

CONSENT FORM for UROLOGICAL SURGERY

(Designed in compliance with  consent form 1)

PATIENT AGREEMENT TO INVESTIGATION OR TREATMENT

Patient Details or pre-printed label

Patient's NHS Number or Hospital number	
Patient's surname/family name	
Patient's first names	
Date of birth	
Sex	
Responsible health professional	
Job Title	
Special requirements <i>e.g. other language/other communication method</i>	

Patient identifier/label

Name of proposed procedure (Include brief explanation if medical term not clear)	ANAESTHETIC
<u>RADICAL CYSTECTOMY AND FORMATION OF NEW BLADDER WITH BOWEL (FEMALE)</u> THIS INVOLVES REMOVAL OF BLADDER, PELVIC LYMPH NODES & REMAINING FEMALE ORGANS (I.E. OVARIES AND UTERUS INCLUDING A PORTION OF VAGINA) AND FORMATION OF A NEW BLADDER USING BOWEL	- GENERAL/REGIONAL - LOCAL - SEDATION

Statement of health professional (To be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy) I have explained the procedure to the patient. In particular, I have explained:

The intended benefits

TREATMENT OF BLADDER CANCER

Serious or frequently occurring risks including any extra procedures, which may become necessary during the procedure. I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient. Please tick the box once explained to patient

COMMON

- TEMPORARY INSERTION OF A NASAL TUBE, DRAIN, STENT
- PAIN OR DIFFICULTY WITH SEXUAL INTERCOURSE DUE TO NARROWING OR SHORTENING OF VAGINA
- NEED TO SELF CATHETERISE IF NEW BLADDER FAILS TO FULLY EMPTY
- IN EVENT OF OVARY REMOVAL MENOPAUSE MAY OCCUR
- BLOOD TRANSFUSION REQUIRED

OCCASIONAL

- BLOOD LOSS REQUIRING REPEAT SURGERY
- CANCER MAY NOT BE CURED WITH REMOVAL OF BLADDER ALONE
- INCONTINENCE OF URINE

RARE

- INFECTION OR HERNIA OF INCISION REQUIRING FURTHER TREATMENT
- ANAESTHETIC OR CARDIOVASCULAR PROBLEMS POSSIBLY REQUIRING INTENSIVE CARE ADMISSION (INCLUDING CHEST INFECTION, PULMONARY EMBOLUS, STROKE, DEEP VEIN THROMBOSIS, HEART ATTACK AND DEATH.)
- DECREASE RENAL FUNCTION WITH TIME

VERY RARE

- DIARRHOEA DUE TO SHORTENED BOWEL / VITAMIN DEFICIENCY REQUIRING TREATMENT
- BOWEL AND URINE LEAKAGE FROM ANASTOMOSIS REQUIRING RE-OPERATION
- SCARRING TO BOWEL OR URETERS REQUIRING OPERATION IN FUTURE
- URETHRAL RECURRENCE OF THE CANCER
- INTRAOPERATIVE RECTAL INJURY REQUIRING COLOSTOMY

ALTERNATIVE TREATMENT: RADIATION TREATMENT TO BLADDER, ILEAL CONDUIT DIVERSION

A blood transfusion may be necessary during procedure and patient agrees **YES or NO (Ring)**

Signature of Health Professional	Job Title
Printed Name	Date

The following leaflet/tape has been provided

BAUS Patient information leaflet (21/025)

Contact details (if patient wishes to discuss options later) _____ Your case worker is _____

Statement of interpreter (where appropriate) I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signature of interpreter:

Print name:

Date:

Copy (i.e. page 3) accepted by patient: yes/no (please ring)

Radical cystectomy and neo bladder formation under GA (removal of bladder, uterus, ovaries, fallopian tubes, cuff of vagina and formation of new bladder using a loop of bowel)

Patient identifier/label

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask - we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

- I agree**
 - to the procedure or course of treatment described on this form.
 - to a blood transfusion if necessary
 - That any tissue that is normally removed in this procedure could be stored and used for medical research (after the pathologist has examined it) rather than simply discarded. PLEASE TICK IF YOU AGREE

- I understand**
 - that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.
 - that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)
 - that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

- I have been told**
 - about additional procedures which may become necessary during my treatment. I have listed below any procedures which **I do not wish to be carried out** without further discussion.

Signature of Patient:		Print please:	Date:
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A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here. (See DOH guidelines).

Signed _____
 Date _____
 Name (PRINT) _____

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance). On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signature of Health Professional	Job Title
Printed Name	Date

- Important notes: (tick if applicable)**
- See also advance directive/living will (eg Jehovah's Witness form)
 - Patient has withdrawn consent (ask patient to sign/date here)



RADICAL CYSTECTOMY WITH BLADDER REPLACEMENT (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.

