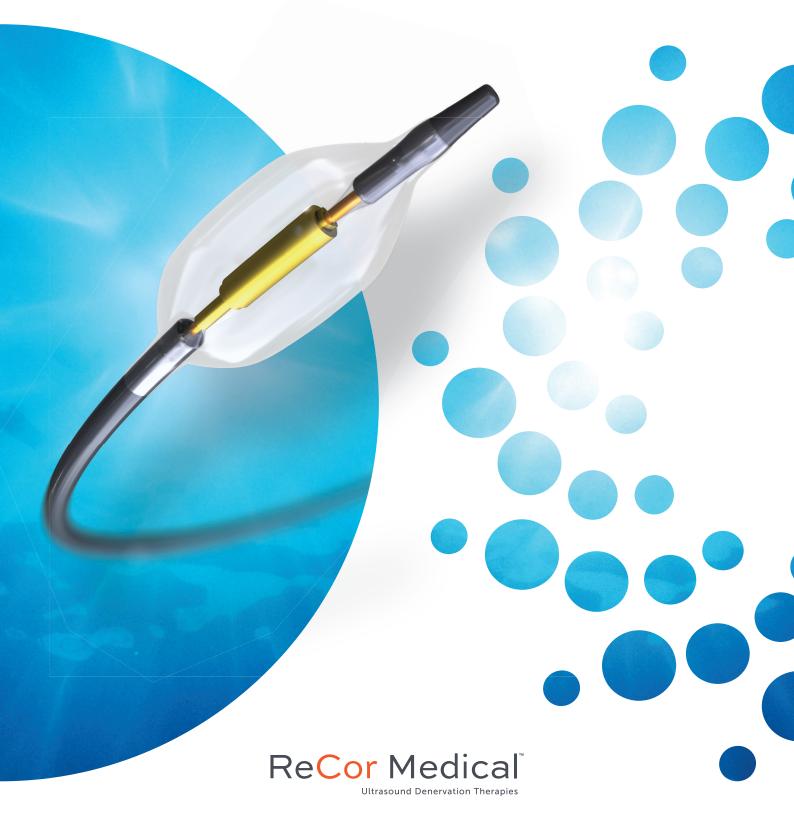


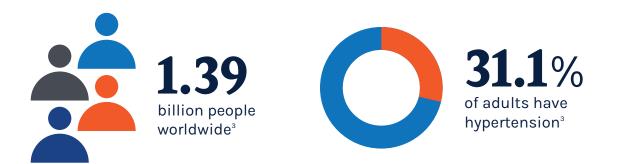
# Advancing the treatment of uncontrolled hypertension

## Paradise<sup>™</sup> Ultrasound Renal Denervation System





## Hypertension impacts billions of patients worldwide



## About 20% of treated patients have resistant hypertension

Even with 3 or more medications, patients struggle to control hypertension leading to an increased risk of cardiovascular complications and mortality.



## The need for different treatment options is clear

For patients struggling to control their hypertension, now there is a treatment that is proven to lower their blood pressure.





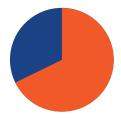


# Ultrasound Renal Denervation (uRDN) is a minimally invasive procedure that lowers high blood pressure by treating overactive renal nerves with ultrasound energy

## The optimal RDN system should:

- Provide full circumferential energy at sufficient depth to target the majority of nerves
- Produce consistent energy for different sizes of vessel
- Protect the arterial wall
- Minimize ablation and procedure time for patient comfort and safety

# Ultrasound RDN demonstrated meaningful blood pressure reduction in multiple clinical trials<sup>5,6</sup>

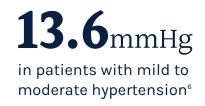


Over 2/3 of treated patients experienced meaningful blood pressure reduction.



In those who responded to the treatment the average drop in ABP was

**17.0**mHg in patients with resistant hypertension on 3+ meds<sup>5</sup>





# Paradise<sup>™</sup> Ultrasound Renal Denervation System

## Maximize denervation with a simplified procedure

### Proven to treat uncontrolled hypertension

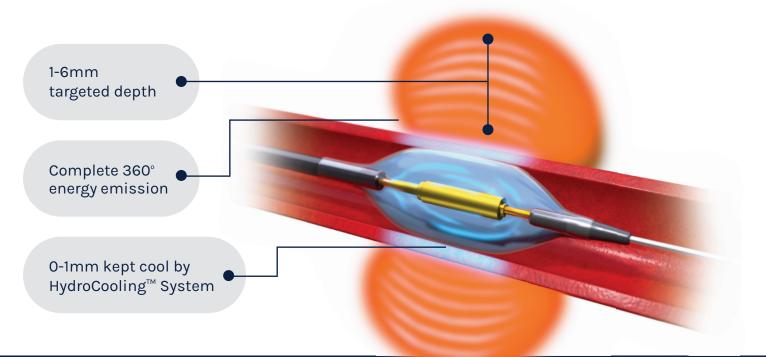
- Complete 360° energy emission in a single sonication for maximum benefits of renal denervation<sup>®</sup>
- BP reduction achieved both with and without anti-hypertensive medication in sham controlled studies<sup>5,6</sup>
- Continuous treatment effectiveness day-and-night<sup>5,6</sup>

