

Decision Summary

Meeting Date	Friday 6 November 2009		
Application #	09009V		
Title of TCP	Low Frequency Ultrasonic Debridement (Sonoca 185)		
<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>Low Frequency Ultrasound Debridement (LFUD) provided by the Sonoca 185 is a new method of debriding wounds that is less traumatic, less painful, and can achieve faster healing rates (mean 2.5 times faster than theatre sharps in prospective randomised trials). It is bactericidal and enables many debridement cases to be performed by nursing or allied health practitioners (e.g. wound consultant, podiatrist), in a less resource intensive setting (e.g. bed-side or in outpatient clinic) rather than by a surgeon in theatre. HealthPACT evidence review concluded LFUD delivered via Sonoca was superior to existing care.</p>			
CONFLICT OF INTEREST DECLARATION			
Applicant	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	No conflicts of interest to declare	
Committee	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	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	
Decreased incidence of bleeding, tissue damage, infection and risks from general anaesthetic			
EFFECTIVENESS			
High quality evidence?	One RCT and other comparative studies provided		
Consistent, clinically important benefit?	Yes – clinically and statistically significant benefits over current practice		
Applicable to Southern Health?	Yes		
Increases the number of wounds totally healed, time to healing, response in recalcitrant wounds. Also decreases pain and length of stay for the patient.			
COST			
Purchase of the equipment requires external funding. Cost of delivering service is less than current practice.			
CLINICAL FEASIBILITY			
Resource implications	Requires additional EFT to backfill current Southern Health staff who will train to deliver this service. Patients are currently inpatients or attending out-patient services so no additional beds or clinic time is required.		
Credentialing and competency assurance undertaken	<p>Credentialing criteria:</p> <ol style="list-style-type: none"> 1. Experience of advanced wound management 2. Appropriate base level of clinical experience (Wound CNC or podiatry degree) 3. Knowledge of the anatomy concerned rated by wound depth and location. <ol style="list-style-type: none"> a. Depth: E.g. Wagners, Stage of pressure ulcer b. Location: Leg, sacrum, abdomen, other c. Type: Pressure ulcers, leg ulcers, dehisced wounds, other. 4. Analgesia. Trained in the analgesia protocol for that site and understand the contraindications/indications of the analgesia strategy in use. <p>The first 10 debridements are performed under supervision. After 50 debridements the user is fully credentialed within the scope of practice defined by wound location, depth and type. Initial training at Southern Health will be provided by experts in the field.</p>		
ISSUES RELATED TO ACCESS & EQUITY AND LEGAL & ETHICAL IMPLICATIONS			
All relevant Southern Health patients will have access to the treatment.			

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 <p>b. Adverse Events</p> <ul style="list-style-type: none"> ▪ If an adverse event occurs the Head of Department/Unit must immediately notify the TGA in addition to the TCPC. <p>c. Compliance with Quality Assurance (<i>must be completed prior to commencement of the TCP at Southern Health</i>)</p> <ul style="list-style-type: none"> ▪ 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 <p>d. Data Collection</p> <ul style="list-style-type: none"> ▪ 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. <p>e. Reporting</p> <ul style="list-style-type: none"> ▪ Patient outcome reporting required at three monthly intervals; January – March, April – June, July – September, October – December; for a two year period. ▪ Progress reports required only 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. <p>f. Review</p> <ul style="list-style-type: none"> ▪ At the conclusion of the two year period the TCP will be reviewed to determine if it should be considered standard practice or if further monitoring is required. 	
Special Conditions	
<p>g. Operational Restrictions</p> <ul style="list-style-type: none"> ▪ Approval of this TCP is subject to successful application for full funding. If only partial funding is received, applicants are required to notify the TCPC and the application will be reviewed prior to implementation. <p>h. Patient Information</p> <ul style="list-style-type: none"> ▪ Patient information must be submitted to the TCPC for review prior to commencement of the TCP 	