

INSERTION of an ARTIFICIAL URINARY SPHINCTER (AUS) in WOMEN Information about your procedure from The British Association of Urological Surgeons (BAUS)

This leaflet contains evidence-based information about your proposed urological procedure. We have consulted specialist surgeons during its preparation, so that it represents best practice in UK urology. You should use it in addition to any advice already given to you.

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http://rb.gy/0q163

KEY POINTS

- An artificial urinary sphincter (AUS) is used to treat stress urinary incontinence in women who have sphincter weakness
- It may also be suitable for some women with stress incontinence caused by sphincter weakness secondary to neurological disorders
- The device has three parts: a cuff, a pump and a fluid-filled reservoir
- The cuff is put around your urethra (waterpipe) and compresses it so that urine does not leak out
- The pump is placed under the skin next to your vagina (in the labia); you need to squeeze the pump each time you want to pass urine
- The commonest complications are infection, mechanical failure and migration of one of the components
- It is currently only offered in a limited number of centres that have expertise in complicated and recurrent stress incontinence
- Although its use is well-established in men, we have less evidence about how well it works in women in the long-term when compared with other treatments for stress incontinence
- All patients should receive a "sphincter card" with information to pass on to other clinicians
- Inserting a catheter can be potentially dangerous after AUS insertion, and can cause permanent damage if not done correctly

What does this procedure involve?

This is an operation to treat stress incontinence (leakage of urine when you exercise, sneeze or strain) in women who have a weak or damaged urinary sphincter. The urinary sphincter is the muscle that normally keeps your urethra (waterpipe) closed so you do not leak. This problem is commonest in women with neurological disease but the operation can also be used to treat women who have already had unsuccessful incontinence surgery.

The procedure involves implanting a device inside your body that holds your urethra gently closed. The device can be opened using a pump underneath the skin of your labia when you need to pass urine.

The artificial urinary sphincter (AUS) has three parts connected together (pictured) and is placed inside your body:

- a soft circular cuff around your urethra just below the neck of your bladder which gently holds the urethra closed to prevent urine leakage
- a small, soft pump under the skin of your labia which you press gently to open the cuff when you want to pass urine
- a small, soft, fluid-filled pressure balloon inside the lower part of your abdomen (tummy)



What are the alternatives?

Stress incontinence can usually be treated without surgery. We recommend that all patients try non-surgical treatment before having an operation, because it avoids the risks of side-effects or complications of surgery.

- Incontinence pads if your symptoms are not a bother to you
- **Pelvic floor exercises** with a continence adviser or physiotherapist can improve stress urinary incontinence in 70% of women
- Weight loss and stopping smoking can also help stress incontinence
- **Continence pessaries** placed temporarily inside your vagina can help leakage that occurs only during exercise

There are several operations used to treat stress incontinence. Each one has advantages and disadvantages, and different operations may be better for different people. You should discuss these with your surgeon before coming to a decision:

- **<u>Urethral bulking</u>** an injection around your urethra
- Mid-urethral tape operations see footnote 1 (e.g. TVT or TOT) using a synthetic mesh tape to support your urethra from below
- Autologous sling procedure using a piece of strong tissue from your own abdominal (tummy) wall to support your urethra from below
- <u>Colposuspension</u> an open operation which lifts the tissues around your bladder neck on to the back of your pelvis

For further information about the options available to treat stress urinary incontinence, see the <u>BAUS leaflet on the comparison of treatment options</u> for stress urinary incontinence in women and the <u>NICE guideline NG123</u>.

What happens on the day of the procedure?

You will be seen by the surgeon and the anaesthetist who will go through the plans for your operation with you.

We may provide you with a pair of TED stockings to wear, and we may give you an injection to thin your blood. These help to prevent blood clots from developing and passing into your lungs. Your medical team will decide whether you need to continue these after you go home.

