

The Symplicity Spyral™ catheter is built on the proven safety and superiority of the Symplicity™ renal denervation platform^{1,2}

- Short ablation and procedure times, single 60-second ablation per artery

- Single-catheter solution, naturally conforms to a wide range of artery shapes and sizes

- Exceptional deliverability, 6 F guidewire-compatible using 0.014" guidewire and rapid exchange system

- Nonocclusive, no need for cooling

- Proven Symplicity™ helical ablation pattern



Symplicity Spyral catheter

Symplicity Spyral™

MULTI-ELECTRODE RENAL DENERVATION CATHETER

20 pirkimo dalis. Inkstų arterijų denervacijos kateteris medikamentiniam gydymui atspariai hipertenzijai gydyti.



Symplicity Spyral™

MULTI-ELECTRODE RENAL DENERVATION CATHETER

Perfect Simplicity

Symplicity renal denervation system components

DESCRIPTIONS

- Symplicity Spyral multi-electrode renal denervation catheter: single-use RDN catheter
Designed for use only with the Symplicity G3™ generator
- Symplicity G3 renal denervation RF generator: reusable RF generator
Designed for use with the Symplicity Spyral and Symplicity Flex catheters
Includes geography-specific electrical cord and foot switch for activation
- Symplicity G3 generator component; cart
- Foot switch: used to activate generator
- Power cable: supplies power to generator unit

Ordering information

CATALOG NUMBER	PRODUCT
RDN016	Symplicity Spyral catheter
RDN017	Symplicity G3 generator (Each includes one foot switch and power cable.)
RDN019	Symplicity G3 generator component; cart
RDN012	Replacement foot switch
PRT075-XX	Replacement power cable (country-specific) (Contact Medtronic representative for catalog number.)
THND190S	Thunder™ guidewire

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www.medtronicRDN.com

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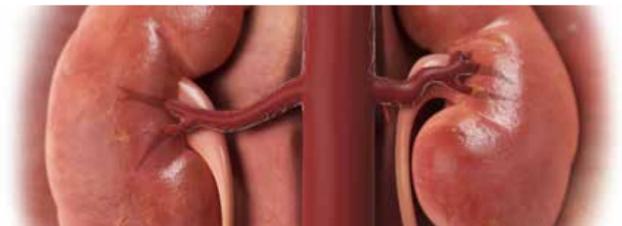
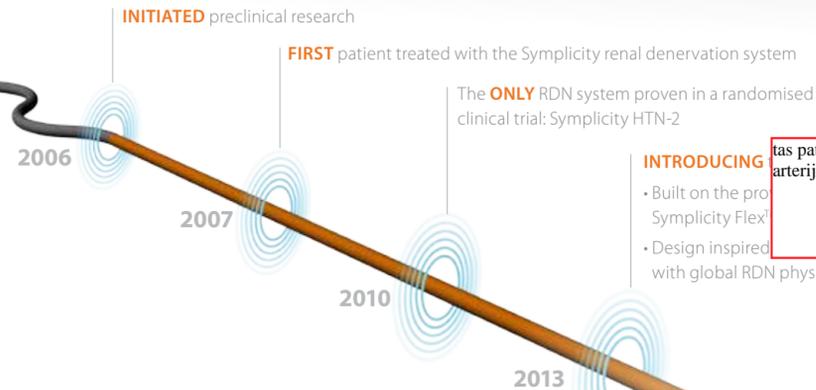
¹Symplicity HTN-1 Investigators. *Hypertension*. 2011;57:911-917.
²Symplicity HTN-2 Investigators. *The Lancet*. 2010;376:1903-1909.

