of recurrence¹⁷ by maximizing ablative margin while minimizing unnecessary parenchyma damage⁵
- Performance is confirmed by independent clinical evidence¹³

EMPRINT™ HP
ABLATION
GENERATOR
PRODUCT DETAILS

ANTENNA COMPATIBILITY

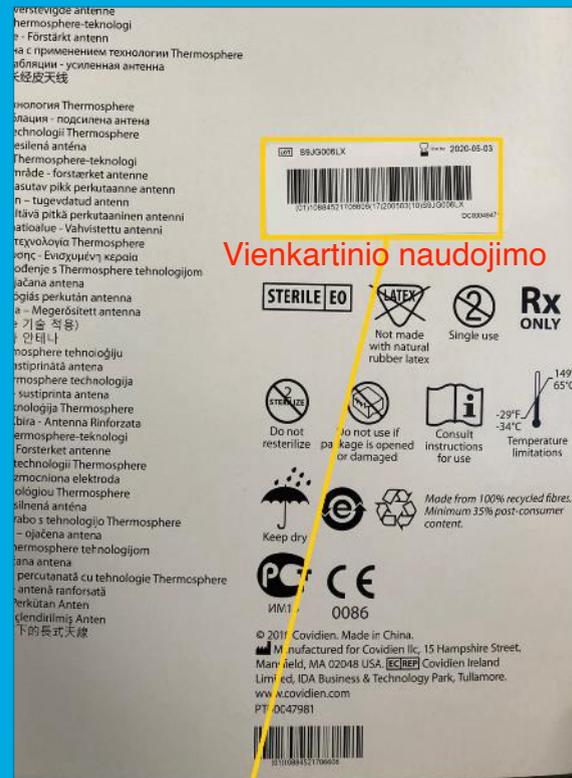
Emprint™ HP is only compatible with updated antennas

- **It is important to check the product compatibility before each case**
(see reference images on the next slide)
- Improvements to the Emprint™ percutaneous ablation antennas have been made to eliminate risk of trocar detachment
- Product codes are unchanged

Product Code	Compatible GTINS	
CA15L1	10884521806511	A8845218065102
CA20L1	10884521806528	A8845218065202
CA30L1	10884521806535	A8845218065302
CA15L2	10884521806542	A8845218065402
CA20L2	10884521806559	A8845218065502
CA30L2	10884521806566	A8845218065602

ANTENNA COMPATIBILITY

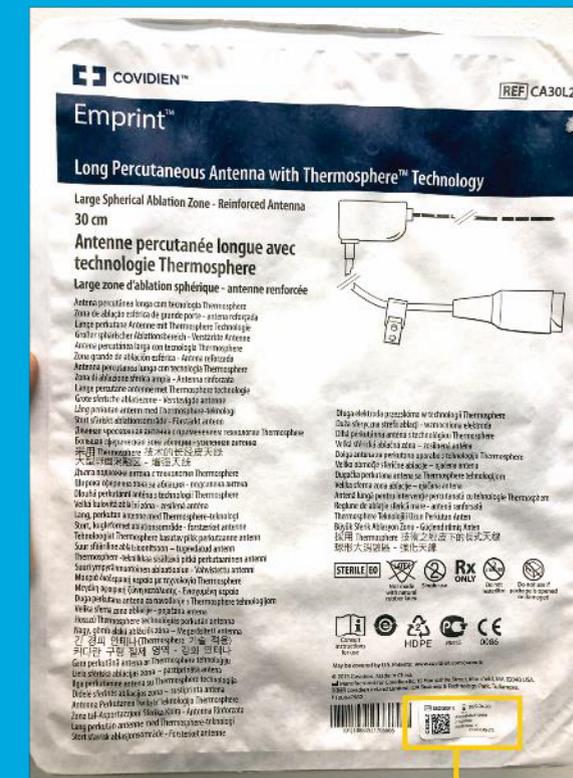
Back of product box



Label on shipper box



Tray peel away label



EMPRINT™ ABLATION SYSTEM

INDICATIONS FOR USE

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

The Emprint™ ablation system is not intended for use in cardiac applications, pregnant patients, and patients with a pacemaker.



