Brevera® Biopsy Needle
Instructions for Use

Introduction

Please read all information carefully. Failure to properly follow the instructions may lead to unintended consequences.

Important: This package insert is designed to provide instructions for clinical use (IFU) for the Brevera breast biopsy device to be used with the Brevera breast biopsy system. It is not a reference to surgical techniques.

Patient Target Group

The Brevera Breast Biopsy System is intended to be used on patients with suspicious breast tissue abnormalities that need to be histologically sampled via biopsy for the primary diagnosis of said abnormality.

Indications

The Hologic Brevera breast biopsy system with CorLumina® imaging technology is intended to provide breast tissue samples for diagnostic sampling of breast abnormalities. The Brevera breast biopsy system excises targeted tissue and optionally delivers in-line radiographic images of the excised tissue. The Brevera breast biopsy system is intended to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. In instances when a patient presents with a palpable abnormality that has been classified as benign through clinical and/or radiological criteria (for example, fibroadenoma, fibrocystic lesion), the Brevera breast biopsy system may also be used to partially remove such palpable lesions. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of histological abnormality, for example, malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedure.

Contraindications

The Brevera breast biopsy system with CorLumina imaging technology is not intended for therapeutic applications.

The Brevera breast biopsy system with CorLumina imaging technology is contraindicated for those patients who, based on the physician's judgment, may be at increased risk or develop complications associated with core removal or biopsy. Patients receiving anticoagulant therapy or who may have bleeding disorders may be considered at increased risk of procedural complications.

Intended User

Mammography Technologist

- Meets all requirements that apply to the location in which the Mammography Technologist operates.
- Completed training on the mammography system.
- Has training in mammography positions.
- Understands stereotactic breast biopsy procedures.
- Understands how to operate a computer and its peripherals.
- Understands sterile procedures.

Radiologists, Surgeons

- Meets all requirements that apply to the location in which the Physician operates.
- Understands stereotactic breast biopsy procedures.
- Understands how to operate a computer and its peripherals.
- Understands sterile procedures.
- Gives local anesthesia.
- Understands basic surgical procedures for core biopsy.

Medical Physicist

- Meets all requirements that apply to the location in which the Medical Physicist operates.
- Understands mammography.
- Has experience with digital imaging.
- Understands how to operate a computer and its peripherals.

Device Description

The Brevera biopsy needle is single-use and is disposable. The user connects the biopsy needle to a reusable device driver and connects the biopsy device components to the console. The biopsy needle primarily consists of a hollow needle with a side aperture and a sharpened inner cannula that, when connected to the Brevera breast biopsy system, rotates and extends across the aperture to acquire targeted tissue. The Brevera device driver contains mechanical and electrical components that drive needle rotation and advancement. During the biopsy process, vacuum created inside the device pulls tissue into the aperture. The cannula translates and rotates to cut the tissue. The tissue sample is then aspirated through a tubing line to a tissue filter. Saline is supplied through the biopsy device to lavage the cavity and deliver tissue to the tissue filter.

Biopsy Needle Nomenclature and Product Selection by Catalog Number

Brevera biopsy needle catalog numbers use the following nomenclature:

REF	Cutting Cannula Needle Gauge	Needle Length (cm)	Aperture Size (mm)	Suffix (if any)
BREVDISP09	09: 9 gauge	13 cm long	20 mm (optionally 12mm based on orientation of the introducer)	None

Refer to www.hologic.com for an updated list of biopsy needle product offerings.

Clinical Benefits

The Brevera Breast Biopsy System performs biopsies in a time-efficient manner by combining vacuum-assisted tissue acquisition, real-time imaging verification and advanced post-biopsy handling in one integrated system. Real time imaging enables visual confirmation of tissue acquisition steps, allowing physicians to make informed clinical decisions with confidence thereby avoiding repeated biopsy procedures.

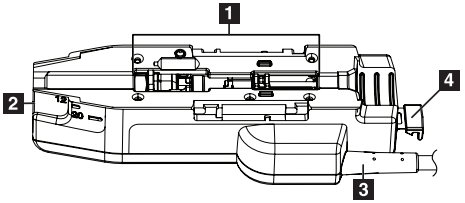
Adverse Effects

The following adverse effects could occur or have been reported in association with the use of the Brevera Breast Biopsy system:

- Hematoma
- Perforation
- Blunt Trauma
- Infection
- Tissue Damage
- Pain
- Bleeding
- Inflammation
- Electric Shock
- Radiation Exposure, Unintended
- Foreign Body Reaction

Device Preparation - Firing or Non-firing Device

Biopsy Device Connections



1. Connection to the biopsy needle
2. Connection point to the biopsy device adapter (groove on bottom)
3. Device driver cord
4. Release latch for the biopsy device adapter

Figure 1: Device Driver Component

Refer to the Brevera User Guide for complete console and device instructions for use.