Transforming the treatment of hypertension

The Symplicity™ renal denervation system consists of a catheter and generator that work in concert to deliver the optimal radiofrequency (RF) energy required to disable sympathetic nerves within the renal arteries. Disabling renal nerves reduces sympathetic nerve drive, resulting in a significant and sustainable reduction in blood pressure. The Symplicity renal denervation system has been proven safe with consistently significant blood pressure reductions.^{1,2}

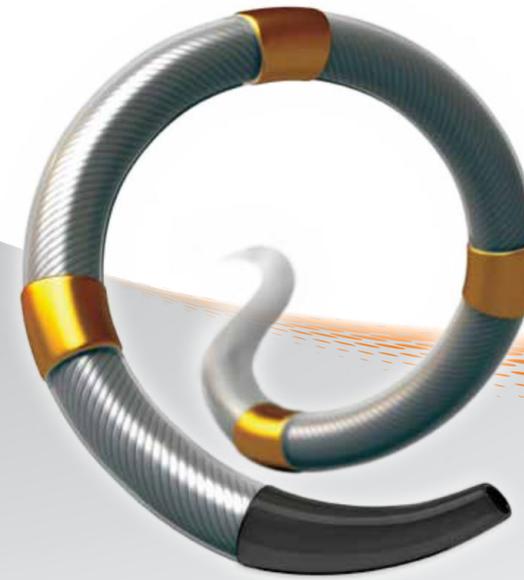
Inkstų denervavimo sistema „Symplicity™“ sudaro kateteris ir generatorius, kurie veikia kartu. Veikimo principas: nervinių skaidulų destrukcija inkstų arterijų sienelėse radiodažninės abliacijos būdu, siekiant nutraukti simpatinės nervų sistemos padėjusią įtaką širdies ir kraujagyslių sistemai. Inkstų nervų išjungimas sumažina simpatinį nervų potraukį, todėl stebimas tvarus ir ryškus kraujospūdžio sumažėjimas.

Medtronic—Pioneering renal denervation (RDN) for treatment-resistant hypertension



Symplicity Spyral™

MULTI-ELECTRODE RENAL DENERVATION CATHETER



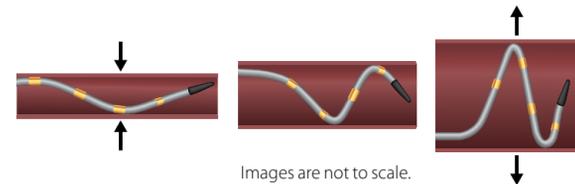
Short ablation and procedure times

- Single 60-second ablation per artery
- Four electrodes deliver energy simultaneously
- Less patient discomfort



Single-catheter solution

- No need for multiple catheters per procedure
- A self-expanding helical design conforms to a wide range of artery shapes and sizes, 3 mm to 8 mm in diameter



Exceptional deliverability

- 6 F guide-compatible, lowering the risk of access-site complications
- Delivery over standard 0.014" nonhydrophilic guidewire with rapid exchange system



Symplicity G3™

RENAL DENERVATION RF GENERATOR

Symplicity G3™ generator algorithm designed for patient safety and clinical efficacy

- Touchscreen interface allows for customisation of electrodes activated
- Fully visible electrode monitoring



The Symplicity™ RDN ablation signature

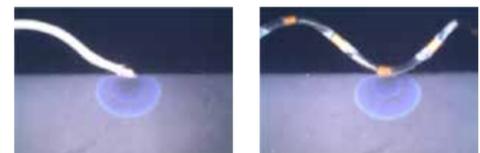
- Consistent helical ablation pattern between Symplicity Flex and Symplicity Spyral catheters³
- Consistent lesion characteristics between Symplicity Flex and Symplicity Spyral catheters³
- Symplicity™ RDN algorithms proven safe in thousands of patients



