A. Does the patient have capacity?

☐ Yes ➔ GO TO section B

☐ No ➔ COMPLETE section A

You must adhere to the Advance Health Directive (AHD), or if there is no AHD, the consent obtained from a substitute decision-maker in the following order: Category 1. Tribunal-appointed guardian; 2. Enduring Power of Attorney; or 3. Statutory Health Attorney.

Name of substitute decision-maker:

Category of substitute decision-maker:

B. Is an interpreter required?

If yes, the interpreter has:

☐ provided a sight translation of the informed consent form in person

☐ translated the informed consent form over the telephone

Name of interpreter:

Interpreter code: Language:

C. Patient/substitute decision-maker requests the following procedure(s)

Inguinal hernia – open repair

Surgical mesh product may be used: ☐ Yes ☐ No

Site/side of procedure:

D. Risks specific to the patient in having an inguinal hernia – open repair

(Doctor/clinician to document additional risks not included in the patient information sheet):

E. Risks specific to the patient in not having an inguinal hernia – open repair

(Doctor/clinician to document specific risks in not having an inguinal hernia – open repair):

F. Alternative procedure options

(Doctor/clinician to document alternative procedure not included in the patient information sheet):

G. Information for the doctor/clinician

The information in this consent form is not intended to be a substitute for direct communication between the doctor/clinician and the patient/substitute decision-maker.

I have explained to the patient/substitute decision-maker the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature: Date:
H. Patient/substitute decision-maker consent

I acknowledge that the doctor/clinician has explained:

- the ‘Inguinal hernia – open repair’ patient information sheet
- the medical condition and proposed treatment, including the possibility of additional treatment
- that if a surgical mesh product is used in the course of this treatment/procedure, the specific risks and benefits of the procedure has been discussed
- the prognosis, and risks of not having the procedure
- alternative treatment 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, I will be treated based on documented discussions (e.g. AHD or ARP [Acute Resuscitation Plan])
- 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 have received the following consent and patient information sheet(s):

- [ ] ‘Inguinal hernia – open repair’
- [ ] Surgical mesh patient information leaflet (PIL) (if required)
- [ ] ‘About your anaesthetic’
- [ ] ‘Blood and/or manufactured blood products transfusion’

On the basis of the above statements,

1) I/substitute decision-maker consent to having an inguinal hernia – open repair.

Name of patient/substitute decision-maker:

Signature: 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/substitute decision-maker consent, assist with/conduct an examination or procedure on a patient while the patient is under anaesthetic.

I/substitute decision-maker consent to a clinical student(s) undergoing training to:

- [ ] observe examination(s)/procedure(s)
- [ ] assist with examination(s)/procedure(s)
- [ ] conduct examination(s)/procedure(s)

Yes No Yes No Yes No
A copy of this form should be given to the patient/substitute decision-maker 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 is providing consent on behalf of the patient, in which case the word ‘you’ means the substitute decision-maker when used in the context of the person providing consent to the procedure.

1. What is an inguinal hernia – open repair and how will it help me?

A hernia, sometimes referred to as a rupture, occurs when a part of an internal organ, sometimes the bowel, pushes through a weak point in the abdominal wall.

Inguinal hernia is the most common type of hernia, and twenty times more common in men than in women. It is likely that about 1 in 20 men will develop an inguinal hernia. The inguinal canal is in the groin. The first signs of a hernia are discomfort and/or a lump. It is common for men to develop a hernia.

Open surgery is performed under a general, spinal or local anaesthetic to repair the weakness in the abdominal wall.

The lump will be relieved by the surgery which may also relieve discomfort in the area. Planned surgical treatment of a hernia is often safer than leaving the hernia until an emergency happens.

