Queensland Government
Queensland Health

INSERTION OF TENSION FREE VAGINAL TAPE (TVT) FOR STRESS INCONTINENCE PLUS CYSTOSCOPY

U.R. No	(Please place patient label here)	
Surname		
Given Names		
D.O.B.		Sex M F
GP		

PROCEDURAL CONSENT FORM

A. INTERPRETER/ CULTURAL NEEDS

An Interpreter Service is required yes☐ no☐
If yes, is a qualified Interpreter present yes☐ no☐
A Cultural Support Person is required yes☐ no☐
If yes, is a Cultural Support Person present yes☐ no☐

B. CONDITION AND PROCEDURE

The doctor has explained that I have the following condition: *(Doctor to document in patient's own words)*

The following procedure will be performed:

The damaged ligaments are replaced by a 1cm wide tape of synthetic mesh. This tape returns the support for the urethra (this is the tube that leads from the bladder to the outside) to the surrounding tissues. The tape is usually put in under general anaesthesia.

This is followed by looking into the bladder to make sure no damage has been done **(cystoscopy).**

C. ANAESTHETIC

See "About your anaesthetic" information sheet for information about the anaesthetic and the risks involved. If you have any concerns, talk these over with your anaesthetist. If you have not been given an information sheet, please ask for one.

D. GENERAL RISKS OF A PROCEDURE

They include:

(a) Small areas of the lungs may collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.

(b) Clots in the legs with pain and swelling. Rarely part of this clot may break off and go to the lungs which can be fatal.

(c) A heart attack because of strain on the heart or a stroke.

(d) Death is possible due to the procedure.

E. RISKS OF THIS PROCEDURE

The success rate is very high (9 in 10 women). The long-term success rate is not yet known.

There are some risks/complications, which include:

(a) The bladder may be over-active after the operation. You may need to go to the toilet a lot, may have sudden urges 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.

(b) 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.

(c) Infection.

(d) Excessive bleeding. This is rare.

(e) A higher risk in obese people. This may cause wound and chest infection, heart and lung problems and blood clots in the veins.

(f) A higher risk in smokers. This may cause wound and chest infections, heart and lung problems and blood clots in the veins.

(g) The urethra (the tube that leads from the bladder to the outside) can sometimes be damaged.

(h) The bladder can sometimes be damaged.

(i) The tape may erode through the urethra in the years after the operation. This would need repair of the urethra and a catheter for 2 weeks.

***Cystoscopy** will be routinely performed at completion of the operation*

(Please refer to the attached cystoscopy consent and patient information sheet)

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	GP		

F. SIGNIFICANT RISKS AND RELEVANT TREATMENT OPTIONS

The doctor has explained any significant risks and problems specific to me, and the likely outcomes if complications occur. The doctor has also explained relevant treatment options as well as the risks of not having the procedure.

(Doctor to document in space provided. Continue in Medical Record if necessary. Cross out if not applicable.)

G. PATIENT CONSENT

I acknowledge that:

The doctor has explained my medical condition and the proposed procedure. I understand the risks of the procedure, including the risks that are specific to me, and the likely outcomes.

The doctor has explained other relevant treatment options and their associated risks. The doctor has explained my prognosis and the risks of not having the procedure.

I have been given a Patient Information Sheet on Anaesthesia (Version 2: 11/2002).

I have been given a Patient Information Sheet (Version 1: 08/2004) about the procedure and its risks.

I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I understand that the procedure may include a blood transfusion.

I understand that a doctor other than the Consultant Surgeon may conduct the procedure. I understand this could be a doctor undergoing further training.

I understand that if organs or tissues are removed during the surgery, that these may be retained for tests for a period of time and then disposed of sensitively by the hospital.

The doctor has explained to me that if immediate life-threatening events happen during the procedure, they will be treated accordingly.

I understand that photographs or video footage maybe taken during my operation. These may then be used for teaching health professionals. (You will not be identified in any photo or video).

I understand that no guarantee has been made that the procedure will improve the condition, and that the procedure may make my condition worse.

On the basis of the above statements,

I REQUEST TO HAVE THE PROCEDURE.

Name of Patient/ Substitue decision maker and relationship ------------------------------

Signature ------------------------------

Date ------------------------------

Substitute Decision Maker Under the Powers of Attorney Act 1998 and/ or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision- maker must give consent on the patient's behalf.

H. INTERPRETER'S STATEMENT

I have given a translation in ..…………..………………. (*state the patient's language here*) of the consent form and any verbal and written information given to the patient/ parent or guardian/ substitute decision maker by the doctor.

Name of Interpreter ------------------------------

Signature ------------------------------

Date ------------------------------

I. DOCTOR'S STATEMENT

I have explained:

- the patient's condition
- need for treatment
- the procedure and the risks
- relevant treatment options and their risks
- likely consequences if those risks occur
- the significant risks and problems specific to this patient.

