

Technical specifications

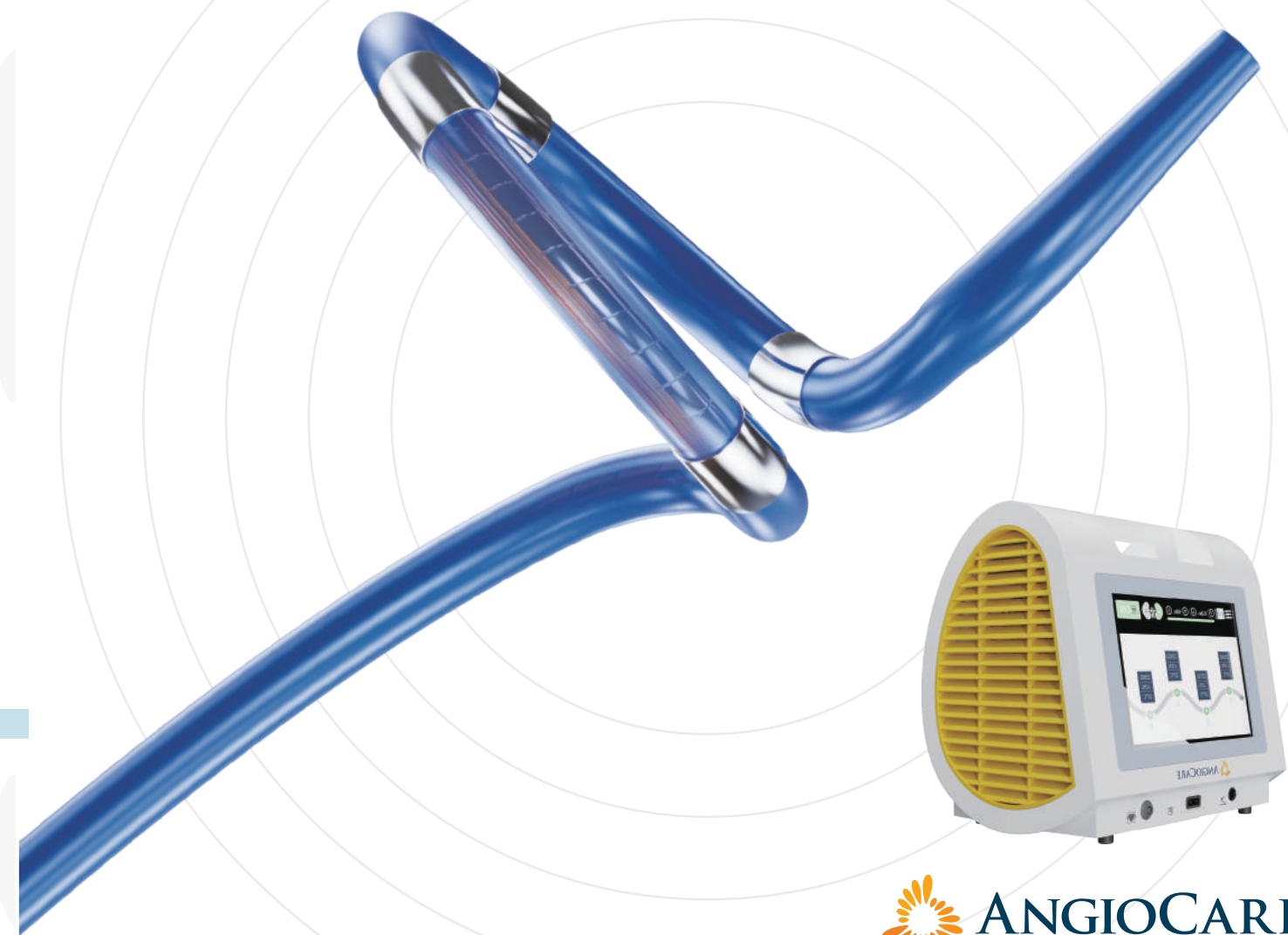
Catheter	Specifications
Catheter maximum OD (Outer Diameter)	0.051"
Tip entry profile	<4F
Tip length	4mm
Tip material	TPU+20%BiOI
Guiding catheter compatibility	6F
Ring diameter	1.20mm
Vessel diameter treatment range	3-8mm
Distance between electrodes	7mm
Distance tip to first electrode	10mm
Electrode material	platinum/iridium alloy
Usable length	900mm;1600mm
Proximal marker	500mm;1200mm;PET
Inner core material	Pebax
Outer shaft material	Line segment:TPU+BiOI; PI; PET. Electrode segment:PET; PI; PET
Working length	900mm;1600mm
Design	OTW
Safety threshold	85°C
Ablation time	60s
Electrode control	on/off independently

