

**Medtronic**

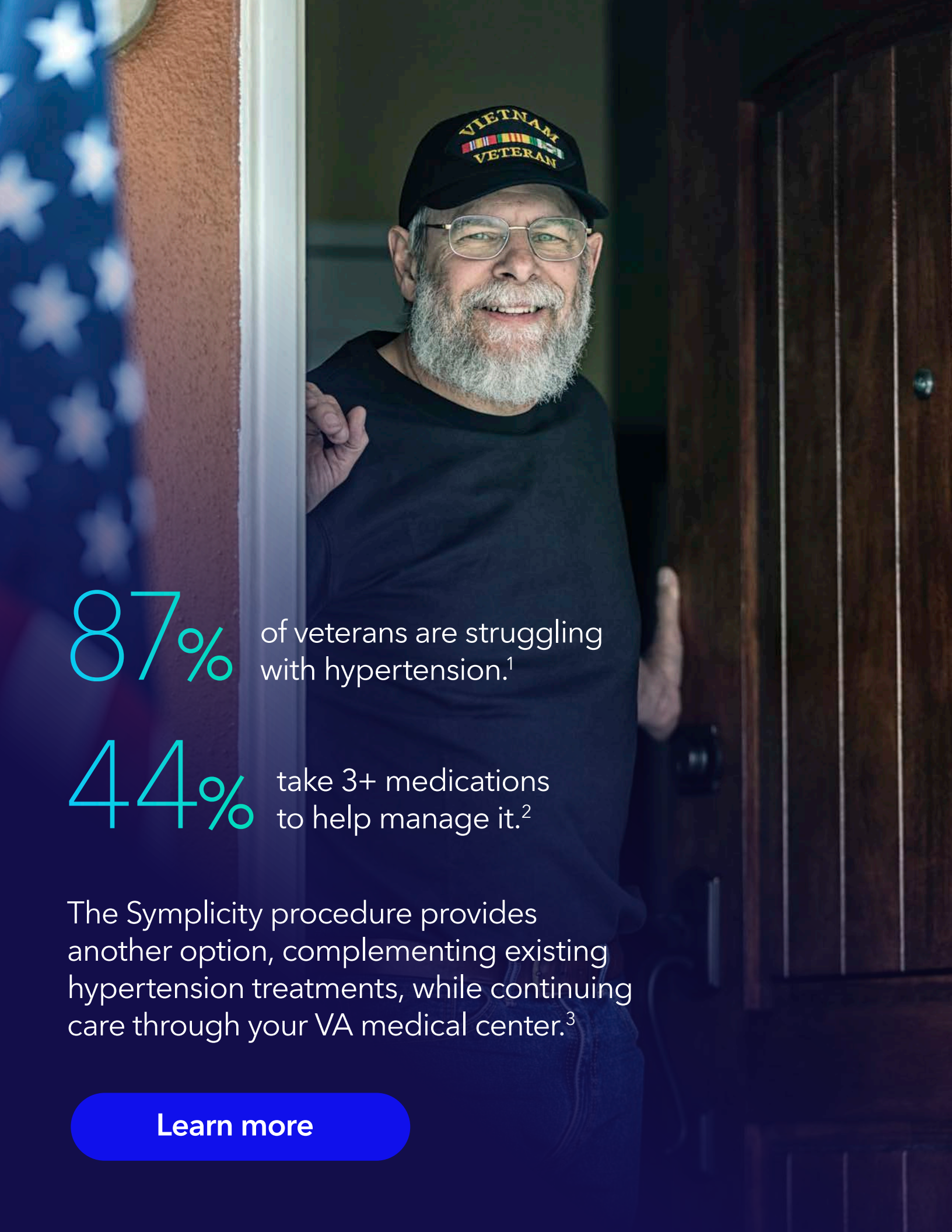
# Introducing a procedure for your veterans with hypertension

The Symplicity™ blood pressure procedure

Lifestyle changes and  
medications have  
defined hypertension  
care – until now.

Results may vary.





