

# Ultrasound Ablation of the Renal Sympathetic Nerves

March 7, 2023

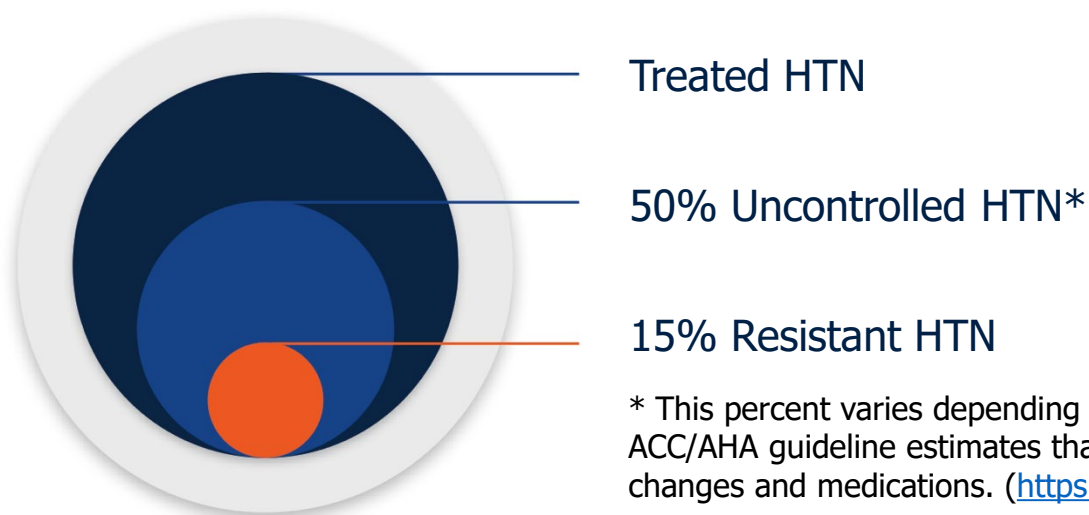
ICD-10 Coordination and Maintenance Committee Meeting

# Background on ICD-10-PCS Code Request

- The Paradise™ Ultrasound Renal Denervation System (Paradise System) has received Breakthrough Device Designation from the FDA in December 2020 and PMA approval for the Paradise™ System is expected in Q2 2023.
  - ReCor Medical has applied for NTAP for the Paradise System as part of the FY 2024 cycle.
- Proposed indication for use for Paradise™ System:
  - To reduce blood pressure in adult ( $\geq 22$  years of age) patients with uncontrolled hypertension, who may be unresponsive to, or who are intolerant to anti-hypertensive medications.
- There is no ICD-10-PCS code to specifically describe ablation of sympathetic nerves around the renal arteries using endovascular ultrasound catheter devices

# Significant Unmet Needs Among Treated Hypertension Patients

The worldwide prevalence of hypertension was estimated at 1.39 billion persons in 2010, representing 31% of all adults.



15% remain uncontrolled despite physicians' best efforts and pharmaceutical treatment with 3 or more medications, leading to an increased risk of cardiovascular complications and mortality.

