

Synthetic vaginal tapes for stress incontinence

Vaginal tapes are implanted to treat stress incontinence (leaking urine with coughing, sneezing or exertion). They are placed under the urethra like a sling or hammock to keep the urethra in the correct position. There are a number of manufacturers who sell these devices in the UK. The majority are made from a polypropylene mesh.

The MHRA has seen a recent increase in numbers of adverse event reports in comparison to numbers received in previous years, increasingly from patients. As a result, the MHRA has launched an investigation to better understand the use of these devices and the complications associated with their use. To this end the MHRA recently held a workshop under the chairmanship of Professor Paul Abrams, which included representatives of the Royal College of Obstetricians and Gynaecologists, the British Association of Urological Surgeons, the British Society of Urogynaecology, and representatives of some manufacturers of these devices, to consider how to make insertion a safer procedure. The meeting covered:

- product development
- introducing a new device into clinical practice
- device implantation in a safe environment
- reporting of patient outcomes and adverse events
- responsibilities of involved parties (clinicians, regulators and manufacturers).

An article that summarises these discussions will be published in the journal *European Urology* (Abrams P, et al. Synthetic Vaginal Tapes for Stress Incontinence: Proposals for Improved Regulation of New Devices in Europe. *Eur Urol* (2011), doi:[10.1016/j.eururo.2011.08.008](https://doi.org/10.1016/j.eururo.2011.08.008)).

Further guidance on the use of incontinence tapes can be found on the NICE (National Institute for Health and Clinical Excellence) website:
<http://guidance.nice.org.uk/CG40>

NICE also provides advice for patients contemplating this procedure:
<http://guidance.nice.org.uk/CG40/PublicInfo/doc/English>

The MHRA is still gathering information on the use and complications associated with these devices and would encourage reporting of adverse events to us using the link below:
<http://www.mhra.gov.uk/Safetyinformation/Reportingsafetyproblems/Devices/index.htm>

Questions that patients who may be undergoing insertion of vaginal tapes for incontinence should discuss with their surgeon prior to surgery:

- Full description of what the treatment involves
- Why this type of treatment is appropriate
- What are the different devices available?
- Pros and cons of different devices
- What are the alternative treatments?
- Possible side effects or adverse events associated with the treatment
- What happens if this particular surgery does not work?
- Has the surgeon performed this operation before and if so in how many patients?
- Has the surgeon performed an audit of his or her results of the procedure proposed? If so, what were the success and complication risks?