

## SMART TEMPLATE

### ROBOTIC NEEDLE-GUIDANCE TEMPLATE FOR IN-BORE MRI-GUIDED PROSTATE BIOPSY

The unique capability of the new template enables clinicians to obtain prostate biopsy specimens with mm-scale accuracy under the MRI-guided procedure.

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# SMART TEMPLATE FOR TRANSPERINEAL PROSTATE BIOPSY GUIDANCE

## ADDRESSED NEED:

Prostate cancer is the most prevalent malignancy in men and the second leading cause of cancer deaths in the United States. Despite its severity, early diagnosis with systematic biopsies and proper treatment improves the survival rate to over 90% in all stages of prostate cancer.

MRI-guided biopsy has shown to provide cancer detection rates of up to 59% in patients with elevated prostate-specific antigen (PSA) levels, as compared to 32% when transrectal ultrasound-guided biopsy was used. Although MRI enables precisely identify suspicious regions within the prostate, the accuracy of needle placement during biopsy is significantly affected when encountering perineal structures such as scar tissue, muscle, pubic bone, and implanted seeds within the needle trajectory. As a result, the precise placement of the biopsy needle in these regions remains a major challenge, leading to repeated and expensive biopsies and potentially delaying treatment.

## TECHNOLOGY/CAPABILITIES:

Smart Template (ST) eliminates the passive grid, enabling countless entry points, and automated positioning and angulation of the needle. The ST has a 4-DoF needle-guiding mechanism allowing a translational range of motion along the vertical and horizontal axis, and a needle rotational motion around the vertical and horizontal axis, respectively. The device can be placed on a custom-made patient table with sliding rails, which allows adjusting the device against the patient perineum to minimize the air gap between the device guide and the skin surface during MRI-guided transperineal prostate biopsy procedure (See figure below). The angled insertion will enable avoidance of the various perineal structures that cause deflection of biopsy needle. This technology enables the precise positioning of the needle into the desired site and reduces the chance of false-negative biopsies and the need for repeated biopsies.

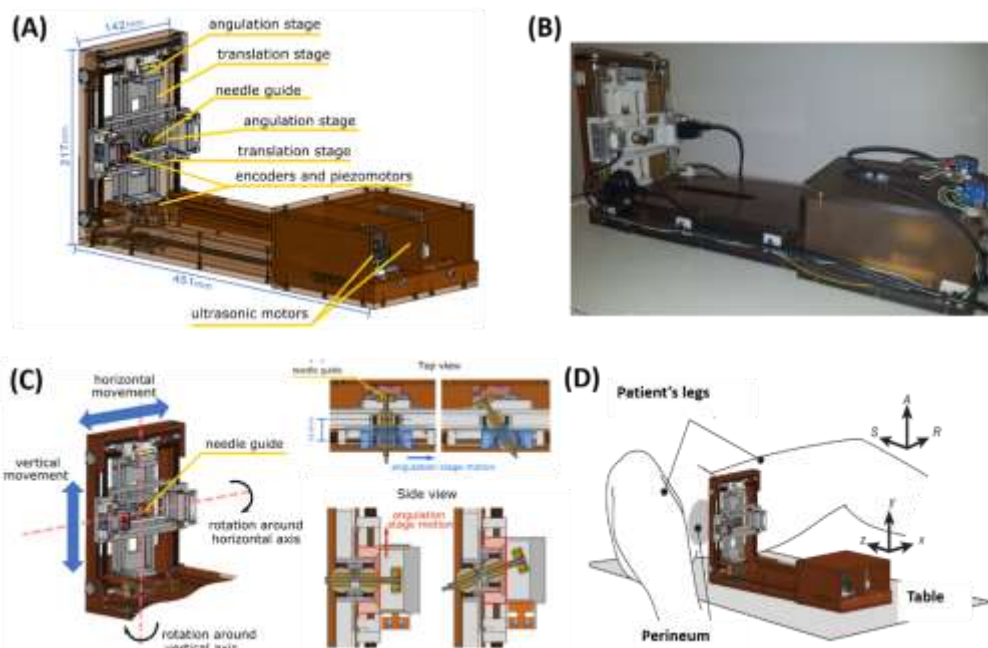


Figure 1. (A) Main components of the new Smart Template. (b) Photo of Smart Template. (C) Horizontal and vertical translation and angulation stages, respectively. (D) Patient and Smart template on a patient table.

## FEATURES:

- Provides an unconstrained selection of the entry point for biopsy needles
- Provides automated translational and angular orientation
- Provides optimal needle trajectory for the transperineal prostate biopsy

**SPECIFICATION:**

<b>Smart Template</b>	Size (Height x Width x Length)	217 mm x 142 mm x 411 mm
	Weight	3.6kg
	Material	Biocompatible Plastic
	Biopsy Coverage Area	65 mm x 56 mm
	Vertical Articulation	± 30°
	Horizontal Articulation	± 30°
	Translation Stage Motor	MR-compatible Ultrasonic motor
	Angulation motor	MR-compatible Piezo motor
<b>Product Classification</b>	Medical Device	US: Class I Registration
	MRI compatibility	ASTM F2503
	Risk Analysis / Risk Management	ISO 14971:2012
	Biocompatibility	ISO 10993-1:2009
	Cleaning	AAMI TIR 12:2010; AAMI TIR 30:2003
	Sterilization	ISO 17664:2017;
<b>Operating Conditions</b>	Temperature	11° C – 29° C (52° F-84° F)
	Humidity	15-65 % ATM non-condensing

**NOTE:** This instrument is not yet FDA approved and therefore is available for investigational use only.

**LICENSING:** This technology is available for licensing

**CONTACTS/INFORMATION/SALES/INQUIRIES**

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