Details of the procedure

- we normally perform the procedure under a general anaesthetic (i.e. with you asleep)
- we usually give you an injection of antibiotics before the procedure, after you have been checked for any allergies
- we make a small cut in the lower part of your abdomen (tummy)
- we pass the cuff around your urethra (waterpipe)
- we put the pump inside your labia (next to your vagina)
- we put the reservoir (pressure balloon) inside the lower part of your abdominal (tummy) cavity through the same incision
- we use dissolvable stitches throughout which normally disappear after two to three weeks

¹ Mid-urethral tape operations are currently "paused" on the recommendation of the July 2020 Cumberlege report

- we put a catheter in your bladder through your urethra
- the artificial sphincter is "deactivated" immediately after the procedure so it cannot work; this means you will probably still be incontinent to start with
- you can expect to be in hospital for a few days after the procedure

We usually remove your bladder catheter the next day. This usually means that you will start to leak urine again as soon as the catheter has been removed. We do not normally activate the artificial sphincter until six weeks after the procedure, when all of your wounds have healed.

Sometimes, we only put in the cuff, and then do a second operation to put in other components at a future date. Your surgeon will discuss this with you before the procedure.

How effective is the procedure in curing stress urinary incontinence?

Around 70% (seven out of 10) of women are completely dry after the operation. Most women are much better after surgery, even though they may still have some leakage. Put another way, more than 90% (nine out of 10) women are satisfied with the result after artificial urinary sphincter insertion. Outcomes for surgery in women with recurrent stress urinary incontinence after previous surgery, however, are not as good.

Are there any after-effects?

The possible after-effects and your risk of getting them are shown below. Some are self-limiting or reversible, but others are not. We have not listed very rare after-effects (occurring in less than 1 in 250 patients) individually. The impact of these after-effects can vary a lot from patient to patient; you should ask your surgeon's advice about the risks and their impact on you as an individual:

After-effect	Risk	
Blood in your urine with stinging or burning when you pass urine	Between 1 in 2 & 1 in 10 patients	
Bruising and discomfort in your lower abdomen and vulva	Between 1 in 2 & 1 in 10 patients	

Short-term or long-term inability to empty your bladder completely that does not get better on its own , requiring a <u>catheter</u> or <u>intermittent self catheterisation</u>	Between 1 in 10 & 1 in 20 patients
Failure of the device which stops working and requires replacement	Between 1 in 10 & 1 in 50 patients
Infection around the device requiring its removal	Between 1 in 10 & 1 in 50 patients
Failure to produce any significant improvement in your leakage	Between 1 in 10 & 1 in 50 patients
Urinary infection requiring antibiotics	Between 1 in 10 & 1 in 50 patients
Overactive bladder symptoms (passing urine frequently and urgently)	Between 1 in 10 & 1 in 50 patients
Infection in your wound(s)	Between 1 in 10 & 1 in 50 patients
Injury to the urethra or vagina at the time of surgery so that the device cannot be safely implanted	Between 1 in 10 & 1 in 50 patients
Migration of parts of the device into the urethra, vagina or abdominal wall requiring removal of the device so that everything can heal before a new one is put in (may happen months or years later)	Between 1 in 50 & 1 in 250 patients
Bleeding requiring blood transfusion	Between 1 in 50 & 1 in 250 patients

Anaesthetic or cardiovascular problems possibly requiring intensive care (including chest infection, pulmonary embolus, stroke, deep vein thrombosis, heart attack and death)



Between 1 in 50 & 1 in 250 patients (your anaesthetist can estimate your individual risk)

Artificial urinary sphincters are mechanical devices which will eventually fail due to "wear and tear". On average, these devices tend to last seven to 10 years. If a device does fail, the procedure can usually be repeated, and the device replaced.

As stated above, outcomes for recurrent stress urinary incontinence that has not been cured by previous surgery are not as good as outcomes for "first-time" surgery.

What information will I need to take home?

You should be given documentation, usually in the form of a "sphincter card", after implantation showing what device has been implanted. You must show this to any clinician involved in your care, particularly if you need catheterisation at a later date. Inserting a catheter can be potentially dangerous after AUS insertion and can cause permanent damage if not done correctly.

The sphincter can be decompressed or deactivated using the pump in your labia. However, unless the clinician is familiar with how to do this, a urologist **must** be called for before any attempt at catheterisation is made.

What is my risk of a hospital-acquired infection?

