

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 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 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

TECHNICAL SPECIFICATIONS

- Default settings:
 - Power: 6 Watt
 - Temperature: 75°C
 - Impedance: 400 Ω
 - Time: 90 seconds per electrode
 - During ablation, real-time values for these parameters are displayed on each channel
 - Operating Mode: Temperature Controlled
 - Temperature Monitoring: 4-channel independent and simultaneous display
 - Automatic safety shutoff when:
 - The temperature exceeds 80°C,
 - The temperature exceeds the setting by more than 5°C for greater than 3 seconds, or
 - The measured impedance falls below 50 Ω or exceeds 400 Ω
- Dimensions: 362 mm x 153 mm x 317 mm (W x H x D without handle)
- Weight: 9.75 kg

SYSTEM COMPONENTS

THE FOLLOWING SYSTEM COMPONENTS ARE PROVIDED WITH THE GENERATOR:

COMPONENT/REORDER NUMBER	DESCRIPTION
(1) EnligHTN Power Cable, reorder number ENL-PC-01	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.
(1) 1641 Connector Cable, reorder number ENL-CC-01	Reusable cables to connect the ablation catheter with the generator. See the ENL-CC-01 Connector Cable Instructions for Use for resterilization instructions. Replacement connector cables may be ordered separately.

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 PREP-01	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.



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Ordering Information

EnligHTN Renal Denervation System

Reorder Number	Product Name
ENL-T115	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
ENL-CC-01	EnligHTN 1641 Connector Cable
PREP-01	Patient Return Electrode
ENL-PC-01	EnligHTN Power Cable - replacement

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Product referenced is approved for CE Mark.

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