Flowsecure™

Artificial Urinary Sphincter with Conditional Occlusion

Information for Surgeons

A brief guide to the device and its functions, indications and contra-indications, the operative procedures and setting the AUS pressures *in situ* with follow-up pressure adjustments.
# Table of Contents

Information for Surgeons ........................................................................................................ 1

Table of Contents ...................................................................................................................... 2

General Information ................................................................................................................. 3

Indications for Use .................................................................................................................... 3

Contra-Indications .................................................................................................................... 3

Device Characteristics ............................................................................................................. 3

Device Function ......................................................................................................................... 3

Components ............................................................................................................................... 3

  Packaging ................................................................................................................................ 3

  Individual Components ............................................................................................................ 3

  Care and Storage of Pre-Sterilised Components .................................................................... 4

Implantation ............................................................................................................................... 4

Pre-operative .............................................................................................................................. 4

  Surgical Team Preparation ...................................................................................................... 4

  Patient Preparation ................................................................................................................ 4

Equipment Needed ................................................................................................................... 4

Unpacking the Components ...................................................................................................... 5

Equipment Preparation ............................................................................................................. 5

  Preparing Haemostats .......................................................................................................... 5

Preparing the Device for Implantation. .................................................................................... 5

  A fully sterile procedure for filling the Flowsecure™AUS with saline .................................. 5

Surgical Procedures .................................................................................................................. 6

  Bulbar Urethral Exposure ....................................................................................................... 6

    Abdominal Incision .............................................................................................................. 6

    Placement of Cuff ................................................................................................................ 7

    Refilling the Cuff .................................................................................................................. 7

    Insertion of pump in the scrotum ....................................................................................... 8

    Placement of Pressure Regulating & Stress Relief Balloons ............................................. 8

Post Operative Care .................................................................................................................. 8

  Immediately Post Operative .................................................................................................. 8

  Discharge .............................................................................................................................. 8

Pressurisation Procedure ........................................................................................................ 8

Equipment Required .............................................................................................................. 8

Patient Preparation .................................................................................................................. 9

Patient Education .................................................................................................................... 10

Imaging ..................................................................................................................................... 10

X-raying the Device ................................................................................................................ 10

Appendix 1 ............................................................................................................................... 11

Bibliography & References ..................................................................................................... 12
General Information

Indications for Use
The Flowsecure® Artificial Urinary Sphincter (AUS) with Conditional Occlusion is an implantable device used to treat stress urinary incontinence in males caused by intrinsic sphincter deficiency (ISD) in cases such as post-prostatectomy incontinence.

Contra-Indications
The main contra-indications for the implantation of the Flowsecure® AUS are listed as follows:
1. Unmanaged detrusor instability
2. Previous radiotherapy of the lower urinary tract
3. Problems affecting manual dexterity or motivation which may prevent patient from operating the device
4. Acute urinary tract infection which may lead to post-operative complications
5. Patients whom the surgeon determines to be not suitable due to risks associated with open surgical procedures and/or with the patient's medical history (physical or mental).
6. Known sensitivity to silicone rubber.

Device Characteristics
The Sphinx Medical Flowsecure™ AUS is a medical grade silicone rubber device which consists of a pressure regulating balloon, a stress relief balloon (for conditional occlusion), a urethral cuff and a control pump with a self-sealing port (see Figure 1).

Device Function
The Flowsecure® AUS has been developed to simulate the normal function of the urethral sphincter in order to maintain continence. For the majority of the time the device keeps the urethra closed by means of a pressurised urethral cuff which prevents the passage of urine. The pressure in the cuff is regulated by a small silicone balloon (pressure regulating balloon). An additional balloon is placed in series with the cuff, the purpose of this balloon (stress relief balloon) is to transfer additional fluid to the cuff during periods of high intra-abdominal pressure such as coughing and sneezing. This feature is called Conditional Occlusion.

When the patient wishes to void the cuff can be deflated by manual operation of the control pump which is placed in the scrotum. The fluid in the cuff is transferred to the regulating balloon and urine can be passed through the urethra. The cuff automatically re-inflates through a slow bleed valve in the control pump, in addition, it can be manipulated for fast re-inflation. The base of the control pump contains a self-sealing port which enables the device to be interrogated percutaneously so that extra fluid can be added to increase the pressure.

