

# EnligHTN™

## Multi-Electrode Renal Denervation System RF Ablation Generator

**Indications for Use:** The EnligHTN RF ablation generator is intended to deliver RF energy to the EnligHTN renal artery ablation catheter.

### PRODUCT BENEFITS

- The touch-screen RF ablation generator is a component of the EnligHTN renal denervation system and facilitates control and monitoring of the ablation process
- Temperature-controlled system with four independent monitoring channels
- Pre-programmed default settings for use with the EnligHTN renal artery ablation catheter
- Proprietary algorithm designed to produce consistent, transmural renal artery ablations
- Automatic safety shutoff at ablation completion and in the event temperatures or impedance exceed the pre-set or safety limits
- Ability to selectively disable EnligHTN ablation electrodes if desired
- Report summary of the procedure available via USB download. It is not necessary to ablate both arteries to get a report

### TECHNICAL SPECIFICATIONS

- Default settings:
  - Power: 8 Watt (maximum per electrode)
  - Temperature: 70°C
  - Impedance: 100 Ω to 400 Ω
  - Time: 60 seconds (all enabled electrodes activated simultaneously)
  - During ablation, real-time values for these parameters are displayed simultaneously
  - Operating Mode: Temperature Controlled
- Temperature Monitoring: 4-channel independent and simultaneous display
- Automatic safety shutoff:
  - If temperature exceeds 75°C for 3 seconds,
  - If impedance falls below 100 Ω or exceeds 400 Ω, or
  - If generator detects unexpected rise in temp on a deactivated electrode, the system will shut off all electrodes
- Dimensions: 331 mm x 331 mm x 96 mm (W x H x D)
- Weight: 7 kg

### SYSTEM COMPONENTS

The following system components are provided with the generator:

COMPONENT/REORDER NUMBER	DESCRIPTION
EnligHTN Power Cord, reorder number ENL-PC-02	Medical-grade power supply approved by international safety agencies. This power supply can be used for various line voltages and frequencies without any modifications. Replacement power cables may be ordered separately.
EnligHTN Footswitch, reorder number ENL-FP-01	The EnligHTN Footswitch is used to activate or deactivate the EnligHTN RF Ablation Generator.

The following system components are provided separately:

COMPONENT/REORDER NUMBER	DESCRIPTION
EnligHTN Renal Artery Ablation Catheter, reorder number ENL-SM-01 or ENL-LG-01	Ablation catheter required for use with the EnligHTN RF ablation generator. See the EnligHTN renal artery ablation catheter Instructions for Use for product details.
EnligHTN Guiding Catheter, reorder number ENL-8F55	Guiding catheter facilitates percutaneous introduction of the EnligHTN renal artery ablation catheter.
Patient Return Electrode, reorder number RETURN-02	Patient return electrodes used with the EnligHTN renal denervation system must be IEC 60601-2-2 compliant. Replacement patient return electrodes must be ordered separately.
1641A Electrophysiology Cable (autoclavable), reorder number ENL-CC-02	Reusable cables to connect the ablation catheter with the adapter cable. See the ENL-CC-02 Electrophysiology Cable Instructions for Use for resterilization instructions. Replacement connector cables may be ordered separately.
Adapter Cable, reorder number ENL-ADAPT	Reusable adapter cable to connect the electrophysiology cable with the generator. Replacement connector cables may be ordered separately.
Banded bag (Sterile Drape), reorder number DRAPE-02	The sterile drape provides a sterile cover for the RF generator touchscreen while allowing adequate ventilation for the back side of the RF generator” under description.
EnligHTN Generator Mounting Pole, reorder number POLE-02	The mounting pole supports positioning and placement of the RF generator during treatment.



# Ordering Information

## EnligHTN Renal Denervation System

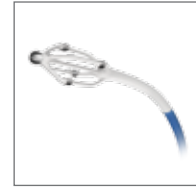
Reorder Number	Product Name
ENL-GEN2	EnligHTN RF Ablation Generator
ENL-LG-01	EnligHTN Renal Artery Ablation Catheter - large
ENL-SM-01	EnligHTN Renal Artery Ablation Catheter - small
ENL-8F55	EnligHTN Guiding Catheter

## EnligHTN Renal Denervation System Accessories

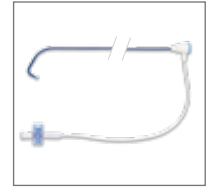
ENL-CC-02	EnligHTN 1641A Electrophysiology Cable (autoclavable)
ENL-ADAPT	EnligHTN Adapter Cable
RETURN-02	Patient Return Electrode (5 packs)
POLE-02	Generator Mounting Pole for EnligHTN Generator
ENL-FP-01	EnligHTN Foot pedal- replacement
DRAPE-02	EnligHTN RF Generator Sterile Drape
ENL-PC-02	EnligHTN Power Cord - replacement



EnligHTN RF Ablation Generator



EnligHTN Renal Artery Ablation Catheter



EnligHTN Guiding Catheter

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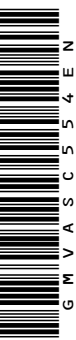
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Product referenced is approved for CE Mark.

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