Recor Medical™

A proven approach to lower blood pressure

Paradise™ Ultrasound Renal Denervation

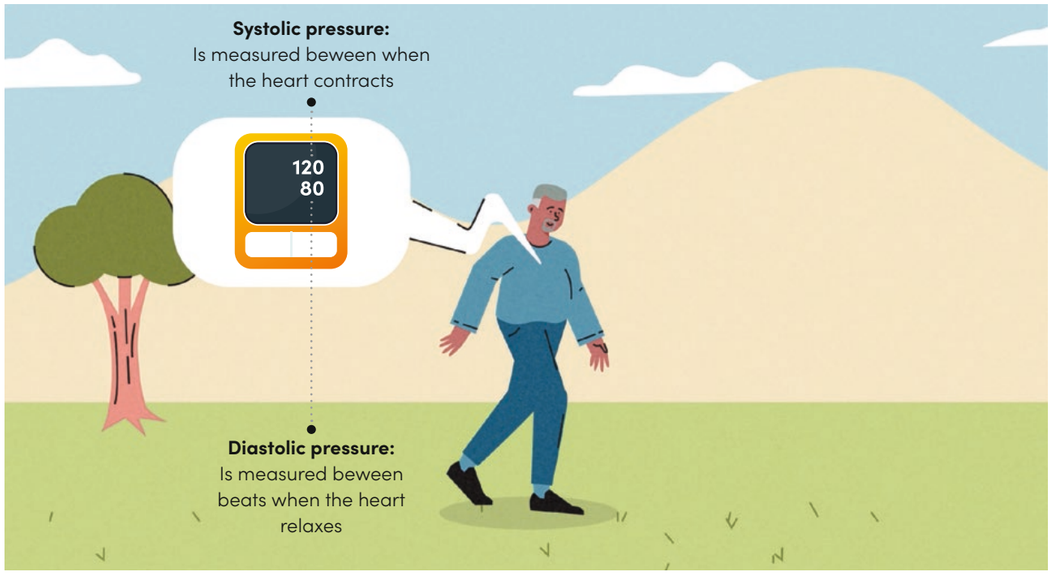
Actor portrayal.

High Blood Pressure (Hypertension)

Blood pressure is the force the blood applies on the artery as it goes through the body. Like air in a tire, blood fills your arteries and can damage your arteries if the pressure is too high and lead to life-threatening conditions.

Systolic and diastolic blood pressure

- The upper readings is the systolic blood pressure (SBP), which indicates the pressure that the blood exerts on the artery walls when the heart beats.
- The lower number, diastolic blood pressure (DBP), indicates what pressure is exerted by the blood on the artery walls, while the heart rests between two beats.



Hypertension is a silent killer[1]

- Most people with high blood pressure have no signs or symptoms, even if blood pressure readings reach dangerously high levels.
- When blood pressure is too high, organ damage can occur. This can lead to serious, sometimes life-threatening secondary issues like heart attack, heart failure or stroke, and kidney failure.

Symptoms and Diagnosis

- High blood pressure is present when the upper (systolic) value is 140mmHg or more or the lower (diastolic) value is 90mmHg or more. Even if only the upper or the lower value is increased, it's still considered high blood pressure.
- Blood pressure is not always the same throughout the day. It's typically lower at night and usually higher early in the morning. With exertion or excitement, the pressure may increase, but should then return to normal. When blood pressure is measured at various times on different days and it's still high, it's diagnosed as high blood pressure.
- Blood pressure measured in a doctor's office (officially called office blood pressure) falls into different categories, depending on its value.

Grades of Hypertension

Identifying adults with hypertension and evalute severity in regards to cardiovascular risk (CV).[1]

Categories	**Systolic Value** (Office Blood Pressure)		**Diastolic Value** (Office Blood Pressure)
Optimal	under 120	**and**	under 80
Normal	120 - 129	**and/or**	80 - 84
Above Normal	130 - 139	**and/or**	85 - 89
Hypertension Grade 1	140 - 159	**and/or**	90 - 99
Hypertension Grade 2	160 - 179	**and/or**	100 - 109
Hypertension Grade 3	180 and more	**and/or**	110 or more
Isolated Systolic Hypertension	140 and more	**and**	under 90

Do you have difficulty controlling your blood pressure? You are not alone.

Only

1/5

of the adults with hypertension have it under control[2]

At age 50, people without high blood pressure have
a life expectancy

5 YEARS LONGER

than people with high blood pressure.[3]

Reducing your blood pressure by 10 mmHg can lower your risk of[4]:

Heart Failure by ↓ **28 %**

Stroke by ↓ **27 %**

Cardiac event by ↓ **20 %**

Three options for treating hypertension[1]

Lifestyle Changes

Blood pressure can be reduced by changes in lifestyle habits:

- **Regular physical activity** (5 x / week 30 min. endurance activity)
- **Stay within normal weight ranges.** A decrease in body weight by 1 kg may lead to a reduction in systolic blood pressure by 1 mmHg.
- **A fruit- and vegetable-rich diet** with little meat and the use of unsaturated instead of saturated fats
- **Low-salt diet** (< 5 g/day table salt)
- **Quit smoking** and **lower alcohol** consumption
- **Reduce stress**

Anti-Hypertensive Medicines

- If you're unable to regulate your blood pressure with lifestyle changes and your blood pressure values are over 140/90mmHg, your doctor may prescribe medication treatment.
- Your doctor may prescribe a pill that combines several active ingredients into a single pill, or it may be necessary for you to take multiple pills. Your doctor will discuss medication options with you and prescribe medications.