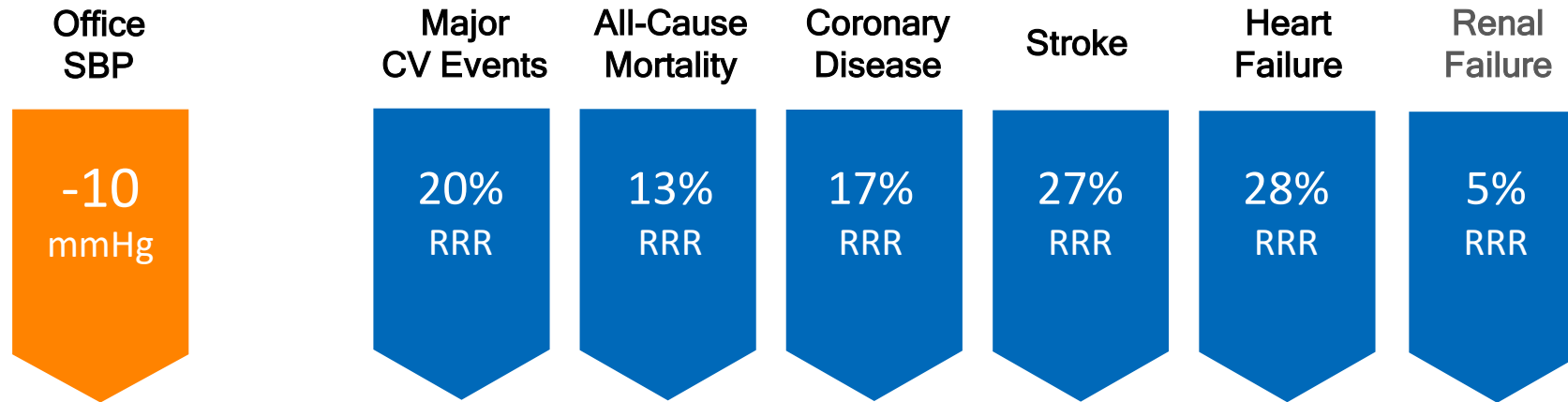
\* This percent varies depending on the definition of hypertension used. Applying criteria for the 2017 ACC/AHA guideline estimates that only 26% have controlled (74% uncontrolled) hypertension with lifestyle changes and medications. (<https://millionhearts.hhs.gov/data-reports/hypertension-prevalence.html>)

**SIGNIFICANT UNMET NEEDS: 50% Uncontrolled HTN, including 15% Resistant HTN**

Dudenbostel T, Siddiqui M, Gharpure N and Calhoun DA. Refractory versus resistant hypertension: Novel distinctive phenotypes. *J Nat Sci.* 2017; 3(9).  
Noubiap JJ, Nansseu JR, Nyaga UF, et al. Global prevalence of resistant hypertension: a meta-analysis of data from 3.2 million patients. *Heart.* 2019; 105(2):98-105.  
Judd E and Calhoun DA. Apparent and true resistant hypertension: definition, prevalence and outcomes. *J Hum Hypertens.* 2014; 28(8):463-8.

# Correlation Between Blood Pressure Reduction and CV Events

RELATIVE RISK REDUCTION (RRR) of a 10 mmHg Reduction in Systolic Office Blood Pressure

