
Hologic Announces FDA Clearance and Commercial Availability of the Affirm™ Prone Biopsy System



New System Pairs 360-Degree Breast Access with Exceptional 2D/3D™ Biopsy Imaging

Hologic, Inc. has announced the U.S. Food and Drug Administration (FDA) clearance and commercial launch of the Affirm™ prone biopsy system, the first dedicated prone biopsy system to offer both 2D and 3D™ imaging-guided breast biopsies.

"At Hologic, we challenge ourselves to advance medical technology so that healthcare professionals and patients can benefit from innovative solutions that significantly improve outcomes and patient experience, while also creating a powerful economic model for our customers," said Pete Valenti, Hologic's Division President, Breast and Skeletal Health Solutions. "The launch of our Affirm™ prone biopsy system is the most significant advancement in prone biopsy technology since we introduced the first system more than 20 years ago. We identified a need for a minimally invasive, stereotactic breast biopsy technology that marries the advances in 3D MAMMOGRAPHY™ exams with the prone positioning many doctors prefer, and are excited to bring this new generation prone biopsy system to market."

With a larger field of view than existing dedicated prone biopsy systems, the new Affirm™ prone biopsy system allows radiologists to better target lesions found during 3D MAMMOGRAPHY™ exams, as well as other screening modalities. Furthermore, this new product features a streamlined workflow with increased automation designed to make using the system fast and easy.

With the patient lying prone, the biopsy system provides true 360-degree access to lesions using a fully integrated C-Arm. Approach angles can be varied with minimal movement on the patient's part, as the patient is supported stably throughout the procedure. In addition to these important benefits for clinicians, the system's design aims to increase patient satisfaction through faster procedure times than Hologic's market leading MultiCare® Platinum system, and comfortable prone positioning that eliminates a direct view of the biopsy needle.

"Until now, we've been struggling to handle complex biopsies for subtle lesions or faint calcifications that we are only able to identify using 3D MAMMOGRAPHY™ exams," said Dr. Alejandro Tejerina of the Centro Patología de la Mama, Fundación Tejerina in Madrid, Spain. "As an early testing site for the Affirm™ prone biopsy system, we've had the opportunity to perform many biopsies using this technology, and are pleased to report that this new biopsy table has helped to solve our challenges. We are able to visualize more tissue and have access to challenging lesion locations, and the procedures are very fast."

The system is CE marked, and Hologic has begun installing Affirm™ prone systems at leading imaging sites in Europe.

The Affirm™ prone biopsy system expands Hologic's breast biopsy portfolio, complementing the Company's Genius™ 3D MAMMOGRAPHY™ exam and Affirm™ upright biopsy system. This portfolio equips hospitals and imaging centers with the options necessary to provide minimally invasive breast biopsies for their patients.

The system is now available for order in the U.S. For additional information on the Affirm™ prone biopsy system, please visit www.affirmpronebiopsy.com.

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