



Cooled Radiofrequency Treatment

Physics of Cooled RF Presentation

Imagine where life could take your patients

Agenda

Indication for Use

Physics

Standard RF

Cooled RF

Lesion Size and Geometry

Application to Pain Management



Cooled Radiofrequency Treatment

Indication for Use

Indication for Use

The COOLIEF* Cooled Radiofrequency Probe is to be used in conjunction with a radiofrequency generator to create lesions in nervous tissue. This device is also indicated for creating radiofrequency lesions of the genicular nerves for the management of moderate to severe knee pain of more than 6 months with conservative therapy, including medication, in patients with radiologically-confirmed osteoarthritis (grade 2-4) and a positive response ($\geq 50\%$ reduction in pain) to a diagnostic genicular nerve block.

Please see Instructions for Use for detailed information regarding proper use that includes indications and lists of warnings, precautions and contraindications



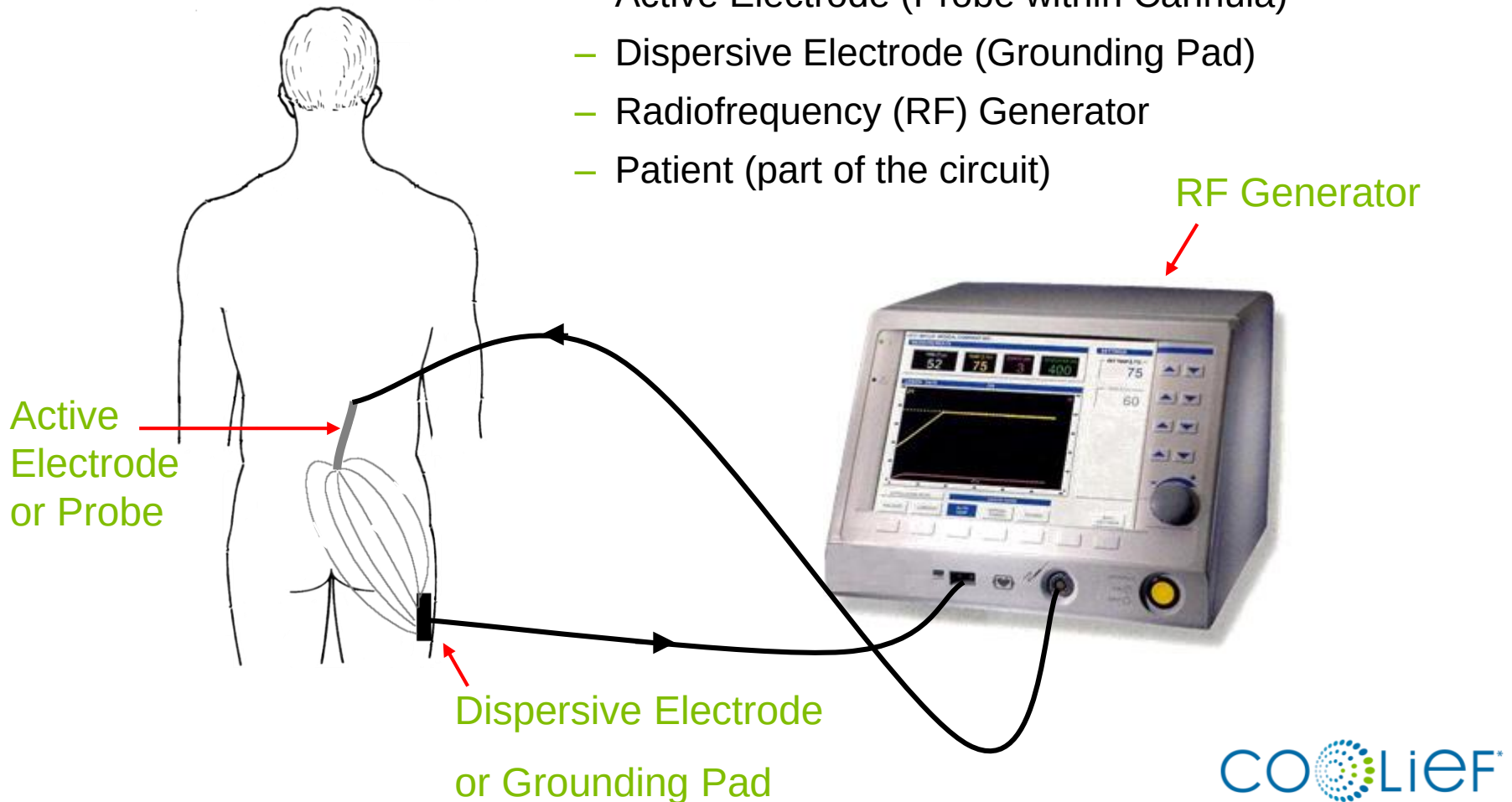
Cooled Radiofrequency Treatment

Standard RF Physics

Standard RF 'Ablation' Components

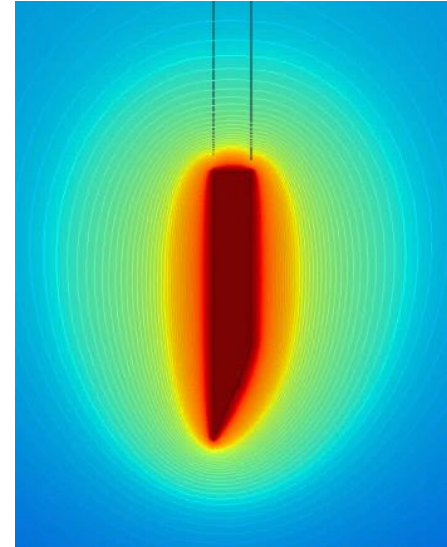
- Monopolar Setup

- Active Electrode (Probe within Cannula)
- Dispersive Electrode (Grounding Pad)
- Radiofrequency (RF) Generator
- Patient (part of the circuit)

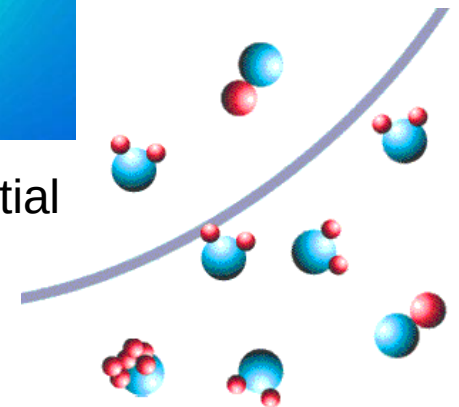


Principle of Ionic Heating

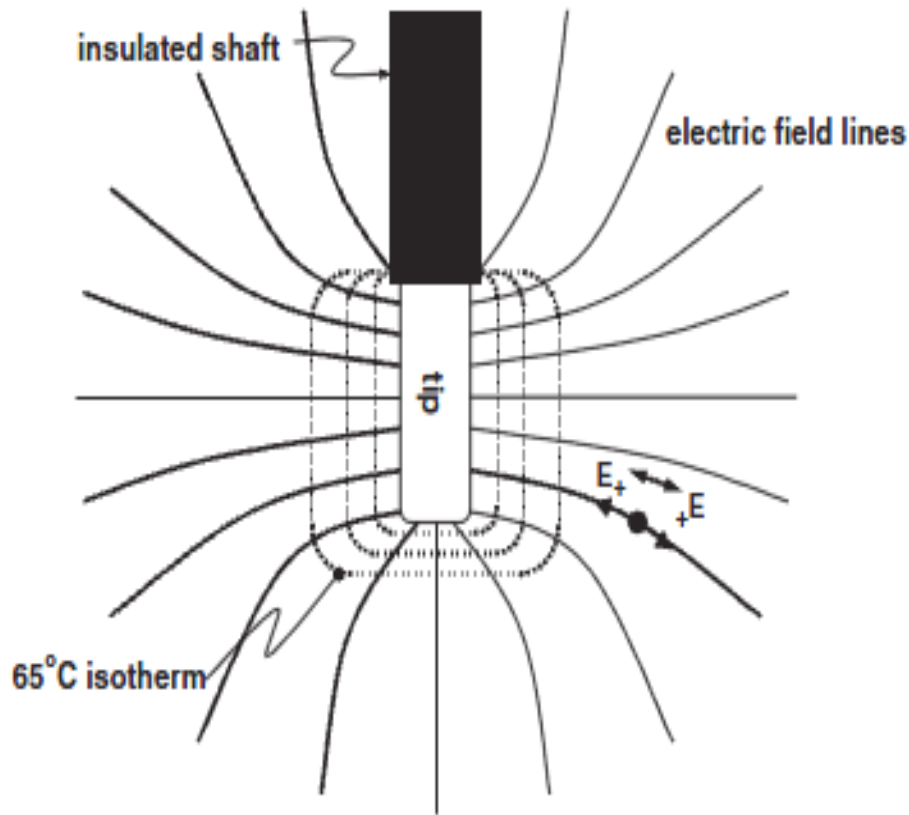
- Charge is alternated (460 kHz)
- Ions in surrounding tissue move creating friction¹
- Friction heats surrounding tissue
- Hot tissue heats probe or electrode by conduction
- Probe thermocouple located at the tip, reads tissue temperature



