Health Technology Review	
Technology Ref.:	HTA-23039
Technology Name:	High Intensity Focused Ultrasound (HIFU)
Approvals by International Bodies:	US-FDA CE- Mark
Company name:	Focal One
Agent in UAE:	NA
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Short Description of the Technology:	High-Intensity Focused Ultrasound (HIFU) is a non-invasive (no incisions/no scars), non-radiation high-performance technology that uses an ultrasound probe to deliver a concentration of high-intensity sounds waves to a targeted area of tissue. The technology has been used in humans since 1993 with demonstrated efficacy. It was approved by the Food and Drug Administration (FDA) for the ablation of malignant prostate tissue in 2015 and is additionally recognised by urological medication associations globally. Clinically, HIFU is used to ablate prostate cancer, and has been used for initial treatment or recurrence after prior therapy (radiation, laser, cryoablation, etc.). This effective treatment option for the prostate has the unique technology to target a specific area of tissue, sparing the rest of the organ. This non-invasive clinical, interventional treatment technology begins by imaging the patient. The machine performs an ultrasound that provides a 3D reconstruction of the prostate. Next, the urologist selects the most appropriate treatment strategy based on the clinical scenario. The procedure is then planned millimetre by millimetre. The Focal OneR then executes the treatment plan ablating only the targeted tissue using an ultrasound probe that is inserted directly into the rectum. The magnitude of the delivered ultrasound energy to the targeted area rapidly raises the temperature of the targeted tissue, causing coagulation necrosis or cell death and damage. The manufacturer of Focal One describes the action like the sun's rays passing through a magnifying glass triggering a burn at the focal point. The use of real-time ultrasound images provides constant monitoring of the procedure. The technology is a repeatable procedure and can be combined with other treatments. Additionally, it offers a low risk of side effects such as incontinence, erectile dysfunction, and hospital stay.

Health Technology Assessment Team Recommendation:	Approve

Summary of Review:

This unique technology makes ,it possible to target and destroy a part of the prostate, sparing the rest of the organ and therefore minimizing side effects. The technology use high intensity sound waves Instead of radiation used to heat up and burn the targeted tissue .

Advantages	Disadvantages
It preserves the erectile nerves and urinary sphincter thanks to the precise targeting of lesions	The main known side effects of the HIFU treatment (total treatment of the gland) are: narrowing of the prostatic urethra (stenosis) that may occur in the months following treatment, stress urinary incontinence or erectile dysfunction.
Less time away from work and leisure activities	
No Blade, No Scar, No Radiation.	
FDA and CE Mark Approval	

We recommend an **approval/approval with limitation of using this technology** with the following conditions:

1. The technology may only be used urologist.
2. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees.
3. Provision of regular updates and reports about the product to DOH upon request.
4. Any other documents or information requested regarding the product and cost to finalize the approval process.

Moreover, DOH has the right to stop the product at any stage if deemed necessary, initial conditions and any subsequent conditions must be satisfied before obtaining final approval. Failure to do so will reflect in provoking the approval.

Technology Image
 Focal One® device

Population, setting and intended user for Technology "HIFU"

- **Population/ Intended User**;
  - Patients who have not yet received any treatment for prostate cancer.
  - HIFU is particularly recommended for radical treatment with patients who have:
    - A localized stage t1 or t2 cancer.
    - A Gleason score of 7 or less.
    - A desire to maintain maximum quality of life after treatment.
- **To be performed by**:
  - By urologist.
- **Clinical Setting:**
  - Hospitals, special urology centers
- **Condition of use:**
  - prostate cancer.
- **Exclusion criteria:**
  - Anal or rectal surgery that prevents insertion of the probe.
  - Artificial sphincter, penile implants and intra-prostatic implants.
  - Latex allergy (due to the composition of the balloon surrounding the treatment probe).
  - Inflammatory Bowel Disease (IBD), previous significant rectal surgeries, urethral strictures, active infections, and anatomical inability to insert the transrectal probe.