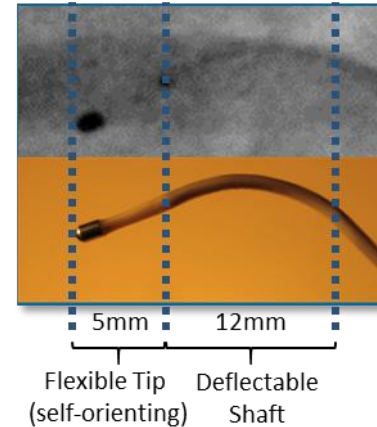


# **New Symplcity Spyral: What is it & how to use it**



**Dr Steven Li Siu Lung  
Director, Heart Centre  
Head, Department of Medicine  
Union Hospital**

# Current Symplicity™ Renal Denervation System



**Ease of catheter flexibility and maneuverability**

**Responsiveness**

**Handle controls**

**6F guide cath compatible**

**Specifically designed for renal anatomy**

- **Fully automated generator**
- **Built-in safety algorithms**
- **Low-power**
- **Straightforward user interface**

# New Multi-Electrode System Design Goals

Reduced Ablation Time

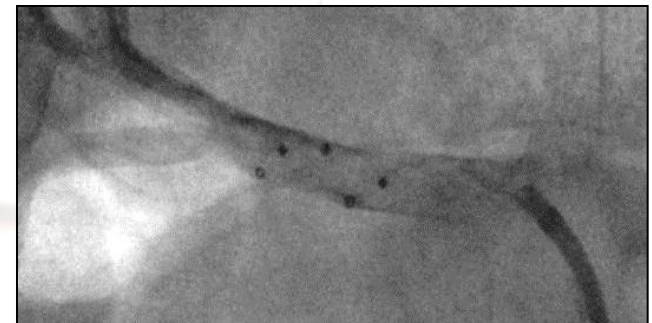
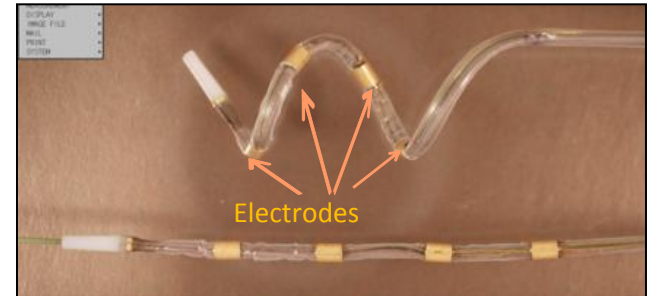
Multi-Electrode

6F Guide Compatible

Monorail Delivery

Non-Occlusive

Vessel Conformability



# Medtronic Symplicity™ RDN Technology Comparison



Technology	Single Electrode	Multi-Electrode
Delivery Access	Direct	Monorail
Guide Catheter Compatibility	6F	6F
# Electrodes	1	4
Electrode Selectability	1	4/3/2/1
# of Placements/Artery	4-6	1
Energy Delivery Time per Placement	2 mins	1 min
Total Energy Delivery Time	16-24 mins	2 mins
Vessel Occlusion	No	No

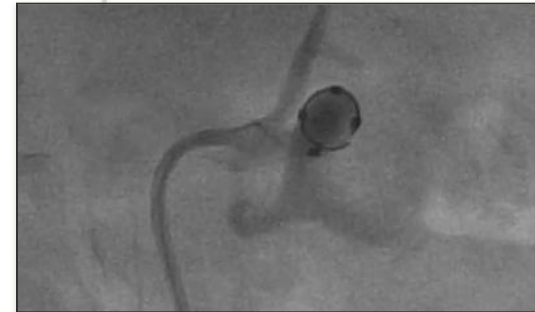
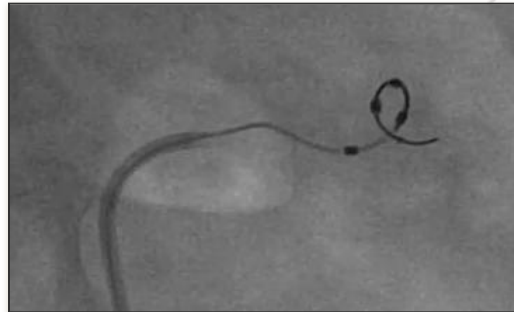
# Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter

