



# FROM SEARCHING TO SOLUTION

Exablate Prostate

INSIGHTEC



# Harness the Therapeutic Power of Focused Ultrasound

## **Incisionless. Precise. Life Uninterrupted.**

Exablate® Prostate delivers up to 1000 ultrasound waves to precisely heat and ablate Prostate tissue with no surgical incisions or radiation. Treatment is guided by MR imaging for patient-specific planning, real-time temperature monitoring as well as real-time confirmation of the ablated region.

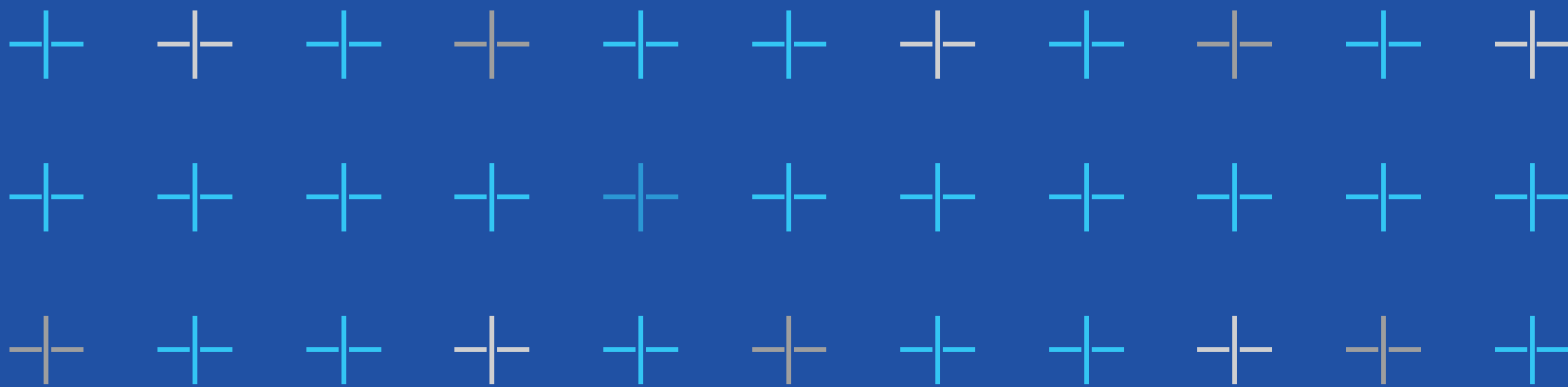
First, the clinical team will use an MRI to visualize the prostate during the entire treatment. The Exablate system utilizes specialized software to create a personalized plan to deliver energy effectively to target from a transrectal approach. The clinical team monitors the treatment in real-time using thermometry data to optimize the outcome and then uses a contrast image at the end of the treatment to confirm the delivery.

# Innovation is No Longer Cutting Edge

- Phased array, piezoceramic transducer with up to 1000 elements
- Advanced focusing algorithms that can be adjusted according to patient's anatomy helping to avoid critical structures
- Personalized treatment plan utilizing focused ultrasound waves at targeted tissue (lesion)
- MRI real-time imaging guidance allows for precise delivery of energy while sparing healthy tissue
- Continuous circulation of water actively cools rectum
- Advanced software for temperature monitoring and treatment control

For specific indications for use in each country, please refer to the Regulatory Approvals page at [www.insightec.com/regulatory-approvals](http://www.insightec.com/regulatory-approvals)









# Transforming Patient Care

Focused ultrasound treatment is performed in the MRI suite, with the treating physician sitting at a desk using MRI & Ultrasound energy to precisely plan the treatment.

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## Incisionless

- Outpatient
- Fast return to daily life and activities

## MRI Guided & Temperature Control

- Precise ablation
- Avoid critical structures

## Tissue Sparing

- Preserve healthy tissue
- Few side effects

## Personalized

- Adjust treatment plan according to Prostate movements and deformations
- Individualize treatment to account for non-homogenous prostate tissue

# Identify. Treat. Protect.



## Patient Preparation

The patient will be positioned lying on their back while under general anesthesia on the MRI table. A urinary catheter will be inserted to drain the bladder during the procedure. Patient heart rate, blood pressure and blood oxygen levels will be monitored throughout the procedure. The Exablate Prostate endorectal probe, wrapped in a single-use balloon and cooled to a temperature of 14°C will be inserted gently for treatment.



