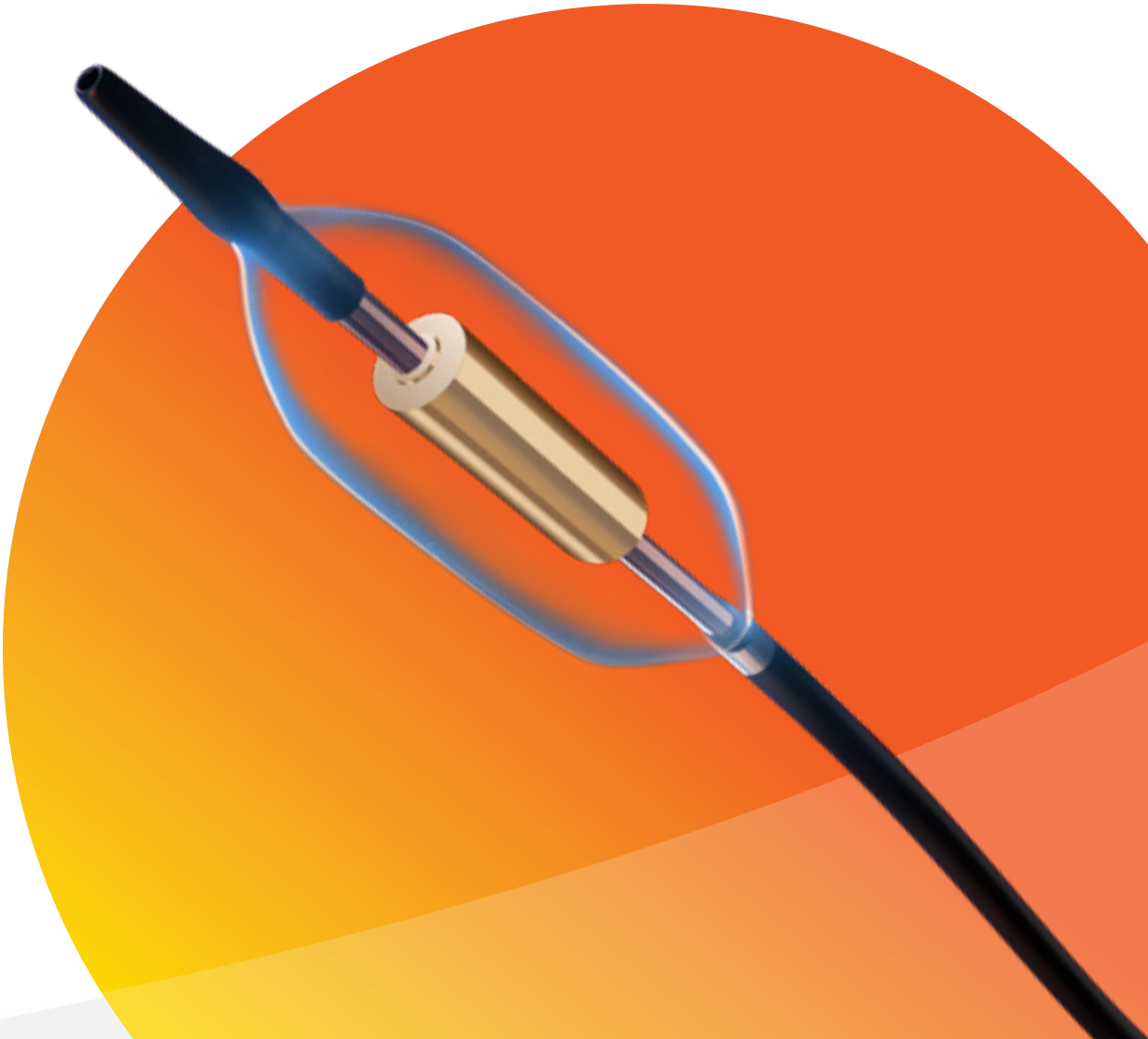