## Design Goal

Reduce procedural time  
Maintain clinical outcomes of original/proven Symlicity Flex™ Catheter

## Symlicity Spyral Product Features

- ✓ 1 minute RF ablation cycle
- ✓ 4 electrodes, independently selectable
- ✓ 6F guide catheter compatible
- ✓ Non-occlusive
- ✓ Natural conformability
- ✓ Rapid exchange



# Symlicity Ablation Pattern

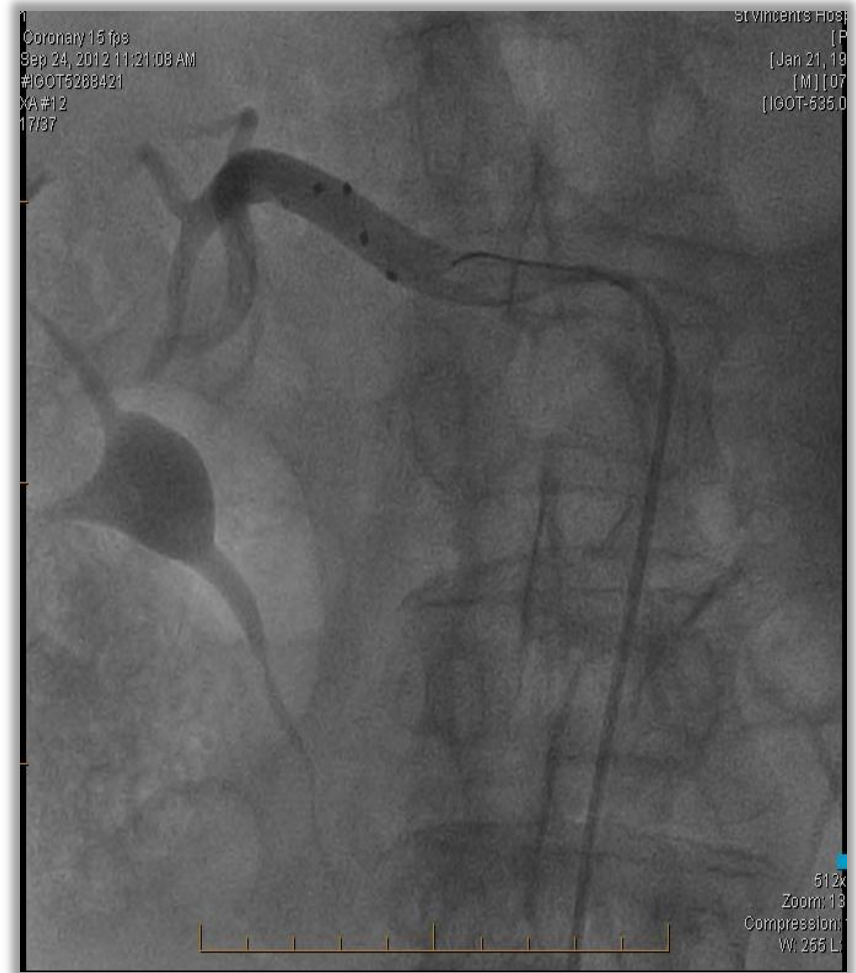
- Standardized ablation pattern
- Similar to Symlicity Flex
- One size for most
  - **Effective in 3-8 mm\* diameter renal arteries**



Symlicity Flex ablation pattern



Symlicity Spyral ablation pattern



\*Feasibility study was conducted in patients with vessel diameter of 4-8 mm



# Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter Case

**With Professor Rob Whitbourn MBBS, BMedSc, BSc (Hons), MD**

- Director, Cardiac Cath Lab & Coronary Intervention  
St. Vincent's Hospital, Melbourne Australia
- Director, The Cardiovascular Research Centre  
St. Vincent's Hospital, Melbourne, Australia
- Assoc, Prof, University of Melbourne
- Professor, Australian Catholic University

Symlicity™  
RENAL DENERVATION SYSTEM



# Symlicity Spyral™ Multi-Electrode Renal Denervation Catheter CE Mark Pending

This information concerns investigational devices only that have not been approved for commercial use by regulatory agencies.