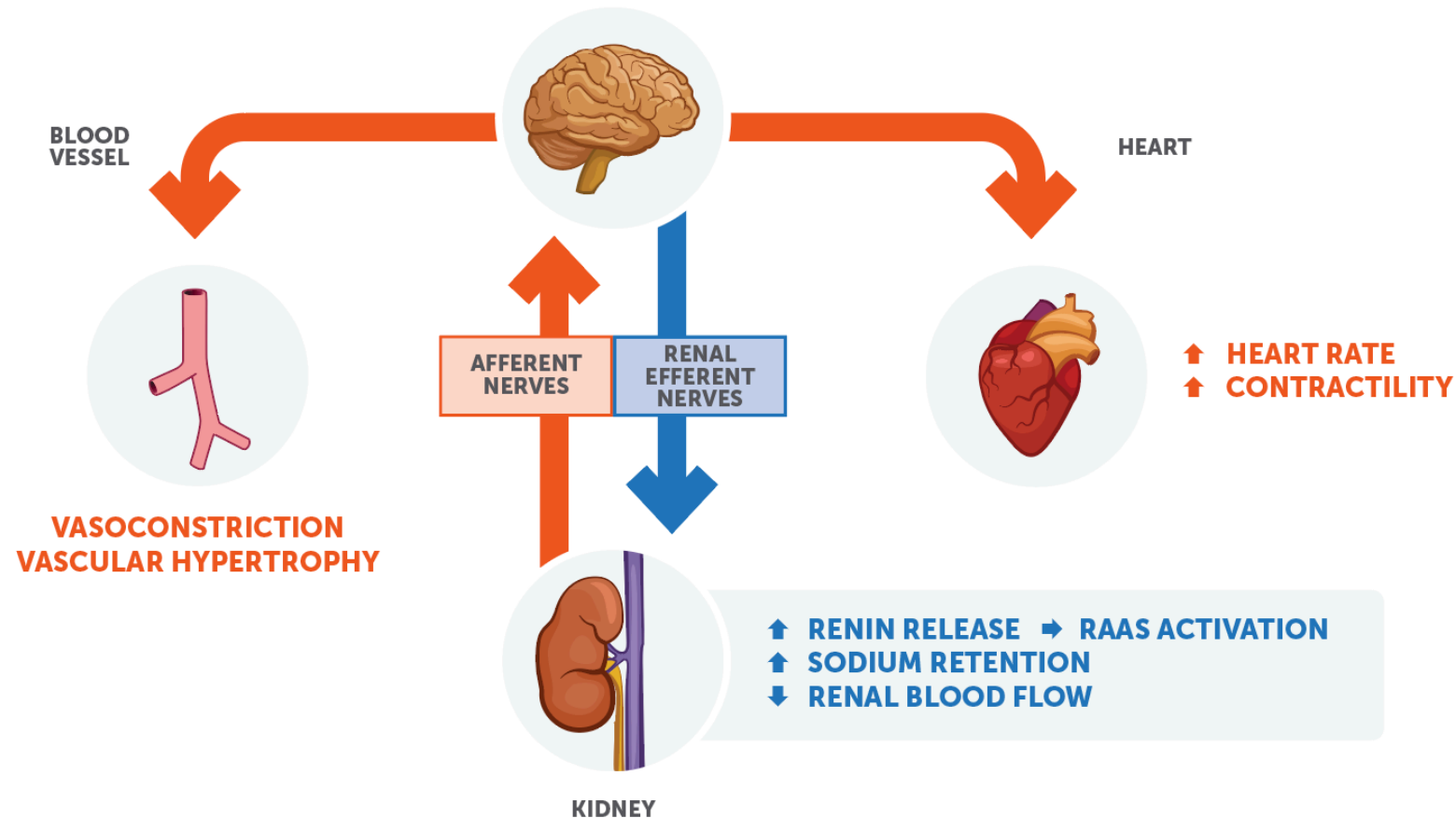


20% RELATIVE RISK REDUCTION of Major CV Events with 10 mmHg BP Drop

Based on meta-analysis of 613,815 patients from 123 studies

Ettehad et al, Blood pressure lowering for prevention of cardiovascular disease and death, *Lancet* 2016; 387: 957-67

# How do Renal Nerves Affect Blood Pressure?



Increased activity of the sympathetic nervous system leads to hypertension

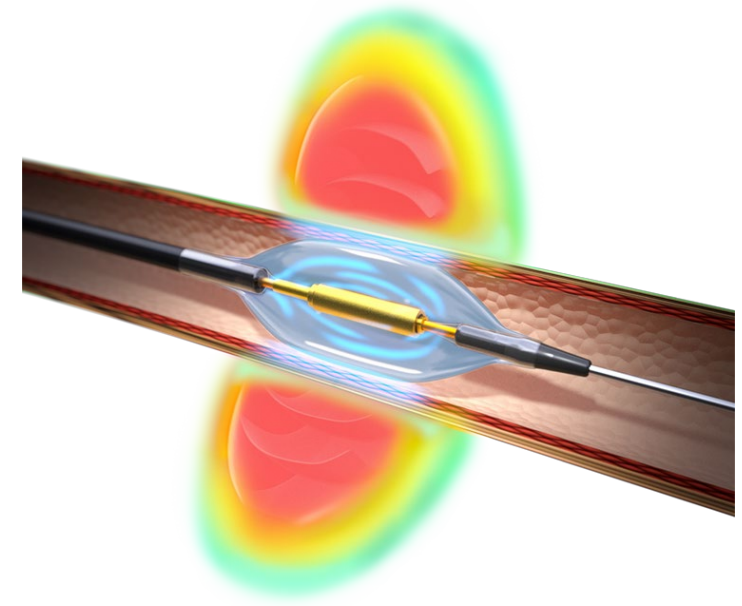
# What is the Paradise™ System Ultrasound Renal Denervation?

