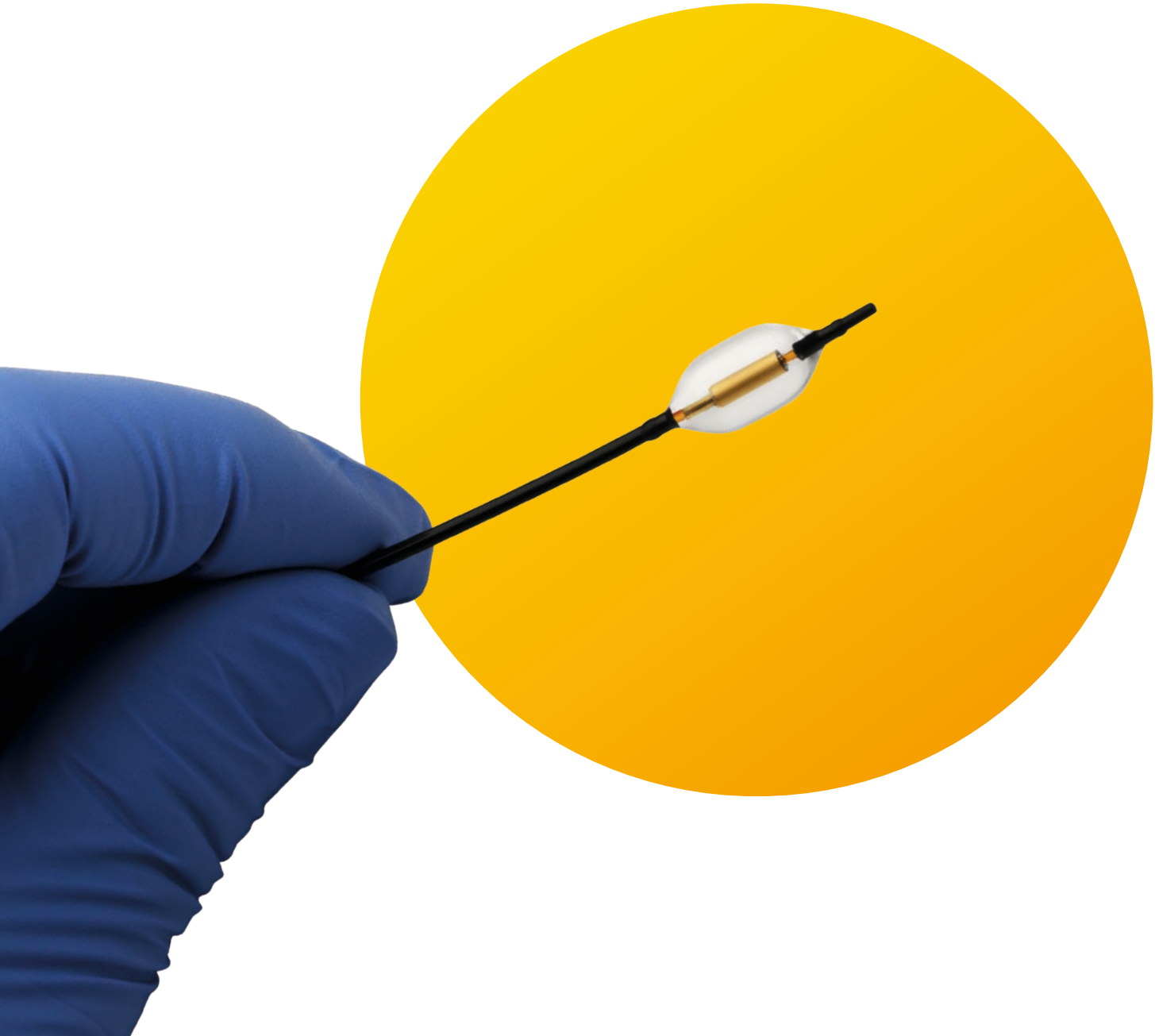
Recor Medical™

Unleash the power of ultrasound.

