Focal·One®

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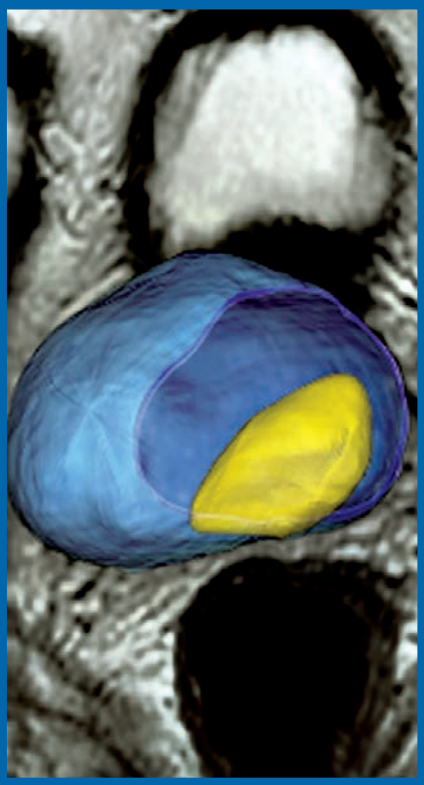
Bringing New Horizons to Therapy

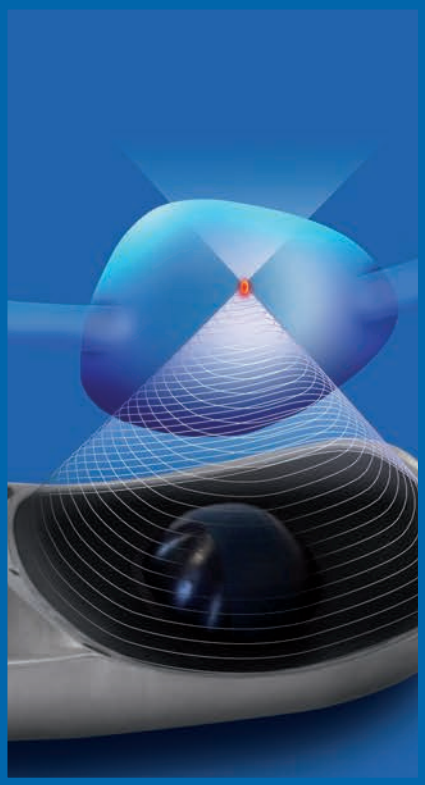

HIFUsion
Focal·One®

Focal HIFU for Prostate Cancer

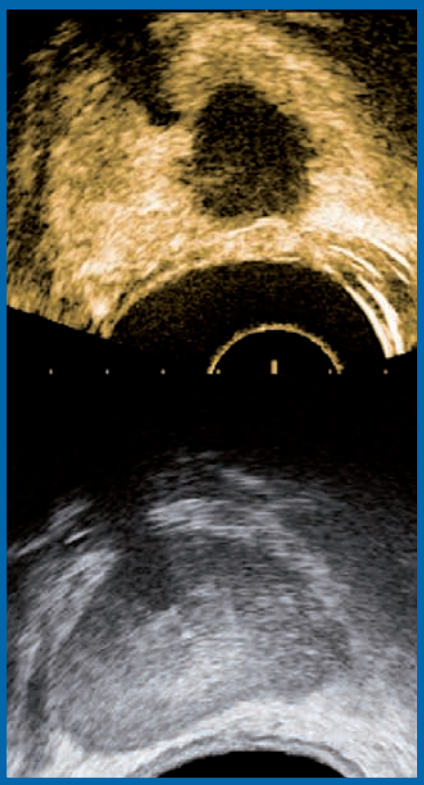
Focal strategy for Prostate Cancer is taking a growing role in today's surgical practice. By combining all the latest technologies in imaging and treatment, Focal One® brings the answer to all requirements for ideal focal therapy: accurate and MR-fused imaging, non-invasive surgical approach, precise and efficient therapeutic energy and end-of-treatment validation imaging.



Tumor
localization



Proven
ablative technology



Efficacy
validation

The 3 pillars
of Focal Therapy

Ideal imaging modalities for optimal tumor localization

Multi-parametric MRI has become the standard for Prostate Cancer 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 treatment of Focal One® thanks to a proprietary non-rigid fusion algorithm (HIFUsion).

