

# ASERNIP/S



Australian Safety  
and Efficacy  
Register of New  
Interventional  
Procedures – Surgical

## Consumer summary

### Intraoperative ablation for the treatment of atrial fibrillation

To navigate in this document in Word, click on the word (underlined in blue) to link to glossary. When using the PDF version, please scroll to the end of the document for definitions of glossary words underlined in blue.

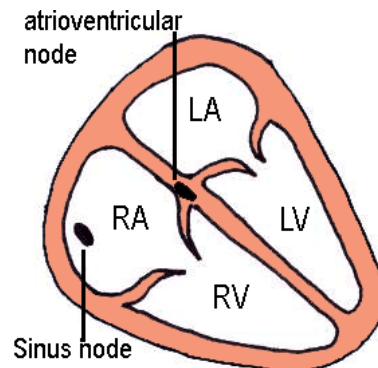
#### Introduction

The following information is about intraoperative [ablation](#), a group of surgical techniques used for treating atrial fibrillation ([AF](#)). ASERNIP-S has reviewed the available published [evidence](#) to compare the safety and effectiveness of this procedure with other surgical procedures, including cardiac surgery alone or the [Maze-III](#) procedure, the current established surgical treatment for [AF](#).

#### What are the atria?

The heart is a pump to move blood around the body. It is made up of four chambers, the right and left atria and ventricles (see figure 1). The [sinus node](#) in the right atrium sends an electrical message to the [atrioventricular node](#) and then on to the ventricles which makes the heart muscles contract.

**Figure 1: Chambers of the heart (cross-section from the front)**



### **What is atrial fibrillation?**

Normally the [sinus node](#) acts as a natural [pacemaker](#), initiating electrical signals which follow natural electrical pathways through the atria, causing the heart to beat regularly. However, in atrial fibrillation ([AF](#)) these pathways become uncoordinated and the atrial contraction becomes ineffective. In the early stages of [AF](#) this may be intermittent, but may progress to become permanent. During AF the ventricles receive the signals irregularly, resulting in an irregular and at times rapid heart beat. Atrial fibrillation is the most commonly occurring [arrhythmia](#) of the heart, with an incidence which increases with age, reaching up to 9 in 100 people (i.e. 9%) from 80 to 89 years of age. People with AF are at a higher risk of stroke and/or dying.

### **Conventional treatments for atrial fibrillation**

The following treatments are used:

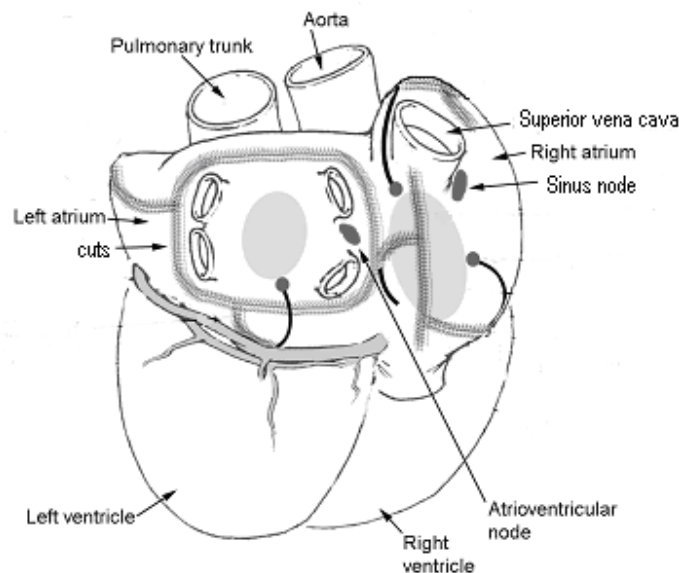
- medical management, using drugs: (1) to alter the rate or rhythm of heartbeat (2) to thin the blood and reduce the risk of stroke
- electric shock given under general anaesthetic
- [catheters](#) passed through the skin into a vein to deliver energy (usually radiofrequency waves or [cryotherapy](#)) to particular areas of the heart

- surgical treatments: cardiac surgery to correct heart disease and the [Maze](#) procedure to treat [AF](#).

### Cardiac surgery and the Maze procedure

In patients whose [AF](#) is associated with underlying heart disease, cardiac surgery alone may be performed to correct the heart disease. However, in the majority of patients cardiac surgery alone does not cure the [AF](#). Special surgical techniques have been developed to cure [AF](#) in conjunction with cardiac surgery (i.e. intraoperative); the most notable of these is the [Maze-III](#) procedure. This involves a number of cuts into the atria in a maze-like pattern, which forms scar tissue blocking the path of the uncoordinated electrical messages causing the [arrhythmia](#). The [Maze-III](#) procedure is a safe and effective surgical treatment; up to 97 out of 100 patients (i.e. 97%) undergoing the operation may still have freedom from [AF](#) 10 years later. However, the [Maze-III](#) procedure is a relatively long and difficult one, with a significant risk of bleeding.