Paradise™ Ultrasound Renal Denervation System

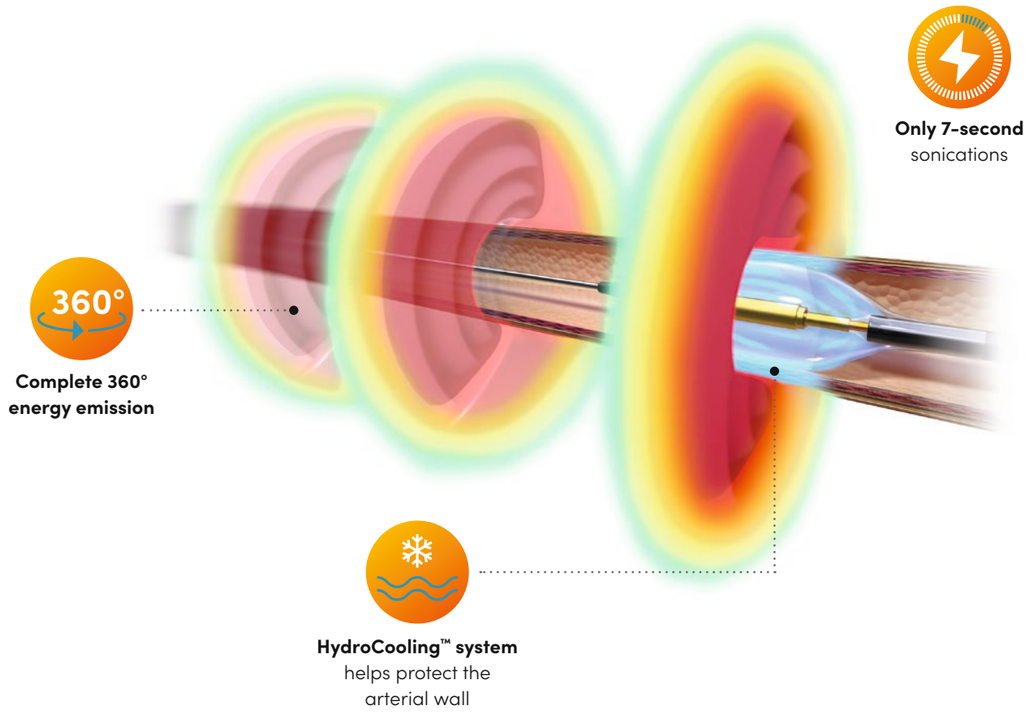


The Paradise™ System

Unleash the power of ultrasound renal denervation (uRDN)

Take on uncontrolled or resistant hypertension with the Paradise™ Ultrasound Renal Denervation (uRDN) system. It is a minimally invasive procedure that lowers high blood pressure by treating overactive renal nerves with ultrasound energy.

With an exclusive design to ensure a safe and effective procedure, Paradise™ Ultrasound RDN offers a proven therapy option to lower blood pressure.[1-3]



- **Complete 360° energy emission in a single sonication** for maximum benefits of renal denervation[4]
- **HydroCooling™ system** helps protect the arterial wall by minimizing the risk of overheating and subsequent tissue damage[5]
- **Only 7-second sonications, with 2-3 sonications per main renal artery** with a targeted depth of 1-6mm[4]

RADIANCE pooled analysis
-10.4 mmHg
office systolic blood pressure at 2 months[6]

Effective

RADIANCE-HTN SOLO study
3 years
sustained results[7]

