Health Technology Review	
Technology Ref.:	HTA22029
Technology Name:	Emsella HIFEM
Approvals by International Bodies:	MoHaP (UAE) and FDA
Company name:	BTL
Agent in UAE:	Corniche Hospital, SEHA
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Short Description of the Technology:	High Intensity Focused Electromagnetic Energy selectively affects mainly skeletal muscle. The Emsella device is the original technology developed to deliver HIFEM specifically to the muscles of the pelvic floor. It was officially launched in the UK for management of urinary incontinence and pelvic organ prolapse in 2018. HiFEM is conducted by delivering magnetic pulses to the muscle innervating motor neurons of the pelvic floor. The Emsella HiFEM applicator is presented as a chair on which the patient sits in the outpatient setting under appropriately trained physician supervision. It has a circular coil in its base that is heated by an electric current of high amplitude. The device uses normal hospital power supply and has no consumables. The alternating electric field generates an alternating magnetic pulse that had a frequency of 3 to 5 kHz. The alternating magnetic field changes the electric current that induces depolarization of excitable tissue, predominantly motor neurons. This activation causes action potentials in the motor neurons to carry the electric signal to the neuromuscular junction, where the muscle is depolarized and contraction initiated.

Health Technology Assessment Team Recommendation:	**Approve**
Summary of Review:	
EMSELLA uses HIFEM energy to cause deep and intense pelvic-floor muscle contractions, helping incontinent patients regain their confidence. HIFEM stimulates the entire pelvic floor area and helps with restoring neuromuscular control.	

Advantages	Disadvantages
Treatment is completely non-invasive and safe	This technology is typically not covered by insurance
local community access to high healthcare technology	Non-invasive, and safe, but has limited data available.
Once the therapy starts, the procedure runs independently	Not as effective in the long-run as pelvic physiotherapy and can be used as an adjunct to pelvic floor physiotherapy program
Improved recovery, complications and longevity	
MoHaP (UAE) and FDA approved	

We recommend an **approve of using this technology** with the following conditions:

1. The technology may only be used after having been prescribed by a healthcare professional
2. Using the technology may only be started after completion of the required training from a qualified instructor
3. Establishing a proper quality monitoring process and reporting of any adverse events or unwarranted consequences including safety issues of employees and patients.
4. Provision of regular updates and reports outcome about the product to DOH upon request.

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

Population, setting and intended user for Technology "Emsella HIFEM"

- **Population/ Intended User**;
- Electromagnetic stimulation of pelvic floor musculature for the purpose of rehabilitation of weak pelvic muscles
- **To be performed by**:
  - Healthcare professionals
- **Clinical Setting:**
  - Hospitals
  - Clean environment
- **Condition of use:**
  - The system is intended to be used for restoration of neuromuscular control for the treatment of male and female urinary incontinence
  - Stress urinary incontinence, urge incontinence, or mixed urinary incontinence as determined by Healthcare professionals
  - Age greater than 18
  - Body mass index (BMI) < 37 kg/m2 4
- **Exclusion criteria:**
  - Patient with any significant pelvic organ prolapse; stage III or greater
  - Patient with untreated malignancy
  - Patient who is pregnant, planning to get pregnant or within 3 months postpartum
  - Patient with implant or IUD containing metal
  - Patient has a pacemaker