Generator	Specifications
RF Output Power	480 kHz, 0.1 to 10 watts/per channel. Total: 0.4-40 watts.
Power Accuracy	±20%
Temperature Range and Accuracy	In 1°C increments, ±3°C between 15-85°C.
Impedance Range and Accuracy	For power output > 50 ohms and < 500 ohms, measurement ±20%.
Dimensions (height x width x depth)	340mm x 335mm x 270 mm
Weight	6.9kg.
Front Controls	RF button, time setting, power setting, wall contact, summary
Rear Controls	Line Power ON/OFF, Volume adjustment.
Display	10.1 inch display for actual temperature, set power, impedance, set and actual treatment time.
Connections	AC Line power isolated USB port. Foot switch, 8-pin Catheter port, and dispersive electrode port.
Input Power	100-240 VAC, 50 -60 Hz, 1.0 Amps Max, universal power supply.

Iberis®

Multi-electrode
Renal Denervation System

Renal Denervation Goes Radial



- Lauder et al. Renal denervation in the management of hypertension. *EuroIntervention*. 2024;20(8):e467-e478. Published 2024 Apr 15. doi:10.4244/EIJ-D-23-00836.
- NCD Risk Factor Collaboration (NCD-RisC). Worldwide trends in hypertension prevalence and progress in treatment and control from 1990 to 2019: a pooled analysis of 1201 population-representative studies with 104 million participants. *Lancet*. 2021;398(10304):957-980. doi:10.1016/S0140-6736(21)01330-1.
- Blood Pressure Lowering Treatment Trialists' Collaboration. Pharmacological blood pressure lowering for primary and secondary prevention of cardiovascular disease across different levels of blood pressure: an individual participant-level data meta-analysis. *Lancet*. 2021;397(10285):1625-1636. doi:10.1016/S0140-6736(21)00590-0.
- Ettehad et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. *Lancet*. 2016;387(10022):957-967. doi:10.1016/S0140-6736(15)01225-8.
- Valenzuela et al. Lifestyle interventions for the prevention and treatment of hypertension. *Nat Rev Cardiol*. 2021;18(4):251-275. doi:10.1038/s41569-020-00437-9.
- Canoy et al. Antihypertensive drug effects on long-term blood pressure: an individual-level data meta-analysis of randomised clinical trials. *Heart*. 2022;108(16):1281-1289. Published 2022 Jul 27. doi:10.1136/heartnl-2021-320171.
- Böhm et al. Efficacy of catheter-based renal denervation in the absence of antihypertensive medications (SPYRAL HTN-OFF MED Pivotal): a multicentre, randomised, sham-controlled trial. *Lancet*. 2020;395(10234):1444-1451. doi:10.1016/S0140-6736(20)30554-7.
- Jiang et al. Efficacy and Safety of Catheter-Based Radiofrequency Renal Denervation in Chinese Patients With Uncontrolled Hypertension: The Randomized, Sham-Controlled, Multi-Center Iberis-HTN Trial. *Circulation*. 2024;150(20):1588-1598. doi:10.1161/CIRCULATIONAHA.124.069215.
- McEvoy et al. 2024 ESC Guidelines for the management of elevated blood pressure and hypertension [published correction appears in *Eur Heart J*. 2025 Feb 11;ehaf031]. doi:10.1093/eurheartj/ehaf031. *Eur Heart J*. 2024;45(38):3912-4018. doi:10.1093/eurheartj/ehaf178.
