COMPARISON OF CLINICAL PERFORMANCE OF LMA PROTECTOR™ *CUFF PILOT*™ AND LMA SUPREME™ AMONG ANAESTHETISED, NON-PARALYSED PATIENTS

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PATIENT INFORMATION SHEET

Research Title:
Comparison of Clinical Performance of LMA Protector™ *Cuff Pilot*™ and LMA Supreme™ Among Anaesthetised, Non-Paralyzed Patients.

Introduction:
You are invited to participate in a research study. Before participating in this study, it is important that you take time to read and understand the information in this Information Sheet.

Purpose of Study:
The purpose of this study is to compare between two airway devices that will be used to provide oxygen to you during anaesthesia in terms of their performance and complications.

What will the study involve?
You are invited to participate as you are planned for general anaesthesia. You will receive our standard anaesthesia care and management like other patients. After you are unconscious, either one of the airway devices (LMA Protector™ Cuff Pilot™ or LMA Supreme™) will be inserted through your mouth to provide oxygen to your body. We will evaluate the time and ease of insertion the selected devices. Your operation will proceed as usual after that. At the end of operation, we will assess you again for presence of sore throat or hoarseness of voice.

Benefits:
The information obtained from this study will help us improve our management of other patients who will be undergoing general anaesthesia using similar airway device in the future.

Risks:
There is no extra risk to you as both the devices are safe, approved for use and bears the *Conformité Européene* (CE) Mark. Other general anaesthesia risks such as dizziness, nausea and vomiting are similar to patients not involved in this study.

Do you have to take part?
Participation in this study is voluntary. If you agree to take part, then you will be asked to sign the "Informed Consent Form". You will be given a copy of the form and this Information Sheet.

Your treatment is not affected if you decide not to participate in this study. You will undergo surgery under general anaesthesia as usual.

Should you decide to participate, you can still withdraw from the study without penalty. Your data will not be used and will be discarded. The researcher may also remove you from the study for a variety of reason. In this event, you will not be penalised or lose your rights as a patient.

Data & Confidentiality:
The data from this study will be made into a report, which may be published. Access to the data is only by the research team and the Research and Ethical Committee of Universiti Kebangsaan Malaysia. The data will be reported in a collective manner with no reference to an individual. Hence, your identity will be kept confidential.

Payment and compensation:
You do not have to pay nor will you be paid to participate in this study. You do have to pay for the usual hospital charges. Should you develop unanticipated complications related to the study, treatment will be given at no cost.

Who can I ask about the study?
If you have any questions, you can direct them to the research team as stated below. You can also contact the Research and Ethical Committee for clarifications.

Principal Investigator: Dr Chan Weng Ken
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INFORMED CONSENT FORM

Research Title: Comparison of Clinical Performance of LMA Protector™ *Cuff Pilot*™ and LMA Supreme™ Among Anaesthetised, Non-Paralyzed Patients.

Researcher's Name: Dr Chan Weng Ken

Supervisor's Name: Dr Liu Chian Yong

I, _____,

I.C. No.: _____,

- have read the information in the Participant Information Sheet **including information regarding the risk in this study**
- have been given time to think about it and all of my questions have been answered to my satisfaction.
- understand that I may freely choose to withdraw from this study at anytime without reason and without repercussion
- understand that my anonymity will be ensured in the write-up.

I voluntarily agree to be part of this research study, to follow the study procedures, and to provide necessary information to the doctor, nurses, or other staff members, as requested.

…….
(Signature)

……..
(Date)

……. Witness (if any)	……. Researcher
……. (Signature)	……. (Signature)
……. (IC Number)	……. (IC Number)
……..… (Date)	……. (Date)