- Endovascular ultrasound catheter with balloon cooling system to protect arterial wall
- Utilizes standard arterial access in a catheterization lab setting
- Provides a circumferential ring of ablative energy (depth of 1-6 mm) to interrupt renal nerve signaling
- Automated energy emission
- Procedure consists of 2-3 sonications (ablations) each lasting 7 seconds delivered bilaterally to appropriately sized renal arteries

ReCor Medical  
Ultrasound Denervation Therapies

## Thermal Profile

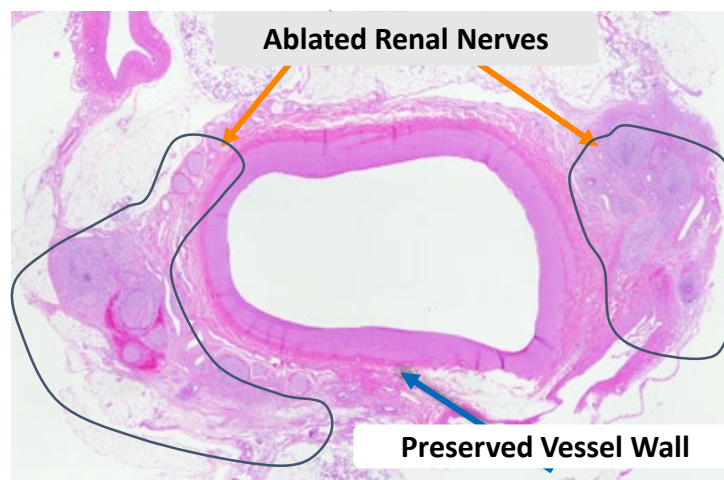
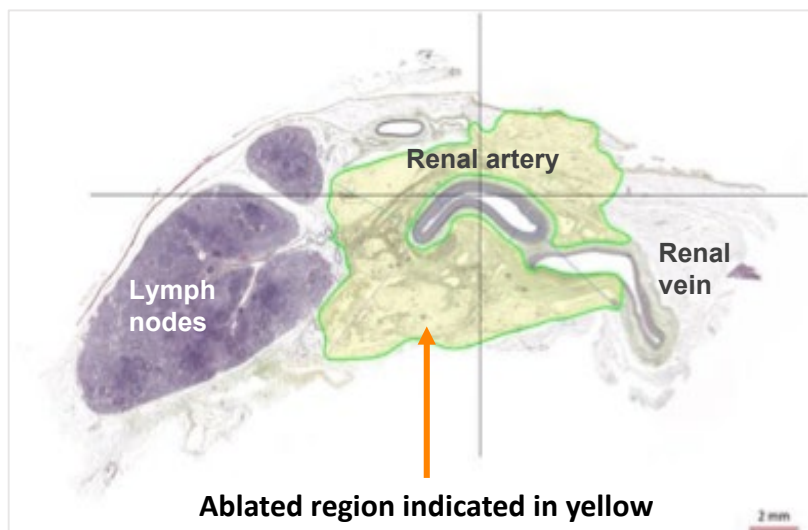
**Ultrasonic Heating** + **Water Cooling**



# Circumferential Sonication and Arterial Wall Protection

## Porcine Model (7-day)

- Renal arterial wall protected from thermal injury
- Significant renal nerve injury at each ultrasound emission
- Target ablation depth of 1-6 mm