87%

of veterans are struggling with hypertension.<sup>1</sup>

44%

take 3+ medications to help manage it.<sup>2</sup>

The Symplicity procedure provides another option, complementing existing hypertension treatments, while continuing care through your VA medical center.<sup>3</sup>

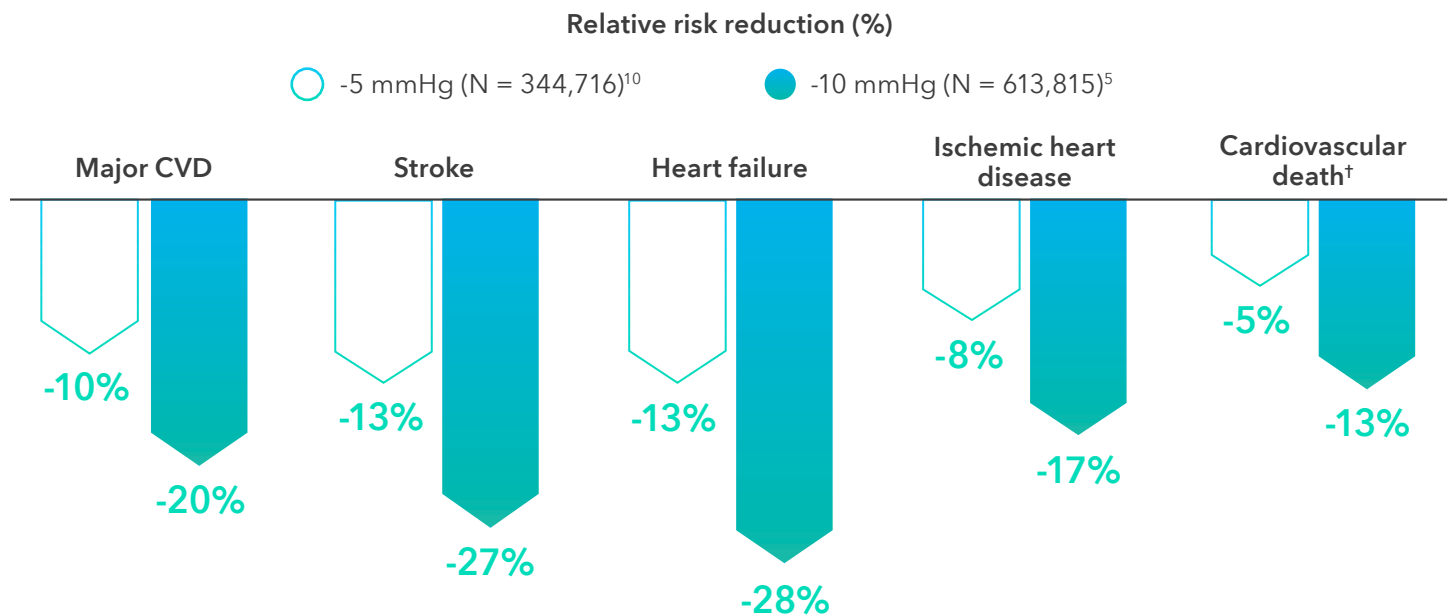
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# A small drop in blood pressure can make a big impact

Hypertension is the leading preventable cause of heart attack, stroke, and death.<sup>4</sup> Reducing office systolic blood pressure (SBP) by just 10 mmHg leads to clinically meaningful reductions in costly cardiovascular events.<sup>1,5,6</sup>

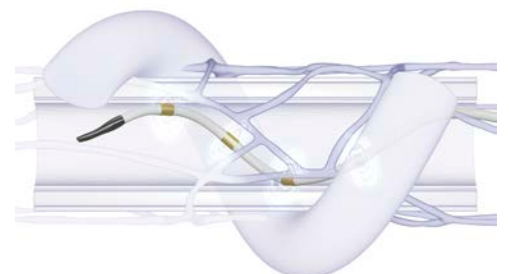
## Clinically meaningful reductions in costly major adverse cardiovascular events (MACE) are a key consideration across the lifetime of care at VA medical centers.<sup>1,6</sup>

Projected reduction in MACE, medication burden, and improved quality of life make the Symplicity procedure a cost-effective, high-value intervention.<sup>5,7-10</sup>



