

eviva[®]

Breast Biopsy System

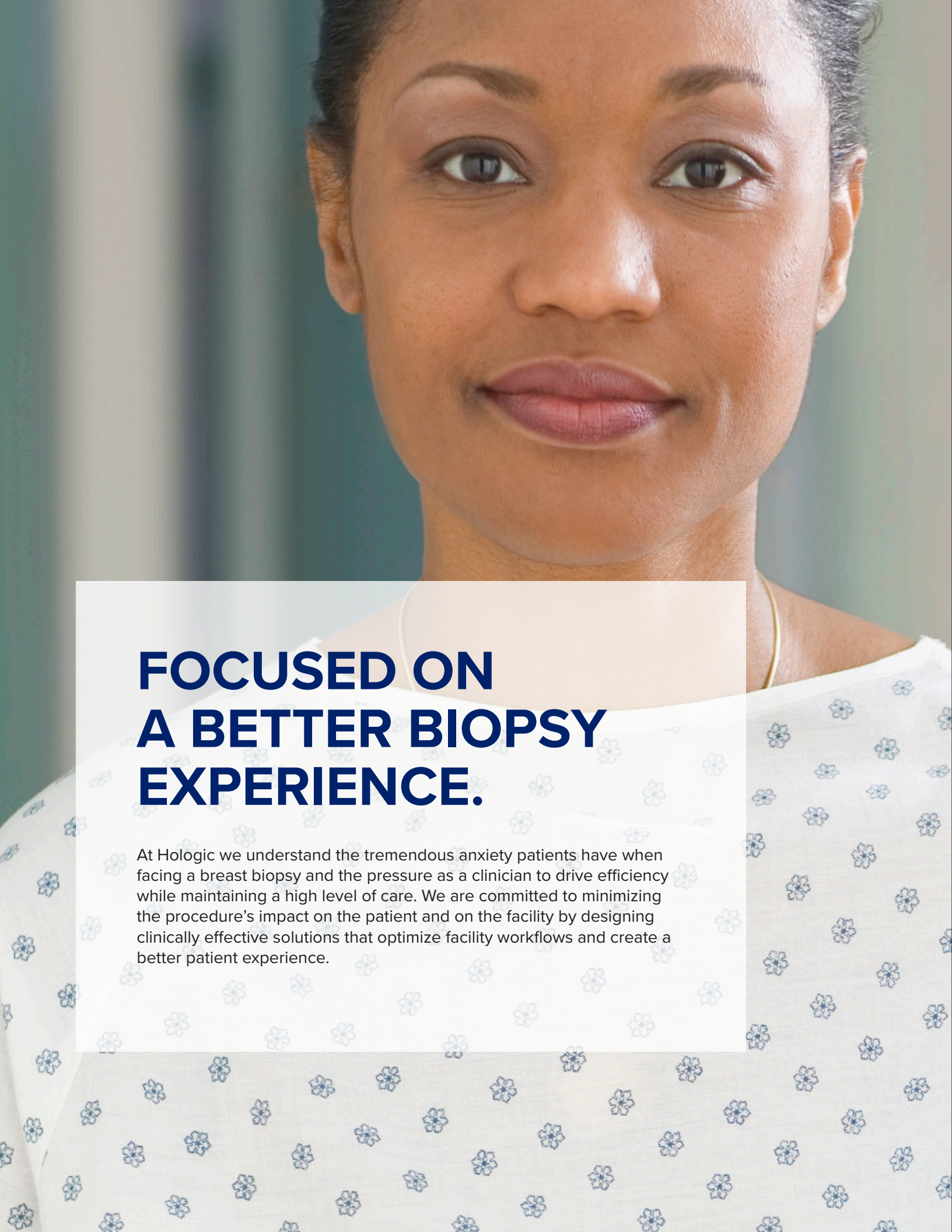
HOLOGIC[®]
The Science of Sure

A CHOICE WORTH MAKING.

A proven and dependable solution for fast, compassionate,
and easy breast biopsy.



Trusted Globally in over
2.4 MILLION BIOPSIES.¹



Trusted by nearly **3,000 facilities worldwide** to quickly deliver the high-quality tissue needed for a confident diagnosis.¹

FOCUSED ON A BETTER BIOPSY EXPERIENCE.