To view the online version of this leaflet, type the text below into your web browser:

[http://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Rad cyst female neobladder.pdf](http://www.baus.org.uk/_userfiles/pages/files/Patients/Leaflets/Rad%20cyst%20female%20neobladder.pdf)

Key Points

- The aim of cystectomy is to remove your bladder and the cancer that it contains
- This usually involves removal of your uterus (womb), ovaries, upper vagina and local lymph glands to give us the best chance of removing all the cancer
- We construct a reservoir for your urine from a section of bowel which is connected to your urethra (waterpipe) to form a “neobladder”
- This procedure can be done using an open or keyhole approach (often with robotic assistance)

What does this procedure involve?

Removal of your bladder, uterus (womb), ovaries, upper vagina and local lymph nodes. We construct a reservoir for your urine from a section of bowel which is connected to your urethra (waterpipe) to form a “neobladder”.

What are the alternatives?

- **[Radical radiotherapy](#)** – if, for any reason, a decision has been made that you should not undergo surgery
- **[BCG instillation into the bladder](#)** – only indicated for high-grade non-muscle invasive cancer; not for muscle-invasive disease

- [Radical cystectomy with formation of a urostomy \(ileal conduit\)](#) or [construction of a catheterisable pouch](#) – radical bladder removal but with, respectively, an external urostomy or a catheterisable reservoir instead of a new bladder
- [Systemic chemotherapy](#) – drugs given by mouth or into your bloodstream; sometimes used before radiotherapy or radical cystectomy

What happens on the day of the procedure?

Your urologist (or a member of their team) will briefly review your history and medications, and will discuss the surgery again with you to confirm your consent.

An anaesthetist will see you to discuss the options of a general anaesthetic or spinal anaesthetic. The anaesthetist will also discuss pain relief after the procedure with you.

We may provide you with a pair of TED stockings to wear, and we usually give you a heparin 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.

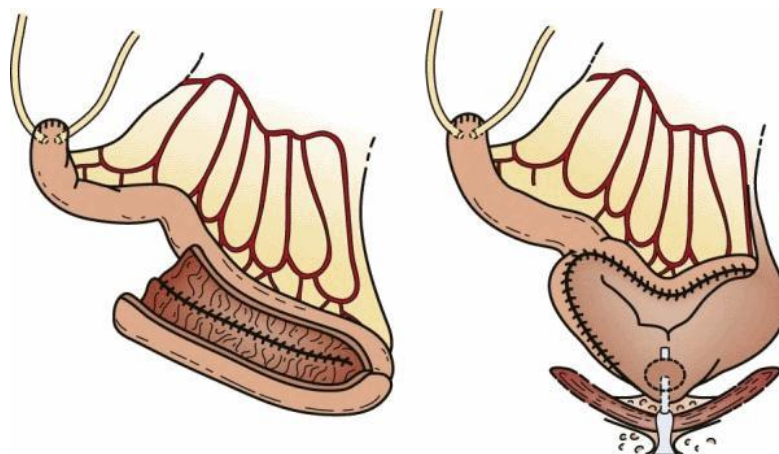
You will normally see a specialist nurse whose job it is to teach you how to manage your neobladder. He/she will also show you how to self-catheterise and perform bladder washouts. We usually mark your abdomen to position a urostomy stoma in case, for any reason, a neobladder cannot be made and you need to have a urostomy (ileal conduit). Try not to wash off this mark before your procedure.

Some urology units admit you the day before your procedure to administer laxatives to clear your bowel; others will admit you on the day of surgery and will not use laxatives. Your urologist will advise on which protocol will be used.

Details of the procedure

- we use a general anaesthetic for the procedure
- your anaesthetist may also use an epidural or spinal anaesthetic to minimise any post-operative pain
- we usually give you an injection of antibiotics before the procedure, after you have been checked for any allergies
- we normally perform the procedure through an incision in your lower abdomen (tummy) or with a laparoscopic (keyhole) approach with or without robotic assistance

- we will remove your bladder, uterus, both ovaries and the upper part of your vagina
- we may be able to preserve the nerves which control sexual function but this is not always possible; you should discuss this with your urologist before the procedure



- we stitch the ureters (the tubes which drain urine from the kidneys to the bladder) to a separated piece of small bowel which is then fashioned into a bladder substitute and joined to your urethra (pictured)
- we re-join the ends of the small bowel from which the urostomy has been made
- we close the wound with stitches or staples
- we normally place one or more drains where the bladder has been removed and leave two small splints in the ureters protruding from your urethra or through the skin of your abdomen
- we put one or two catheters in your new bladder, one through your urethra and one coming out through your abdominal wall
- the procedure can take anything from two to six hours to perform, depending on complexity and whether an open or keyhole technique is used
- you should expect to be in hospital for seven to 14 days.








Following radical cystectomy, some urology units have introduced [Enhanced Recovery Pathways](#). These actually start before you are admitted to hospital. After your surgery, they are designed to speed your recovery, shorten your time in hospital and reduce your risk of re-admission.