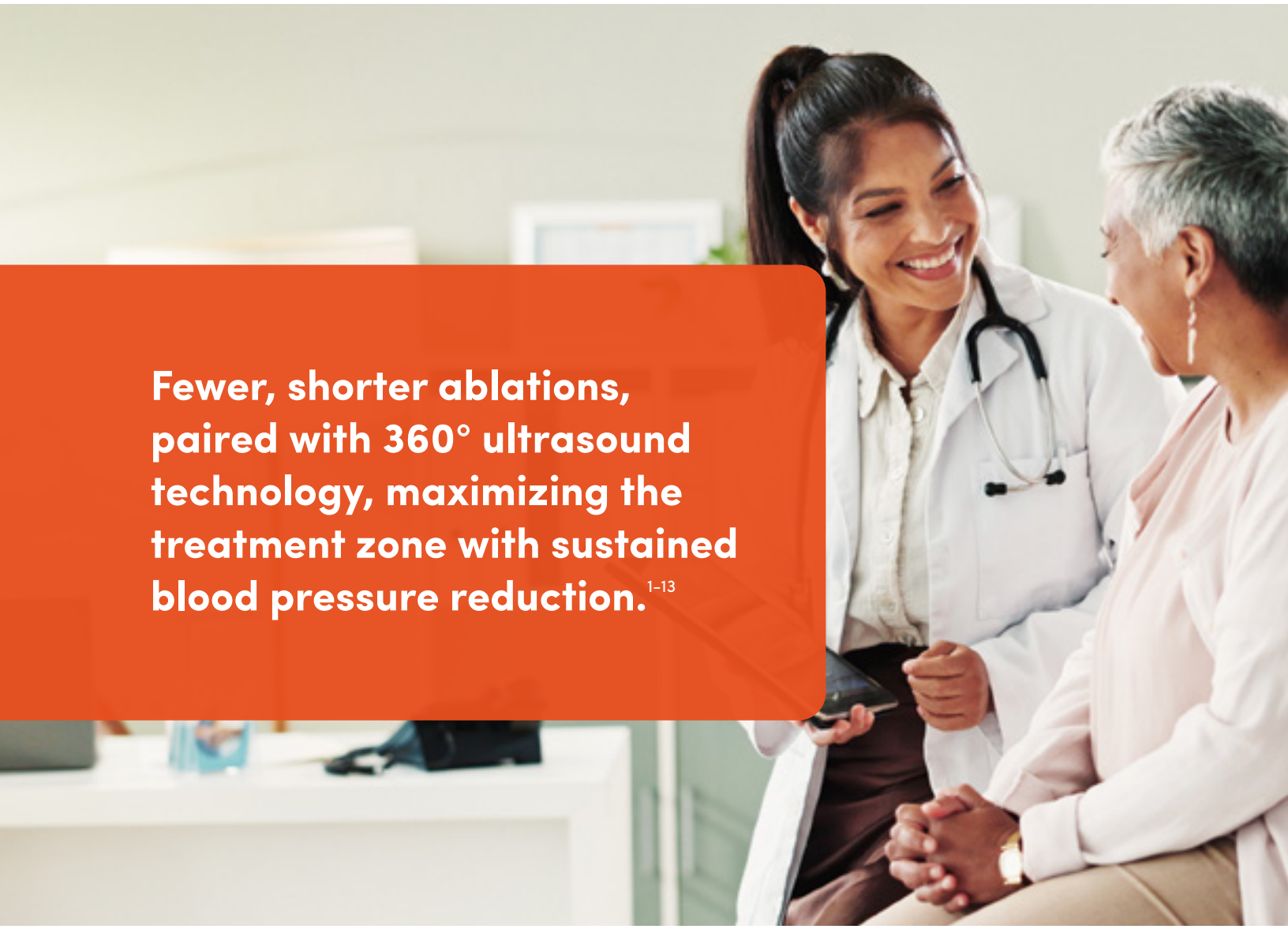
Recor
Medical®