## Planning

First, a series of MRI images will be taken for the purpose of planning the treatment. The physician will identify the diseased tissue lesion and will develop a treatment plan using the Exablate Prostate software. Once all is confirmed, treatment will begin.



## Treatment

During treatment, focused ultrasound waves will heat and destroy the target tissue. The Magnetic Resonance Imaging (MRI) will provide clear real-time images and real-time temperature monitoring of treatment. The ablated tissue will be assessed providing real-time confirmation of the ablated region.





## Post Treatment

After treatment, the endorectal transducer will be removed and the patient will be moved to recovery per standard of care prior to discharge. If needed, the urinary catheter will remain in the bladder for up to a week, based on the doctor's decision. Patients may be prescribed medication to prevent potential catheter complications and, if needed, to alleviate pain.

# Clinical Evidence

**An Insightec-sponsored pivotal trial of 101 subjects, evaluating safety at 12 months and effectiveness at 6 months, showed:**

- 91% had a negative biopsy rate at 6 months
  - 92% had no erectile dysfunction at 12 months
  - No serious adverse events at 6 months
  - Highest recorded adverse effects at 12 months include erectile dysfunction and urinary incontinence at 8% and 3.5%, respectively.
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## Important Safety Information

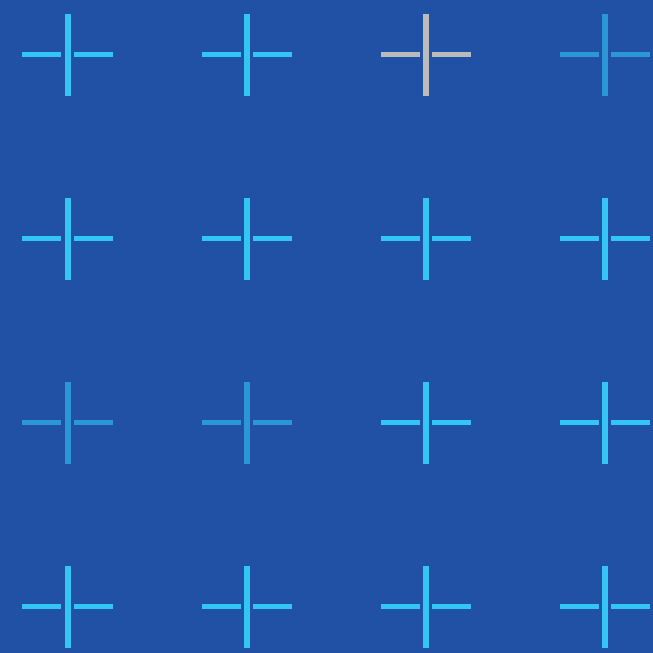
Patients and physicians should have a detailed conversation regarding risks and complications, also known as adverse events, that patients may experience. This procedure may not be suitable for patients who aren't eligible for MRI treatment (such as those with a pacemaker), general anesthesia or epidural.

In addition to the information in this brochure, full safety information can be found at <https://insightec.com/exablate-prostate>

