Instructions for Use

CE 0123

Product name: Breast Lesion Localization Wires (GW)

General description of the product:

Breast Lesion Localization Wire consists of an introducer needle and a semi-rigid localization wire. The introducer needle is comprised of a plastic molded hub (operating handle), 1cm depth reference marks, and an ultrasound enhancement on the distal end to aid in needle placement under ultrasound or X-ray guidance. An adjustable depth stopper allows the user to restrict forward movement, localizing the needle tip to the biopsy site. The semi-rigid localization wire has 1cm location marking at the distal end of the wire and a palpable operating marking to signify the point at which the barb at the distal end of the wire will be deployed. The operating handle is color-coded, which indicates gauge size of the needle. The needle is protected in a needle sheath. According to the shape of the localization wire,Two types are available: GW-Q and GW-SQ. From each type there are several variants due to the needle gauge sizes and lengths.

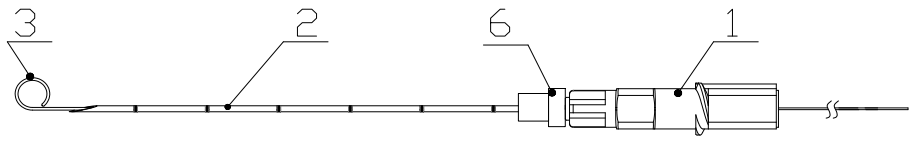
The shaft of introducer needle is made of medical grade stainless steel (SUS304/06Cr19Ni10). The localization wire is made of medical Ni-Ti alloy. The operating handle is made of acrylonitrile butadiene styrene (ABS). The depth stopper is made of HDPE.

Breast Lesion Localization Wire is used during breast lesion surgery as a guide for the surgeon to follow in the excision of the lesion. The product is used by physicians trained and experienced in diagnostic and interventional techniques. Standard techniques for excision should be employed.

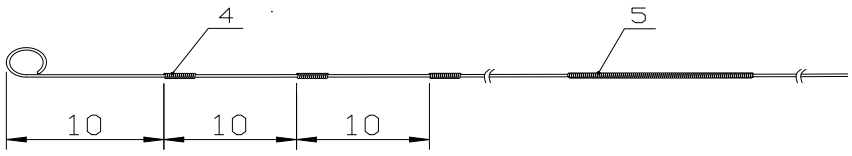
The device is delivered in a sterile state with EO sterilization. The shelf life is defined for 3 years after sterilization. A re-sterilization by users is not allowed.

According to gauge and length of the needle, following variants are available:

GW-Q 20-30	GW-SQ 18-120
GW-Q 20-50	GW-SQ 18-150
GW-Q 20-77	
GW-Q 20-107	
GW-Q 18-120	
GW-Q 18-150	



1. Operating handle; 2. Introducer needle; 3. Localization wire; 6. Depth stopper;



4. Localization mark; 5. Operating mark

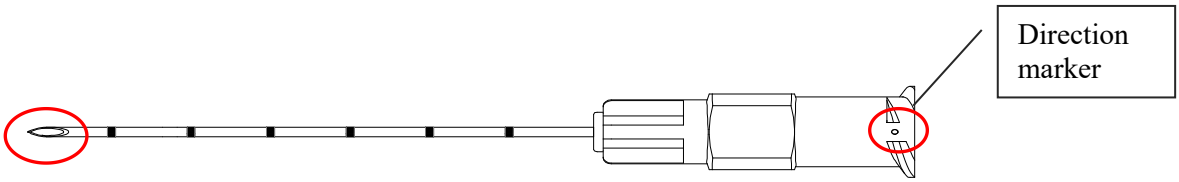
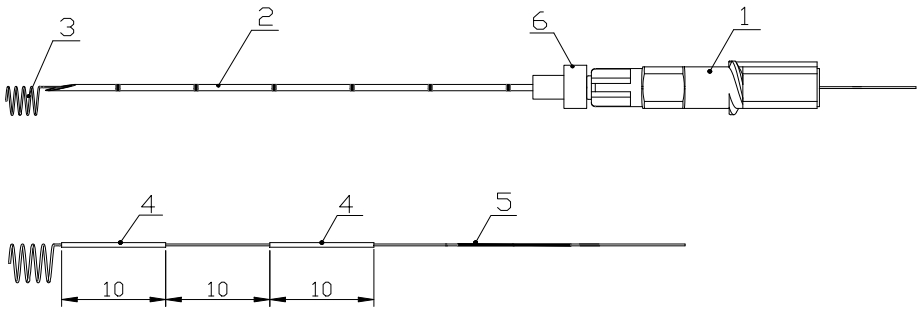


Fig 1. Breast Lesion Localization Wires—— Type Q



1. Operating handle; 2. Introducer needle; 3. Localization wire; 4. Localization mark; 5. Operating mark; 6. Depth stopper;

Fig 2. Breast Lesion Localization Wires—— Type SQ

Intended use:

Breast Lesion Localization Wire is intended for use during breast lesion surgery as a guide for the surgeon to follow in the excision of the lesion.

Contraindications:

Breast Lesion Localization Wire is not intended for use when a excision of the lesion are contraindicated. No device-specific contraindications are known currently. Contraindications related to the surgery are to be determined by surgical operators.

