



**Queensland Government**  
**Computed Tomography (CT) Cholangiogram with Biliscopin™ Consent**  
 Adult (18 years and over)

Facility: .....

(Affix identification label here)

URN:

Family name:

Given name(s):

Address:

Date of birth:

Sex:  M  F  I

**A. Does the patient have capacity to provide consent?**

- 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?**

- Yes  No

If yes, the interpreter has:

- provided a sight translation of the informed consent form in person  
 translated the informed consent form over the telephone

*It is acknowledged that a verbal translation is usually a summary of the text on the form, rather than word-by-word translation.*

Name of interpreter:

Interpreter code:

Language:



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

I confirm that the referring doctor/clinician has explained that I have been referred for the following procedure:

Computed Tomography (CT) cholangiogram with Biliscopin™:  Yes  No

Name of referring doctor/clinician:

**D. Risks specific to the patient in having a Computed Tomography (CT) cholangiogram with Biliscopin™**

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

**E. Risks specific to the patient in not having a Computed Tomography (CT) cholangiogram with Biliscopin™**

*(Doctor/clinician to document specific risks in not having a Computed Tomography [CT] cholangiogram with Biliscopin™):*

**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:



DO NOT WRITE IN THIS BINDING MARGIN

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SW9604

CT CHOLANGIOGRAM WITH BILISCOPIN™ CONSENT



**Queensland  
Government**

**Computed Tomography (CT)  
Cholangiogram with Biliscopin™  
Consent**

Adult (18 years and over)

(Affix identification label here)

URN:

Family name:

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**H. Patient/substitute decision-maker consent**

I acknowledge that the doctor/clinician has explained:

- the 'Computed Tomography (CT) Cholangiogram with Biliscopin™' 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 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):**

- 'Computed Tomography (CT) Cholangiogram with Biliscopin™'

On the basis of the above statements,

**1) I/substitute decision-maker consent to having a Computed Tomography (CT) cholangiogram with Biliscopin™.**

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)  Yes  No
- assist with examination(s)/procedure(s)  Yes  No
- conduct examination(s)/procedure(s)  Yes  No

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# Computed Tomography (CT) Cholangiogram with Biliscopin™

Adult (18 years and over) | Informed consent: patient information

**A copy of this patient information sheet 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.*



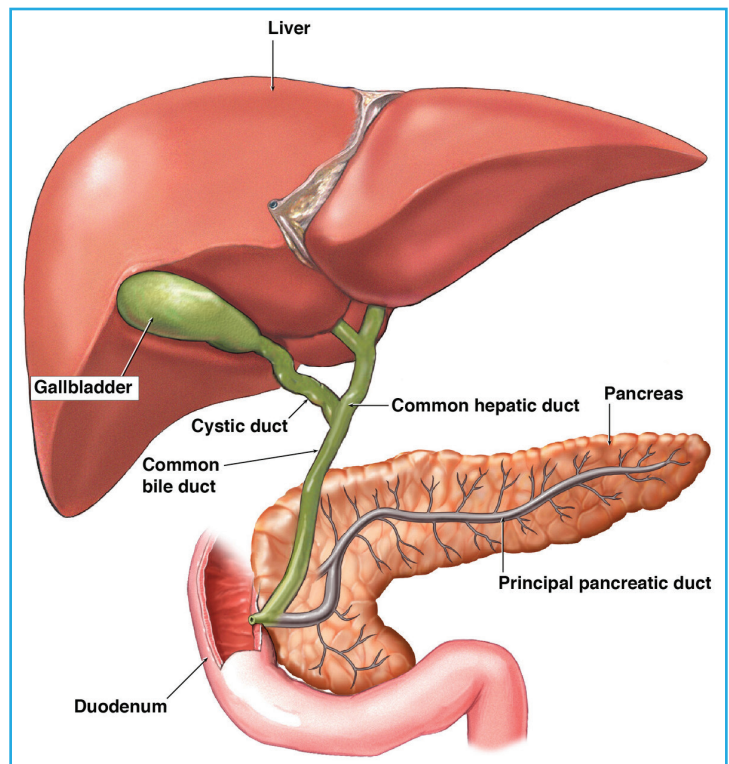
## 1. What is a Computed Tomography (CT) cholangiogram with Biliscopin™ and how will it help me?

Computed Tomography (CT) scans produce cross-sectional images of the body using x-ray radiation. The CT machine looks like a large doughnut with a narrow table in the middle. The table moves through the circular hole in the centre of the scanner. The CT machine is open at both ends. The information from the scan may provide a specific disease diagnosis and/or information on your condition.

