

The logo for Focal One, featuring the word "Focal" in a white sans-serif font, followed by a small red dot, and then the word "One" in a larger white sans-serif font with a registered trademark symbol (®) to its upper right. The background of the top half of the slide is a dark blue grid of prostate MRI slices, with large, glowing blue concentric circles overlaid.

**Focal One®**

# **Robot-Assisted Prostate Tumorectomy**

## Product Presentation

- Rationale for Focal Therapy
- Pre-Treatment imaging
- Dynamic Focusing
- Treatment validation: Contrast-Enhanced Ultrasound
- Focal One® Device Concept



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## **Rationale for Focal Therapy**

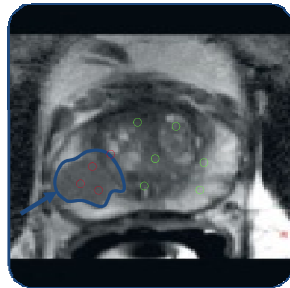
## Rationale for Focal Therapy

- Focal therapy represents the perfect balance between **Active Surveillance** and **Over-treatment**
- Focal Therapy is the **future** of prostate cancer therapies
- Focal therapy relies on **accurate imaging** to target the area to be treated
- Focal Therapy needs **controlled energy** to treat the designated area
- Focal therapy needs precise tools to **evaluate** the treated area

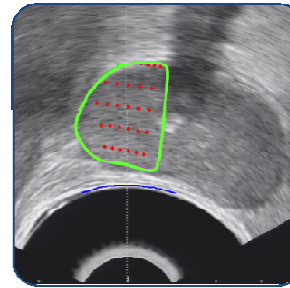


# The 3 pillars of Focal Therapy

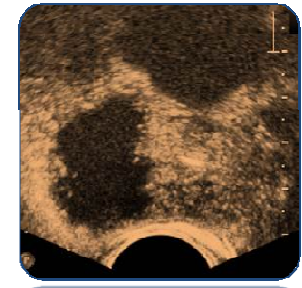
## 1. Localization



## 2. Ablation



## 3. Validation



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## The 3 pillars of Focal Therapy

1. Localization

2. Ablation

3. Validation



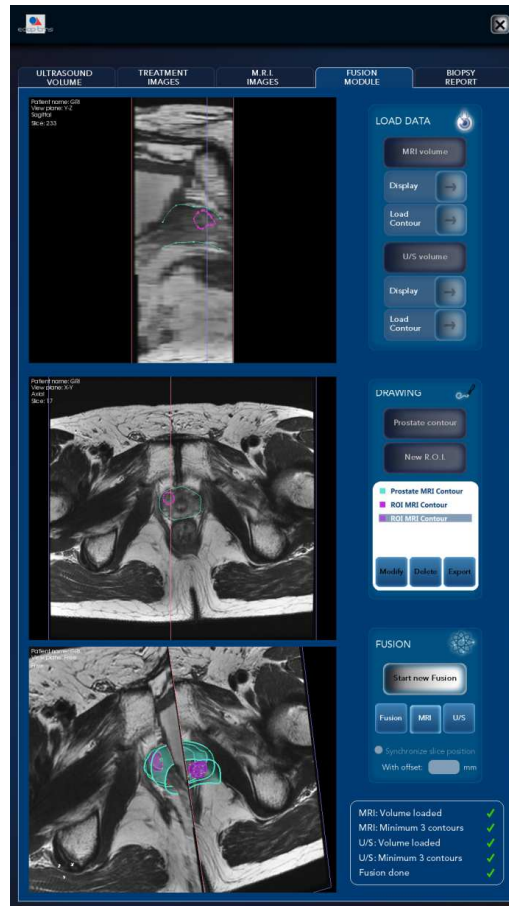
ALL IN ONE DEVICE



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## **Pre-treatment Imaging**