Elastic Fusion

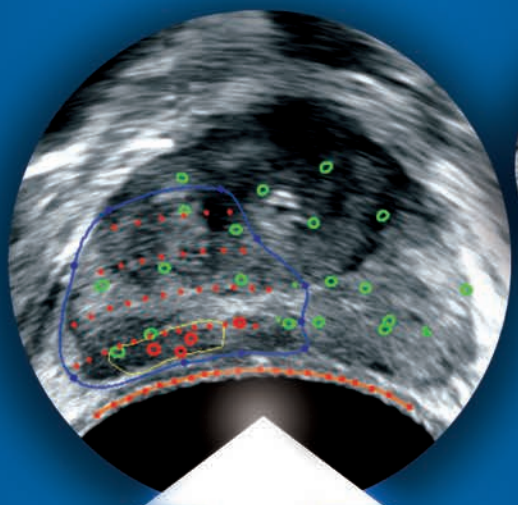
Multi-parametric MR Images are imported from PACS or CD.

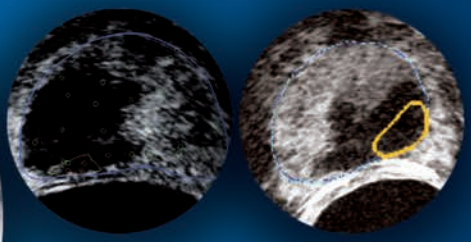
3D biopsy data can be imported from various transrectal and transperineal devices.