Symplicity Flex catheter ablation pattern



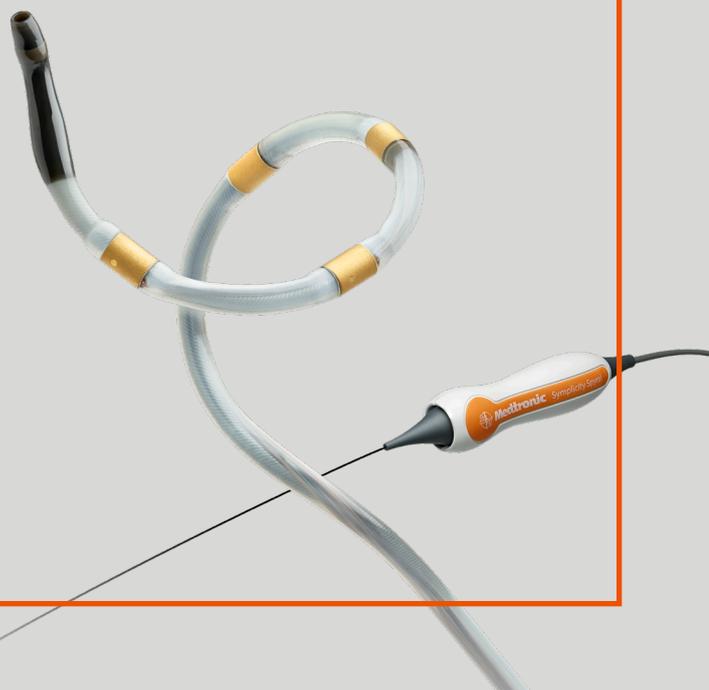
Symplicity Spyral catheter ablation pattern



³Preclinical data. May not be indicative of clinical performance.

¹ Symplicity HTN-1 Investigators. *Hypertension*. 2011;57:911-917.
² Symplicity HTN-2 Investigators. *The Lancet*. 2010;376:1903-1909.

YOU SAW THE
FUTURE OF RENAL
DENERVATION.
**TOGETHER WE'RE
MAKING IT HAPPEN.**



THE PERFORMANCE YOU EXPECT.
THE PROOF YOU DEMAND.
THE PARTNERSHIP YOU NEED.

Symplicity Spyril™ Multi-Electrode Renal Denervation Catheter
Symplicity G3™ Renal Denervation RF Generator

Medtronic

TRANSFORMING HYPERTENSION TREATMENT

Many interventionalists have long believed renal denervation (RDN) could change hypertension treatment. Clinical evidence now shows that belief was justified.^{1,2}

Trust the Medtronic Renal Denervation system to:

- Deliver safety and efficacy backed by clinical and real-world data^{1,2,3}
- Reduce blood pressure regardless of a patient's baseline medication burden^{1,3}
- Provide "always on" benefits, all day and all night^{3,4}





PROVEN PERFORMANCE

- Lowers blood pressure in a clinically meaningful way^{1,2,3}
- Clinical data from the SPYRAL OFF MED Pivotal trial show that RDN had statistically superior blood pressure reductions compared to sham at three months^{3*}
- Consistent, repeatable, four-quadrant ablation⁵
- Zero device- or procedure-related major adverse events through three months in the RDN treatment arm of the Pivotal trial³



UNPARALLELED DATA

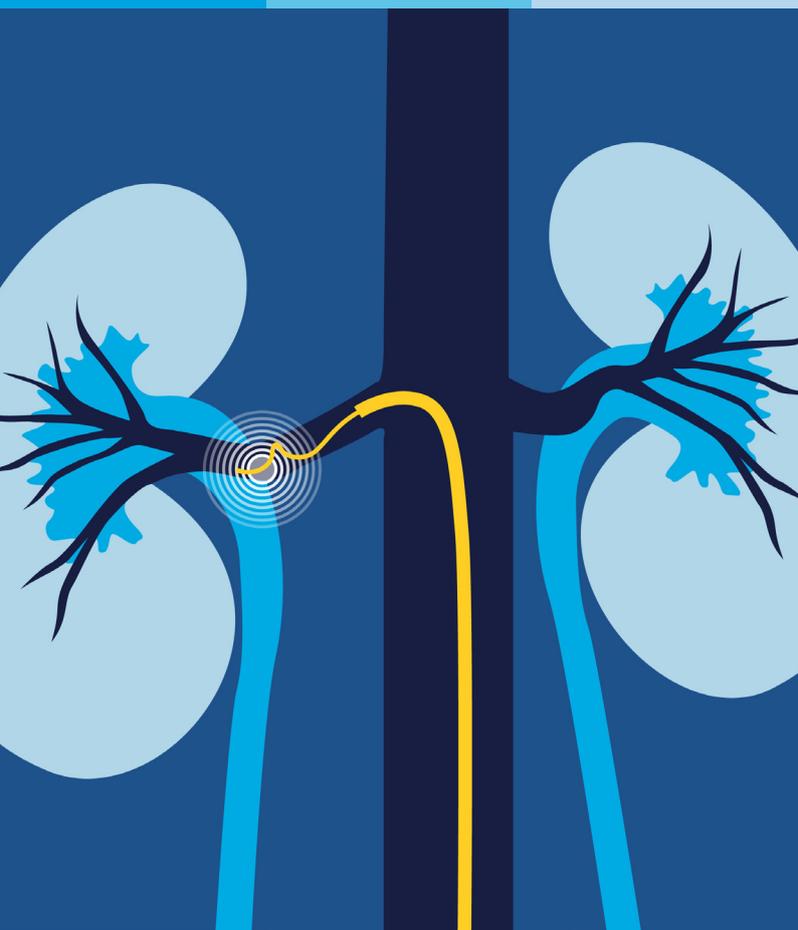
- Supported by three randomised, sham-controlled trials that demonstrated safety and efficacy^{1,6}
- More published findings and patient-years of follow-up than any other RDN technology⁷
- Unique GSR observational study tracking long-term outcomes for up to 3,000 patients²

