

Focal One[®]

ROBOTIC FOCAL HIFU

The Leading
Prostate Focal Therapy
Controlled by Urologists



PROSTATE CANCER

Worldwide

**1.4 Million New Cases
and 375,000 Deaths.***



NORTH AMERICA

239 000

† 37 000

EUROPE

475 000

† 108 000

ASIA

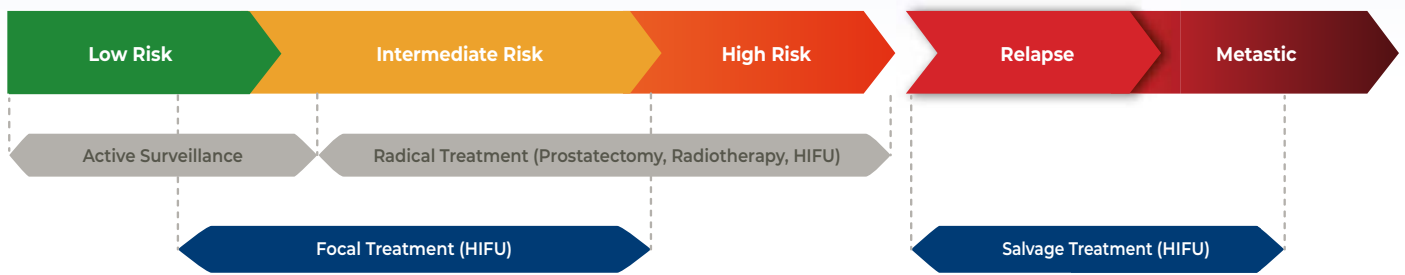
371 000

† 120 000



Treatment

FOCAL THERAPY FILLS AN IMPORTANT TREATMENT GAP IN PROSTATE CANCER



- Advanced imaging, targeted biopsies and genomic testing have changed the ability to localize disease and risk stratify prostate cancer.

- Patients are seeking an option between active surveillance and radical therapy.

- HIFU provides a safe, effective and minimally invasive option for patients with low and intermediate risk disease, as well as a salvage therapy.

ACTIVE SURVEILLANCE ⁽¹⁾	FOCAL ONE® (HIFU)	RADICAL TREATMENT ⁽²⁾
<ul style="list-style-type: none"> ⊕ Non-invasive ⊕ No side effects ⊖ Only for low risk prostate cancer ⊖ Requires close patient monitoring & multiple biopsies ⊖ Cancer likely to evolve and require radical treatment 	<ul style="list-style-type: none"> ⊕ For low to intermediate risk prostate cancer ⊕ Minimally invasive treatment ⊕ Quality of life preservation ⊕ Brief hospitalisation ⊕ Feasible under loco-regional anaesthesia ⊕ Can be repeated^(*) <small>^(*) HIFU treatment offers the advantage of being repeatable right after the initial session, allowing for a convenient and flexible approach to achieving your desired results.</small> ⊕ Other treatment options can be considered <p style="text-align: center;">Focal One® is the Optimal Treatment for Well Selected Patients</p>	<ul style="list-style-type: none"> ⊕ Effective even against high risk prostate cancer ⊖ High risk of side effects (Urinary incontinence & Erectile dysfunctions) ⊖ Risk of surgery associated complications ⊖ Rectum & Bladder irritation from radiation ⊖ Long recovery time ⊖ No retreatment possible in case of relapse

⁽¹⁾ **HIFUSA Clinical study**
 Multicenter, Randomized Study, Evaluating the Efficacy and Tolerability of HIFU Therapy Compared to Active Surveillance in Patients With Significant Low Risk Prostate Cancer - NCT03531099

⁽²⁾ **HIFI Clinical study**
 Evaluation of HIFU in Treatment of Localized Prostate Cancer and of Recurrence After Radiotherapy NCT04307056
FARP Clinical study
 Focal Prostate Ablation Versus Radical Prostatectomy - NCT03668652

Focal One[®]

THE ONLY FULLY ROBOTIC & FULLY INTEGRATED HIFU SYSTEM



> FULLY ROBOTIC

- + No manual adjustments
- + 5 Fully robotic motions
- + Rectal wall distance & temperature monitoring

