Lyrette™ for stress urinary incontinence

**TECHNOLOGY**

Lyrette™, formerly known as Renessa, is a transurethral device developed by Verathon Medical Ltd to deliver non-ablative radiofrequency energy to women with stress urinary incontinence (SUI) caused by hypermobility. It is intended to provide a treatment option for SUI before invasive surgery.

The Lyrette™ transurethral SUI system uses low power, non-ablative radiofrequency to deliver controlled heating to submucosal sites in the bladder neck and proximal urethra to induce localised thermal collagen re-modelling.

During the short non-surgical procedure, a local anaesthetic is administered to the tissues at the base of the bladder and a catheter is inserted through the urethra into the bladder. A small balloon at the tip of the catheter is inflated to help position it. The target area in the bladder neck is then heated for no more than 10 minutes to denature the collagen in the tissue. Over the following weeks during the healing process the body will remodel the damaged collagen, resulting in firmer tissue that is less compliant and more resistant to leaks. The procedure can be performed as an outpatient or day case setting and patients are expected to be able to return to normal activities within a day.

Lyrette™ is FDA approved for use in the US. The company anticipate a CE mark in 2015 with launch for private and NHS clinical use planned for mid 2015.

**POTENTIAL FOR IMPACT**

SUI occurs when the pelvic floor muscles are too weak to prevent the release of urine when the bladder is put under pressure, for instance when coughing or laughing. It is very common in women and it is thought that as many as 1 in 5 women over the age of 40 have some degree of stress incontinence. Current treatment options for SUI include exercises to strengthen the pelvic floor muscles and medication. Surgery, including tape procedures, sling procedures and colposuspension, may be offered if other treatment options have been unsuccessful.
The company claim that a key innovative feature of this device is that the Lyrette™ procedure is the only non-surgical, outpatient procedure that treats the primary cause of female SUI. They state that Lyrette™ is a quick procedure with a short recovery time. In contrast, surgery can require up to six weeks recovery time and also carries risks of complications. In addition, the Lyrette™ procedure does not require a hospital stay and may offer a cheaper alternative to surgery if proven to be effective. This may result in a reduction in the number of surgeries for SUI, thereby saving costs and allowing resource reallocation within the NHS. The company also state that Lyrette™ is a single treatment, however, in theory the procedure can be repeated with potentially beneficial results if the results from the first procedure were beneficial but incomplete. Staff training on how to use the device would be required.

The company also expect Lyrette™ to increase the number of patients with SUI that can be treated, for example, patients in whom surgery is inappropriate, such as women who are planning to have more children. If proven to be effective and to be without significant adverse effects, Lyrette™ may significantly improve the quality of life of patients with SUI.

**EVIDENCE**

**PUBLISHED PAPERS AND ABSTRACTS**


**COMPLETE UNPUBLISHED STUDIES**

No complete, unpublished studies of this device were identified for this alert.
ONGOING STUDIES


INFORMATION FROM

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