

APPENDIX 8 – OVERVIEW OF PROTOCOL AMENDMENTS

Amendment number	Details of significant alterations to protocol	Resulting protocol version and date
1	<ul style="list-style-type: none"> • Clarified various sections in the protocol • Altered the time window for a patient to consider trial entry • Updated flow charts • Clarified the use of suction and telephone follow ups. 	2.0 01/12/2012
2		
3	<ul style="list-style-type: none"> • Adjustments to the follow up visit windows • Administrative details were updated throughout the protocol. 	3.0 14/08/2013
4	<ul style="list-style-type: none"> • Change of time allowance between the randomisation and the study procedure from 24 to 72 hours • Minor admin changes and clarifications to the protocol. 	4.0 26/09/2013
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6	<ul style="list-style-type: none"> • Edited the safety reporting section of the protocol • Updated administrative details throughout the protocol • Added appendix 6 	5.0 01/06/2014
7	<ul style="list-style-type: none"> • Updated secondary endpoints following ratification of statistical analysis plan version 1.0 • Updated study end date • Updated trial recruitment centre and PI details • Minor clarifications 	6.0 06/10/2014