Durable

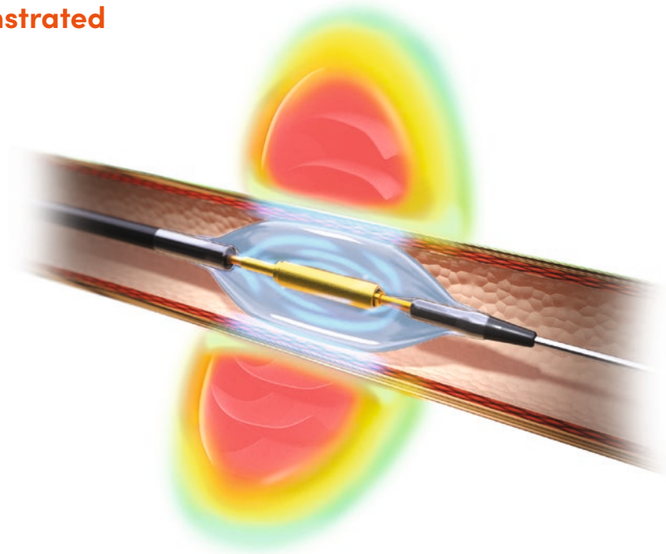
RADIANCE II pivotal trial
0
major adverse events*[3]

Safe

*Major adverse events defined as the composite outcome of pre-specified events including all-cause mortality.

Paradise™ ultrasound RDN demonstrated effectiveness and safety in both:

- **Mild-to-moderate hypertension patients (≤ 2 medications)**
  RADIANCE-HTN SOLO[1] and RADIANCE II[3]
- **Resistant hypertension patients (≥ 3 medications)**
  RADIANCE-HTN TRIO[2] and ACHIEVE STUDY[8]

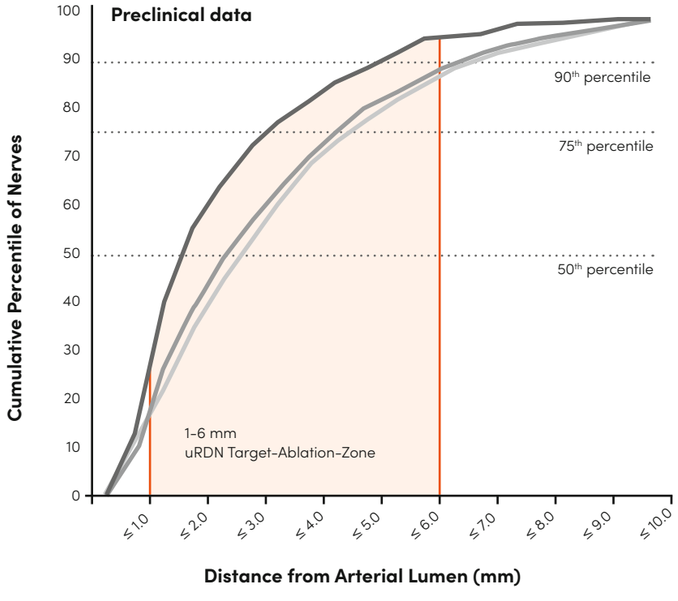


ZERO
major device-related adverse events[3]

NO
impact on renal function at 2 months[3]

ZERO
clinically significant renal arterial stenosis at 6 months[3]

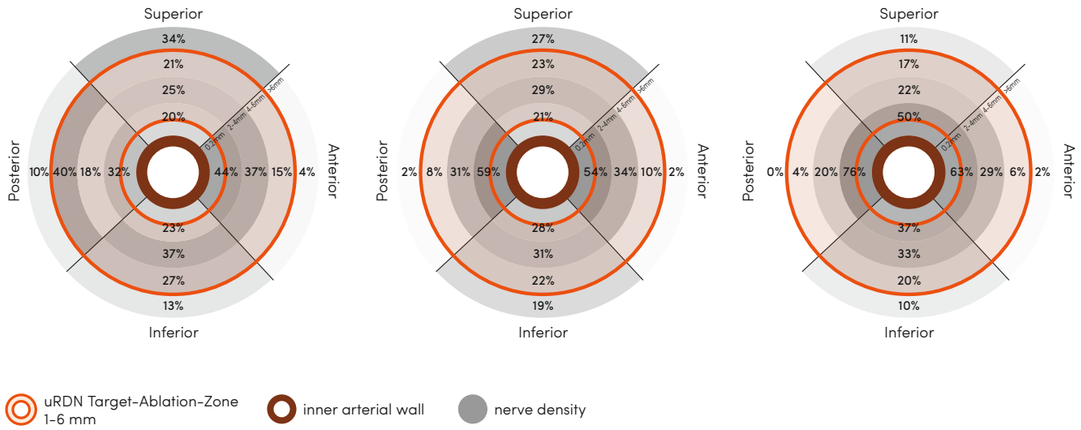
An effective approach to achieve reliable results



