Flexible Endoscope at Point of Care

A mobile, re-usable and flexible hysteroscope at point of care

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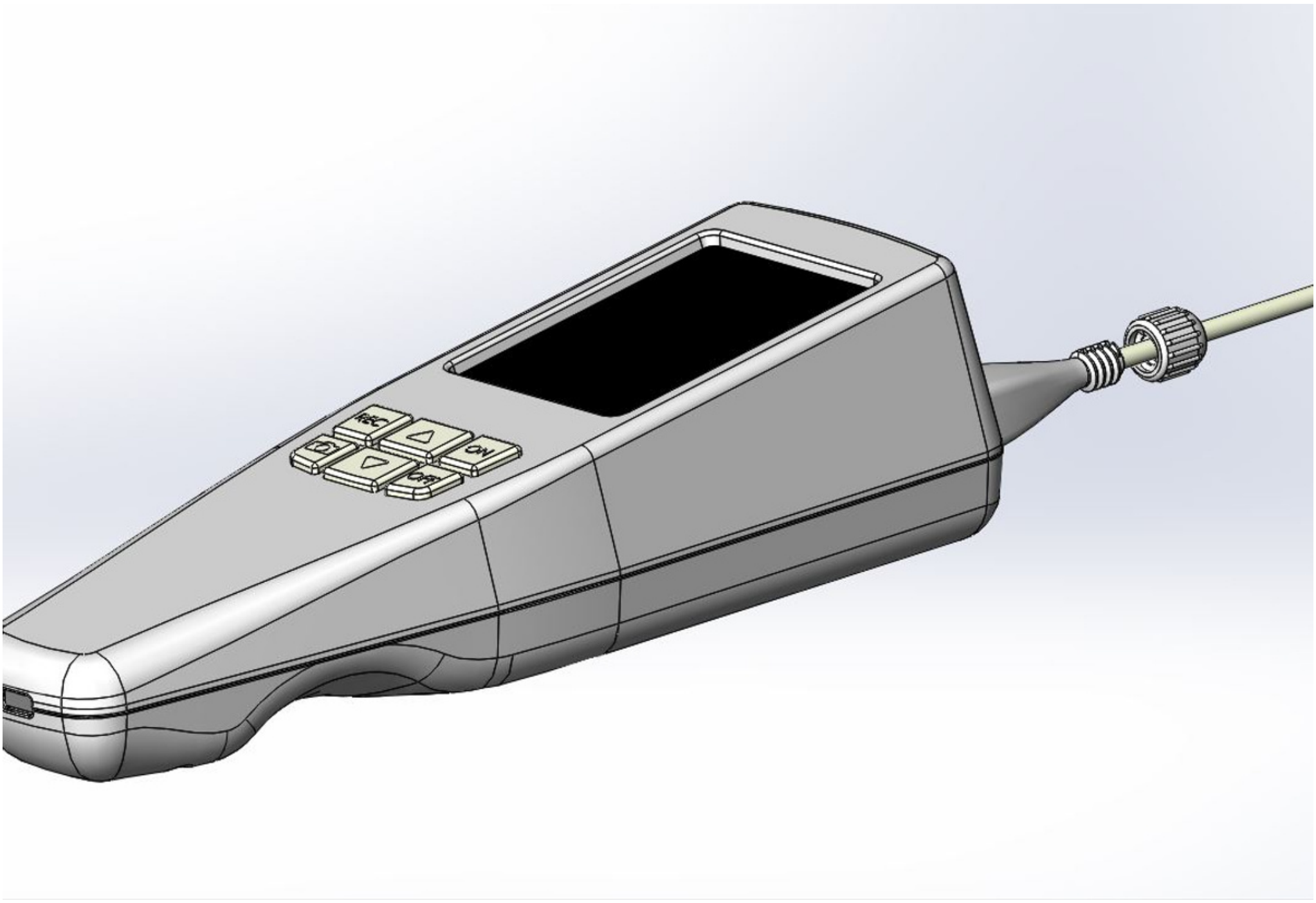

Image provided by university

Background

Hysteroscopy is a procedure that requires the direct visualization of the uterine cavity to diagnose and treat abnormal uterine conditions. Health professionals regard it as the gold- standard for diagnosis because of its effectiveness and efficiency.