We will encourage you to get up and about as soon as possible. This reduces the risk of blood clots in your legs and helps your bowel to start working again. You will sit out in a chair shortly after the procedure and be shown deep breathing/leg exercises. We will encourage you to start drinking and eating as soon as possible.





We normally remove your drains when they have stopped draining. The splints in your bladder substitute will be removed 10 to 14 days after the procedure provided an X-ray along the splints shows that the ureters and bowel have been joined securely.

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
Discomfort or difficulty with sexual intercourse due to narrowing or shortening of your vagina	 Almost all patients
Menopausal symptoms if your ovaries are removed	 Almost all patients
Need for self-catheterisation to wash out and empty your neobladder (the frequency of this usually decreases as time goes by)	 Almost all patients
Your cancer may not be cured by the procedure (this possibility will have been discussed with you before the operation)	 Between 1 in 2 & 1 in 10 patients
Need for blood transfusion	 Between 1 in 2 & 1 in 10 patients
Paralytic ileus (failure of your bowel to work) for several days causing nausea, bloating & vomiting, and requiring an intravenous drip and stomach drainage tube through your nose until it recovers	 Between 1 in 2 & 1 in 10 patients
Incontinence of urine is common in the early weeks and improves in most women but can persist, especially at night	 Between 1 in 3 & 1 in 7 patients (15 to 30%)

Anaesthetic or cardiovascular problems possibly requiring intensive care (including chest infection, pulmonary embolus, stroke, deep vein thrombosis, heart attack and death)		Between 1 in 10 & 1 in 50 patients (your anaesthetist can estimate your individual risk)
Infection in your wound or an abscess in your abdominal (tummy) cavity		Between 1 in 10 & 1 in 50 patients
Decrease in kidney function over time		Between 1 in 10 & 1 in 50 patients
Need to abandon a keyhole procedure and convert to open surgery because of operative difficulties		Between 1 in 10 & 1 in 50 patients
Difficulty emptying your neobladder requiring intermittent self-catheterisation		Between 1 in 10 & 1 in 50 patients
Long-term bladder stone formation		Between 1 in 10 & 1 in 50 patients
Long-term recurrent urinary infections		Between 1 in 10 & 1 in 50 patients
Biochemical imbalance due to reabsorption of acid from your neobladder requiring regular treatment with bicarbonate tablets		Between 1 in 10 & 1 in 50 patients
Need for return to theatres for re-operation due to bleeding, bowel leakage, urine leakage or bowel obstruction		Between 1 in 50 & 1 in 250 patients
Hernia of the incision (or keyhole ports) requiring further surgical repair		Between 1 in 50 & 1 in 250 patients
Scarring, narrowing or hernia formation around your urostomy requiring revision		Between 1 in 50 & 1 in 250 patients

Diarrhoea/vitamin deficiency due to shortened bowel requiring specific dietary supplements or other treatment	 Between 1 in 50 & 1 in 250 patients
Late stricturing (scarring) scarring of the bowel or ureters requiring further surgery	 Between 1 in 50 & 1 in 250 patients
Rectal injury at the time of surgery requiring a temporary colostomy (bowel opening on your abdomen)	 Between 1 in 50 & 1 in 250 patients
Spontaneous rupture of your neobladder with urinary leakage requiring further surgery	 Between 1 in 50 & 1 in 250 patients

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. This figure is higher if you are in a “high-risk” group of patients such as patients who have had:

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

What can I expect when I get home?

- you will be given advice about your recovery at home
- you will be given a copy of your discharge summary and a copy will also be sent to your GP
- any antibiotics or other tablets you may need will be arranged & dispensed from the hospital pharmacy
- by the time you get home, you should be able to perform “daily living” activities such as making a cup of tea, preparing food and emptying your stoma bag
- you will feel tired for several weeks and may need to take regular “cat naps” during the day
- we will arrange for the stitches or clips in your wound to be removed after 10 to 12 days
- if you get a fever or start vomiting, especially if associated with unexpected pain in your abdomen, you should contact your GP immediately

- a follow-up appointment will be made for you six to 12 weeks after your surgery

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 "[Having An Operation](#)" 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.

For several years, BAUS has collected data from urologists undertaking this surgery. You can view these data, by unit and by Consultant, in the [Surgical Outcomes Audit](#) section of the BAUS website.

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

Smoking can cause bladder cancer, increase the risk of cancer recurrence and make complications more likely after surgery. We strongly advise anyone with bladder cancer to stop smoking. For smoking advice:

- contact your GP;
- access your local [NHS Smoking Help Online](#); or
- ring the free NHS Smoking 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 [contact the DVLA](#) 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 evidence-based sources including:

- the [Department of Health \(England\)](#);
- the [Cochrane Collaboration](#); 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 [Plain English Campaign](#).

Disclaimer

We have made every effort to give accurate information but 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 do have any questions, you should contact your urologist, specialist nurse or GP.