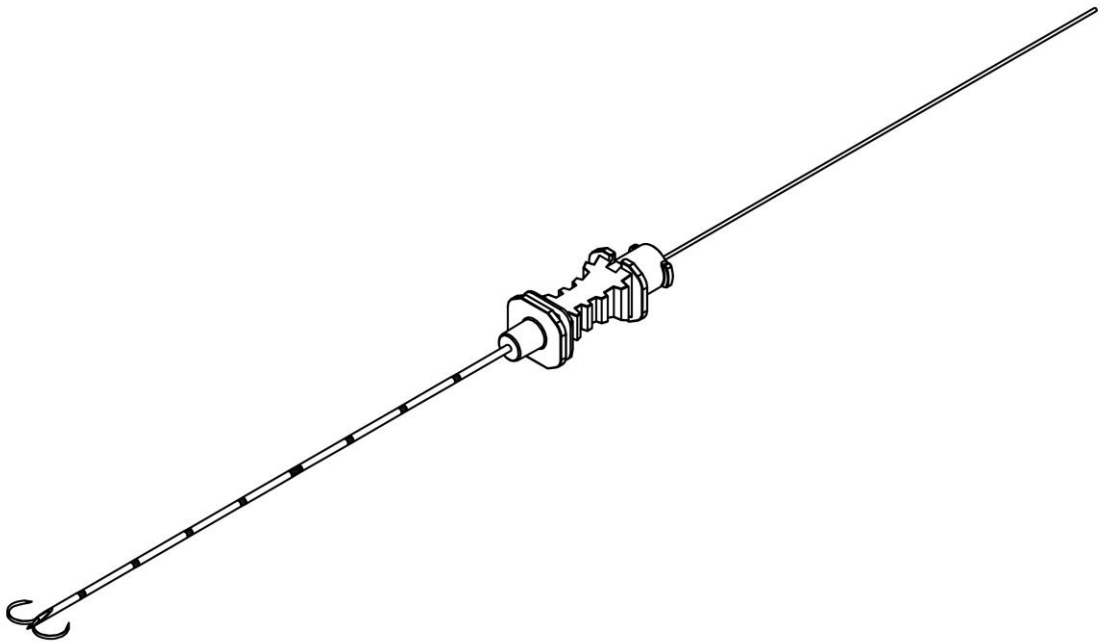
Tuloc

REF *271660 271661 271663*

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA



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INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA

Tuloc

Breast Localization Wire

Intended use:
The product is intended as a preoperative marker of non-palpable suspected breast lesions to facilitate the intraoperative localization of the findings by the surgeon.

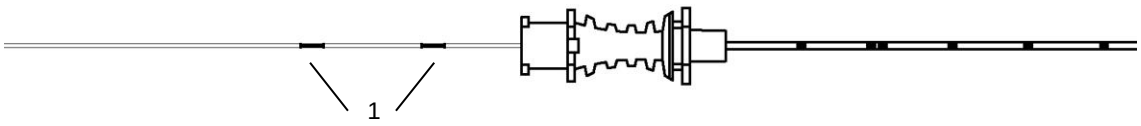
Product description:
The *Tuloc* consists of a hypodermic needle and a preloaded marking wire with distal double arches (*Figure 1*).
The marker wire has a marking (*Figure 1*) which provides the user with an orientation guide during the operation.

Contraindications:
All contra-indications applicable to the relevant area of application, as known according to the rules of the art of medicine and anticipated for the use of cannulas and marker systems for preoperative marking of breast lesions, shall apply.

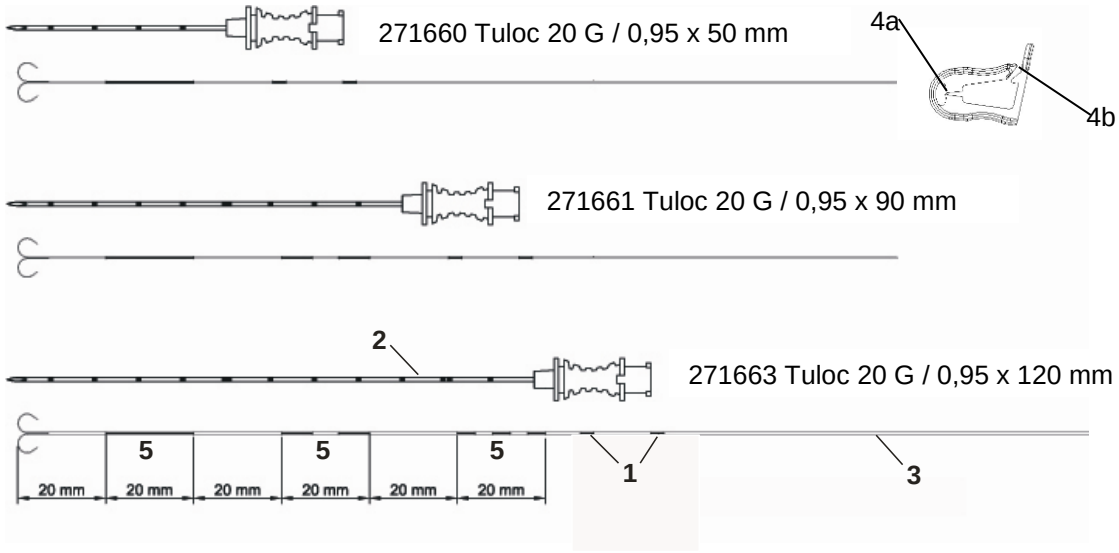
Possible known complications:
Wire dislocation, accidental cutting of wire, wire break, bleedings, infections, aesthetic complications