Emprint™ HP Generator

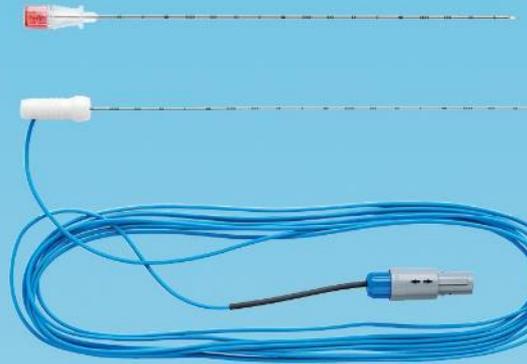
Integrated Cart

Cooling Pump

Foot Switch



Antenna



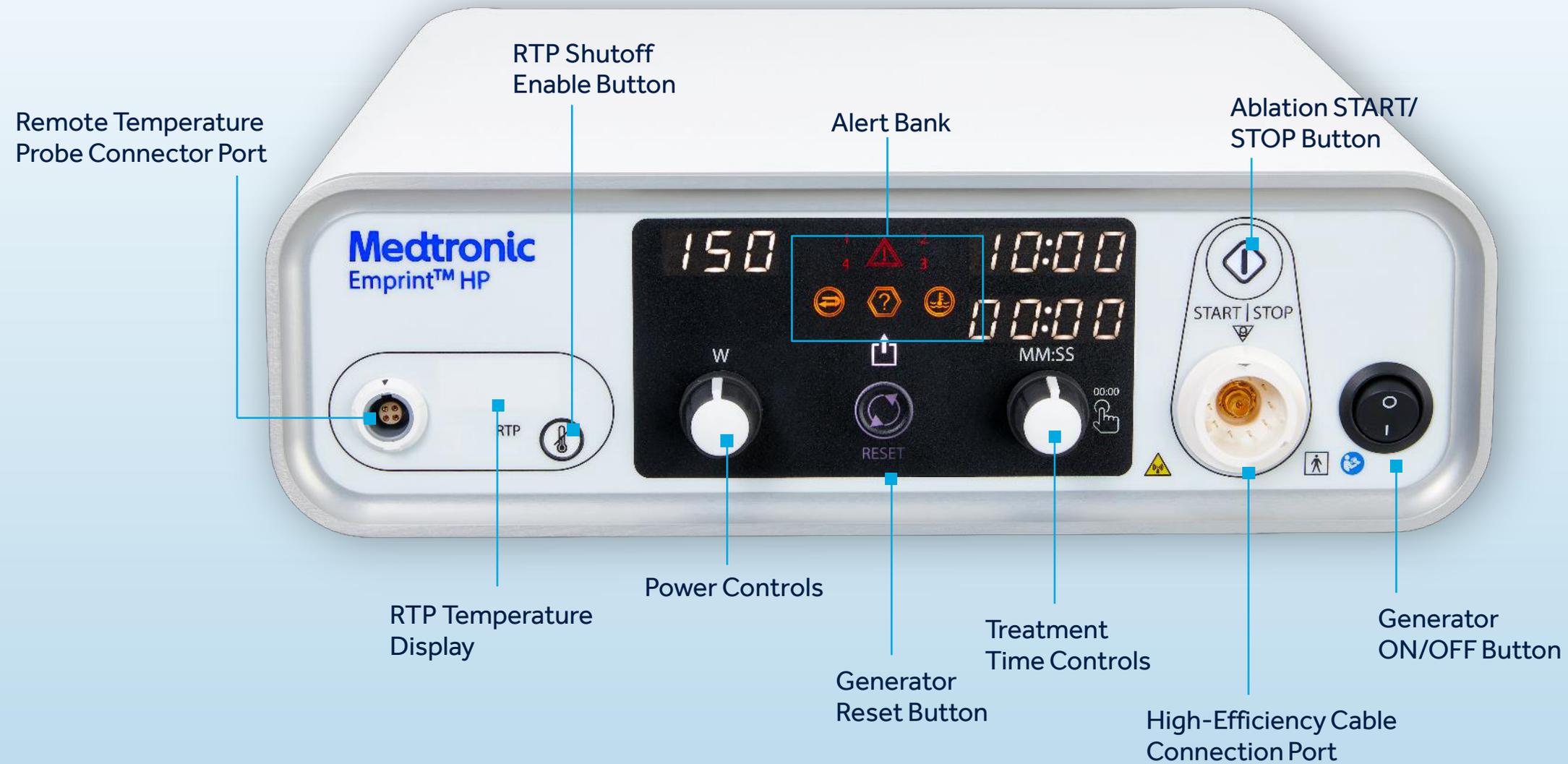
Remote Temperature Probe



Reusable Cable

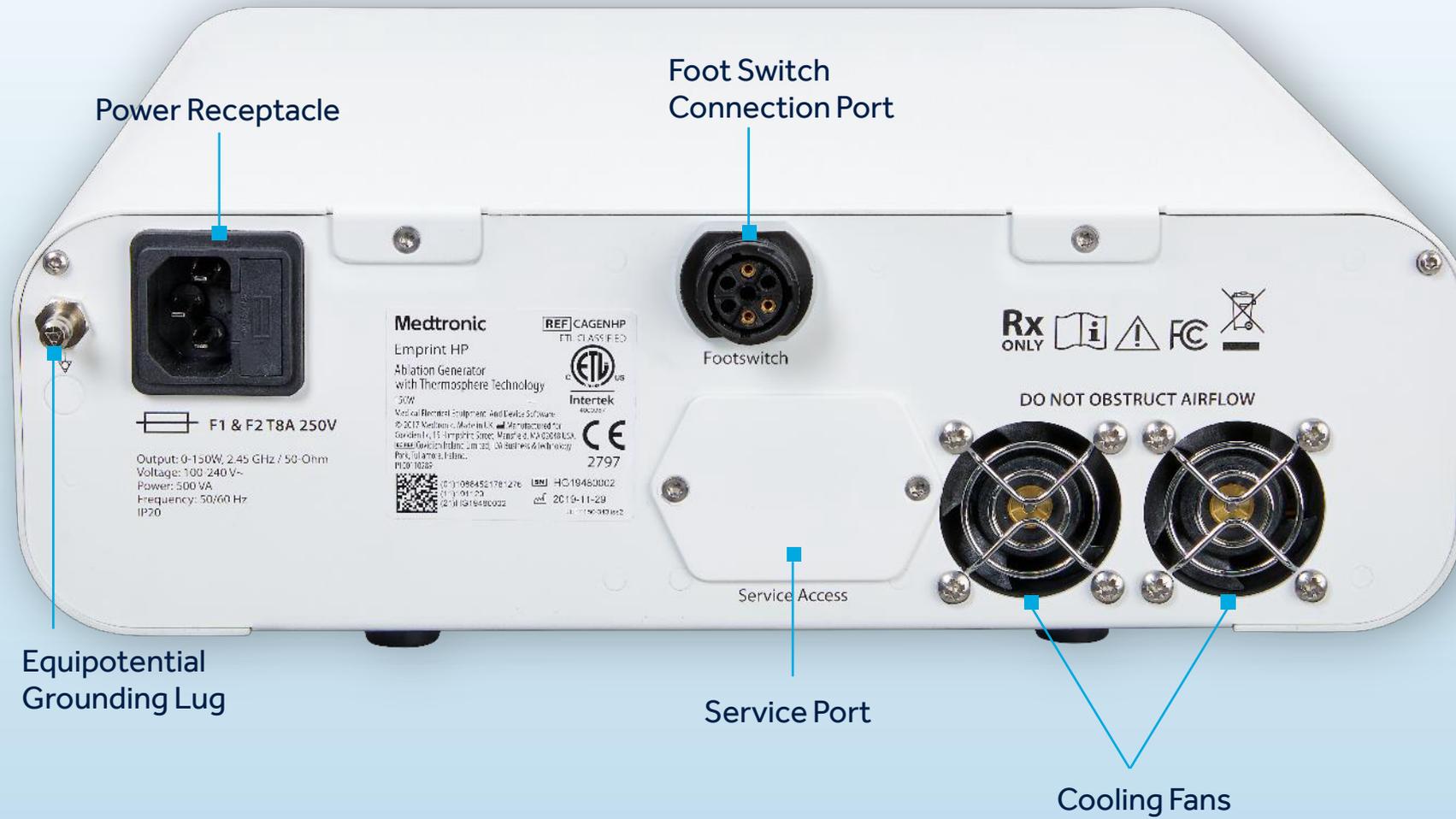
EMPRINT™ HP ABLATION GENERATOR

FRONT PANEL



EMPRINT™ HP ABLATION GENERATOR

BACK PANEL

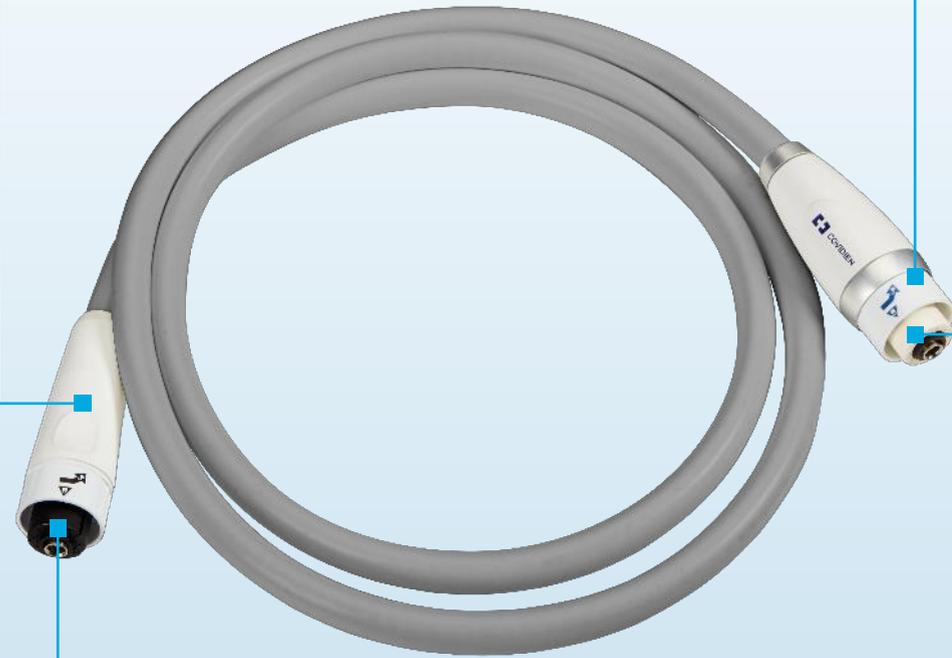


EMPRINT™ HP
ABLATION
GENERATOR
COMMON
ACCESSORIES

EMPRINT™ ABLATION SYSTEM

REUSABLE CABLE AND PUMP

Cable Release Grips



Generator Connector
(Black Connector Tip)

Antenna Connector
(White Tip w/ Covidien Logo)

Reusable Cable Symbols

Top symbol assists in proper connection alignment.

