

Decision Summary

Meeting Date	Friday 9 October 2009		
Application #	09008N		
Title of TCP	WATCHMAN Left Atrial Appendage Occlusion Device		
<input checked="" type="checkbox"/> New TCP	<input type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
<p>Most ischaemic strokes associated with atrial fibrillation (AF) are caused by embolization of thrombi from the left atrial appendage (LAA). Warfarin has been the treatment of choice to prevent these strokes. However due to shortfalls and concerns related to lifelong warfarin therapy only around 50% of patients who are eligible and would benefit from long term warfarin therapy are treated with it (ATRIA study. 1999).</p> <p>The Watchman is a viable alternative to warfarin designed to occlude the LAA and prevent the occurrence of strokes in those patients with non-valvular AF who are at heightened risk of stroke.</p>			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	There are no conflicts of interest to declare	
Committee	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	There are no conflicts of interest to declare	
SAFETY			
<input checked="" type="checkbox"/> Safer than current practice	<input type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
After the learning curve associated with this procedure the device is safer than current treatment (warfarin).			
EFFECTIVENESS			
High quality evidence?	One RCT, three case series		
Consistent, clinically important benefit?	The evidence suggests that the procedure is not inferior to warfarin.		
Applicable to Southern Health?	Yes		
COST			
\$8000 with the delivery system plus additional costs for bed days. Cost of the device to be met by MonashHeart. The applicants intend to apply for a DRG code to enable additional funding. The committee			
CLINICAL FEASIBILITY			
Resource implications	Within existing capacity		
Credentialing and competency assurance undertaken	<p>Credentialing requires online training with an exam followed by supervision of initial cases by an experienced proctor.</p> <p>Dr Jeff Alison to be the only practitioner credentialed for this procedure until cases exceed 10 per year.</p> <p>Future practitioners seeking credentialing should already be experienced in left atrial surgery to reduce the learning curve.</p> <p>No more than two practitioners should be credentialed to perform the procedure at Southern Health.</p>		
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
Only ten patients per year can be treated within current available budgets. It is likely that many more patients will be eligible for this procedure. Access should be based on clinical need. All eligible patients should be discussed at Cardiac Conference and priority given to those who will benefit most. A protocol for eligibility based on clinical indications should be developed as the practitioners become more familiar with the procedure and outcomes.			
Final decision by the Southern Health Technology/Clinical Practice Committee			
<input type="checkbox"/>	Recommended: Approved with no further need for assessment.		
<input checked="" type="checkbox"/>	Restricted Recommendation – Audit: Approval subject to implementation under audit conditions. Conditions are specific to the technology.		
<input type="checkbox"/>	Restricted Recommendation – Clinical Trial: Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.		
<input checked="" type="checkbox"/>	Restricted Approval – Operational Restrictions: Endorsed, however financial or operational restrictions apply.		
<input type="checkbox"/>	Not Recommended		
General Conditions			
<p>a. The Head of Department/Unit is required to notify the Secretariat of TCPC in the event of:</p> <ul style="list-style-type: none"> ▪ Any change in protocol and the reason for that change together with an indication of ethical implications 			

- Adverse effects of the TCP and steps to deal with them
- Any unforeseen events
- b. Adverse Events**
 - If an adverse event occurs the Head of Department/Unit must immediately notify the TGA in addition to the TCPC.
- c. Compliance with Quality Assurance (*must be completed prior to commencement of the TCP at Southern Health*)**
 - Applicants are required to complete either the Quality Assurance supplement letter or a new Quality Assurance application (whichever is applicable) and forward to Southern Health HREC
- d. Data Collection**
 - Data to be collected in all patients receiving the new TCP and reports provided to TCPC. The TCPC will provide details of data required by DHS.
- e. Reporting**
 - Reporting required at six monthly intervals; January – June and July – December; for a two year period.
 - Reports to be forwarded to TCPC Secretariat. TCPC to forward reports to DHS.
- f. Review**
 - At the conclusion of the two year period the original application will be reviewed by the TCPC to determine if it should be considered standard practice.

Special Conditions

- g. Patient Information**
 - Additional information required in the patient information under the following headings:
 - Are there any alternatives to implantation of the WATCHMAN left atrial appendage occlusion device?
 - What will happen if I decide not to have the procedure?
 - Summary
 - Under the heading “What complications can happen?”
 - Incidence of risks should be recorded and major and minor risks separated into two groups
 - The patient information should include wording to suggest that there may be additional unknown risks associated with this procedure.
 - Under the heading “What does the procedure involve?”, in the second paragraph the Committee would like clarified how long the patient can expect to stay on aspirin after the procedure
 - Patient information to be resubmitted to TCPC for review prior to commencement of the procedure
- h. Registry data**
 - Applicant to arrange for Southern Health patient data to be included in the international register for this procedure.
- i. Cost data**
 - Review of costs per patient to be provided after the first ten procedures
- j. Credentialing**
 - Dr Jeff Alison to be the only practitioner credentialed for this procedure until cases exceed 10 per year
 - No more than two practitioners should be credentialed to perform the procedure at Southern Health

SH Policy	Quality and Risk Management	ACHS	Leadership and Management
Reviewer	Director, Centre for Clinical Effectiveness	Last review date	January 2008
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	August 2010

This hard copy may not be the latest version of this document.

Please see the Southern Health Policy and Protocol intranet site for current policies, protocols and guidelines.