Electric Potential

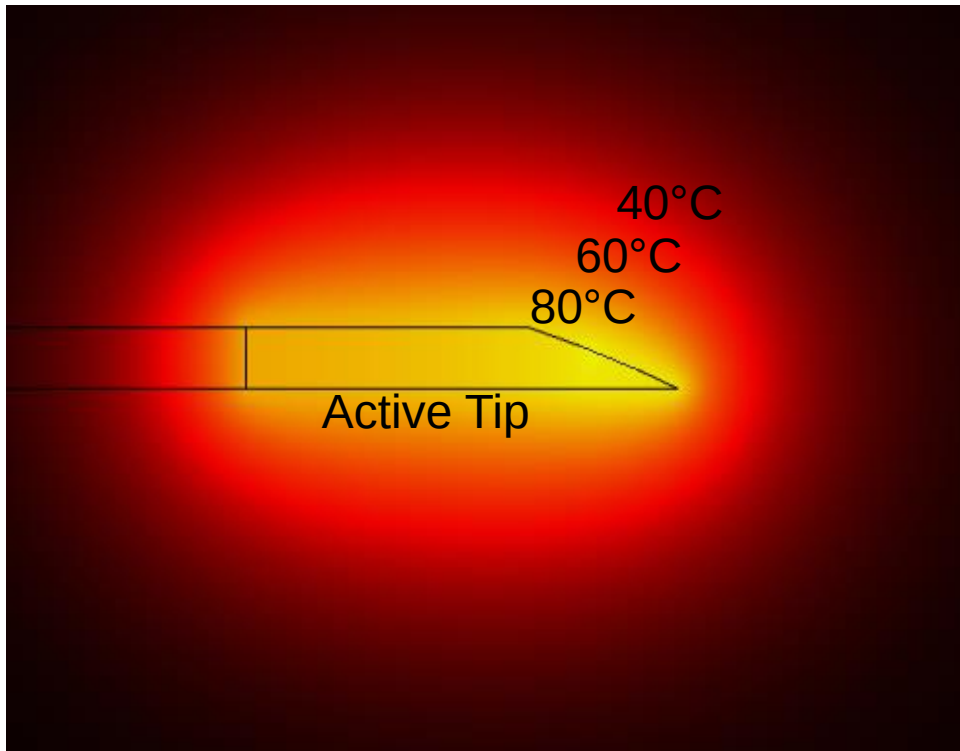


Factors Responsible for Ionic Heating



- Electrical Properties
 - Tissue electrical conductivity
 - Local current density
- Thermal Properties
 - Thermal conductivity
- Ablative Mechanism
 - Thermally destroys nerve fibers-
 - Coagulation
 - Protein denaturation

Temperature Distribution for Standard RF



- Temperature drops as radius from tip increases
- Hottest tissue is at the probe/tissue interface (limiting factor $> 90^{\circ}\text{C}$)³
- Neurodestruction begins to occur when temp reaches $> 45^{\circ}\text{C}$ ⁴
- A small zone of reversible damage surrounds lesion

3. Goldberg SN, et al. Radiofrequency Tissue Ablation: Importance of Local Temperature Along the Electrode Tip Exposure in Determining Lesion Shape and Size. *Acad Radiol* 1996Mar;3(3):212-218 ("2-Goldberg")

4. Goldberg SN, Gazelle GS, Mueller PR. Thermal ablation therapy for focal malignancy: a unified approach to underlying principles, techniques, and diagnostic imaging guidance. *AJR Am J Roentgenol* 2000Feb; 174(2):323-31 ("3-Goldberg")

- 60°C tissue temperature exhibits instantaneous tissue coagulation

Independent Lesion Parameters

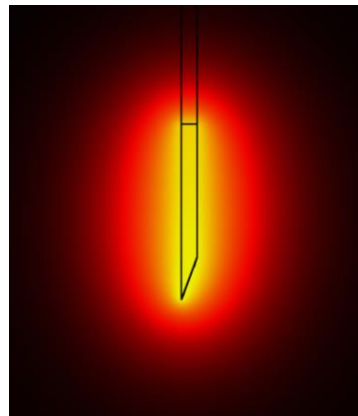
Lesion geometry is a function of:

- Active Tip Geometry
 - Gauge (diameter)
 - Length
- Temperature
- Time (Duration of RF Delivery)

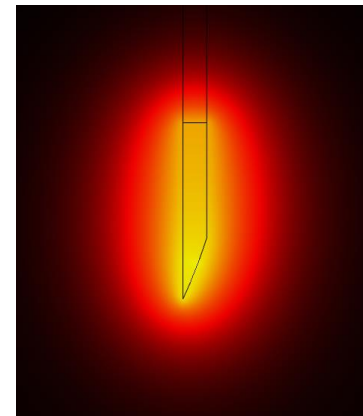
Independent Lesion Parameters

Lesion geometry is a function of:

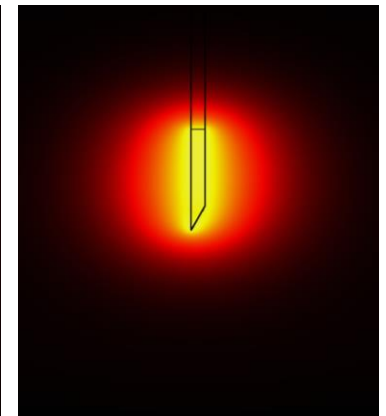
- **Active Tip Geometry**
 - Gauge (diameter) ^{5,6}
 - Length ⁶
- Temperature
- Time



20 Ga. 10mm



18 Ga. 10mm



20 Ga. 5 mm

5. Bogduk N, Macintosh J, Marsland A. Technical limitations to the efficacy of radiofrequency neurotomy for spinal pain. *Neurosurgery* 1987Apr;20(4):529-35.

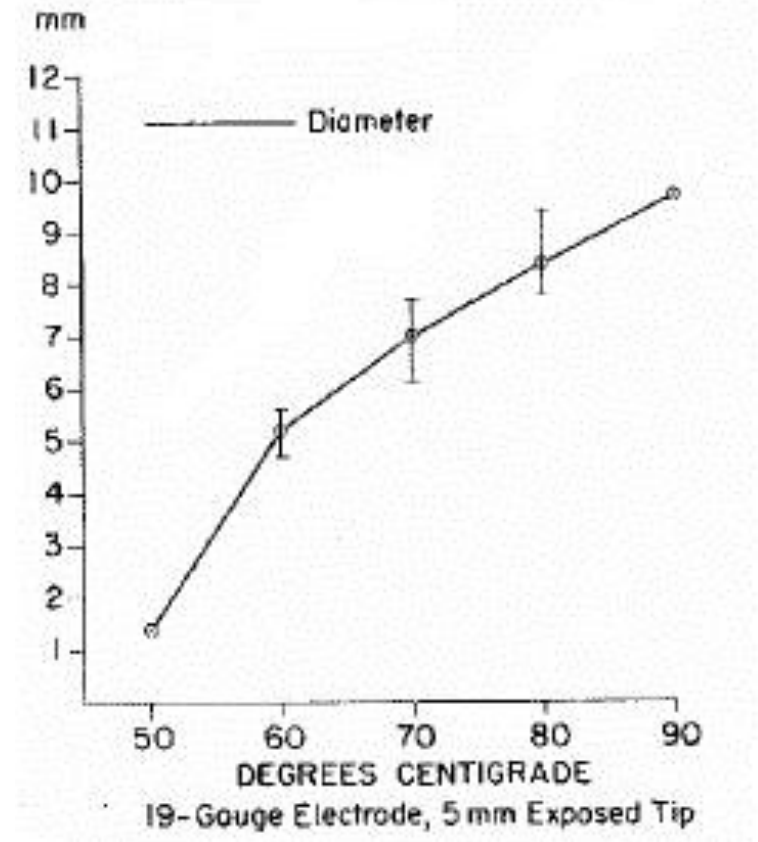
6. Goldberg SN, Gazell GS, Dawson SL, Rittman WJ, Mueller PR, Rosenthal DI. Tissue Ablation with Radiofrequency: Effect of Probe Size, Gauge, Duration, and Temperature on Lesion Volume. *Acad Radiol* 1995May;2(5):399-404.