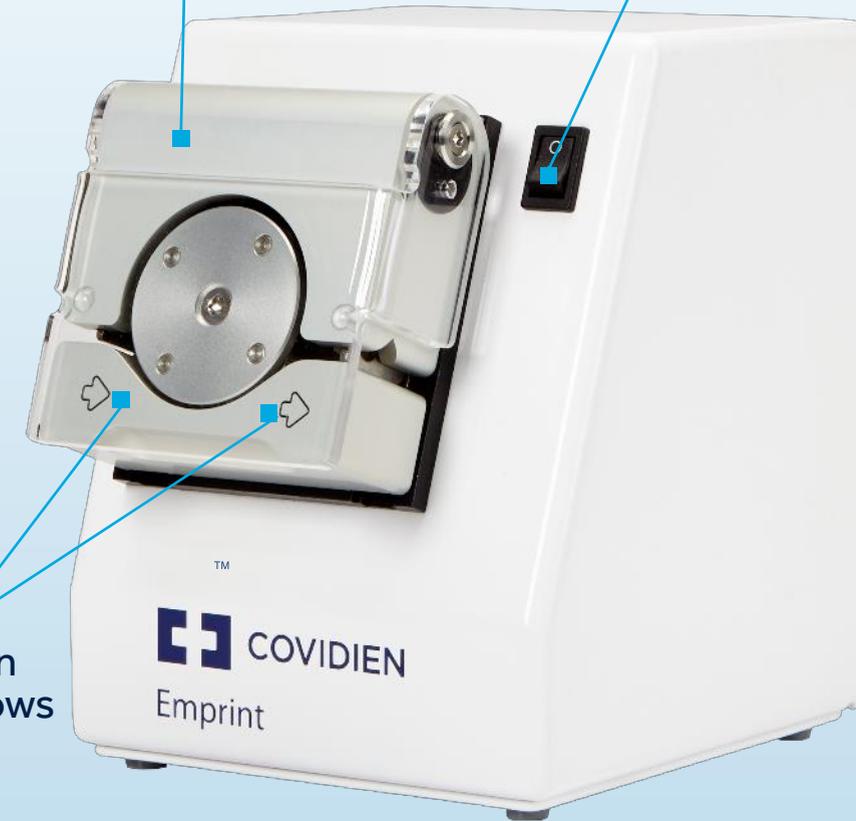


Bottom symbol indicates how to disconnect.