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

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

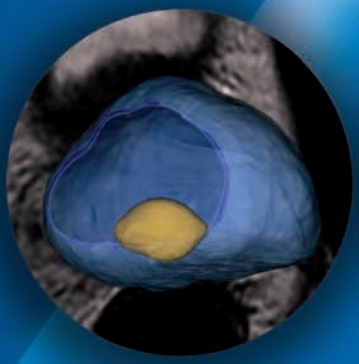
Biopsy and MRI Guided Focal HIFU

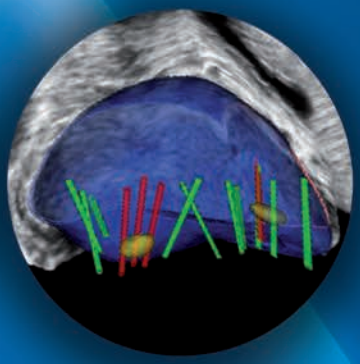




Validation of Treated Area
Elastic Fusion MRI/Biopsies
+ Contrast Imaging

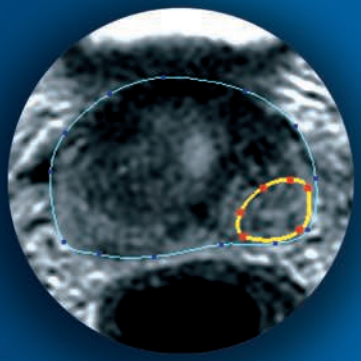
Fused
MRI + U/S

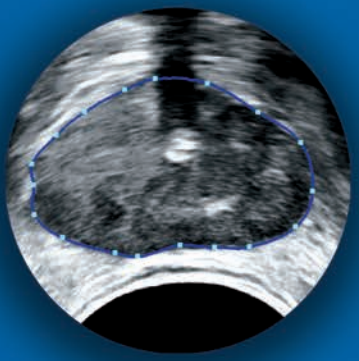


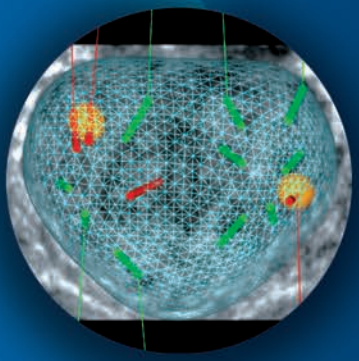


Fused
Biopsies + U/S

HIFUsion
Proprietary Elastic Fusion Algorithm





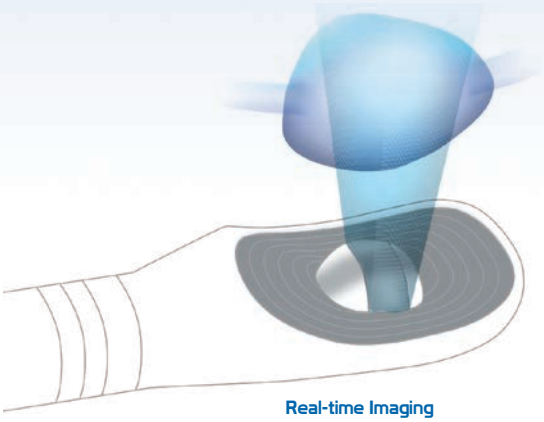


MRI

U/S Contour

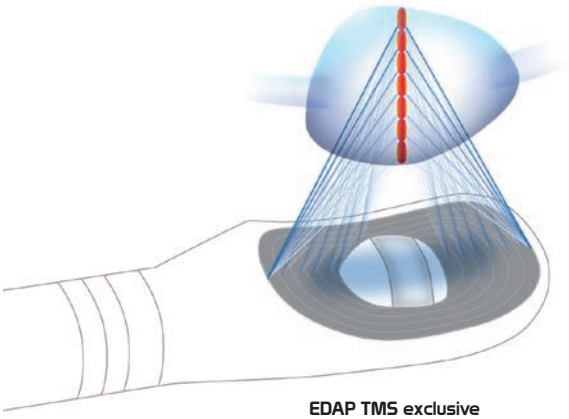
3D Biopsies

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 treated

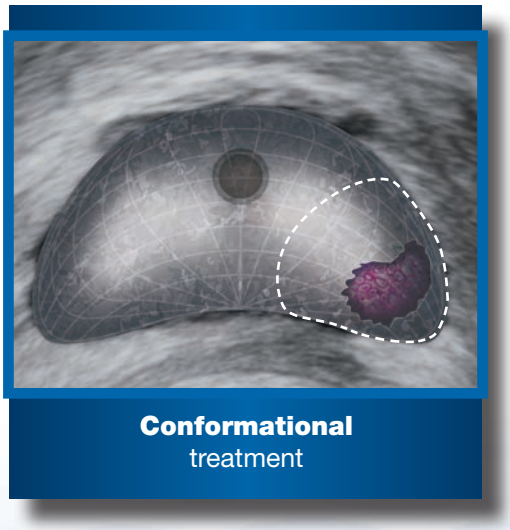
- MR and 3D biopsies target automatically displayed on live ultrasound.
- Design precisely area to be treated and follow HIFU shots.

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 MRI and biopsy information overlaid.
- Small size of unitary HIFU lesion.
- Ablation of a precise area around the tumor while sparing the surrounding tissue.



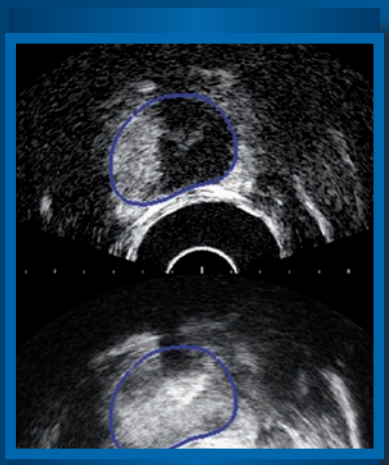
Conformational treatment

Robotic HIFU

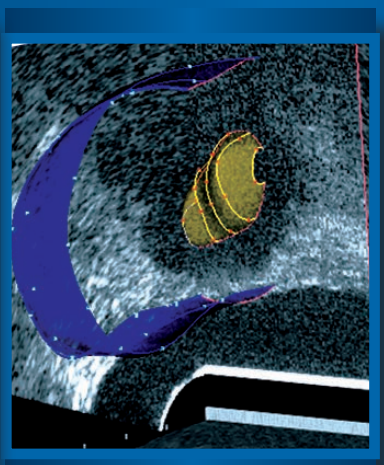
- Complete motorization of all movements (3 translations and 1 rotation).
- Robotic execution of planned treatment.
- Real-time control and adjustment of rectal wall distance.

Real-time treatment validation: Contrast-enhanced Imaging

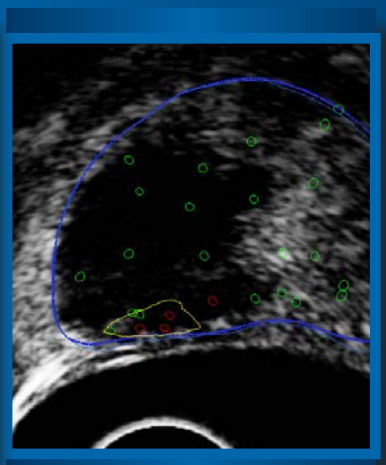
Immediate visualization of devascularized area with micro-bubble ultrasound contrast agent.