WARNING: Before use, inspect the protective packaging and needle to verify that neither has been damaged during shipment. If it appears that the packaging or needle has been compromised, do not use the needle.

WARNING: Do not connect the biopsy needle until the system is powered on and the device driver is homed and ready.

1. Place the sealed packaging for the biopsy needle on the console tray.
2. Peel open the sterile packaging of the biopsy needle.
3. Remove the biopsy needle from the tray, leaving the tubing and the tissue filter in the tray. Make sure the biopsy needle gears are fully forward, toward the needle tip.

WARNING: To maintain sterility, leave the protective sheath on the tip of the biopsy needle.

4. Hold the biopsy needle in one hand, with the gears facing down and the sheathed needle tip facing to the right. Line up the tab on the biopsy needle with the notch in the device driver.

WARNING: Do not place fingers on the metal parts of the device driver. These parts can move before a biopsy needle is installed.

5. Carefully move the biopsy needle straight down, aligning the back of the tab with the back of the notch, until the needle engages with the driver. Do not drag the biopsy needle across the device driver.

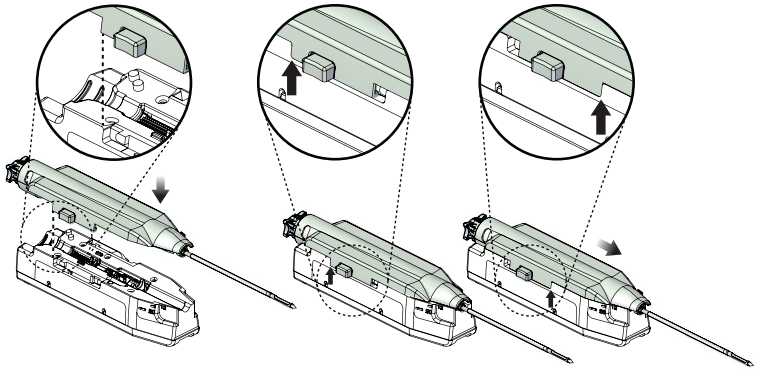


Figure 2: Connect the Biopsy Needle to the Device Driver

WARNING: Do not place fingers on the device driver when system power is on. Parts can move unexpectedly.

6. Slide the biopsy needle forward (to the right) until it locks into position with a click.

WARNING: Make sure that the biopsy needle is fully latched onto the device driver.

7. Get a saline bag and remove the protective cap. (A 250 cc saline bag is recommended.)
8. Remove the saline tubing from the biopsy needle packaging.
9. Insert the spike into the saline bag.

WARNING: Make sure you use an aseptic technique when spiking the saline bag to prevent contamination.

10. Place the saline bag on the saline bag hook on the left side of the console.
11. Route the saline tubing from the spike through the saline tubing notch, counterclockwise around the saline tubing management plate, and through the saline tubing conduit.
12. Insert the larger diameter section of the saline tubing into the saline pinch valve. Make sure the saline tubing is fully seated.

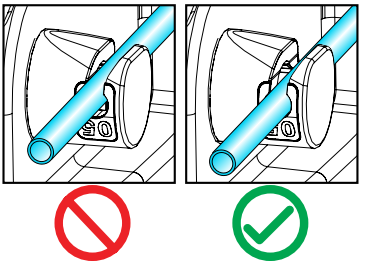


Figure 3: Placement of the Saline Tubing in the Saline Pinch Valve

13. Insert the vacuum tubing into the guide at the top of the saline tubing management plate.

WARNING: Make sure the needle guide is installed correctly before use.

Installing and Removing the Tissue Filter Cap

A. To install, gently lower the tissue filter cap onto the tissue filter until the two tabs snap into place.

WARNING: Make sure that the protrusions in the center of the tissue filter cap align with the grooves on the tissue filter spindle. Make sure both tabs are fully latched.