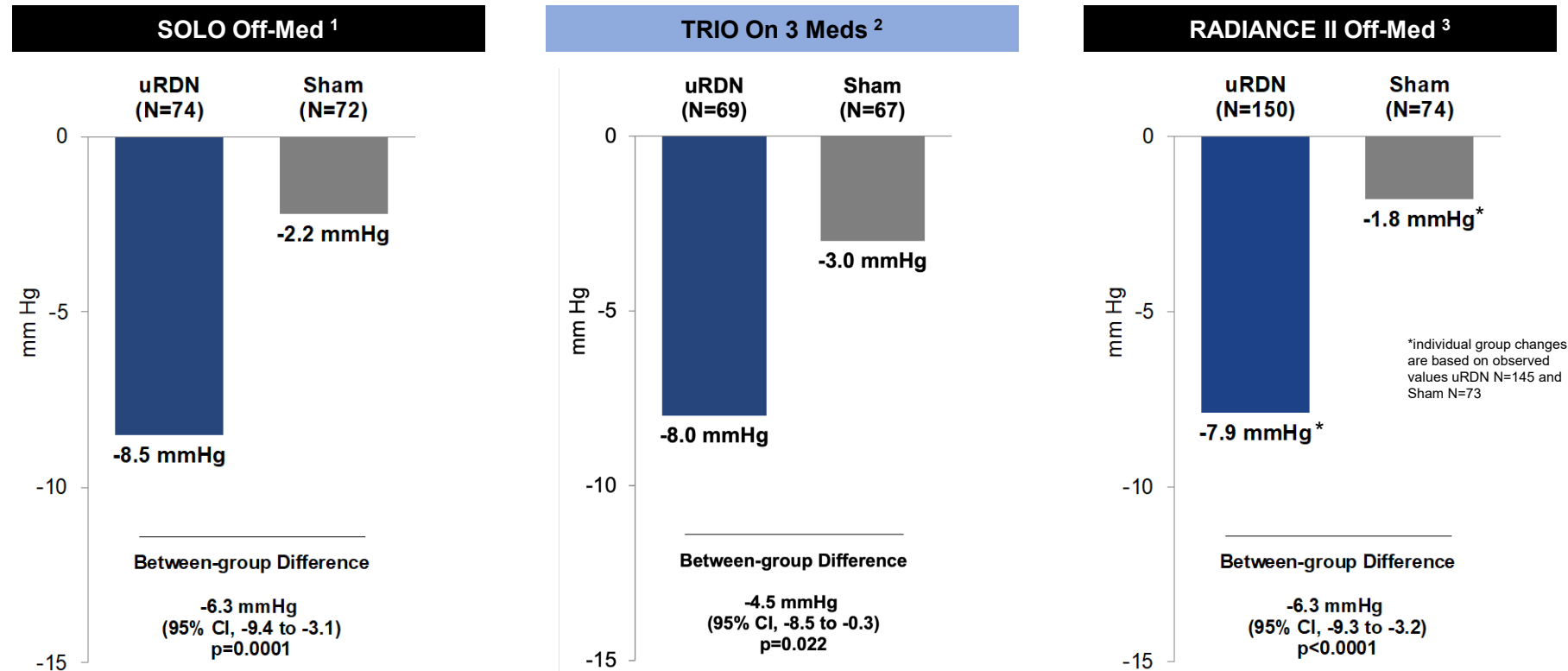
Histology of Swine renal artery after renal denervation. Renal nerves are ablated, yet arterial wall is preserved.

Paradise™ Catheter helps protect artery wall

# Clinical Trials

- Endovascular ultrasound renal denervation (uRDN) with the Paradise™ System has been shown to lower BP in patients with both mild-moderate hypertension and hypertension resistant to a triple combination pill in three international, prospective, randomized, sham-controlled trials (IDE studies)
  - RADIANCE HTN-SOLO,
  - RADIANCE HTN-TRIO
  - RADIANCE II
- Establishing the magnitude of overall blood pressure lowering and consistency of effect is clinically important when considering this device-based therapy to treat hypertension.