~80%
target nerves
with each ultrasound treatment[9]

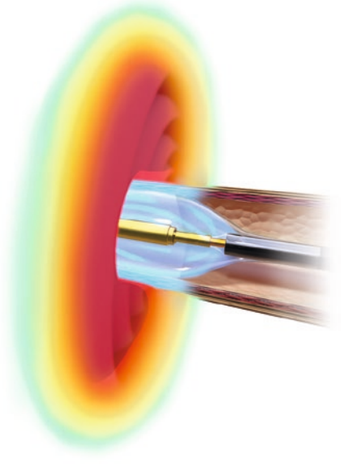
Proximal (n=3070)
Middle (n=2952)
Distal (n=2008)

The Paradise™ system is designed to denervate about 80% of renal nerves by targeting a 1-6 mm ablation zone using 360° circumferential ultrasound emission.[9]



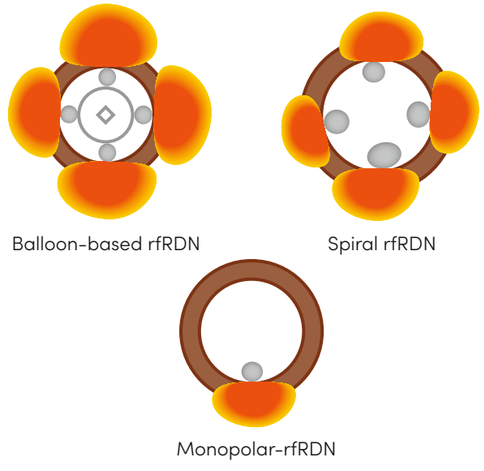
Comparison of technology

True circumferential ablation with ultrasound energy (uRDN)[10,11]



Schematic illustration of uRDN technology*[10,11]
Illustration of the Paradise™-System

Spot ablation with radiofrequency energy (rfRDN)[10,12]



Schematic illustration of different rfRDN technologies*[10,12]
Illustration of lesion size using three different applicators.

* lesion size of the ablation zones of uRDN and rfRDN are not drawn to scale

RADIOSOUND-HTN[13,14]: Randomized head-to-head comparison of uRDN and rfRDN

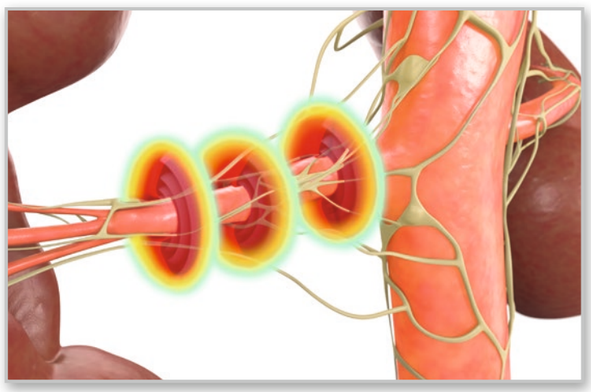
With short 7-second ablations delivered 3.2 times on average per side, Paradise™ Ultrasound RDN provides meaningful blood pressure reductions while:

- Shortening fluoroscopy time
- Reducing contrast load

	uRDN Main Only (n = 42)	rfRDN Main + Branches (n = 39)
Total ablation time	**<1.0** minute	**>8.0** minutes
Contrast agent used	**98.7** ml	**143.1** ml
Fluoroscopy time	**8.1** minutes	**16.8** minutes