Your risk of getting an infection in hospital is between 4 & 6%; this includes getting *MRSA* or a *Clostridium difficile* bowel infection. Individual hospitals may have different rates, and the medical staff can tell you the risk for your hospital. You have a higher risk if you have had:

- long-term drainage tubes (e.g. catheters);
- long hospital stays; or
- multiple hospital admissions.

What can I expect when I get home?

• you will get some swelling and bruising of the lower abdomen and labia which can last several days

- you will still have urine leakage when you go home because the device is not activated
- avoid all heavy lifting or strenuous exercise until the device has been activated
- a follow-up appointment will be made for you a few weeks after the procedure to have your device activated and to be instructed in its use

Your data and data protection

It is important that surgeons monitor the success rates and complications of the operations they perform, to be sure that their patients get good results. This helps us to tell future patients what to expect and makes sure that all surgeons are performing well. All stress incontinence operations were previously recorded on a BAUS database but, following the publication of the <u>Cumberlege report and its recommendations</u>, an independent National Pelvic Floor Registry has been set up.

BAUS will support full participation in this national audit that aims to mandate collection of data on all pelvic floor operations, including all surgery carried out for stress urinary incontinence. This will allow surgeons to see how well the surgery is being done under their care and, secondly, will help us to examine national trends for all these procedures.

Some basic patient data (e.g. name, NHS number and date of birth) are entered and securely stored. This is required so that members of the clinical team providing your care can go back to the record and add followup data, such as length of stay or post-operative complications. This helps your surgeon to understand and fully document the various outcomes of the procedure.

General information about surgical procedures

Before your procedure

Please tell a member of the medical team if you have:

- an implanted foreign body (stent, joint replacement, pacemaker, heart valve, blood vessel graft);
- a regular prescription for a blood thinning agent (e.g. warfarin, aspirin, clopidogrel, rivaroxaban, dabigatran);
- a present or previous MRSA infection; or
- a high risk of variant-CJD (e.g. if you have had a corneal transplant, a neurosurgical dural transplant or human growth hormone treatment).

Questions you may wish to ask

If you wish to learn more about what will happen, you can find a list of suggested questions called "<u>Having An Operation</u>" on the website of the Royal College of Surgeons of England. You may also wish to ask your surgeon for his/her personal results and experience with this procedure.

Before you go home

We will tell you how the procedure went and you should:

- make sure you understand what has been done;
- ask the surgeon if everything went as planned;
- let the staff know if you have any discomfort;
- ask what you can (and cannot) do at home;
- make sure you know what happens next; and
- ask when you can return to normal activities.

We will give you advice about what to look out for when you get home. Your surgeon or nurse will also give you details of who to contact, and how to contact them, in the event of problems.

Smoking and surgery

Ideally, we would prefer you to stop smoking before any procedure. Smoking can worsen some urological conditions and makes complications more likely after surgery. For advice on stopping, you can:

- contact your GP;
- access your local NHS Smoking Help Online; or
- ring the Smoke-Free National Helpline on **0300 123 1044**.

Driving after surgery

It is your responsibility to make sure you are fit to drive after any surgical procedure. You only need to <u>contact the DVLA</u> if your ability to drive is likely to be affected for more than three months. If it is, you should check with your insurance company before driving again.

What should I do with this information?

Thank you for taking the trouble to read this information. Please let your urologist (or specialist nurse) know if you would like to have a copy for your own records. If you wish, the medical or nursing staff can also arrange to file a copy in your hospital notes.

What sources have we used to prepare this leaflet?

This leaflet uses information from consensus panels and other evidencebased sources including:

- the Department of Health (England);
- the <u>Cochrane Collaboration</u>; and
- the National Institute for Health and Care Excellence (NICE).

It also follows style guidelines from:

- the Royal National Institute for Blind People (RNIB);
- the Information Standard;
- the Patient Information Forum; and
- the <u>Plain English Campaign</u>.

DISCLAIMER

Whilst we have made every effort to give accurate information, there may still be errors or omissions in this leaflet. BAUS cannot accept responsibility for any loss from action taken (or not taken) as a result of this information.

PLEASE NOTE: the staff at BAUS are not medically trained, and are unable to answer questions about the information provided in this leaflet. If you have any questions, you should contact your Urologist, Specialist Nurse or GP in the first instance.