Terapijos efektyvumo įrodymai. Publikuotos multicentrinės, prospektyvios, randomizuotos studijos, įrodančios poveikio efektą. Stebėti ilgalaikiai rezultatai su daugiau nei 3000 pacientų.



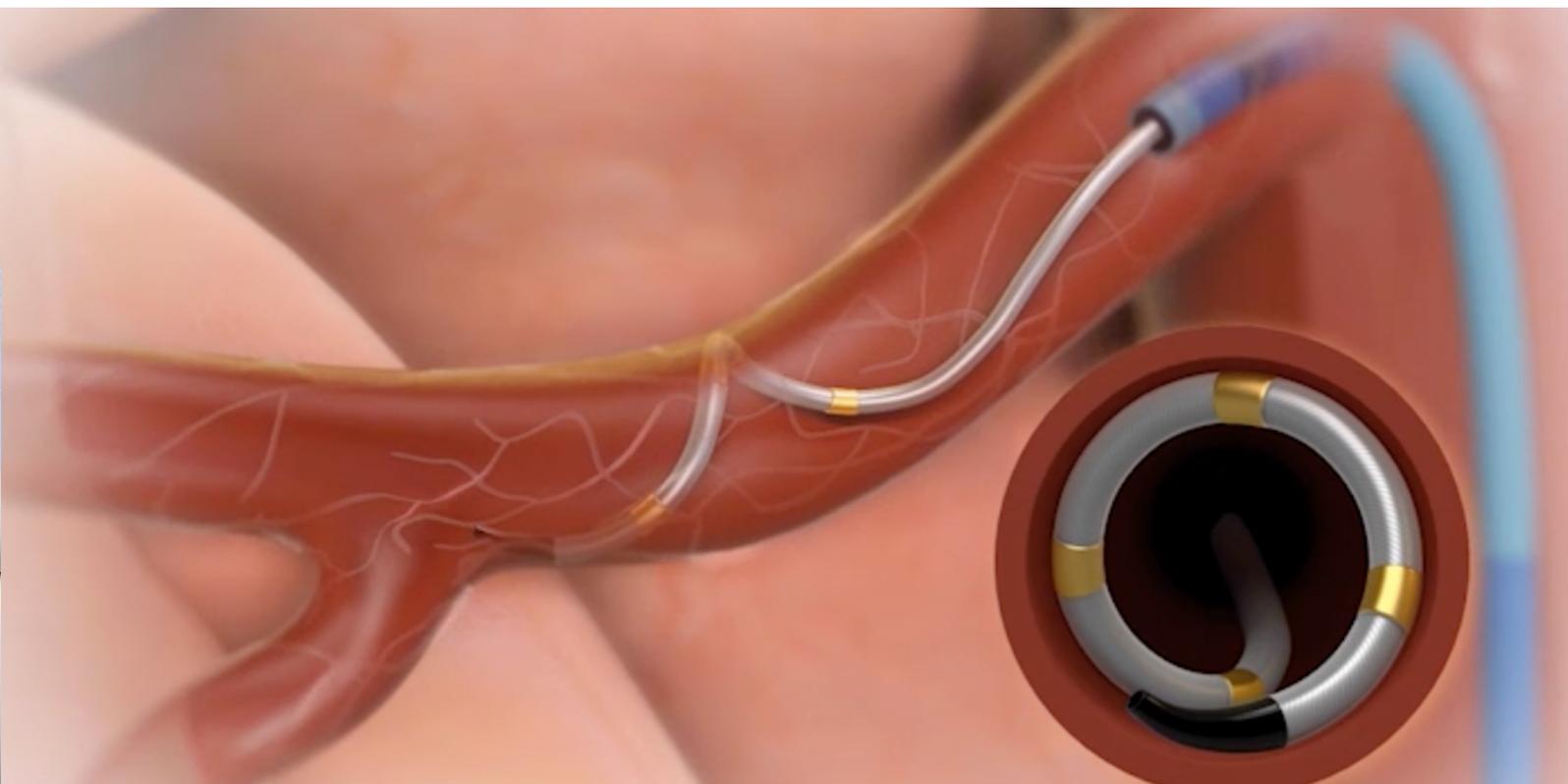
PARTNERSHIP OPPORTUNITIES

- Allows clinicians to align with an industry leader that has a proven legacy of success
- Provides access to best-in-class training and case support



SYMPPLICITY SPYRAL™

MULTI-ELECTRODE RENAL DENERVATION CATHETER



The Symplicity Spyral™ catheter positions electrodes to generate 360 degrees of ablation. It can treat the distal branches to maximize the probability of complete denervation.

- Reaches the main artery, branches, and accessory vessels^{5,6,7}
- Treats a broad diameter range (3–8mm) to accommodate a wide range of patients^{5,6,7}
- Treats distal branches where nerves are close to the artery lumen⁸
- Features a helical (spiral) electrode pattern that ablates all four quadrants simultaneously
