

MiraLoc™ Wire Localizer

Device Description

MiraLoc™ Wire Localizer consists of a needle and a preloaded marking wire with distal double arches. It is a thin wire inserted into the breast tissue to guide surgeons in locating and removing a tumor or abnormal tissue.

| Size (G) | Length (cm) | Variant |
|-----------------|--------------------------------------|--|
| 18, 19, 20 & 21 | 5, 7, 9, 10, 12, 14, 16, 18, 20 & 22 | Needle, Wire localizer, Introducer & Stopper |

Intended Purpose

The MiraLoc™ Wire Localizer is designed for preoperative marking and localization of non-palpable breast lesions or other soft tissue abnormalities to guide surgical excision for a period of less than 24 hours.

Indications For Use & Contraindications

Device is indicated for: preoperative marking and localization of non-palpable breast lesions or other soft tissue abnormalities to guide surgical excision. Contraindications include but not limited to local infection over the insertion site, Allergy or Hypersensitivity, Coagulopathy, High risk of wire migration or displacement.

Potential Complications

Wire dislocation, Marker Removal, Wire Breakage, Hematoma, Discomfort, Infection, Skin dimpling, Difficulty in Wire Removal, Inadequate lesion localization, Allergic reaction and Accidental cutting of wire.

Warnings And Precautions

- Only trained and qualified healthcare professionals with knowledge, experience and training in percutaneous soft tissue marking should perform wire localization procedures to minimize risks associated with incorrect insertion or handling.
- Improper use may result in inaccurate placement, patient harm, or procedural complications.
- The wire localizer is supplied sterile and is intended for single use only. Do not reuse or re-sterilize.
- Inspect the packaging before use. Do not use the device if the sterile barrier system is damaged, opened or compromised or if the device is visibly damaged.
- Follow aseptic techniques during insertion to minimize the risk of infection. Any signs of infection, such as redness, swelling or pain at the insertion site should be promptly addressed.
- Ensure the patient remains immobilized during the procedure to avoid displacement of the wire.
- Confirm the wire's position using imaging after placement to ensure accurate localization of the target lesion.
- The wire must be removed during the surgical procedure. Failure to remove the wire may result in complications such as migration or foreign body reactions.
- Inform the patient about the procedure and the device being used, including potential risks and the importance of adhering to follow-up care instructions.
- DO NOT use the system in patients with breast implants.
- The product is NOT suitable in direct contact with electrosurgical instruments. There is danger of spark discharging and injury.
- Care must be taken, when using electrosurgical instruments: the product can be damaged in direct contact. If damage to the marking wire occurs, a follow-up checks and if necessary, removal of wire fragments remaining in the body is required.
- This device is MR Unsafe. The device is known to pose hazards in all MRI environments. Exposure to the MR environment may result in serious injury.

Precautions

- Needle tip is sharp. Use carefully, especially while unpacking the Needle.
- Make sure that the marker wire is located inside of the Needle and that the curved parts of the wire do not protrude out of the tip of the Needle.
- Verify that the wire is not bent, kinked, or damaged prior to insertion.
- Maintain aseptic technique throughout the procedure to prevent infection.
- Handle the wire with care to avoid kinking, bending, or breakage, which may impact the device's performance.
- Avoid excessive force when inserting or manipulating the wire to minimize the risk of tissue trauma or device damage.
- Ensure familiarity with the wire's specific design and use before performing the procedure.
- Reassess wire position after any patient movement or if procedural delays occur.
- Immobilize the patient during and after wire placement to prevent accidental displacement or migration of the wire.
- Monitor the patient for signs of discomfort, infection, or adverse reactions during and after the procedure.
- Carefully control the depth of wire insertion to avoid puncturing adjacent structures or organs.

Instructions for use

1. Before opening the package, verify that it is intact and undamaged. Check the expiration date of sterilization.
2. Open the package aseptically.
3. Disinfect the puncture area and administer local anaesthesia at the insertion site.
4. Use a scalpel to make a small incision at the puncture site to ease needle insertion.
5. Before starting the puncture make sure that the curved parts of the wire do not protrude out of the tip of the needle.
6. Under sonographic or mammographic guidance, insert the needle into the breast until the needle tip reaches the target lesion.
7. Once the needle is positioned at the target site, insert the localizer wire through the proximal end of the needle while keeping the needle steady. The marker wire includes:
 - Three reference beads near the curved (deployable) end for precise localization.
 - One distal bead that indicates the appropriate insertion depth.Advance the wire until the distal depth-indicating bead is just inside the cannula and all three localization beads are positioned at the lesion site.
8. After confirming correct placement of the reference beads using imaging, inspect the wire's position. If the placement is incorrect, you may carefully withdraw the wire back into the cannula. Reposition the needle as needed, then redeploy the wire as described in steps 5–7.
9. Carefully remove the needle from the breast tissue.
10. Fix the stopper over the wire almost to the surface of the skin of the breast
11. Treat the wound.
12. After the procedure, please ensure the appropriate disposal of the cannula in the proper cannula container.

Supply and Storage

The device is packed in package made of polyethylene and Tyvek. Supplied sterilized by Ethylene Oxide gas in peel open package. Device shall be stored at temperature range from 20°C to 40°C and away from direct sunlight and avoid contact or exposure to corrosion gas.

Target Population Group

Patients with nonpalpable breast lesions, including both cancerous and benign abnormalities, requiring surgical excision to guide the surgeon to the precise location of the lesion during an operation.

Report Any Serious Incident

These instructions for use are based on experience from physicians and (or) their published literature. Refer to your local Blueneem sales representative for information on available literature.

Symbol Glossory And Definations

Standard Reference:

ISO 15223-1 Medical devices — Symbols to be used with information to be supplied by the manufacturer

| Symbol | Symbol Title |
|--------|---|
| | Do not re-sterilize |
| | Do not use if package is damaged and consult instructions for use |
| | Consult instructions for use |
| | Temperature limit |
| | Keep away from sunlight |
| | Do not re-use |
| | Not made with natural rubber latex |
| | Sterilized using ethylene oxide |
| | Non-pyrogenic |
| | Keep dry |
| | Medical device |
| | Single sterile barrier system with protective packaging inside |
| | Does not contain DEHP |
| | Unique device identifier |
| | Date of Manufacture |
| | Use-by date |
| | Batch code |

| | |
|--|---|
| | Catalogue number |
| | Authorized Representative in the European Community/ European Union |
| | Manufacturer |
| | Caution |
| | Prescription |
| | MR Unsafe |



- This device is to be sold by/on the directions of a physician. Sterile (ETO) if package is unopened or undamaged.
- Read all the instructions before use.
- On completion of the procedure, dispose off device and its components if any as per institutional and local regulatory guidelines for bio-hazardous medical waste dispose.



Manufacturer

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