Symlicity Spyral™ cathéter est un dispositif médical de classe IIb. Pour plus d'informations, une documentation commerciale incluant les mentions obligatoires est à votre disposition sur le stand.

Symlicity™  
RENAL DENERVATION SYSTEM





## Patient History

- 65 year old Caucasian male
- Baseline eGFR = 45 ml/min/1.73m<sup>2</sup>
- Significant Past Medical History:
  - 18 year history of Hypertension
  - Angina/Coronary Artery Disease with Stent 2012
  - History of Atrial Fibrillation
  - Type II Diabetes (treated with insulin and oral meds)
  - Hypercholesterolemia
  - Former Smoker
  - Family History of Hypertension

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Symlicity™  
RENAL DENERVATION SYSTEM

## Patient History

- Medications:
  - Moxonidine 400mg daily
  - Lercanidipine 20mg daily
  - Fosinopril 20mg daily
  - Metroprolol XL 95mg daily
  - HCTZ 12.5mg daily
  - Furosemide 40mg daily
- Patient had previously been prescribed Aldosterone antagonist (Spironolactone or Eplerenone)

Symlicity Spyril™ cathéter est un dispositif médical de classe IIb. Pour plus d'informations, une documentation commerciale incluant les mentions obligatoires est à votre disposition sur le stand.

Symlicity™  
RENAL DENERVATION SYSTEM

LAO 1"  
CAUD 14"



