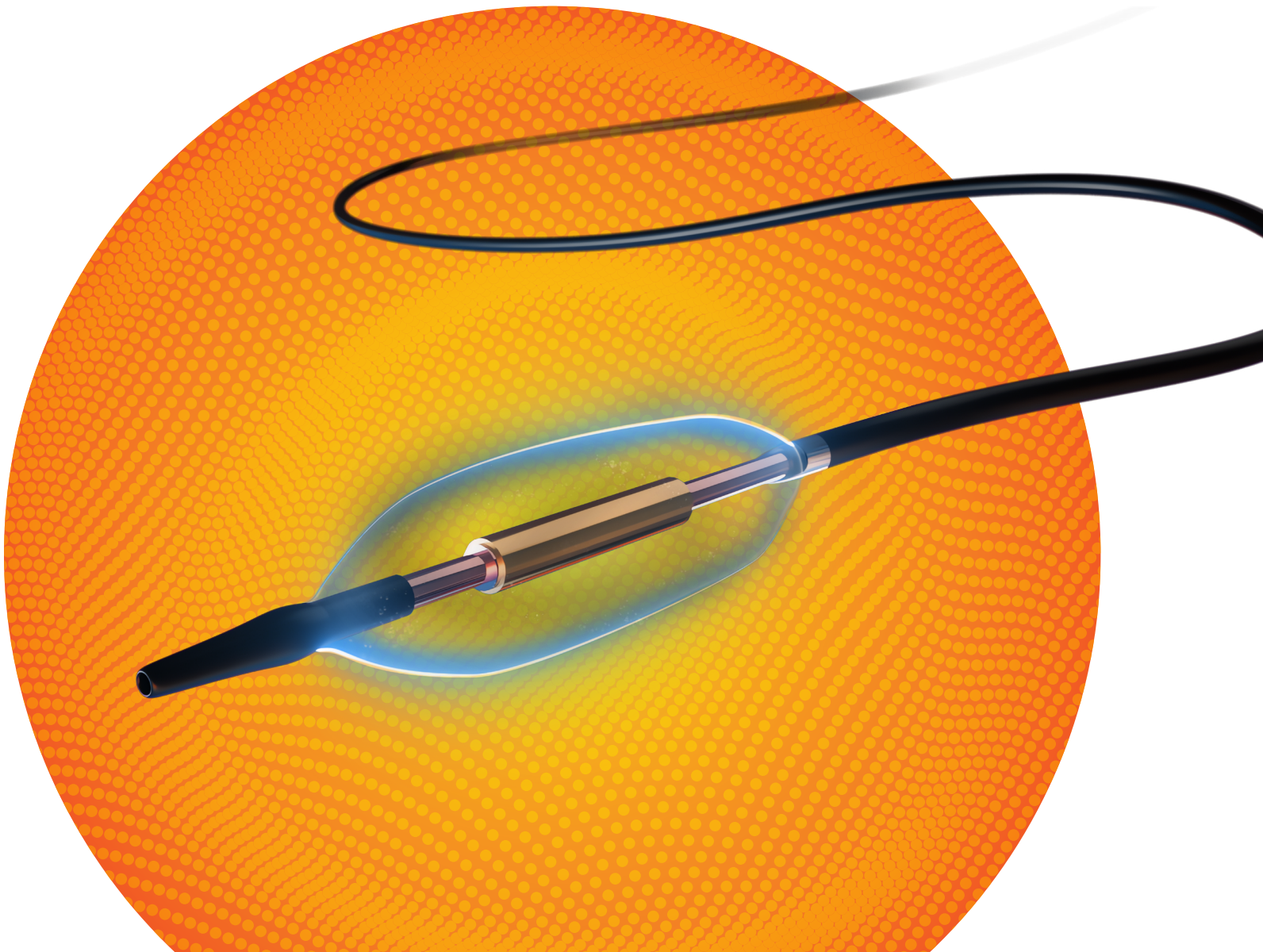




# Experience a new path to lowering blood pressure.

The Paradise™ Ultrasound Renal Denervation Procedure



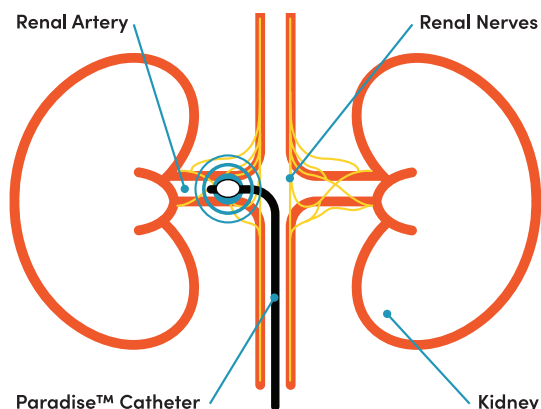
# Drive to blood pressure goal.

