

Change of use of Technology or Clinical Practice (TCP)

This screening tool is designed to inform the Southern Health Technology/Clinical Practice Committee (TCPC) of any changes of use to current TCPs and to identify potential risks for the patient, clinician and organisation as a result of the change. If risks of changing the use of the current TCP are considered high, the TCPC may request further information.

If you need assistance to complete any of the screening questions please contact:

Evidence of Effectiveness

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Coding

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Current Bed Utilisation and Financial Impact

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Credentialing and Scope of Practice

Julie Byrne (Medical Support Unit)
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Application Form							
Title of Technology/Clinical Practice		Paired Kidney Donation					
Program		Special Medicine			Department/Unit		Nephrology
Brief summary of change of use		In the setting where an otherwise suitable kidney donor is immunologically unsuitable for their intended kidney transplant recipient they may donate to a recipient for whom they are immunologically suitable in return for that recipient's donor's kidney.					
<input checked="" type="checkbox"/> New indication for current patient group		<input type="checkbox"/> New patient group		<input type="checkbox"/> Modification of equipment		<input type="checkbox"/> New operators/practitioners	<input type="checkbox"/> Other
Reason for change of use		<input type="checkbox"/> Safety		<input checked="" type="checkbox"/> Effectiveness		<input type="checkbox"/> Cost Effectiveness	
Brief summary of supporting evidence		National initiative by the Federal Government to increase kidney transplantation rates. Transplantation is known to increase patient survival and quality of life compared with dialysis for patients with end stage renal failure. This programme simply switches 2 donors who cannot for some reason donate to their intended recipient thereby allowing 2 transplant to proceed which would otherwise not. There is nothing new in the techniques to be followed for the transplant or follow-up care itself.					
Sites TCP is in current use		<input checked="" type="checkbox"/> Clayton	<input type="checkbox"/> Moorabbin	<input type="checkbox"/> Dandenong	<input type="checkbox"/> Casey	<input type="checkbox"/> Kingston	<input type="checkbox"/> Other
Sites where change of use applies		<input checked="" type="checkbox"/> Clayton	<input type="checkbox"/> Moorabbin	<input type="checkbox"/> Dandenong	<input type="checkbox"/> Casey	<input type="checkbox"/> Kingston	<input type="checkbox"/> Other
If change does not apply to all sites please explain why		Transplant only done at Clayton					
NO	YES						
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>1. Are there any conflicts of interest to declare that relate to this change of use? <i>(This includes any benefits received from groups that have a vested interest in the change of use proposed eg paid positions including invited lectures and membership of advisory panels; working parties or other groups for which honoraria or considerations in kind were received; shares and other commercial dealings; financial or other sponsorship of research; significant subsidies, whether partial or complete, for any travel, accommodation or entertainment; gifts of any kind greater than \$100 in value.) Please see the Southern Health Conflict of Interest Protocol.</i></p> <p><i>If Yes, please provide details.</i></p>					
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>2. Is there any reason to suspect increased harm to patients with the change of use? <i>(Consider side effects, contraindications and adverse events that might be different with the change of use)</i></p> <p><i>If Yes, please list reasons for suspected increase in harm to patients.</i></p>					
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>3. Are there any establishment costs related to the change of use?</p> <p><i>If Yes, please provide details of costs and how cost will be met. Costs to be approved by the relevant Executive Director.</i></p>					
<input checked="" type="checkbox"/>	<input type="checkbox"/>	<p>4. Will there be an increase in resource use and/or ongoing costs with the change of use? <i>(Consider staffing and salaries, administration, specialist medical practitioners, nursing, allied health, pharmacy, theatre, intensive care, imaging, pathology, special consumables, dietary supplements, outpatient services, organisational overheads.)</i></p> <p><i>If Yes, please compare current and future costs with details of the relevant items listed above and how the costs will be met. If there is an increase in resource use and/or ongoing costs to approval is required by the relevant Executive Director.</i></p> <p>There may be a minor increase in kidney transplant rate at MMC but would be expected to be at most 5 transplants a year. This</p>					