- Ciuffetti et al. Renal Denervation for the Treatment of Hypertension: A Scientific Statement From the American Heart Association. *Hypertension*. 2024;81(10):e135-e148. doi:10.1161/HYP.0000000000000240.
- Mancia et al. 2023 ESH Guidelines for the management of arterial hypertension The Task Force for the management of arterial hypertension of the European Society of Hypertension: Endorsed by the International Society of Hypertension (ISH) and the European Renal Association (ERA). *J Hypertens*. 2023;41(12):1874-2071. doi:10.1097/HJH.0000000000003480.
- Barbato et al. Renal denervation in the management of hypertension in adults. A clinical consensus statement of the ESC Council on Hypertension and the European Association of Percutaneous Cardiovascular Interventions (EAPCI). *Eur Heart J*. 2023;44(15):1313-1330. doi:10.1093/eurheartj/ehad054.
- Zejnen et al. The position of renal denervation in treatment of hypertension: an expert consensus statement. *Neth Heart J*. 2023;31(1):3-11. doi:10.1007/s12471-022-01717-4.
- Rodríguez-Leor et al. Renal denervation for the management of hypertension. Joint position statement from the SEH-LELHA and the ACI-SEC. *REC Interv Cardiol*. 2022;4:39-46. doi:10.24875/RECICE.M21000235.
- Bruno et al. Italian Society of Arterial Hypertension (SIIA) Position Paper on the Role of Renal Denervation in the Management of the Difficult-to-Treat Hypertensive Patient. *High Blood Press Cardiovasc Prev*. 2020;27(2):109-117. doi:10.1007/s40292-020-00367-0.
- Ferrante et al. Radial Versus Femoral Access for Coronary Interventions Across the Entire Spectrum of Patients With Coronary Artery Disease: A Meta-Analysis of Randomized Trials. *JACC Cardiovasc Interv*. 2016;9(14):1419-1434. doi:10.1016/j.jcin.2016.04.014.
- Wozniak et al. Origin of the renal arteries from sides of aorta. *Folia Morphol (Warsz)*. 2000;58(4):259-261.

CAUTION: The law restricts these devices to sale by or on the order of a physician and these products are intended for the use by or under the direction of a physician. Please check the IFU and the product labelling supplied with each device for indications, contraindications, warnings, precautions, potential adverse events. For further information, contact your local representative. Iberis is not available in the United States and any other country where applicable health authority product registration has not been obtained. Information contained herein only for presentation outside the US and France.

© 2025 ANGIOCARE. All Rights Reserved.
All trademarks, logos, and product names are the property of ANGIOCARE and are protected by copyright and trademark laws.

For further information or assistance, please contact:

DISTRIBUTED BY:



Sales and Customer Service
BIOSENSORS EUROPE SA
Rue de Lausanne 29-1110 Morges-Switzerland
Tel. +41(0)21 804 80 00 - Fax +41(0)21804 80 01

