

Focal·One®

www.edap-tms.com



edap tms
Bringing New Horizons to Therapy

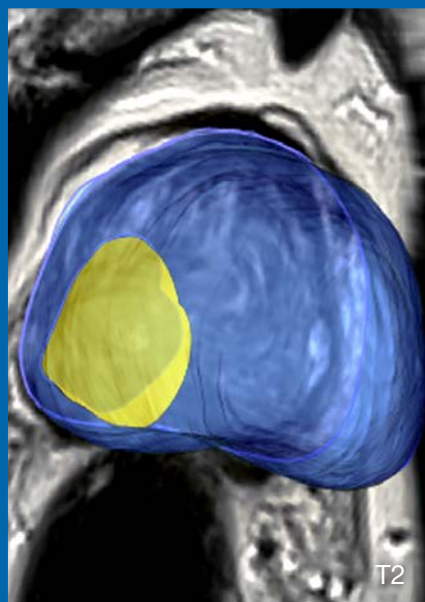




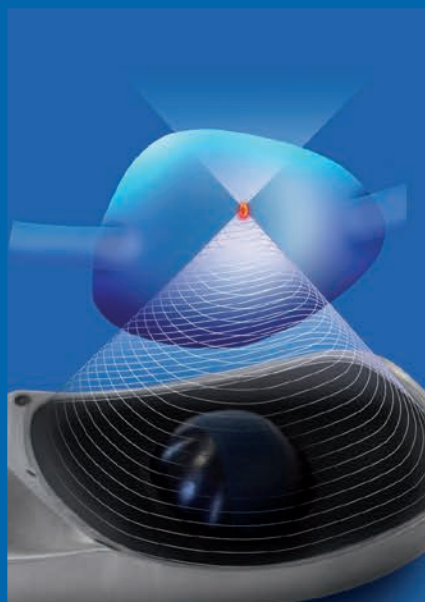
Focal One®

HIFU Focal Ablation of Prostate

Focal strategy for prostate conditions is playing a growing role in today's clinical management. By combining the latest imaging and ablation technologies, Focal One® brings the answer to current requirements for ideal focal therapy: accurate MRI and 3D Biopsy image fusion, non-invasive approach, as well as precise and efficient HIFU energy.



Target
Localization



Precise
HIFU Technology



Proven
Ablation

The **3** pillars
of Focal Ablation

Ideal Imaging Modalities for Optimal Target Localization

Multi-parametric MRI has become the standard for prostate imaging. As a first-line diagnostic tool, it has become universally used to identify tumor localization and guide biopsy in order to improve their

detection rate. The biopsy-proven tumor localization on the MRI as well as the biopsy locations and results are used to guide the focal ablation of Focal One® thanks to a proprietary non-rigid fusion algorithm (HIFUfusion).



Elastic Fusion



Multi-parametric MR Images are imported from PACS or CD.



3D biopsy data can be imported from various transrectal and transperineal devices.

