

Atrioseptostomy Consent

Infant/Child

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?

- No Parent/legal guardian/other person* with parental rights and responsibilities to provide consent and complete this form
→ **COMPLETE** section A

*Formal arrangements, such as parenting/custody orders, adoption, or other formally recognised carer/guardianship arrangements. Refer to the Queensland Health 'Guide to Informed Decision-making in Health Care' and local policy and procedures. Complete the source of decision-making authority as applicable below.

If applicable, source of decision-making authority (*tick one*):

- Court order → Court order verified
 Legal guardian → Documentation verified
 Other person* → Documentation verified

Name of parent/legal guardian/other person*:

Relationship to child:

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. Parent/legal guardian/other person* requests the following procedure(s)

Atrioseptostomy

D. Risks specific to the patient in having an atrioseptostomy

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

E. Risks specific to the patient in *not* having an atrioseptostomy

(Doctor/clinician to document specific risks in not having an atrioseptostomy):

F. Alternative treatment options

(Doctor/clinician to document alternative treatment 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 parent/legal guardian/other person*.

I have explained to the parent/legal guardian/other person* the contents of this form and am of the opinion that the information has been understood.

Name of doctor/clinician:

Designation:

Signature:

Date:

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H. Parent/legal guardian/other person* consent

I acknowledge that the doctor/clinician has explained:

- the "Atrioseptostomy" patient information sheet
- the child's 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 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
- if an immediate life-threatening event happens during the procedure/treatment/investigation/examination, health care will be provided in accordance with good clinical practice and in the child's best interests
- that a doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure/treatment/investigation/examination; 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 have received the following consent and patient information sheet(s):

- "Atrioseptostomy"
- "About your child's anaesthetic"
- "Fresh blood and blood products transfusion"

On the basis of the above statements,

I consent to the patient having an atrioseptostomy.

Name of child:

Name of parent/legal guardian/other person*:

Signature:

Date:

- I am not aware of any legal or other reason that prevents me from providing unrestricted consent for this child for this treatment.

A copy of this form should be given to the parent/legal guardian/other 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.



1. What is an atrioseptostomy and how will it help my/the child?

Atrial septostomy (atrioseptostomy) is an operation where a small hole is made between the upper two chambers of the heart. It is used to address some life-threatening heart defects seen in infants. These defects include transposition of the great arteries, where the aorta is connected to the right ventricle, and the pulmonary artery is connected to the left ventricle – the opposite of a normal heart's anatomy.

The cardiologist uses a catheter with a very small balloon to help enlarge the opening between the top two chambers of the heart to allow blood to mix and relieve symptoms caused by your child's heart defect.

Additional information about the equipment used in this procedure

The catheter used in this procedure is a highly specialised piece of equipment, designed for use in babies requiring this rare surgery. There is a shortage of suppliers of septostomy catheters in Australia due to a limited number of manufacturers globally making this highly specialised product. Typically, devices (including catheters) used in surgery in Queensland Health are approved for use by the Therapeutic Goods Administration (TGA). There are currently no septostomy catheters available in Australia with TGA approval. This is sometimes the case with very specialised equipment.

In circumstances such as these, where patients require access to medical devices that are not approved by the TGA, a medical practitioner may be granted special authority by the TGA, to access a specified unapproved therapeutic good for specific patients with a particular medical condition. This is known as the Special Access Scheme (refer to www.tga.gov.au/form/special-access-scheme). The TGA monitors all products accessed via the Special Access Scheme.

The catheter used in this procedure (Life Healthcare Numed Z-5 Septostomy Catheter) is the only septostomy catheter available in Australia and will be accessed through the Special Access Scheme. The Special Access Scheme requires you to be informed of the following:

- that the Life Healthcare Numed Z-5 Septostomy Catheter is not currently approved in Australia
- of the possible benefits of treatment and any known risks and side effects
- that unknown risks and late side effects are possible
- of the lack of alternative approved septostomy catheters available at the present time in Australia.



2. What are the risks?

There are risks and complications with this procedure. There may also be risks specific to each child's individual condition and circumstances. Please discuss these with the doctor/clinician and ensure they are written on the consent form before you sign it.

Risks include but are not limited to the following:

Common risks and complications

- infections may occur, requiring antibiotics and further treatment
- bleeding may occur and may require a return to the operating room. Bleeding may also lead to the need for a blood transfusion
- bleeding is more common if you (the mother) or your child has been taking blood thinning drugs or certain complementary medicines
- small areas of the lung may collapse, increasing the risk of chest infection. This may need antibiotics and physiotherapy.

Rare risks and complications

- failure of the device/catheter used to undertake the procedure. There is a risk that if the balloon does not deflate during the procedure, it will be hard to remove. If this complication were to occur, surgical intervention may be required to enable removal of the balloon. If fragmentation were to occur, there is a risk that parts of the balloon could shower around the body, causing complications such as a stroke
- heart attack or stroke may occur
- blood clot in the blood vessels or heart causing pain and swelling. In rare cases, part of the clot may break off and go to the lungs, heart, brain or other organs
- blood vessel or cardiac rupture leading to uncontrollable bleeding
- cardiac valve damage leading to significant valve leakage
- death as a result of this procedure can occur.

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 atrioseptostomy?

Without this procedure your child will continue to have low oxygen levels which may cause complications, such as failure of heart function, brain injury and kidney damage. If these complications occur, surgical repair of the heart may not be possible. Please discuss these with the doctor/clinician.

If you choose for your child 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/treatment/investigation/examination. Please contact the doctor/clinician to discuss.



3. Are there alternatives?

Making the decision to have a procedure requires the parent/legal guardian/other person* to understand the options available. Please discuss any alternative treatment options with your doctor/clinician before signing the consent form.



4. What should I expect after the procedure?

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



5. Who will be performing the procedure?

A doctor/clinician other than the consultant/specialist may assist with/conduct the clinically appropriate procedure/treatment/investigation/examination. This could be 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 with the doctor/clinician.



6. Where can I find support or more information?

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

The Canberra Heart Clinic 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 child's medical condition, treatment options and proposed procedure/treatment/investigation/examination.



8. Contact us

In an emergency, call Triple Zero (000).

If it is not an emergency, but you have concerns, contact (1800 022 222), 24 hours a day, 7 days a week.