B. To remove, pinch the two tabs on the tissue filter cap and pull the cap up.

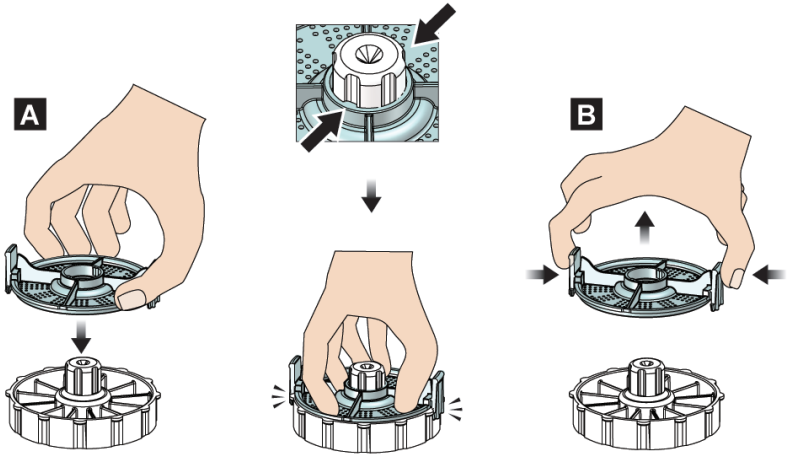


Figure 4: Installing and Removing the Tissue Filter Cap

Performing a Biopsy and Concluding the Procedure

Refer to the Brevera User Guide for complete console and device instructions for use.

Warnings and Precautions

- Use caution when attaching sharp devices to the adapter.
- As with any medical procedure, make sure that users wear appropriate personal protective equipment to guard against potential contact with bodily fluids.
- The Brevera biopsy needle procedure should be performed only by persons with sufficient training and familiarity with this procedure. Consult medical literature relative to techniques, complications, and hazards before performing any minimally invasive procedure.
- The Brevera biopsy needle should only be used by physicians trained in percutaneous biopsy procedures.
- **℞ONLY** Caution: Federal law restricts this biopsy needle to sale by or on the order of a physician.
- Use sound professional judgment when using the Brevera breast biopsy device on patients with breast implants.
- Avoid operator or instrument contact with the sheathed needle part of the Brevera biopsy needle.
- Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic may not be compatible with the Brevera breast biopsy system. Use of such products can lead to unanticipated results and possible injury to the user or patient.
- Instruments or devices that come into contact with bodily fluids can require special disposal handling to prevent biological contamination.
- Dispose of all opened disposable instruments whether used or not.
- Do not resterilize or reuse the Brevera biopsy needle or the introducer. Resterilization or reuse can compromise the integrity of the instrument. This can lead to potential risks of failure of the biopsy needle to perform as intended or to cross-contamination associated with using inadequately cleaned and sterilized devices.
- A complete and comprehensive preoperative medical history and physical examination are suggested. Radiographic evaluation and laboratory tests may be included.
- The Brevera breast biopsy system with CorLumina imaging technology is not for use with MRI or Ultrasound.
- One or more components of this device contain substances defined as Carcinogenic, Mutagenic and Reproductive Toxin (CMR 1A and/or CMR 1B) and/or endocrine disrupting in a concentration above 0.1% weight by weight. However, the biological risk has been assessed and the product remains safe. More information on CMR substances is available on the European Chemicals Agency website: https://echa.europa.eu/

Brevera Biopsy Needle is compatible with the following systems and accessories:

Catalog Number	Description
BREV100	Brevera 100 System
BREV200	Brevera 200 System
BREVDRV	Driver
BREVADPTR	Adapter
BREVADPTRM	Adapter for MammoTest®
BREVSTYLBRKT	Stylet Bracket
EVIVA_CALIBRATE_13CM	Calibration Handpiece 13cm
EVIVA_NG_HOLDER	Needle Guide Holder for MammoTest
BREVADPTRG	Adapter for GE Senographe® Stereotaxy
EVIVA_BUSHING_GE	Bushing for GE Senographe Stereotaxy
BREVTF01	Single Chamber Tissue Filter
BREVTF12	12 Chamber Tissue Filter
EVIVA_NG09L	Needle Guide
EVIVA_NG09R	Needle Guide
ATEC CANISTER	Suction canister with lid
SMark-Eviva-13	Titanium Biopsy Site Marker
SMark-Eviva-2S-13	Titanium Biopsy Site Marker
SMark-E13-ss1	Stainless Steel Biopsy Site Marker
SMark-E13-ss2	Stainless Steel Biopsy Site Marker
SMark-E13-ss3	Stainless Steel Biopsy Site Marker
TriMark-Eviva-13	Titanium Biopsy Site Marker
TriMark-Eviva-2S-13	Titanium Biopsy Site Marker
TUMARK-BREV-S-VISION	Nitinol Biopsy Site Marker
TUMARK-BREV-S-X	Nitinol Biopsy Site Marker
TUMARK-BREV-S-Q	Nitinol Biopsy Site Marker
TUMARK-BREV-P-VISION	Nitinol Biopsy Site Marker
TUMARK-BREV-P-X	Nitinol Biopsy Site Marker
TUMARK-BREV-P-Q	Nitinol Biopsy Site Marker