21

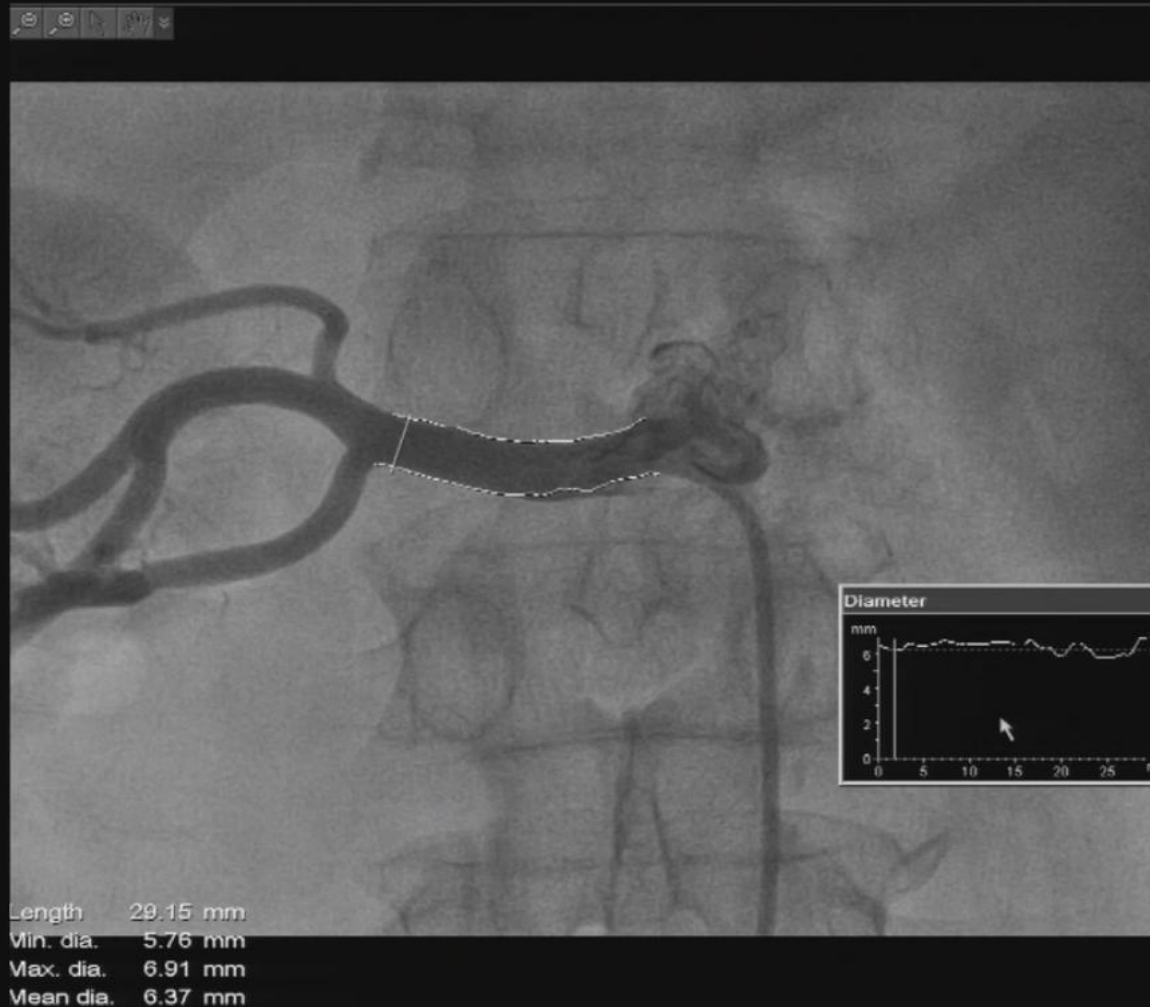


# Angiogram on Right Renal Artery

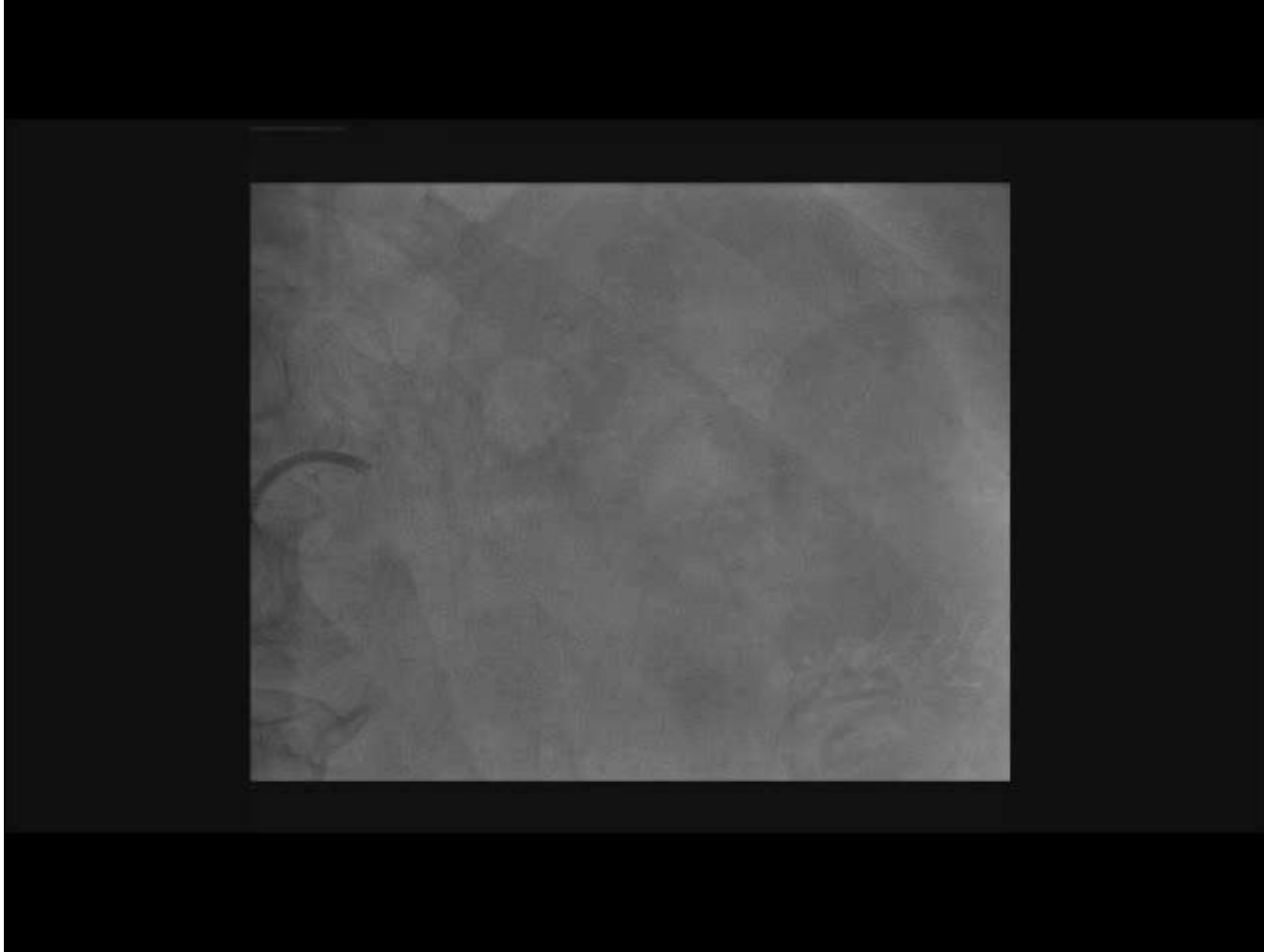


# QCA on Right Renal Artery

Mean Dia.  
6.37mm



# Angiogram on Left Renal Artery



# QCA on Left Renal Artery

Mean Dia.  
6.35mm





## Symlicity Spyral™ Catheter Conforms to Vessel Shape and Size

Diameter (mm)	Treatment Length (mm)
3.0* – 4.9	22 mm
5.0 – 5.9	21 mm
6.0 – 6.9	20 mm
7.0 – 8.0	19 mm