At Hologic we understand the tremendous anxiety patients have when facing a breast biopsy and the pressure as a clinician to drive efficiency while maintaining a high level of care. We are committed to minimizing the procedure's impact on the patient and on the facility by designing clinically effective solutions that optimize facility workflows and create a better patient experience.



FAST

- Remove 6 consistent cores in under 30 seconds with 4.5 second biopsy cycle time.*
- Keep total control with manual needle rotation at your fingertips, no programming required.
- Manage patient bleeding without stopping the procedure with saline lavage and constant aspiration.



COMPASSIONATE

- Offer patients a positive cosmetic outcome with maximal core samples and minimal incision size.²
- Keep patients calm. Biopsy with a quiet remote pneumatic firing system that helps not startle the patient versus other adapter release systems.³
- Manage patient pain with local anesthetic directly to the biopsy site with every core.³
- Obscure blood from patient view with translucent color tubing.



EASY

- Optimize access to challenging lesions close to the chest wall using a low-profile needle.
- Manage a wide spectrum of patients with needle size, length, and aperture options.
- Manage thin breast compressions as small as 16mm.⁷
- Work seamlessly on Hologic's market leading Affirm® prone and upright biopsy guidance systems with all needle parameters pre-programmed.⁵
- Easily mark the site with integrated site marking solutions.

OFFER A SPECTRUM OF COMPASSIONATE CARE.



Eviva® breast biopsy devices enable access to more patients.⁶

With multiple 9g and 12g needle options in standard and petite configurations; superficial, chest wall, and retroareolar lesions are easily handled by choosing the right needle for the task. The Eviva breast biopsy system gives more women an alternative to open surgical biopsy, so they can **get back to their lives, sooner.**⁷



94%

94% of Eviva® device users stated that the Eviva device maximizes patient satisfaction.⁸

EASY TO GET THE RIGHT TISSUE.

The Eviva® breast biopsy system provides physicians a high level of both consistency and control in every procedure.

“The pneumatic firing capability of the Eviva device represents a major advance over conventional biopsy systems. The decrease in the sound of the firing mechanism has a major impact on patients’ perception of the procedure, reducing their overall anxiety and perception of pain.”

- Dr. Stuart Kaplan
Mount Sinai Medical Center, Miami, FL⁴



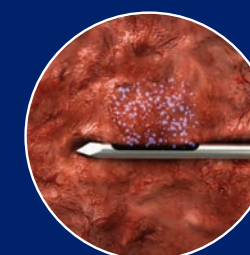
Start with a **quiet fire.**



Reduce pain with automatic delivery or manual bolus of local anesthetic directly to the biopsy site with every sample.³



You control the tissue sampling location with the tactile thumb wheel.



Easily **aspirate the biopsy cavity** with integrated saline lavage and continuous vacuum **designed to transport quality cores smoothly.**

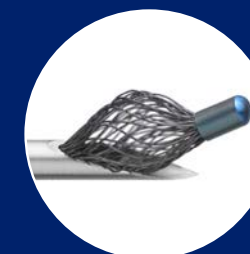
Offer patients a positive cosmetic outcome post-biopsy, with maximized core retrieval and minimal incision size.⁹