Pump Head Cover

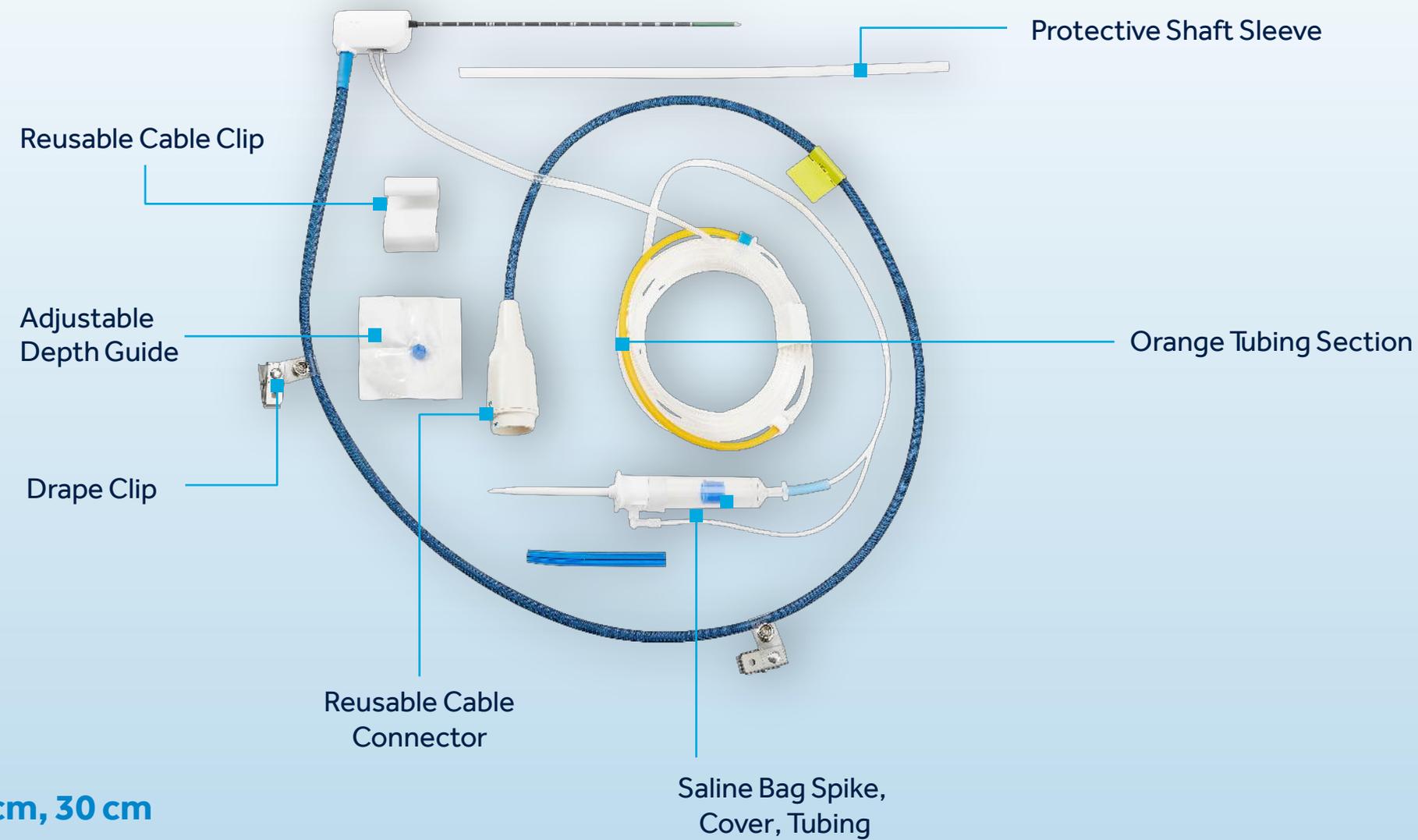
Main Power Switch



Flow Direction
Indicator Arrows

EMPRINT™ ABLATION SYSTEM

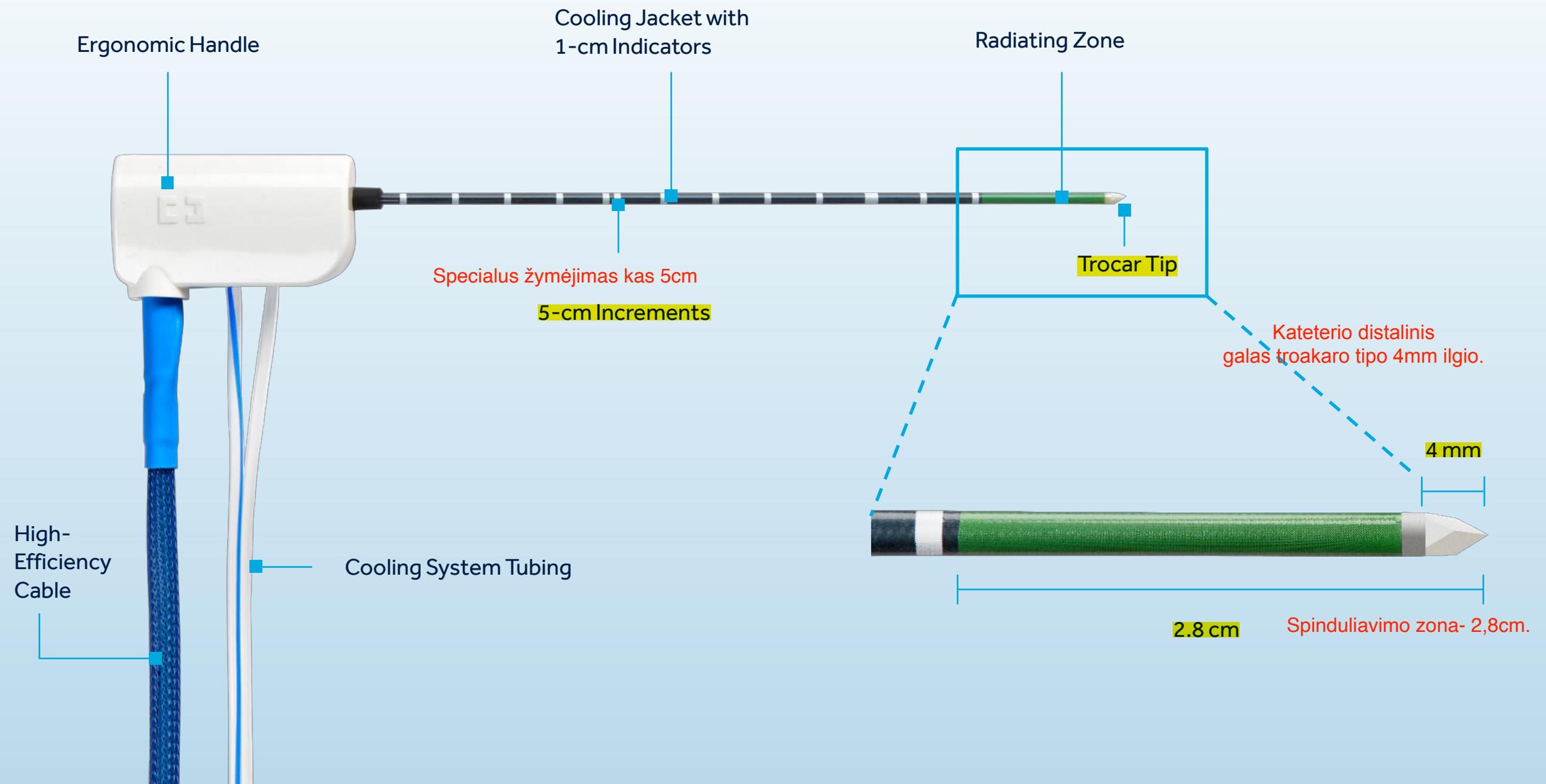
PERCUTANEOUS ABLATION ANTENNA



Available Lengths: 15 cm, 20 cm, 30 cm
Antenna Gauge: 13 ga

EMPRINT™ ABLATION SYSTEM

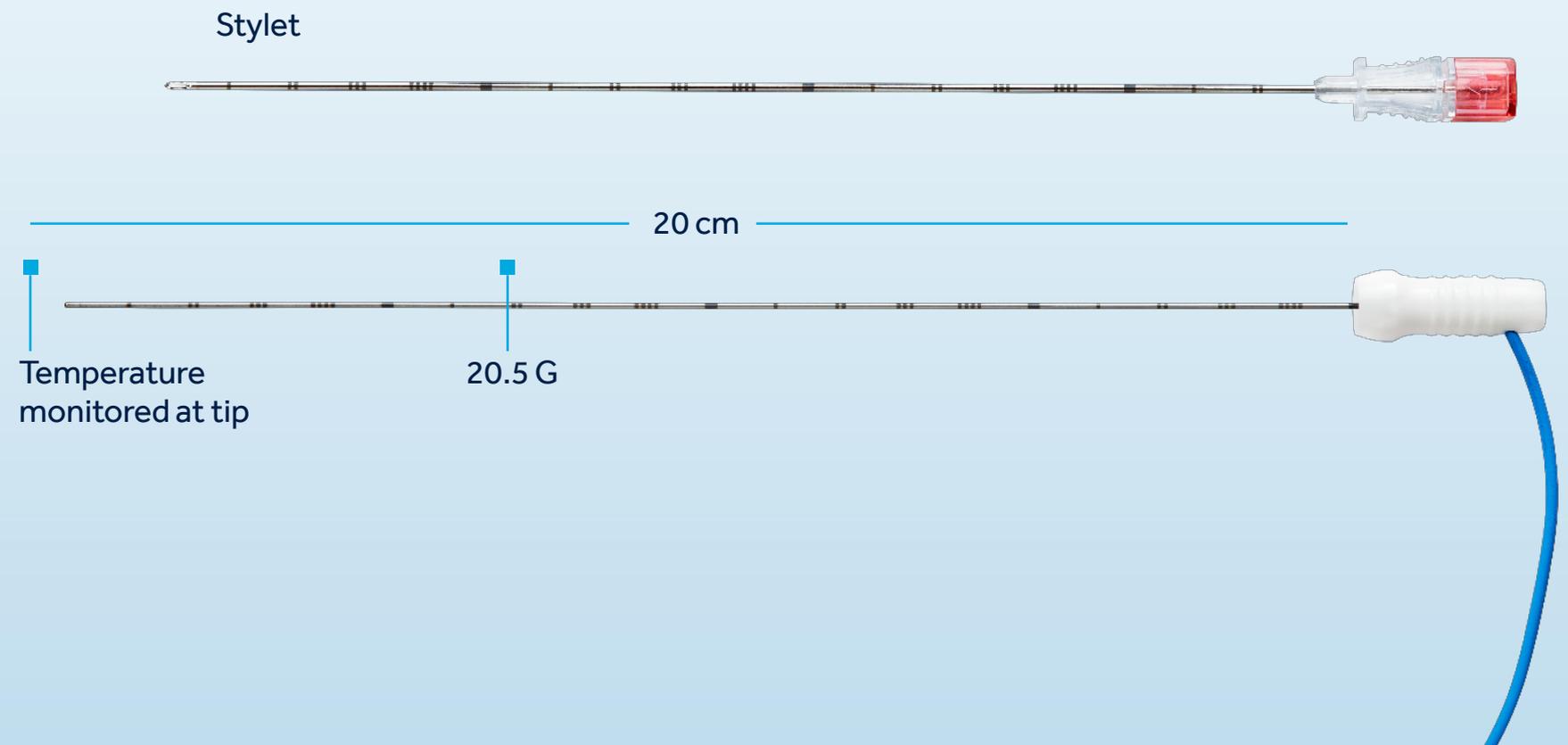
PERCUTANEOUS ABLATION ANTENNA



EMPRINT™ ABLATIONS SYSTEM

REMOTE TEMPERATURE PROBE

- Verify tissue temperature in real time at any predefined location independently from the ablation electrode
- Automatic ablation shutoff when a preset tissue temperature is achieved



EMPRINT™ HP
ABLATION
GENERATOR
SYSTEM SET-UP
& OPERATION

SETUP AND OPERATION

EMPRINT™ ABLATION SYSTEM



Turn on the Emprint™ system generator.



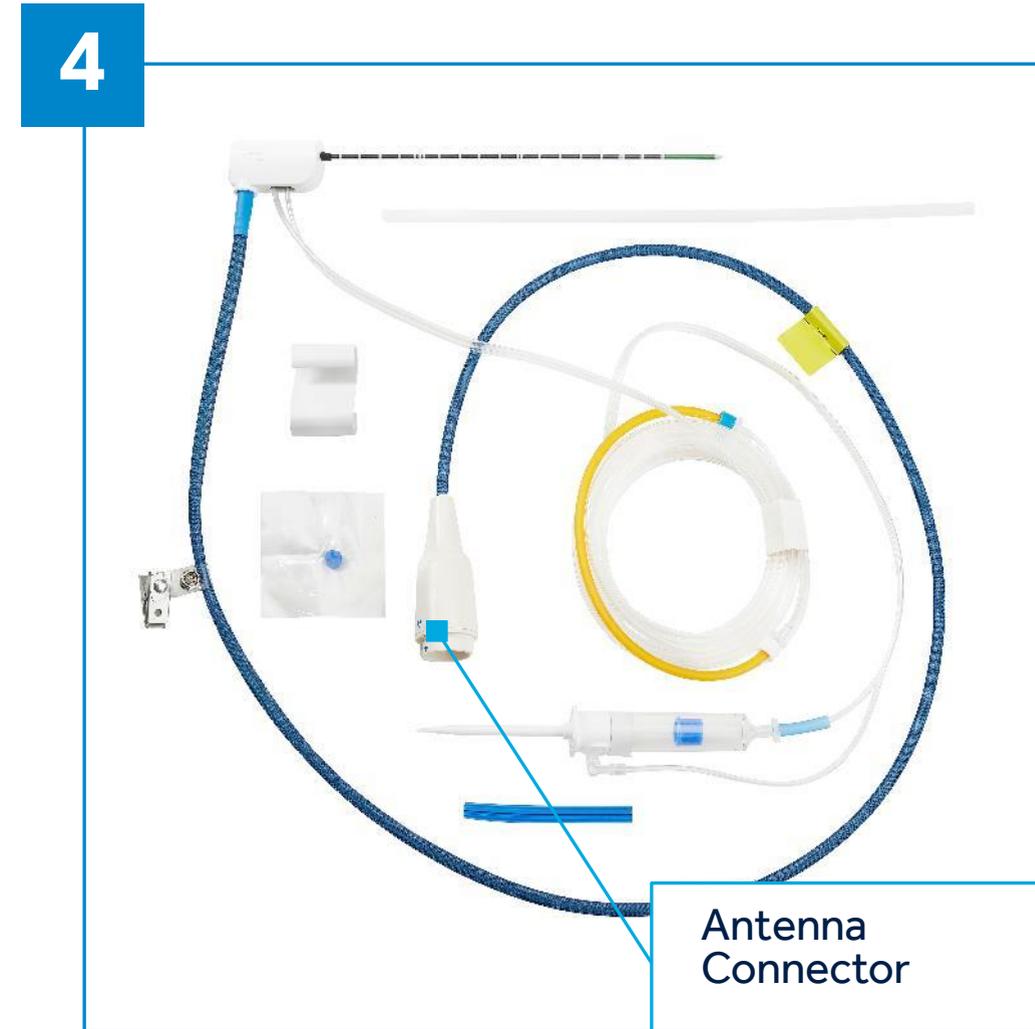
Locate reusable cable (not sterile).