A proven approach in managing hypertension.

Paradise® Ultrasound Renal Denervation System



Experience the power of 360° ultrasound.



Fewer, shorter ablations, paired with 360° ultrasound technology, maximizing the treatment zone with sustained blood pressure reduction.[1-13]

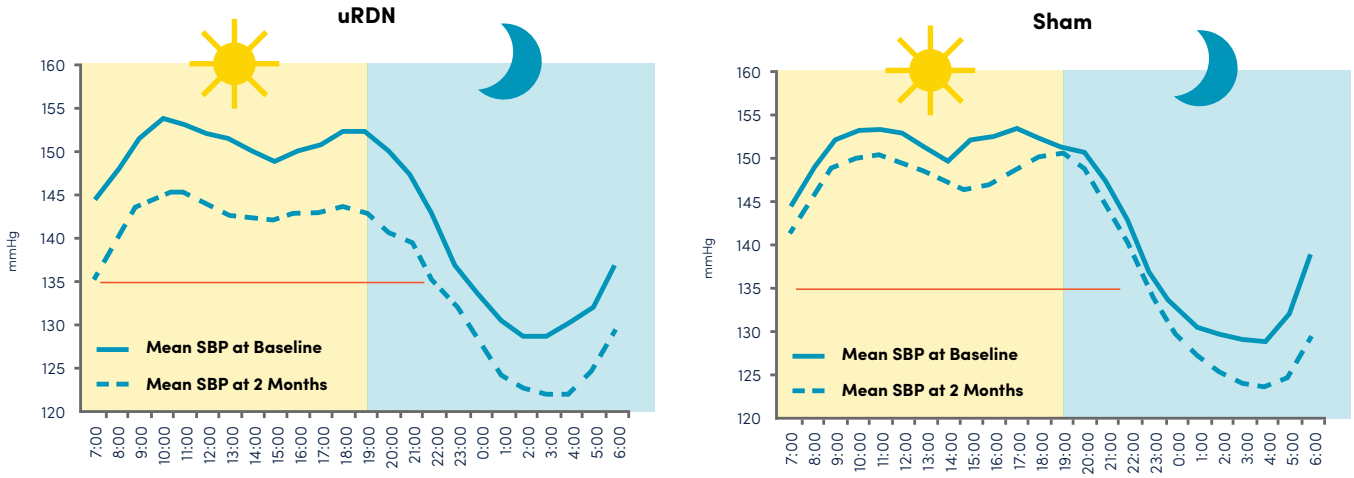
1. Data on file. Recor Medical; Treatment site may vary with anatomy. Please refer to Paradise Catheter IFU for treatment strategy. 2. Paradise® 6Fr Catheter IFU and Paradise® Generator Operator Manual IFU. 3. Symplicity Spyral™ Catheter Instructions for Use Manual Rev.(A) 4. Symplicity Spyral™ Clinical Study Summary M041982C001 A 2023-08-14. 5. Fengler et al. Circulation. 2019 Jan 29;139(5):590-600. 6. Fengler et al. JACC: Cardiovascular Interventions. Vol 16. No. 3. 2023: 359-369. 7. Azizi et al. Lancet. 2018 Jun 9;391(10137):2335-2345.; 8. Azizi et al. JAMA. 2023 Feb 28;329(8):651-661. 9. Azizi et al. Lancet. 2021 Jun 26;397(10293):2476-2486. 10. Kirtane et al. JAMA Cardiol. 2023;8(5):464-473. 11. Rader et al. EuroIntervention 2022;18-online 12. Bloch et al. Hypertens Res. 2024. 13. V. Zeijen, ACHIEVE Study update. TCT 2023

Works 24-hours.

The Paradise uRDN one-time procedure provides an "always-on" effect with 24-hour blood pressure control for continuous, day-and-night blood pressure reductions.[1]

Lower ambulatory BP throughout 24-hour period.

RADIANCE Pooled Analysis



Global hypertension guidelines and consensus statements support the use of RDN to lower blood pressure.