Independent Lesion Parameters

Lesion geometry is a function of:

- Active Tip Geometry
 - Gauge (diameter)
 - Length
- **Temperature**⁷
- Time

Average Thermal Lesion Size vs Temp⁶

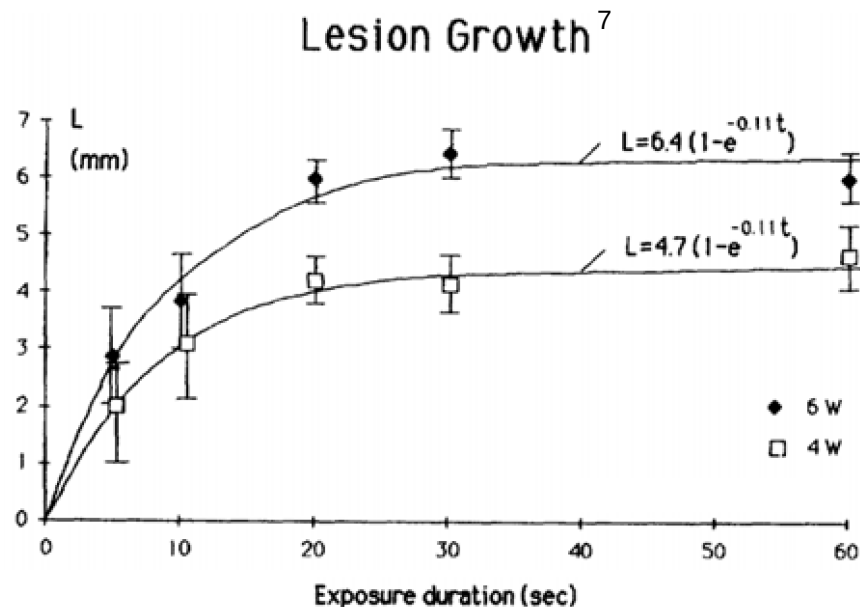


7. Alberts WW, Wright EW, Jr., Feinstein B, Von Bonin G. Experimental radiofrequency brain lesion size as a function of physical parameters. *J Neurosurg* 1966Oct;25(4):421-3.

Independent Lesion Parameters

Lesion geometry is a function of:

- Active Tip Geometry
 - Gauge (diameter)
 - Length
- Temperature
- **Time**^{6,8}



Summary: Standard RF

- **Lesion size:**

- **Probe surface area**

- Adds to interface variability, limiting lesion size

- **Set temperature**

- Tissue temps $> 100^{\circ}\text{C}$ cause tissue carbonization and vapor formation, limiting lesion size³

- **Ablation duration**

- Tissue temp saturates in seconds-to-minutes, limiting lesion size⁹⁻¹⁰

Cooled RF overcomes the lesion size limitations inherent to Standard RF

3 – Goldberg

9. Eick OJ. Factors Influencing Lesion Formation During Radiofrequency Catheter Ablation. *Indian Pacing Electrophysiol J* 2003 Jul-Sep;3(3):117-128.

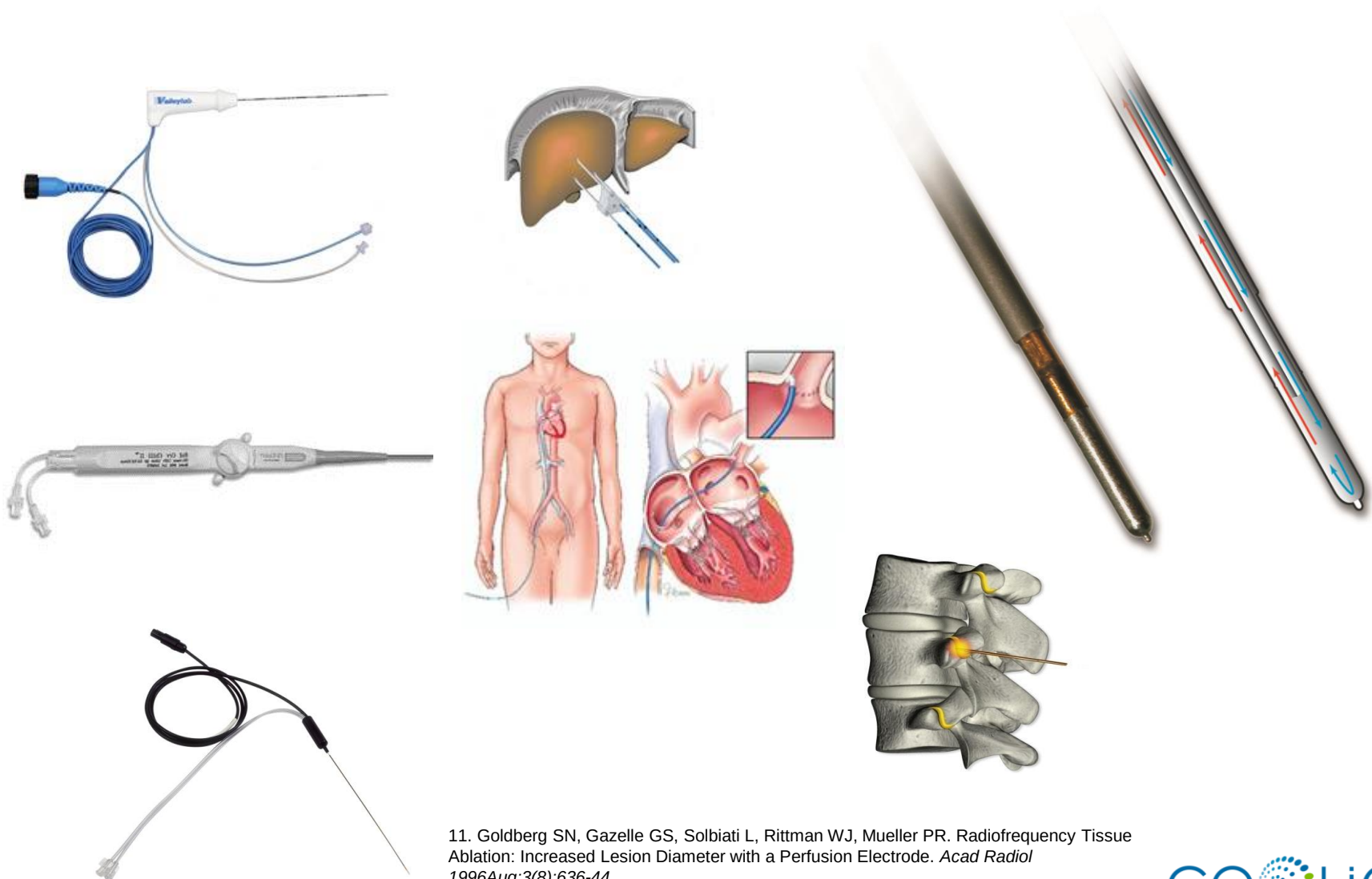
10. Vallejo R, Benyamin R, Tilley DM, Kelley CA, Cedeno DL. An ex vivo comparison of cooled-radiofrequency and bipolar-radiofrequency lesion size and the effect of injected fluids. *Reg Anesth Pain Med* 2014 Jul-Aug;39(4):312-21.