Components

Packaging
The Flowsecure™ AUS is supplied dry and pre-sterilised in double packaged plastic pockets to enable visualisation of the device. The device and packaging is delivered in a labelled cardboard box for additional protection.

Individual Components

Implant
The Flowsecure™AUS comes as a one-piece device ready for filling at operation with sterile saline,
Sterilisation - Supplied Sterile

All components of the AUS are supplied sterile, processed by validated strictly controlled sterilisation cycles. Sterility is verified in accordance with relevant standards.

Sterility of the implant is maintained only if the package is intact and undamaged.

Shelf Life

For shelf life, refer to the label on the package of individual component or the box label.

Care and Storage

Store the sterile components in a clean dry place at room temperature. For maximum protection during storage, leave the packaged components inside their dust cover boxes.

Single Use

All components of the AUS are intended for SINGLE USE ONLY. DO NOT REUSE EXPLANTED PRODUCTS. DO NOT RERESTERILIZE ANY PRODUCT.

Explanted products should not be reused because re-cleaning and re-sterilization procedures may not adequately remove biological residues, such as blood, tissue and other matter, which could retain resistant pathogens.

Trocar

A plastic trocar if required can be supplied, but not supplied. This is used to route the cuff of the device through the appropriate tissue planes of the lower abdomen to the perineum.

Care and Storage of Pre-Sterilised Components

In order to protect the integrity of the sterile packaging of the device it is important that whilst stored it remains in the outside cardboard box and is placed on a protected shelf or in a cabinet. The environment should be clean, dry and near room-temperature.

Implantation

Pre-operative

Surgical Team Preparation

Prior to implantation of the Flowsecure® AUS, the surgeon and operating team should be familiar with the operating procedure and stages of implantation. Prior to implantation the surgical team should scrub for ten minutes using povidone-iodine solution (provided the patient is not iodine sensitive) or any other approved hospital scrub procedure.

Patient Preparation

The patient should be fully informed of the procedure and give consent. The surgeon should discuss the possible risks associated with the surgery, anaesthetic and implantation. The possibility of allergic reaction to the materials of the device may also be considered. However, no causal relationship has been established between the incidence of immunological disorders and implanted medical grade silicone rubber.

Prior to surgery the patient may be prescribed prophylactic antibiotic cover which may reduce the risk of infection.

Once in the operating room the patient is placed in the lithotomy position and the abdominal and genital area are shaved and cleansed with povidone-iodine solution or using an approved hospital preoperative scrub procedure.

The patient is prepped and draped for perineal and lower abdominal incision.

Equipment Needed

The implantation of the Flowsecure® AUS requires a standard urethroplasty surgical kit as well as some additional supplies. Each surgeon may also have preferences about what equipment he/she requires.

Additional equipment is listed below:
- 12 Fr Foley catheter
- Shod forceps (eg haemostats)
- Sterile Orange hypodermic needle
- 25 (Gauge) 16mm (5/8")
- Sterile 10ml syringe
- Sterile bowl
• Sterile 50ml syringe
• Sterile saline
• Umbilical tape
• Trocar

Unpacking the Components
Prior to unpacking the AUS the integrity of both packets should be inspected – if there is a suspected breach of sterility the device should be returned to the distributor or manufacturer. The AUS should be checked with careful handling for obvious damage to its integrity. The device is supplied with a number of labels detailing batch number and use by date. These should be retained and placed in the appropriate surgical and patient notes as pertaining to hospital procedure.

Equipment Preparation

Preparing Haemostats
During implantation it is useful to clamp some of the tubes to keep the urethral cuff deflated. In order to protect the silicone tubing from damage when clamping it is recommended to cover the jaws of the haemostat with small sections of silicone tubing. All the teeth of the haemostat should be covered. The jaws should only be clamped to the first click to prevent excessive pressure on the tubing.

