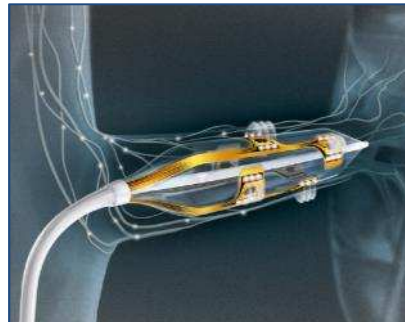# The Vessix™ Renal Denervation System
BACKGROUND INFORMATION

THE VESSIX™ SYSTEM


Vessix™ Generator

Vessix™ Catheter

Bipolar energy distribution

- The System features two major components: the Vessix™ Catheter, and the Vessix™ Generator.

- The Vessix™ Catheter is a balloon-based technology with an array of radiofrequency electrodes arranged in a precise pattern designed to deliver a modest dose of energy to disrupt the renal nerves that surround the renal artery.

- The Vessix™ System is designed to minimise patient discomfort and maximise procedural efficiency. The System offers the shortest treatment time of 30 seconds per artery, and is designed to require only a single catheter placement in most anatomies.

- During the procedure, the Vessix™ Catheter occludes blood flow to the renal artery during the 30 second therapy delivery allowing for a directed and highly controlled flow of energy to the target nerves.

- The Vessix™ System verifies electrode/vessel wall apposition and independently deactivates any electrode not in contact with the vessel wall.

- Vessix™ is the only bipolar renal denervation system, allowing for localised and more precise energy distribution. The bipolar approach controls the distribution of energy between two electrode poles, confining the delivery of therapy to only the targeted tissues.

Electrode Poles
Thermistor

1
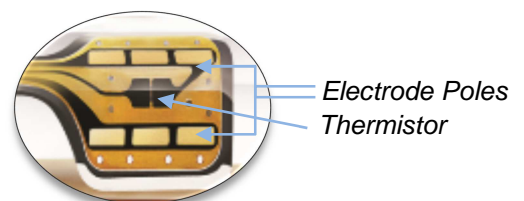
- Bipolar energy eliminates the need for cooling systems and a monopolar-based patient grounding pad.

- The Vessix™ System is designed to reduce the risk of injury to tissue beyond the treatment site, delivering the lowest effective energy dose (≤ 1 Watt), eight to 25-times lower than competitive monopolar systems.

# CLINICAL BACKGROUND

VESSIX™ CLINICAL DATA

- Boston Scientific has conducted extensive research on the location of the renal nerves.

- This research, and similar studies conducted by other investigators, suggest that the vast majority of renal nerves are located within 3 mm of the vessel lumen.[1,2]

- The Vessix™ System's unique bipolar approach controls the distribution of energy between two electrode poles, confining the delivery of therapy to only the targeted nervous tissue surrounding the renal arteries.

The vast majority of renal nerves are located within 3 mm of the vessel lumen.

JACC: 85% of the renal nerves lie within two mm of the lumen[3]
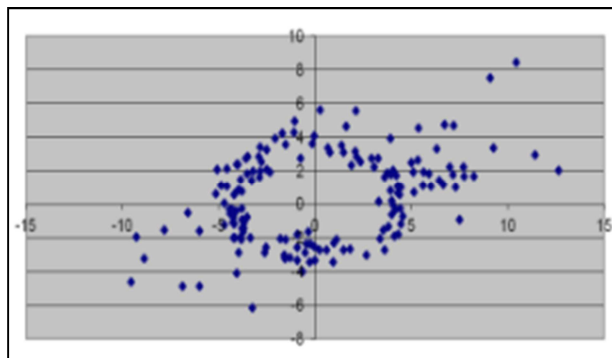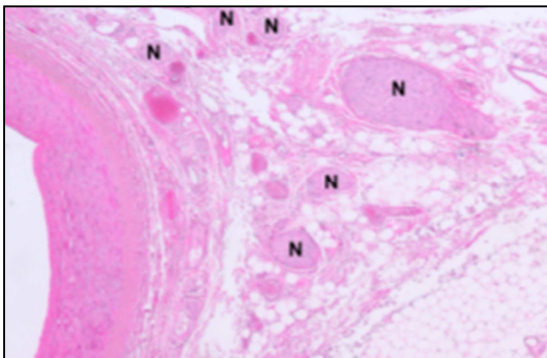
Atherton, D *et al*.: 90.5% of nerves reside within two mm of the vessel wall[1]
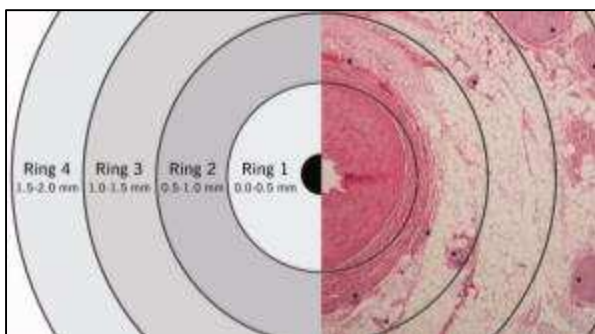
The Vessix™ System features a differentiated energy delivery process that was designed specifically to target renal nerves at the correct depth.

2

REDUCE-HTN

- The Vessix™ System is currently being evaluated in the REDUCE-HTN post-market clinical study.

- REDUCE-HTN will enroll approximately 150 patients and will evaluate the effectiveness of the Vessix™ System in reducing systolic and diastolic blood pressure at 6 months as compared to pre-treatment baseline blood pressures.

- An update on REDUCE-HTN will be presented at EuroPCR on May 22, 2013 by principal investigator Horst Sievert, M.D., CardioVascular Center Frankfurt, Frankfurt, Germany.

VESSIX™ REGULATORY STATUS

- The Vessix™ System received CE Mark and TGA approval in Australia in 2012.

- Boston Scientific commenced the launch of the Vessix™ System in select countries in 2013.

- The Vessix™ System is not approved for use or sale in the United States. Boston Scientific expects to initiate the U.S. IDE trial to evaluate the Vessix™ System in late 2013 or early 2014.

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[1] Atherton, D. S., Deep, N. L. and Mendelsohn, F. O. (2012), Micro-anatomy of the renal sympathetic nervous system: A human postmortem histologic study. Clin. Anat., 25: 628–633. doi: 10.1002/ca.21280.

[2] Tunstall R, et al. TCT-216 A Preclinical Comparative Histological Evaluation of the Renal Artery and Nerves in the Human Cadaver and Swine model. J Am Coll Cardiol. 2012;60(17_S):. doi:10.1016/j.jacc.2012.08.238.

[3] JACC: A Preclinical Comparative Histological Evaluation of the Renal Artery and Nerves in the Human Cadaver and Swine model.

PI-158802-AA