Hologic 9g device and sample

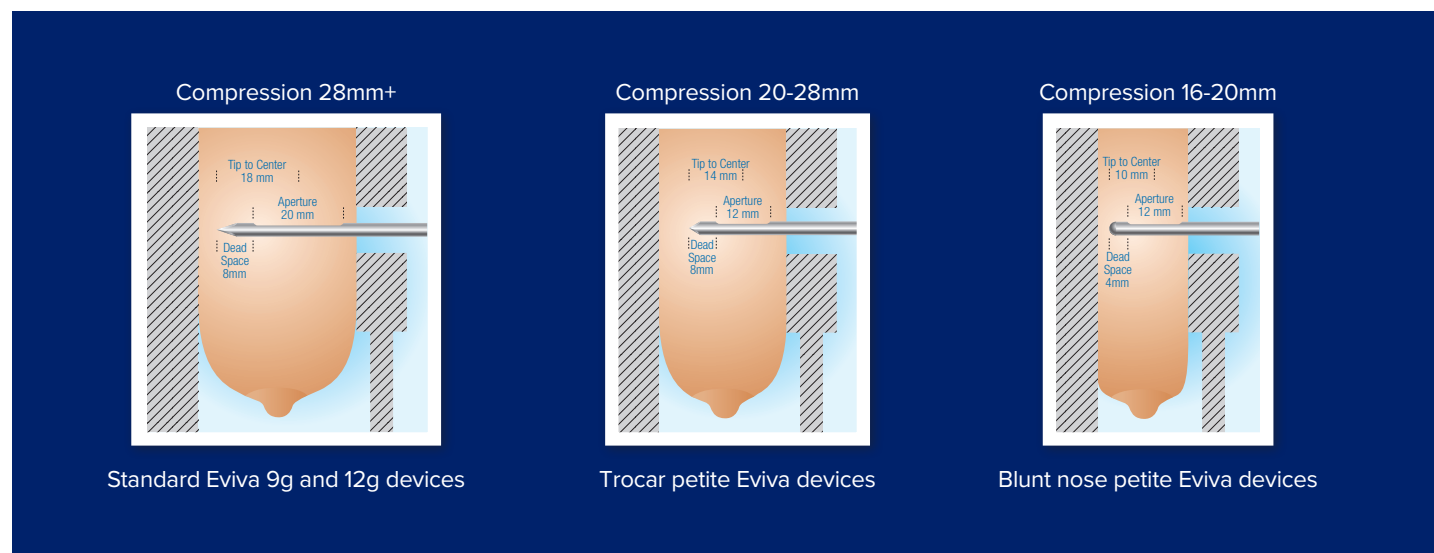
- 3.7mm incision → ●
- 2.8mm sample → ●

Competitive 8g device and sample

- 6.1mm incision → ●
- 3.3mm sample → ●







Easily, confidently, and accurately **deploy the biopsy site marker** using the integrated introducer sheath and end-deploy markers.³



INTEGRATED TO BE FAST.

The Hologic Eviva® breast biopsy system was designed for use with our advanced Affirm® prone and upright breast biopsy guidance systems in both stereotactic 2D and 3D™ biopsy procedures, offering optimized access for faster, more accurate procedures;¹¹⁻¹³ at a **lower dose**.



 <p>Acquires high quality core samples</p>	 <p>Minimizes complications and maximizes patient satisfaction</p>	 <p>Reduces false negatives and minimizes unnecessary recalls</p>	 <p>Easy-to-operate</p>
---	---	--	--

CONFIRMATION IN THE ROOM.

Faxitron® Core Specimen Radiography System

Eliminate delays for core sample verifications with the core specimen radiography system designed to provide high-resolution imaging in the room, helping you accelerate procedures and get patients out of compression faster.¹⁰

Efficient.
Intuitive.



9/10 CLINICIANS AGREE

the Eviva device offers a better patient experience compared to other vacuum assisted breast biopsy devices when it comes to what's important.⁸



The Affirm™ Prone breast biopsy system with the Eviva breast biopsy device.

Adapters available for MammoTest™ and MammoTest™ lateral arm approach, Fuji Innovality and Fuji Amulet, GE Senographe DS® and GE Senographe® Essential lateral arm approach and GE Senographe® Essential vertical approach, Siemens MAMMOMAT® Inspiration vertical approach and lateral approach, Siemens® Opdim, Giotto Image with Biopsy Digit



Trident® HD Specimen Radiography System

Hologic has a complete set of specimen imaging products for Radiology, Surgery and Pathology to help you improve efficiency, optimize the patient experience and deliver the best outcomes possible.

Be sure to talk with your Hologic representative about which specimen radiography solution is right for your patients.



Faxitron® Path specimen imaging system

Note: Availability may vary by country. Faxitron® Core system also known as CoreVision® System. Faxitron™ Path system also known as PathVision™ System.

DESIGNED FOR DEPLOYMENT.

