

### Decision Summary

<b>Meeting Date</b>	Friday 9 May 2008		
<b>Application #</b>	08007 (follow-on application previously 07003)		
<b>Title of TCP</b>	"Arctic Front" Cryo-balloon pulmonary vein insertion		
<input type="checkbox"/> New TCP	<input checked="" type="checkbox"/> Substitute/replacement for existing	<input type="checkbox"/> Extended use of existing	<input type="checkbox"/> Other
Cryo-ablation is presented as a safer alternative to the current practice of radiofrequency ablation in patients with paroxysmal atrial fibrillation. This procedure was given restricted approval by the TCPC in 2007 for use in training/demonstration procedures at Southern Health. The current application is to address cost and operational issues prior to approval for ongoing use.			
<b>CONFLICT OF INTEREST DECLARATION</b>			
<b>Applicant</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflict of interest	
<b>Committee</b>	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	Individual committee members declared potential conflicts of interest in relation to previous interaction with the applicant. The committee decided that these interactions would not act as conflicts of interest in the decision-making process.	
<b>SAFETY</b>			
<input checked="" type="checkbox"/> Safer than current practice	<input type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
The risk of complications of the procedure is reduced. A world-wide survey of catheter ablation reported at least one major complication in 6% of patients. In a multi-centre prospective case series of 346 patients no major complications were identified with cryo-balloon ablation. The procedure is shorter, reducing the length of time under general anaesthetic.			
<b>EFFECTIVENESS</b>			
High quality evidence?	No comparative studies are available		
Consistent, clinically important benefit?	Prospective case series suggest equivalent effectiveness to current practice		
Applicable to Southern Health?	Yes		
There is no high quality evidence regarding the clinical effectiveness of this procedure, however from the information available it appears to have similar effect to current practice, with a considerable reduction in major complications			
<b>COST</b>			
No information is available on cost-effectiveness or cost-benefit. Cost savings are anticipated due to reduction in complication rates, shorter theatre time, shorter length of stay and reduced requirement for 3D mapping. The expected number of patients referred per annum (six) can be covered within the current Cardiology budget.			
<b>CLINICAL FEASIBILITY</b>			
Resource implications	Adequate resources are available to perform these procedures		
Credentialing and competency assurance undertaken	Cryo-ablation is undertaken using procedural techniques that are in current practice at MMC and the medical and nursing staff involved have the required expertise. There is some learning required in relation to the sequence of events, timing and team work related to the new procedure. The MMC team have already noticed a reduction in time taken for the procedure as they become more familiar with it. Dr Jeffrey Alison will be the only doctor undertaking the procedure.		
This procedure is feasible at Southern Health: existing staff have appropriate training and expertise, no additional resources will be required and it can be achieved within current budgets			
<b>ISSUES RELATED TO ACCESS &amp; EQUITY AND LEGAL &amp; ETHICAL IMPLICATIONS</b>			
All expected referrals can be treated within current systems and funding arrangements. Patient information will be provided prior to obtaining informed consent. Data to be collected on all patients and reports provided to TCPC at six monthly intervals.			

Final decision by the Southern Health Technology/Clinical Practice Committee	
<input type="checkbox"/>	<b>Recommended:</b> Approved with no further need for assessment.
<input checked="" type="checkbox"/>	<b>Restricted Recommendation – Audit:</b> Approval subject to implementation under audit conditions. Conditions are specific to the technology.
<input type="checkbox"/>	<b>Restricted Recommendation – Clinical Trial:</b> Endorsed, however approval subject to implementation in clinical trial with Southern Health Human Research and Ethics Committee approval.
<input type="checkbox"/>	<b>Restricted Approval – Operational Restrictions:</b> Endorsed, however financial or operational restrictions apply.
<input type="checkbox"/>	<b>Not Recommended</b>
Conditions <ul style="list-style-type: none"> <li>▪ Data collection tool (spreadsheet/database) to be forwarded to TCPC</li> <li>▪ Data to be collected on all patients and reports provided to TCPC at six monthly intervals</li> <li>▪ Adverse events to be reported immediately to TGA and TCPC</li> </ul>	

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

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