I have given the patient/ substitute decision-maker an opportunity to:

- ask questions about any of the above matters
- raise any other concerns

which I have answered as fully as possible.

I am of the opinion that the patient/ substitute decision-maker understood the above information.

Name of Doctor ------------------------------

Designation ------------------------------

Signature ------------------------------

Date ------------------------------

INSERTION OF TENSION FREE VAGINAL TAPE (TVT) FOR STRESS INCONTINENCE PLUS CYSTOSCOPY

THE CONDITION

Urinary continence depends on the bladder entrance being supported by strong ligaments that hold it up it from the muscles of the pelvic floor

These ligaments can be torn or stretched, by vaginal child birth, chronic straining due to constipation or by an inherited weakness of the collagen in the ligaments. If this happens, you may pass urine when you cough, sneeze etc.

The procedure is usually for patients who:

- have genuine stress incontinence
- have had a previous but failed operation for genuine stress incontinence
- those who are very overweight
- those who have major damage to the muscle about the urethra

The procedure usually takes about 30 minutes. You will get better quite quickly. Sometimes you may have pain or discomfort about the cuts. This is treated with painkillers and should only last a few days.

It takes 6 weeks for scars to form, so you need to take it easy for a few weeks. You should:

- only go back to work if this does not involve heavy lifting.
- not have sex for 6 weeks after the surgery.

PROCEDURE

The following procedure will be performed:

The damaged ligaments are replaced by a 1cm wide tape of synthetic mesh. This tape returns the support for the urethra to the surrounding tissues.

The tape is usually put in under general anaesthesia.

Two 1 cm cuts are made, one each in the fold of the groin. A further 3 cm cut is made just inside and on the front wall of the vagina.

This is followed by looking into the bladder ***(cystoscopy)*** to make sure no damage has been done.

Please refer to the patent information and consent for cystoscopy.

ANAESTHETIC

See "About your anaesthetic" information sheet for information about the anaesthetic and the risks involved. If you have any concerns, talk these over with your anaesthetist. If you have not been given an information sheet, please ask for one.

GENERAL RISKS OF A PROCEDURE

They include:

(a) Small areas of the lungs may collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.

(b) Clots in the legs with pain and swelling. Rarely part of this clot may break off and go to the lungs which can be fatal.

(c) A heart attack because of strain on the heart or a stroke.

(d) Death is possible due to the procedure.

RISKS OF THIS PROCEDURE

The success rate is very high (9 in 10 women). The long-term success rate is not yet known.

There are some risks/complications, which include:

(a) The bladder may be over-active after the operation. You may need to go to the toilet a lot, may have sudden urges 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.

(b) Problems with passing urine are uncommon. This rarely needs long term management. If this happens, the tape may be divided through the vaginal cut.

(c) There is a small risk of the urinary incontinence returning.

(d) Infection.

(e) Excessive bleeding. This is rare.

(f) A higher risk in obese people. This may cause wound and chest infection, heart and lung problems and blood clots in the veins.

Continued over page…

(g) A higher risk in smokers. This may cause wound and chest infections, heart and lung problems and blood clots in the veins.

(h) The urethra (the tube that leads from the bladder to the outside) can sometimes be damaged.

(i) The bladder can sometimes be damaged.

Cystoscopy will be routinely performed at completion of the operation to check for this.

(Please refer to the attached Cystoscopy consent and patient information sheet)

I ACKNOWLEDGE THAT:

The doctor has explained my medical condition and the proposed surgical procedure. I understand the risks of the procedure, including the risks that are specific to me, and the likely outcomes.

The doctor has explained other relevant treatment options and their associated risks. The doctor has explained my prognosis and the risks of not having the procedure.

I have been given a Patient Information Sheet on Anaesthesia. (Version 2: 11/2002).

I have received a Patient Information Sheet (Version 1: 08/2004) about the procedure and its risks.

I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks, and my treatment options.

My questions and concerns have been discussed and answered to my satisfaction.

I understand that the procedure may include a blood transfusion.

I understand that a doctor other than the Consultant Surgeon may conduct the procedure. I understand this could be a doctor undergoing further training.

I understand that if organs or tissues are removed during the surgery, that these may be retained for tests for a period of time and then disposed of sensitively by the hospital.

The doctor has explained to me that if immediate life-threatening events happen during the procedure, they will be treated as appropriate.

I understand that photographs or video footage maybe taken during my operation. These may then be used for teaching health professionals. (You will not be identified in any photo or video).

I understand that no guarantee has been made that the procedure will improve the condition, and that the procedure may make my condition worse.

On the basis of the above statements,

I REQUEST TO HAVE THE PROCEDURE.

