Investor Relations | Hologic

Hologic Receives CE Mark for MyoSure® MANUAL Device in Europe

--Designed to Simplify Intrauterine Tissue Removal In Theater and In-Office--

MARLBOROUGH, Massachusetts, Jan. 3, 2018 /PRNewswire/ -- Hologic, Inc. (Nasdaq: HOLX) announced today that the MyoSure® MANUAL device, which was designed to simplify tissue removal procedures regardless of setting, has received CE mark in Europe. The MyoSure MANUAL device joins the MyoSure suite of gynecologic surgical products that offer simple and effective solutions to resect and remove tissue.

Hologic offers the complete MyoSure system, which is a minimally invasive hysteroscopic treatment for women with problematic tissue that requires no cauterization, ultimately preserving uterine form and function. The system enables quick and convenient removal of tissue, including a range of fibroids and polyps that may be the root cause of abnormal uterine bleeding (AUB), which affects up to 30% of pre-menopausal women.[1]

"There is an increased demand to simplify tissue removal procedures regardless of where they are being performed, in-office or in the theater. We continuously look to meet this need by developing innovative solutions that provide flexibility and convenience for both physicians and patients in any setting," said Edward Evantash, M.D., Medical Director and Vice President of Medical Affairs, Hologic. "The MyoSure MANUAL device is designed to simplify tissue removal procedures in theatre, ambulatory or outpatient settings, requiring minimal set up and no fluid management capital equipment, while offering direct visualization when used with the MyoSure hysteroscope."

The MyoSure MANUAL device has a fully integrated vacuum with no external suction required. It involves the support of a one-liter saline bag – there is no need for a controller or additional fluid management capital equipment. The clear tissue trap allows visual confirmation of tissue removed during the procedure and holds up to 4g of tissue; it also detaches to send to pathology. In addition, the MyoSure MANUAL device gives physicians multi-function control of the 360° blade. Other devices in the MyoSure suite of products include the MyoSure®, MyoSure® REACH, MyoSure® XL, and MyoSure® LITE devices.

"The MyoSure MANUAL device is an exciting addition to our growing portfolio of gynecologic solutions in Europe, all of which have been developed with the patient and physician in mind," said Jan Verstreken, Hologic's President, EMEA & Canada. "This new device expands our MyoSure suite of products, which provide solutions for a wide range of pathologies. It indicates our ongoing commitment to meeting our customers' needs and improving their patients' experience by offering solutions that are effective and convenient."

For more information about the MyoSure MANUAL device, please visit www.myosure.com/manual. For women looking for more information on abnormal uterine bleeding, visit www.wearwhiteagain.co.uk.

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.

Important Safety Information

The MyoSure MANUAL tissue removal device is intended for hysteroscopic intrauterine procedures by trained gynecologists to resect and remove tissue. The MyoSure MANUAL tissue removal device should not be used in a patient who is pregnant or suspects pregnancy, has clinical evidence of an active pelvic infection or history of a recent pelvic infection, or has cervical malignancies or previously diagnosed uterine cancer.

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.

Media Contact:
Jane Mazur
+1 508.263.8764 (direct)
+1 585.355.5978 (mobile)
jane.mazur@hologic.com

Investor Contact:
Michael Watts
+1 858.410.8588
Michael.watts@hologic.com

References

1. Committee on Practice Bulletins—Gynecology. Practice bulletin no. 128: diagnosis of abnormal uterine bleeding in reproductive-aged women. *Obstet Gynecol.* 2012;120:197-206. doi: 10.1097/AOG.0b013e318262e320

Photo - http://mma.prnewswire.com/media/623963/Hologic_Myosure_Manual.jpg

---

Additional assets available online: Photos (1)

http://investors.hologic.com/2018-01-03-Hologic-Receives-CE-Mark-for-MyoSure-R-MANUAL-Device-in-Europe