



NEWS RELEASE

FDA Grants Clearance for LOCalizer™ Implantable Tag for Long-Term Placement in Breast Lesions

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Wire-free lesion localization marker can now be implanted for more than 30 days, creating more flexibility for providers and patients during breast surgeries

MARLBOROUGH, Mass., January 17, 2019 – Hologic (Nasdaq: HOLX) today announced that the U.S. Food and Drug Administration (FDA) has cleared the **LOCalizer** radiofrequency identification (RFID) marker for long-term placement. With this clearance, the marker can now be implanted more than 30 days prior to a breast-conserving surgery, providing even greater flexibility and convenience to patients and providers.

Initially cleared by the FDA in 2017, LOCalizer is a non-radioactive, radiofrequency localization system designed for precise marking and targeting of lesions in breast-conserving surgery. LOCalizer was designed to replace the traditional wire-guided localization method, which requires placement of a wire the day of surgery. The LOCalizer system is manufactured by Health Beacons, Inc. and is exclusively distributed by Hologic.

Following placement days ahead of surgery, the miniature implantable tag can be detected by a portable, handheld reader that indicates the location and distance to the lesion, enabling the surgeon to pinpoint the correct area of breast tissue for removal. Each tag also features a unique identification number that is displayed on the reader. This improved workflow is designed to help reduce scheduling and logistical hurdles for care teams, and aims to deliver added convenience for an enhanced patient experience.



“As advancements continue to be made in breast cancer detection, we’re focused on building the innovative tools that create a better experience for physicians and patients who are navigating the complex logistics of breast surgeries,” said Pete Valenti, Hologic’s Division President, Breast and Skeletal Health Solutions. “This clearance is a significant step forward as we continue to set the standard in breast health today and into the future. It also reflects the momentum we’re building as we extend our shared focus on improving breast health throughout the patient journey.”

Dr. Dona Hobart, Breast Surgeon and Medical Director of the Center for Breast Health at Carroll Hospital in Maryland, has been using the LOCalizer system for almost a year. “The LOCalizer system is designed to address the challenges of other localization methods as well as enable surgeries tailored appropriately to each patient, which is a positive advancement in patient care,” said Hobart.

The LOCalizer system is part of a growing portfolio of breast surgery and pathology solutions following Hologic’s recent acquisition of Faxitron. For more information about the LOCalizer system, visit <https://www.faxitron.com/product/localizer>

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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