Paradise uRDN procedure treats the root cause of hypertension by calming the overactive nerves. When medications and lifestyle changes are not enough, it delivers safe and sustained reductions.

## How it works.

The Paradise uRDN procedure works by delivering ultrasound energy to renal arteries to disrupt overactive sympathetic nerves, reducing nerve signaling that contributes to high blood pressure.

It is a short procedure that takes about an hour. It is not an implant. Patients go back to their referring physician for follow-up.



For every 10mmHg systolic blood pressure reduction a patient achieves they reduce the risk of:<sup>1</sup>

Major cardiovascular  
events by **-20%**

Coronary Heart  
Disease by **-17%**

Stroke  
by **-27%**

Heart failure  
by **-28%**

## A proven approach to managing hypertension.

**-10.4  
mmHg**

Office systolic blood  
pressure at 2 months<sup>2</sup>  
(n=293)

**RADIANCE RCTs Pooled results**

**-18.4  
mmHg**

Office BP at 2 months in responders  
(≥5 mmHg decrease at 2M)<sup>3</sup>  
(n=43)

**RADIANCE TRIO (On-MED)**

**-17.2  
mmHg**

Office BP at 3 years<sup>4</sup>  
(n=51)

**RADIANCE SOLO (Off-MED)**

# Trust in proven safety.

A one-time, minimally invasive, outpatient procedure delivering meaningful BP reductions for years. Proven safe with no impact to kidney function<sup>1</sup>, and without the side effects of drugs.

## Safe treatment proven procedural protection

**ZERO** major adverse events  
in the pivotal trial<sup>6</sup>

**NO** impact on renal  
function at 2 months<sup>1</sup>

**ZERO** clinically significant renal  
arterial stenosis at 6 months<sup>1</sup>



### Is the Paradise uRDN procedure right for your patients?

Paradise uRDN procedure candidates may include a range of patients like ones listed below<sup>\*\*</sup>:

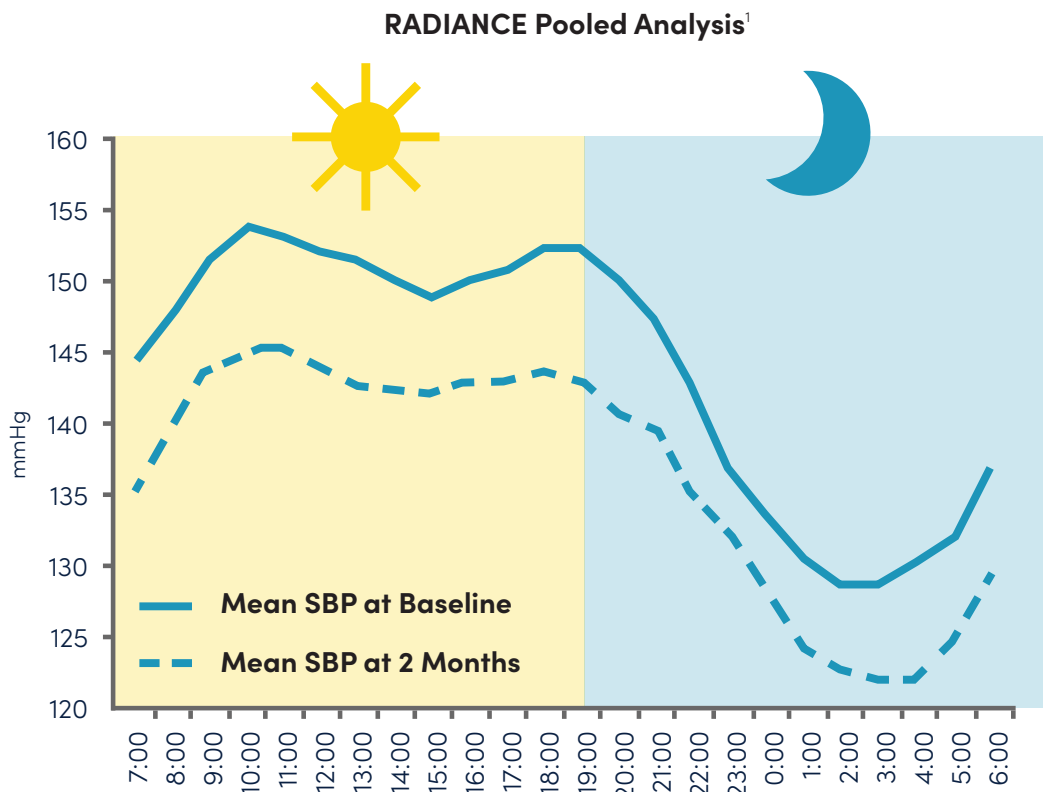
- Patients who have history of or at high risk of cardiovascular events.
- Patients who have elevated BP despite 3+ medications.
- Patients who are on multiple medications and have documented non-adherence.
- Patients who have history of hypertensive emergency.