## Pre-treatment planning



### 1- MRI

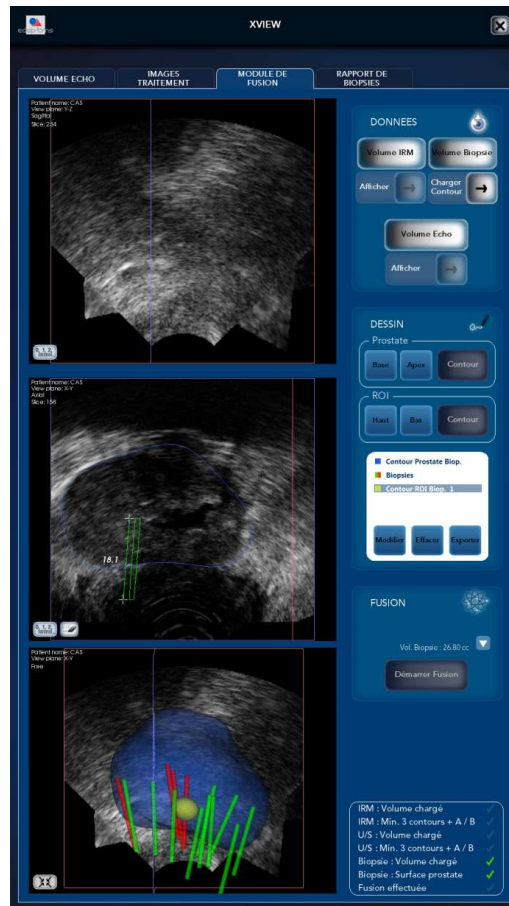
- Import MRI images from CD/DVD/PACS (Dicom)
- Edit Contour of Prostate and Target areas
  - Load previously defined contour
  - Start contouring on Focal One®