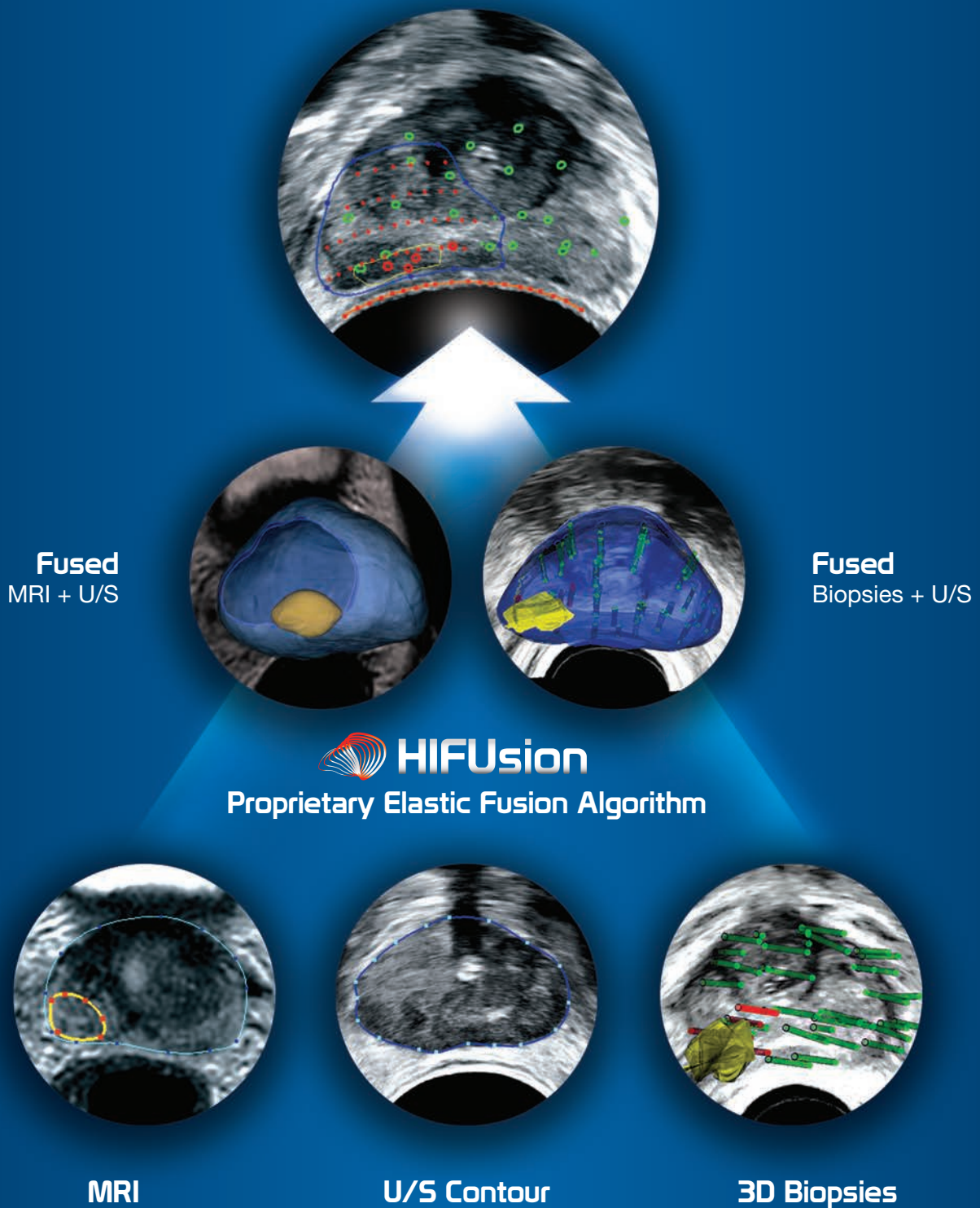


Prostate and target contours are defined prior to the procedure on a stand-alone software or on the Focal One® device at the time of the procedure.

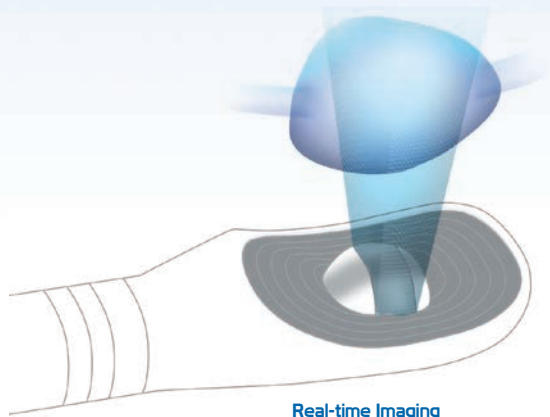


Non-rigid fusion algorithm (HIFUfusion) will virtually deform the MR and/or biopsy ultrasound volumes to automatically match its 3D contours with the real-time ultrasound volume.