Warnings:
- Only qualified physicians with knowledge, experience and training in percutaneous soft tissue marking should use the *Tuloc*.
- This manual does not include descriptions or instructions for surgical techniques. It is the responsibility of the physician performing any procedure to determine the appropriateness of the type of procedure to be performed and the use of this product and to determine the specific technique for each patient.
- DO NOT use the system in patients with breast implants.
- The product is NOT suitable for MRI use (magnetic resonance imaging)! Danger of injury!
- The *Tuloc* tissue site marking system is only sterile, if used before the expiration date and if package is unopened and undamaged. DO NOT use after the expiration date or if package is open or damaged.
- Single patient use only. DO NOT reuse or resterilize.
- The product is NOT suitable in direct contact with electrosurgical instruments! 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 check and, if necessary, removal of wire fragments remaining in the body is required.

Precautions:
- Cannula tip is sharp. Use care especially while unpacking the cannula.
- Make sure that the marker wire is located inside of the cannula and that the curved parts of the wire do not protrude out of the tip of the cannula. Both circular marks (1) of the wire must be visible.
- **Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**



Device Description:
The *Tuloc* is a sterile, single use, tissue site marking system consisting of a nickel-titanium marker wire (3) and a puncture needle (2) and 1 cm depth marks to aid in cannula placement. The puncture needle is designed with a bevelled tip for convenient introduction. The marker wire is designed with two different markings, the first (1) marker allows the use to confirm that the curved parts of the wire do not protrude out of the tip of the cannula prior to deployment and the second markers (5), which are 20 mm apart, inform the user of the distance towards the distal end of the guide wire to facilitate the targeted removal of a tumor. To avoid the risk of a change of the wire position in the distal direction a wire fixation (4) is usable.



Directions for Use:

1. Prior to opening the package, make sure that the package has not been opened and/or damaged. In addition, check the sterilization expiration date.
2. Open the package.
3. Disinfect the puncture area and administer local anesthetic in the insertion area.
4. Use the scalpel to carry out an incision in the puncture site to facilitate the insertion into the skin.
5. Before starting the puncture make sure that the curved parts of the wire do not protrude out of the tip of the cannula. Both circular marks (1) of the wire must be visible.
6. Needle insertion: insert the needle under sonographic or mammographic guidance into the mamma such that the tip of the needle reaches the tumor itself or the tumor region.
7. After positioning the needle in the target area, the marker wire can be placed in the tumor area by holding the needle position and introducing the wire into the cannula from the proximal to the distal end. The guide wire tip is fully extended and in a curved shape once the two marks (1) on the guide wire are invisible.
   Note: The wire may be pushed into the cannula only until the last visible marking on the wire (1) has been inserted into the cannula attachment!
   IMPORTANT: Do not advance wire into the cannula any further past the second marking on the wire!
8. Prior to the removal of the needle, a proper positioning of the rolled wire can be inspected. Should the position be other than optimal, the wire can be withdrawn into the cannula. After rectifying the needle position, the wire can be deployed again according to the description in points 5 and 6 for preoperative marking.
9. Carefully remove the needle (2) from the mamma. If possible, bring the patient in an upright position. Relax the compression of the breast, if necessary. Slide the opened fixation part over the wire almost to the surface of the skin of the breast (**Caution**: The breast must be decompressed when this is done. There must still be some space between skin and fixation part). The wire must lie between the brackets (4a) of the fixation part. The wire is fixed through the closure being locked in place (4b). This measure prevents the risk of change in position of the wire along the distal end.
10. Treat the wound.
11. After the procedure, please ensure the appropriate disposal of the cannula (2) in the proper cannula container.

Storage Instructions:
Store in a dark, dry place with a temperature between 41 – 86 °F (5 – 30 °C).

Order Numbers:

Article Number	Size	Name
271660	20 G / 0,95 x 50 mm	Tuloc
271661	20 G / 0,95 x 90 mm	Tuloc
271663	20 G / 0,95 x 120 mm	Tuloc

Symbols:

SYMBOLS	EXPLANATION
	**Read instruction before use**
	**Order number**
	**LOT / Batch number**
	**Date of manufacture**
	**Manufacturer**
	**Expiration date**
	**Sterilized using ethylene oxide**
	**Do not reuse**
	**Do not resterilize**
	**Do not use damaged goods**
	**Temperature limit**
	**Not made with natural rubber latex**
	**Keep dry**
	**Keep away from sunlight & heat**

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