| | _ | | | | |
|--|---------|--|-----------|--|--|
| Queensland | | (Affix identification label here) | | | |
| Government | URN: | | | | |
| Nonhrostomy with or without | Family | ily name: | | | |
| Nephrostomy with or without Ureteric Stent Consent | Given | n name(s): | • | | |
| Oreteric Stellt Collsellt | Addre | ress: | | | |
| Facility: | Date o | of birth: Sex: M F | | | |
| A. Does the patient have capacity to provide | | C. Patient <i>OR</i> substitute decision-maker <i>OR</i> p | | | |
| consent? | | legal guardian/other person confirms the following procedure(s) | owing | | |
| Complete for ADULT patient only | | I confirm that the referring doctor/clinician has explained | ed that I | | |
| Yes → GO TO section BNo → COMPLETE section A | | have been referred for the following procedure: | ou that i | | |
| You must adhere to the Advance Health Directive (AHD | | Nephrostomy: | | | |
| or if there is no AHD, the consent obtained from a subsidecision-maker in the following order: Category 1. Tribu | | Ureteric stent insertion: Yes Site/side of procedure: | s No | | |
| appointed guardian; 2. Enduring Power of Attorney; or | ıııaı- | Site/side of procedure. | | | |
| 3. Statutory Health Attorney. | | | | | |
| Name of substitute decision-maker: | | | | | |
| Cotogony of autositivita decision makery | | | | | |
| Category of substitute decision-maker: | | Name of referring doctor/clinician: | | | |
| | | | | | |
| Complete for CHILD/YOUNG PERSON patient only | | D. Risks specific to the patient in having a | | | |
| Yes Although the patient is a child/young person, the patie be capable of giving informed consent and having suf | | | | | |
| maturity, understanding and intelligence to enable the fully understand the nature, consequences and risks of | m to | (Doctor/clinician to document additional risks not inclutue the patient information sheet): | ded in | | |
| proposed procedure and the consequences of non-tre | eatment | | | | |
| - 'Gillick competence' (Gillick v West Norfolk and Wis Area Health Authority [1986] AC 112) | bech | | | | |
| → GO TO section B | | | | | |
| No Parent/legal guardian/other person* with parental right responsibilities to provide consent and complete this | | | | | |
| → COMPLETE section A | OIIII | | | | |
| *Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to t | he | | | | |
| Queensland Health 'Guide to Informed Decision-making in Health Car and local policy and procedures. Complete the source of decision-mak | e' | | | | |
| authority as applicable below. | J | | | | |
| If applicable, source of decision-making authority (tick of | ne): | E. Risks specific to the patient in <i>not</i> having a | a . | | |
| ☐ Court order → ☐ Court order verified ☐ Legal guardian → ☐ Documentation verified | | nephrostomy with or without ureteric stent | | | |
| Other person Occumentation verified | | (Doctor/clinician to document specific risks in not havi | a ng a | | |
| Name of parent/legal guardian/other person: | | nephrostomy with or without ureteric stent): | I | | |
| | | | | | |
| Relationship to child/young person: | | | | | |
| | | | | | |
| B. Is an interpreter required? | | | | | |
| ☐ Yes ☐ No | | | | | |
| If yes, the interpreter has: | | | | | |
| provided a sight translation of the informed consent f | orm | | | | |
| in person translated the informed consent form over the teleph | one | | | | |
| It is acknowledged that a verbal translation is usually a | | F. Alternative procedure options | | | |
| summary of the text on the form, rather than word-by-word | | (Doctor/clinician to document alternative procedure no included in the patient information sheet): | ot | | |
| translation. | | and an are parent morniation drooty. | | | |
| Name of interpreter: | | ٦ | | | |
| Interpretor code: | | <u> </u> | | | |
| Interpreter code: Language: | | ٦ | | | |
| | | | | | |

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| | Queensland Government |
|------|---------------------------------|
| CONT | Government |