SETUP AND OPERATION

EMPRINT™ ABLATION SYSTEM



Connect reusable cable to generator.



Remove antenna from packaging.

SETUP AND OPERATION

EMPRINT™ ABLATION SYSTEM



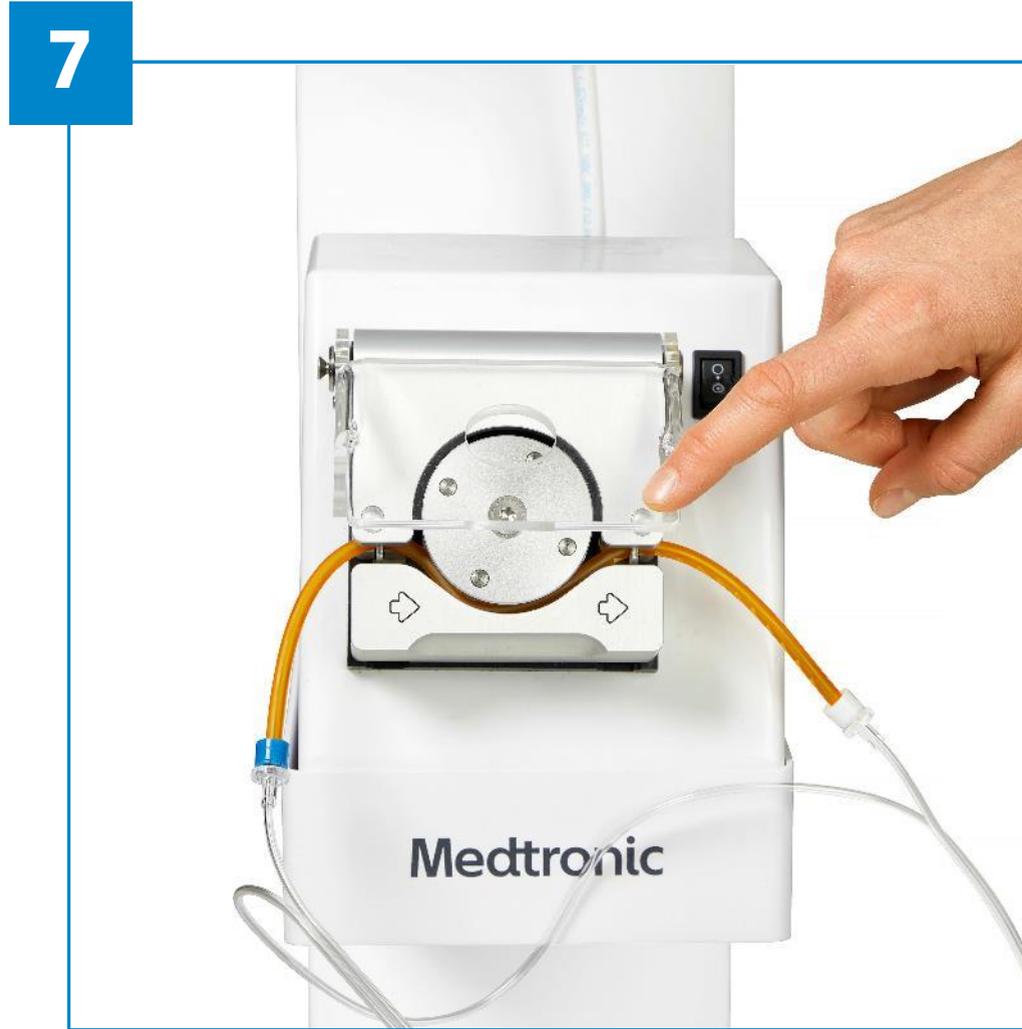
Open the clear pump-head door.



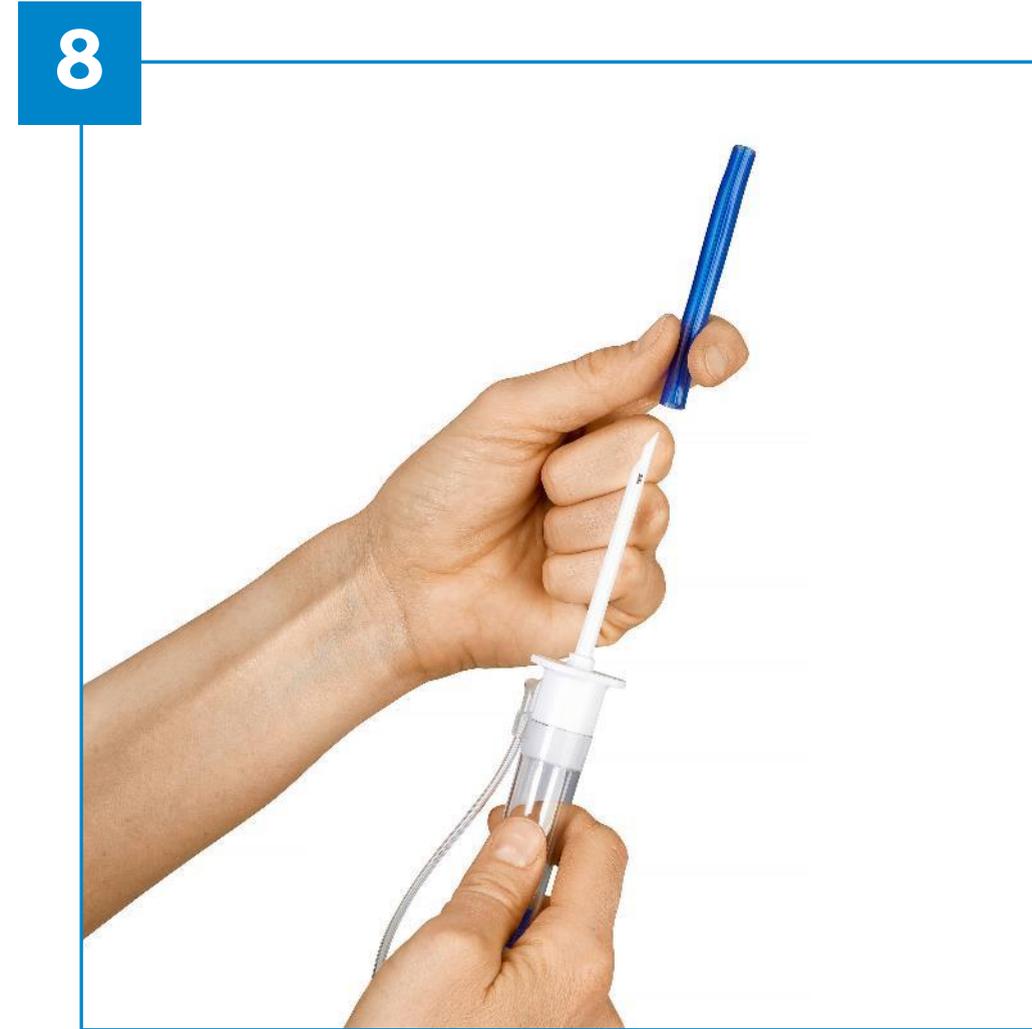
Insert orange tubing section with arrow direction matching arrows on pump.

SETUP AND OPERATION

EMPRINT™ ABLATION SYSTEM



Close the pump-head cover.



Remove the blue cap from the IV bag spike.