Preparing the Device for Implantation.
A fully sterile procedure for filling the Flowsecure™AUS with saline

1. Place the whole device into a sterile tray (see Figure 2).
2. Fill a 50ml sterile syringe with 30 ml of sterile saline. Attach a sterile 25G (orange) 16mm (5/8”) standard hypodermic needle to the syringe [NB Only this type of needle must be used].
3. Lift the pump upwards, with the filling port at the top, clear of the other components in the tray.
4. Whilst holding the pump around the filling port between the thumb and index finger take care when inserting the needle in-line through the centre of the metal “guard ring” and the self sealing port until the tip is just inside the pump chamber.
5. Slowly inject all 30ml from the syringe into the AUS. The saline will enter each of the component parts of the AUS together with some air.
6. Carefully remove the syringe with needle from the device. Retain the needle in its protective cover for further use in the procedure. Place the pump back down into the tray.
7. Lift the cuff up and gently squeeze, again with thumb and index finger (at blue arrows), all the saline and air into the stress balloon (see Figure 3). Let the cuff refill with saline from the stress balloon and repeat if necessary until most air bubbles are out of the cuff. Clamp off the tube between the cuff and stress balloon gently with haemostats at position shown. Most of the air will now be in the Stress Balloon.

8. With the pump raise up and the stress balloon tubes facing upwards with the air at the top of the stress relief balloon (see Figure 4) gently squeeze with even pressure around the balloon (blue arrows). All the air can be moved into the pump and the pressure regulating balloon.
9. Next step is to vent all the air (ideally) from the pressure regulating balloon and the pump by re-inserting the retained hypodermic needle (from step 6 above) carefully through the self-sealing port so as just to penetrate the air pocket in the pump (see Figure 5). Gently squeeze with even pressure around the balloon (blue arrows) so that its residual air moves to the pump and vent until the pump also is free of air (ideally) and now filled with saline.

10. Finally, remove the hypodermic needle and haemostat. Test the system by first pressing the Rapid Refill valve to re-distribute fluid around the device and then squeeze and release the pump twice to check that the cuff deflates. Again rapidly re-inflate to refill the cuff. A final test is to squeeze and release the pump twice again to deflate the cuff and then check for automatic slow re-inflation. The AUS is now ready for implantation.

Surgical Procedures

Bulbar Urethral Exposure

1. Place an urethral catheter (Foley 14F) in the patient to facilitate urethral dissection.

2. The first step in the implantation procedure is to make a perineal incision and dissect around the bulbar urethra.

3. Place some umbilical tape around the urethra until the cuff is placed in position (Figure 6).

Abdominal Incision

4. Make an incision in the abdominal wall (Figure 7).

5. Pass the trocar through the abdominal incision and route it through the tissues to the perineal incision (Figure 8).
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**Figure 8**

**Placement of Cuff**

6. Remove stylet from the trocar. Gently squeeze all the fluid out of the cuff into the stress balloon and clamp off the tube just below the balloon with a shod haemostat. Pass the deflated cuff through the trocar to the perineal site *(Figure 9)*

**Figure 9**

7. Remove the trocar downwards over the cuff at the perineal site leaving the pump and balloons protruding from abdominal incision above.

8. The cuff *(Figure 10)* is placed around the urethra and the two-holed tab is passed through loop (a tapered lead-in is provided to assist this procedure.) The cuff can be adjusted for two circumferences, 4.5cm or 5.5cm. Depending on the size of the urethra the appropriate tab hole is located over the button and using a haemostat is pulled through the hole to secure the cuff in position. The cuff should not be tight (ie can rotate freely around the urethra). The lead-in of the tab and any excess tab can be cut away and the corners rounded.

9. The completed cuff insertion should have the appearance shown in *(Figure 11)* with the connecting tube placed parallel to the cuff by rotating the cuff to the left or right as preferred.

**Figure 10**

**Figure 11**

**Refilling the Cuff**

10. Remove the haemostat from the tube connecting the stress balloon to the cuff to allow the cuff to refill around the urethra.