Nephrostomy with or without **Ureteric Stent Consent**

G Information for the dector/clinician

| (Affix identification label here) | | | | | |
|-----------------------------------|------|---|---|--|--|
| URN: | | | | | |
| Family name: | | | | | |
| Given name(s): | | | | | |
| Address: | | | | | |
| Date of birth: | Sex: | M | F | | |

| o. Illioilliation for the acctor/climicia | 411 |
|---|------------------|
| The information in this consent form is not a substitute for direct communication betwee clinician and the patient <i>OR</i> substitute deciparent/legal guardian/other person. | een the doctor/ |
| I have explained to the patient <i>OR</i> substitute <i>OR</i> parent/legal guardian/other person the form and am of the opinion that the informat understood. | contents of this |
| Name of doctor/clinician: | |
| | |
| Designation: | |
| | |
| Signature: | Date: |
| | |

H. Patient OR substitute decision-maker OR parent/ legal guardian/other person consent

I acknowledge that the doctor/clinician has explained:

- the 'Nephrostomy with or without Ureteric Stent' patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- · the specific risks and benefits of the procedure
- the prognosis, and risks of not having the procedure
- · alternative procedure options
- that there is no guarantee the procedure will improve the medical condition
- that the procedure may involve a blood transfusion
- that tissues/blood may be removed and used for diagnosis/ management of the condition
- that if a life-threatening event occurs during the procedure:
- an adult patient will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- a child/young person's health care will be provided in accordance with good clinical practice and in the best interests of the patient
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure; this may include a doctor/clinician undergoing further training under supervision
- that if the doctor/clinician wishes to record video, audio or images during the procedure where the recording is not required as part of the treatment (e.g. for training or research purposes), I will be asked to sign a separate consent form. If I choose not to consent, it will not adversely affect my access, outcome or rights to medical treatment in any way.

I was able to ask questions and raise concerns with the doctor/clinician.

I understand I have the right to change my mind regarding consent at any time, including after signing this form (this should be in consultation with the doctor/clinician).

| | I/substitute decision-maker/parent/legal guardian/other person have received the following consent and patient information sheet(s): |
|---|--|
| | ☐ Nephrostomy with or without Ureteric Stent' |
| | ☐ 'Computed Tomography (CT) Scan' |
| | ☐ 'Ultrasound' |
| | ☐ 'About Your Anaesthetic' (Adult patient only) |
| | ☐ 'About Your Child's Anaesthetic' (Child/young person patient only) |
| | ☐ 'Blood and/or Manufactured Blood Products Transfusion (Full/Limited Consent)' (Adult patient only) |
| | ☐ 'Transfusion Consent: Fresh and/or Manufactured Blood Products (Full/Limited Consent)' (Child/young person patient only) |
| 1 | On the basis of the above statements, |
| _ | 1) I/substitute decision-maker/parent/legal guardian/ |
| | other person consent to having a nephrostomy with or without ureteric stent. |
| | Name of patient/substitute decision-maker/parent/legal guardian/other person: |

If the patient is a child/young person:

Signature:

I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child/young person for this procedure (not applicable if the child/young person is Gillick competent and signs this form).

Date:

2) Student examination/procedure for professional training purposes:

For the purpose of undertaking training, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to patient OR substitute decision-maker OR parent/legal guardian/other person consent, assist with/ conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker/parent/legal guardian/other

| training to: | ergoing | |
|---|---------|------|
| observe examination(s)/procedure(s) | Yes | □No |
| assist with examination(s)/procedure(s) | Yes | □No |
| conduct examination(s)/procedure(s) | Yes | ☐ No |
| | | |

Nephrostomy with or without Ureteric Stent

Queensland Government

Adult and Child/Young Person | Informed consent: patient information

A copy of this patient information sheet should be given to the patient or substitute decision-maker or parent/legal guardian/other person of a child or young person to read carefully and allow time to ask any questions about the procedure. The consent form and patient information sheet should be included in the patient's medical record.

In this information sheet, the word 'you' means the patient unless a substitute decision-maker, parent, legal guardian or other person is providing consent on behalf of the patient, in which case the word 'you' means the substitute decision-maker, parent, legal guardian or other person when used in the context of the person providing consent to the procedure.



1. What is a nephrostomy with or without ureteric stent and how will it help me?

A nephrostomy is an artificial tract created to allow drainage of urine from the kidney to an external drain. A soft thin tube is placed through the tract into the kidney to drain the urine. A nephrostomy is performed when the ureter (drainage tube that connects your kidney to your bladder) is blocked. This can be the result of various conditions, such as kidney stones, tumour, infection or blood clots. Left untreated the build-up of urine puts pressure on the kidney, which may damage it.

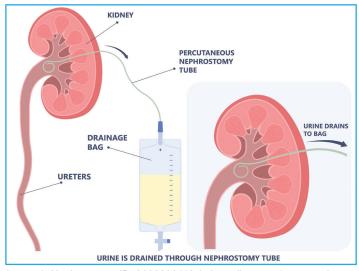


Image 1: Nephrostomy. ID: 2030890118 (adapted). www.shutterstock.com

Depending on your circumstances you may require the insertion of a ureteric stent. A ureteric stent is an internal drainage tube placed in your kidney, through your ureter and into your bladder. The stent bypasses the blockage to allow drainage of urine from the kidney into the bladder. This procedure can be done as a second step to a nephrostomy, or at a later time.

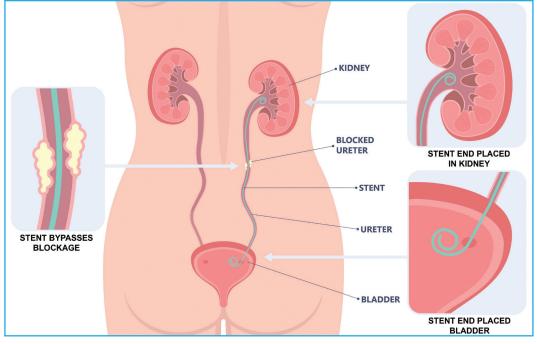


Image 2: Ureteral stent. ID: 2020088231 (adapted). www.shutterstock.com

Imaging is used for guidance in this procedure. For more information on imaging methods and the risks involved in their use, please read the *Computed Tomography (CT) Scan* or *Ultrasound* patient information sheet (if you do not have these information sheets, please ask for them.

Preparing for the procedure

The Medical Imaging department will give you instructions on how to prepare for the procedure. It is important to follow the instructions that are given to you. Your procedure might be delayed if you don't follow all the preparation steps.

Medical imaging staff will notify you beforehand if you are required to stop taking any blood-thinning medicine. List or bring all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show the doctor/clinician what you are taking.

These procedures will require the use of a local anaesthetic and sedation. If a patient is unable to co-operate under sedation (for example a child or young person), a general anaesthetic may be required.

Do not drink alcohol, smoke, vape or take recreational drugs for at least 24 hours before the procedure as these may alter the effects of the sedation anaesthetic. If you have a drug or medication dependence, please tell your doctor/clinician.

Please tell the doctor/clinician if you are breastfeeding or pregnant, or suspect that you may be pregnant.

On the day of the procedure

- Nothing to eat or drink ('nil by mouth'): you
 will be told when to have your last meal and
 drink. Do NOT eat (including lollies), drink,
 or chew gum after this time otherwise your
 procedure may be delayed or cancelled.
 This is to make sure your stomach is empty
 so that if you vomit, there will be nothing to
 go into your lungs.
- If you are taking medicines, most should be continued before a procedure and taken at the usual time, even on the day of the procedure, with a sip of water. There are some important exceptions:

- your doctor/clinician will provide specific instructions about your medicines
- take to the hospital all your prescribed medicines, those medicines you buy over the counter, herbal remedies and supplements to show your anaesthetist what you are taking.
- If you feel unwell, telephone the Medical Imaging department for advice.
- Tell your doctor/clinician and the anaesthetist if you have:
 - health problems (e.g. diabetes, high blood pressure, infectious diseases, serious illnesses), including if regular treatment or a stay in hospital is needed
 - family problems with anaesthesia
 - false teeth, caps, loose teeth or other dental problems
 - been taking prescribed and/or over the counter medicines, herbal remedies and supplements; this may include and is not limited to blood thinning medicines, the contraceptive pill, antidepressants and/or medicines for treating diabetes (e.g. insulin)
 - allergies/intolerances of any type and their side effects.
- You will be required to change into a hospital gown and remove some of your jewellery.

Sedation

Sedation is the use of medicines that help make you feel relaxed and drowsy for your procedure. You may remember some or little about what has happened. You may still be aware of your surroundings, and should be able to follow simple instructions, such as holding your breath when instructed by the doctor/clinician.

For a parent/legal guardian/ other person of a patient having a nephrostomy with or without ureteric stent

To prepare the patient for this procedure and to ease their concerns, tell them what they can expect to happen during the procedure. This information sheet will assist you with this. We welcome your help and support in preparing the patient for the procedure and in explaining why it's so important to lie still.

At the discretion of the procedure staff:

- a parent/adult (unless pregnant) may be invited into the procedure room to support the patient
- if the patient is having a general anaesthetic you may be able to see them off to sleep. Once they are asleep you will be asked to leave the procedure room and wait in the waiting area.

Other children are not allowed into the procedure room, and they must be supervised at all times by another parent/adult.

During the procedure

An intravenous (I.V.) cannula is a small plastic tube which will be inserted into a vein in your arm. This is for any medicine or fluids required during the procedure, including sedation.

Routine observations, such as blood pressure and heart rate, will be taken before the start of the procedure.

The skin of your lower back will be cleaned and a sterile drape will be applied to cover your body. The doctor/clinician will inject local anaesthetic into the skin where the nephrostomy tube will be inserted.

A small cut is made into your skin. You must remain as still as possible. At times, you may be asked to hold your breath.

Using imaging as a guide the doctor/clinician will insert a needle into the kidney.

lodinated 'contrast', also known as x-ray dye, will be injected to check the position of the needle in the kidney. Once access into the kidney is confirmed, a wire is passed through the needle and the needle is removed.

The wire maintains access into the kidney and a route for the nephrostomy tube to be inserted.

If required, a ureteric stent may be inserted over a wire and passed through to the ureter and into the bladder (this step is done before the nephrostomy tube is inserted). The wire may irritate your bladder and make you feel like you need to pass urine. This feeling is only temporary.

The nephrostomy tube is then inserted into your kidney and connected to an external drainage bag to collect the urine.

The nephrostomy tube may be sutured to help keep it in place and a dressing applied.

After the procedure is complete, you will be transferred from the procedure room to a recovery area. Your observations and procedure site will be monitored regularly.

The recovery time varies depending on the sedation given. It varies between 2 hours to 6 hours.

You will be transferred to a ward when you are alert and your observations (blood pressure, oxygen levels, breathing and heart rate) are stable.

The I.V. cannula will be removed after you have recovered.



2. What are the risks?

In recommending the procedure, the doctor/ clinician believes that the benefits to you from having the procedure exceed the risks involved. There are risks and possible complications associated with the procedure which can occur with all patients – these are set out below. There may also be additional risks and possible complications specific to your condition and circumstances which the doctor/clinician will discuss with you. If you have any further concerns, please ensure that you raise them with the doctor/clinician prior to giving consent to the procedure.

Common risks and complications

- minor pain, bruising and/or infection from the I.V. cannula
- pain or discomfort at the insertion site. This may require medication
- bleeding or bruising may occur at the insertion site

- bleeding or bruising is more common if you have been taking blood thinning medicines, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavix), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
- the catheter may become kinked or blocked. Sometimes it needs to be moved or replaced
- failure of local anaesthetic which may require a further injection of anaesthetic or a different method of anaesthesia may be used
- nerve damage, is usually temporary, and should get better over time. Permanent nerve damage is rare
- (stent insertion only) the ureteric stent may become blocked. It may need to be removed
- (stent insertion only) increased urgency and frequency of urination. This is usually temporary and should get better within a few days
- (stent insertion only) discomfort and pain in kidney and bladder during and after urination. This is usually temporary.

Uncommon risks and complications

- infection, requiring antibiotics and further treatment
- damage to surrounding structures such as blood vessels, organs and muscles, requiring further treatment
- excessive bleeding in the kidney. This may require other treatment and/or corrective surgery
- damage to normal kidney tissue. This may require monitoring and/or other treatment
- an allergy to injected drugs, requiring further treatment
- the procedure may not be possible due to medical and/or technical reasons
- (stent insertion only) the ureteric stent may move. It may need to be replaced or removed.

Rare risks and complications

- allergic reaction to the contrast. This could result in a rash, hives, itching, nausea, fainting or shortness of breath. Medication may be given to relieve this
- seizures and/or cardiac arrest due to local anaesthetic toxicity
- skin burns or damage from exposure to x-rays
- death because of this procedure is very rare.

If general anaesthetic or sedation is given, extra risks include:

- faintness or dizziness, especially when you start to move
- fall in blood pressure
- · nausea and vomiting
- weakness
- heart and lung problems, such as heart attack or pneumonia
- · stroke resulting in brain damage.

Risks of radiation

The risks of radiation exposure from this procedure need to be compared to the risks of your condition not being treated. Exposure to radiation may cause a slight increase in the risk of cancer to you over your lifetime. However, the potential risk is small compared to the expected benefit of this procedure¹.

What are the risks of not having a nephrostomy with or without ureteric stent?

There may be adverse consequences for your health if you choose not to have the proposed procedure. Please discuss these with the referring doctor/clinician.

If you choose not to have the procedure, you will not be required to sign a consent form.

If you have signed a consent form, you have the right to change your mind at any time prior to the procedure. Please contact the referring doctor/clinician to discuss.



3. Are there alternatives?

A retrograde ureteric stent is an alternative procedure to bypass the blockage and allow internal drainage from the kidney to the bladder. The stent is placed through the bladder, via the ureter into your kidney using a camera called a cystoscope. This is performed in theatre by a urologist.

Making the decision to have a procedure requires you to understand the options available. Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

It is normal for your urine to be blood stained. This should settle within a couple of hours after your procedure.

If a ureteric stent was inserted, the nephrostomy catheter should be removed at a later date. The doctor/clinician will discuss this with you and how long you are likely to need the nephrostomy catheter.

Go to your nearest Emergency department or GP (your local doctor) if you become unwell or experience any of the following:

- · light sensitivity
- · agitation
- · amnesia
- seizures
- pain unrelieved by simple pain relievers
- continuous bleeding or swelling at the puncture site
- redness or inflammation at the puncture site
- fever
- other warning signs the doctor/clinician may have asked you to be aware of.

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital and what level of activity is suitable after your procedure.

If you had sedation, this will affect your judgement for about 24 hours. For your own safety:

- Do NOT drive any type of car, bike or other vehicle.
- Do NOT operate machinery including cooking equipment.
- Do NOT make important decisions or sign a legal document.
- Do NOT drink alcohol, smoke, vape or take recreational drugs. They may react with the anaesthetic medications.



5. Who will be performing the procedure?

Doctors, radiographers, nuclear medicine technologists, sonographers, nurses, and medical imaging assistants make up the medical imaging team. All or some of these professionals may be involved in your journey.

A doctor/clinician other than the consultant/ specialist may assist with/conduct the clinically appropriate procedure. This could include a doctor/clinician undergoing further training, however all trainees are supervised according to relevant professional guidelines.

If you have any concerns about which doctor/ clinician will be performing the procedure, please discuss this with the doctor/clinician.

For the purpose of undertaking professional training in this teaching hospital, a clinical student(s) may observe medical examination(s) or procedure(s) and may also, subject to your consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

You are under no obligation to consent to an examination(s) or a procedure(s) being undertaken by a clinical student(s) for training purposes.

If you choose not to consent, it will not adversely affect your access, outcome or rights to medical treatment in any way.

For more information on student care, please visit www.health.gld.gov.au/consent/students.



6. Where can I find support or more information?

Hospital care: before, during and after is available on the Queensland Health website www.qld.gov.au/health/services/hospital-care/before-after where you can read about your healthcare rights.

You can also see a list of blood thinning medications at www.health.qld.gov.au/consent/bloodthinner.

Further information about informed consent can be found on the Informed Consent website www.health.qld.gov.au/consent. Additional statewide consent forms and patient information sheets are also available here.

Staff are available to support patients' cultural and spiritual needs. If you would like cultural or spiritual support, please discuss this with your doctor/clinician.

Queensland Health recognises that Aboriginal and Torres Strait Islander patients will experience the best clinical care when their culture is included during shared decision-making.



7. Questions

Please ask the doctor/clinician if you do not understand any aspect of this patient information sheet or if you have any questions about your proposed procedure.

If you have further questions prior to your appointment, please contact the Medical Imaging department via the main switchboard of the facility where your procedure is booked.



8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact 13 HEALTH (13 43 25 84), 24 hours a day, 7 days a week.

References:

 Australian Radiation Protection and Nuclear Safety Agency (ARPANSA). Ionising radiation in our everyday environment, 2021. Available from <u>www.arpansa.gov.au</u>