SETUP AND OPERATION

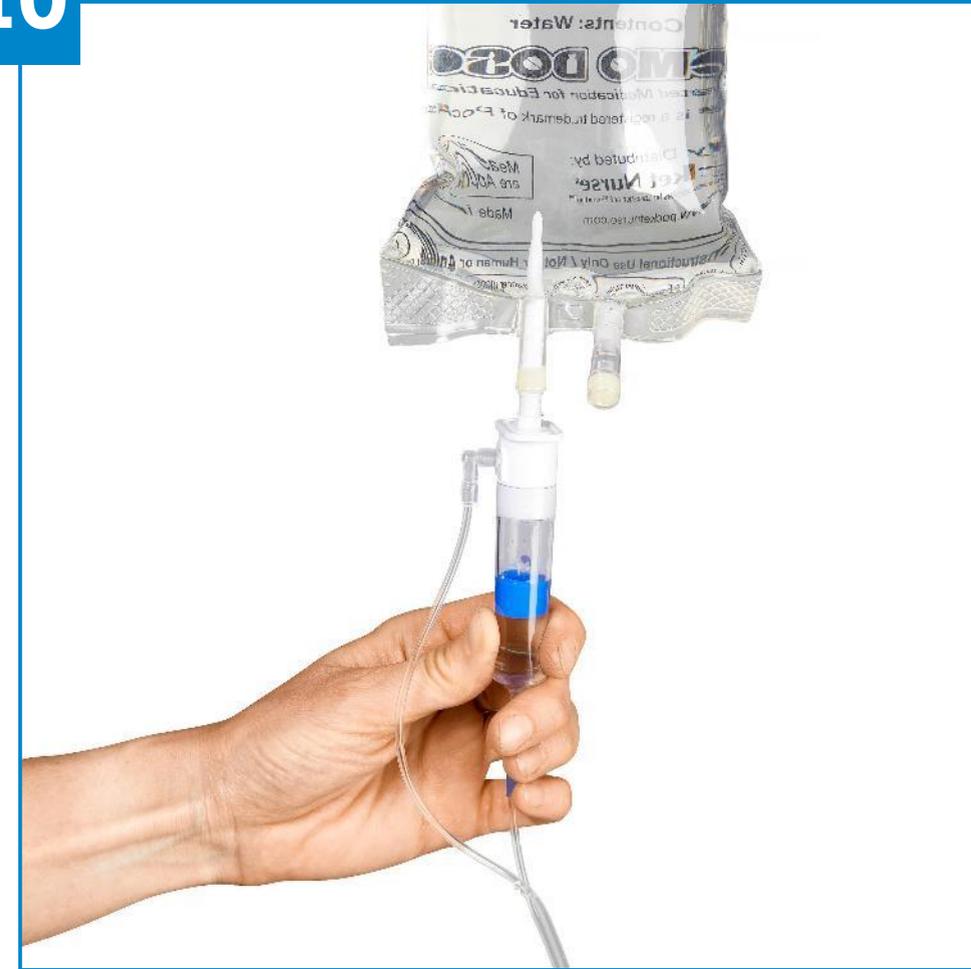
EMPRINT™ ABLATION SYSTEM

9



Insert bag spike into the port on a 1L or larger sterile saline IV bag.

10

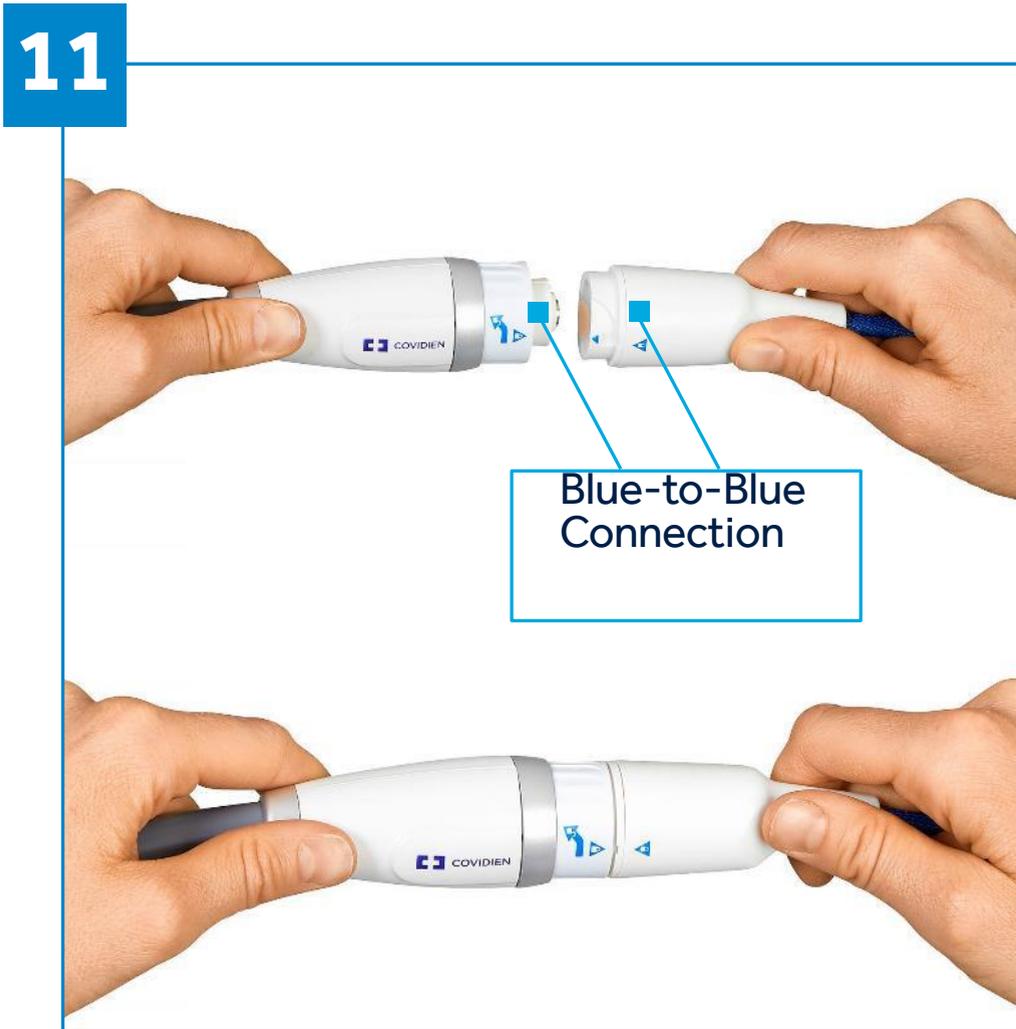


Gently squeeze the sides of the chamber until half full of saline.

*Refer to Emprint™ Ablation System User's Guide for complete setup Instructions.

SETUP AND OPERATION

EMPRINT™ ABLATION SYSTEM



Attach the antenna connector to the reusable cable.



Activate pump action by pressing the pump activation start/stop switch.