		number is within the normal variation for transplants per year and is not expected to require additional resources.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	5. Will the change of use impact on other clinical disciplines or services? (Consider items in question 4) <i>If Yes, please provide details of which clinical disciplines will be affected and how.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	6. Will the change of use require a new code? <i>If Yes, please provide the new code.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	7. Will any change to the current department/unit procedures list be required to incorporate the change of use? (ie for credentialing and scope of practice) <i>If Yes, please notify the appropriate Program Director</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	8. Do any staff require additional training and credentialing for the change of use? (Consider if credentialing and competency assurance is required by staff to ensure safe implementation) <i>If Yes, please list those persons who will be credentialed and how/where they will be trained.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	9. Will staff be required to change their practice for the change of use? (Consider if staff will be required to change their practice, are there anticipated barriers associated with this, will staff require further education, will the change of use require a dissemination and implementation program?) <i>If Yes, please provide details of your plan for implementation across all relevant sites.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	10. Will any relevant, previously eligible patients not have access to the change of use? (Consider whether the patient group currently accessing the TCP will still have access to it when the change is introduced) <i>If Yes, please provide details of which patients will not have access and why.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	11. Are there any ethical issues to be considered with the change of use? <i>If Yes, please describe ethical issues to be considered.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	12. Are there any legislative or regulatory requirements related to the change of use? (Consider TGA approval, Australian Standards, Professional body requirements, prescribing legislations, etc.) <i>If Yes, please describe legislative and regulatory requirement related to change of use.</i>
<input checked="" type="checkbox"/>	<input type="checkbox"/>	13. Does this TCP have a radiation source? <i>If Yes, please confirm that it complies with the Southern Health licensing agreement</i>
<input type="checkbox"/>	<input checked="" type="checkbox"/>	14. Do the current patient information materials require amendment for the change of use? (Consider if specific risks arising from the proposed change of use have been included and patients explicitly informed.) <i>If Yes, please verify that amendments have been made.</i> A specific patient information sheet and consent form have been generated and is attached
<input checked="" type="checkbox"/>	<input type="checkbox"/>	15. Are there any additional risks to patients, staff or the organisation due to this change of use? (Consider injury, damage to reputation, financial and legal implications.) <i>If Yes, please describe potential risks to patients, staff or the organisation.</i>
		16. Additional Comments Please see detailed attachment on the programme
Name of Head of Department/Unit		Professor Peter Kerr
Name of appropriate Executive Director (Acute, Continuing Care or Mental Health, Medical Services and Quality)		Dr Wayne Ramsey
<input checked="" type="checkbox"/>	I declare that the Head of Department has received and approved a copy of this completed application	Date 11/01/2010
<input checked="" type="checkbox"/>	I declare that the appropriate Executive Director has approved any expenses or additional use of Southern Health resources that arise from the change of use of this TCP (as outlined in this application)	Date 11/01/2010
Applicant Name	Dr William Mulley	Position Nephrologist
Phone	9594 3518	Fax 9594 6530
		Email bill.mulley@southernhealth.org.au

Please complete both the application (above) and evaluation (below) forms and submit electronically to:

Richard Nasra at richard.nasra@southernhealth.org.au

Decision

Approved Approved with conditions (*see below*) Not Approved

Conditions of Approval

- *That existing renal / renal transplant policies and procedures are expanded to include the procedure for paired kidney exchange*
- *That all necessary adaptations are made to the consent policy to incorporate PKE*

Approval is granted subject to any conditions outlined above. Implementation of the change should not commence until all conditions are met.

Please forward confirmation that the conditions have been met to Richard Nasra at richard.nasra@southernhealth.org.au by <insert date>.