Efficient and intuitive procedure

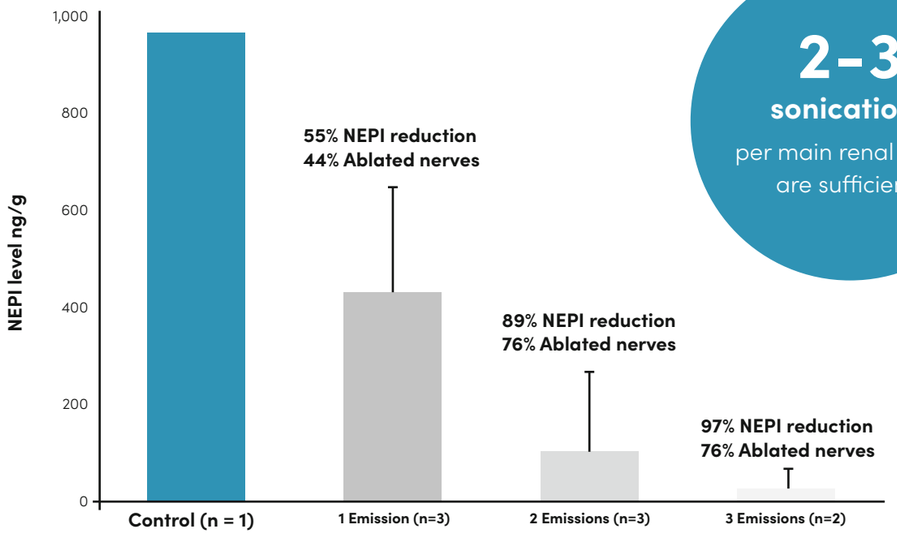
- Minimizes **procedure time to about an hour** by requiring only 2-3 short 7-second ablations on each main renal artery
- Majority of procedure **can be completed in the main vessel**
- **Intuitive system setup** compatible with standard accessories



The Paradise™ System delivers 2-3 treatments of 360°-ultrasound energy per main renal artery

Significant reduction of norepinephrine (NEPI) levels in the kidney after 7 days with 2-3 ultrasound ablations in the main renal artery:[5]

- **Two ablations** reduces the NEPI level **by 89%** and denervates 76% of the nerves



2-3
sonications
per main renal artery are sufficient[5]

Preclinical data: Norepinephrin-Reduction in pigs with 2-3 sonications

Made for efficiency

Paradise™ Catheter

State-of-the-art catheter

- Exclusive **SonoWave 360° ™** transducer
- **Non-compliant balloon** with HydroCooling™ system
- **Atraumatic** tip for patient safety

Paradise™ Generator

Intuitive generator

- **Simple, user-friendly** interface with ultra-efficient workflow
- **Pre-programmed energy level** customized to the patient's anatomy
- Hand-held remote to perform procedure from **sterile field**

How it works

www.recormedical.eu

See how Paradise™ Ultrasound RDN works:
Scan the QR Code

IMPORTANT SAFETY INFORMATION

Rx Only. Brief Summary - Prior to use, please reference the Instructions for Use

Indications for Use
The Paradise Catheter is indicated for percutaneous renal denervation.

Contraindications
The Paradise Catheter is contraindicated for patients with any of the following: • Renal arteries diameter < 3 mm and > 8mm. • Renal artery with Fibromuscular dysplasia (FMD).
• Stented renal artery. • Renal artery aneurysm. • Renal artery stenosis of any origin >30%. • Iliac/femoral artery stenosis precluding insertion of the Paradise Catheter.
• Less than 18 years of age. • Pregnant. • Known allergy to contrast medium.

