| Health Technology Review | |
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| **Technology Ref.:** | HTA23063 |
| **Technology Name/Version/Model:** | Symplicity Spyral™ Multi-Electrode Renal Denervation (RDN) System |
| **Approvals by International Bodies:** | The device holds FDA approval and a CE Mark. |
| **Company name:** | Medtronic |
| **Agent in UAE:** | Medtronic META |
| **Email:** | nour.rifai@medtronic.com |

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| **Short Description of the Technology:** | Renal denervation (RDN) is an innovative minimally invasive, device-based, percutaneous procedure designed to lower blood pressure (BP) by ablating overactive renal artery nerves without permanent device implantation. The renal artery nerves are specifically targeted because they lead to the kidneys and help regulate BP, but also, they can become overactive and cause elevated BP. RDN is performed percutaneously by inserting a catheter (connected to a generator) through the femoral artery to the renal artery, using fluoroscopy as a guide. Once inside the renal artery, the electrode delivers radiofrequency (RF) energy to ablate the renal sympathetic nerves within the renal artery wall, reducing sympathetic efferent and sensory afferent signaling to and from the kidneys, hence reducing BP.1<br>The Symplicity Spyral™ RDN system comprises the Spyral™ multi-electrode RDN catheter and the G3™ RF generator. The Symplicity Spyral™ catheter features a unique, spiral and flexible 4-electrode array to generate simultaneous and consistent or selective four-quadrant ablation in an evenly distributed pattern using RF energy delivery. The Symplicity Spyral™ catheter is compatible with a 6 Fr guide catheter and is delivered over a 0.014-inch guide wire via a rapid exchange system. The Symplicity Spyral™ catheter is highly conformable to artery shape and size and accommodates vessel diameters of 3–8 mm – ensuring that a wide range of patients can be treated. Its non-occlusive design ensures the catheter will not obstruct renal blood flow during the procedure. The Symplicity Spyral™ catheter is powered by the Symplicity G3™ RF generator to deliver precisely controlled RF energy according to a programmed algorithm. The Symplicity G3™ generator features a touch screen interface. The Symplicity G3™ generator also uniquely offers physicians control and flexibility with the ability to turn specific electrodes on and off to accommodate different anatomies.2 Additionally, it modulates power delivery in real time via temperature and impedance feedback for each electrode independently to ensure therapy is applied appropriately.2<br>CE Mark for Symplicity Spyral™ Multi-Electrode Catheter and Symplicity G3™ Generator was obtained in October 2013 and it is indicated for the treatment of uncontrolled hypertension. |

| Health Technology Assessment Team Recommendation: | Approve |
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**Summary of Review:**

The technology is a new minimally invasive treatment that aims to reduce blood pressure in people with uncontrolled hypertension. The applicant submitted the papers for the Symplicity Spyral renal denervation (RDN) system. This device is FDA and CE marked. The technology works to Supply precisely controlled and targeted radiofrequency energy to the renal nerves, and this will disrupt the overactive sympathetic signaling between the kidneys and brain to reduce blood pressure, the technology is not widely practiced in the world due to conflicting evidence over its effectiveness.

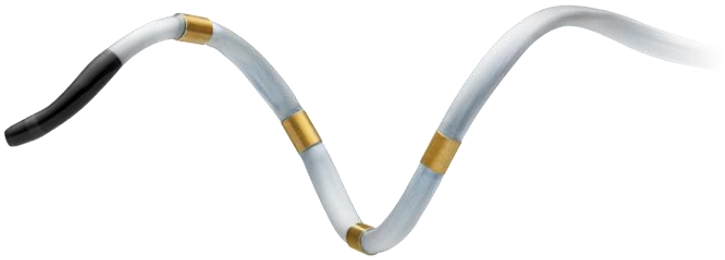
| Advantages | Disadvantages |
|---|---|
| The device is FDA and CE Marked | Renal denervation is an investigational therapy that is not universally approved by regulatory agencies |
| The clinical trial and studies show that the technology have the following benefits:<br>– Complementary to medication<br>– Non-drug intervention<br>– Lower BP, continuously over 24 hrs.<br>– Results durable for ≥ 3 years.<br>– Favorable procedural &long-term safety | The sustainability of the antihypertensive effect of RDN is a relevant question with only limited data available at present. |
| Renal denervation offers an innovative treatment for patients with hypertension that is not well controlled by medication, the treatment can reduce the hypertension medication dosage, or allow for patients to stop medication altogether. | Rare complications of renal denervation include:<br>• Bradycardia (slow heart rate)<br>• Pseudoaneurysm, leaking in the artery that causes a bruise.<br>• Renal artery stenosis (narrowing)<br>• Tears in the renal arteries |
| As a minimally invasive procedure with just a tiny incision, renal denervation involves a short hospital stay and people benefit from a quick recovery with less pain. | As RDN is a relatively new procedure, little is known about its long-term effects. However, it has been shown to be an effective treatment for resistant hypertension. |
| Studies suggest that renal denervation could be an effective adjuvant procedure to optimize medication regimens in treating resistant or refractory hypertension. | Further studies and research required before the routine use of RDN for the control of hypertension. |
| No evidence of device recalls, or safety alerts has been reported. | |

We recommend an **approval of using this technology** for Market entry with the following conditions:

1. The approval of utilizing the Symplicity Spyral™ Multi-Electrode Renal Denervation (RDN) System for the Managment of uncontrolled hypertension.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.

**Moreover,** DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

**Technology Image**



## Population, setting and intended user for Technology "Symplicity Spyral™ Multi-Electrode Renal Denervation (RDN) System."

- **Population/ Intended User**;
  - This treatment is performed in patients suffering from resistant/uncontrolled hypertension.
- **To be performed by**:
  - By interventional cardiologist:
- **Clinical Setting:**
  - Hospitals, special surgery centers
- **Condition of use:**
  - As per Physician instructions
- **Exclusion criteria:**

RDN should be avoided in patients with an unsuitable anatomy of the renal artery/access site or any condition that would increase the risk o