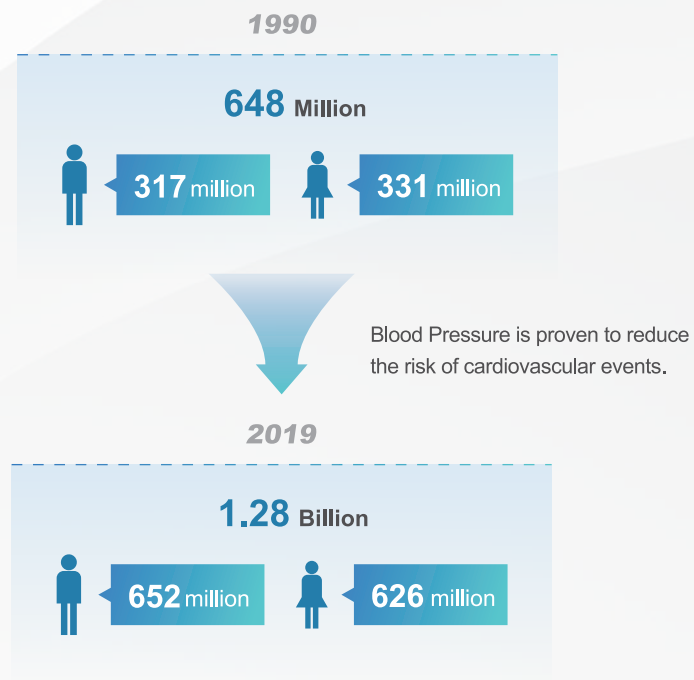
www.biosensors.com



The RIGHT moment to build your renal denervation (RDN) program

Renal denervation (RDN) is a recognized effective treatment option to help lower blood pressure for hypertensive patients. With the introduction of the Iberis® RDN system, physicians now have a unique device to perform RDN via radial access. Radial access for RDN may shorten the hospital stay, increase patient comfort, and reduce vascular complications, thereby further improving the safety profile of the procedure¹.

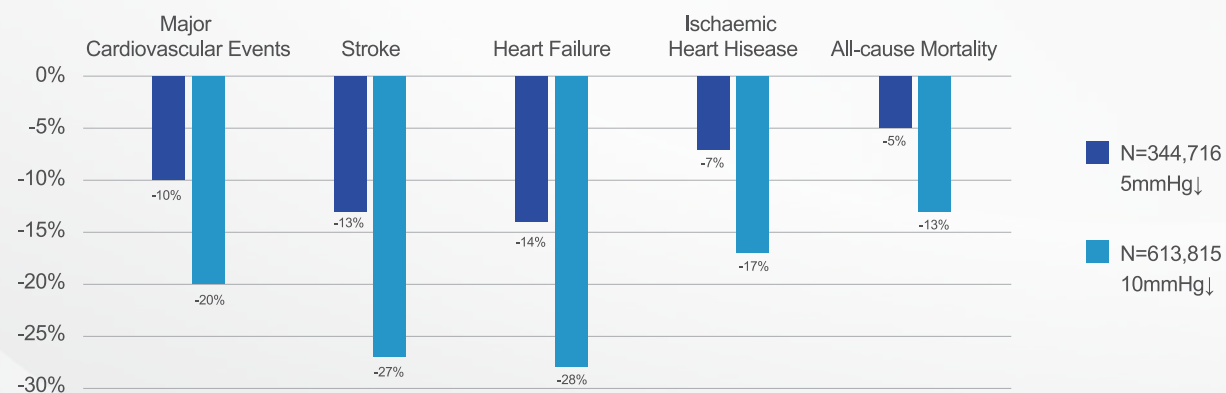
THE TARGET PATIENT POPULATION IS INCREASING²



The number of hypertensive patients aged 30-79 have doubled globally in less than 20 years while only 1/5 have controlled their hypertension.

LOWERING BLOOD PRESSURE IS PROVEN TO REDUCE THE RISK OF CARDIOVASCULAR EVENTS

A 5 mmHg³/10 mmHg⁴ reduction in Systolic Blood Pressure (SBP) can effectively reduce the incidence of cardiovascular events.



