
Hologic Receives Health Canada Medical Device License for Three-in-One Omni Hysteroscope



Flexible, modular design with powerful visualisation gives doctors a single device with three sheath options to both diagnose and treat patients

MARLBOROUGH, Mass., March 4, 2019 -- Hologic, Inc. (Nasdaq: HOLX) announced today that Health Canada has issued a medical device license for its [Omni™ hysteroscope](#), an innovative three-in-one modular scope with advanced visualization capabilities designed for both diagnostic and therapeutic hysteroscopic procedures. Gynaecologists can use the new Omni hysteroscope in out- and in-patient settings.

“Experts agree that direct visualization of the uterine cavity in women with abnormal uterine bleeding is the gold standard that allows gynaecologists to accurately identify and collect quality samples and remove pathology – in a safer and more effective manner than blind biopsy and curettage,”¹ said Edward Evantash, M.D., Medical Director and Vice President of Global Medical Affairs, Hologic. “Featuring three easily interchangeable sheaths in one scope, our new Omni scope gives gynaecologists excellent visualization capabilities with the convenience of seeing and treating pathology in a more streamlined procedure.”

The Omni scope is designed to help gynaecologists simplify the process of diagnosing and treating patients. Often, a surgeon requires a diagnostic scope to look in the uterine cavity for fibroids or polyps, then switches to an operative scope to biopsy or treat the pathology. With the new Omni scope, gynaecologists can use the same scope with different sheath options to conveniently see and treat pathology.²

Additional features include:²

- Premium MyoSure optics for quality visualisation and clarity throughout the procedure.
- Sheaths designed with smaller diameters (3.7 mm diagnostic sheath; 5.5 mm operative sheath; 6 mm operative sheath) to reduce dilation required and promote patient comfort and easy insertion.
- Long 200 mm working length facilitates easier access and treatment for obese patients.
- Simple assembly and disassembly so sheaths can be changed out easily between procedures.
- Operative sheaths can be used with Hologic's Aquilex™ hysteroscopic fluid management system.
- Compatible with all [MyoSure®](#) tissue removal offerings including MyoSure REACH, MyoSure XL, MyoSure LITE, and MyoSure MANUAL devices.

“We continue to drive innovation designed with both our customers and the women they treat in mind,” said Jan Verstreken, Regional President, EMEA and Canada, Hologic. “Our customers are under pressure to deliver high-quality care to their patients in innovative ways. Our new Omni Hysteroscope provides them with a pioneering device that can treat a diverse range of patients.”

Important Safety Information

The Omni™ hysteroscope is intended to provide viewing of the cervical canal and uterine cavity for the purpose of performing diagnostic and operative procedures. The Omni hysteroscope is not appropriate for patients who are exhibiting acute pelvic inflammatory disease or exhibit the

following conditions: inability to distend uterus, cervical stenosis, cervical/vaginal infection, uterine bleeding or menses, invasive carcinoma of the cervix, recent uterine perforation, medical contraindications, or intolerance to anesthesia. For detailed benefit and risk information, please consult the Instructions for Use.

References:

1. Salim S, et al. Diagnosis and Management of Endometrial Polyps: A Critical Review of the Literature. J Minim Invasive Gynecol, 2011;18(5):569-581

2. Omni hysteroscope Instruction for Use. October 2018.

Source: Hologic, Inc.

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