Biopsy and MRI Guided Focal HIFU

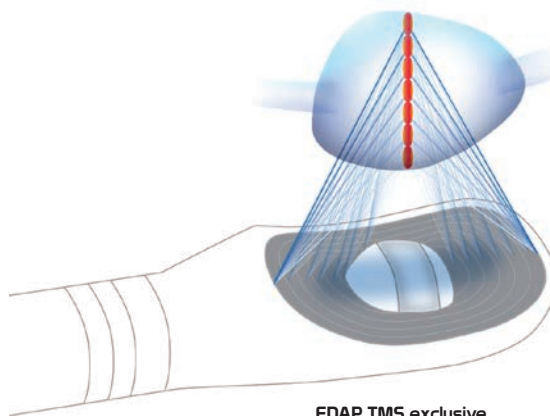


Conformational Treatment



Real-time Imaging

- 7.5 MHz Imaging Transducer
- 3 MHz HIFU transducer



EDAP TMS exclusive
Dynamic Focusing technology



Precise contouring of zone to be ablated

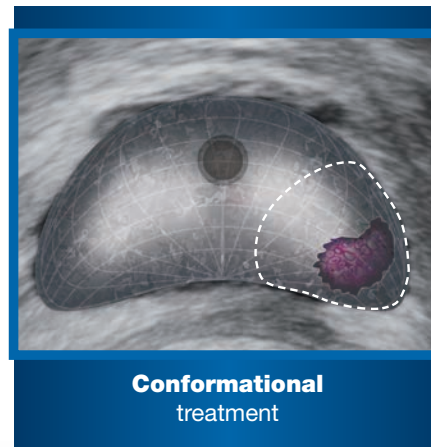
- MRI targets and 3D biopsies automatically displayed on live ultrasound.
- Precisely define the area to be ablated and follow the HIFU shots.

Dynamic Focusing

- Electronic displacement of focal point without any mechanical movement.
- The Dynamic Focusing technology allows a precise non-invasive destruction of the target area within the prostate.

Conformational treatment

- Precise planning capabilities.
- Clear visualization of anatomical structures with overlaid MRI and biopsy information.
- Small size of unitary HIFU lesion.
- Ablation of a precise area around the tumor while sparing the surrounding tissue.

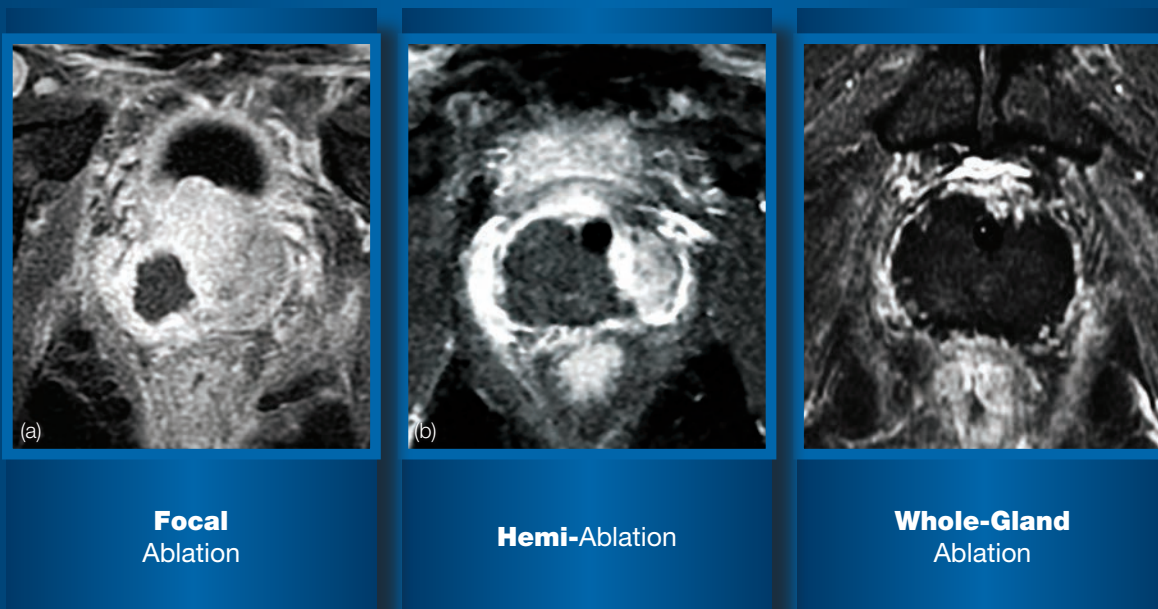


Robotic HIFU

- Complete motorization of all movements (3 translations and 1 rotation).
- Robotic execution of planned ablation.
- Real-time control and adjustment of rectal wall distance.

