

Investigation of the feasibility of an articulated
laparoscopic camera system - Precision Robotics' Sirius
Robotic Flexible Endoscopic System in gynaecological
laparoscopic surgery

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Study on Precision Robotics' Sirius Robotic Flexible Endoscopic System in Gynaecological Laparoscopic Surgery

Information Sheet and Consent

What is the Sirius Robotic Flexible Endoscopic System?

- Precision Robotics' Sirius Robotic Flexible Endoscopic System is a fully integrated compact 3D laparoscopic camera system with a flexible robotic tip that can change its viewing direction.
- The articulated tip has three degrees of freedom enabling C and S-shaped bending providing a wider field of view compared to conventional laparoscopes.
- This flexibility and wider field of view can potentially help gynaecological laparoscopic surgeons perform their surgery better, especially for advanced laparoscopic procedures such as Single Incision Laparoscopic Surgery(SILS) and Vaginal Natural Orifice Transluminal Surgery(vNOTEs).
- The Sirius Robotic Flexible Endoscopic System has completed all preclinical testing as well as safety checks.
- Clinical trials are in progress and GHK has been selected as one of the centres for clinical trials in Hong Kong.

Aim of the Study

- To assess the safety, reliability and efficacy of an articulated laparoscopic camera system - Precision Robotics' Sirius Robotic Flexible Endoscopic System in gynaecological laparoscopic surgery particularly for Single Incision Laparoscopic Surgery(SILS) and Vaginal Natural Orifice Transluminal Endoscopy(vNOTEs).
- The aim of this clinical trial is to assess if the Sirius Robotic Flexible Endoscopic System can replace the conventional endoscope in gynaecological laparoscopic procedures.
- The only difference in the laparoscopic procedure is the replacement of the conventional endoscope by the Sirius Robotic Flexible Endoscopic System. All other instruments and procedures remain the same.

Participation in the trial

- As you are about to undergo a laparoscopic gynaecological procedure, you have been invited to participate in the trial.
- Photographic and/or video images may be taken during the operation for education/ research/ documentation purpose. Your name and ID number will not be recorded and so your identity will not be disclosed. Please inform the staff if you have any objection.
- Participation in the trial is voluntary, and your laparoscopic surgery will be done in the usual manner with a conventional endoscope should you choose not to participate in the trial.

- The Sirius Robotic Flexible Endoscopic System will be used during the laparoscopic procedure, and the conventional endoscope will be on standby to replace it if necessary, for example in the unlikely event of a failure of the Sirius Robotic Flexible Endoscopic System to work. Your safety is always our priority.

Risk and complication of the procedure may include, but are not limited to the following

- There is no anticipated additional risk for your laparoscopic surgery.
- In the unlikely event of an equipment failure of the Sirius Robotic Flexible Endoscopic System, a conventional endoscope is always on standby to replace it without delay.

I acknowledge that the above information concerning my operation/procedure have been explained to me and discussed with me by the medical staff and I fully understand them. I have been given the opportunity to ask questions pertinent to my condition and management and satisfactory answers have been provided by medical staff.

I agree/disagree to participate in this trial.

Signature: _____

Date: _____