## **Designed for patient safety**

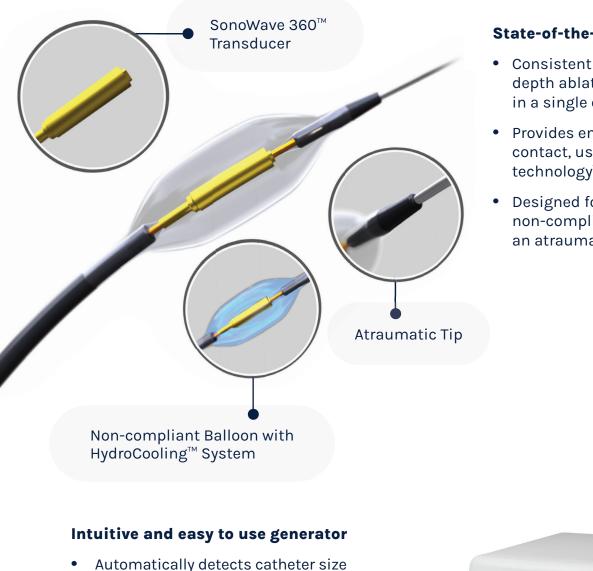
- HydroCooling<sup>™</sup> System protects the arterial wall<sup>7</sup> by minimizing risk of overheating and subsequent tissue damage
- 0% major adverse device related events+5
- No renal arterial injury or new onset of stenosis<sup>±6</sup>
- Short sonication time can lead to reduced radiation exposure, anaesthesia, and pain<sup>7</sup>

### **Simplified procedure**

- Only 7-second sonications, with 2-3 sonications per main renal artery<sup>5-7</sup>
- Majority of procedure can be completed in the main vessel
- Intuitive system setup compatible with standard accessories<sup>®</sup>



## The Paradise<sup>™</sup> Ultrasound **Renal Denervation System gives you** an innovative treatment option



- Automatically detects catheter size and adjusts energy level<sup>®</sup>
- Consistent energy emission irrespective of arterial dimension<sup>8</sup>
- Efficient workflow through a simple, user-friendly interface that can be set up quickly<sup>8</sup>

### State-of-the-art catheter

- Consistently targets 1-6 mm depth ablating ~80% nerves in a single emission<sup>®</sup>
- Provides energy without tissue contact, using HydroCooling technology<sup>7,8</sup>
- Designed for safety, with a non-compliant balloon and an atraumatic tip<sup>8</sup>



## **Components & Ordering Information**

Components	Specs	Part Number
Paradise™ Catheter	<ul> <li>SonoWave 360 Transducer (~5mm long) in each balloon catheter</li> <li>Over-the-Wire (OTW) balloon catheter compatible with 0.014", 180–190cm guidewire</li> <li>85cm working length compatible with 55cm guide catheter or guiding sheaths (0.081" minimum inner diameter)</li> <li>Treats renal arteries 3-8mm in diameter</li> <li>Supplied sterile, single use</li> </ul>	3.5mm balloon: PRDS-063-02 4.2mm balloon: PRDS-064-02 5mm balloon: PRDS-065-02 6mm balloon: PRDS-066-02 7mm balloon: PRDS-067-02 8mm balloon: PRDS-068-02
Paradise™ Generator	Portable customized generator <b>Height:</b> 29.0cm <b>Width:</b> 26.0cm <b>Depth:</b> 39.8cm <b>Weight:</b> 11.0kg	PRDS-USG-2X
Paradise™ Cartridge	Supplied sterile, single use	PRDS-CT-02
Paradise™ Cable	Supplied sterile, single use	PRDS-CC-02

Give your patients struggling to manage hypertension a safe and effective treatment– **The Paradise<sup>™</sup> Ultrasound Renal Denervation System** 



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+ Major adverse events within 30 days of procedure attributable to Paradise system.

± Renal artery or other major vascular complication requiring intervention and/or new onset renal artery stenosis of >70%.

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2. Foreman, K. et al. Forecasting life expectancy, years of life lost, and all-cause and cause-specific mortality for 250 causes of death: reference and alternative scenarios for 2016-40 for 195 countries and territories. Lancet 2018; 392: 2052-90. 3. Mills KT, Stefanescu A, He J. The global epidemiology of hypertension. Nat Rev Nephrol. 2020;18(4):223-237. 4. Ettahad et al. Blood pressure lowering for prevention of cardiovascular disease and death: a systematic review and meta-analysis. Lancet. 2016 March; 387(10022):P957-967. 5. Azizi et al. Ultrasound renal denervation for hypertension resistant to a triple medication pill (RADIANCE-HTN TRIO): a randomised, multicentre, single-blind, sham-controlled trial. Lancet. 2018 Jun 9;391(10137):2335-2345. 7. Pathak et al. Renal sympathetic nerve denervation using intraluminal ultrasound within a cooling balloon preserves the arterial wall and reduces sympathetic nerve activity. EuroIntervention. 2015 Aug;11(4):477-84. 8. Data on file. ReCor Medical. 9. Rader et al. TCT 2021.

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