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.

Patient Target Group

The target patient population of ATEC Breast Biopsy and Excision System includes patients undergoing breast tissue removal for diagnostic sampling of breast abnormalities.

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.

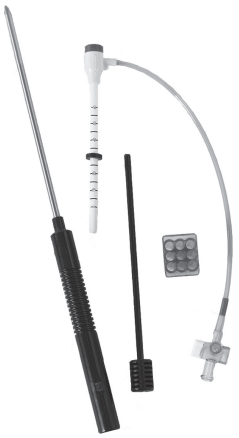
Contraindications

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.



Intended user

The ATEC Breast Biopsy and Excision System should be used only by physicians trained in open or percutaneous biopsy procedures.

Expected Clinical Benefit

The ATEC Breast Biopsy and Excision System enables physicians to use a minimally invasive system to extract small biopsy samples of potentially malignant breast tissue.

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 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

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 More Information

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

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

EC REP European Representative
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Tel: +32 2 711 46 80

Symbols Used on Labeling

Symbol	Description	Standard
Rx ONLY	Prescription use only	FDA 21 CFR 801.109
EC REP	Authorized Representative in the European Community	ISO 15223-1, Reference 5.1.2
CE XXXX	CE Mark with notified body reference number	MDR Regulation (EU) 2017/745
Translations in Box	Translations in Box	Hologic
www.hologic.com/package-inserts	Consult instructions for use	ISO 15223-1, Reference 5.4.3, Hologic
	Follow instructions 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
REF	Catalog number	ISO 15223-1, Reference 5.1.6
LOT	Batch code	ISO 15223-1, Reference 5.1.5
QTY	Quantity	Hologic
	Manufacturer	ISO 15223-1, Reference 5.1.1
CC	Country of Manufacture	ISO 15223-1, Reference 5.1.11
Patents	Patents	Hologic
STERILIZE	Do not re sterilize	ISO 15223-1, Reference 5.2.6
	Do not re-use	ISO 15223-1, Reference 5.4.2
STERILE R	Sterilized using irradiation	ISO 15223-1, Reference 5.2.4

	Use-by Date	ISO 15223-1, Reference 5.1.4
	Caution	ISO 15223-1, Reference 5.4.4
	Not safe for magnetic resonance imaging	ASTM F2503 Reference no. Table 2, Symbol 7.3.3;7.4.9.1; Fig. 9
	Safe for magnetic resonance imaging	ASTM F2503 Reference 7.4.6.1; Fig. 6, 7
	Conditional use for magnetic resonance imaging	ASTM F2503 Reference 6.4.6.1; Fig 6
	Medical device	ISO 15223-1, Reference 5.7.7
	Single sterile barrier system with protective packaging outside	ISO 15223-1, Reference 5.2.14
	Single sterile barrier system	ISO 15223-1:, Reference 5.2.11
YYYY-MM-DD	Date format: YYYY represents the year MM represents the month DD represents the day	Hologic
	Country code for translation	ISO 3166

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