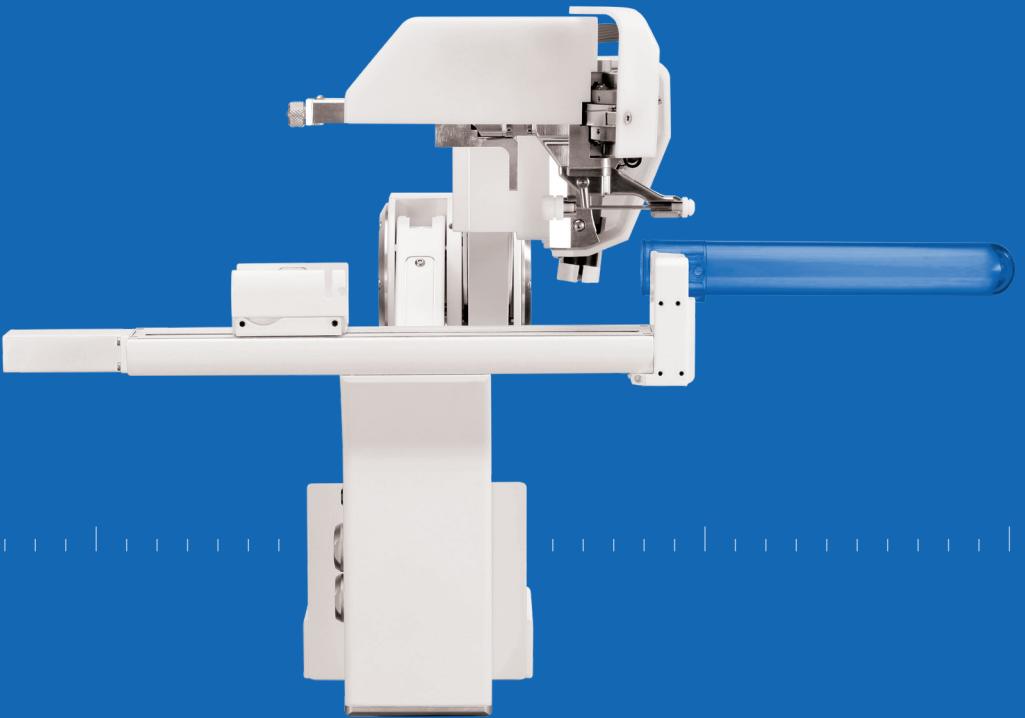


iSR'OBOT™

MONA LISA

Robotic Prostate Biopsy Navigation System



BIOBOT



LEADHEALTHCARE
리드 헬스 케 어

The Precision Urologists Require and Patients Deserve

A cutting-edge robotic system for transperineal prostate procedures, designed with both patients and physicians in mind



1. Robotic precision

Ensures high-accuracy needle positioning for transperineal prostate biopsies

2. Advanced imaging

Features MRI-ultrasound fusion capability

3. Efficiency and consistency

Allows physicians to perform transperineal prostate biopsies in a repeatable and reproducible manner

First- and Best-in-Class Robotic Prostate Biopsy and Treatment Solutions

Redefining the standard of care in urology through technological innovation

iSR'OBOT™
MONA LISA

A New Era in Prostate Care

Traditional transrectal prostate biopsies come with significant drawbacks:

High infection risk

+ Up to 7% infection and 3% sepsis rates¹
+ 6.9% 30-day readmission rate²

Underdiagnosis

Traditional ultrasound biopsies only detect 23% of clinically significant cancers³

Limited prostate access

Transrectal biopsies cannot adequately sample the anterior or apex regions of the prostate

The New Standard of Care:: Transperineal Biopsies

The standard of care is shifting to transperineal biopsies, utilizing MRI-ultrasound fusion guidance to provide:

- O1 Better visualization**
- O2 Maximal prostate coverage**
- O3 Virtually zero infection risk⁴**

But embracing this new standard without an intelligent device requires a steep learning curve that hinders adoption.⁵

The Robotic Advantage

Robotic-controlled needle positioning offers urologists the precision needed for transperineal procedures, ensuring:

O1

Higher accuracy in cancer detection⁶

O2

Repeatable and reproducible procedures

O3

A leveling of the learning curve for transperineal needle positioning

Key Features

O1 Robotic accuracy for needle positioning and depth control

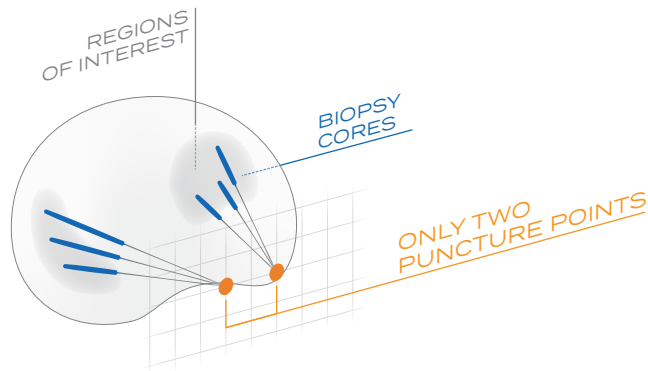
Mona Lisa's navigational system ensures precise needle positioning and depth control for fast and accurate biopsy collection, even at the apex, anterior and peripheral areas.

O2 Prostate stability

Housed in a specially designed probe sheath, the ultrasound probe moves unobstructed, minimizing prostate deformation and providing essential stabilization for accurate sampling.