Cooled Radiofrequency Treatment

Cooled RF Physics

Internally Cooled Electrodes ¹¹⁻¹²

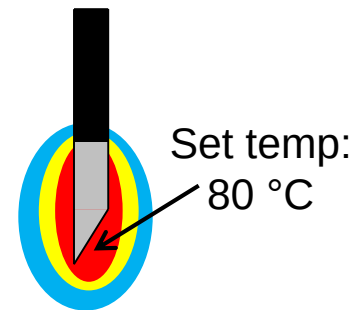


11. Goldberg SN, Gazelle GS, Solbiati L, Rittman WJ, Mueller PR. Radiofrequency Tissue Ablation: Increased Lesion Diameter with a Perfusion Electrode. *Acad Radiol* 1996Aug;3(8):636-44.
12. Lorentzen T. A Cooled Needle Electrode for Radiofrequency Tissue Ablation: Thermodynamic Aspects of Improved Performance Compared with Conventional Needle Design. *Acad Radiol*. 1996Jul;3(7):556-63.

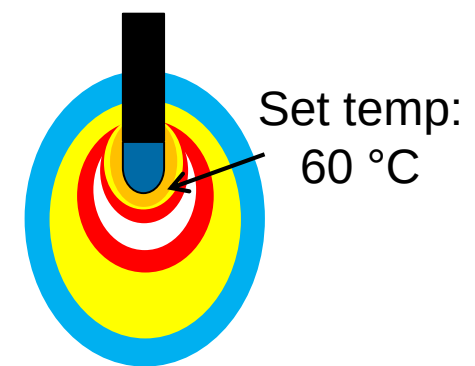
Internally Cooled Electrodes

- The Cooled RF Set Temperature (default setting $T=60^{\circ}\text{C}$) displayed on the generator refers to the cooled electrode temperature
- Immediate surrounding tissue is $\geq 80^{\circ}\text{C}^{13}$

