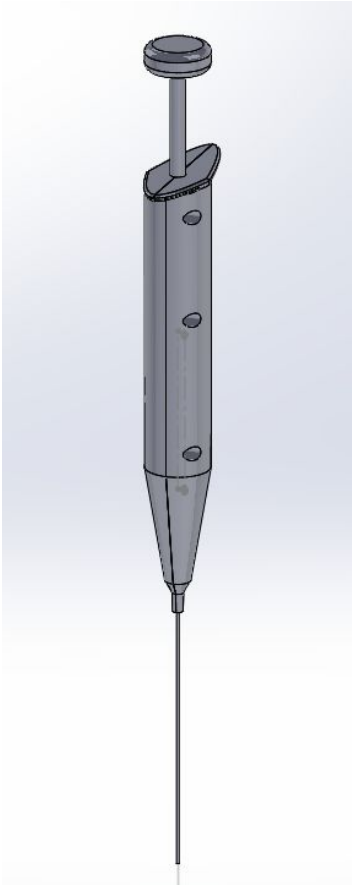
The PolyGuide

Breast Lesion Localization System



Instructions for Use

BioTechnix
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Manufactured in CHARLESTON SC USA

STERILE EO

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INSTRUCTIONS FOR USE

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

A. General Information and Device Description:

The BioTechnix PolyGuide Breast Lesion Localization System is a two-component device consisting of a needle cannula with an integral ejection system and a polymer localization wire. The BioTechnix PolyGuide Breast Lesion Localization System is a disposable single patient use device and is available in various lengths.

B. How Supplied:

The product is supplied sterile and nonpryogenic unless the package has been opened or damaged. **Sterilized using Ethylene Oxide. For single use only. Do not reuse. Do not resterilize.**

C. Indications for Use:

The BioTechnix PolyGuide Breast Lesion Localization System is intended for use in localizing non palpable breast lesions requiring surgical excision and must be permanently visible under ultrasound, x-ray (mammography), and MRI.

D. Contraindications:

No need for wire localization in palpable lesions or when the patient is scheduled for a mastectomy

E. Warnings:

1. The BioTechnix PolyGuide Breast Lesion Localization System as been designed for single use only. Reusing this medical device bears the risk of cross-patient contamination as medical devices are difficult or impossible to clean once bodily fluids or tissues have come into contact with the device. The residue of these materials can promote contamination of the device which may lead to infection.
2. **DO NOT** resterilize the BioTechnix PolyGuide Breast Lesion Localization System. After resterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential microbial contamination which may lead to infection. Cleaning, reprocessing, and/or resterilization of the device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

F. Precautions:

1. This device should only be used by a physician trained in its indicated use, limitations, and possible complications of percutaneous needle techniques.
2. The introduction of the device into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc.).
3. Before using, inspect the packaging for damage, punctures or compromised seal that would cause the device to become non-sterile and therefore detrimental to the patient's health.
4. Before using, inspect the device for damaged point, bent shaft or other imperfections that would prevent proper function of the device. If the components are damaged or bent, **DO NOT USE**.
5. If the ejection system is fired prematurely, either in packaging or prior to use, **DO NOT USE**.

G. Potential Complications:

Potential complications are site specific and may consist of the following:

i. Hematoma
ii. Hemorrhage
iii. Infection
iv. Adjacent tissue injury
v. Pain
vi. Bleeding
vii. Hemoptysis
viii. Hemothorax
ix. Non-target tissue, organ or vessel perforation
x. Pneumothorax

H. Equipment Required:

1. Appropriate imaging modality
2. Surgical gloves and drapes
3. Local anesthetic
4. Scissors
5. Other equipment as necessary

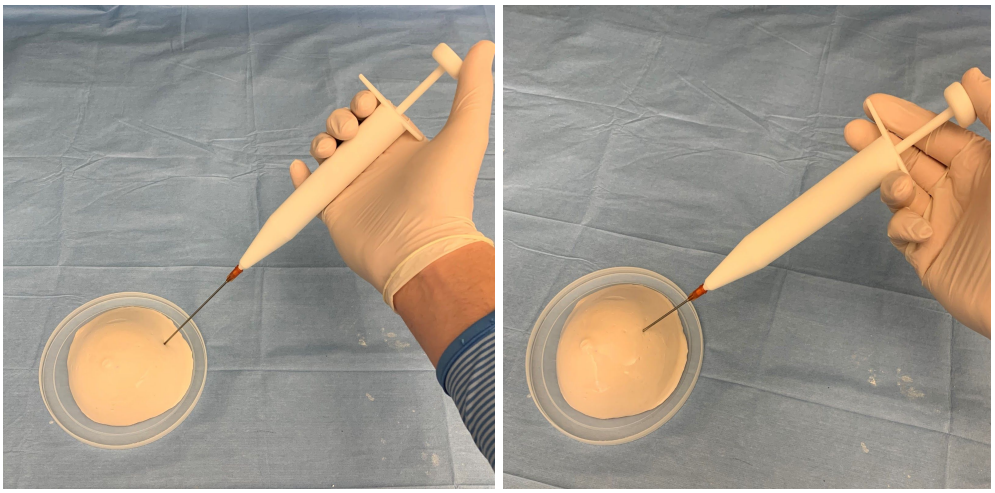
I. Directions for Use:

