CONSENT FORM **FOR** **TENSION FREE VAGINAL TAPE (TVT TAPE) + Cystoscopy**	Med Rec. No: <<Patient Demographics:Record Number>> Surname: <<Patient Demographics:Surname>> Forename: <<Patient Demographics:First Name>> DOB: <<Patient Demographics:DOB>>

This means the damaged ligaments are replaced by a 1 cm wide tape of synthetic mesh. This tape returns the support for the urethra to the surrounding tissues that had been lost. The TVT Tape is usually put in under local anaesthesia whilst you are under sedation, or general anaesthetic.
Two 1 cm cuts are made, both in the pubic hair, one on either side of the middle. A further 1 cm cut, is made just inside and on the front wall of the vagina.
The tape is threaded from the vaginal cut, one half o the tape on each side of the urethra (this is the tube that leads from the bladder to the outside) out through the cut in the pubic hair. This is followed by looking into the bladder, during which time you will be asked to cough. The tape is slowly tightened until the urine loss with coughing stops. The tape is cut off and the cuts are all closed.
A camera is introduced into the bladder during the procedure to check the passage of the tape.

RISKS
These are the more common risks. There may be other unusual risks that have not listed here. Please ask ***Dr Rana*** *if you have any general or specific concerns.*

I understand there are risks associated with any **anaesthetic,** and I can discuss these with the Anaesthetist. I may have side effects from any of the drugs used. The more common side effects include light-headedness, nausea, skin rash and constipation.

- Wound. Pain, bruising and redness is common.
- There is a 1/300 risk of a hematoma requiring drainage. Longer term risks include Hernia formation (less than 1/1000 risk), and Keloid scar formation.
- Haemorrhage. The risk of significant bleeding is less than 5%. The risk of requiring a transfusion, or further surgery to deal with bleeding, is less than 1%.
- Infection. This may occur in various sites, including the chest, pelvis, wounds and bladder. In most cases infection can be treated with antibiotics, but on occasions may require further surgery.
- Damage to other organs. These include bowel/rectum (risk less than 2%), bladder (risk less than 2%), or the ureter (tube from kidney to bladder) (risk less than 1%). If this happens the usual procedure is to carry out immediate repair. This may include bowel surgery, colostomy, bladder or ureteric repair. On occasions this damage may not be immediately recognised, and so there may be a delay in diagnosis, and subsequent repair.
- Bladder, bowel and sexual function. There may be short-term and long-term changes in function. Urinary catheterisation may be required.
- Venous thromboembolism. Blood clots can develop in the veins of the legs or pelvis, which may cause pain and swelling. If these become loose, they may travel to the lungs (Pulmonary embolus), making me short of breath. Occasionally this may be fatal. Patients are frequently given elasticated stockings to protect against clot formation, and some patients are given anticoagulant injections.
- Fluid may develop in the pelvis or the top of the vagina, and may require antibiotics or further surgery.
- Electric diathermy can short-circuit, used to control bleeding and cause a skin burn.
- A fistula is the rare (less than one in 5000) complication involving the development of an abnormal opening between two adjoining structures, and symptoms depend on the structures involved. Repair usually involves complex surgery.
- Scar tissue can cause adhesions between loops of bowel, and there is a small risk of subsequent bowel blockages, which may require further treatment or surgery.
- Very rarely severe complications could result in death.

I understand that a **TVT** has the following risks/complications which include:

- The success rate is very high (9 in 10 women). The long-term success rate is not yet known.
- The bladder may be overactive after the operation. You may need to go the toilet a lot, may have sudden urge to pass urine and may leak urine.
- These symptoms are usually managed by bladder retraining and drug therapy. A small proportion of patients will continue to have long-standing bladder symptoms despite treatment

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- Problems with passing urine are uncommon. This rarely needs long term management. If this happens, the tape may be divided through the vaginal cut. There is a small risk of the urinary incontinence returning.
- Infection.
- Excessive bleeding. This is rare.
- Small risk of tape erosion or infection which may require revision or removal.
- Damage to bladder/urethra, which may require several days of catheterization.

I understand some of the above **risks are more likely** if I smoke, am overweight, diabetic, have high blood pressure or have had previous heart disease.

INDIVIDUAL RISKS:

I understand the following are possible significant **risks and complications specific to my individual circumstances,** that I have considered in deciding to have this operation:

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DECLARATION BY PATIENT:

- I acknowledge that ***Dr Rana*** has informed me about the procedure, alternative treatments and answered my specific queries and concerns about this matter.
- I acknowledge that I have discussed with ***Dr Rana*** any significant risks and complications **specific to my individual circumstances** that I have considered in deciding to have this operation.
- I agree to **any other additional procedures** considered necessary in the judgement of my gynaecologist during this operation.
- I consent to a **blood transfusion**, if needed.
- I agree to the disposal by the hospital authorities of any tissues or parts that may be removed during the operation. I understand that some tissues or samples may be kept as part of my hospital records.
- I have received a copy of this form to take home with me.
- If any staff member is exposed to my blood (needle stick injury) then I consent to a sample of my blood being collected for testing for infectious diseases, such as hepatitis B, C and HIV. I understand that the blood sample will not be tested until I have been informed and I have given my consent.

Signature of Patient		**Date**	

If the patient is unable to give consent, a proxy form must be completed and attached.

DECLARATION BY DOCTOR:

- I declare that I have explained the nature of the patient's condition, the procedure to be performed, and discussed the risks that particularly concern the patient.
- I have given the patient an opportunity to ask questions and I have answered these.

Doctor's Signature		**Date**	
Doctor's Name *(please print)*	Dr Ritu Rana		

INTERPRETER'S DECLARATION:

I confirm I have accurately interpreted the contents of this form and the related conversations between the patient and the doctor.

Interpreter's Signature		**Date**	
Interpreter's Name *(please print)*			