- Compatible with 6F guide catheters

tas pats kateteris turi tikti renalinėms arterijoms, kurių diametras nuo 3 iki 8 mm

SYMPPLICITY G3™

RENAL DENERVATION RF GENERATOR

The Symplicity G3™ Renal Denervation RF Generator works with the Symplicity Spyral™ catheter to deliver controlled radio frequency (RF) energy during renal denervation.

- Delivers precisely controlled RF energy according to a programmed algorithm⁷
- Allows electrode selection for treatment delivery⁷
- Assesses temperature and impedance feedback independently for each electrode⁷
- Algorithm responds to apply therapy appropriately⁷



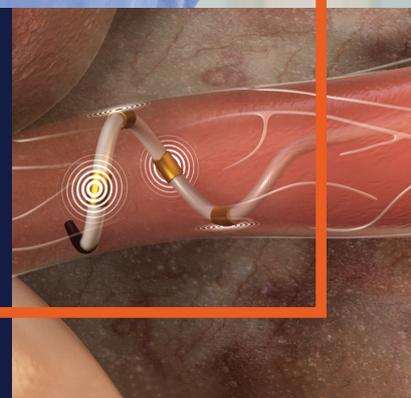
-Abliacijos proceso valdymas – pilnai automatizuotas.
-Stebimi parametrai procedūros metu – varža ir temperatūra kateterio ir arterijos sienelės kontakto vietoje.
-Pavojaus pranešimai galimai pavojingais ar neefektyviais abliacijos proceso atvejais – būtini (varžos, temperatūros ir kitų parametų ribų viršijimas).