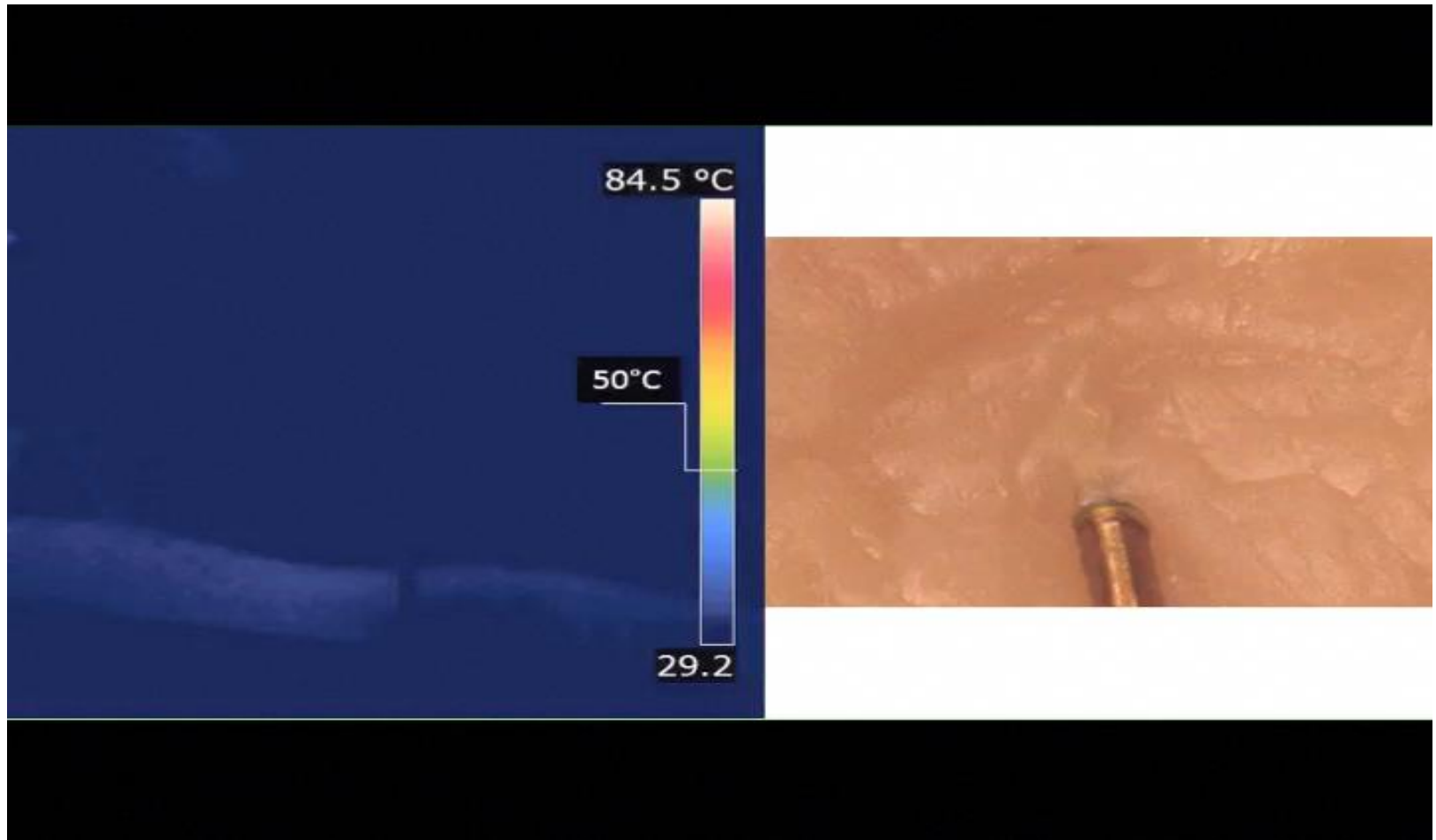
Standard RF



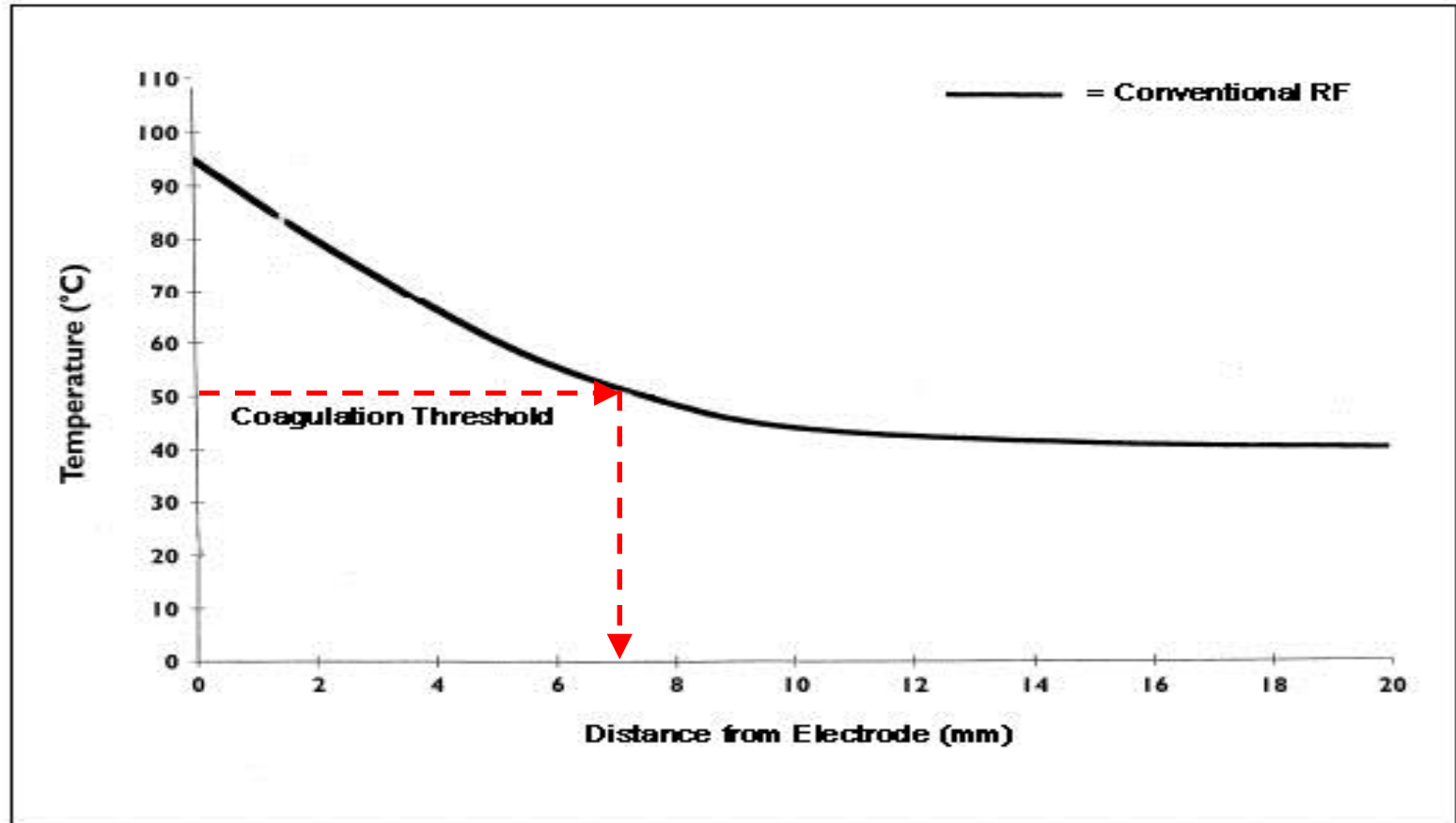
Cooled RF



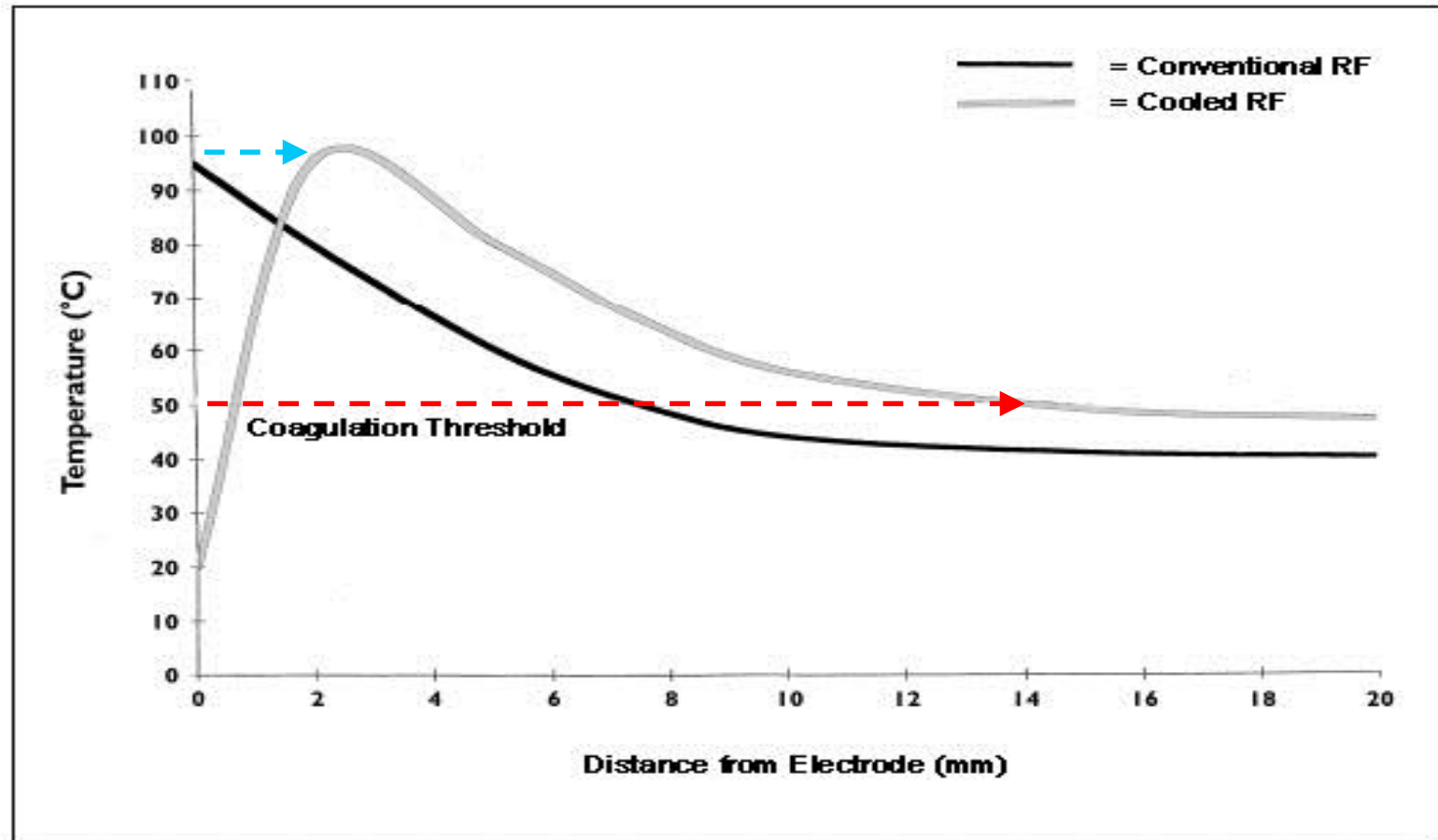
Video showing a Cooled RF Ablation



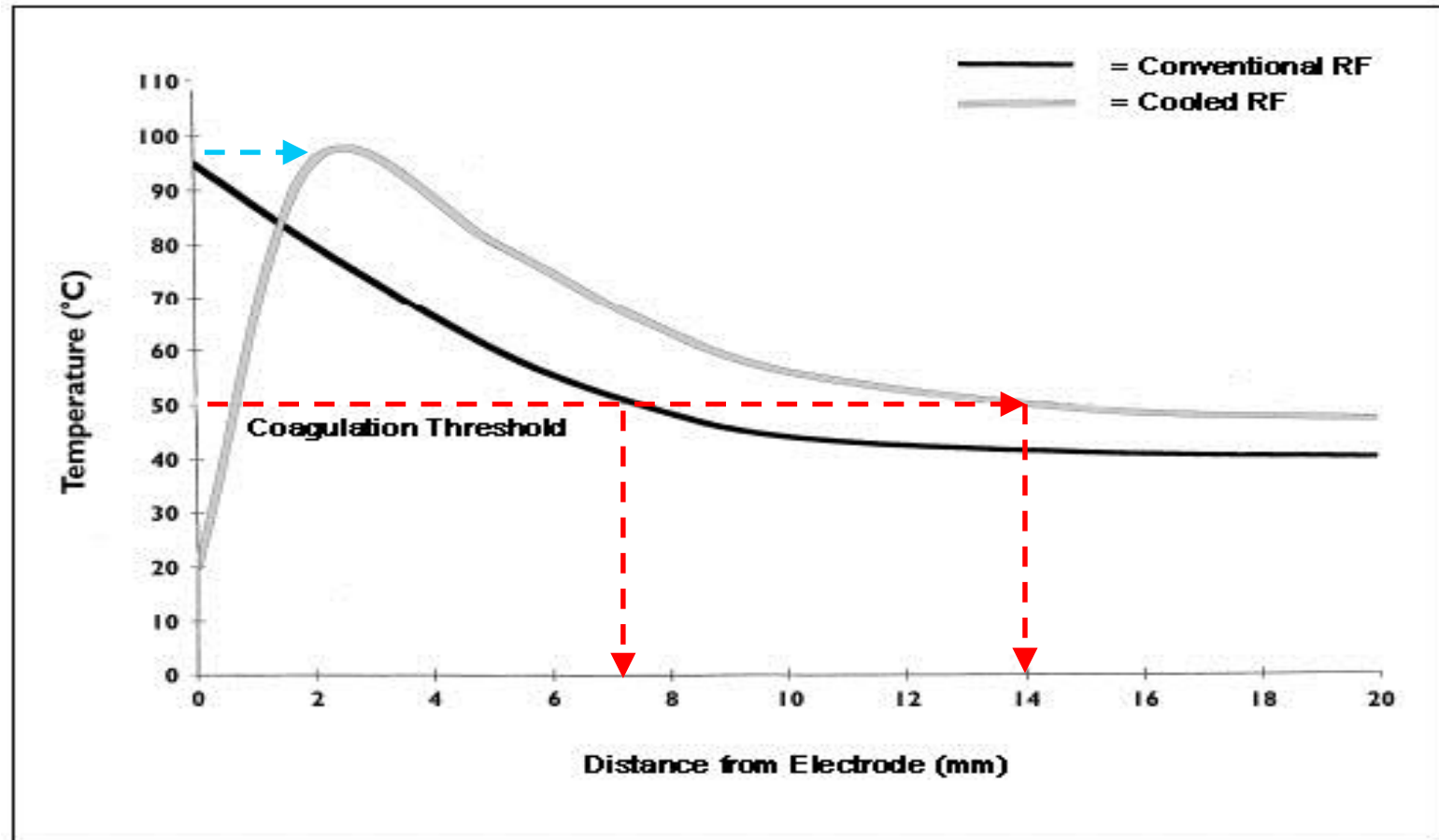
Physics of Cooled RF



Physics of Cooled RF



Physics of Cooled RF