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## Pre-treatment planning

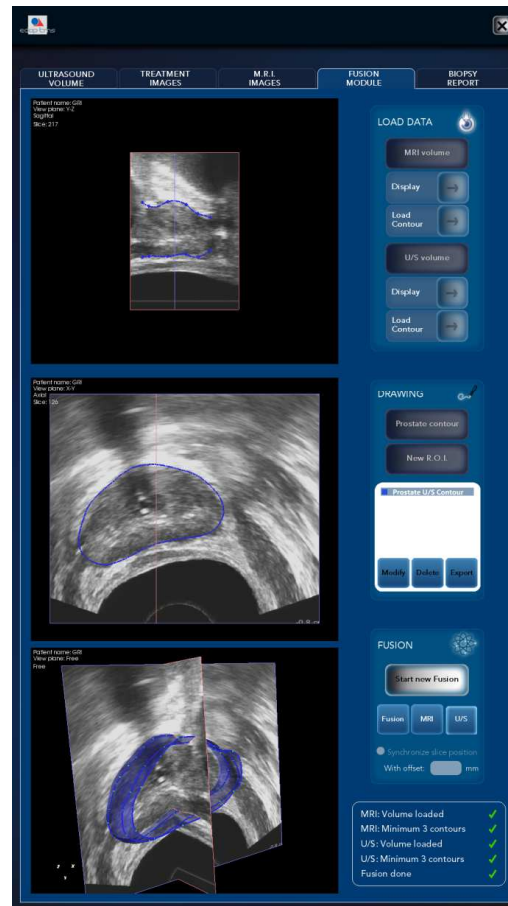
### 2- Biopsy

- Import biopsy volumes from CD/DVD/PACS





## Pre-treatment planning

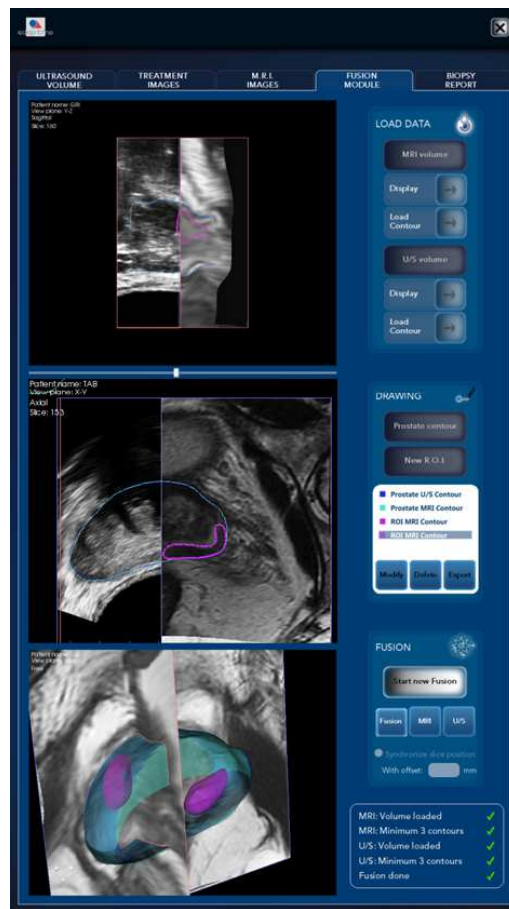


### 3- Real-time Ultrasound Volume

- Acquire Ultrasound Volume
- Edit Contour of Prostate

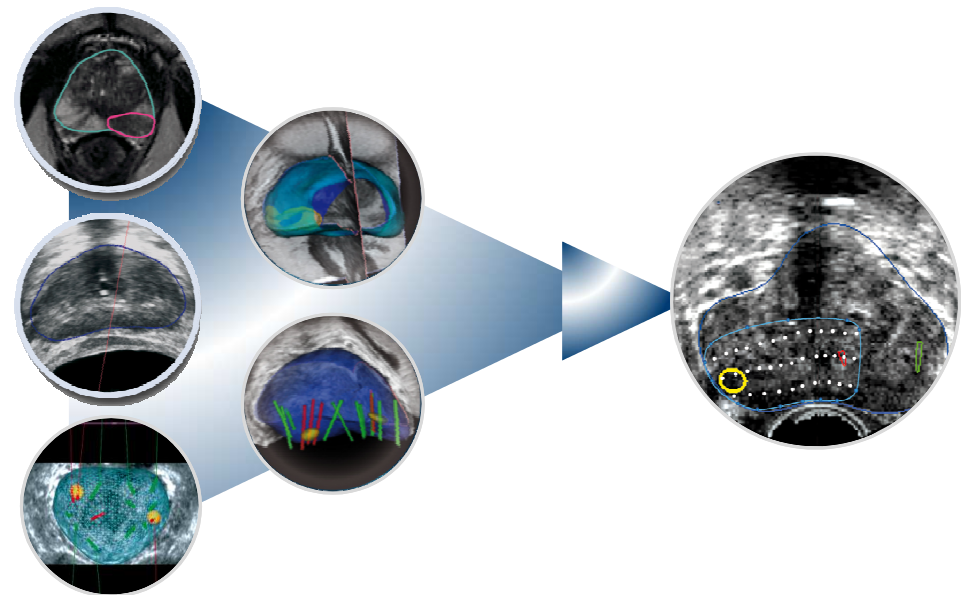


## Pre-treatment planning



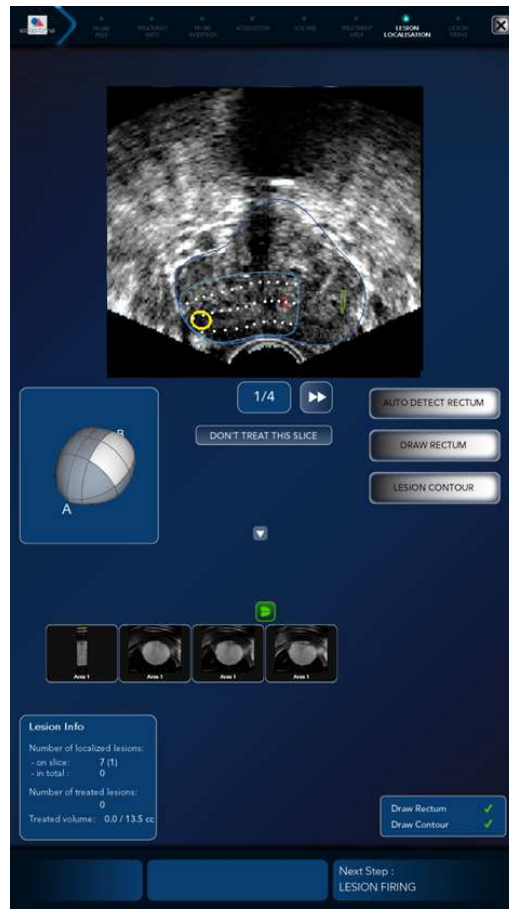
### 4- MRI / Biopsy / Ultrasound elastic fusion