Patient Selection	AHA 2025[1]	ESC 2024[2]	SCAI 2023[3]	ESH 2023[4]
Controlled Hypertension				
Uncontrolled hypertension (less than 3 medications)				+
Resistant hypertension (3+ medications)*	+	+	+	+
Intolerant to drugs	+	+	+	+
Non-adherent to drugs	+	+	+	+

+ Supported

*Patients who met escape criteria had baseline values carried forward. Kirtane et al. JAMA Cardiol. 2023;8(5):464-473.Potential procedure-rated AEs including pain, vascular access site complications, and vasospasm are most common. Individual results may vary.

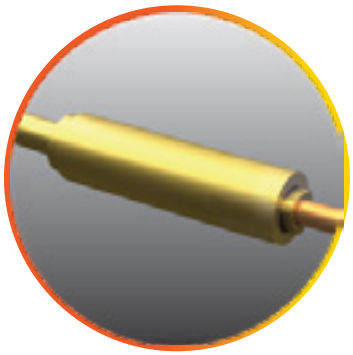
1. Jones D, et al, Hypertension, https://doi.org/10.1161/HYP.0000000000000024 (AHA guideline is Resistant Hypertension 4+ medication) 2. European Heart Journal, ehae178, https://doi.org/10.1093/eurheartj/ehae178 3. Swaminathan et al. Journal of the Society for Cardiovascular Angiography & Interventions, published ahead of print on 21 August, 2023. 4. Mancia et al. J Hypertension 41(12):p 1874-2071, December 2023.

Experience a high standard in RDN.

The Paradise® Ultrasound Renal Denervation System powers your procedures with 360° ultrasound technology, a breakthrough in RDN that penetrates effectively with targeted depth, reaching the sympathetic nerves around the renal artery—all while staying in the main renal arteries without going into distal branches.[1,2]

Maximize Performance

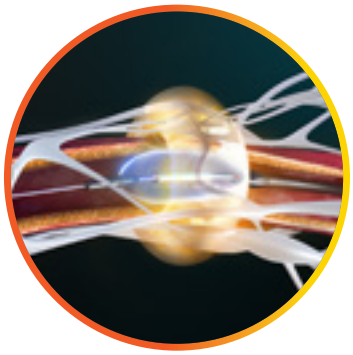
- Emits circumferential ultrasound with instantaneous tissue penetration[1]
- 6 mm targeted depth regardless of vessel size, reaching nerves consistently[1]
- Minimal impact by heat sink[1]
- Luminal cooling to minimize thermal injury



SonoWave 360™ Cylindrical Transducer

Unlock Efficiency

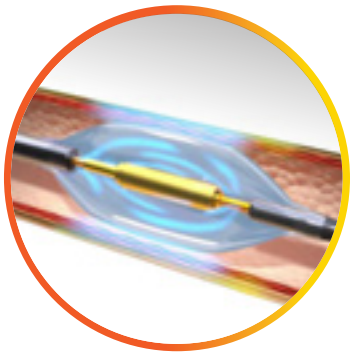
- Stay in the main without going into distal branches[1,2]
- Less contrast and fluoroscopy[3,4]
- Minimize discomfort for your patients



360° Ultrasound Technology

7 **seconds per ablation**

2–3 **ablations per artery**[1]



HydroCooling™ System

1. Data on file. Sakakura K,Roth A, Ladich E, et al. CVPath&ReCor Medical White Paper. 2. Treatment site may vary with anatomy. Please refer to Paradise Catheter IFU for treatment strategy. 3. Fengler et al. Circulation. 2019 Jan 29;139(5):590-600. 4. Fengler et al. JACC: Cardiovascular Interventions. Vol 16. No. 3. 2023:359-369.

Deliver lasting outcomes.

