Sonata™ System for the removal of uterine fibroids

**TECHNOLOGY**

The Sonata™ System (previously VizAblate®), developed by Gynesonics, is an incisionless, transcervical system that combines ultrasound image guidance with radiofrequency (RF) ablation. The system is designed to treat symptomatic uterine fibroids in a hospital outpatient setting, depending on anaesthetic requirements.

Sonata™ consists of an intrauterine ultrasound probe at the tip of a radiofrequency ablation device, which is inserted through the cervix into the endometrial cavity.

Other components include an RF generator that controls energy delivery to maintain a constant temperature of 105ºC. The probe is used to identify the borders of the fibroid using the SMART Targeting Guide, which optimises the ablation area, whilst minimising the risk of thermal injury to adjacent organs. Options for anaesthesia include general or regional anaesthesia, as well as conscious sedation.

Sonata™ is CE marked and the company anticipates launch for routine clinical use in the UK during 2016.

**POTENTIAL FOR IMPACT**

Fibroids are benign tumours that develop within the uterine wall and are one of the most common gynaecological problems among women in the UK. They are often asymptomatic, but they can cause symptoms such as abnormal uterine bleeding and dyspareunia (painful intercourse). They may also be associated with reproductive problems such as subfertility and miscarriage. Fibroids can be singular or multiple.

Treatment depends on whether the fibroid causes symptoms and/or whether the woman is...
planning a future pregnancy. Symptomatic fibroids, depending on their size, number and location, can be managed by hysterectomy (surgical removal of the uterus) or myomectomy (surgical removal of the fibroid). Smaller submucous fibroids can be removed by hysteroscopic resection. Uterine artery embolisation may also be used, which involves injecting small particles into the arteries in the groin with the aim of blocking the blood supply to the fibroids to relieve symptoms and reduce fibroid size. Magnetic resonance (MR) guided focused ultrasound may be suitable to locate the fibroids and direct high-intensity ultrasound energy to destroy fibroid tissue. Hormone-based treatments may be used on a short-term basis to relieve symptoms or to shrink the fibroids before surgery or other interventional treatment.

The Sonata™ System is a less invasive treatment option for submucous, intramural and transmural fibroids. The company claim that Sonata™ may be suitable for treating up to 80% of all fibroid types, which includes those not currently suitable for hysteroscopic resection. Sonata™ has the potential to avoid many of the complications associated with laparoscopic or open procedures, such as ureteral injury and haemorrhage. The transcervical approach may also reduce BMI-related access issues. The company claim that most patients experience an improvement in bleeding symptoms within three months of treatment.

The technology is predicted to have an impact on the following domain of the NHS Outcomes Framework (see: www.england.nhs.uk/resources/resources-for-ccgs/out-frwrk): Domain 2 Enhancing quality of life in people with long-term conditions.

**EVIDENCE**

**PUBLICATIONS**


**ONGOING STUDIES**


**INFORMATION FROM**

This Alert is based on limited information from the company and a time-limited internet search.