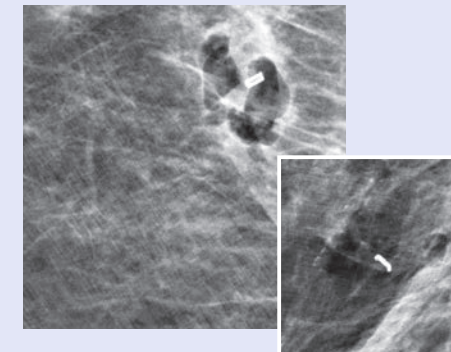
Hologic provides an array of biopsy site marking options specific for the Eviva system, with a total of **NINE** distinct shapes composed of bio-compatible permanent titanium, stainless steel, or nitinol.

SecurMark® Marker

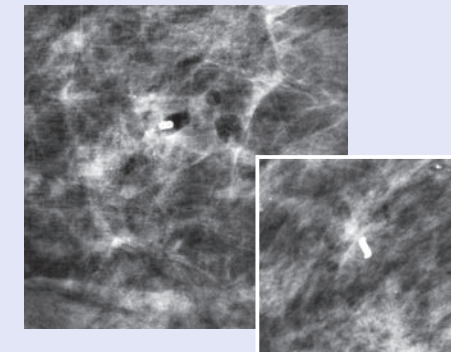
Bio-absorbable suture-like net carries a bio-compatible permanent marker, designed to minimize migration within the biopsy cavity and enhance ultrasound visualization for three to four weeks post-biopsy.¹⁵



SecurMark Biopsy Site Markers



SecurMark biopsy site marker in stainless steel shape one (1) under mammography



SecurMark biopsy site marker in stainless steel shape two (2)

TriMark® Marker

Reliable and simple bio-compatible Titanium metal markers, optimal for thin-breasted patients and superficial lesions.



TriMark Biopsy Site Markers

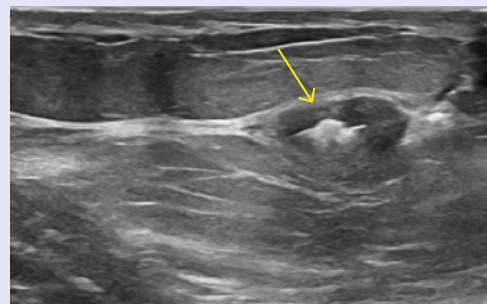
Tumark® Marker

Intelligently designed to provide long term ultrasound visibility, non-bio-absorbable, bio-compatible permanent marker with excellent visibility under mammography at deployment.¹⁴



Tumark Biopsy Site Markers

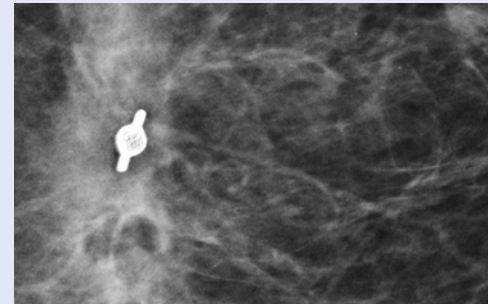
Tumark® under Ultrasound



Vision marker

Image courtesy of Dr. Peggy Avagliano

Tumark® under Mammography



Vision marker

Image courtesy of Dr. Lashonda Soma

A COMPLETE SOLUTION.

The Eviva® breast biopsy device is the preferred device for physicians wanting a simple, fast, and proven stereotactic breast biopsy device. Physicians have found that total procedure time with the Eviva breast biopsy system is greatly reduced,⁸ largely due to:

Fast - Total tissue acquisition typically lasting one minute or less.*

Compassionate - Deliver local anesthetic to the biopsy site with every core.

Easy - No software required to program or operate the console.

“Set-up time is faster, 5 minutes on average. The design of the system gives you a nice visual to follow for steps needed, frees up the tech once the radiologist starts to sample, and allows us to turn the room over faster.”

I have seen a real commitment on Hologic’s part to improving the overall experience for patients having breast biopsies as well as improving efficiency for the radiologist and technologists. Patients routinely say, “It was much better than I thought it would be.”