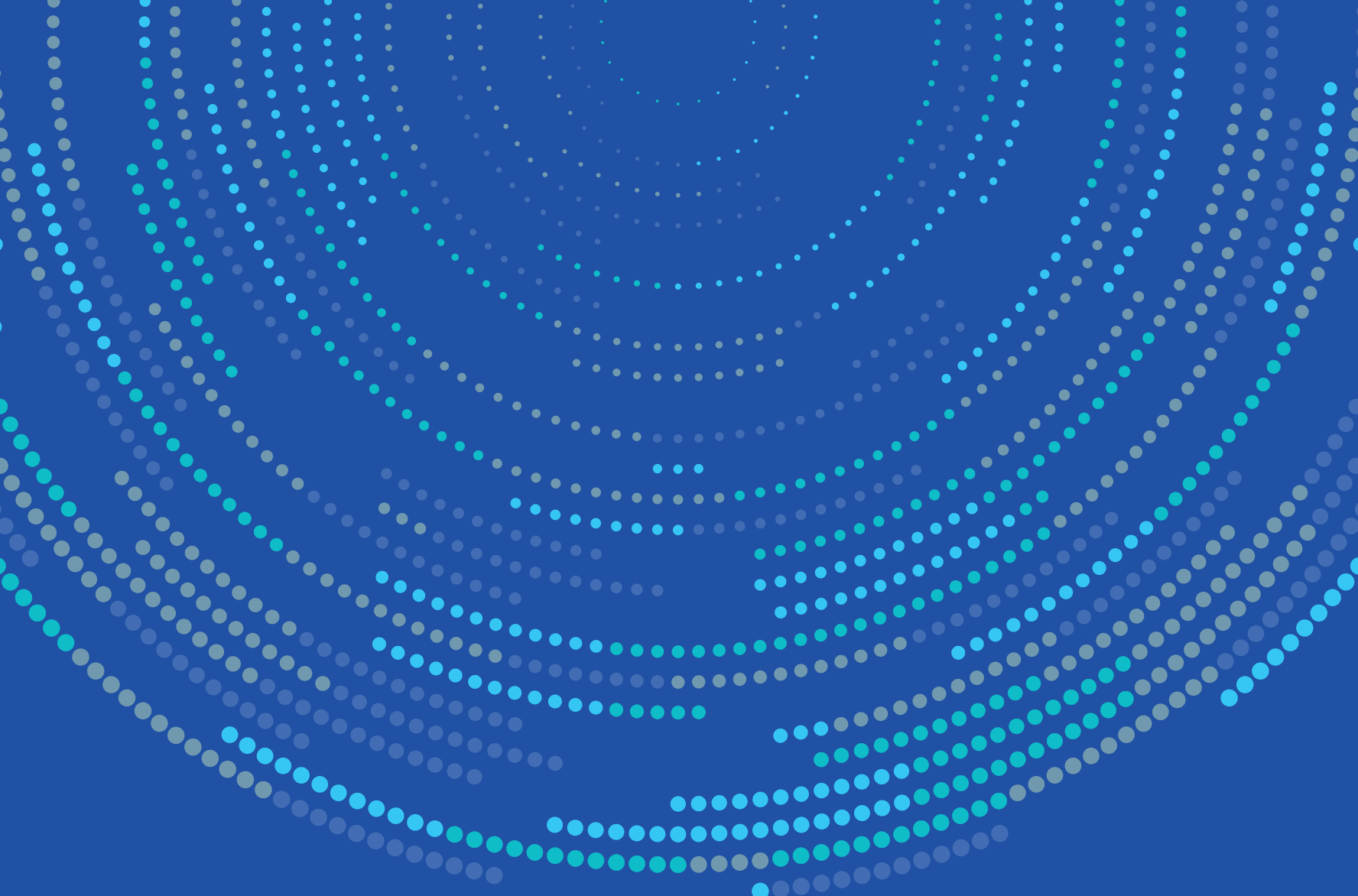
# Potential Risks Associated with Exablate Prostate

The majority of AEs reported were either mild (86.5%) or moderate (13%). There was one AE categorized as Severe for a UTI event, which resolved in less than a week. At 12 months, the most common recorded adverse events included erectile dysfunction (16%) and urinary incontinence (7%). The remaining unresolved AEs at 24 months were less than 1% and included ejaculation disorder, urinary frequency, hematospermia, urinary hesitancy, urinary urgency, prostate cyst, and urethra stricture. The number in parenthesis is the percentage of subjects experiencing the event based on a 101 subject study.

Potential risks related to the procedure include pain, bruising, or infection in the area of the IV catheter; soreness/ discomfort, blood clot, deep vein thrombosis (DVT) or pulmonary embolism due to lying stationary during the procedure; and risks arising from anesthesia, MRI contrast agent, and urinary catheter used during the procedure.







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