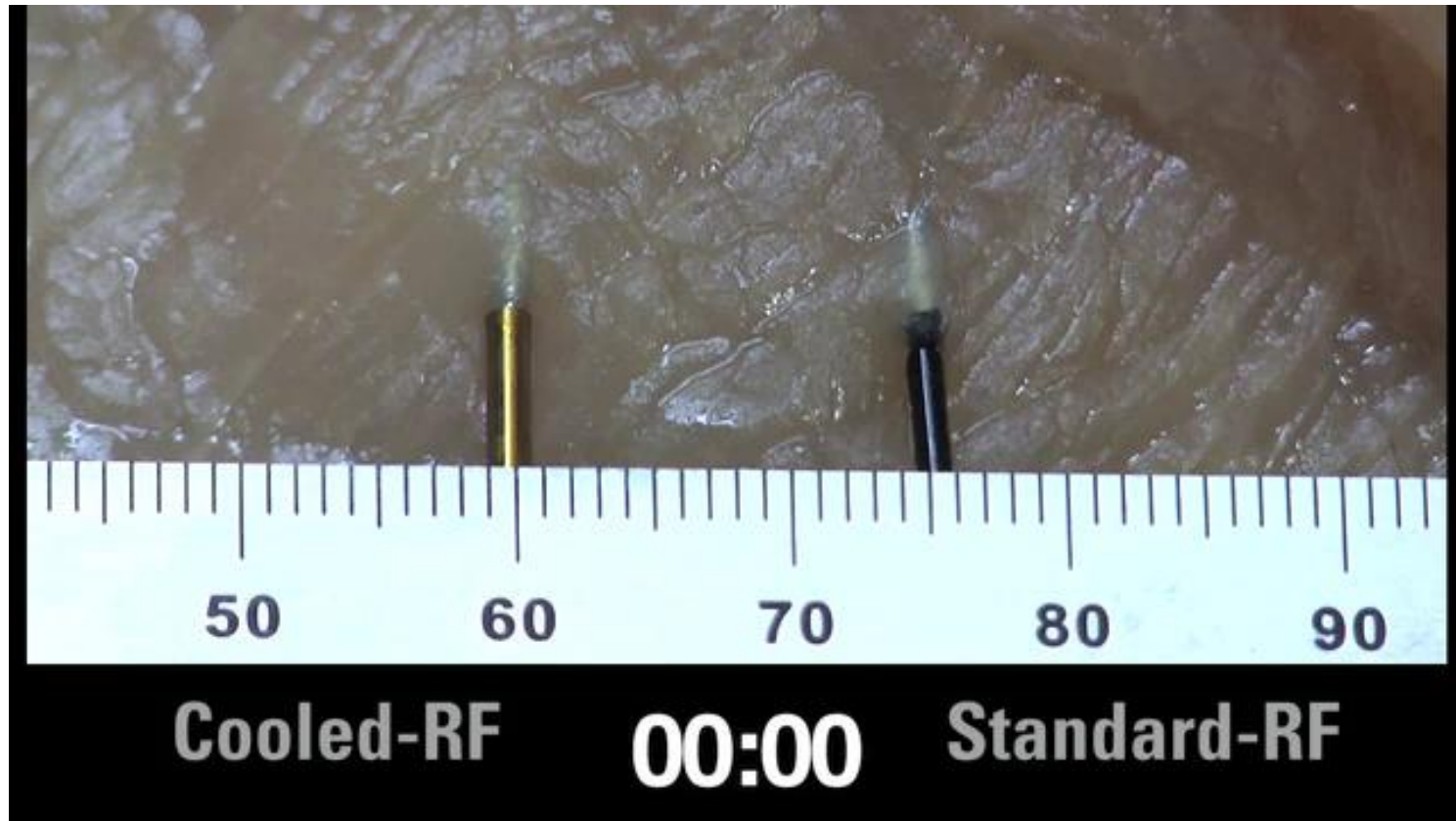




Cooled Radiofrequency Treatment

Lesion Size and Geometry

Cooled RF vs Standard RF



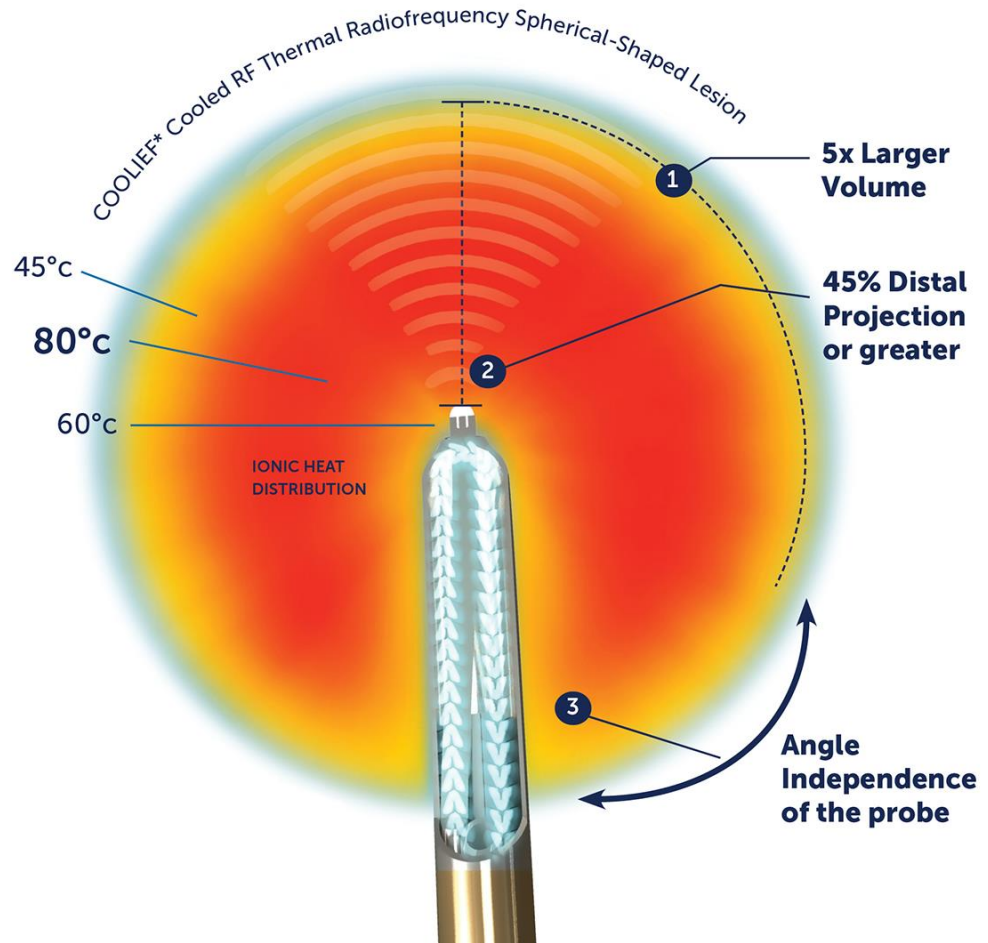
Lesion performed in chicken (37°C):

Cooled RF set temp. of 60°C with 18Ga, 4mm active tip;

Standard RF set temp. of 80°C with 20Ga, 5mm active tip length.

