



Health Technology Review	
Technology Ref.:	HTA-24005
Technology Name/Version/Model:	High-Intensity Focused Ultrasound (HIFU)
Approvals by International Bodies:	CE Mark
Company name:	Healthpoint Hospital
Agent in UAE:	Dr. Omar Abdalla Alnaqbi
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Short Description of the Technology:	SONOVEIN® is a robotic solution for the non-invasive echotherapy Treatment of varicose veins and venous reflux disease. It is totally non-invasive, with ultrasound energy being beamed from a transducer applied to the skin above the vein. The therapeutic ultrasound is focused on the target vein, using a linear ultrasound array to obtain an image of the target vein. The focused ultrasound generated heat at a precise point deep to the skin, guided by the real time ultrasound image. Each treatment cycle, a volume of tissue about the size of a grain of rice is ablated at about 85-90°C, causing closure of an incompetent vein by fibrosis.
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Health Technology Assessment Team Recommendation:	Approve
Summary of Review:	
High-Intensity Focused Ultrasound (HIFU)- SONOVEIN HD THC903359-B is the first robotic and 100% non-invasive solution for echotherapy treatment for varicose veins and venous reflux disease. We recommend as It is use AI to developments latest in ultrasound technology to treat the veins from outside the body, making it 100% non-invasive.	
Advantages	Disadvantages
Non-invasive, minimizing the need for surgical incisions.	Skin Sensitivity: Patients with sensitive skin may experience temporary redness in the treated area following HIFU.
Targets specific tissue, sparing surrounding healthy areas.	Temporary Side Effects: HIFU can cause temporary side effects, such as pain or discomfort during and after the procedure.
Shorter recovery times and reduced side effects compared to traditional treatments.	Risk of Incomplete Treatment: As for any other noninvasive venous treatment, the effectiveness of HIFU can depend on factors like the size and location of the targeted tissue especially in obese patients.
No evidence of recalls or safety alerts.	

No additional accessories (guide wires, puncture kits or catheters) needed.

We recommend an approval of using this technology for Market entry with the following conditions:

1. High-Intensity Focused Ultrasound (HIFU) Version - SONOVEIN HD THC903359
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

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 “High-Intensity Focused Ultrasound (HIFU) Version - SONOVEIN HD THC903359-B”

- **Population/ Intended User;**
 - varicose veins
 - incompetent perforating veins
 - active venous ulcers
 - venous impotence
- **To be performed by:**
 - Specialist trained in duplex ultrasonography.
- **Clinical Setting:**
 - Hospitals, Specialized clinics.
- **Condition of use:**
 - All patient affected by ALL symptomatic grades of venous insufficiency.
- **Exclusion criteria:**
 - Pregnancy .
 - Infection at the Treatment Site.