1. Inspect the package and product for damage and expiration date. If undamaged and unexpired, open the package and transfer the product onto the sterile field utilizing aseptic technique.
2. Using aseptic technique, remove the device from the package. Before using, inspect the polymer wire/needle cannula for damaged tips, bent shafts, deformed looking elements or other imperfections that would prevent proper function of the device. If the polymer wire/needle cannula or ejection system are damaged, bent or do not move together easily, **DO NOT USE**.

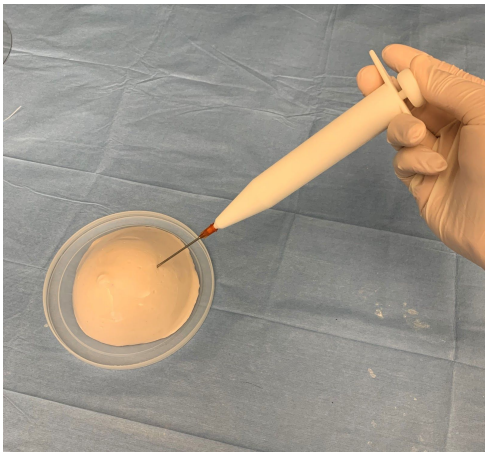
Localization Procedure:

The localization procedure should be performed using appropriate aseptic techniques.

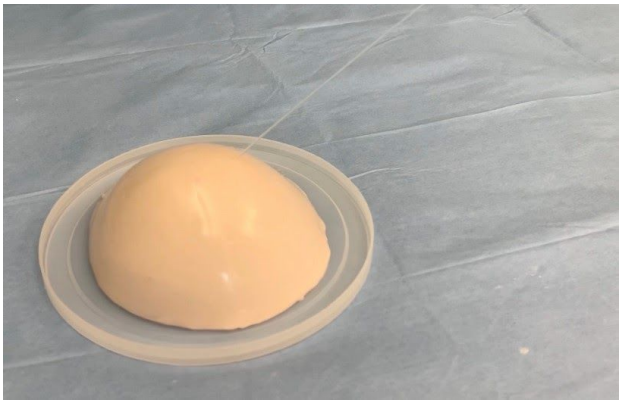
1. Identify the desired tissue entry location. Under imaging, advance the cannula into the tissue. Advance the needle to the mass and the pierce through the mass to the distal side.



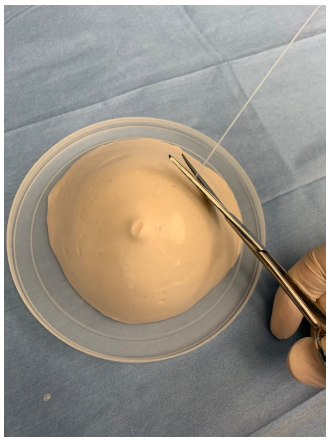
2. Press down on the plunger to inject the polymer wire into the mass.

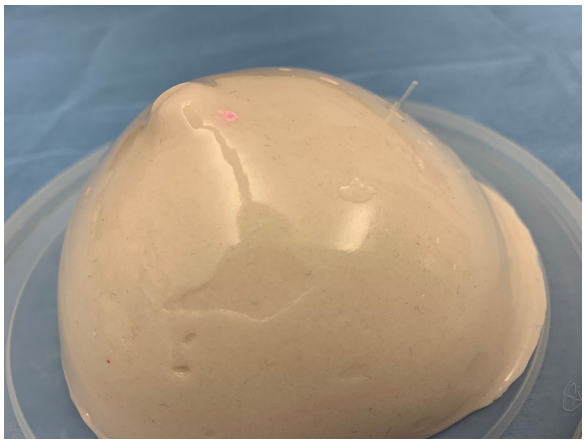


3. Once the polymer wire is in the desired location, remove the metal cannula and ejection system.

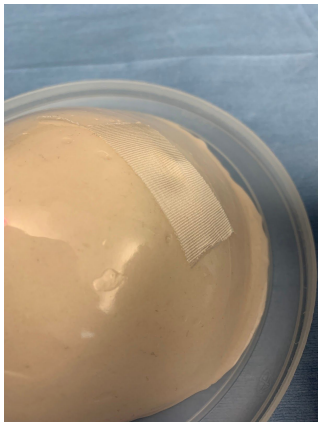


4. Cut away excess polymer wire using scissors being sure to leave at least 1cm of polymer protruding from the surface of the skin.





5. Bend any protruding polymer wire and secure to the skin using the provided sterile medical tape.



CONTACT INFORMATION

For more information regarding the BioTechnix PolyGuide Breast Lesion Localization System and its use, please contact BioTechnix via one of the listed methods of communication.

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