- Automatic registration of 3D contours of prostate (3D translations and rotations)
- Elastic (non-rigid) transformation
- Transformation applied to MRI targets and biopsy trajectories to be visualized in the ultrasound



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## Pre-treatment planning



### Treatment Area Planning

- Precise contouring of the area to be treated
- Visualization of MRI targets and 3D biopsy data
- Automatic dispatch of individual lesions

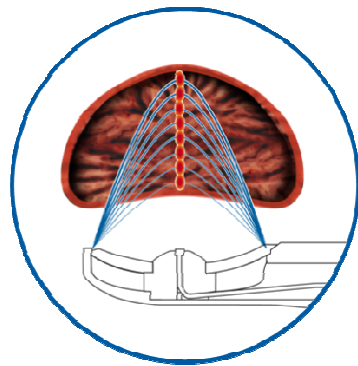


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## **Dynamic Focusing Technology**

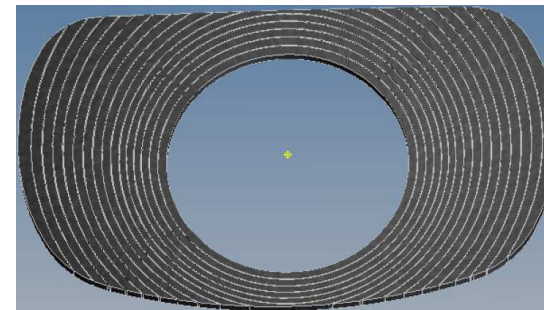
# Focal One® Dynamic Focusing Probe

## Dynamic focusing treatment



- 8 focal points from 32mm to 67mm ( $\Delta f = 5$  mm)
- Unitary HIFU lesion stacking
- Shooting process : 1s ON / focus ; no OFF
- Unitary HIFU lesion height = 5mm
- Max Reachable depth (A-P Distance): 40 mm

- 16 isocentric rings = 16 ways
- Equal surfaces
- Electronic displacement of focal point
- Natural focal point @ 60 mm

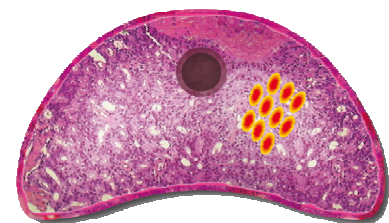
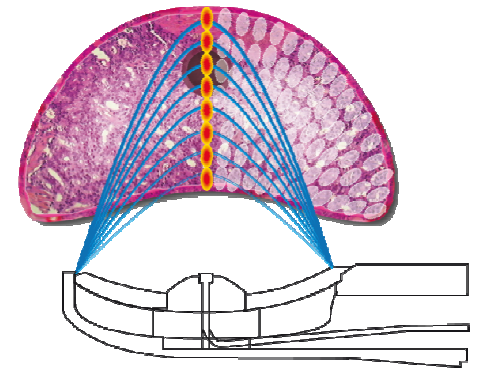


## Dynamic Focusing Advantages

- Access to **Anterior Part** of large prostates (A-P up to 40 mm)
- More **homogeneous** lesions
- **Faster** treatment (for the same volume)
- **Conformational** treatment



Dynamic Focusing Technology allows a « **pure focal** » treatment





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## Pre-treatment planning



## Treatment tracking

- Ability to pause at any time during the process
- Modify planning of slice being treated
- Ability to update the planning of upcoming slices
- Review the patient information (baseline, biopsy reports, etc.) without stopping the treatment
- Track the progress of the overall treatment with virtual 3D prostate