**Figure 2: Maze-III procedure (view of heart from the back)**



## **Energy ablation**

Rather than cutting into the atria, the maze pattern can also be created using [cryotherapy](#), radiofrequency waves, microwave, laser or ultrasound energy sources. The destruction of the tissue using these methods is called [ablation](#).

### **How does the use of energy ablation compare with conventional surgery treatments for atrial fibrillation?**

ASERNIP-S reviewed the available published [evidence](#) to compare the safety and effectiveness of energy [ablation](#) with cardiac surgery alone or the [Maze-III](#) procedure.

In terms of safety, there was no clear difference between the procedures for the patient's risk of dying. There did not appear to be any greater risk of bleeding for [ablation](#) using [cryotherapy](#) or radiofrequency waves compared with cardiac surgery alone. There are potential risks associated with longer bypass times but these were not apparent on the available evidence. Very small numbers of patients undergoing [ablation](#) experienced punctures of the oesophagus or narrowing of the circumflex [coronary artery](#), which are serious and potentially lethal complications. There was not enough [evidence](#) to make any conclusions about the incidence of stroke.

In terms of effectiveness, studies showed that the [cryotherapy](#), radiofrequency waves and microwave [ablation](#) procedures were more likely to lead to normal heartbeat than cardiac surgery alone. Some studies reported that patients were 3 to 4 times more likely to be in sinus rhythm (normal heartbeat) 12 months after radiofrequency [ablation](#) combined with cardiac surgery compared with cardiac surgery alone. At least 68 patients in 100 (68%) undergoing any of the types of energy [ablation](#) achieved sinus rhythm. There were no consistent differences in effectiveness between [cryotherapy ablation](#) versus [Maze-III](#), and not enough [evidence](#) to compare other energy sources.

### **Conclusion and recommendations**

From the limited [evidence](#) (rated as 'poor'), the ASERNIP-S Review Group agreed on the following classifications and recommendations:

### *Classifications*

**Safety** - There was insufficient [evidence](#) to determine whether intraoperative [ablation](#) was more or less safe than cardiac surgery alone, or the [Maze-III](#) procedure. Very rare complications specifically related to intraoperative ablation have been reported.

**Efficacy** – Intraoperative ablation is at least as effective as cardiac surgery alone or the Maze-III procedure, and the addition of intraoperative ablation to the correction of the underlying heart disease improves the probability of resolution of [AF](#). There were no studies comparing isolated intraoperative [ablation](#) with medical management of [AF](#).

### *ASERNIP-S recommendations*

A [randomised controlled trial](#) comparing intraoperative [ablation](#) with cardiac surgery alone is needed to measure long-term survival and stroke rate. Surgeons performing intraoperative [ablation](#) for the treatment of [AF](#) should also take part in a national [audit](#).

(July 2004)

### **Acknowledgments**

Figure 2 was prepared by Rebecca Morgan.

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**Important note**      The information provided is based on up-to-date research. However, it is not intended to replace the advice of your medical practitioner. Please ask your doctor if you have any further questions about the management of this condition.

### **For further information about ASERNIP-S**

Contact Professor Guy Maddern, ASERNIP-S Surgical Director, PO Box 553, Stepney, SA 5069, ph. (08) 83637513, fax (08) 83622077, or visit the website (<http://www.surgeons.org/asernip-s.htm>). If you would like to provide feedback on this consumer summary, please contact us at [consumer.asernip@surgeons.org](mailto:consumer.asernip@surgeons.org)

ASERNIP-S is a program of the Royal Australasian College of Surgeons (RACS).

**INTRAOPERATIVE ABLATION FOR THE TREATMENT**  
**OF ATRIAL FIBRILLATION**  
**CONSUMER INFORMATION GROUP MEMBERS**

**ASERNIP-S Director**

Professor Guy Maddern  
Surgical Director  
ASERNIP-S  
PO Box 553 STEPNEY SA 5069

**Advisory Surgeon**

Mr Hugh Paterson  
Department of Cardiothoracic Surgery  
Westmead Hospital  
PO Box 533  
Wentworthville NSW 2145

**Consumer Representatives**

Barbara Beacham  
Primary Health Care Research Information Service  
Department of General Practice  
Flinders University, Adelaide BEDFORD PARK SA 5042

Jane Doyle  
Channel Seven Adelaide Pty Limited  
45 Park Terrace GILBERTON 5081

**ASERNIP-S Program Manager**

Dr Wendy Babidge

**ASERNIP-S Research Manager**

Philippa Middleton

**ASERNIP-S Project Officer**

Eleanor Ahern

## The ASERNIP-S Classification System

### Evidence Rating

The [evidence](#) (i.e. studies included in the review) for ASERNIP-S [systematic reviews](#) is rated as *Good*, *Average* or *Poor*, according to the:

- quality of the [evidence](#). High quality [evidence](#) comes from a study that has a low risk of [bias](#) and no other major flaws (such as lack of enough follow-up data or big differences between the patients selected for the groups).
- availability of the [evidence](#). This refers to how much [evidence](#) there is to obtain.

