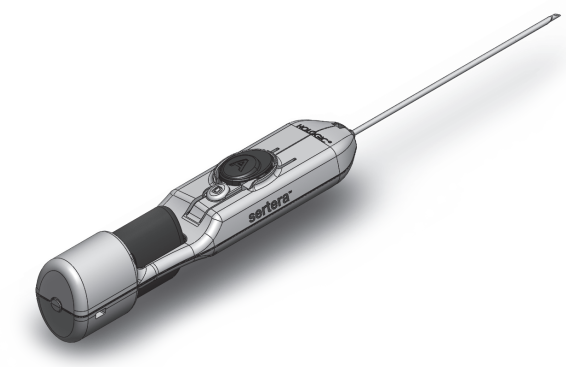
sertera™

Biopsy Device



HOLOGIC®

sertera
Biopsy Device
Instructions for Use

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 use (IFU) for the Sertera biopsy device. It is not a reference to surgical techniques.

Indications

(Product Codes: Sertera-12 and Sertera-14)

The Sertera biopsy device is intended to obtain percutaneous core biopsy samples from soft tissue and tumors of the breast. When used for breast biopsy, the product is for diagnosis only. It is not intended for use in bone.

Contraindications

Sound professional judgment should be used for patients where increased risk or complications may be associated with biopsy based on the physician's judgment, such as patients receiving anticoagulant therapy or those who have known bleeding disorders.

Device Description

The Sertera biopsy device is a spring loaded core biopsy device which is used to obtain percutaneous core biopsy samples from soft tissue and tumors of the breast. When used for breast biopsy, the product is for diagnosis only. The device is for single-patient use and the entire handpiece is fully disposable. The device consists of an inner needle with a side aperture and a sharpened outer cannula that extends at high speed over the aperture to acquire targeted tissue.

Device Preparation (all steps to be performed per standard interventional technique)

1. Prior to use of the Sertera biopsy device, inspect the protective packaging and device to verify that neither has been damaged during shipment. If it appears that the packaging has been compromised, do not use the device.
2. Carefully remove the Sertera biopsy device from its protective packaging.
3. Remove the protective sheath from the Sertera biopsy device.
4. Completely compress and release the blue arming mechanism at the back end of the device to retract the outer cutting cannula.
5. Completely compress and release the blue arming mechanism at the back end of the device a second time to retract the inner needle.

Performing a Biopsy (all steps to be performed per standard interventional technique)

1. Identify targeted area.
2. Prepare the site as required.

   NOTE: If desired, the inner needle may be advanced prior to insertion of the Sertera™ biopsy device into the patient.
3. There are two options for firing the device once it has been armed:
   a. Delay Mode (Pre-Fire) - depress the white D button to advance the inner needle independent of the outer cannula. The position of the sample notch can be verified prior to depressing the blue A button, which will release the outer cannula to excise and capture the tissue sample. The delay mode can also be used to advance the inner needle outside of the tissue. The needle with the aperture exposed is then advanced to the target area, and the core is acquired by fully depressing the blue A button.
   b. Automatic Mode - fully depress the blue A button to advance the inner needle and outer cannula in sequence to acquire the tissue sample.
4. Insert the tip of the needle and advance to the desired location.
5. Once the needle is in the targeted area for biopsy, you may acquire the specimen via Delay or Automatic mode overviewed in step #3.
6. Remove the Sertera biopsy device.
7. Completely compress and release the blue arming mechanism at the back end of the device to retract the outer cannula and expose the tissue core.

   a. Retrieve the tissue core.

   NOTE: Use caution when retrieving tissue cores from the aperture of the Sertera biopsy device. Do not place fingers near or within the aperture at any time during a biopsy procedure, as the cutting outer cannula may be armed and could potentially fire, resulting in user injury.

   b. To obtain additional cores, completely compress and release the blue arming mechanism at the back end of the device a second time to retract the inner needle and repeat steps 1-6 of this section.
8. If finished obtaining cores, remove the Sertera biopsy device and properly dispose of it.
9. If desired, deploy biopsy site marker according to manufacturer's instructions for use.

Warnings and Precautions

- The Sertera biopsy device is not recommended for use with MRI.
- The Sertera biopsy procedure should be performed only by persons having adequate training and familiarity with this procedure. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.
- The Sertera biopsy device should be used only by physicians trained in percutaneous biopsy procedures.
- **℞ONLY** Caution: Federal law restricts this device to sale by or on the order of a physician.
- Sound professional judgment should be used when the Sertera biopsy device is used on patients with breast implants.
- Avoid operator or instrument contact with the needle portion of the Sertera biopsy device.
- The Sertera biopsy device should not be tested by "dry" firing the cutting needle. Damage to the device may occur, dulling the cutting edge.
- Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic, Inc. may not be compatible with the Sertera biopsy device. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Dispose of all opened instruments whether used or unused.
- Do not resterilize and/or reuse the Sertera biopsy device. Resterilization and/or reuse may compromise the integrity of the instrument. This may lead to potential risks of failure of the device to perform as intended and/or cross-contamination associated with using inadequately cleaned and sterilized devices.

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.

How Supplied

The Sertera biopsy device is sterilized by gamma irradiation and supplied for single patient use. Discard into an appropriate container after use.

For More Information

For Technical Support or reorder information in the United States, please contact:

Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 800-442-9892
www.hologic.com

Symbols:

The following symbols may be found on the product labeling for the Sertera biopsy device:

QTY	Number of Devices Enclosed
YYYY-MM-DD	Expiration date is represented by the following: YYYY represents the year MM represents the month DD represents the day
℞ ONLY	U.S. federal law restricts this device to sale by or on the order of a physician
	Do not use if package is damaged
	Do not resterilize
	Do not re-use
MR	MR Unsafe
	Consult instructions for use
STERILE R	Sterilized using irradiation
	Manufacturer
	Use by
LOT	Batch code
REF	Catalog number
SN	Serial number

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