SETUP AND OPERATION

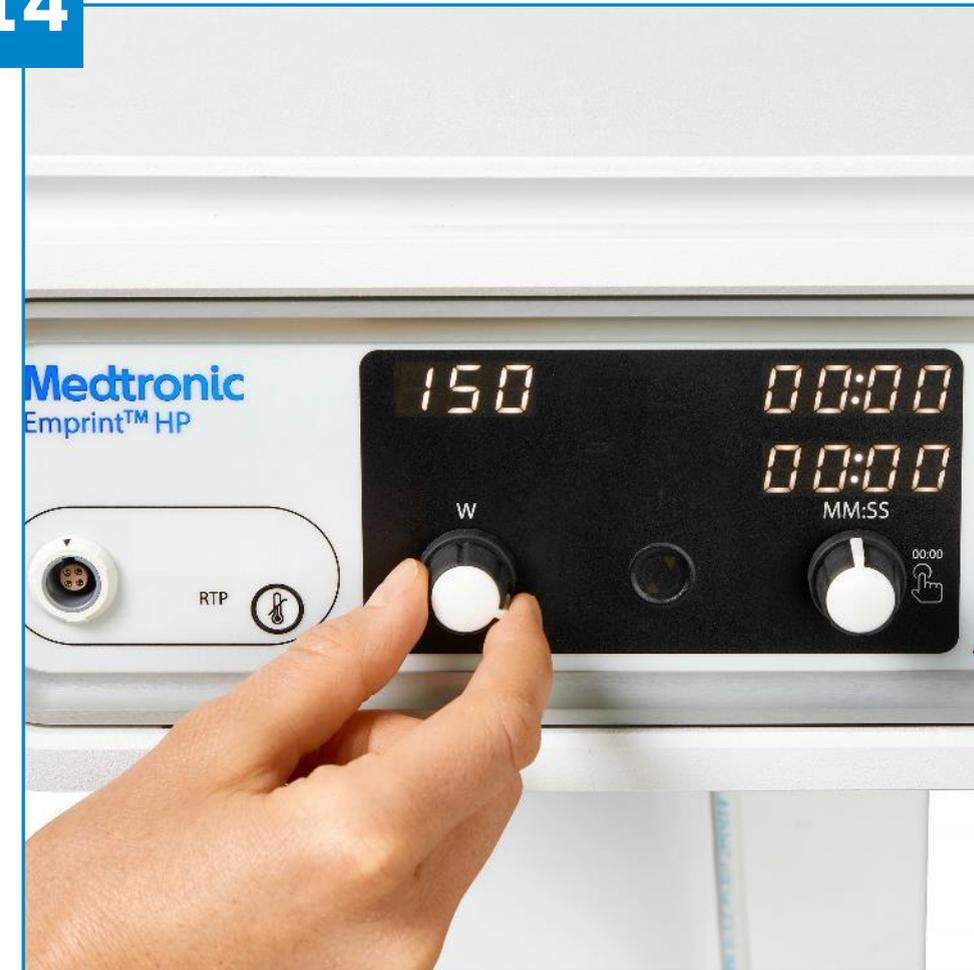
EMPRINT™ ABLATION SYSTEM

13



Allow pump to prime antenna with fluid until all air bubbles in tubing or IV are gone.

14

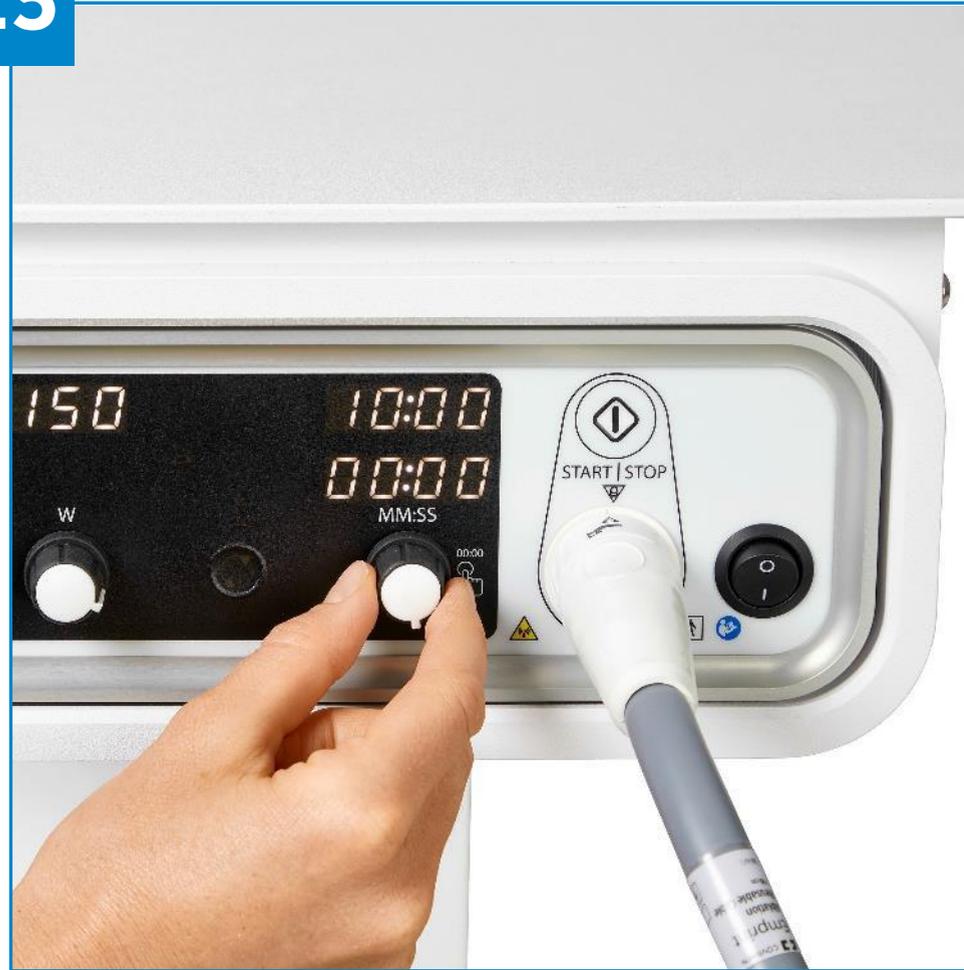


Set generator to desired power setting.

SETUP AND OPERATION

EMPRINT™ ABLATION SYSTEM

15



Set generator to desired time setting.

16



Push START/STOP button to start ablation.

EMPRINT™ HP
ABLATION
GENERATOR
BEST PRACTICES

BEST PRACTICES

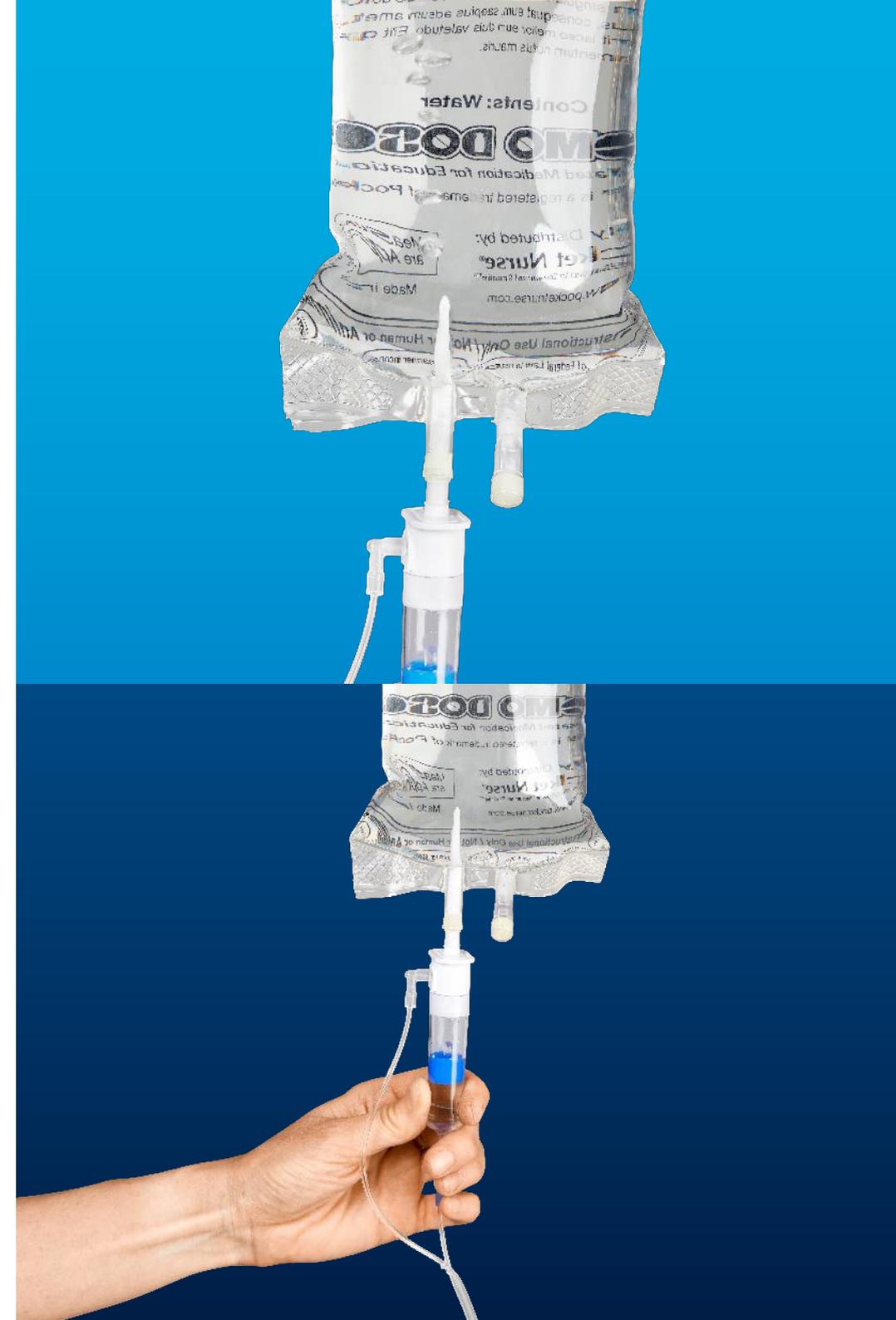
SALINE IV BAG

Fully insert the bag spike into the saline IV bag

Fully insert the bag spike into the port on a 1 L or larger sterile saline IV bag. Confirm the IV bag spike extends well into the main reservoir of the IV.