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
- trouble passing urine after the operation due to spasm of the bladder sphincter
- swelling of the testicle and scrotum in male patients but most cases will resolve. Also the penis may show bruising
- infections can occur, requiring antibiotics and further treatment. Infections necessitating removal of mesh/stitches may require antibiotics or further treatment/surgery
- bleeding could occur and may require a return to the operating room
• bleeding is more common if you have been taking blood thinning drugs, such as warfarin, aspirin, clopidogrel (Plavix, Iscover, Coplavit), prasugrel (Effient), dipyridamole (Persantin or Asasantin), ticagrelor (Brilinta), apixaban (Eliquis), dabigatran (Pradaxa), rivaroxaban (Xarelto) or complementary/alternative medicines, such as fish oil and turmeric
• one of the small nerves in the groin can be cut or caught in a stitch or scar causing long-term/chronic groin discomfort/pain/numbness
• chronic pain caused by post-operative scarring
• the testicle may sit a little higher in the scrotum after surgery, this may happen over time due to scar tissue
• the scar can thicken, turn red and may be painful. This is permanent and can be disfiguring
• the hernia may come back. People who smoke, are obese or have diabetes are at increased risk of recurrence. Further surgery may be needed to repair the hernia
• operating on a recurrent hernia with or without previously inserted mesh or stitches may increase the risk of infection and bleeding and pain and recurrence
• small areas of the lung can collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy
• increased risk of wound infection, chest infection, heart and lung complications, and blood clot in the leg or lungs for people who are obese, smokers, or have diabetes. Emergency surgery increases the risk with these conditions
• iatrogenic injury (injury to organs during surgery) may occur. This could be a hole (perforation) to the bowel causing leakage of bowel contents into the abdomen. Additional treatment, including further surgery to repair the hole, may be needed.

Uncommon risks and complications
• adhesions (bands of scar tissue) can form and lead to bowel obstruction or long-term pain
• the tube carrying sperm from the testicle to the prostate may be injured in male patients as a result of scar tissue formation or surgical trauma. This may have an adverse impact on fertility
• heart attack or stroke could occur due to the strain on the heart
• blood clot in the leg causing pain and swelling. In rare cases, part of the clot may break off and go to the lung.

Rare risks and complications
• injury to the testicular blood supply resulting in either shrinkage or death of the testicle on that side
• death because of this procedure is rare.

Risks of surgical mesh

This procedure may require the use of surgical mesh. Surgical mesh is classified by the Therapeutic Goods Administration (TGA) as a class III medical device (high risk device). For more information about surgical mesh and the risks involved, please refer to the additional patient information leaflet (PIL) that has been provided to you. Discuss any concerns with the doctor/clinician. There are risks and possible complications associated with surgical mesh:
• chronic (long-term) pain can be caused by the mesh or the surgery. This could require further surgery to remove mesh, to revise the hernia repair, or pain medication to manage the pain
• mesh migration means mesh could move around inside the body. This can cause pain
• mesh can become infected at the time of surgery, even months or years later. If mesh becomes infected, you may require antibiotics and/or further surgery to have it removed
• mesh is a foreign body (not a natural part of the body) and can lead to autoimmune or inflammatory syndromes
• bowel can adhere to mesh product, this may cause a bowel obstruction or fistula that requires a further operation(s) to correct.

This procedure will require an anaesthetic.

For more information about the anaesthetic and the risks involved, please refer to the anaesthetic information sheet that has been provided to you. Discuss any concerns with the doctor/clinician.

If you have not been given an anaesthetic information sheet, please ask for one.
What are the risks of not having an inguinal hernia – open repair?

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

3. Are there alternatives?

Making the decision to have a procedure requires the patient/substitute decision-maker to understand the options available.

Sometimes watchful waiting or close monitoring of the hernia for signs of growth is possible. This can be discussed with your doctor/clinician.

Some patients may wear a hernia support belt or corset garment to support the hernia. These cannot treat hernias but some people find they relieve discomfort.

Depending on the circumstances, surgical repair can sometimes be done with mesh or without mesh (using stitches instead). Your hernia repair may be able to be done via keyhole surgery instead of open surgery.

Please discuss any alternative procedure options with your doctor/clinician before signing the consent form.

4. What should I expect after the procedure?

You will be given a patient implant card (PIC) with the specific details of any surgical mesh used. The information on the card enables improved traceability of the device if there are any issues or recalls.

Your healthcare team will talk to you about what to expect after your procedure and upon discharge from hospital.

If you become unwell, experience any of the complications listed or are concerned about your recovery, contact your GP immediately.

5. Who will be performing the procedure?

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.

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

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.

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 medical condition, treatment options and proposed procedure.

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.