Proven HIFU Ablation

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

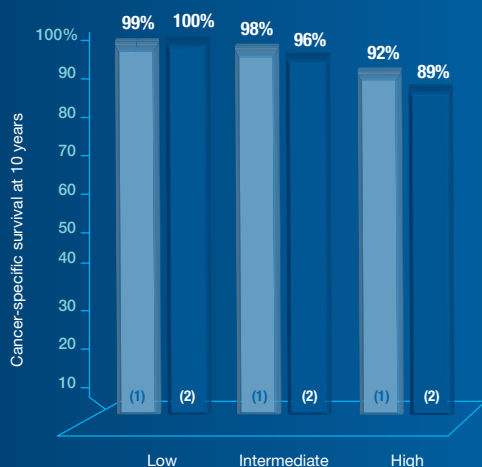


(a) (b) Courtesy of Pr. O. Rouvière and Pr. S. Crouzet - Hospices civils de Lyon

HIFU Clinical Evidence

10 year follow-up data

High Intensity Focused Ultrasound for Prostate Cancer is backed-up with more than 80 peer-reviewed articles showing long-term, large cohort results.



Proven oncological efficacy at 10 years for primary treatment

(1) Crouzet S et al. Eur Urol. 2014 May;65(5):907-14 - (2) Ganzer R et al. BJU Int. 2013 Aug; 112(3):322-9

Focal HIFU

Hemiablation strategy results

French multicentric (10 centers) study on hemispherical HIFU promoted by French Association of Urology.*

111	Patients treated by Hemi-HIFU – mean follow-up of 30.4 months
95%	Absence of Clinically Significant Cancer (OSC: Gleason score ≥ 7 or cancer core length $> 3\text{mm}$ regardless of grade or > 2 positive cores)
89%	Radical Treatment Free Survival (RTFS) at 2 years
97%	Continence preservation
78%	Erectile Function preservation

* Rischmann et al.; Eur Urol 71, n°2 (Feb 2017): 267-73



You Master Urology



We Master Therapeutic Ultrasound

A recognized leader in the global therapeutic ultrasound market for almost 40 years, EDAP TMS develops, manufactures, promotes and distributes minimally-invasive medical devices for urology based upon proprietary ultrasound technology. EDAP TMS is actively operating worldwide via an extensive network of corporate offices, subsidiaries and distribution partners. By constantly investing in Research & Development and partnering with internationally renowned medical research institutions, EDAP TMS has

developed a strong valuable patent portfolio based on its innovative technologies. With its complete range of robotic High Intensity Focused Ultrasound (HIFU) devices, EDAP TMS is a globally recognized innovator in non-invasive ablation for prostate tissue. By combining the latest technologies in imaging and treatment modalities, EDAP TMS introduced the Focal One® in the U.S. in 2018 as the answer to all requirements for focal ablation of prostate tissue as a complement to the existing Ablatherm®. EDAP Technomed Inc. is

the company's wholly owned subsidiary responsible for operations in the United States. As a pioneer and key player in the field of extracorporeal shock wave lithotripsy (ESWL), EDAP TMS introduced the first modular lithotripter. The latest generation of shock wave source is utilized exclusively by EDAP TMS in its Sonolith® range of ESWL systems (Sonolith® i-sys and Sonolith® i-move).

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EDAP Technomed, Inc. - 5321 Industrial Oaks Blvd, Suite 110 - Austin, TX 78735
Tel: 512 832 7956 - Fax: 512 832 7958 - www.edap-tms.com - contact@edap-usa.com

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