- Susan Zignego, Lead Mammography Technologist
Advocate Aurora Grafton Medical Center, Grafton, WI



RADIOLOGY

PRIMARY CARE



RISK

RADIOLOGY



BREAST SCREENING

RADIOLOGY



DETECTION & DIAGNOSIS

RADIOLOGY

BIOPSY

BREAST SURGERY



LOCALIZE

BREAST SURGERY



SENTINEL LYMPH NODE BIOPSY

BREAST SURGERY



REMOVAL, FILLING & MARKING

PATHOLOGY



SPECIMEN EVALUATION

TREATMENT



TREATMENT & MONITORING

Purpose. Passion. Promise.

At Hologic, we deliver trailblazing technologies to keep you on the forefront of breast care. Our passion drives us in the relentless pursuit of innovative tools that set new paradigms for the early detection, accurate diagnosis, intervention and treatment of breast cancer — technologies to help you protect and preserve the lives of your patients. With you, we are on a mission to help women live longer, healthier lives.

For more information on the Hologic family of breast health solutions, please visit hologic.com.

References

*Hologic data on file, Internal testing performed at Hologic and maintained in PLM system

1. Hologic data on file. **2.** Hologic data on file, Compared to Mammotome revolve[®] 8G. **3.** Hologic data on file, AW-02708 - Instructions for use - Eviva - Stereotactic guided breast biopsy system **4.** Hologic data on file, Dr. Stuart Kaplan, "Eviva white paper: The benefits of the Eviva vacuum-assisted stereotactic breast biopsy device" - WP-00023 **5.** Hologic data on file, VER-03935 - Verification report - Affirm Targeting Accuracy with Eviva and ATEC devices. **6.** Hologic data on file, Compared to ATEC[®] breast biopsy device. **7.** Hologic data on file, VER-05759, VER-04202, VER-04111, VER-03205, VER-03792, DHM-02115, DHM-02203 **8.** Hologic data on file, MISC-06068, Attachment 1 Kadence study, "Eviva Audit – Identifying optimal claims for the Eviva Breast Biopsy device", July 2015 **9.** Hologic data on file, Compared with Mammotome revolve[®] 8G. **10.** Hologic data on file, Compared to Specimen imaging on mammography unit outside of the biopsy suite, 2015 Kadence International survey of 200 healthcare professionals. **11.** Hologic data on file, Compared with stereotactic (2D) biopsy. **12.** Schrading 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. 2015 274:3, 654-662 E-pub 2014 Nov 12. **13.** 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). **14.** Tumark[®] Marker Data Collection Study, 2017, DHM-06169, 3 clinicians at 3 hospitals for 90 marker placements, 2017, In 85% of marker placements, physicians stated that the ultrasound visibility was good to excellent upon deployment. In 56% of marker placements, physicians stated that ultrasound visibility was excellent upon deployment. **15.** Clinical Evaluation Report, DHM-08585. Visibility is dependent on surrounding tissue, experience may vary.

www.hologic.com | BSHSalesSupportUS@hologic.com | +1.800.442.9892

Hologic Headquarters
United States / Latin America
250 Campus Drive
Marlborough, MA 01752
USA Tel: +1.508.263.2900
Sales: +1.781.999.7453
Fax: +1.781.280.0668
Email: info@hologic.com

Hologic Europe
Everest (Cross Point)
Leuvensesteenweg
250A 1800
Vilvoorde, Belgium
Tel: +32.2.711.4680
Fax: +32.2.725.2087

Hologic Asia Pacific Limited
One Temasek Avenue
21-04 Millenia Tower
Singapore 03192
Tel: +65 6206 5833

Hologic Australia
Suite 302, Level 3
2 Lyon Park Road
Macquarie Park NSW 2113
Australia
Tel: +61.2.9888.8000
Fax: +61.2.9870.7555

PB-00213 rev. 002 (02/20) Hologic Inc. ©2020 All rights reserved. Hologic, Affirm, Affirm Prone, CoreVision, Eviva, Faxitron, SecurMark, TriMark, Tumark, and associated logos are trademarks and/or registered trademarks of Hologic, Inc., and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals in the U.S. and other markets and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative.