Patient referral form

for the Symplicity™ blood pressure procedure

Once completed, share this referral form directly with your Symplicity center or Symplicity proceduralist.

Patient

Name	Date of Birth Month/Day/Year	Phone	Date of Referral Month/Day/Year

Referring Provider

Name	Phone

The Symplicity Spyral™ multi-electrode renal denervation catheter and the Symplicity G3™ renal denervation RF generator are 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.[1]

Patients may benefit if they:

- ☐ **Have uncontrolled hypertension,** where lifestyle modifications and anti-hypertensive medications haven't adequately controlled their blood pressure.
- ☐ **Are willing to undergo an interventional procedure** following shared decision-making and an attempt at lifestyle modifications and medical therapy.

Baseline patient information

Recent office BP _____/_____

Recent home BP _____/_____

Are you aware of:

- ☐ Any drugs that elevate BP†
- ☐ Renal artery stenosis
- ☐ Primary aldosteronism
- ☐ eGFR <45

If you are looking for more information you can contact our practice

Practice name	Physician name	Practice URL	Or you can contact us directly Phone: Fax: Email:

How would you prefer to receive follow-up information for this patient?

☐ EHR notes ☐ Phone ☐ Fax ☐ Other

For more information, visit medtronic.com/SymplicityProcedure

† Amphetamines, antidepressants, atypical antipsychotics, decongestants, herbal supplements, immunosuppressants, oral contraceptives, NSAIDs, recreational drugs, systemic corticosteroids, angiogenesis inhibitor (list is not exhaustive).[2]

[1] Symplicity™ Spyral IFU

[2] AHA/ACC Hypertension Care Guidelines 2017

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Symplicity Spyral™ renal denervation system Brief Statement

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 < 3 mm or > 8 mm • 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.