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Hologic Launches Definity Cervical Dilator to Provide Gentle and Seamless Dilation During Gynecologic Procedures

November 4, 2019

Physicians can now access a wide variety of uterine cavities effortlessly with innovative SureAccess balloon technology

MARLBOROUGH, Mass.--(BUSINESS WIRE)-- Hologic, Inc. (Nasdaq: HOLX) has launched the Definity™ cervical dilator, a major advancement for gynecological procedures that uses SureAccess™ balloon technology to gently and effortlessly access uterine cavities without a tenaculum, lessening patient discomfort and reducing risk of perforation during dilation.¹⁻³

This press release features multimedia. View the full release here: <https://www.businesswire.com/news/home/20191104005748/en/>



Definity cervical dilator (Photo: Business Wire)

"Physicians have been relying on dilation technology that is mostly unchanged from the original cervical dilator invented in 1879," said Lucas Churchill, Vice President of Research & Development, GYN Surgical Solutions, Hologic. "We're committed to identifying unmet needs of our customers and are proud to deliver significant advancements to one of the most commonly used devices in gynecology. In addition, the Definity dilator is a great example of our ability to leverage strategic partnerships to deliver technological innovations that advance women's health."

Using SureAccess balloon technology,¹ the Definity dilator is designed to eliminate multiple passes and minimize false tracking, reducing injury to the cervix,^{2, 3} even in patients with complex or challenging cervical anatomy.

"Physicians frequently encounter variable cervical anatomy, which can create risk and increase discomfort for patients and time delay with procedures," said Edward Evantash, M.D., Medical Director and Vice

President of Global Medical Affairs, Hologic. "The Definity dilator is an innovative alternative to fixed size dilators for a range of intrauterine procedures. This gives physicians more confidence in the dilation process so they can focus on their procedures, not accessing the cavity."

The Definity dilator is commercially available in the U.S. and comes in multiple sizes (5 mm, 7 mm and 9 mm) to accommodate a wide variety of procedures. The product was developed in partnership with CrossBay Medical, Inc., and will be featured along with other devices in the Hologic suite of surgical solutions during the American Association of Gynecologic Laparoscopists (AAGL) annual meeting from Friday, November 8 to Wednesday, November 13 at booth #913. For more information on the product, visit www.GYNSurgicalSolutions.com/Definity.

About Hologic, Inc.

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.

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IMPORTANT SAFETY INFORMATION

The Definity™ cervical dilator catheter system is intended to be used whenever cervical softening and dilation is desired. Some examples are: treatment of cervical stenosis, IUD placement and removal, placement of instruments for intrauterine radiotherapy, endometrial biopsy, global endometrial ablation, uterine tissue removal, uterine curettage, diagnostic hysteroscopy, operative hysteroscopy. This device is not intended for use in the induction of labor. Use of the Definity cervical dilator catheter system is contraindicated in patients with: an active genital tract infection such as genital herpes, pelvic structure abnormality that prevents passage of the device, or invasive cervical cancer. This device is also contraindicated for the induction of labor. 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.

SOURCE: Hologic, Inc.

References:

¹ Hologic Data on File. VER-09559. Bench test utilizing 2.4mm model.

² Definity IFU, 2019.

³ As compared to fixed dilators.

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