A CT cholangiogram is a CT scan of the gallbladder and bile ducts. Biliscopin™ (meglumine iotroxate) contrast is injected over time into a vein via a fine needle (cannula) in your arm. The Biliscopin™ is processed by your liver and excreted into your bile. CT imaging with Biliscopin™ allows the doctor/clinician to see your gallbladder and where the bile flows. A CT cholangiogram is a non-invasive alternative for visualising the gallbladder and biliary tree, looking for bile leaks, gallstones or obstructions.

Before you are given Biliscopin™ we will ask you some questions to make sure it is safe for you.

*Image: Gallbladder and bile ducts.  
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## 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 of your preparation requirements.

Please tell the staff if you are breastfeeding or pregnant, or suspect that you may be pregnant.

The CT scan itself will not cause you any pain. It is very important that you lie very still for the procedure. Supporting straps, foam pads and light weights may be used to help with this.

## During the procedure

You will be required to change into a hospital gown and remove some of your jewellery.

The procedure is performed in two parts:

1. First part: The infusion of Biliscopin
2. Second part: The CT cholangiogram

### First part: The infusion of Biliscopin™

Biliscopin™ is administered via an intravenous (I.V.) cannula. An I.V. cannula is a small plastic tube inserted into a vein using a needle, usually in your hand or arm.

On average, the infusion will take between 30–60 minutes.

Biliscopin™ has some very common side effects. These include:

- a very warm or 'flushed' feeling over your body
- you may experience a 'metallic' taste or smell which usually lasts less than a minute.

A nurse will remain with you to monitor your observations.

### Second part: The CT cholangiogram

The CT scan will be performed after the infusion is finished.

You will be positioned on the CT table by the radiographer. The radiographer will not be in the room during the scan, but they will be able to see you, through a large glass window, and speak with you via an intercom.

During the scan, the table will move through the CT scanner and a whirring or humming sound may be heard. You should remain as still as possible, as the slightest movement can blur the images. For some scans, you will be asked to hold your breath for up to 20 seconds. The CT scans take approximately 10 to 20 minutes (not including preparation time).

If the I.V. cannula is no longer required, it will be removed after your procedure.



## 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 of Biliscopin™

- no known common risks and complications.

### Uncommon risks and complications of Biliscopin™

- allergic reactions rarely occur but when they do, they usually occur within the first hour with most happening in the first 5 minutes. Late reactions have been known to occur up to a week after the injection, but delayed reactions are mild. The reactions vary from:
  - » mild – hives, running nose, sneezing, coughing, nausea, itching eyes
  - » moderate – widespread hives, headaches, facial swelling, vomiting, shortness of breath, excessive yawning, stomach pain
- temporary changes in heart rate, heart rhythm or function which may cause a heart attack
- high or low blood pressure which is usually temporary
- temporary agitation or confusion
- temporary loss of memory
- disturbed speech, vision and hearing, seizures and tremors
- sleepiness.

### Rare risks and complications of Biliscopin™

- asthma or a build-up of fluid in the lungs resulting in difficulty or stopping breathing
- pain at the injection site
- diarrhoea

- fever, chills or sweating which is usually temporary
- salivation
- toxic effects on the liver, kidneys or pancreas
- unconsciousness and shock
- death because of using this procedure is very rare.

### Common risks and complications of the procedure

- minor pain, bruising and/or infection from the I.V. cannula. This may require treatment
- bruising is more common if you have been taking blood thinning drugs, 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.

### Uncommon risks and complications of the procedure

- injected Biliscopin™ may leak outside of the blood vessel, under the skin and into the tissues. This may require treatment. In very rare cases, surgery may be required if the skin breaks down around the injection site
- the procedure may not be possible due to medical and/or technical reasons.

### 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 procedure<sup>1</sup>.

### Precautions

As Biliscopin™ is not suitable for some people, you will be asked a series of questions before it is given. The answers allow staff to identify any risk factors that you may have.

Please tell the staff if you take Metformin for diabetes as it may affect the way Biliscopin™ works in your body.

Please be aware that your results may be altered by your exposure to Biliscopin™ if you have these tests booked:

- thyroid function tests
- urine specimens.

### What are the risks of not having CT cholangiogram with Biliscopin™?

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



### 4. What should I expect after the procedure?

The Radiologist (doctor) will review the final images after the procedure and send the report to your treating team.

You will receive the results of the examination from your treating team at your next follow-up appointment. Please make an appointment if you do not already have one.

Biliscopin™ will not affect your ability to carry out normal activities; you should be able to continue with your day as normal.

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



## 5. Who will be performing the procedure?

Radiographers, doctors, 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 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.

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.qld.gov.au/consent/students](http://www.health.qld.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](http://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](http://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](http://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 medical condition, treatment options and 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:

1. Australian Radiation Protection and Nuclear Safety Agency (ARPANSA) Ionising radiation in our everyday environment [www.arpansa.gov.au](http://www.arpansa.gov.au)