

Denervx™ Whitepaper

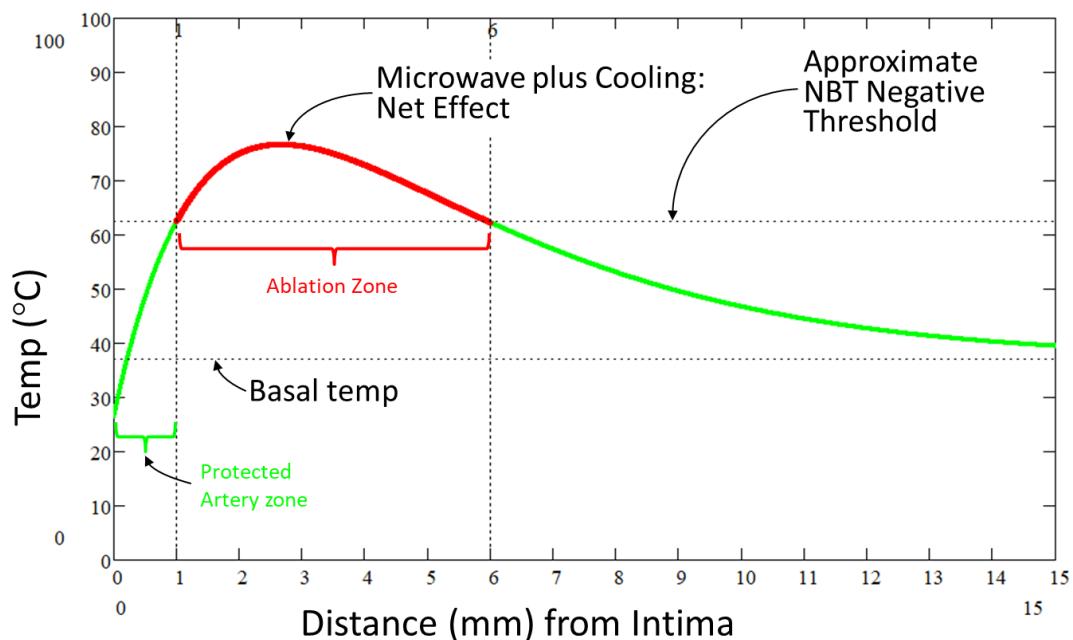
Denervx has developed a catheter-based Cooled Microwave technology for the treatment of hypertension via a bilateral renal artery denervation procedure. In porcine studies, the treatment results in a robust, circumferential and longitudinal ablation of the nerves surrounding the artery while providing protection of the arterial wall.

