

ATEC[®]

**Breast Biopsy and Excision System
Ultrasound Introducer**



Instructions For Use

HOLOGIC[®]

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ATEC® Ultrasound Introducer

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 ATEC® ultrasound introducer. It is not a reference to surgical techniques.

Indications

The ATEC ultrasound introducer is indicated to be used as an aspiration needle and/or as an introducer with another biopsy needle in percutaneous biopsies of the breast for diagnostic purposes only.

Contraindications

Sound professional judgement should be used when performing biopsies on patients who are using anticoagulant therapy and/or patients with known hemophilia problems.

Device Description

The ATEC ultrasound introducer is for use in conjunction with the ATEC Breast Biopsy and Excision System to obtain percutaneous core biopsy samples from soft tissue. The ATEC ultrasound introducer is designed specifically for use with the 9cm and 12cm length, 20mm aperture ATEC breast biopsy devices. The ATEC ultrasound introducer is a sterile single-use system of devices comprised of a stylet with an echogenic aperture and introducer. The ATEC ultrasound introducer provides single insertion access to the targeted area of interest and assists in deploying the appropriate biopsy site marker.

Device Preparation

(All steps to be performed per standard interventional technique)

1. Standard aseptic patient preparation should be employed prior to the use of the ATEC ultrasound introducer.
2. Prior to use of the ATEC ultrasound introducer, inspect the 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.
3. Carefully remove the ATEC ultrasound introducer from its protective packaging and remove its protective sheath.
4. If a 9cm ATEC ultrasound introducer is being used with a CeleroMark, SecurMark for Celero, or SecurMark Ultrasound biopsy site marker, remove the spacer provided in the packaging and install it onto the biopsy site marker until it engages into place. (Figure 1)

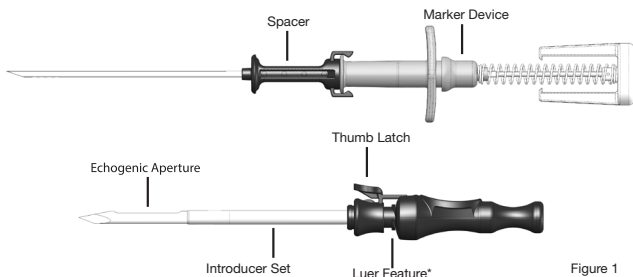


Figure 1

*Note: A luer taper or luer lock syringe may be attached to provide additional fluid and/or pain management.

5. Set-up the appropriate ATEC handpiece per standard operating procedures to perform an ultrasound-guided biopsy utilizing the ATEC Breast Biopsy and Excision System.

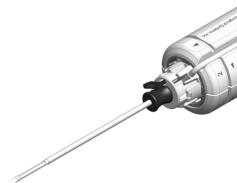
Instructions for Use

1. Identify the target area under ultrasound visualization.
2. Insert the tip of the stylet and advance to the desired location. The echogenic side aperture will be visible under ultrasound-guidance and should be placed in the same area of interest where the ATEC handpiece will be used.

Note: The Introducer may be attached directly to the ATEC breast biopsy device to gain access to the area of interest without use of the stylet.

3. Remove the stylet, leaving the introducer in place. The stylet may be detached from the introducer by depressing the thumb latch mechanism on the introducer hub.

4. Advance the ATEC handpiece to the targeted area by sliding it into the introducer hub until the thumb latch engages the biopsy device hub. (Figure 2)
5. Prior to performing a biopsy using the ATEC handpiece, verify aperture position using ultrasound-guidance.
6. Once the ATEC handpiece is inserted into the introducer hub and latched, follow the instructions for handpiece use in the ATEC Console Operator's Manual to perform the biopsy.



ATEC handpiece with introducer attached

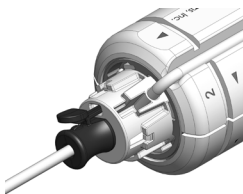


Figure 2

7. Once core acquisition has been completed, return the console to biopsy mode and remove the ATEC handpiece. The handpiece may be detached from the introducer by depressing the latch mechanism on the introducer hub. The ATEC ultrasound introducer can be left in place for biopsy site marker placement, otherwise remove it with the ATEC handpiece.
8. For biopsy site marker deployment, insert the deployment device into the proximal end of the introducer and carefully advance the deployment device until it engages the introducer hub thumb latch. (Figure 3)

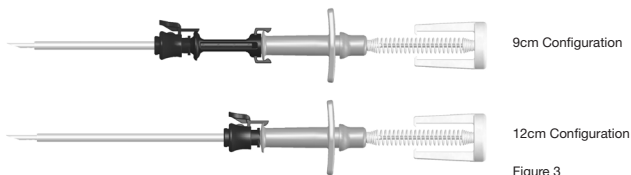


Figure 3

9. Deploy the biopsy site marker per the instructions for use provided with the biopsy site marker.
10. Remove the introducer and biopsy site marker as a unit and properly dispose of them.

Warnings and Precautions

- The ATEC ultrasound introducer is for diagnostic use only and is NOT indicated for therapeutic use.
- The ATEC ultrasound introducer is NOT intended to be used outside the standards, specifications, and limitations as outlined in this IFU and other related materials.
- The ATEC ultrasound introducer is not recommended for use with MRI.
- As with any medical procedure, please ensure that users wear appropriate personal protective equipment to guard against potential contact with body fluids.
- Observe caution while handling sharp components.
- Breast biopsies using the ATEC ultrasound introducer 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.
- This device should be used only by physicians trained in percutaneous biopsy procedures.
- Sound professional judgment should be used when the ATEC ultrasound introducer is used on patients with breast implants.
- Avoid operator or instrument contact with the needle portion of the ATEC ultrasound introducer.
- Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic, Inc. may not be compatible with the introducer set. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- Dispose of all opened instruments whether used or unused.
- Do not resterilize the ATEC ultrasound introducer. Re-sterilization and/or reuse may compromise the integrity of the instruments. This may lead to potential failure of the device to perform as intended and/or cross-contamination associated with using inadequately cleaned or sterilized devices.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- **ONLY** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

How Supplied

The ATEC ultrasound introducer is sterilized by radiation and supplied sterile and packaged for single patient use. Discard into an appropriate container after use.

As Identified on Labels:

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

For More Information

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



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Symbols Used on Labeling

Authorized Representative in the European Community	
Batch code	
Catalogue number	
CE marking of conformity with notified body identification number	
Do not use if package is damaged	
Use by	
Manufacturer	
U.S. federal law restricts this device to sale by or on the order of a physician	
Do not re-use	
Do not re-sterilize	
Sterilized using irradiation	

Consult instructions for use	
Quantity	

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