Traditional hysteroscopy systems, and the equipment required for its use, can be expensive and inaccessible for Global Health needs. Furthermore, these systems employ rigid hysteroscope tips that can cause patient discomfort, often leading to the need for general anesthesia. This in turn limits the procedures to the operating theatre and adds to waiting time delays.

These limitations coupled with bulky and fragile equipment result in an immobile system only available in a tertiary healthcare facility, requiring highly skilled professionals.

Market trends also favor minimally invasive devices that enhance the patient experience and enable the broader use of technology other than traditional users.

Technology Overview

The University of Cape Town's solution is a reusable mobile hysteroscopy system for application at the point of care. The University's Medical Devices Laboratory has worked with some of the best gynecologists in South Africa to understand their challenges and to co-design the solution with their constraints in mind.

The result is the FlexiGyn device which provides for single-handed operation and its ease of use broadens the scope for health professionals, including nurses, who could operate it.

FlexiGyn is a system that consists of a handheld control base and a flexible rod. A built-in CMOS camera and LED light source are located at the distal end of the flexible rod. The flexible rod can bend up to 180° in 4 directions through user-controlled input via its novel smart bending system which is powered by a rechargeable battery. The results is a system with controlled flexibility that ensures maximum patient comfort.

The system integrates with a smartphone or a tablet for visualization, which also enables the user to save any videos or images.

A final part of the system is a sterile disposable sheath that covers the flexible rod and isolates it from patient contact, eliminating the need for intensive sterilization after use. The sheath also has two working channels, one for distention media and the other for insertion of operative instruments. A significant benefit of the device is its application both inside and outside of the operating theater without the need for general anesthesia. This is made possible through the device's small diameter and inherent flexibility.

The system also offers incredible mobility because of its single-handed operation, is operated from battery, it has a built-in camera and light source, and integrates with a smartphone or tablet.

Stage of Development

The inventors have a working prototype which has been demonstrated on test dummies. The user experience has also been validated by experienced gynecologists and urinary gynecology specialists.

The synthetic, sterile sheath cover is under development and proof of concept will be attained in 12 to 18 months.

Benefits

The benefits of the FlexGyn system include:

- The 180 degree, 4-directional distal end overcomes the rigidity of similar systems, improving the patient experience during hysteroscopy procedures. Watch a demonstration video here:

- The single-handed operation gives healthcare professionals the freedom of movement.
- The built-in CMOS camera and light source on the distal end aides the image quality and visualization of the patient's uterine cavity.
- The customized sheath design reduces the need for extensive sterilization of the FlexiGyn body.
- The system is mobile, robust and designed for resource-limiting settings. This does not however limit its potential use in Doctor's rooms world-wide.

Applications

The primary area of application is in the female genital tract.

Potential users include gynecologists, senior nurses and urologists.

The technology that encompasses the highly flexible rod could however be translated to other gastro-intestinal scopes and other endoscopic devices.

Opportunity

UCT is looking for a development partner established in, or would like to branch into the field of flexible and mobile endoscopic devices.

The ideal partner will have:

- an understanding of the endoscopy market, its drivers, access to supply chain and support network for the commercialization and implementation.
- the requisite manufacturing capability according ISO 13485 standards, or equivalent.
- access to capital to complete the next stage of development with UCT as a partner.

UCT would like to enter into an Option Agreement with a partner at this exploratory stage which will provide access to a commercial license, following the development and evaluation phase.

UCT's inventors will also avail themselves during the development stage to facilitate the technology transfer.

Patents

- UK provisional: 1803497.5
- European regional patent application: 19160859.5
- US patent application: 16/292,650
- South African patent: 2019/01364

IP Status

- Patent application submitted
- Provisional patent

Seeking

- Development partner
- Commercial partner
- Licensing
- Seeking investment