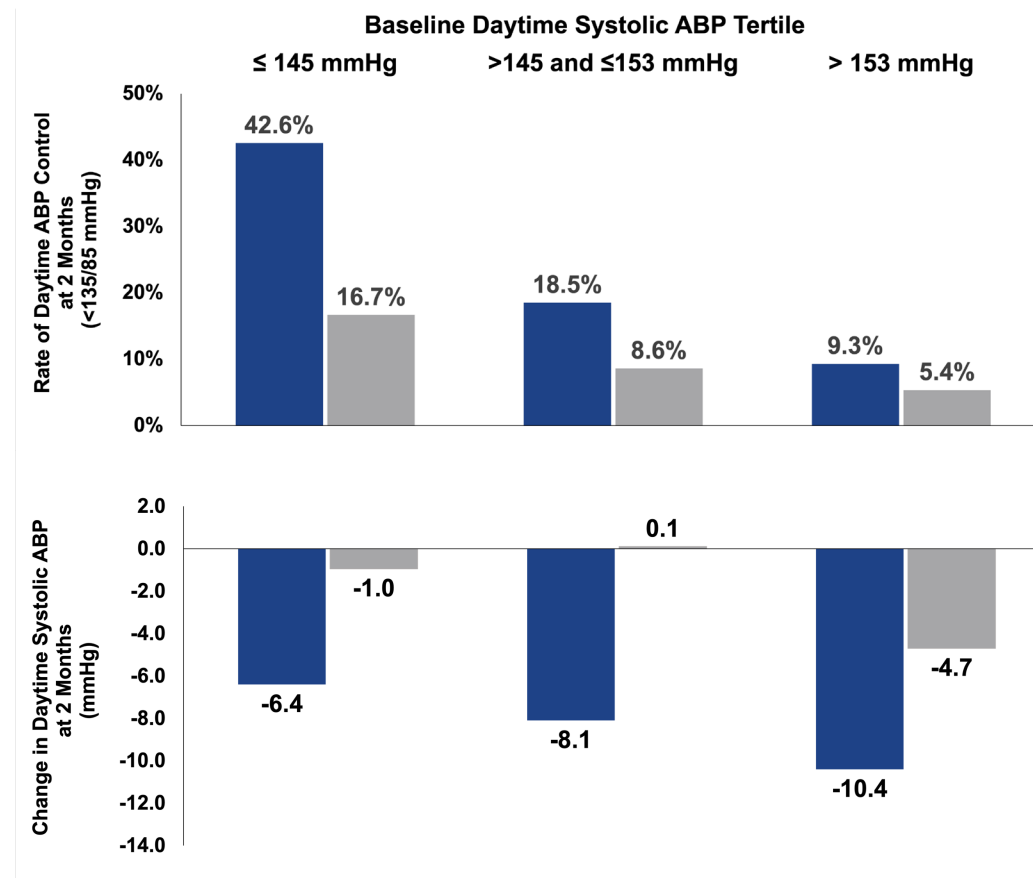
# SOLO, TRIO, RADIANCE II: Primary Endpoint Change in Daytime Ambulatory Systolic BP (mmHg) at 2 Months



Individual group changes are means for SOLO and RADIANCE II and medians for TRIO. Between-group differences are adjusted for baseline blood pressure

1. Azizi et al. *Lancet*. 2018 Jun 9;391(10137):2335-2345.
2. Azizi et al. *Lancet*. 2021 Jun 26;397(10293):2476-2486.
3. Kirtane et al. TCT2022.

# Pooled Analysis of Three RCTs (RADIANCE-II, RADIANCE SOLO & RADIANCE –TRIO): Daytime ABP Control and BP Change at 2 Months Stratified by Baseline BP



P for Trend  
Total Population: P<.001  
uRDN: P<.001  
Sham: P=.040

■ uRDN  
■ Sham

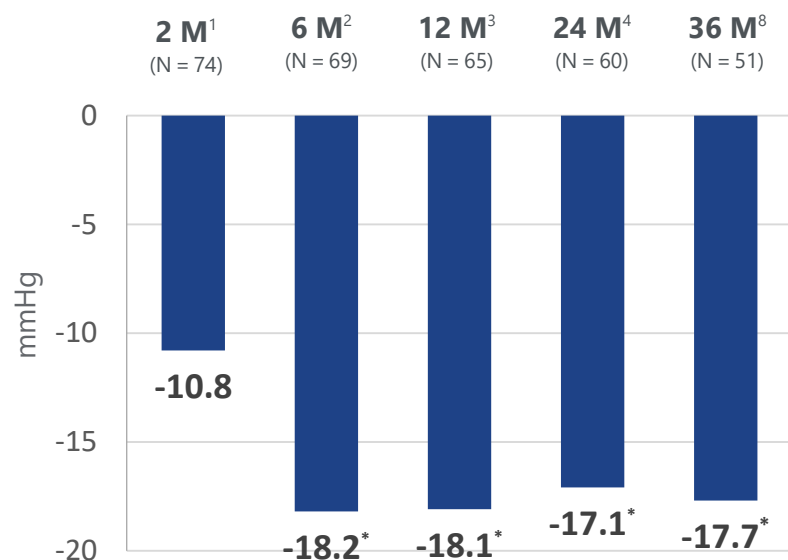
P for Trend  
Total Population: P=.0055  
uRDN: P=.025  
Sham: P=.10

Kirtane et al. TCT2022.