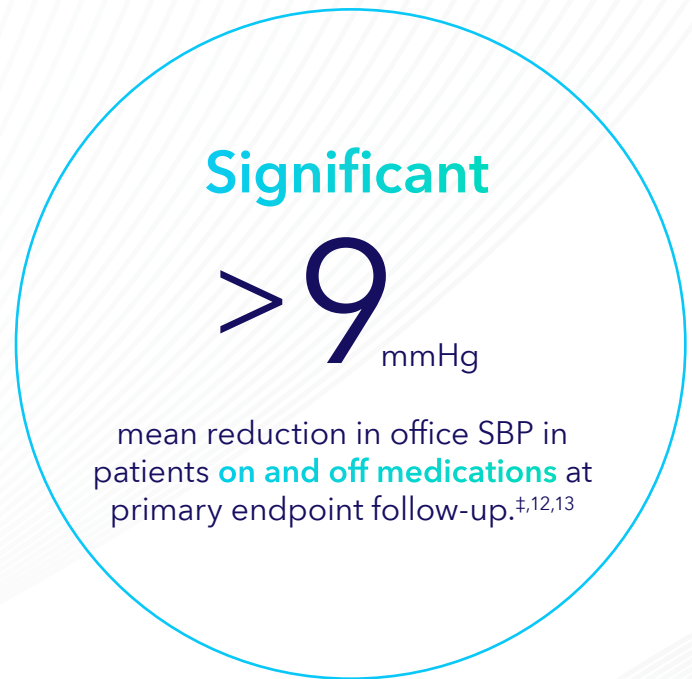
# A single catheter to treat a wide range of vessel sizes

Only the Symplicity Spyril™ renal denervation system, which is used during the Symplicity procedure, can deliver therapy throughout all eligible vessels sized 3-8 mm with a single catheter – including the distal main and branches where the nerves are nearest to the vessel.<sup>‡,3,11</sup>



# Significant, safe, and sustained blood pressure reductions

The Symplicity procedure is proven to reduce blood pressure in the presence and absence of medications in multiple clinical trials and a real-world patient registry.<sup>12-15</sup>



## Randomized, sham-controlled trials

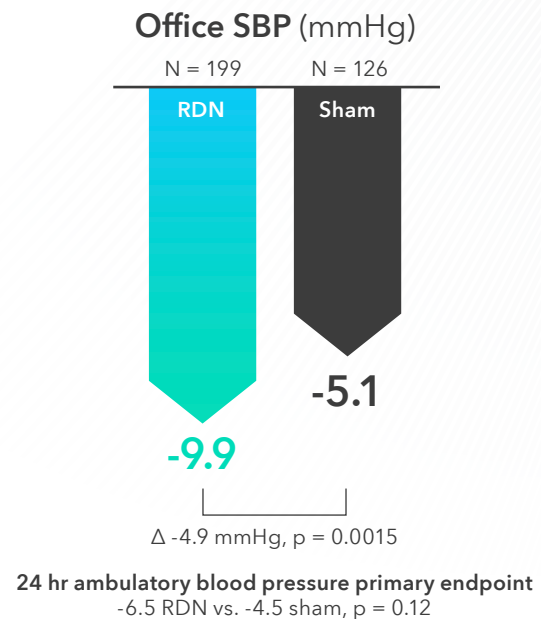
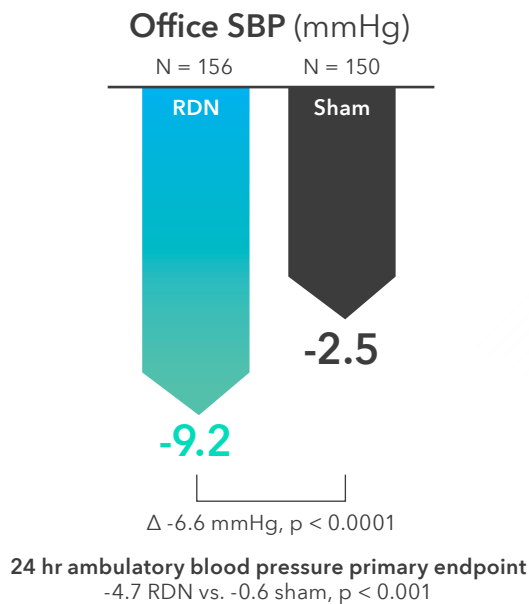
### SPYRAL HTN-OFF MED Pivotal Trial<sup>12</sup>

Significant blood pressure reductions in the **absence of medications** at 3 months.

### SPYRAL HTN-ON MED Trial<sup>13</sup>

Significant blood pressure reductions in the **presence of medications** at 6 months.