11. Attach a sterile 25G *(orange)* 16mm *(5/8")* hypodermic needle to a 10ml syringe and pierce the self-sealing port at the base of the pump unit. Make
sure needle penetrates in the middle and in line with the pump.

12. Withdraw fluid from the device until the stress relief balloon just becomes indented. The device should now be at about atmospheric pressure.

**Insertion of pump in the scrotum**

13. To place the control pump in the scrotum use blunt dissection with fingers and pushing up scrotal wall on the appropriate side to appear inverted at abdominal incision. Take pump and lower down into a pocket created in the scrotum until it is sited comfortably in the base of the scrotum (Figure 12).

14. The ideal position of the pump in the left or right base of the scrotum should have previously been decided with the patient.

15. If considered necessary, a couple of loose degradeable sutures can be placed around the fairing of the tubes leaving the pump to ensure that the pump does not migrate upwards during the initial healing period.

After 24 hours the indwelling catheter should be removed and the patient should try to void on urge. If possible the pump should be operated to remove any fluid from the cuff prior to voiding. However, if the area is too sensitive this is not necessary as the amount of fluid in the implant should not be sufficient to cause obstruction to flow.

If the patient is unable to void without large residual it may be necessary to teach the patient intermittent catheterisation in case of retention. The patient should continue to use pads or condom drainage to contain leakages.

**Discharge**

The patient can be discharged 2 to 4 days post operatively at the discretion of the surgeon and depending on general health. The patient should continue with any antibiotic cover. An outpatient appointment should be made for two to four weeks following implantation for pressurisation of the device.

**Pressurisation Procedure**

The Flowsecure® AUS is pressurised by injection of sterile saline through the self-sealing port in the base of the control pump. The pressure in the device depends upon the amount of fluid injected. The pressure volume characteristics are shown in the graph in Figure 10 (or better to use the larger graph in Appendix 1.) This feature allows the device to be set at any desired pressure without needing to change the pressure balloon. The device pressure can also be changed at any stage post-operatively through percutaneous injection of fluid which can be carried out on an out-patient basis.

**Equipment Required**

The pressurisation procedure is best carried out as a sterile procedure in a clean clinical space.

- Sterile dressing pack
- Sterile drapes
- Sterile gloves
- Hydrex® (chlorhexidine gluconate solution 2.5%). If patient is sensitive then use povidone-iodine solution
- Sterile syringe 50ml

**Post Operative Care**

**Immediately Post Operative**

The indwelling catheter should remain in place for 24 hours. Antibiotic cover should be prescribed at the discretion of the surgeon.
- Sterile 25G (Orange) short 16mm (5/8") hypodermic needle
- Sterile saline sachet
- Sterile saline for injection

**IMPORTANT**

It is vital that the wall of the pump unit is not pierced with the needle. If this occurs the device may be permanently damaged necessitating explantation of the whole device.

It is essential that only a 25G (Orange) short 16mm (5/8") hypodermic needle be used and that the needle is always aligned parallel with the sides of the pump and penetrates the self-sealing port straight and through the “guard ring.”

Only the base of the pump with its metal “guard ring” has the ability to be injected safely.

**Patient Preparation**

- Explain the procedure to the patient
- Lay patient supine and identify location of the pump
- Draw up require amount of sterile saline into the syringe. Place the 25G (Orange) short 16mm (5/8") hypodermic needle onto the syringe and expel excess air.
- Clean scrotum with Hydrex and drape with sterile towels.
- Grasp pump with left hand pulling the skin taut over the end of the pump. Stabilise the pump with the middle finger of the left hand behind the pump. The dent in the end of the pump should be easily visualised
- Wipe excess Hydrex® from skin over pump with sterile saline and wipe dry.
- Line up needle and pump so they are parallel with needle located in centre of pump base.
- Push needle slowly through skin into centre of dent in the base of pump. Just prior to reaching the pump, clear the end of the needle by injecting 0.1ml of saline into the tissue space.
- Push needle into pump ensuring that the needle remains parallel with walls of pump (Figure 13).
- Inject required volume of sterile saline into pump. The initial pressure recommended is around 30-40cmH₂O requiring about 2ml of sterile saline to be injected as determined from the graph (Figure 14). A more detailed graph with notes is shown in Appendix 1 (p11).
  - Remove needle and syringe
  - Instruct patient to pump the device about 3 times to redistribute fluid.