> DYNAMIC FOCUSING TECHNOLOGY

- + Conformational treatment
- + Small size of unitary HIFU lesion

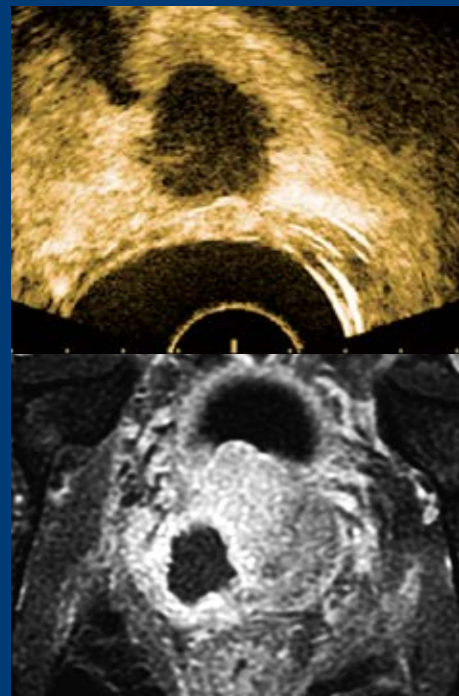
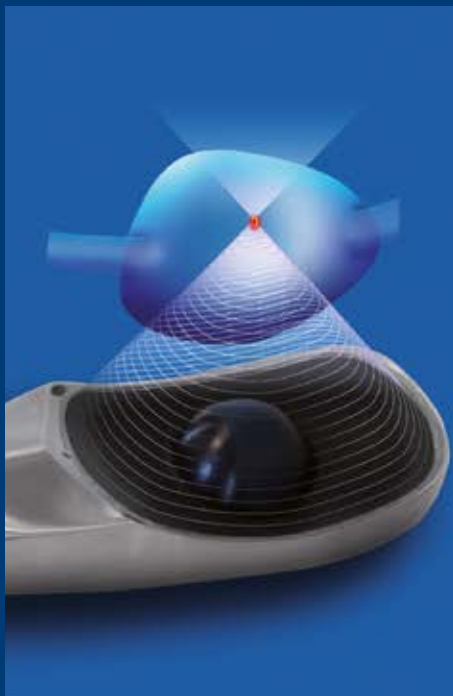
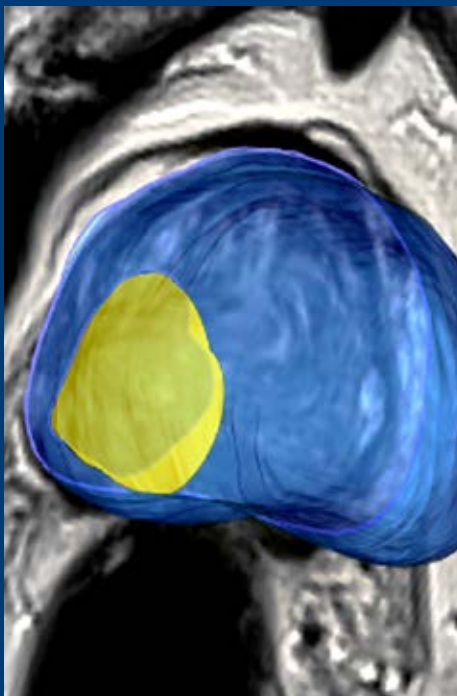
> HIFUSION[®]

- + Proprietary open-platform
- + MRI & biopsy fusion

> FULLY INTEGRATED WORKSTATION

- + Flexible cart
- + Compatible with standard or beds
- + Patient safety features

THE **3 Pillars** OF FOCAL ONE®



> PLAN

- **Real-time ultrasound imaging:** 7.5 MHz imaging transducer.
- **HiFusion®:** MRI targets and 3D biopsies automatically displayed on live ultrasound.
- **Precisely define the area to be ablated.**

> ABLATE

- **Dynamic focusing:** Electronic displacement of focal point without any mechanical movement (up to 8 individual 5 mm points, with 67 mm anterior depth).
- **Conformational treatment:** Ablation of a precise area around the tumour while sparing the healthy surrounding tissue.
- **Faster treatment:** 30 cc/hour (vs. older technologies 10 cc/hour).

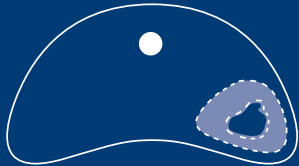
> VALIDATE

- **Efficacy validation:** Contrast Enhanced Ultrasound technology (CEUS) to confirm de-vascularized areas.
- **Validate treatment** while patient is still in OR, and retreat if necessary.