Significant blood pressure drop at 2 months with meaningful reduction out to at least 3 years.[1-6]

Randomized Clinical Trial

2 months

RADIANCE (Pooled)

–10.4 mmHg

Reduction in office systolic BP from baseline at 2 months in RADIANCE pooled RCTs[7]

All Patients (N=261)

RADIANCE-HTN TRIO

–9.0 mmHg

Office SBP reductions from baseline at 2 months[3]

(On-Meds, Single triple pill) Resistant HTN (N = 136)

Real-world EMEA GPS Registry

6 months among real-world EMEA GPS patients

–19.6 mmHg

Office SBP Reduction from baseline **prospective, uncontrolled HTN patients (OSBP ≥ 140 mmHg)** treated in EMEA (N=92)

Long-term Data

2 & 3 years

RADIANCE POOLED

2 Years

–15.7 mmHg

Office SBP reduction from baseline[5,]**

(N = 243)

RADIANCE-HTN TRIO

3 YEARS

–17.3 mmHg

Office SBP reduction from baseline[6,*,]**

(On-Meds, Single triple pill), Resistant HTN**

Baseline Office SBP ≥ 150, mmHG (N=30)

ZERO
major adverse events in the pivotal trial[7]

NO
impact on renal function at 2 months[7]

ZERO
clinically significant renal arterial stenosis at 6 months[7]

* In patient population with baseline office SBP 150 mmHg. ** Baseline measurement occurred following 4-week standardization on a 3-drug single-pill. *** Linear mixed-effect models adjusted for medications. Potential procedure-related AEs including pain, vascular access site complications, and vasospasm are most common. † Findings derived from a post-hoc analys § Those who experience >5 mmHg drop in Office BP.

1. Azizi M. et al., JAMA. 2023;329:651-661. 2. Azizi M. et al., Lancet. 2018;391:2335-2345. 3. Azizi M. et al., Lancet. 2021;397: 2476-2486. 4. Data on file 5.Rader et al. EuroIntervention.2022;18:e677-e685. 6. Bloch et al. Hypertens Res. 2024. *Baseline measurement occurred following 4-week standardization on a 3-drug single-pill 7. Kirtane et al. JAMA Cardiol. 2023;8(5): 464-473. 8. V. Zeijen, ACHIEVE Study update. TCT 2023 Potential procedure-rated AEs including pain, vascular access site complications, and vasospasm are most common.

Important Safety Information

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

Indications for Use
The Paradise Ultrasound Renal Denervation System (Paradise System) is indicated to reduce blood pressure as an adjunctive treatment in hypertension patients in whom lifestyle modifications and antihypertensive medications do not adequately control blood pressure.

Contraindications
The Paradise Catheter is contraindicated in any of the following:
- Renal arteries diameter <3 mm and >8mm
- Renal artery Fibromuscular disease (FMD)
- Stented renal artery
- Renal artery aneurysm
- Renal artery diameter stenosis >30%
- Pregnancy
- Presence of abnormal kidney (or secreting adrenal) tumors
- Iliac/femoral artery stenosis precluding insertion of the catheter

Warnings
- Failure to use the recommended balloon size may result in renal artery stenosis, dissection, perforation, aneurysm, significant vasospasm requiring intervention, ablation of unintended tissues or structures, and/or no ablation of target tissue achieved.
- Energy emission in an unintended location may result in unintended tissue damage.
- 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 arterial target zone.

Precautions
- Patients with known allergy to contrast medium may be at increased risk of hypersensitivity reactions.
- Only use specified coolant (Sterile water) for fluid supply. DO NOT USE SALINE.
- 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
Ablation or thermal injury to vessel, adjacent tissue or other structures, 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, Vasovaga response, Stroke or transient ischemic event

Potential risks of arterial catheterization procedure
Allergic reaction to contrast, Arterio-enteric fistula, Arterio-venous fistula, Bleeding, Cardiopulmonary arrest, Complications related to pain and anti-anxiety medications, Death, Deep vein thrombosis, Edema, Embolism (pulmonary, renal, peripheral vasculature, plaque), Hematuria, Infection, Myocardial infarction, Pain, Vascular access site complications (pseudoaneurysm, pain, swelling, hematoma)

The Paradise System is FDA approved in the United States, is CE marked and approved for sale in markets where the CE mark is accepted per approved indications for use and received manufacturing and marketing approval in Japan.

Recor Medical®

See how it works
www.recormedical.com