Average baseline office SBP for both RDN and sham arms in both trials = 163 mmHg



**20% lower medication burden at six months with the Symplicity procedure.<sup>13</sup>**

(2.9 RDN vs. 3.5 sham,  $p = 0.04$ )

## Safe

Pooled data from SPYRAL  
HTN-ON MED and OFF MED Trials

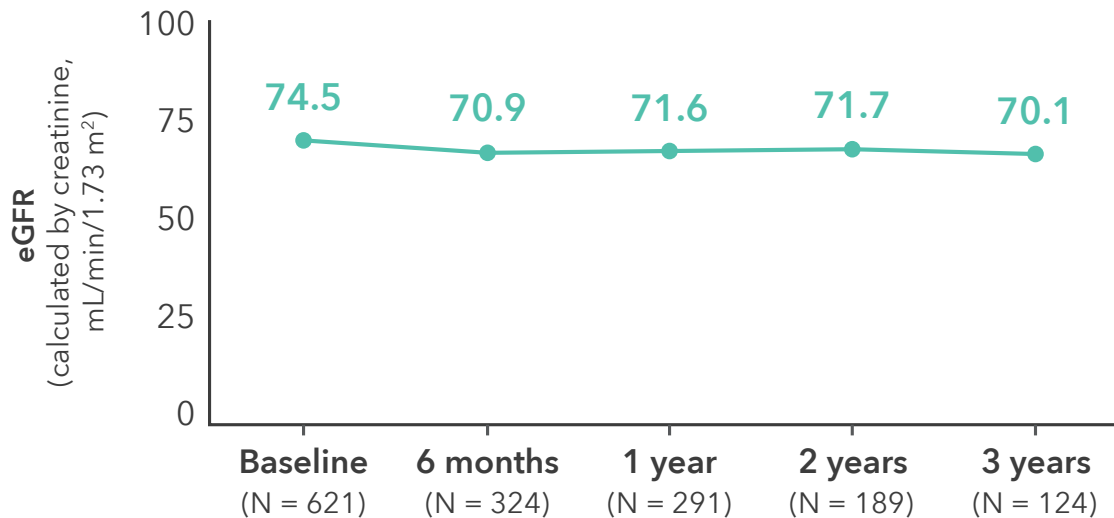
# < 0.4%

major adverse events at  
composite endpoint.<sup>13</sup>  
(N = 253)

No new incidence of renal artery stenosis  
(> 70%) at 6 months.<sup>13</sup>

### Global SYMPLICITY Registry Real-world data

Stable kidney function at three-year follow-up<sup>16</sup>



Excellent safety profile with low adverse  
event rates and stable kidney function.<sup>13,16</sup>

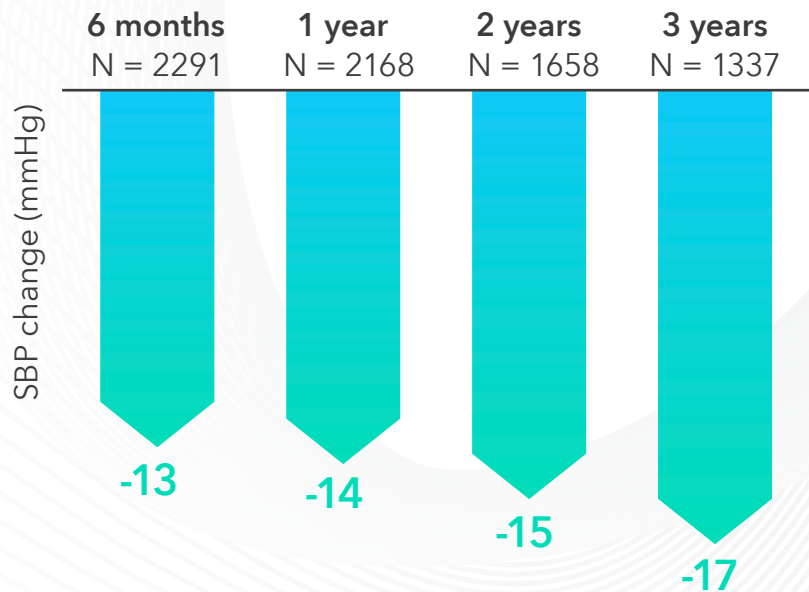
Sustained

17 mmHg

mean reduction in office SBP in real-world patients at 3 years.<sup>§,15</sup>  
(N = 1,337)

Only the Symplicity RDN system has demonstrated sustained blood pressure reductions through three years in over 1,300 real-world patients.<sup>§,15</sup>

Global SYMPLICITY Registry<sup>15</sup>  
Real-world data



Baseline BP  $165 \pm 25$  mmHg  
 $p < 0.001$  at all time points vs. baseline BP

Durable results that amplified over time.<sup>15</sup>

Results may vary.