MY NOTES TO TALK TO THE DOCTOR ABOUT

Queensland Government
Queensland Health

CYSTOSCOPY - FEMALE

U.R. No	(Please place patient label here)	
Surname		
Given Names		
D.O.B.		Sex M F
GP		

A. INTERPRETER/ CULTURAL NEEDS

An Interpreter Service is required yes☐ no☐
If yes, is a qualified Interpreter present yes☐ no☐
A Cultural Support Person is required yes☐ no☐
If yes, is a Cultural Support Person present yes☐ no☐

B. CONDITION AND PROCEDURE

The doctor has explained that I have the following condition: *(Doctor to document in patient's own words)*

The following procedure will be performed:

An examination of the bladder using a telescope-like instrument which is passed into the bladder. This allows the doctor to look inside the bladder and examine the bladder and the passage where the urine comes out.

C. ANAESTHETIC

See "About your anaesthetic" information sheet for information about the anaesthetic and the risks involved. If you have any concerns, talk these over with your anaesthetist.

If you have not been given an information sheet, please ask for one.

D. GENERAL RISKS OF A PROCEDURE

They include:

(c) Small areas of the lungs may collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.

(d) Clots in the legs with pain and swelling. Rarely part of this clot may break off and go to the lungs which can be fatal.

(e) A heart attack because of strain on the heart or a stroke.

(f) Death is possible due to the procedure.

(g) Increased risk in obese people of chest infection, heart and lung complications and thrombosis.

(h) Increased risk in smokers of chest infections, heart and lung complications and thrombosis.

E. RISKS OF THIS PROCEDURE

There are some risks/ complications, which include:

(a) Rarely damage to the urethra - the passage that brings the urine out of the bladder. A false passage may be produced causing leakage of urine or in the long term, a narrowing that may affect flow of urine.

(b) Damage to the bladder with puncturing of the bladder. This may need further surgery.

(c) Swelling at the exit of the bladder which may stop the passage of urine. A tube (catheter) may need to be put in place to drain the urine until the swelling goes down.

(d) Bacteria may get into the blood stream with the development of septicaemia. Further treatment with antibiotics may be necessary.

(e) Bleeding which may stain the urine colour and sometimes cause blockage of urine flow.

(f) Burning and scalding of urine for a few days after the procedure. This usually settles.

(g) Further procedures may be required if it cannot be done at the time of cystoscopy.

F. SIGNIFICANT RISKS AND RELEVANT TREATMENT OPTIONS

The doctor has explained any significant risks and problems specific to me, and the likely outcomes if complications occur.

The doctor has also explained relevant treatment options as well as the risks of <u>not</u> having the procedure.

(Doctor to document in space provided. Continue in Medical Record if necessary. Cross out if not applicable.)

CYSTOSCOPY - FEMALE	U.R. No	(Please place patient label here)	
	Surname		
	Given Names		
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G. PATIENT CONSENT

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I have been given a Patient Information Sheet on Anaesthesia (Version 2: 11/2002).

I have been given a Patient Information Sheet (Version 3: 06/2004) about the procedure and its risks.

I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks, and my treatment options. My questions and concerns have been discussed and answered to my satisfaction.

I understand that the procedure may include a blood transfusion.

I understand that a doctor other than the Consultant Surgeon may conduct the procedure. I understand this could be a doctor undergoing further training.

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On the basis of the above statements,
I REQUEST TO HAVE THE PROCEDURE.

Name of Patient/ Substitute decision maker and relationship ---------------------------------

Signature ---------------------------------

Date ---------------------------------

Substitute Decision Maker Under the Powers of Attorney Act 1998 and/ or the Guardianship and Administration Act 2000. If the patient is an adult and unable to give consent, an authorised decision- maker must give consent on the patient's behalf.

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Name of Doctor ---------------------------------

Designation ---------------------------------

Signature ---------------------------------

Date ---------------------------------

Queensland Government
Queensland Health

CONSENT INFORMATION - PATIENT COPY

CYSTOSCOPY - FEMALE

PROCEDURE

An examination of the bladder using a telescope-like instrument which is passed into the bladder. This allows the doctor to look inside the bladder and examine the bladder and the passage where the urine comes out.

ANAESTHETIC

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GENERAL RISKS OF A PROCEDURE

They include:

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(d) Death is possible due to the procedure.

(e) Increased risk in obese people of chest infection, heart and lung complications and thrombosis.

(f) Increased risk in smokers of chest infections, heart and lung complications and thrombosis.

RISKS OF THIS PROCEDURE

There are some risks/ complications, which include:

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(b) Damage to the bladder with puncturing of the bladder. This may need further surgery.

(c) Swelling at the exit of the bladder which may stop the passage of urine. A tube (catheter) may need to be put in place to drain the urine until the swelling goes down.

(d) Bacteria may get into the blood stream with the development of septicaemia. Further treatment with antibiotics may be necessary.

(e) Bleeding which may stain the urine colour and sometimes cause blockage of urine flow.

(f) Burning and scalding of urine for a few days after the procedure. This usually settles.

(g) Further procedures may be required if it cannot be done at the time of cystoscopy.

I ACKNOWLEDGE THAT:

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I REQUEST TO HAVE THE PROCEDURE.