SYMPPLICITY G3™ RENAL DENERVATION RF GENERATOR

TRUST PROVEN TECHNOLOGY^{1,2,3}

The Symplicity G3™ generator works with the Symplicity Spyril™ catheter to deliver controlled radio frequency (RF) energy during renal denervation. The Medtronic Renal Denervation system has more real-world data, more published findings and more patient-years in follow-up than any other RDN device.³



TECHNICAL SPECIFICATION

During RDN treatment, the Symplicity G3™ generator delivers precisely controlled RF energy according to a programmed algorithm.⁴ The generator assesses temperature and impedance feedback independently for each electrode.⁴ If a treatment parameter moves out of its pre-defined range the algorithm responds appropriately.⁴

RDN proceso metu „Symplicity G3™“ generatorius tiekia tiksliai kontroliuojamą RF energiją pagal užprogramuotą algoritmą. Generatorius įvertina temperatūrą ir varžą, gaunamas grįžtamasis ryšys nepriklausomai nuo kiekvieno elektrodo. Pavojaus pranešimai galimai pavojingais ar neefektyviais abliacijos proceso atvejais vyksta iš karto (varžos, temperatūros ir kitų parametų ribų viršijimas).

COMPONENTS



- Symplicity G3™ renal denervation RF generator
- Foot switch (optional)
- Mobile cart (optional)

MATERIALS

GENERATOR	<ul style="list-style-type: none">Painted and nonpainted sheet metalPolycarbonate/acrylonitrile butadiene styrene blend (external covers)Thermoplastic elastomer (cord management strap)Glass (projected capacitance touchscreen)
FOOT SWITCH	<ul style="list-style-type: none">Painted sheet metalPVC (foot switch hose)Thermoplastics
CART	<ul style="list-style-type: none">ABS plasticPainted aluminium

CABLE

AC POWER CABLE	NEMA 5-15	<3.1 m
ALTERNATE AC POWER CABLES	CEE 7/7	2.5 m
	SANS 164-1	2.5 m
	AS/NZS 3112	2.5 m
	BS 1363	2.5 m
	CEI 23-50 S11	2.5 m
	SEV 1011	2.5 m
	SI-32	2.5 m
	DK-2-8A	2.5 m

SIZES

GENERATOR	<ul style="list-style-type: none">Dimensions: 29.9 cm x 36.7 cm x 18.9 cm (11.8 in x 14.5 in x 7.5 in)Weight: <9kg (<19.8lbs) excluding accessoriesDisplay screen: 26.4 cm (10.4 in)
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PERFORMANCE

GENERATOR	<ul style="list-style-type: none">RF power output to a maximum of 6.5 W per electrode (26 W total)Delivers energy if measured impedance is ≥ 175 ohms and < 1200 ohmsInput power of 100 to 240 V ~, 50 to 60 Hz universal power supply
STERILISATION PROCESS	<ul style="list-style-type: none">Generator shall not be sterilised
LATEX	<ul style="list-style-type: none">Not present
PHTHALATE	<ul style="list-style-type: none">Not present
ANIMAL SUBSTANCE	<ul style="list-style-type: none">Not present

Refer to the *Instructions for Use (IFU)* and *User Manual* for full product information.

References:

- Townsend RR, et al. *Lancet*. 2017; 390:2160-2170
- Kandzari DE, et al. *Lancet*. 2018;391:2346-2355
- Mahfoud F, et al. Three-year Safety and Efficacy in the Global Symplcity Registry: Subgroup Analyses. EuroPCR 2019
- Medtronic data on file

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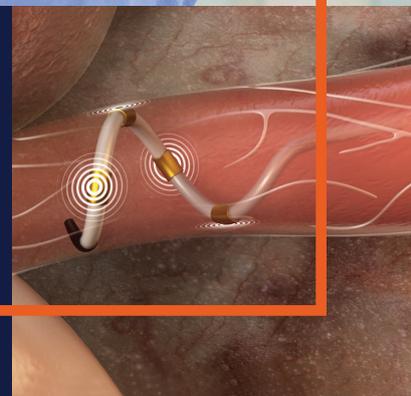
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SYMPPLICITY SPYRAL™ MULTI-ELECTRODE RENAL DENERVATION CATHETER

Inkstų arterijų denervacijos kateteris medikamentiniam gydymui atspariai hipertenzijai gydyti.