**Note:** GSR is an active registry. Patients treated < 3 years will be continuously added to follow-up data.

# How the Medtronic VAMC Telehealth program can help

When adopting the Symplicity procedure, hospitals and clinics are typically responsible for establishing processes to support:

## Patient identification



## Patient screening



## Ongoing patient monitoring



Since some of these processes are already incorporated into Medtronic VAMC Telehealth programs, you can spend more time on patient care and less time on program management.

## Which veterans may be right for the Symplicity procedure?

41% of veterans within the Medtronic VAMC Telehealth program are already being monitored for hypertension.<sup>17</sup> Those who may benefit from the Symplicity procedure include:



### **Veterans with uncontrolled hypertension**

Consider those whose blood pressure is not adequately controlled despite lifestyle modifications and medications.



### **Veterans willing to undergo an interventional procedure**

Consider those who opt for the procedure following shared decision making and an attempt at lifestyle modifications and medical therapy.

## Hypertension

is the #1 disease state managed by the VA Telehealth program.<sup>17</sup>

† 13% reduction is in all-cause mortality; -5% is specific to CV death.

‡ May not be indicative of clinical performance.

§ Includes Symplicity Spyral and Flex catheters.

1. Yamada M, Wachsmuth J, Sambharia M, et al. The prevalence and treatment of hypertension in Veterans Health Administration, assessing the impact of the updated clinical guidelines. *J Hypertens*. June 1, 2023;41(6):995-1002.
2. Furmaga EM, Cunningham FE, Cushman WC, et al. National utilization of antihypertensive medications from 2000 to 2006 in the Veterans Health Administration: focus on thiazide diuretics. *J Clin Hypertens (Greenwich)*. October 2008;10(10):770-778.
3. Medtronic Symplicity Spyral multi-electrode renal denervation catheter and Symplicity G3 generator instructions for use.
4. Bundy JD, Mills KT, Chen J., et al. Estimating the Association of the 2017 and 2014 Hypertension Guidelines With Cardiovascular Events and Deaths in US Adults: An Analysis of National Data. *JAMA Cardiol*. 2018 Jul 1;3(7):572-581.
5. Ettehad D, Emdin CA, Kiran A, et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *Lancet*. March 5, 2016;387(10022):957-967.
6. Darkins A, Kendall S, Edmonson E, Young M, Stressel P. Reduced cost and mortality using home telehealth to promote self-management of complex chronic conditions: a retrospective matched cohort study of 4,999 veteran patients. *Telemed J E Health*. January 2015;21(1):70-76.
7. Schmieder RE, Mahfoud F, Mancia G, et al. Clinical event reductions in high-risk patients after renal denervation projected from the global SYMPLICITY registry. *Eur Heart J Qual Care Clin Outcomes*. September 12, 2023;9(6):575-582.
8. Kandzari DE, Cao KN, Ryschon AM, Sharp ASP, Pietzsch JB. Catheter-Based Radiofrequency Renal Denervation in the United States: A Cost-Effectiveness Analysis Based on Contemporary Evidence. *J Soc Cardiovasc Angiogr Interv*. Published online August 13, 2024.
9. Sharp ASP, Cao KN, Esler MD, et al. Cost-effectiveness of catheter-based radiofrequency renal denervation for the treatment of uncontrolled hypertension: an analysis for the UK based on recent clinical evidence. *Eur Heart J Qual Care Clin Outcomes*. Published online January 9, 2024.
10. Rahimi K, Bidel Z, Nazarzadeh M, et al. Pharmacological blood pressure lowering for primary and secondary prevention of cardiovascular disease across different levels of blood pressure: an individual participant-level data meta-analysis. *Lancet*. May 1, 2021;397(10285):1625-1636.
11. Recor Paradise Ultrasound Renal Denervation System Instructions for Use.
12. Böhm M, Kario K, Kandzari DE, et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet*. May 2, 2020;395(10234):1444-1451.
13. Kandzari D, Townsend R, Kario K, et al. Safety and Efficacy of Renal Denervation in Patients Taking Antihypertensive Medications. *J Am Coll Cardiol*. November 7, 2023;82(19):1809-1823.
14. Mahfoud F, Kandzari DE, Kario K, et al. Long-term efficacy and safety of renal denervation in the presence of antihypertensive drugs (SPYRAL HTN-ON MED): a randomised, sham-controlled trial. *Lancet*. April 9, 2022;399(10234):1401-1410.
15. Mahfoud F, et al. Outcomes following radiofrequency renal denervation according to antihypertensive medications: subgroup analysis of the Global SYMPLICITY Registry DEFINE. *EuroPCR* 2023.
16. Schlaich M, et al. Long-term safety and efficacy of renal denervation with the Symplicity Spyral catheter in the Global SYMPLICITY Registry. Presented at American Society of Nephrology Kidney Week, San Diego, CA. November 4-7, 2021.
17. Based on Medtronic Veterans Affairs Medical Center (VAMC) Telehealth program data on file. Accessed October 2024.

