Renal Denervation (RDN)
NOVEL CATHETER-BASED TREATMENT FOR HYPERTENSION

RDN Therapy with the Symplicity Renal Denervation System

What is the rationale for RDN?
The nerves leading in and out of the kidneys play a central role in sympathetic nervous system hyperactivation, which is an established contributor to hypertension (high blood pressure).\(^1\) Surgical disruption of sympathetic nerves has been a proven method for lowering blood pressure.\(^2\) RDN therapy with the Symplicity Renal Denervation System represents a breakthrough and first-of-its-kind device-based treatment for resistant hypertension, which is 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 RDN work?
RDN addresses uncontrolled hypertension by reducing 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 RDN 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 through 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. Renal denervation does not involve a permanent implant.
What impact does the procedure have on the patient?

Clinical research shows that RDN therapy with the Symplicity Renal Denervation System can provide significant and sustained reduction in blood pressure levels for patients with uncontrolled blood pressure despite multiple antihypertensive medications. This research includes Symplicity HTN-1\(^5\) and Symplicity HTN-2\(^6\).

- Symplicity HTN-1 was a series of pilot studies involving 153 patients at 19 centres in Australia, Europe and the USA. In these studies, patients achieved a mean blood pressure reduction of -25/-11 mmHg at six months and the reduction was sustained through 24 months. There was no evidence of vascular injury or stenosis at the treatment sites at six months, confirmed by imaging (CTA/MRA), and renal function was sustained (eGFR and creatinine). These data were published in the April 2009 issue of *The Lancet*.

- Symplicity HTN-2 was a randomised, controlled clinical trial of 106 patients in Europe, Australia and New Zealand. Patients randomised to RDN therapy achieved a mean blood pressure reduction of 32/12 mmHg at six months, whereas patients in the control group randomised to receive antihypertensive medications alone had blood pressures that did not vary from baseline (1/0 mmHg). The investigators noted no serious procedure- or device-related events and the overall occurrence of adverse events did not differ between groups. These data were published in the November 2010 issue of *The Lancet*.

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