EnligHTN™ Multi-Electrode Renal Denervation System

This device is commercially available for use in select international markets.

A Predictable Pattern in Renal Denervation

The EnligHTN multi-electrode renal denervation system enables cutting-edge renal denervation efficiencies by reducing the number of catheter manipulations needed.

**Product Overview**

**A Breakthrough Technology on Many Points**

The EnligHTN™ multi-electrode renal denervation system enables cutting-edge efficiencies in procedural-based hypertension control by reducing the number of catheter manipulations needed to disrupt the sympathetic nerve network — with speed and placement accuracy. Renal denervation has been demonstrated to effectively reduce systolic blood pressure.

**Fast**

EnligHTN administers a predictable pattern of four ablations with each placement — in 90-second intervals — potentially reducing renal denervation procedure time.

**Efficient**

Unique multi-ablation basket design provides four ablations without readjustment.

**Precise**

Consistent, four-point contact with arterial wall designed to increase procedural accuracy.

**Minimized Exposure**

Minimal catheter repositioning may result in shorter procedure time, reduced contrast and fluoroscopic exposure.

Your Partner in Renal Denervation Treatment

The EnligHTN renal denervation system offers advanced renal artery ablation therapy and is designed to deliver radiofrequency (RF) energy to the renal nerves to achieve targeted denervation. The core system components are the EnligHTN™ RF ablation generator, the EnligHTN™ renal artery ablation catheter and the EnligHTN™ guiding catheter.
References:
1. St. Jude Medical. Data on file
2. St. Jude Medical Instruction for Use, Ablation catheter #100066547, Generator # 100069276.
3. Medtronic Symplicity Instruction for Use

*EnligHTN™ is not indicated for reduced exposure time.

Technical Specifications

EnligHTN Renal Artery Ablation Catheter

Specifications

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Specification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Catheter Length</td>
<td>115 cm</td>
</tr>
<tr>
<td>Guiding Catheter Compatibility</td>
<td>8 F ID (2.2 mm)</td>
</tr>
<tr>
<td>Electrode Basket length</td>
<td>Small: 16 mm</td>
</tr>
<tr>
<td></td>
<td>Large: 18 mm</td>
</tr>
<tr>
<td>Expanded Basket Size</td>
<td>Small: 6 mm</td>
</tr>
<tr>
<td></td>
<td>Large: 8 mm</td>
</tr>
<tr>
<td>Recommended Basket Sizing for associated internal vessel diameter</td>
<td>Small: 4-6 mm</td>
</tr>
<tr>
<td></td>
<td>Large: 5.5 mm – 8 mm</td>
</tr>
</tbody>
</table>

Reorder Information

EnligHTN Renal Denervation System

EnligHTN Renal Artery Ablation Catheter - small  ENL-SM-01
EnligHTN Renal Artery Ablation Catheter - large  ENL-LG-01

EnligHTN RF Ablation Generator

Specifications

<table>
<thead>
<tr>
<th>General Default Settings</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Power</td>
<td>6 Watt</td>
</tr>
<tr>
<td>Temperature</td>
<td>75° C</td>
</tr>
<tr>
<td>Impedance</td>
<td>400 Ω</td>
</tr>
<tr>
<td>Time</td>
<td>90 seconds per electrode</td>
</tr>
<tr>
<td>Dimensions</td>
<td>362 mm x 153 mm x 317 mm (W x H x D without handle)</td>
</tr>
<tr>
<td>Weight</td>
<td>9.75 kg</td>
</tr>
<tr>
<td>Temperature Monitoring</td>
<td>4-channel independent and simultaneous display</td>
</tr>
</tbody>
</table>

Components:
The following system components are provided with the generator

EnligHTN Power Cable
1641 Connector Cable (Reusable cables to connect to the ablation catheter with the generator)

The following system components are provided separately
EnligHTN Renal Artery Ablation Catheter
EnligHTN Guiding Catheter
Patient Return Electrode

Reorder Information
EnligHTN Renal Denervation System
EnligHTN RF Ablation Generator

EnligHTN Guiding Catheter
(Coming Soon)

Specifications
Package includes one 55 cm RDC-21 guiding catheter and one dilator
Inner Diameter (ID) 0.088”
Compatible with commonly used 8 F introducer sheaths
RDC-21 tip
55 cm length
Radiopaque marker band

Reorder Information
EnligHTN Renal Denervation System
EnligHTN Guiding Catheter

EnligHTN 1641 Connector Cable

Reorder Information
EnligHTN Renal Denervation System
EnligHTN 1641 Connector cable

Patient Return Electrode

Reorder Information
EnligHTN Renal Denervation System
Patient Return Electrode

EnligHTN Power Cable
How it Works

Predictable Pattern. Repeatable Results

The multi-electrode catheter delivers a symmetrical ablation pattern with minimal catheter manipulations using low-level radiofrequency energy for renal denervation through a percutaneous vascular access site. The EnligHTN™ RF ablation generator activates each electrode sequentially for 90 seconds for a total treatment time of 360 seconds per basket activation.

Introducing EnligHTN™ Multi-Electrode Renal Denervation System

Video Length: 5:18

The Benefits of Multi-Electrode Ablation

1. Unique basket design reduces variability. Consistent placement of ablation sets enables repeatable results, minimal manipulations with the potential to save time and leave less room for error.

The Rewards of a predictable pattern

The EnligHTN™ system delivers a repeatable ablation pattern using four evenly spaced electrodes for fast, precise renal denervation. Multi-electrode basket requires minimal adjustments and may lead to a faster renal denervation procedure. Less procedure time may enable workflow and cost efficiencies. The EnligHTN™ RF generator uses a proprietary temperature-controlled algorithm to develop transmural lesions for effective denervation.1,2

References:
2. St. Jude Medical Instruction for Use, Ablation Catheter #100066547, Generator # 100069276.
3. Medtronic Symplicity Instruction for Use.

Clinical Data

St. Jude Medical: Further Evaluating the Use of Ablation Technology for Resistant Hypertension

With a history of expertise in ablation devices and tools, St. Jude Medical is conducting research to evaluate a new approach to renal denervation.

EnligHTN: Ablation Induced Renal Sympathetic Denervation.

The objective of this feasibility study is to evaluate the safety and efficacy of the St. Jude Medical EnligHTN renal denervation system in treatment of patients with resistant hypertension (see chart below for study design).
References:

1. ClinicalTrials.gov Identifier NCT01438229