Tuloc Premium

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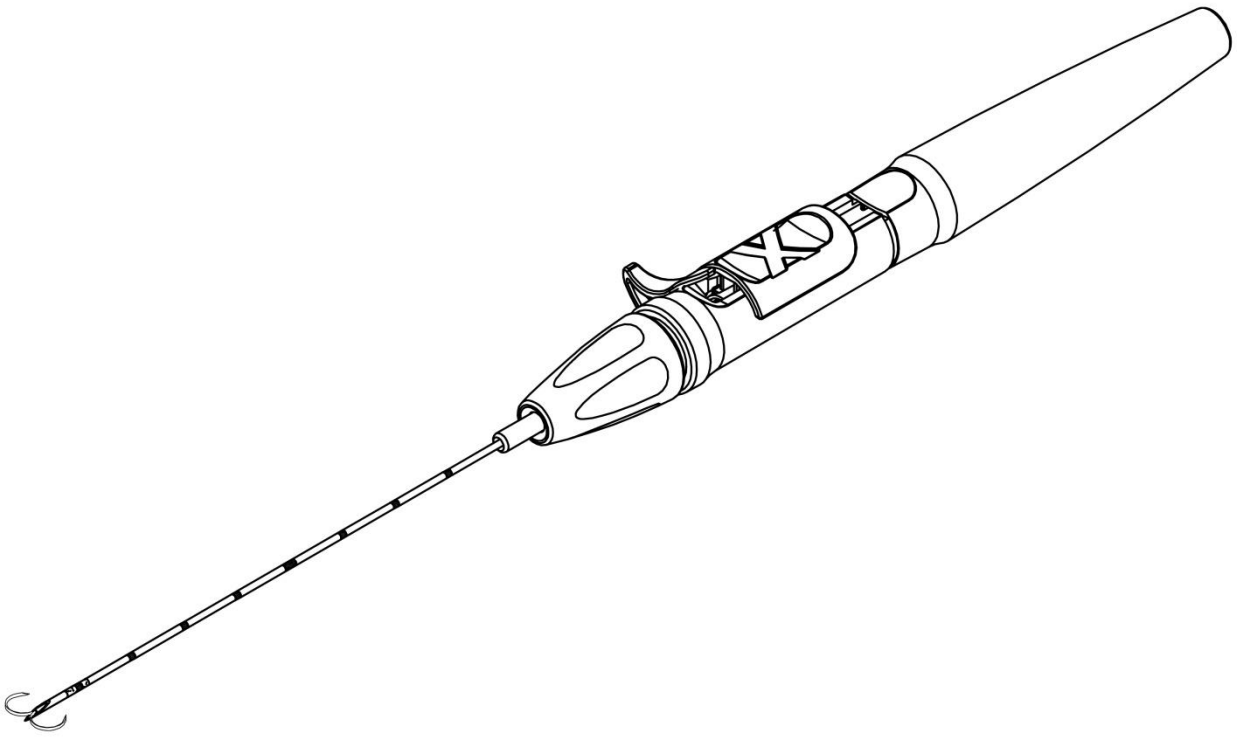
INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA



Art.no.: 999877V13-US

SOMATEX®
MEDICAL TECHNOLOGIES GMBH

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA

Important Information:
Read this instruction manual thoroughly and be familiar with its contents prior to use. Failure to read the entire manual and familiarize yourself with all instructions before using the ***Tuloc Premium*** Correctable Localization System is unsafe and can result in life threatening or severe injury to the patient or user and to damage or malfunction of the device.

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.

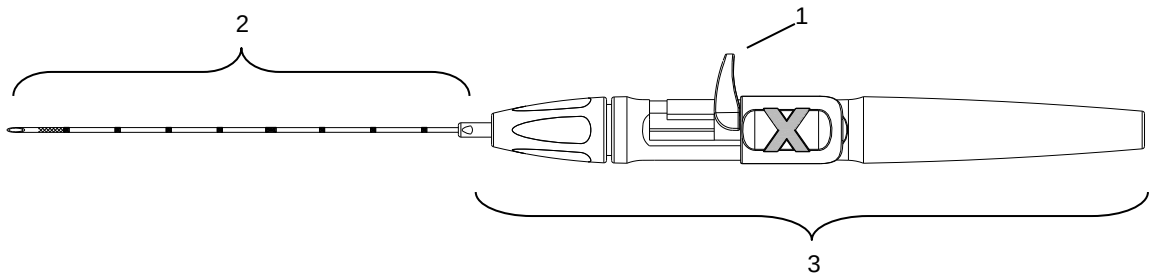
Contraindications:
All contra-indications applicable to the relevant area of application, as known according to the rules of the art of medicine and anticipated for the use of cannulas and marker systems for preoperative marking of breast lesions, shall apply.
The Tuloc Premium is contraindicated in patients with a nickel allergy.