Radial Access for vascular interventions has proven to be safer¹⁶



Courtesy of Dr Xiongjing Jiang, Fuwai Hospital, CAMS & PUMC

The take-off of the renal arteries favor a radial route

In about 15-20% of patients, the angle between the main renal artery and the long axis of the abdominal aorta is <60° on at least one side, or there is severe tortuosity of the renal-abdominal aorta.¹⁷

RADIUS-HTN study (NCT05234788)

Renal Artery Denervation Using radial access in uncontrolled HyperTension

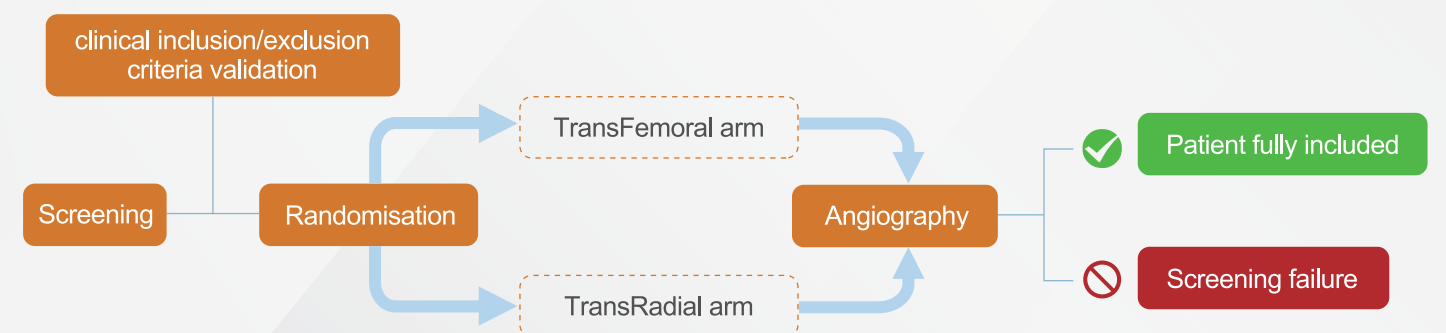


To compare the safety and efficacy of radio frequency renal denervation using the Iberis Renal Denervation System (AngioCare) via radial access compared with femoral access.

STUDY PRIMARY ENDPOINT

Change in systolic Office Blood Pressure (OBP) at 3 months via trans-radial versus trans-femoral access (non-inferiority)

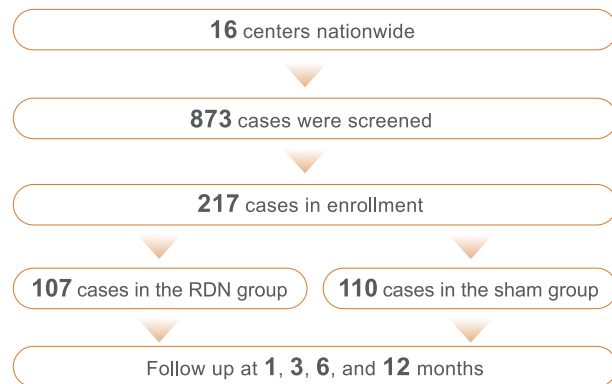
STUDY FLOW



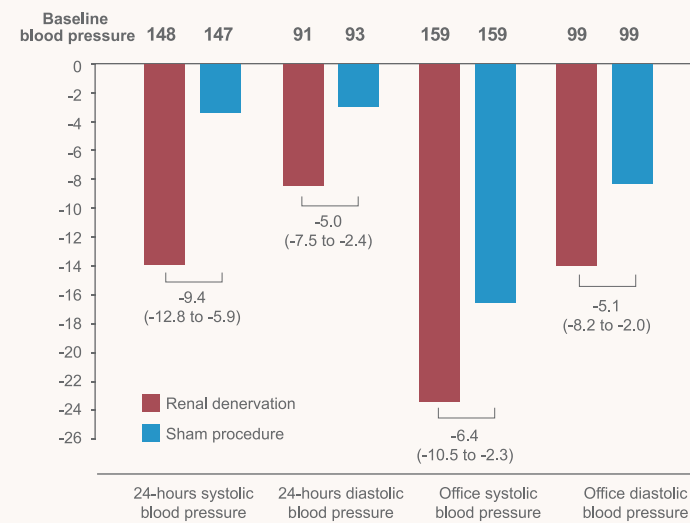
IBERIS-HTN study (NCT02901704)⁸

Randomized, Sham-Controlled, Multi-Center Iberis-HTN Trial
RDN with Iberis is safe and reduces ambulatory and office BP at 6 months compared with sham