Principle

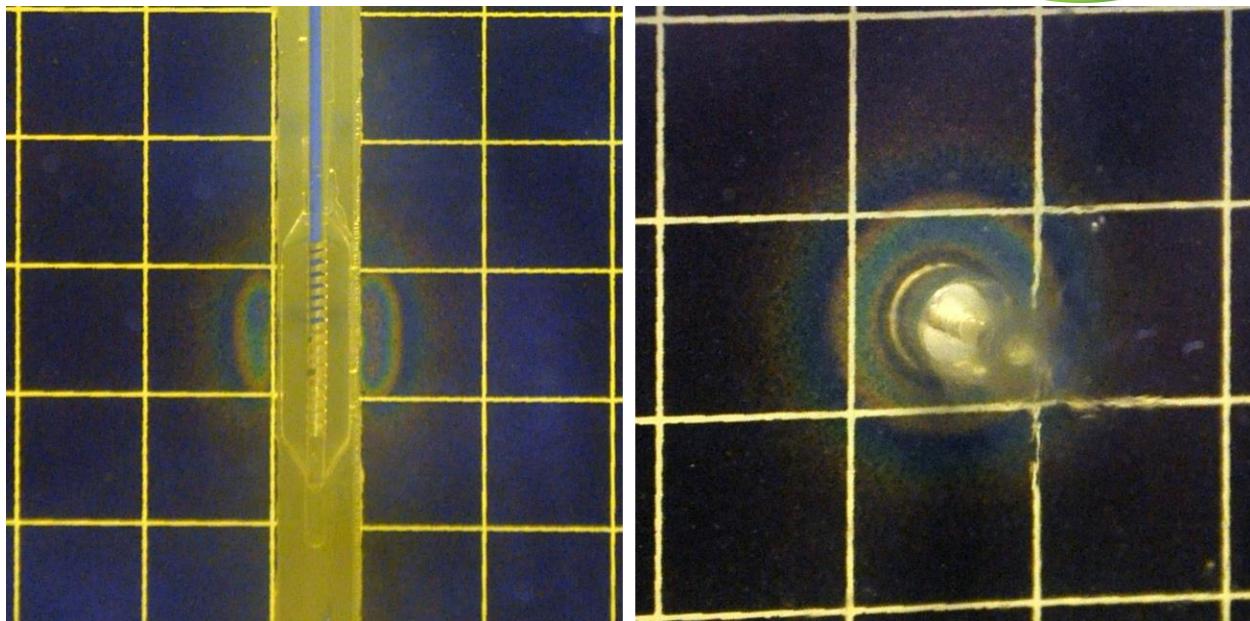


Catheter

The Denervx™ catheter is shown above. The helical dipole emits microwave energy that provides uniform heating of tissue at a distance and results in circumferential ablation. Simultaneously, chilled sterile water is circulated through the cooling balloon to cool and protect the artery by thermal conduction. Only one application per renal artery is needed. The resulting thermal profile is shown below; temperature is coolest in tissue contacting the cooling balloon (intima) and reaches thermal toxic threshold at approximately 1mm distance. Maximum temperature is achieved between 2 and 3mm and remains above thermal toxicity out to 6mm. The ablation dimensions, both inner and outer, may be adjusted by varying treatment parameters (power, coolant temperature, time, etc.)



Denervx™ Thermal Profile

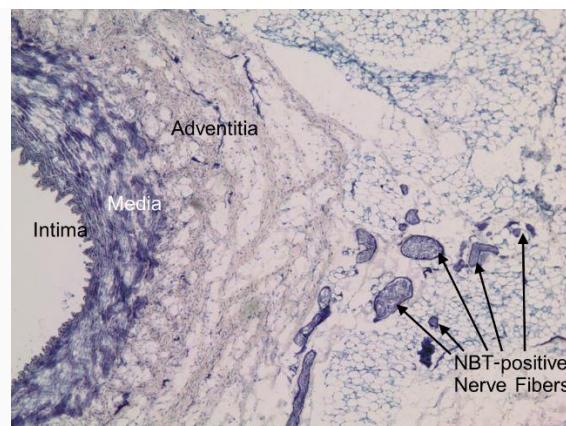


Liquid Crystal film illustrates heating

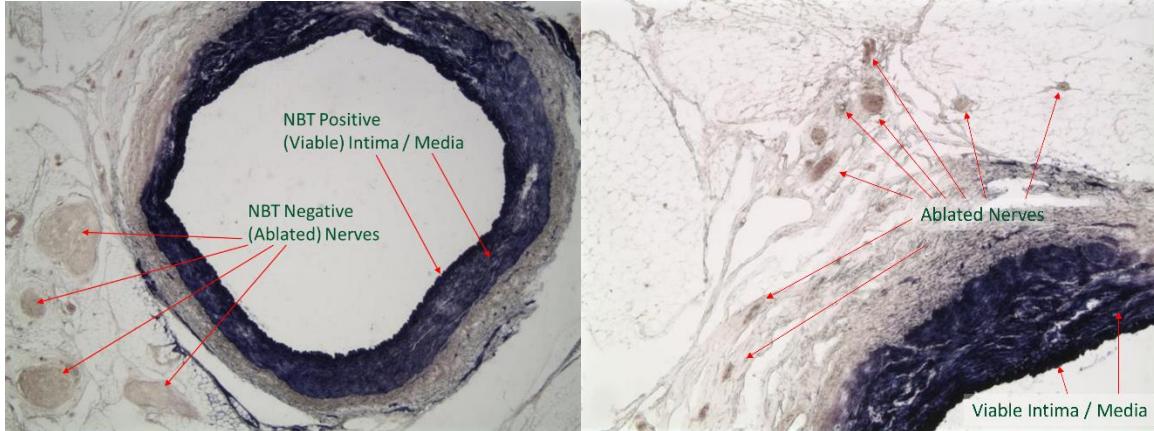
Benchtop testing includes tissue phantom testing in a tissue equivalent gel formulated to mimic the dielectric and thermophysical properties of tissue. A liquid crystal thermal sensing film is incorporated so the temperature field may be directly visualized. The example above shows a typical temperature field of about 10mm in longitudinal distance. The cross-sectional view shows a ring of elevated temperature surrounding a cooler zone adjacent the balloon.