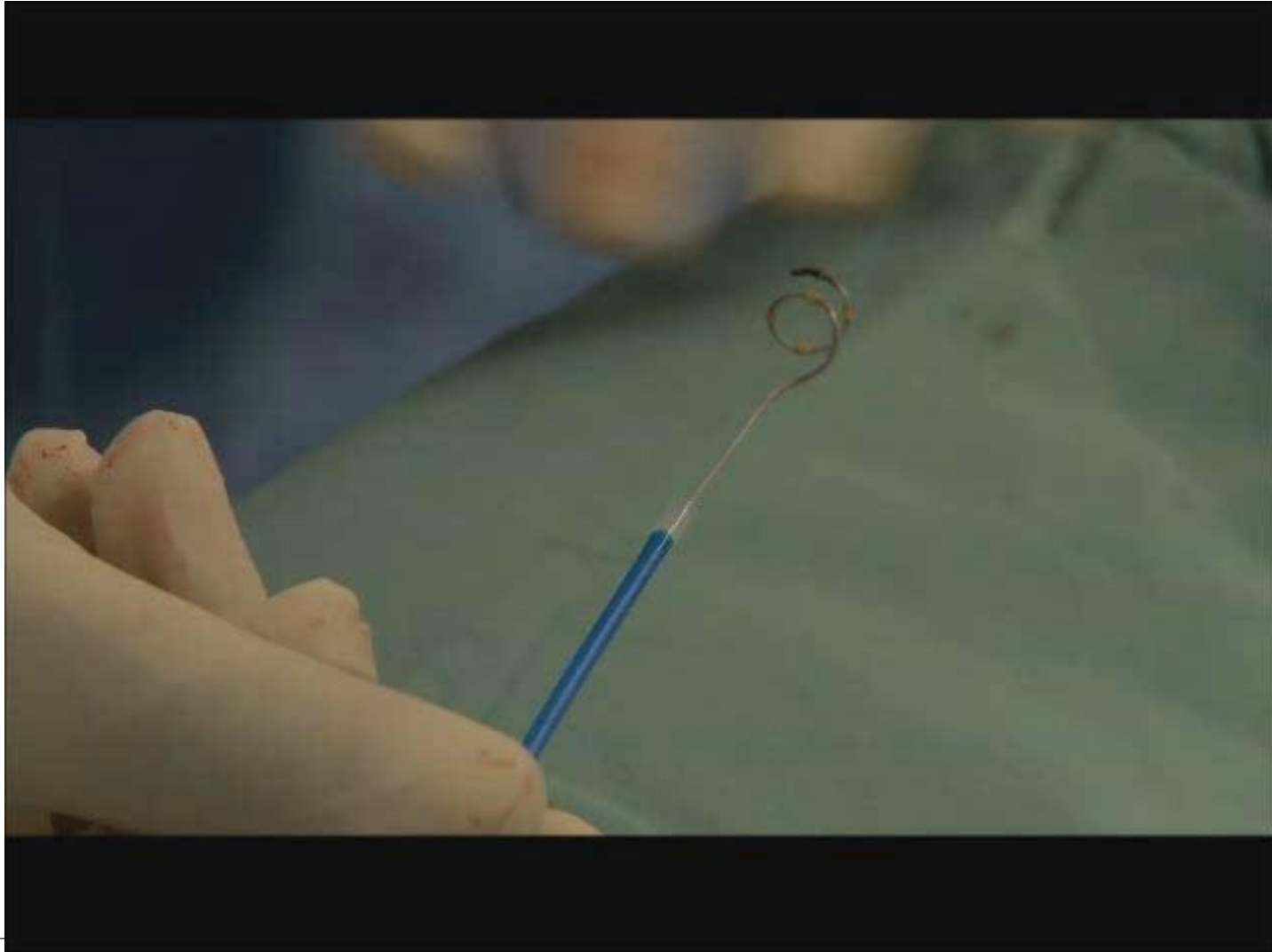
\* Symlicity Spyral™ catheter vessel diameter range for FIM study is 4-8mm.  
Symlicity Spyral™ catheter vessel diameter range for commercial use is 3-8mm.

Symlicity Spyral™ cathéter est un dispositif médical de classe IIb. Pour plus d'informations, une documentation commerciale incluant les mentions obligatoires est à votre disposition sur le stand.

Symlicity™  
RENAL DENERVATION SYSTEM



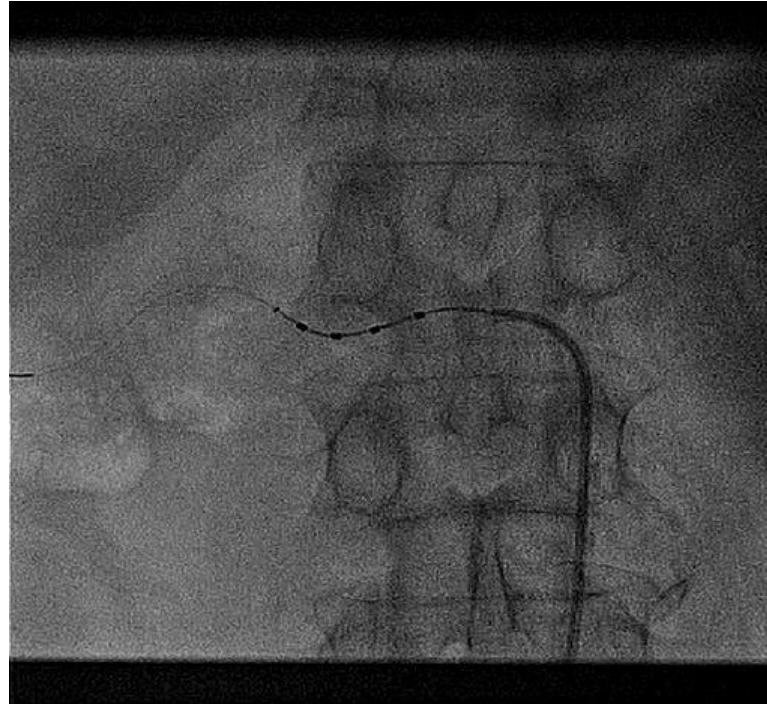
# Symplectomy Spiral (Preparation)