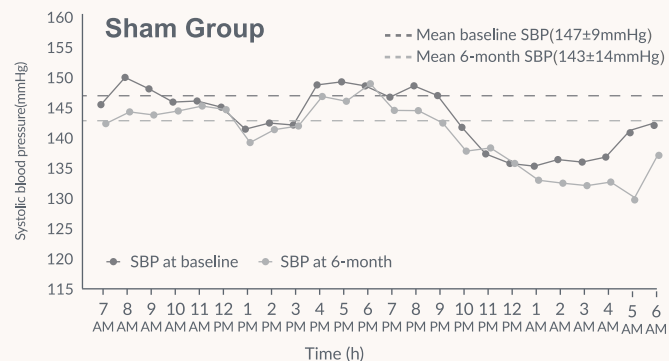
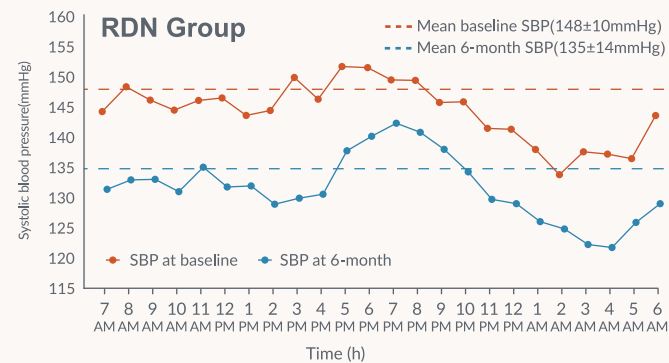
Basic Information of Iberis-HTN



Blood pressure decreases at 6 months



RDN effects are “always-on” throughout the day confirmed by 24-hour ABPM Changes at 6-month



Safety Endpoints of the Iberis-HTN study (6M)

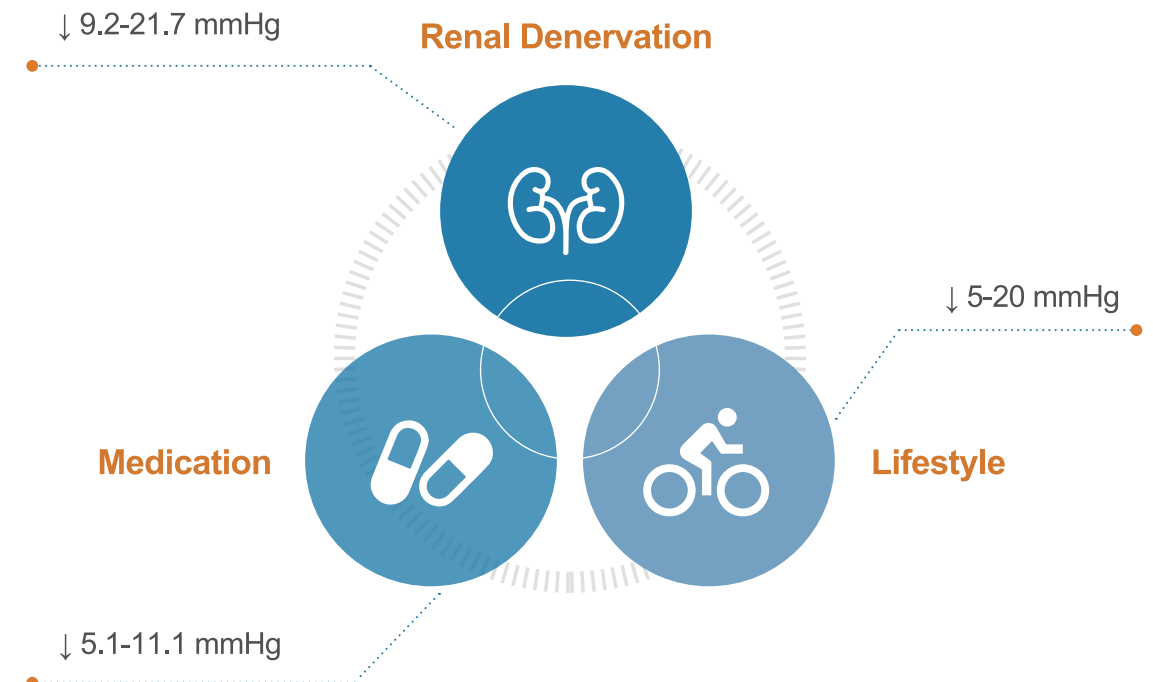
	Renal denervation (n=107)	Sham procedure (n=110)
All-cause mortality	0(0)	0(0)
Acute myocardial infarction	0 (0)	0 (0)
Coronary revascularization	2(1.9)	1(0.9)
Cerebrovascular event	0 (0)	0 (0)
Renal artery re-intervention	0 (0)	0 (0)
End-stage renal disease*	0 (0)	0 (0)

