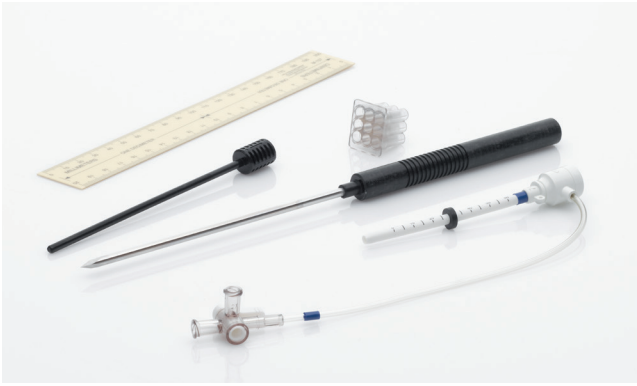
ATEC®

Breast Biopsy and Excision System
Introducer Localization System



Instructions for Use

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ATEC® Introducer Localization System

Instructions for Use

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

Important: This package insert is designed to provide Instructions for Use of the ATEC Introducer Localization System. It is not a reference to surgical techniques.

Indications

The ATEC Introducer Localization System (ILS) is intended 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

When performing biopsies in conjunction with the ATEC Introducer Localization System (ILS) sound professional judgement should be used on patients who are using anticoagulant therapy and/or patients with known hemophilia problems.

Device Description

The ATEC ILS is a sterile, single use system of devices comprised of an introducer stylet, introducer sheath, needle guide and localizing obturator. The ATEC ILS is intended for use with the ATEC Breast Biopsy and Excision System when performing vacuum assisted breast biopsies.

Magnetic resonance imaging (MRI) procedures should be performed according to the following guidelines.

Instructions for Use

1. Standard aseptic patient preparation should be employed prior to use of the ATEC ILS.

2. Prior to use of the ILS, inspect the protective packaging and device to verify that neither has been damaged during shipment. If it appears the packaging has been compromised, do not use the device.

3. Insert the introducer stylet into the introducer sheath. Position the depth stop on the introducer sheath at the appropriate location according to the pre-determined “Z” value.

4. A standard protocol should be employed to anesthetize the patient and the biopsy site.

5. Insert the sterile needle guide into the compression grid at the identified target area.

6. Insert the introducer sheath/introducer stylet assembly into and through the needle guide to the depth stop. Rotate the sheath/stylet assembly while advancing. This will create access to the target area.

7. Remove the introducer stylet from the introducer sheath while leaving the introducer sheath in place. Insert the localizing obturator into the introducer sheath. Move the patient into the imaging field and image to confirm target accuracy.

Note 1: The usable length of the localizing obturator is equal to the distance from the hub of the ATEC handpiece to the middle of the sampling aperture.

Note 2: The localizing obturator shows up as a “black dot” on the image screen in the sagittal view and as a “black line” in the axial view and provides identification, localization and confirmation of the target area.

8. Move the patient out of the imaging field and remove the localizing obturator. Insert the ATEC handpiece through the introducer sheath to the biopsy site in preparation for the biopsy to be performed.

9. Ensure the ATEC handpiece is advanced until handpiece hub is contacting the hub of the introducer sheath. Then, follow the instructions for handpiece use in the ATEC console Operator’s Manual to perform the biopsy.

10. Once the biopsy is completed, remove the ATEC handpiece while leaving the introducer sheath in place. Re-image the patient to confirm acquisition of the suspect target area.

11. If desired, place a biopsy site marker. Follow the instructions for use.

12. Take a final image of the target area to confirm marker location. Remove Introducer Sheath and Needle Guide and dispose per standard procedures.

Warnings and Precautions

- Care should be taken when removing sharp objects from the patient, in order to prevent needle stick injury.
- The ATEC introducer stylet is not recommended for use within the bore of an MRI magnet.
- Breast biopsies using the ATEC ILS 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 open or percutaneous biopsy procedures.
- **℞ONLY** Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.
- Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic, Inc. may not be compatible with the ATEC ILS. 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 ATEC ILS. Resterilization and/or reuse may compromise the integrity of the instruments. 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.
- Sound professional judgement should be used when performing biopsies on patients with implants.
- The ATEC ILS has been tested up to 3 Tesla for acceptability of artifact and magnetic draw safety. Use of the ATEC ILS in magnets beyond this strength is not recommended.

How Supplied

The ATEC ILS is sterilized by gamma radiation and supplied packaged for single 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:

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

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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 resterilize	
Sterilized using irradiation	
Consult instructions for use	

This device contains di-(2ethylhexyl) phthalate, DEHP; Benzyl butyl phthalate, BBP	
Quantity	
MR Conditional	

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