Subsequently the required volume to give the best social continence can be calculated from the graph in Appendix 1

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**Figure 13**

**Sphinx Medical Flowsecure™ Pressure Volume Curve for Adjusting AUS Pressure**

[N.B. Ideally operate within the green zone]

**Figure 14**

**Post-pressurisation continence tests**
**Tests of Efficacy**
These can be done immediately following pressurisation. After showing the patient how to deflate the cuff for voiding he can be asked to fill his bladder by drinking until a desire to void is reached. The patient should be asked to give 5 strong coughs, 5 seconds of Valsalva manoeuvre and if possible 5 squats. The volume leaked can be measured and recorded. The Patient should then be asked to void into a flow machine so that rate and volume can be measured and recorded.

**Longer Term Tests of Efficacy**
The patient can be asked to continue wearing pads (or convene with leg bag) to record pad use and/or leaked volume by weight.

**Patient Education**
Following pressurisation of the device, the patient should be shown how to pump the device, in order to pass urine. The rapid re-inflate facility can also be demonstrated. If the patient is using intermittent catheterisation to empty the bladder then the importance of pumping before inserting the catheter should be stressed.
A flow rate should be performed to ensure that the patient is pumping down sufficiently.
An emergency card should be issued to inform healthcare professionals that the patient has an implant and that catheterisation should only be performed after pumping down the device to deflate the cuff.

**Imaging**

**X-raying the Device**
The Flowsecure® AUS with Conditional Occlusion does not contain radio-opaque solution and therefore cannot be imaged under normal x-ray radiography. However there are 2 other methods which can be used to image the device in order to investigate function.

**Magnetic Resonance Imaging**
The device can be imaged using Magnetic Resonance Imaging as described in the paper by Deng et al.

The function of the cuff can be visualised using flexible cystometry with the cuff inflated and deflated.

**Ultrasound Diagnostics**
The balloons of the AUS can be easily visualised using ultrasound. With appropriate settings the outline, particularly the highlighting top and bottom of the balloons can be seen (Figure 15).

![Figure 15](image)

The straight line distance between these highlights will give the diameter of the balloons. When the cuff is normally inflated between voidings then both the stress relief and pressure regulating balloons should be very nearly the same diameter and pressure. From the diameter of one of the balloons, and using the following formula the added volume can be determined.

\[
\left(\frac{4}{3}\pi(D/2)^3\right) - 9
\]

From the added volume it is possible to determine the approximate pressure in the system by referring to the graph in Appendix 1.

By using this ultrasound technique it is also possible to determine normal functioning of the device during voiding.
Pump the sphincter cuff down with about 2-3 good squeezes and notice the enlargement of one balloon (the regulator) whilst the other (the stress relief balloon) diminishes in size. After waiting for about 10-15 minutes, during which time the cuff will be fully reinflated, the two balloons should have returned to approximately the same size.
Appendix 1

Notes:

1. Before using this chart for pressurisation of the Flowsecure you must read the notes (beginning on page 8 above) which describes this procedure.

2. Best practice at initial visit to the clinic for pressurisation of the AUS is to determine the level of incontinence being experienced by the patient and ability to void. If incontinence is still significant for the patient then inject 2ml only to give a device pressure between 30-40 cmH₂O.

3. The patient’s continence can be checked over the following month using a bladder diary. If the patient is not satisfied with this degree of continence then inject a further 1ml to take the pressure up to between 40-50 cmH₂O.

4. If further adjustments become necessary then 1ml at a time should made. Ideally pressures should not be taken beyond 70 cmH₂O (about 5ml total added volume) but if believed necessary then consult a Urologist first.
Bibliography & References:


Notes:
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Acknowledgements:

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Note – This document is only a brief guide and does not claim to be a definitive statement on surgical practices or other techniques. The authors have written this guide free from any liability for omissions, errors or statements which the reader may regard as inaccurate and misleading.