Data are presented as n (%). *Defined as estimated glomerular filtration rate <15 ml/min/1.73 m2 or thence for renal replacement therapy.

Compared with the sham group, the RDN group had no serious device - related adverse events, and there was no statistically significant difference in clinical adverse events.

RDN PROVIDES AN EFFECTIVE OPTION FOR HYPERTENSIVE PATIENTS⁵⁻⁸

RDN is proven and approved as an adjunctive treatment when lifestyle modifications and medications are not sufficient to control blood pressure.



GUIDELINE RECOMMEND RENAL DENERVATION AS A VALID OPTION FOR UNCONTROLLED HYPERTENSIVE PATIENTS

	ESC Guidelines 2024 ⁹	AHA Statement 2024 ¹⁰	ESH Guidelines 2023 ¹¹	ESC-EAPCI Statement 2023 ¹²	Netherlands 2022 ¹³	Spain 2021 ¹⁴	Italy 2020 ¹⁵
Uncontrolled HTN	✓	✓	✓			✓	✓
Resistant HTN (≥ 3 drugs)	✓	✓	✓	✓	✓	✓	✓
Intolerant to medications	✓	✓	✓	✓	✓	✓	✓
Non-adherent to medications	✓	✓		✓		✓	✓
Increased CV risk	✓	✓		✓		✓	✓
Patient preference	✓	✓	✓	✓	✓	✓	✓

HTN: Hypertension

The RIGHT device for every anatomy

Ablation is performed by radiofrequency (RF) energy delivered to the renal sympathetic nerves via 4 independent electrodes located at the distal part of the catheter. The ablation is piloted via a generator delivering the RF energy and monitoring both the impedance and temperature.

RADIAL FIRST RADIAL BEST

Radial access for PCI has proven to offer less trauma to patients, shorter recovery time, lower local complications of vascular puncture, and significantly fewer intraoperative and postoperative complications compared to femoral access.¹⁶

Renal Arterial Access Favors Transradial Access



Courtesy of Dr Mehmet Kocaağa, Private Yalova Atakent hospital

Iberis includes a specially designed radial access catheter to bring the benefits of radial access to RDN:

160 cm long *

Full nitinol shaft for better navigability

* 90 cm femoral catheter also available. Refer to the technical chart on last page for more details

HIGH ABLATION EFFICIENCY

- Wall contact detection to evaluate electrode and vessel wall apposition
- Excellent conformability and high radial force of the catheter attributable to unique shaft design



ENHANCED SAFETY

- Continuous temperature and impedance monitoring
- Automatic safety features including electrode shutdown



Each electrode is monitored independently and can be disconnected manually

CATHETER FLEXIBILITY

- Navigability: simple access to the main, branch and accessory arteries (4F catheter)
- One size fits all: ablate arteries of 3-8mm diameter with the same device