### *Good*

Most of the [evidence](#) is either from:

- a high quality [systematic review](#) of all relevant [randomised controlled trials](#), or
- at least one large high quality [randomised controlled trial](#).

### *Average*

Most of the [evidence](#) is from:

- high quality [quasi-randomised trials](#), and/or
- comparative studies, without major flaws, in which the patients are placed into groups without being randomized, and/or
- an inconclusive [systematic review](#) based on small [randomised controlled trials](#), and/or
- [randomised controlled trials](#) that are of moderate or uncertain quality.

The results of these studies are more likely to be influenced by other factors compared to high-quality [randomised controlled trials](#). However, these studies show to some extent that there is still a reasonable chance (moderate probability) that outcomes are valid.

### *Poor*

Most of the [evidence](#) is from:

- [case series](#)
- studies mentioned above, with major flaws or a high risk of [bias](#)
- studies in which there is not enough [evidence](#).

## Safety and Efficacy Classification

### SAFETY

- *At least as safe compared to comparator\* procedure(s)*  
The [systematic review](#) shows that the new procedure is as safe as, or safer than, the comparator.
- *Safety cannot be determined*  
There is not enough [evidence](#) to determine the safety of the new procedure.
- *Less safe compared to comparator\* procedure(s)*  
The new procedure is not as safe as the comparator.

### EFFICACY

- *At least as efficacious compared to comparator\* procedure(s)*  
The [systematic review](#) shows that the new procedure is as effective as, or more effective than, the comparator.
- *Efficacy cannot be determined*  
There is not enough [evidence](#) to determine the effectiveness of the new procedure.
- *Less efficacious compared to comparator\* procedure(s)*  
The new procedure is not as effective as the comparator.

### RESEARCH RECOMMENDATIONS

The Review Group may recommend that more data be collected through an [audit](#) or a controlled (ideally randomised) clinical trial.

### CLINICAL RECOMMENDATIONS

The Review Group may make recommendations regarding the use of the new procedure in clinical practice to ensure the procedure is performed on appropriate patients by sufficiently qualified/experienced centres.

\* A comparator may be the current “gold standard” procedure, an alternative procedure, a non-surgical procedure or no treatment.

## Glossary

**Ablation:** The destruction of tissue using [cryotherapy](#), radiofrequency waves, microwave, laser or ultrasound energy sources.

**AF:** Atrial fibrillation

**Arrhythmia:** Variation in the normal rhythm of the heartbeat

**Atrioventricular node:** Node in the wall dividing the left and right atria and ventricles. The node receives electrical messages from the [sinus node](#) and transmits them to the ventricles, leading to contraction of the muscles of the ventricles.

**Audit:** In surgical practice this refers to the process of measuring and monitoring the diagnosis, investigation, surgical treatment, resulting outcomes and follow-up of patients.

**Bias:** The influence of other factors, i.e. those not being measured, on the results of a study.

**Cardiopulmonary bypass:** The total circulation may be routed through the cardiopulmonary bypass ([CPB](#)) apparatus, or heart-lung machine, during cardiac surgery. A solution is poured into the arteries supplying the heart muscle to prevent it from contracting. This enables the surgeon to operate on a stationary, bloodless heart.

**Case series:** A series of single patients, usually treated at the same centre within a particular timeframe. This often reflects the historical experience of that centre.

**Catheter:** A long tube which can be passed through blood vessels to organs in the body.

**Coronary artery:** Artery supplying the heart muscle.

**Cryotherapy:** Destruction of tissue using freezing.

**Evidence:** The studies included in the review.

**Maze procedure:** This treatment for cardiac [arrhythmia](#) involves a number of cuts into the atria in a maze-like pattern, which forms scar tissue blocking the path of the uncoordinated electrical messages causing the [arrhythmia](#).

**Pacemaker (natural):** The cardiac pacemaker ([sinus node](#)) sends electrical signals to the heart to trigger regular contractions of heart muscle.

**Quasi-randomised trial:** A trial using a method which is not completely randomised of placing patients into treatment groups. There is a greater risk of selection [bias](#) in quasi-random trials where placement is not adequately concealed compared with [randomised](#)

[controlled trials](#), in which surgeons or patients do not know to which groups patients have been allocated.

**Randomised controlled trial:** A study in which researchers randomly place participants in groups. This is done to minimise bias. The new surgical procedure will be performed on one group of patients, while the other group of patients will undergo the conventional operation. Researchers measure and compare the outcomes of the patients from the different groups.

**Sinus node:** Node in the right atrium of the heart which sends out regular electrical messages leading to contraction of the heart muscles.

**Systematic review:** ASERNIP-S conducts literature reviews on the safety and effectiveness of new surgical techniques before they are widely accepted into the health care system. Each review collects all relevant information, or [evidence](#), on new and standard techniques used to treat a medical condition. The quality of [evidence](#) is assessed. ASERNIP-S then makes recommendations on the safety and effectiveness of the procedures that are then endorsed by RACS.