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## **Treatment Validation**

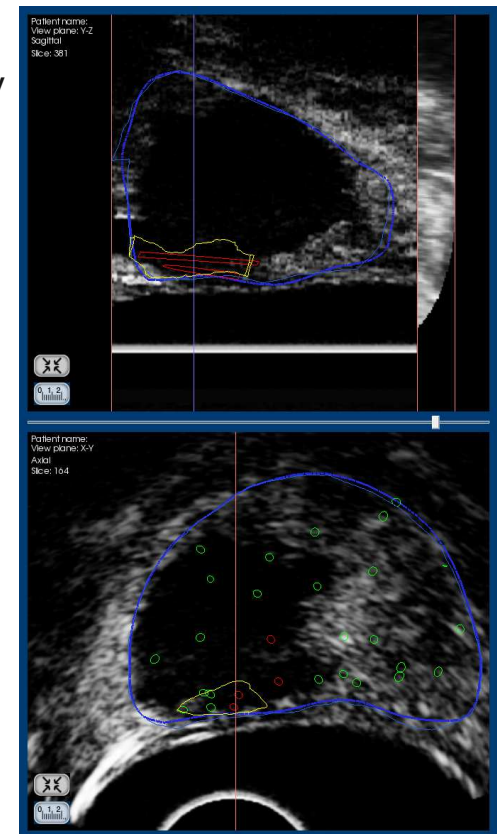
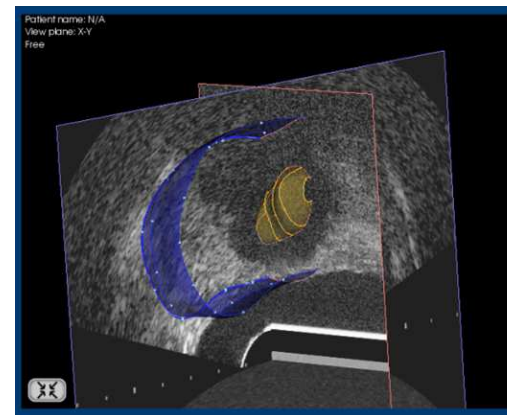
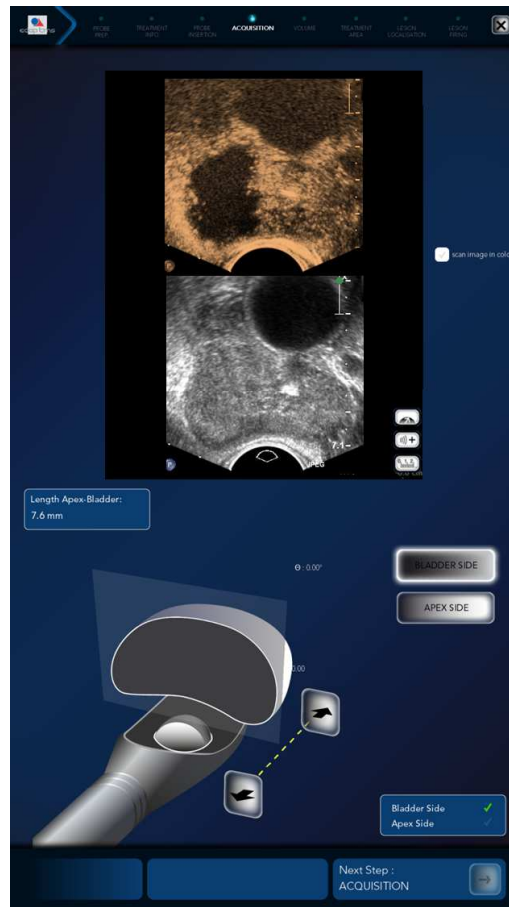
# Focal One®

edap tms  
Bringing New Horizons to Therapy

## Contrast-Enhanced Ultrasound

### Treated area validation

- Use of standard Contrast-Enhanced Ultrasound Technology (Sonovue™)
- Allows to confirm de-vascularized area
- Allows to re-treat areas not completely treated





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## **Focal One® design concept**

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## **Patient Positioning: Standard OR table**



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## **Urologist positioning**



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## Transport Position



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## Transport



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