Gently squeeze the sides of the drip chamber

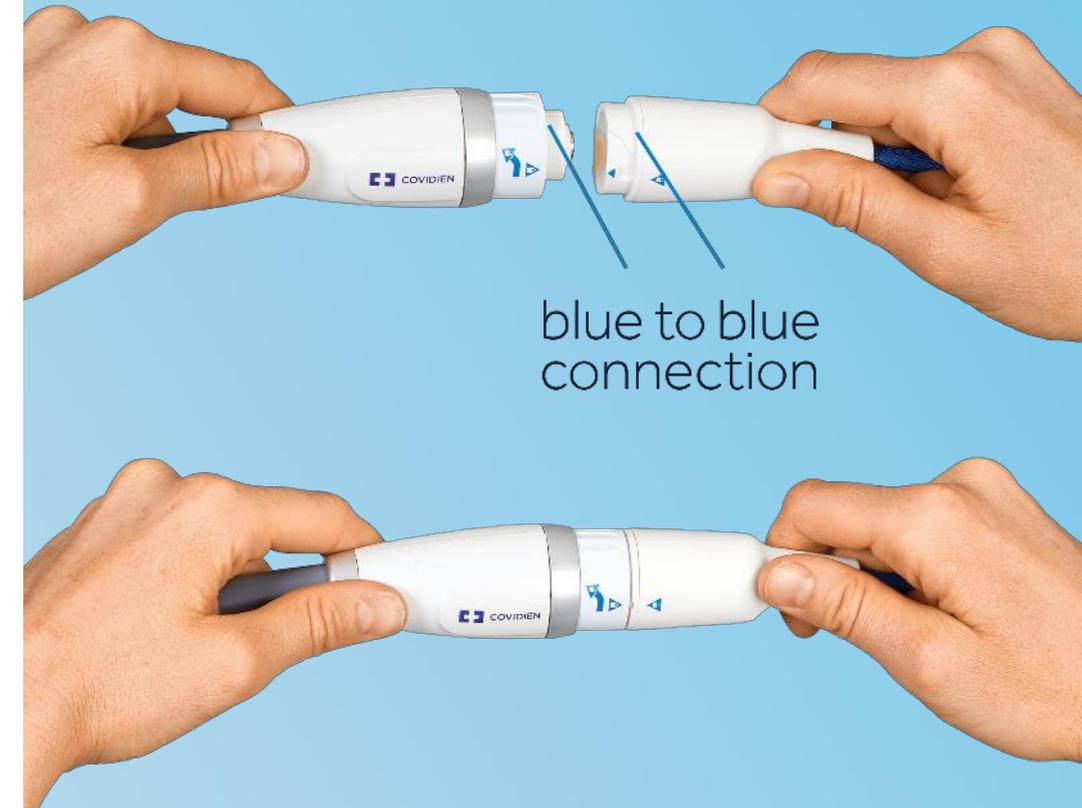
To prime the drip chamber, gently squeeze the sides of the chamber until the drip chamber is half full of saline.



BEST PRACTICES

MAKE A STRAIGHT BLUE-TO-BLUE PIN CONNECTION

- When connecting the reusable cable to the Emprint™ antenna, make the connection in a straight line —not at an angle.
- The blue arrows on each connector indicate proper alignment.
- Connecting the reusable cable to the antenna at an angle, or twisting, may cause the connector pin to bend and result in a poor connection or an error message.



BEST PRACTICES

POINT ARROWS ON PUMP AND TUBING IN SAME DIRECTION

To ensure proper direction of the cooling flow, open the clear pump head door and insert the orange tubing into the pump with the arrows on the tubing pointing in the same direction as the arrows on the pump.



EMPRINT™ HP
ABLATION
GENERATOR
ALERTS

SYSTEM ALERTS

Alert & Alarm	Cause	Remediation
<p>Antenna Not Identified</p> 	<p>Meaning: When an antenna is not properly connected, this warning is activated.</p> <p>Generator Response: Generator will not start microwave power.</p>	<p>Check connections between antenna and generator. Replace antenna if a secure connection doesn't resolve alert state.</p>
<p>RTP Trip Alarm</p> 	<p>Meaning: RTP shutoff feature was enabled and measured probe temperature has met or exceeded 45 degrees C during ablation.</p> <p>Generator Response: Microwave power delivery is disabled.</p>	<p>When the measured probe temperature is below 45 degrees C, clear the alert by pressing RESET and continue the procedure.</p>
<p>Antenna Temperature Limit Exceeded</p> 	<p>Meaning: Internal antenna temperature has exceeded limit.</p> <p>Generator Response: Microwave power is disabled until internal temperature returns to a safe operating range.</p>	<p>Ensure cooling system is turned on and saline flow is not obstructed. Clear the alert by pressing RESET and continue the procedure.</p>
<p>Reflected Power Trip</p> 	<p>Meaning: Reflected power is unusually high.</p> <p>Generator Response: Microwave power delivery is disabled until the condition is resolved.</p>	<p>Indication that device was activated in air. Ensure antenna is placed in tissue before activation. If antenna is properly placed, this alert may indicate antenna is damaged and should be replaced before proceeding. Clear the alert by pressing RESET and continue the procedure.</p>
<p>General Warning</p> 	<p>Meaning: The generator has detected a fault.</p> <p>Generator Response: Power is disabled on this trip.</p>	<p>Restart generator. If issue persists, power off generator completely for 10 minutes. If issue persists after 10 minutes, record general warning number, power the system off, and consult Medtronic sales and service department.</p>

DISCLAIMERS & INDICATION STATEMENT

Indications for use

- The Medtronic Emprint™ ablation platform with Thermosphere™ technology 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 Medtronic Emprint™ ablation system is not intended for use in cardiac procedures.

Warnings

- Microwave ablation procedures are not recommended for patients with cardiac pacemakers or other implanted electronic devices. Potential risks have not been evaluated.
- Microwave ablation procedures are not recommended for pregnant patients. Potential risks to the patient an/or fetus have not been established.
- Do not defibrillate a patient with an antenna inserted. Completely remove the antenna from the patient before defibrillation.

DISCLAIMERS & INDICATION STATEMENT

Residual risks include:

Foreign body in patient, foreign body reaction, additional needle stick or puncture, delay of treatment, post ablation syndrome, pain, fever, malaise, nausea, vomiting, myalgia, inflammation, hemorrhage, hemoptysis, hematoma, infection, peritonitis, abscess, ascites, seroma, wound dehiscence, adhesions, ischemia, necrosis, urinary retention, emphysema, pleural effusion, pneumothorax, pulmonary or upper respiratory fistula, hemothorax, dyspnea, biliary stenosis, biliary obstruction, biloma, cholangitis, biliary cirrhosis, haemobilia, gastrointestinal fistula, liver dysfunction, hepatic insufficiency, hepatic infarction, jaundice, colonic perforation, renal fistula, embolism, death, atrial fibrillation, tachycardia, cardiomyopathy, arteriovenous fistula, and cancer seeding.

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