

## Hologic Receives CE Mark for Three-in-One Omni Hysteroscope in Europe

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

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) announced today that it has received a CE mark in Europe for its **Omni™ hysteroscope**, an innovative three-in-one modular scope with advanced visualization capabilities designed for both diagnostic and therapeutic hysteroscopic procedures. Obstetricians and gynecologists (ObGyns) can use the new Omni hysteroscope in out- and in-patient settings.

This press release features multimedia. View the full release here:  
<https://www.businesswire.com/news/home/20190304005177/en/>

Omni™ hysteroscope (Graphic: Business Wire)

“Experts agree that direct visualization of the uterine cavity

in women with abnormal uterine bleeding is the gold standard that allows ObGyns to accurately identify and collect quality samples and remove pathology – in a safer and more effective manner than blind biopsy and curettage,”<sup>1</sup> 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 ObGyns excellent visualization capabilities with the convenience of seeing and treating pathology in a more streamlined procedure.”

The Omni scope is designed to help ObGyns 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, ObGyns can use the same scope with different sheath options to conveniently see and treat pathology.<sup>2</sup>

Additional features include:

- Premium MyoSure optics for quality visualization 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."

## About Hologic

Hologic, Inc. is an innovative medical technology company primarily focused on improving women's health and well-being through early detection and treatment. For more information on Hologic, visit [www.hologic.com](http://www.hologic.com).

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## 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**.

## Forward-Looking Statements

This news release may contain forward-looking information that involves risks and uncertainties, including statements about the use of Hologic products. There can be no assurance these products will achieve the benefits described herein or that such benefits will be replicated in any particular manner with respect to an individual patient, as the actual effect of the use of the products can only be determined on a case-by-case basis. In addition, there can be no assurance that these products will be commercially successful or achieve any expected level of sales. Hologic expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any such statements presented herein to reflect any change in expectations or any change in events, conditions or circumstances on which any such data or statements are based.

This information is not intended as a product solicitation or promotion where such activities are prohibited. For specific information on what products are available for sale in a particular country, please contact a local Hologic sales representative or write to **womenshealth@hologic.com**.

## References:

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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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