Warranty

Except as otherwise expressly stated in the Agreement: i) Equipment manufactured by Hologic is warranted to the original Customer to perform substantially in accordance with published product specifications for one (1) year starting from the date of shipment, or if Installation is required, from the date of Installation ("Warranty Period"); ii) digital imaging mammography x-ray tubes are warranted for twenty-four (24) months, during which the x-ray tubes are fully warranted for the first twelve (12) months and are warranted on a straight-line prorated basis during months 13-24; iii) replacement parts and remanufactured items are warranted for the remainder of the Warranty Period or ninety (90) days from shipment, whichever is longer; iv) consumable Supplies are warranted to conform to published specifications for a period ending on the expiration date shown on their respective packages; v) licensed Software is warranted to operate in accordance with published specifications; vi) Services are warranted to be supplied in a workman-like manner; vii) non-Hologic Manufactured Equipment is warranted through its manufacturer and such manufacturer's warranties shall extend to Hologic's customers, to the extent permitted by the manufacturer of such non-Hologic Manufactured Equipment. Hologic does not warrant that use of Products will be uninterrupted or error-free, or that Products will operate with non-Hologic authorized third-party products. These warranties do not apply to any item that is: (a) repaired, moved, or altered other than by Hologic authorized service personnel; (b) subjected to physical (including thermal or electrical) abuse, stress, or misuse; (c) stored, maintained, or operated in any manner inconsistent with applicable Hologic specifications or instructions, including Customer's refusal to allow Hologic recommended Software upgrades; or (d) designated as supplied subject to a non-Hologic warranty or on a pre-release or "as-is" basis.

How Supplied

The Brevera biopsy needle is supplied sterile for single patient use. Discard into an appropriate container after use.

Product Complaints and Technical Support

Report any complaints or problems in the quality, reliability, safety, or performance of this product to Hologic. If the device has caused or added to patient injury, immediately report the incident to Hologic Authorized Representative and Competent authority of the respective member state or country. The Competent Authorities, for medical devices, are usually the individual Member States' Ministry of Health, or an agency within the Ministry of Health.

For technical support or reorder information in the United States, please contact:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 1-877-371-4372
www.hologic.com

CE 2797

International customers, contact your distributor or local Hologic Sales Representative:

EC REP

Hologic BV
Da Vincilaan 5
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AU SPONSOR

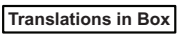
Hologic (Australia and New Zealand) Pty Ltd
Suite 302, Level 3
2 Lyon Park Road
Macquarie Park NSW 2113
Tel: 02 9888 8000

Troubleshooting

Refer to the Brevera User Guide for complete troubleshooting information.

Symbols Used on Labeling

The following symbols may be found on the product labeling for the Brevera biopsy needle:

Symbol	Description	Standard
	Prescription use only	21 CFR 801.109
	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
	CE Mark with notified body reference number	MDR Regulation (EU) 2017/745
	Translations in Box	Hologic
	Consult instructions for use	ISO 15223-1, Reference 5.4.3
	Follow instrctions for use	IEC 60601-1, Reference No. Table D.2, Safety sign 10 (ISO 7010-M002)
	Do not use if package is damaged	ISO 15223-1, Reference 5.2.8
	Catalog number	ISO 15223-1, Reference 5.1.6
	Batch code	ISO 15223-1, Reference 5.1.5
	Quantity	Hologic
	Manufacturer	ISO 15223-1, Reference 5.1.1
	Country of Manufacture	ISO 15223-1, Reference 5.1.11
	Patents	Hologic
	Do not re sterilize	ISO 15223-1, Reference 5.2.6
	Do not re-use	ISO 15223-1, Reference 5.4.2
	Sterilized using irradiation	ISO 15223-1, Reference 5.2.4
	Sterilized using ethylene oxide	ISO 15223-1, Reference 5.2.3

	Contains hazardous substances	ISO 7000-3723
	Use-by Date	ISO 15223-1, Reference 5.1.4
	MR Unsafe	ASTM F2503 Reference no. Table 2, Symbol 7.3.3;7.4.9.1; Fig. 9
	Medical device	ISO 15223-1, Reference 5.7.7
	Single sterile barrier system with protective packaging inside	ISO 7000-3708
YYYY-MM-DD	Date format: YYYY represents the year MM represents the month DD represents the day	Hologic
	Country code for translation	ISO 3166

MAN-07918-002 Revision 001
April 2023