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

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

DECISION SUMMARY: COU10_PROSIMA PELVIC FLOOR REPAIR SYSTEM

Summary of decisions made regarding change of use of Technology or Clinical Practice (TCP) in 2010

The tool for change of use applications was designed to inform the Southern Health Technology/Clinical Practice Committee (TCPC) of any changes of use to current TCPs and to identify potential risks for the patient, clinician or organisation as a result of the change.

Based on the information provided by clinicians, this document provides a summary of the decisions made by the TCPC for a change of use application.

Title	Prosima Pelvic Floor Repair system (Johnson & Johnson) - anterior, posterior, combined				
Program	Women's and Children's health	Department/Unit	Urogynaecology	Reviewed by TCPC	09/07/2010
Brief summary of change of use	This mesh reinforced kit used for pelvic organ prolapse surgery (for recurrent vaginal prolapse) is an improvement of currently used anchored kits by removing the need to deploy mesh arms via external trochars. The same monofilament polypropylene mesh is used and approximated to the same ligamentous structures in a tension free manner. The Prosima systems also come with a vaginal support device (akin to a vaginal support pessary) with an inflatable balloon. The vaginal support device together with the inflatable balloon negates the need for a vaginal pack. More importantly, the vaginal support device provides optimal reinforcement to allow the mesh incorporation.				
<input type="checkbox"/> New indication for current patient group	<input type="checkbox"/> New patient group	<input checked="" type="checkbox"/> Modification of equipment	<input type="checkbox"/> New operators/practitioners	<input type="checkbox"/> Other	
Reason for change of use	<input checked="" type="checkbox"/> Safety	<input type="checkbox"/> Effectiveness	<input type="checkbox"/> Cost Effectiveness		
Decision					
<input checked="" type="checkbox"/> Approved		<input type="checkbox"/> Approved with conditions (<i>see below</i>)		<input type="checkbox"/> Not Approved	
Conditions of Approval					
<ul style="list-style-type: none"> ▪ Nil 					

SH Policy Reviewer	Quality and Risk Management Director, Centre for Clinical Effectiveness	ACHS Last review date	Leadership and Management October 2009
Authoriser	Chair, Technology/Clinical Practice Committee	Next review date	October 2011

DECISION SUMMARY: COU11_PINNACLE PELVIC FLOOR REPAIR SYSTEM (UPHOLD, CAPIO)

Summary of decisions made regarding change of use of Technology or Clinical Practice (TCP) in 2010

The tool for change of use applications was designed to inform the Southern Health Technology/Clinical Practice Committee (TCPC) of any changes of use to current TCPs and to identify potential risks for the patient, clinician or organisation as a result of the change.

Based on the information provided by clinicians, this document provides a summary of the decisions made by the TCPC for a change of use application.

Title	Pinnacle Pelvic Floor Repair system (Uphold, Capiro) – (Boston Scientific)				
Program	Woman's and Children's Health	Department/Unit	Urogynaecology	Reviewed by TCPC	09/07/2010
Brief summary of change of use	<p>This mesh reinforced kit is used for pelvic organ prolapse surgery (for recurrent vaginal prolapse) is an improvement of currently used anchored kits by removing the need to deploy mesh arms via external trochars. The same monofilament polypropylene mesh is used and anchored to the same ligamentous structures via a (Capiro) suture capture device. The Pinnacle systems comprise of Pinnacle Anterior/Apical, Pinnacle Posterior, Uphold (this is exactly the same system as Pinnacle Anterior/Apical, except it has a smaller amount of mesh with only 2 instead of 4 arms, suitable for apical prolapse). All systems comes with the Capiro device, which is a suture capture device incorporated within the Pinnacle/Uphold systems. Capiro is also a stand alone device. The Mya Hook is a much larger instrument which requires greater dissection to reach the sacrospinous ligament; further, it is no longer manufactured.</p>				
<input type="checkbox"/> New indication for current patient group	<input type="checkbox"/> New patient group	<input checked="" type="checkbox"/> Modification of equipment	<input type="checkbox"/> New operators/practitioners	<input type="checkbox"/> Other	
Reason for change of use	<input checked="" type="checkbox"/> Safety	<input type="checkbox"/> Effectiveness	<input type="checkbox"/> Cost Effectiveness		
Decision					
<input checked="" type="checkbox"/> Approved		<input type="checkbox"/> Approved with conditions (see below)		<input type="checkbox"/> Not Approved	
Conditions of Approval					
<ul style="list-style-type: none"> ▪ Nil 					