TRUST PROVEN TECHNOLOGY^{1,2,3}

The Symplicity Spyral™ multi-electrode renal denervation (RDN) catheter is part of the Medtronic Renal Denervation system, which has more real-world data, more published findings and more patient-years in follow-up than any other RDN device.³



TECHNICAL SPECIFICATION

The Symplicity Spyral™ catheter denervates the renal artery using radio frequency (RF) energy. Each catheter has a distal self-expanding array of four electrodes and is advanced to the treatment site by tracking over a 0.014" guidewire. When the Symplicity Spyral™ catheter reaches the treatment location, the guidewire is retracted and the array deploys in a unique helical (spiral) configuration that automatically positions the electrodes to generate 360 degrees of ablation through the artery wall.

Symplicity Spyral™ inkstų denervacijos kateteris inkstų arteriją denervuoja radijo dažnio (RF) energija. Kiekvienas kateteris turi distalinį savaime besiplečiantį keturių tolygiai išdėstytų elektrodų masyvą, dirbančių sinchronizuotai; Tiksliai ir lengvai valdoma kateterio galiuko rotacija (360° kampu) bei automatiškai dozuoja slėgio į arterijos sienelę jėga, leidžiančios optimaliai parinkti denervacijos taškus arterijų sienelėse.

COMPONENTS



- Catheter: 1.5 m length
- Electrodes: 4 RF monopolar, gold, radio-opaque, 1.5 mm length
- Thermocouple: T-type
- Tip marker: platinum/iridium alloy
- Handle: injection moulded
- Integrated extension cable for connection with the Symplicity G3™ renal denervation RF generator

4 tolygiai išdėstyti elektrodai.
Minkštas atraumatiškas kateterio
galiukas

MATERIALS

HANDLE	▪ ABS, thermoplastic elastomer overmould
CATHETER	▪ Proximal shaft: polyethylene block amide laminated over stainless steel ▪ Intermediate tubing: polyether block amide with braided stainless steel ▪ Distal electrode array jacket: thermoplastic urethane ▪ Tip: thermoplastic ▪ Guidewire lumen: high-density polyethylene liner ▪ Spiral shaping element: nickel/titanium ▪ Guidewire loading tool: thermoplastic
THERMOCOUPLE	▪ T-type

SIZES

CATHETER	▪ 117-cm working length-compatible with 100 cm or shorter guide catheters ▪ 6 F guide catheter ▪ 0.052" maximum diameter
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Darbinė dalis 117 cm ilgio;
PTA nukreipėju (guiding-catheter);

PERFORMANCE

CATHETER	▪ Rapid exchange (RX) design compatible with 0.014" guidewire ▪ Guidewire retraction used to deploy the spiral electrode array ▪ RX joint: 30 cm from distal tip ▪ Vessel diameter treatment range: 3–8 mm ▪ Four independently controlled RF monopolar govt ▪ Treatment length: 17–21 mm if all electrodes are activated ▪ Tip length: 5 mm ▪ Tip marker: 1 mm proximal of distal tip ▪ Femoral shaft marker: 55 cm from distal tip
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Tas pats kateteris tinka renalinėms arterijoms,
kurių diametras nuo 3 iki 8 mm

STERILISATION PROCESS	▪ E-beam and 10 ⁻⁶ SAL
SHELF LIFE	▪ 2 years
LATEX	▪ Not present
PHTHALATE	▪ Not present
ANIMAL SUBSTANCE	▪ Not present

Refer to the Instructions for Use (IFU) and User Manual for full product information.

References:

1. Townsend RR, et al. *Lancet*. 2017; 390:2160–2170
2. Kandzari DE, et al. *Lancet*. 2018;391:2346–2355
3. Mahfoud F, et al. Three-year Safety and Efficacy in the Global Symplixity Registry: Subgroup Analyses. EuroPCR 2019

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Symlicity SPYRAL™ RDN Catheter

- 4-electrode array mounted on a 4F catheter that self-expands into a helical configuration with electrodes located 90° from each other circumferentially
- Radiofrequency energy treatment is delivered simultaneously to all 4 renal artery quadrants for 60 seconds
- After guide wire withdrawal (lower image under fluoroscopy), catheter adopts a spiral conformation in the renal artery

Kateteris suderinamas su 4F renālīnēs kreivēs PTA nukreipēju