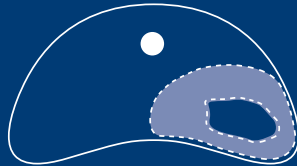
Focal One[®]

TREATMENT STRATEGIES FOR PARTIAL ABLATION OF THE PROSTATE*

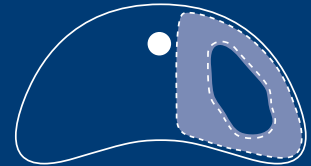
The Focal One[®] procedure can be tailored or personalized to every patient and clinical condition.



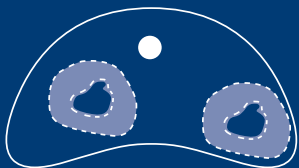
Focal Ablation



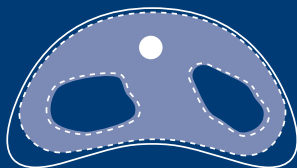
Zonal Ablation



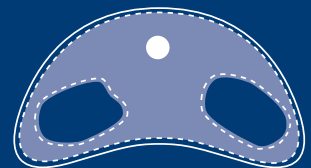
Hemi-Ablation



Multi-Focal Ablation



Sub-Total Ablation**



Whole-Gland Ablation**

Standardized Nomenclature and Surveillance Methodologies After Focal Therapy and Partial Gland Ablation for Localized Prostate Cancer: An International Multidisciplinary Consensus - Eur Urol. 2020 September ; 78(3): 371-378. doi:10.1016/j.eururo.2020.05.018.

*The examples below are not intended to be exhaustive, but are merely illustrative. ** A TURP should be considered for sub-total and wholegland ablations.

Clinical Evidence

FROM MAJOR FOCAL ONE[®] CLINICAL PUBLICATIONS

Clinical Benefits*

HIFU - Salvage Treatment Free Survival Rate (12 months) **96%**

HIFU - Salvage Treatment Free Survival Rate (24 months) **88.6%**

Safety & Functional Outcomes*

Continence Preservation **72.3%**

Erection Preservation **78.5%**

Rectal Fistula **0.3%**

*Data obtained from Focal One clinical evaluation report for 1st line treatment

One Academy

BECOMING A FOCAL ONE® EXPERT

Level 1

Theoretical requirements (e-learning) and expert site visit

Level 2

First 20 treatments on site with a Focal One® expert (Proctor or application specialist)

Level 3

Certification by performing 10 treatments in full autonomy

Level 4

Reaching expert level by performing 30 cases in full autonomy



FOCAL ONE® TRAINING PROGRAM

The Focal One® Training Program is offered to every urologist beginning the Focal One® journey, whether it's on a newly purchased machine or an existing one®. We are committed to ensuring that all users of the Focal One® receive high-level training for optimal use of the system.

ON-GOING SUPPORT FROM OUR EXPERTS

EDAP TMS provides fast, high standard service to all Focal One® users around the world with one goal: constant user satisfaction.

KEEP TRACK OF YOUR PATIENTS WITH THE

One Registry

One Registry: Clinical data collection of patients treated with High Intensity Focused Ultrasound (HIFU) for their prostate cancer.

- + Accessible on the Internet
- + European Registry
- + For all patients treated with the Focal One®
- + Prospective and retrospective
- + No imposed protocol
- + 5 year minimum follow-up period
- + Treat in accordance with European guidelines
- + Be part of future European publications



For more information, please contact EDAP TMS Medical Affairs Team (Affaires-Cliniques@edap-tms.com).



A **Solution** for **Every Need**

Customer Care Centre

LOCAL PRESENCE AND SKILLS

Subsidiaries and partners

With an extensive network of subsidiaries and distribution partners, EDAP TMS guarantees local and prompt service to all Focal One® users worldwide. The EDAP TMS technical staff is highly skilled, experienced and able to intervene on all devices with great flexibility and reactivity.

In-house technician

For hospitals and clinics' greater autonomy, EDAP TMS may train an in-house technician dedicated to servicing Focal One® device on site. EDAP TMS provides a specific technical training program with dedicated staff and materials in order to offer in-house hospitals and/or clinics' technicians full training on the functioning and components of the device.

MAINTENANCE

Preventive and control visits

With preventive visits, the Focal One® is well maintained and upgraded with latest software and hardware configurations. Moreover, service bulletins are regularly issued to inform our partners on upgrades and maintenance evolutions.

Service contracts

All Focal One® devices installed worldwide are under a post-warranty service contract. EDAP TMS offers customized maintenance programs to suit all users' needs.

Focal One®
ROBOTIC FOCAL HIFU

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