Technological advantages of Cooled vs Standard RF

- ✓ **5 times larger in volume** versus standard RF
- ✓ **Distal projection of 45% or greater** beyond the probe tip
- ✓ **Enables angle independence** so physicians can reach variable nerve paths

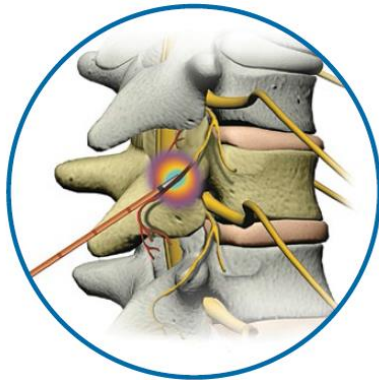




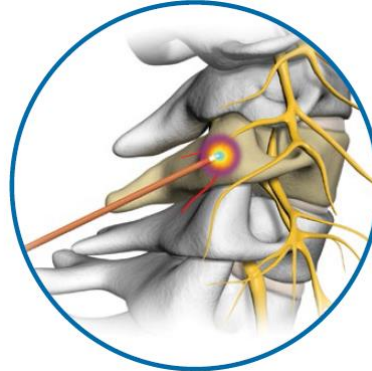
Cooled Radiofrequency Treatment

Application to Pain Management

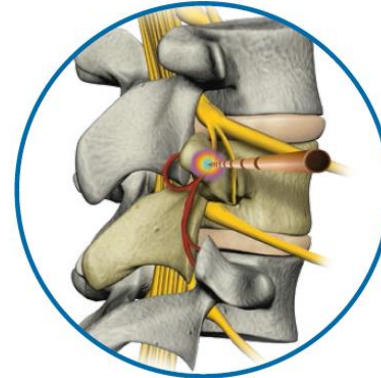
Cooled RF Monopolar Applications



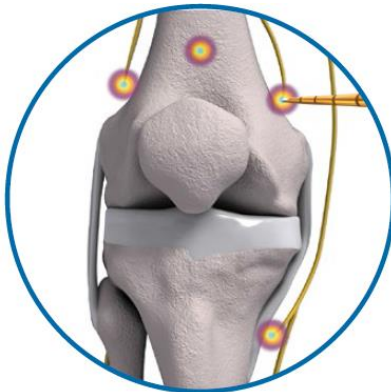
THORACIC



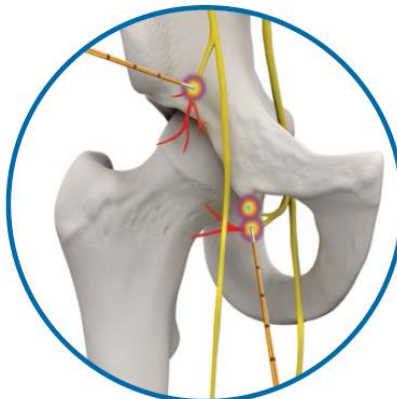
CERVICAL



LUMBAR



KNEE



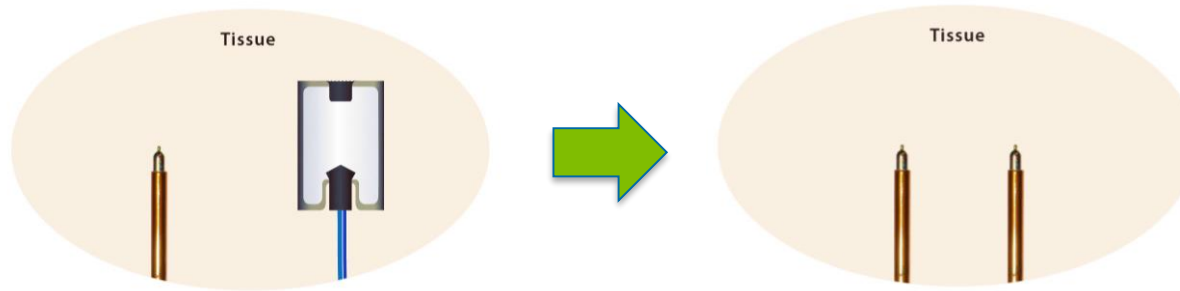
HIP



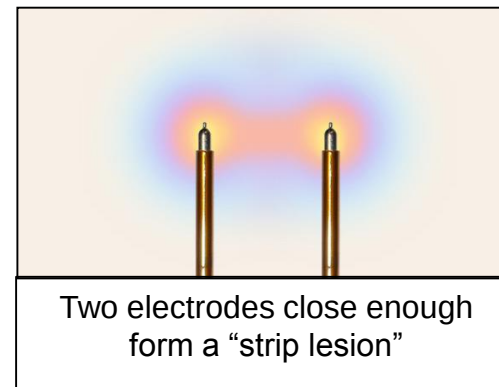
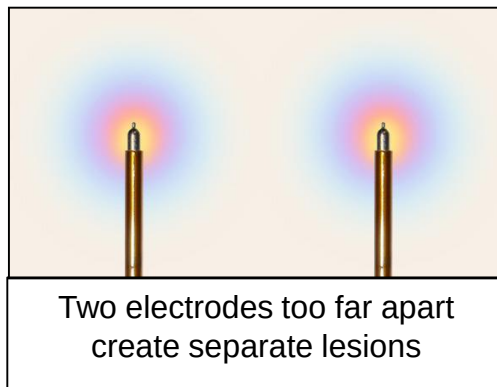
SACROILIAC

From Monopolar to Bipolar

- Two electrodes with same surface area (no grounding pad)
 - Same amount of current flows through both electrodes resulting in similar current densities

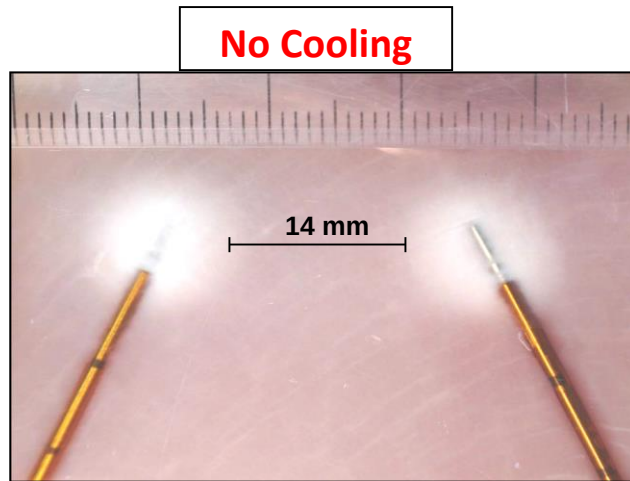


- Current is concentrated between the electrodes creating larger lesions¹⁴

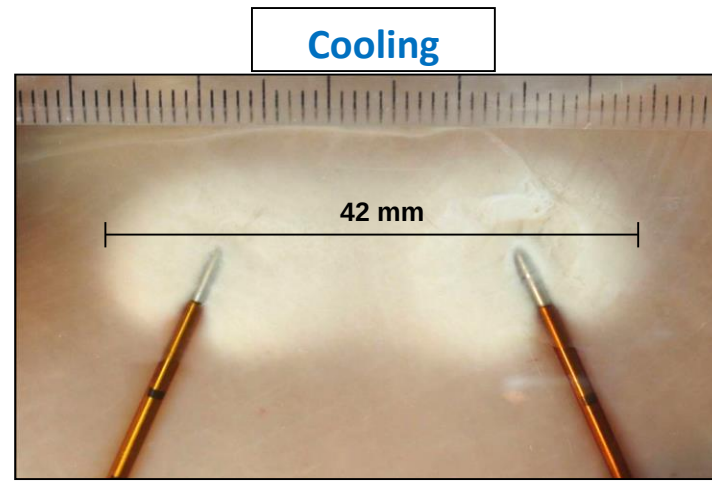


14. Lee JM, Han JK, Kim SH, Sohn KL, Choi SH, Choi BI. Dual probe radiofrequency ablation: an in vitro experimental study in bovine liver. *Invest Radiol.* 2004Feb;39(2): p. 89-96.

