

Appendix 5. Additional Clinical Data

Additional Regulatory History

Medtronic first evaluated the Symplicity Spyral rRDN catheter under IDE (approved in 2013) in the Symplicity AF study, a multi-center, randomized, feasibility study in 70 subjects with symptomatic drug refractory paroxysmal atrial fibrillation and uncontrolled HTN (b)(4)



Patient Preference Supplement Information

Table 5.1 shows the patient preference study attributes and levels.

Table 5.1. Patient Preference Study Attribute and Levels

Type of Attribute	Attribute	Patient-Facing Attribute Label	Attribute Levels
Mode of administration	Interventional	Minimally invasive surgical procedure to lower blood pressure	Procedure
			No procedure
Mode of administration	Number of oral antihypertensive pills per day	Number of daily pills	No daily pills
			1 pill each day
			2 pills each day
			3 pills each day
Efficacy	Reduction in office systolic BP	Reduction in systolic blood pressure measured in the doctor's office	1-point (1-mmHg) reduction in BP
			5-point (5-mmHg) reduction in BP
			10-point (10-mmHg) reduction in BP
			18-point (18-mmHg) reduction in BP
Duration of effect	Duration of effect	How long the blood pressure reduction from the treatment lasts	1 year
			3 years
			10 years
Safety (oral	Risk of reversible drug side	Risk of drug side effects	None (0 out of 100 people [0%])

Type of Attribute	Attribute	Patient-Facing Attribute Label	Attribute Levels	
antihypertensive medications)	effects such as fatigue/drowsiness or dizziness, frequent urination, swollen ankles, sexual problems, persistent cough, or acute kidney injury due to oral antihypertensive medication	while taking blood pressure pills that may lead to more doctor visits	4 out of 100 people (4%)	
			12 out of 100 people (12%)	
			20 out of 100 people (20%)	
Safety (RDN)	Risk of temporary and reversible pain and/or bruising at the site of vascular access for RDN	Risk of temporary and reversible pain and/or bruising in the upper thigh after the minimally invasive blood pressure procedure (up to 1 month)	None (0 out of 100 people [0%])	
			4 out of 100 people (4%)	
			12 out of 100 people (12%)	
			20 out of 100 people (20%)	
Safety (RDN)	Risk of vascular injury, including narrowing of the artery to the kidney	Risk of injury to blood vessel requiring another surgery (likely minor) within 18 months	<i>Narrow-risk range:</i>	<i>Wide-risk range:</i>
			None (0 out of 100 people [0%])	None (0 out of 100 people [0%])
			1 out of 100 people (1%)	
			5 out of 100 people (5%)	5 out of 100 people (5%)
				20 out of 100 (20%) people

BP = blood pressure; FDA = Food and Drug Administration; HTN = hypertension; RDN = renal denervation; SBP = systolic blood pressure.