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RCB No. 200002150H

NHG DSRB Ref: **2015/00989**

02 June 2016

Dr Zhang Jinbin

Department of Anaesthesia

Tan Tock Seng Hospital

Dear Dr Zhang

NHG DOMAIN SPECIFIC REVIEW BOARD (DSRB) APPROVAL

STUDY TITLE: A randomised comparison of AMBU® AuraGainTM & LMA Supreme TM in patients undergoing laparoscopic surgery under general anaesthesia.

We are pleased to inform you that the NHG Domain Specific Review Board has approved the application as titled above to be conducted in **Tan Tock Seng Hospital**.

The approval period is from **02 June 2016** to **21 October 2016**.The NHG DSRB reference number for this study is **2015/00989**. Please use this reference number for all future correspondence.

Please note that clinical trials involving a Medicinal Product can only be initiated after a Clinical Trial Certificate has been issued or the Health Sciences Authority has given a written notification that a Clinical Trial Certificate is not required.

The documents reviewed are:

a) NHG DSRB Application Form: **Version No. 1**

b) AuraGain vs LMA Supreme in Laparoscopy Protocol: **Version 4.0 dated 20/05/2016**

c) Informed Consent Form: **Version 3.0 dated 05/01/2016**

d) Patient Information Sheet: **Version 1 dated 07/04/2016**

e) AuraGain vs LMA Supreme in Laparoscopy Data Collection Form: **Version 5.0 dated 29/09/2016**

f) AuraGain Product Brochure

g) AuraGain Information Sheet

h) LMA Supreme Product Brochure

The NHG DSRB acknowledges the receipt of the following documents:

i) Informed Consent Form Version 3.0 with Short Consent Form (Chinese): **Version dated 05/01/2016**

j) Informed Consent Form Version 3.0 with Short Consent Form (Malay): **Version dated 05/01/2016**

k) Informed Consent Form Version 3.0 with Short Consent Form (Tamil): **Version dated 05/01/2016**

Continued approval is conditional upon your compliance with the following requirements:

1. Only the approved Informed Consent Form should be used. It must be signed by each subject prior to initiation of any protocol procedures. In addition, each subject should be given a copy of the signed consent form.

2. No deviation from or changes to the study should be implemented without documented approval from the NHG DSRB, except where necessary to eliminate apparent immediate hazard(s) to the study subjects.

3. Any deviation from or changes to the study to eliminate an immediate hazard should be promptly reported to the NHG DSRB within seven calendar days.

4. Please note that for studies requiring Clinical Trial Certificate, apart from the approval from NHG DSRB, no deviation from, or changes of the Research Protocol and Informed Consent Form should be implemented without documented approval from the Health Sciences Authority unless otherwise advised by the Health Sciences Authority.

5. Please submit the following to the NHG DSRB:

a. All Unanticipated Problems Involving Risk To Subjects Or Others (UPIRTSOs) must be reported to the NHG DSRB. For more than minimal risk studies, all problems involving local deaths must be reported immediately within 24 hours after first knowledge by the Investigator, regardless of the causality and expectedness of the death. For no more than minimal risk studies, only problems involving local deaths that are related or possibly related to the study must be reported immediately within 24 hours after first knowledge by the

Investigator. All other problems that fulfil the UPIRTSOs reporting criteria must be reported as soon as possible but not later than seven calendar days after first knowledge by the Investigator

b. Report(s) on any new information that may adversely affect the safety of the subject or the conduct of the study.

c. NHG DSRB Study Status Report Form – this is to be submitted 4 to 6 weeks prior to expiry of the approval period. The study cannot continue beyond **21 October 2016** until approval is renewed by the NHG DSRB.

d. Study completion – this is to be submitted using the NHG DSRB Study Status Report Form within 4 to 6 weeks of study completion.

You are strongly encouraged, in consultation with your sponsor (where applicable), to register this trial with http://www.clinicaltrials.gov. The registration is free.

Established since May 2006, the NHG Research Quality Management (RQM) Program seeks to promote the responsible conduct of research in a research culture with high ethical standards, identify potential systemic weaknesses and make recommendations for continual improvement. Hence, this research study may be randomly selected for a review by the Research Quality Management (RQM) team. For more information, please visit www.research.nhg.com.sg.

The NHG DSRB operates in accordance to the ICH GCP, Singapore Guideline for Good Clinical Practice and all applicable laws and regulations.

Yours Sincerely

A/Prof Low Yin Peng

Chairman

NHG Domain Specific Review Board D

Cc: Institutional Representative, TTSH

c/o Clinical Research Unit, TTSH

Departmental Representative of Anaesthesia, TTSH

(This is an electronic-generated letter. No signature is required.)

NHG DSRB – DOMAIN D MEMBERSHIP LIST

(Term from April 2014 to March 2016) / Quorum for Domain: 5

STUDY TITLE: A randomised comparison of AMBU® AuraGainTM & LMA Supreme TM in patients undergoing laparoscopic surgery under general anaesthesia.

Date of the Meeting at which the application as titled above was reviewed: 22 October 2015

MEMBER'S NAME	PRIMARY SCIENTIFIC / NON-SCIENTIFIC SPECIALTY	INSTITUTION	MALE / FEMALE	PRESENT FOR THE MEETING
A/Prof Low Yin Peng (Chairman)	Orthopaedics	Tan Tock Seng Hospital	M	Yes
A	Obstetrics & Gynaecology	National University Hospital	M	No
B	Urology	National University Hospital	M	Yes
C	Orthopaedics	Mount Elizabeth Medical Centre	M	No
D	Rehabilitation	Alexandra Hospital	M	Yes
E	Orthopaedics	Mount Elizabeth Medical Centre	M	Yes
F	Anaesthesia	Khoo Teck Puat Hospital	M	No
G	Surgery	Khoo Teck Puat Hospital	M	No
H	General Surgery	Tan Tock Seng Hospital	M	Yes
I	Surgery	National University Hospital	M	Yes
J	Sociology	National University Singapore	F	Yes
K	Statistics and Applied Probability	National University Singapore	M	Yes
L	Quality Management	Khoo Teck Puat Hospital	F	Yes
M	Legal Studies	Tan Tock Seng Hospital	F	No

N	Business Policy	National University Singapore	F	No

The NHG DSRB operates in accordance to the ICH GCP, Singapore Guideline for Good Clinical Practice and all applicable laws and regulations. Please note that it is the NHG DSRB policy to not reveal the names of the members of the Board. Please be assured that members of the Board with any potential conflict of interest for a particular study abstained from decision making and voting for that study.