O3 Dual-cone technology

Mona Lisa's innovative dual-cone approach minimizes pubic arch interference, creating a virtual pivot point for multiple needle entries and ensuring maximal prostate coverage.



O4 Flexible biopsy planning

An automated yet flexible biopsy planning system allows urologists to customize biopsy plans effortlessly. The user-friendly interface permits the addition, movement or deletion of core locations at any point.

O5 Elastic MRI-ultrasound fusion

Instant fusion of MRI and live ultrasound models provides physicians with 3D visualizations for precise targeting of the region of interest.

+

→ Needle deflection adjustment

Addressing needle deflection due to prostate tissue heterogeneity and needle tip design

→ Comprehensive report

3D images and clinical data in reports

Simple Workflow

Biopsy planning and execution

O1

Scan and model

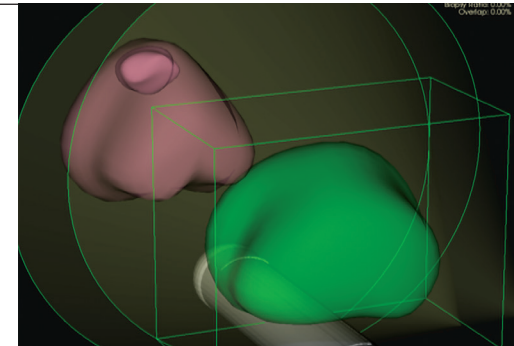
- ‡ Radiologist imports MRI scan using software (UroFusion) to model prostate and mark ROI
- ‡ Ultrasound images are automatically captured via the motorized robotic arm
- ‡ Urologist models prostate on ultrasound images for 3D reconstruction



O2

Fuse and plan

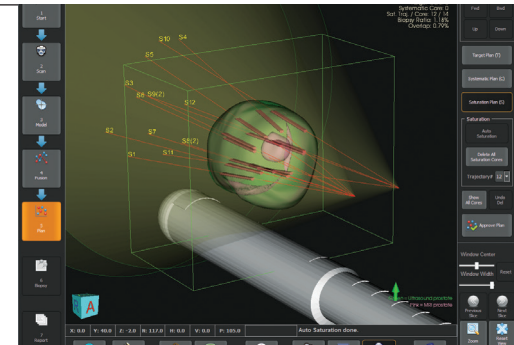
- ‡ Software (UroBiopsy) instantly merges MRI and ultrasound 3D models
- ‡ Target and saturation plans autogenerate core locations based on ROI and prostate 3D model; options for systematic plans available



O3

Biopsy and report

- ‡ Robotic arm provides guidance for needle positioning based on physician-approved biopsy plan
- ‡ Physician inserts the needle through the robotic guide
- ‡ Automatic generation of comprehensive reports with clinical data and 3D images



Certifications

- ‡ FDA (US):
- ‡ CE mark (Europe)
- ‡ NMPA (China)
- ‡ TGA (Australia)
- ‡ HSA (Singapore)
- ‡ EN ISO 13485:2016

1. Kalalahti, I., Huotari, K., Erickson, A.M. et al. Infectious complications after transrectal MRI-targeted and systematic prostate biopsy. *World J Urol* 40, 2261-2265 (2022).
2. Batura D, Rao GG. The national burden of infections after prostate biopsy in England and Wales: a wake-up call for better prevention. *J Antimicrob Chemother* 2013;68:247-9.
3. Loeb S, Carter HB, Berndt SI, Ricker W, Schaeffer EM. Complications after prostate biopsy: data from SEER-Medicare. *J Urol* 2011; 186: 1830-1834.
4. Valerio, M., Donaldson, I., Emberton, M., Ehdal, B., Hadaschik, B. A., Marks, L. S., Mozer, P., Rastinehad, A. R., & Ahmed, H. U. (2015). Detection of Clinically Significant Prostate Cancer Using Magnetic Resonance Imaging-Ultrasound Fusion Targeted Biopsy: A Systematic Review. *European urology*, 68(1), 8-19.
5. Patel, A. & Servian, P. & Winkler, Mathias & Tiong, L.C. & Yuen, John & Ho, Hey & Chen, Kenneth & Kruck, S. & Grummet, Jeremy. (2017). Robotic MRI/US fusion transperineal biopsy using the iSR'obot Mona Lisa: Technique, safety and accuracy. *European Urology Supplements*. 16. e2092-e2093.
6. Halstuch D, Baniel J, Lifshitz D, Sela S, Ber Y, Margel D. Characterizing the learning curve of MRI-US fusion prostate biopsies. *Prostate Cancer Prostatic Dis.* 2019;22(4):546-551. DOI: 10.1038/s41391-019-0137-2.
7. Patel MI, Muter S, Vladica P, Gillatt D. Robotic-assisted magnetic resonance imaging ultrasound fusion results in higher significant cancer detection compared to cognitive prostate targeting in biopsy naive men. *Transl Androl Urol.* 2020;9(2):601-608.

DOC-00174

REV 06

BIOBOT

제조사

Biobot Surgical Pte Ltd.

79 Ayer Rajah Crescent #04-05

Singapore 139955

<https://biobotsurgical.com>



LEADHEALTHCARE

리드헬스케어

공급사

(주) 리드헬스케어

서울특별시 송파구 오금로 235, 2층 (방이동, 썬스빌딩)

Tel : (02) 415-3601 Fax : (02) 425-3605

E-mail : contact@leadhealthcarekorea.com