What is the rationale for renal denervation?

The nerves leading in and out of the kidneys play a central role in sympathetic nervous system (SNS) hyperactivation, which is an established contributor to hypertension (high blood pressure).¹ The SNS connects the brain, heart, blood vessels and kidneys—each of which plays an important role in the regulation of the body’s blood pressure. Surgical disruption of sympathetic nerves has been a proven method for lowering blood pressure.² Renal denervation with the Symplicity renal denervation system from Medtronic represents a breakthrough and first-of-its-kind device, currently under investigation in the United States for treatment-resistant hypertension; a significant global healthcare problem affecting approximately 1.2 billion people worldwide and directly associated with increased risks of heart attacks, stroke, heart failure, kidney disease and death.³

How does renal denervation work?

Renal denervation reduces the drive of the sympathetic nervous system, which is central to blood pressure regulation. It is a minimally invasive procedure that modulates the output of the sympathetic nerves located outside the renal artery walls.⁴

What is the procedure?

The Symplicity renal denervation system accomplishes renal denervation using a system consisting of a proprietary generator and a flexible catheter. The catheter is introduced through the femoral artery in the upper thigh and is threaded up into the renal artery near each kidney. Once in place, the tip of the catheter delivers low-power, radio-frequency (RF) energy according to a proprietary algorithm, or pattern, to modulate the surrounding sympathetic nerves. After energy delivery in multiple locations along each artery, the Symplicity® catheter is removed—there is no permanent implant.
**What is SYMPLICITY HTN-3?**

**SYMPLICITY HTN-3** is a randomized, controlled trial designed to evaluate the safety and effectiveness of renal denervation with the Symplicity renal denervation system in patients with treatment-resistant hypertension and systolic blood pressure greater than or equal to 160 mmHg. The FDA approved the protocol for this study on July 11, 2011, and patient enrollment began in September 2011. The study will randomize approximately 530 patients to receive either renal denervation and treatment with antihypertensive medications or treatment with antihypertensive medications alone. The primary endpoints of the study are the change in blood pressure from baseline to six months following randomization and incidence of major adverse events.

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For further information, please call and/or consult Medtronic at the toll-free numbers or websites listed:

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