Warnings and Precautions
• Failure to use the recommended balloon size may result in renal artery dissection, perforation, aneurysm, significant vasospasm requiring intervention, ablation of unintended tissues or structures, or no ablation of target tissue achieved. • Do not move the Paradise Catheter during sonication. • Do not sonicate in renal artery at locations with visible plaque.
• Do not deliver sonications in an overlapping configuration. • Only use specified coolant (Sterile water) for fluid supply. DO NOT USE SALINE. • Never advance or withdraw the Paradise Catheter against unknown or excessive resistance. Avoid multiple balloon inflations to achieve apposition of the balloon to the renal artery wall; multiple balloon inflations may result in increased vessel trauma. • The Paradise Catheter is for single use only. Do not resterilize or reuse. Reuse, reprocessing, or resterilization will compromise device integrity which may result in patient injury, illness, or death. • Do not touch the Paradise Catheter balloon during sonication, as it may result in serious injury. • The Paradise System may interfere with or adversely affect the operation of cardiac pacemakers or other active implants unless proper precautions have been taken or managed per the manufacturer's instructions. When in doubt regarding possible hazards, seek qualified advice and/or consult with the manufacturer(s) prior to initiating a procedure. The Paradise Catheter is a Type CF, defibrillation-proof Applied Part.

Potential risks of renal denervation procedure/response to treatment. The following are possible risks associated with the denervation procedure/ response to treatment.
These potential risks may include ablation or thermal injury to the vessel, adjacent tissue, or other structures from energy application, acute kidney injury, angina, anxiety, arrhythmia, atrial tachycardia, bradycardia, gastrointestinal complications (diarrhea, nausea, vomiting), hypotension/ dizziness and/or headaches, hypertension, hyperhidrosis, pain (transient abdominal, lower back), renal failure or renal insufficiency, renal artery aneurysm or pseudoaneurysm, renal infarction, renal artery dissection, or perforation, renal artery stenosis, vasospasm, vasovagal response, stroke or transient ischemic event.

Potential risks of arterial catheterization procedure
There are primary risks of the renal denervation procedure which are similar to the risks of all procedures requiring catheterization of the arteries of the body. The following are potential risks of the catheterization procedure (including renal angiogram): allergic reaction to contrast, arterio-enteric fistula, arterio-venous fistula, bleeding, cardiopulmonary arrest, complications related to pain and anti-anxiety medication protocol, death, deep vein thrombosis, edema, embolism (pulmonary, renal, peripheral vasculature, plaque), hematuria, infection, myocardial infarction, pain. Vascular access site complications (pseudoaneurysm, pain, swelling, hematoma).

SOURCES

1. Azizi et al., Lancet. 2018;391(10137):2335-2345.
2. Azizi et al., Lancet. 2021;397(10293):2476-2486.
3. Azizi et al., JAMA. 2023;329(8):651-661.
4. Data on file. Recor Medical. Inc.
5. Pathak et al., EuroIntervention. 2015;11(4):477-84.
6. Kirtane et al., JAMA Cardiol.2023; 8(5):464-473.
7. Rader et al., EuroIntervention. 2022 ;18(8) :e677-e685.
8. Zeijen et al., TCT 2023.
9. Sakakura et al., JACC. 2014; Aug 19;64(7):635–643.
10. Qian et al., EuroIntervention 2017;12:e1907-e1915.
11. uRDN: FEM (Finite Element Modeling) thermal simulation based on data on file.
12. Cheng et al., Int J Hyperthermia. 2021;38(1):1251-1262. rfRDN: FEM thermal simulation.
13. Fengler et al., Circulation. 2019;139(5):590-600.
14. Fengler et al., JACC: Cardiovascular Interventions.2023;16: 359-369.

Recor Medical™

RECOR MEDICAL NORTH AMERICA

1049 Elwell Court
Palo Alto, CA 94303, USA

RECOR MEDICAL / OTSUKA MEDICAL DEVICES EUROPE GMBH

Europa-Allee 52
60207 Frankfurt am Main

FOLLOW RECOR MEDICAL ON

recormedical.eu