SH Policy Reviewer	Quality and Risk Management Director, Centre for Clinical Effectiveness	ACHS Last review date	Leadership and Management October 2009
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DRAFT

Decision Summary

Meeting Date	12 November 2010		
Application #	COU12		
Title of TCP	tension free vaginal tape TVT (Exact, Abbrevo) , Bulkamid – (Johnson & Johnson)		
Nature of Change of Use	<input type="checkbox"/> New indication	<input type="checkbox"/> Extension of current use	<input type="checkbox"/> Increased Scope
Modification of instrument			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
Committee	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
SAFETY			
<input type="checkbox"/> Safer than current practice	<input checked="" type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice	
EFFECTIVENESS			
High quality evidence?	No		
Consistent, clinically important benefit?	<p>TVT-Exacto: has a disposable handle which is also slimmer and therefore easier to use. The tape will be cut with a laser instead of a cold cut.</p> <p>TVT-Abbrevo: has a different delivery system which avoids a groin incision and therefore there is less post operative groin pain for the patient. The handle is also disposable.</p> <p>Both devices are cost neutral, have no additional risks as compared to the current gold standard and have no additional training or credentialing requirements.</p> <p>Bulkamid: Short term studies show that it is effective, and has low complications particularly infection and migration. There are no additional training requirements for the surgeons.</p>		
Applicable to Southern Health?	yes		
COST			
Cost Neutral			
CLINICAL FEASIBILITY			
Resource implications	<p>No resource implications.</p> <p>Bulkamid is considerably cheaper than the alternative bulking agent, microplastic.</p>		
Credentialing and competency assurance undertaken	No additional credentialing requirements. Minor change in delivery system for a established technology.		
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
No issues with change of use			
Final decision by the Southern Health Technology/Clinical Practice Committee			
<input checked="" type="checkbox"/>	Recommended: Approved with no further need for assessment.		

<input 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 type="checkbox"/>	Restricted Approval – Operational Restrictions: Endorsed, however financial or operational restrictions apply.
<input type="checkbox"/>	Not Recommended
Conditions	
<ul style="list-style-type: none"> ▪ Nil 	

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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Decision Summary

Meeting Date	12 November 2010		
Application #	COU13		
Title of TCP	MiniArc Precise (American Medical Systems)		
Nature of Change of Use	<input type="checkbox"/> New indication	<input type="checkbox"/> Extension of current use	<input type="checkbox"/> Increased Scope
<input checked="" type="checkbox"/> Modification of instrument			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
Committee	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		
SAFETY			
<input type="checkbox"/> Safer than current practice		<input checked="" type="checkbox"/> Equivalent to current practice	<input type="checkbox"/> Less safe than current practice
EFFECTIVENESS			
High quality evidence?	No		
Consistent, clinically important benefit?	The safety profile and cost are similar to the older version of Miniarc. Older version is likely to be phased out in time.		
Applicable to Southern Health?	yes		
COST			
Cost Neutral			
CLINICAL FEASIBILITY			
Resource implications	No resource implications.		
Credentialing and competency assurance undertaken	No additional credentialing requirements. Minor change in delivery system for a established technology.		
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
No issues with change of use			
Final decision by the Southern Health Technology/Clinical Practice Committee			
<input checked="" type="checkbox"/>	Recommended: Approved with no further need for assessment.		
<input 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 type="checkbox"/>	Restricted Approval – Operational Restrictions: Endorsed, however financial or operational restrictions apply.		
<input type="checkbox"/>	Not Recommended		
Conditions			
▪ Nil			

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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