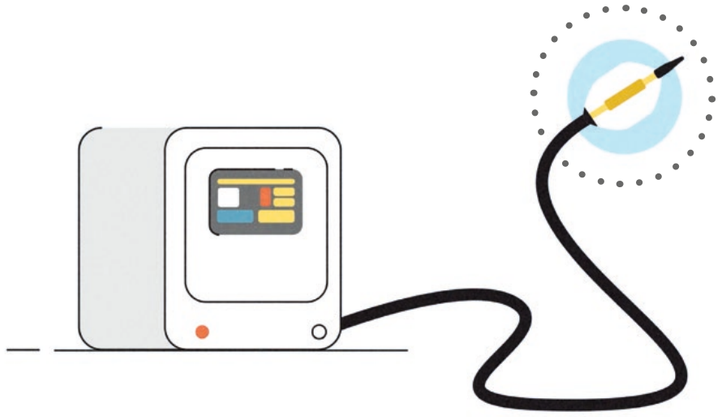
Ultrasound Renal Denervation

- Some people aren't successful in lowering their blood pressure with lifestyle changes and antihypertensive medication, also some may be intolerant to some drugs or do not want to take it or have secondary causes of hypertension.
- So, in addition to lifestyle changes and medications, renal denervation with ultrasound technology is another option to treat high blood pressure.
- People with high blood pressure typically have overactive renal (kidney) nerves, and it has been shown that decreasing activity of these overactive nerves can help reduce blood pressure. RDN is a minimally invasive treatment that uses energy to deactivate the overactive nerves that cause high blood pressure.

The Paradise™ ultrasound RDN treatment

In many people with high blood pressure, the nerves leading to the kidneys have become overactive, causing blood pressure to increase. The Paradise procedure uses ultrasound energy to calm the nerves near the kidneys to help lower blood pressure.

- One-time, safe, minimally invasive treatment proven to reduce high blood pressure[5-8]
- Fast recovery allows for an easy return to regular life
- Provides 24-hr blood pressure reductions without the side effects of medications.[5-8]



Learn how Paradise™ Ultrasound RDN works:
www.recormedical.eu/patients

Going for treatment with the Paradise™ Ultrasound RDN procedure was a great decision for me because now I have only one blood pressure medication.

Prior to it, it was all over the board, I was taking all those medications and my blood pressure was up and down. For me personally, it is a lifesaver.

David, 48 years old

Actor portrayal.

Frequently Asked Questions

Where does the treatment take place?

Ultrasound Renal Denervation takes place or usually takes places in an interventional suite. After Ultrasound Renal Denervation treatment, your doctor will determine how long you need to stay. Ask your doctor more about Ultrasound Renal Denervation treatment.

How long does the treatment take?

Your doctor will perform two or three 7-second treatments in the arteries that go to each kidney. The overall treatment time is approximately less than an hour, which includes preparation time as well.

Is the treatment painful?

Your doctor will typically give you medications to keep you comfortable during the treatment. The access site is prepared with a local anesthetic and painkillers are administered intravenously as needed to minimize pain.

Will my kidneys function the same as before the treatment?

Clinical studies[5-8] with the Paradise™ System for Renal Denervation have shown no impact to the kidney function following the treatment.

How can I benefit from this treatment?

Treatment with the Paradise™ System can lower blood pressure. However, the results of the treatment can vary with individuals and their conditions. Understand how Paradise System can benefit you by discussing your condition with your doctor.

Can I discontinue my blood pressure medication after the treatment?

After your treatment with the Paradise™ System, your doctor will monitor your blood pressure and will let you know if you may adjust, reduce or modify your medications and/or lifestyle.

Is Ultrasound Renal Denervation suitable for me?

You should consult with your doctor to determine whether the Ultrasound Renal Denervation treatment with the Paradise™ System is an appropriate treatment for you.

Your doctor

This patient brochure is intended for informational purposes only and does not contain medical advice. This brochure should not be used as an alternative to consulting with your healthcare professional. Speak to your healthcare professional to obtain additional information or to discuss any questions that you may have. You should discuss with your healthcare professional questions specific to your health and the treatment options that are appropriate for you. Always talk with your healthcare professional about diagnosis and treatment, including medications, and ensure you understand and carefully follow the information you are given.

Learn more at www.recormedical.eu

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References:
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2. World Health Organisation; https://www.who.int/news-room/fact-sheets/detail/hypertension; accessed on 1/11/2023
3. Hight blood pressure increases risk of stroke, American Stroke Association Infographic. 2023
4. Ettehad D, et al. The Lancet. 2016;387:957-67.
5. Azizi M. JAMA. 2023;329(8):651-661
6. Azizi M. et al. Lancet. 2018 Jun 9;391(10137):2335-2345.
7. Azizi M. et al. Lancet. 2021 Jun 26;397(10293):2476-2486.
8. Kirtane A. et al. JAMA Cardiol. 2023;8(5):464-473

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 treatmentThe 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)

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