# Symplcity Spyral (Right Side Ablation)



# Symlicity Spyral



- The Spyral multi-electrode RF ablation catheter is introduced straight, over a guidewire.
- Electrodes are equally spaced along the distal tip
- As the guidewire is retracted the device coils into its helical shape

# Symplecity Spyrar



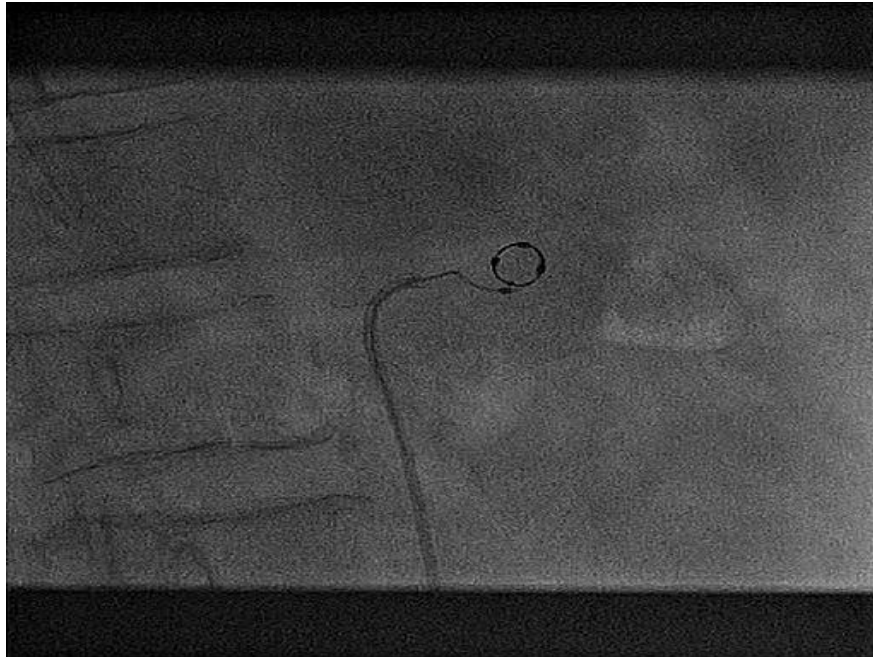
Helical shape allows electrodes to be positioned  $90^\circ$  to each other

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# Symplectivity Spyrar (Left Side Ablation)



# Symplecity Spyrar



Electrodes well apposed to vessel wall

# Symplicity Spyral™ Multi-Electrode Renal Denervation Catheter

- The catheters are used in conjunction with a dedicated multi-electrode generator which;
    - measures tissue impedance to verify catheter wall contact prior to ablation.
    - instigates simultaneous firing of all 4 electrodes
    - RF energy delivered through the catheter to the target nerves for 60 seconds
-

# SymPLICITY Spyral™ Multi-electrode RDN Catheter

- A Feasibility Study undertaken
  - results of first 29 patients reported at PCR2013
  - 100% device success
  - 1 min RF ablation on each side\*
  - Short duration of RDN procedure
- Preclinical & clinical data consistent with the SymPLICITY Flex™ catheter



\*2 patients had > 1 treatment per artery