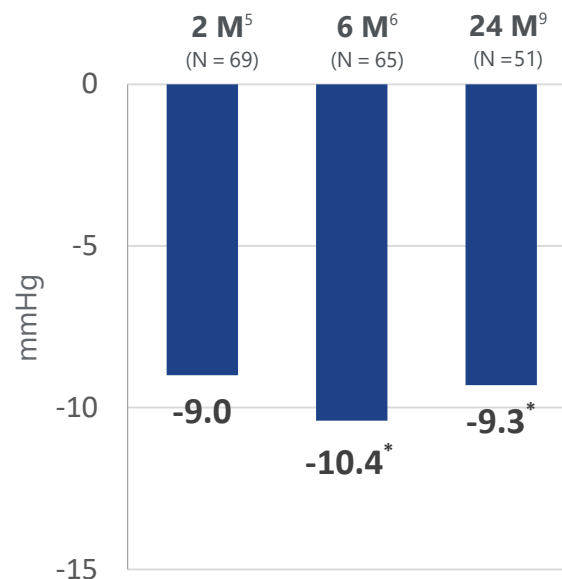
ITT population with observed values, excluding all subjects that started medications prior to 2 months (uRDN N=261 and Sham N=180)

# Office Systolic BP Durability Through at least 36M

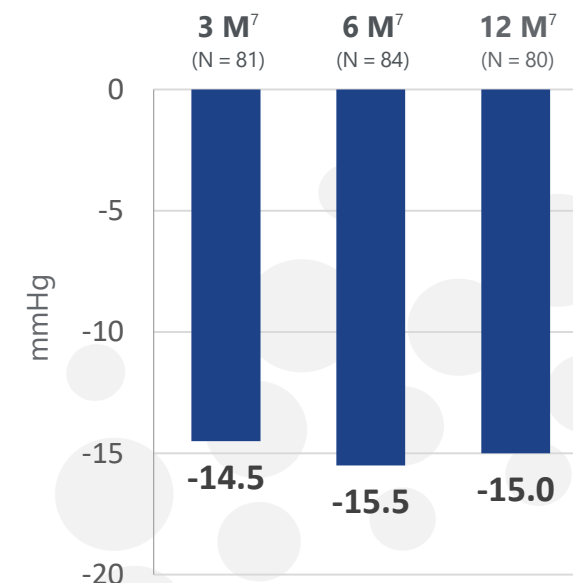
**RADIANCE-HTN SOLO**



**RADIANCE-HTN TRIO**



**ACHIEVE Study**



Long-term Durability Demonstrated in the  
RADIANCE-HTN and ACHIEVE Studies

\* Medication titrated

1. Azizi et al. *Lancet*. 2018 Jun 9;391(10137):2335-2345. 2. Azizi et al. *Circulation*. 2019;139:2542-2553. 3. Azizi et al. *JACC Cardiovasc Interv*. 2020 Dec 28;13(24):2922-2933. 4. Rader et al. TCT 2021 5. Azizi et al. *Lancet*. 2021;397:2476-2486. 6. Kirtane et al. TCT 2021. 7. Daemen et al. *J Hypertens*. 2019 Sep;37(9):1906-1912. 8. Rader et al. *EuroIntervention* 2022;18-online 9. Schmieder et al. TCT 2022

# Existing ICD-10 Codes and Code Request

## **Diagnosis**

- The following ICD-10-CM codes are associated with the device:

I10 Essential primary hypertension

I15.1 Hypertension secondary to renal disorders

I15.8 Other secondary hypertension

I15.9 Secondary hypertension, unspecified

## **Documentation**

- The approach for documenting the procedure in the medical record will vary by provider
- Documentation Example:
  - Internal procedure code established by the provider
  - Notes ultrasound renal denervation or ablation of renal (sympathetic) nerves using ultrasound in the medical record