



# The First Non-invasive BPH Treatment

Benign Prostatic Hyperplasia (BPH) affects more than 50% of men over 50

- **Company name:** NINA Medical
- **Sector:** Medical Devices
- **Headquarters:** Nazareth, Israel
- **Founded:** June 2019
- **Stage:** Pre-Product
- **Website:** <https://ninamed.com>

- **Fundraising history:** \$1.3M from NGT3VC, IIA and private investors.
- **Milestones achieved:** Prototype. In-vivo study (pigs). Veterinarian treatments (dogs, on-going).
- **Fundraising target:** We are raising \$5M in series-A.
- **Next milestone:** First In Human in 24 months from closing.

## ▶ Team

- **Shmuel Ben-Ezra** co-founder and CEO
- **Yoni Hertzberg** co-founder and CTO
- **Zohar Gendler** Chairman
- **Nizar Mishael** CFO
- **Prof. Gilad E. Amiel**, Haifa Medical Director
- **Dr. Marc T. Feder**, New Jersey Advisor
- **Dr. Elliot M. Paul**, New York Advisor
- **Prof. Mark Emberton**, London Advisor

## ▶ Market opportunity: most BPH patients avoid medical care

Benign Prostatic Hyperplasia (BPH) is a non-cancerous enlargement of the prostate gland, resulting in a gradual obstruction of the urethra. It is an age-related disease, with prevalence of more than 50% in men over the age 50. BPH has a prominent impact on quality-of-life of the aging man, and it is a risk factor for complications.

The typical BPH patient will try to postpone conventional healthcare that regularly involves rectal examination and transurethral (through the penis) procedures; usually, he will seek alternatives as long as he can bear the symptoms.

In the USA, about 30 million men suffer from BPH, but only 12 million consume conventional medical care; the rest (some 18 million) **avoid medical solutions**; they try supplements, herbs, acupuncture, or simply adapt and compromise on their quality of life.

**Unmet need:** a new category in the BPH market – the non-invasive treatment with an improved patient experience that will address the segment of the avoiding patients.

## ▶ Our solution: improved patient experience in BPH treatment

NINA Medical is developing the LOTUS-1 diagnostic-therapeutic system for BPH. With LOTUS-1, the patient is in sitting position, awake and relaxed during the 30-minute procedure at the urologist's office. The LOTUS-1 approaches the prostate from the perineum, extracorporeally; diagnostic ultrasound is used for pelvic floor imaging and prostate examination, while image-guided high-intensity focused ultrasound (HIFU) is used for thermal ablation of prostate tissue.

**Both imaging and therapy are executed in a non-invasive manner from the perineum.**

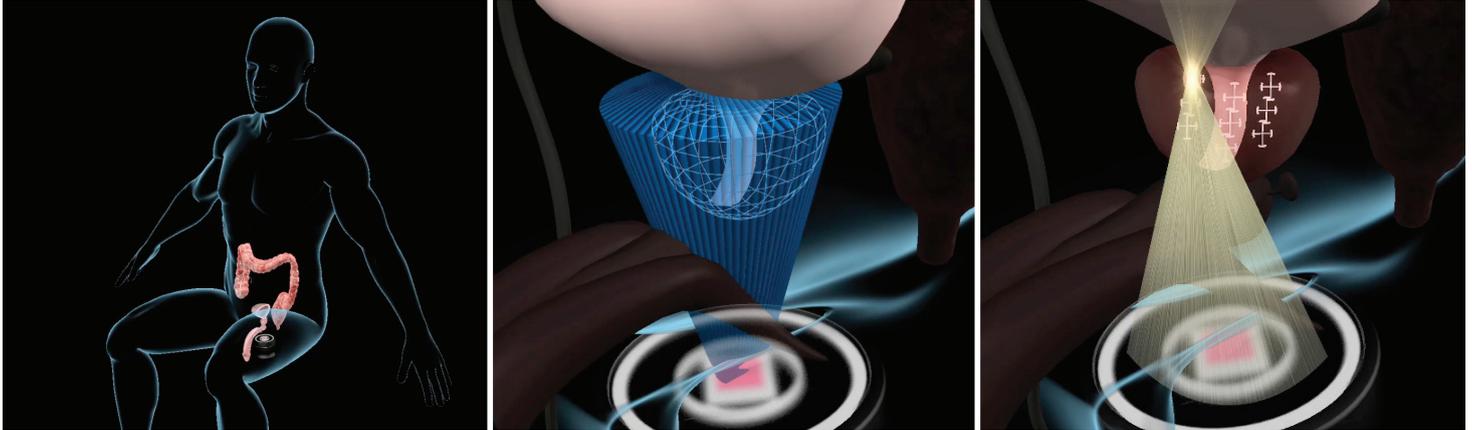
Several target points will be selected for ablation around the urethra under the company's innovative ultrasound guidance (see section below). Using HIFU ablation, thermal necrosis is generated at the focal point only, leaving surrounding tissue intact.

Expected clinical outcomes include prostate volume reduction and symptom relief.



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## ► Technology: new ultrasound technique for HIFU imaging

The unconventional perineal approach is now enabled by the combination of two technologies: HIFU, an established technology for the ablation of prostate tissue on one hand, and the novel ultrasound imaging invented by the company on the other hand. NINA's imaging provides **live display of the HIFU in the body in real time**, enabling continuous focal-point tracking prior to and during the ablation process, for improved safety and efficacy in HIFU applications.

The technology is distinguished from others that use MRI for quasi real-time focal point tracking (INSIGHTEC), and from others that use ultrasound imaging for real-time guidance, but they lack the feedback from the focal point prior to ablation (EDAP/Sonablate).

Patent applications **US2019/0232090**, **US2021/0045714** (filed in USA, EU and CH).  
Two unpublished patent applications (PCT).

## ► Business model: Pay Per Use

Our projected customers are urologists and high-end men's health centers that will enroll to the **NINA noNINvAsive®** program. The model is based on revenue sharing with the customer; NINA will charge for competitive enrolment fees at start-up, plus annual fees for maintenance. Main revenue will come from the pay-per-use channel. Assuming eight cases per week, A single LOTUS-1 installation has the potential to generate a revenue of about \$400K to NINA Medical per year.

## ► Roadmap

**2022 – 2023:** Preclinical development.

**2023 – 2024:** First In Human clinical trials.  
Series-B fundraising.

**2025 – 2026:** Clinical trials, FDA/CE clearance,  
commercial installation in selected sites.

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