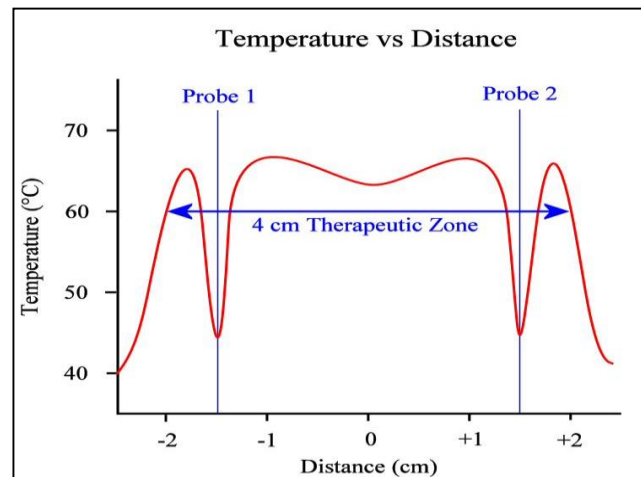
Bipolar: Non-Cooled vs Cooled



Testing performed in chicken (37°C) for 25:00 at a set temperature of 80 °C.



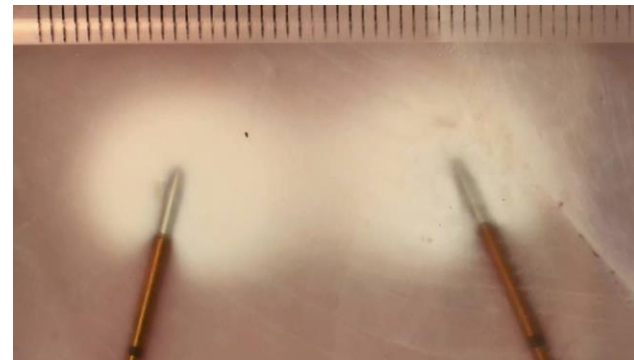
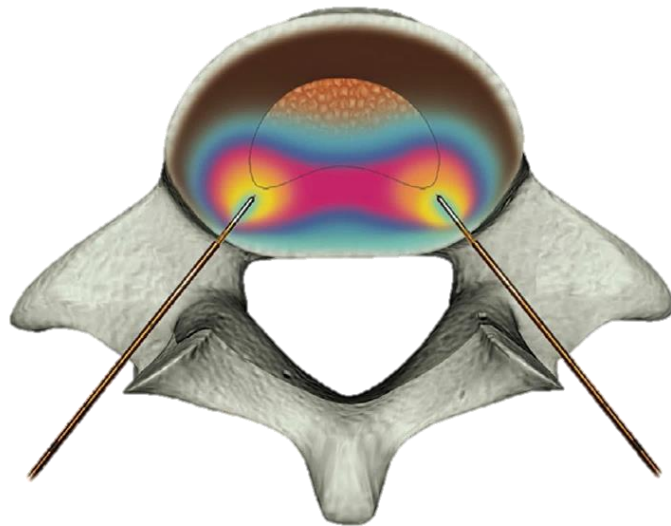
Testing performed in chicken (37°C) for 25:00 at a set temperature of 55 °C.



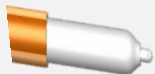
Application to Discogenic Pain

COOLIEF* TRANSDISCAL* Cooled RF System

- Internally-cooled, bipolar RF system for thermal treatment of the intervertebral disc
- Heats and deactivate a large volume of tissue (without excessive heating) appropriate for lumbar discs
- Aimed to generate reproducible thermal lesions in posterior and posterolateral annulus

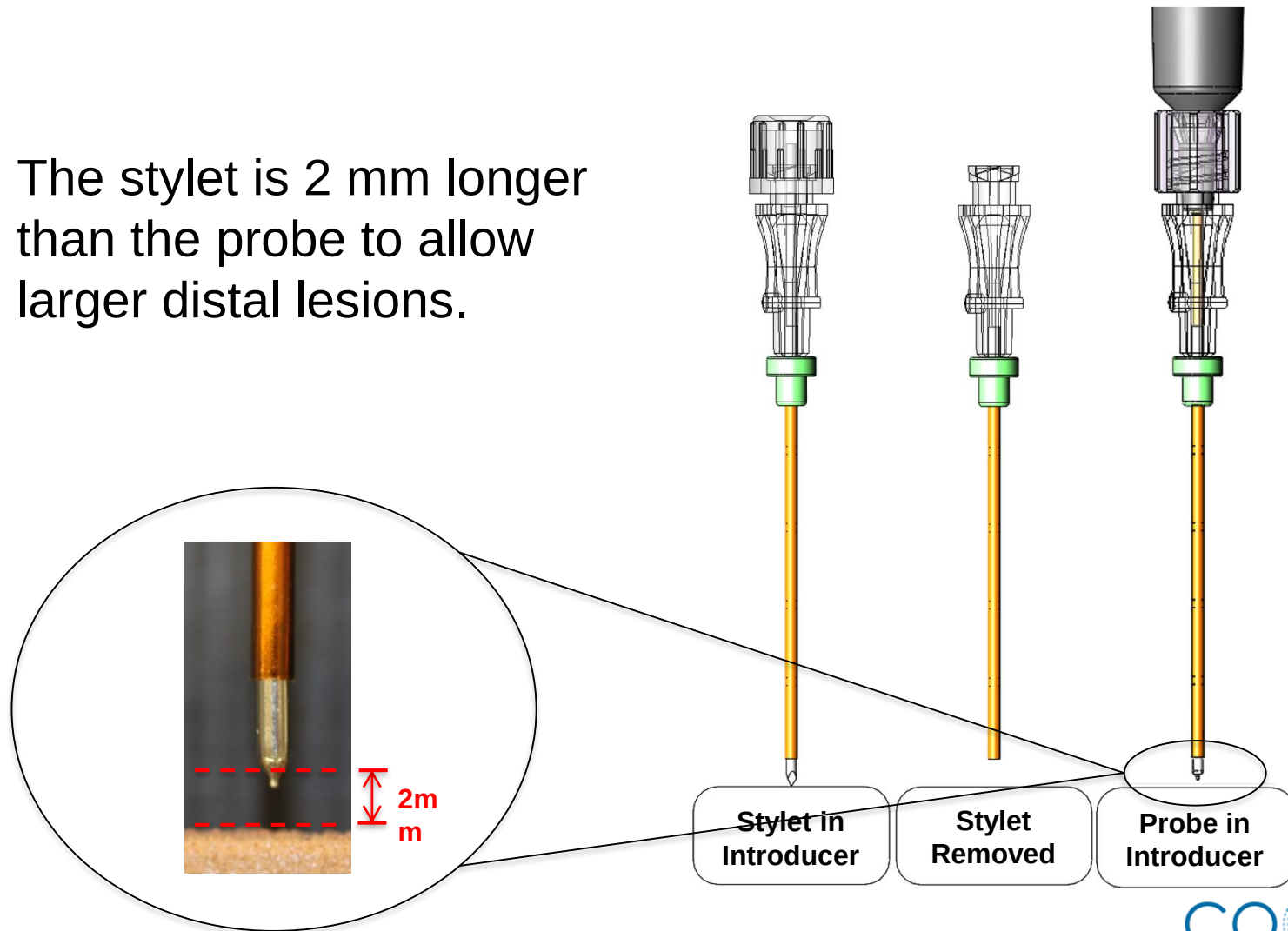


Procedural Settings Summary

Cooled RF Kit	Active Tip	Set Temp.	Time (min:sec)	Ramp Rate
COOLIEF* Cooled RF Kits	2mm 	60°C	2:30	40-80°C/min
	4mm 			
	5.5mm 			
COOLIEF* SINERGY* Kit	4mm 	60°C	2:30	40-80°C/min
COOLIEF* TRANSDISCAL* Kit	6mm 	50°C	15:00	2°C / min

Stylet / Probe Comparison

- The stylet is 2 mm longer than the probe to allow larger distal lesions.



System Components

Equipment

1. PMG
2. Pain Management Pump Unit
3. Pump Connector Cable
4. Cooled RF Connector Cable
5. Dispersive Electrode (Ground Pad)

Disposable Kits

- COOLIEF* Cooled RF Kit
- COOLIEF* SINERGY* Cooled RF Kit
- COOLIEF* TRANSDISCAL* Cooled RF Kit





Cooled Radiofrequency Treatment

Thank You

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