Porcine Histology:

Extricated tissue studies were performed by pathologist Jim Coad, MD at WVU. Tissue samples were stained using NBT stain, and examples are shown below of both untreated (control) and treated specimens. In treated specimens, the NBT stain evidences a circumferential ablation zone surrounding a viable renal artery.

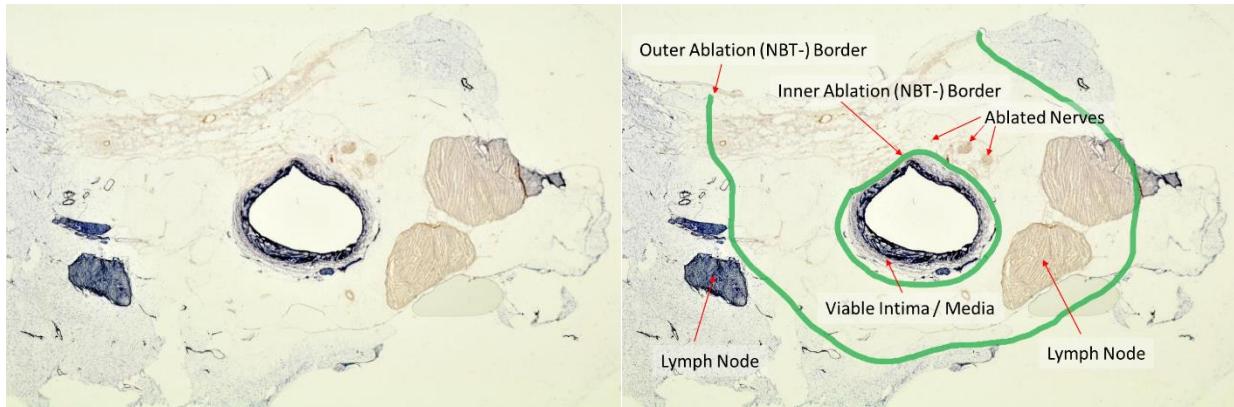


Untreated (Control), Viable Tissue with NBT Staining



Example, Treated Specimen

Circumferential ablation including renal nerves (NBT negative) surrounding viable (NBT positive) Artery



Additional Example, Treated Specimen

Circumferential ablation including renal nerves (NBT negative) surrounding viable (NBT positive) Artery

Pathology by James E. Coad, MD; WVU

IP

- 5 Issued patents:
 - US9,333,035, "COOLED MICROWAVE DENERVATION"
 - US10,092,352, "COOLED MICROWAVE DENERVATION"
 - US10,179,029, "COOLED MICROWAVE DENERVATION CATHETER CONFIGURATION AND METHOD"
 - US10,390,881, "COOLED MICROWAVE DENERVATION CATHETER WITH INSERTION FEATURE"
 - US11,786,302, "COOLED MICROWAVE DENERVATION"
- Continuation application pending to earliest priority date (includes COPD claims)
- Freedom to practice analysis completed
- Clear path to market with patented technology

Why Cooled Microwave?

- Uniform, Circumferential Energy Delivery to produce Circumferential Nerve Ablation
- Protection of the Renal Artery
- Flexible Distal Tip – no rigid transducer
- Antenna lengths to ablate sufficient length of nerves so only one ablation per artery is needed
- Histology evidencing ablation where nerves are while protecting artery
- Clear path to market with patented technology

Contact:

Eric Rudie, Inventor, Chairman & CTO

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- Extensive domain experience (Over 30 years) in tissue ablation technology.
- Inventor of the Urologix Technology (ULGX); (May 1991 – Late 2003).
- President & GM, Rudie Consulting, LLC (2004 – present).
- GM, CIRTEC, Engineering Outsource/Contract Manufacturer, (2009 – 2012).
- Technology Development Director, Transoma Medical (2003 – 2007).
- Inventor of over 40 issued US patents and many published US patent applications.
- Many published papers & invited presentations related to ablation. (i.e. Thermal Biology Workshop, UMN)
- BSEE & MSEE with emphasis on Analog, RF, Microwave & Antennas.