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Hologic Introduces First 2D/3D™ Dedicated Prone Biopsy System at European Congress of Radiology

The CE-Marked Affirm™ Prone Biopsy System Provides Enhanced 2D/3D™ Biopsy Imaging and Faster, Easier Access to the Breast [i]

HOLX

MARLBOROUGH, Mass., March 2, 2016 / [PRNewswire](#)/ -- Hologic, Inc. (Nasdaq: HOLX) announced today the European launch of the CE-marked Affirm™ prone biopsy system — the first dedicated prone biopsy system capable of both 2D and 3D™ imaging-guided breast biopsies.

The new product is an important step forward in biopsy technology — allowing radiologists to better target lesions found during 3D MAMMOGRAPHY™ screening, as well as other screening modalities — with exceptional imaging, improved workflow and seamless, 360-degree access to the breast.

"As screening and diagnostic technology has advanced with the widespread use of 3D MAMMOGRAPHY™, it has become abundantly clear that prone biopsy technology was lagging behind," said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "We are excited to bring the Affirm™ prone biopsy system to the European market, and in doing so, mark one of the biggest steps forward in prone biopsy technology since the systems were first introduced over 20 years ago. A significantly improved imaging capabilityⁱⁱ and a streamlined workflow will provide healthcare providers with increased confidence for these critical procedures so that they can provide the best patient experience."

The Affirm™ prone biopsy system expands Hologic's breast biopsy portfolio, complementing the Company's Selenia® Dimensions® mammography system and Affirm™ upright biopsy system. This portfolio provides radiology facilities all the options necessary to provide minimally invasive breast biopsies for their patients without compromise.

Thousands of clinicians worldwide have trusted prone patient positioning for breast biopsy as it supports the patient stably throughout the procedure while isolating them from the biopsy needle. This provides a better overall patient experience.

The new system will be unveiled at the annual European Congress of Radiology meeting in Vienna, Austria from March 2-6. ECR is the largest medical imaging meeting in Europe and attracts participants from across the world.

Hologic is offering several tomosynthesis-related events at ECR:

- **ECR Satellite Symposium**, "The Use of 3D MAMMOGRAPHY™ Exams in High Volume Screening," on Friday, March 4 from 2:00 p.m. – 3:00 p.m. [I assume this is CET; need to include.]
- **Seven Educational Sessions** from March 3-5 focusing on the clinical value of vacuum-assisted 3D™ breast biopsy.
- **Seven Educational Sessions** from March 3-5 on the clinical use of 3D MAMMOGRAPHY™ exams with a focus on reading and interpreting cases.

In addition to the Affirm™ prone biopsy system, other innovative products to be featured at ECR include:

- The Horizon™ bone densitometry (DXA) system, a single platform for osteoporosis and obesity assessment;
- I-View™ software, the first and only Contrast-Enhanced 2D Mammography exam that can be combined with tomosynthesis;
- Low dose 3D MAMMOGRAPHY™ exams with C-View™ software, delivering superior clinical performance to 2D mammography for all breast types^{iii,iv,v} in a faster, more comfortable and lower dose 3D MAMMOGRAPHY™ exam;
- Affirm™ upright biopsy system for Selenia® Dimensions®, the proven 3D™ breast biopsy system providing superior upright biopsy performance^{vi,vii} and
- Eviva® and ATEC® breast biopsy systems, designed to conduct minimally invasive biopsy procedures under stereotactic, tomosynthesis, ultrasound or MRI guidance.

For additional information on the Affirm™ prone biopsy system, please visit www.affirpronebiopsy.com, and for registration details, email iims@hologic.com.

The Affirm™ prone biopsy system is not currently for sale in the United States.

About Hologic

Hologic, Inc. is a leading developer, manufacturer and supplier of premium diagnostic products, medical imaging systems and surgical products. The Company's core business units focus on diagnostics, breast health, GYN surgical, and skeletal health. With a unified suite of technologies and a robust research and development program, Hologic is dedicated to The Science of Sure. For more information on Hologic, visit www.hologic.com.

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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.

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ⁱ Compared to the MultiCare® Platinum system.

ⁱⁱ Compared to existing dedicated prone biopsy systems

ⁱⁱⁱ FDA PMA submission P080003/S001 physician labeling

^{iv} Skaane P, Bandos A, Eben E, et al. "Two-View Digital Breast Tomosynthesis Screening with Synthetically Reconstructed Projection Images: Comparison with Digital Breast Tomosynthesis with Full-Field Digital Mammographic Images" *Radiology*. 2014 Jun;271:3, 655-663. Epub 2014 Jan 24.

^v Zuley M, Guo B, Catullo V, et al. "Comparison of Two-dimensional Synthesized Mammograms versus Original Digital Mammograms Alone and in Combination with Tomosynthesis Images." *Radiology*. 2014 Jun;271(3):664-71. Epub 2014 Jan 21.

^{vi} Schradling S, Martine D, Dirrichs T, et al. "Digital Breast Tomosynthesis-guided Vacuum-assisted Breast Biopsy: Initial Experiences and Comparison with Prone Stereotactic Vacuum-assisted Biopsy." *Radiology*. 2014 Nov 11.

[vii] Smith A, Sumpkin J, Zuley M, et al. "Comparison of Prone Stereotactic vs. Upright Tomosynthesis Guided Vacuum Assisted Core Breast Biopsies." (paper presented at the annual meeting for the Radiological Society of North America. Chicago, IL, November 2014).