Complications:

Potential complications are site specific and may consist of hematoma, hemorrhage, infection, adjacent tissue injury, pain, bleeding, hemoptysis, hemothorax, non-target tissue, organ or vessel perforation and pneumothorax.

Precautions and Warnings:

- The Breast Lesion Localization Wire should be used by a physician who is completely familiar with the indications, contraindications, precautions, limitations, typical findings and possible side effects of percutaneous needle techniques.
- The introduction of the device into the body should be carried out under imaging control (ultrasound, X-Ray, CT, etc). **NOTE: This product has not been tested for MR Imaging compatibility.**
- Before using, inspect the device for damage that would prevent proper function. If the components are damaged or bent, DO NOT USE.
- The wire is meant to be a guide only. DO NOT use it as a retractor.
- Exercise caution during surgical excision of the lesion to avoid cutting the wire with a scalpel.
- Do not attempt to reshape the barb of the wire in any manner; this may cause the barb to fracture. If the barb of the wire is deformed or bent incorrectly, discard product.

- Caution should be exercised when using any localization wire on patients with breast prostheses so as not to puncture them during placement or transportation.
- The device is intended for single-use only. An infection or transmission of diseases could occur, if the device were to be re-used;
- A re-sterilization by users is not allowed.
- After use, this product may be a potential biohazard. Handle and dispose of in accordance with acceptable medical practice and applicable local, state, and federal laws and regulations.

Use Instruction:

- 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.
- While holding the cannula hub stationary, grasp the proximal end of the wire and slowly withdraw. S. Fig. A. The wire is fully withdrawn when the operating marking (the band of tight twists) on the wire are visible outside the cannula hub. S. Fig. B.

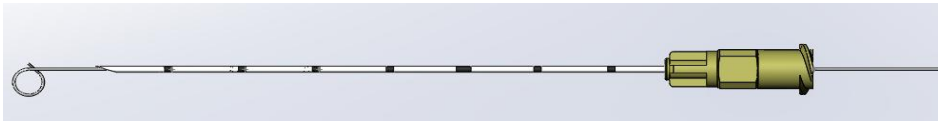


Fig. A

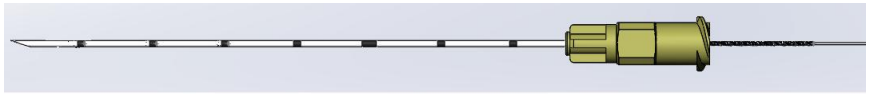


Fig. B

- Locate the lesion using the appropriate imaging technique.
- Insert the localization needle into the breast, directing it to the lesion (preferably parallel to the chest wall to reduce the possible risk of pneumothorax). Use the depth reference marks (centimeter markings) to position the needle point into the breast lesion (depth reference marks are 1cm apart), s. Fig.C.

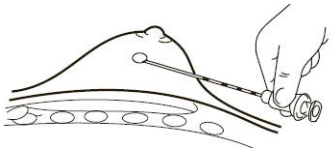


Fig. C

- Confirm needle placement with appropriate imaging technique. If necessary, reposition the needle and reconfirm placement.
- To deploy the barb, the localization wire should be held in place and the needle withdrawn until the ending of the operating marking on the wire is at the proximal end of the needle hub.S. Fig. D.

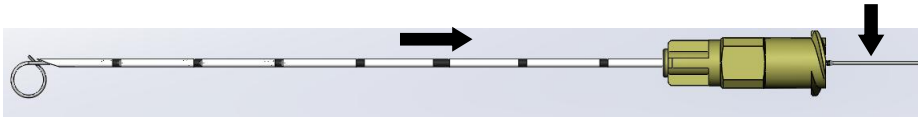


Fig.D

- If the localization wire needs to be repositioned or removed, withdraw the barb into the needle cannula by holding the proximal end of the wire stationary and slowly advancing the needle cannula forward. The barb is fully withdraw into the cannula when the operating marking on the wire are visible outside the cannula hub. S. Fig. B

  The reposition the needle cannula to the desired location and re-set the barb.

- The needle can now be removed and an x-ray and/or ultrasound can be taken to confirm the placement of the barb.
- The remaining exposed wire should be secured to the skin surface, using an appropriate method to prevent the wire from moving during transport to surgery (Fig. E). The wire clip may be placed on the wire at the surface to help avoid wire migration. Use sufficient pressure to place the wire clip on the wire (Fig. F).

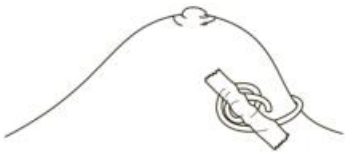


Fig. E

Fig. F

Packaging: 1 piece/pack

Manufacturing date and expiry: s. label

Validity of sterilization: 3 years

Graphics, Symbols, and Abbreviations Explained

STERILE EO	Sterilized Using Ethylene Oxide		Keep Away from Sunlight
	Single Use		Keep dry
	Do Not Use if Package is Damaged	40 °C -10 °C	Temperature Limitation -10~40 °C
LOT	Batch Code	80%	Humidity Limitation until to 80%
	Manufacturing Date		Do Not Re-sterilize
	Used By		Please Read the Instructions carefully Before Use
	Consult operating instructions		

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