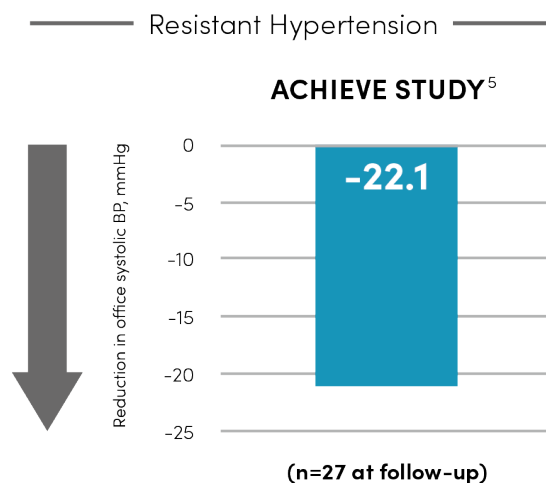
[Learn more](#)

# Deliver lasting outcomes.

Transforming how you and your patients can manage uncontrolled hypertension, with a meaningful blood pressure drop at 6 months, sustained reduction out to many years, and **24-hour, always-on** treatment effect.



Paradise Ultrasound procedure led to a sustained reduction in office systolic blood pressure through 8 years.<sup>5</sup>



# It's not another pill, It's another way.

Renal Denervation is a consensus-backed procedure proven to manage high blood pressure

The American Heart Association's 2024 RDN statement recommends that RDN should be considered for patients with **resistant, uncontrolled hypertension**.

| Patient Selection                                 | AHA 2024 <sup>7</sup> | SCAI 2023 <sup>8</sup> | ESC 2024 <sup>9</sup> |
|---------------------------------------------------|-----------------------|------------------------|-----------------------|
| <b>Resistant hypertension</b><br>(3+ medications) | +                     | +                      | +                     |
| <b>Intolerant to drugs</b>                        | +                     | +                      | +                     |
| <b>Non-adherent to drugs</b>                      | +                     | +                      | +                     |

The Paradise system is now fully reimbursed and covered by Medicare Fee-For-Service.<sup>10</sup>

**It's the proof. It's the safety.  
It's the outcome.**

**Paradise Ultrasound Renal Denervation Procedure**

**Reach out to your Recor representative to learn which hospitals in your area offer the Paradise uRDN procedure.**

**recormedical.com**

**References:** 1. Ettehad et al. Lancet 2016; 387: 957–67. 2. Kirtane A. et al. JAMA Cardiol. 2023;8(5):464–473 3. Azizi M. et al. Lancet. 2021 Jun 26;397(10293):2476–2486. 4. Rader et al. EuroIntervention 2022;18–online 5. Zeijen et al. ACHIEVE Study, TCT 2023 6. Azizi M. JAMA. 2023;329(8):651–661 7. Cluett J, et al. Hypertension. 2024;81:e00–e00 8. Swaminathan et al. Journal of the Society for Cardiovascular Angiography & Interventions, published ahead of print on 21 August, 2023. 9. European Heart Journal, ehaf178, <https://doi.org/10.1093/eurheartj/ehaf178>. 10. The Paradise System is eligible for additional reimbursement via a Transitional Pass-Through (TPT) Payment for qualifying outpatient procedures. Full TPT Payment depends on appropriate hospital billing practices. Medicare FFS coverage is based on "Reasonable and Necessary Guidelines". Link for more information on what qualifies as reasonable and necessary: <https://www.novitas-solutions.com/webcenter/portal/MedicareJH/pagebyid?contentId=00099545>

#### **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 >8 mm • 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, Vasovagal 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)

**Recor**  
Medical®

1049 Elwell Court  
Palo Alto, CA 94303

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