## Indications

The Symplicity Spyral™ renal denervation system is indicated to reduce blood pressure as an adjunctive treatment in patients with hypertension in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

## Contraindications

The Symplicity Spyral system is contraindicated in patients with any of the following conditions: • Renal artery diameter < 3mm or > 8mm • Renal artery fibromuscular dysplasia (FMD) • Stented renal artery (<3 months prior to RDN procedure) • Renal artery aneurysm • Renal artery diameter stenosis >50% • Pregnancy • Presence of abnormal kidney (or secreting adrenal) tumor • Iliac/femoral artery stenosis precluding insertion of the catheter.

## Warnings and Precautions

A thorough understanding of the technical principles, clinical applications, and risks associated with vascular access techniques and percutaneous transluminal catheterization in renal arteries is necessary before using this device.

The safety and efficacy of the Symplicity Spyral system has not been established in patients with isolated systolic hypertension or in patients with prior renal artery interventions including renal stents, renal angioplasty, or prior renal denervation. The Symplicity Spyral system has not yet been studied in patients who are breastfeeding, under the age of 18, or with secondary hypertension • Avoid treatment with the Symplicity Spyral™ catheter within 5 mm of any diseased area or stent. • Implantable pacemakers (IPGs) and implantable cardioverter defibrillators (ICDs) or other active implants may be adversely affected by RF ablation. Refer to the implantable device's Instructions for Use. • The patient's heart rate may drop during the ablation procedure. • Proper pain medication should be administered at least 10 min before ablating renal nerves.

## Potential Adverse Events

Potential adverse events associated with use of the renal denervation device or the interventional procedures include, but are not limited to, the following conditions: • Allergic reaction to contrast • Arterial damage, including injury from energy application, dissection, or perforation, • Arterial spasm, or stenosis • Arterio-enteric fistula • AV fistula • Bleeding • Blood clots or embolism • Bruising • Cardiopulmonary arrest • Complications associated with medications commonly utilized during the procedure, such as narcotics, anxiolytics, or other pain or anti-vasospasm medications • Death • Deep vein thrombosis • Edema Electrolyte imbalance • Heart rhythm disturbances, including bradycardia • Hematoma • Hematoma - retroperitoneal • Hematuria • Hypertension • Hypotension (may cause end organ hypoperfusion) • Infection • Kidney damage including renal failure or perforation • Myocardial infarction • Nausea or vomiting • Pain or discomfort • Peripheral ischemia • Pulmonary embolism • Proteinuria • Pseudoaneurysm • Radiocontrast nephropathy • Renal artery aneurysm • Skin burns from failure of the dispersive electrode pad • Stroke • Other potential adverse events that are unforeseen at this time.

Please reference appropriate product *Instructions for Use* and *User Manual* for more information regarding indications, contraindications, warnings, precautions, and potential adverse events.

**CAUTION:** Federal (USA) law restricts this device to sale by or on the order of a physician.

For further information, please call and/or consult Medtronic at 800-633-8766 or the Medtronic website at medtronic.com.

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