Shadow
contouring



Fused
MRI + contrast U/S

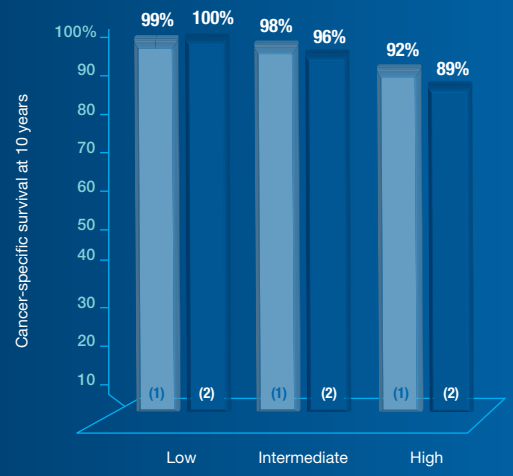


Fused biopsies
+ contrast U/S

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

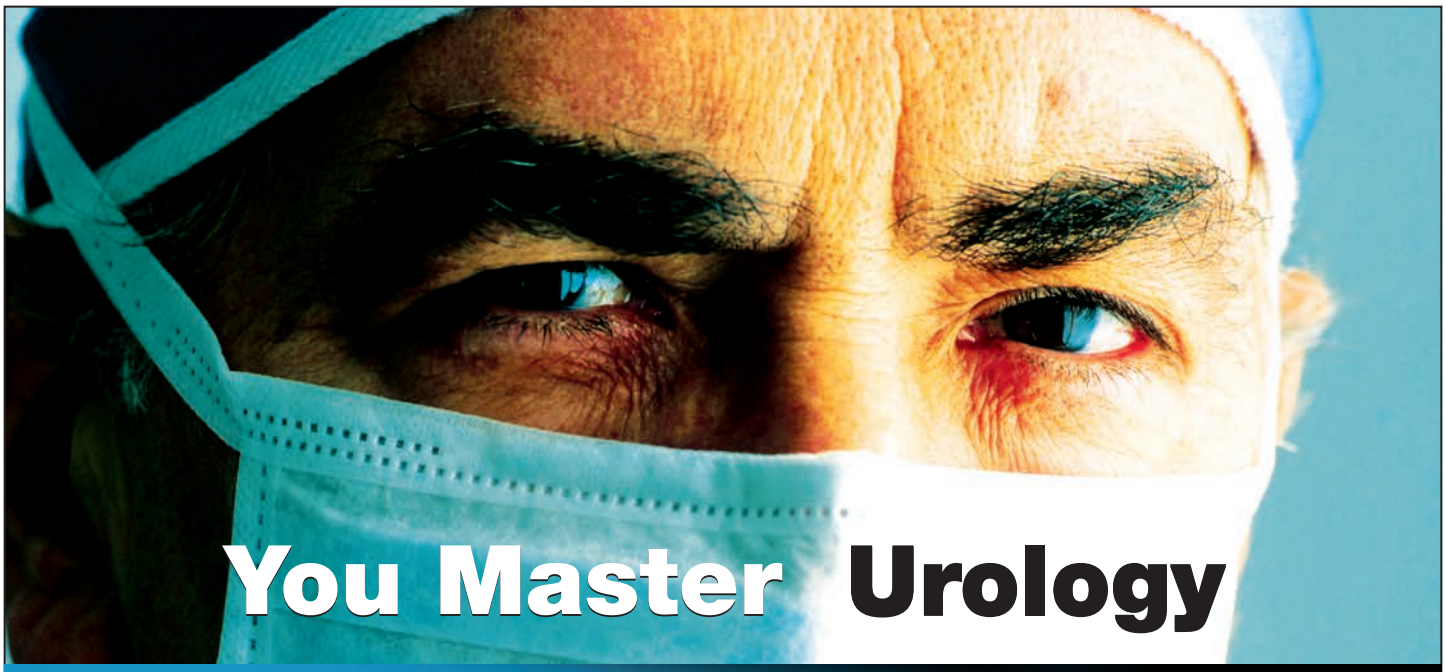
Focal HIFU

Hemiablation strategy results

French multicentric (10 centers) study on hemi-spherical 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 (CSC: Gleason score ≥7 or cancer core length >3mm 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



We Master Therapeutic Ultrasound

Global leader in therapeutic ultrasound and present in the market for more than 35 years, EDAP TMS (NASDAQ: EDAP) develops, manufactures, promotes and distributes minimally-invasive medical devices for urology using 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 HIFU devices, EDAP TMS is the most innovative company in minimally-invasive treatment for localized prostate cancer. By combining the latest technologies in imaging and treatment modalities, EDAP TMS just introduced the Focal One® as the answer to all requirements for ideal focal therapy of prostate cancer as a complement to the existing Ablatherm® HIFU. As a pioneer and key player in the field of extracorporeal 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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