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

Warnings:
- Only qualified physicians with the required knowledge, experience and training shall use the product.
- 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 procedure to be performed and of the use of this device and to determine the specific technique for each patient.
- When using the device near a breast implant, handle with care to avoid puncturing the breast implant.
- The product 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.
- The product is NOT suitable for MRI use (magnetic resonance imaging)! Danger of injury!
- 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.

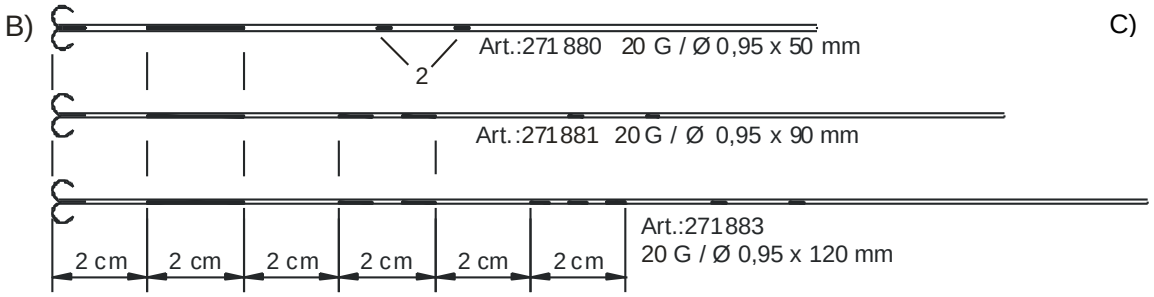
Precautions:
- Cannula tip is sharp. Use care especially while unpacking the cannula.
- Make sure that the marker wire is located inside of the cannula and that the curved parts of the wire do not protrude out of the tip of the cannula.
- The lever of the handle has to be in the right position (see A (1)) at the proximal end.
- **Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**

A)



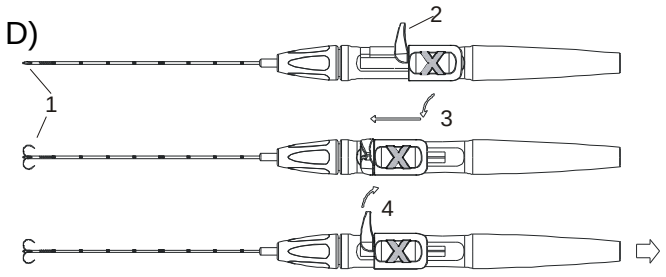
Device Description:
The ***Tuloc Premium*** Correctable Localization System is a sterile, single use, tissue site marking system consisting of a nickel-titanium marker wire (see B), a puncture needle (see A (2)), 1 cm depth marks to aid in cannula placement and a handpiece consists of handle (see A (3)) for placement of cannula and liver (see A (4)) for release of marker wire. The puncture needle is designed with a bevelled tip for convenient introduction. The marker wire is designed with different markings, 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 (see B (2)). To avoid the risk of a change of the wire position in the distal direction a wire fixation (see C) 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. The lever of the handle has to be in the right position (see A (1)) at the proximal end.
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 moving the lever sideways to the left, then pushing it all the way forward (see D (3)).
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 again by pulling back the lever (see D (2)), move the cannula tip into the desired position, re-extend the arches and note the new position of the arches.
9. After positioning the needle in the target area, the marker wire can be placed in the tumor area by moving the lever sideways to the left, then pushing it all the way forward (see D (3)). Before removing the cannula, turn lever to the right until it clicks into place (see D (4)). The lever will not now retract the wire!
10. Carefully remove the needle 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 (see C (4a)) of the fixation part. The wire is fixed through the closure being locked in place (see C (4b)). This measure prevents the risk of change in position of the wire along the distal end.
11. Treat the wound.
12. After the procedure, please ensure the appropriate disposal of the cannula in the proper cannula container.



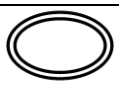
Storage Instructions:

Protect from moisture. Keep dry.
Keep away from sunlight and heat (temperature 5 – 30 °C / 41 – 86 °F).

Order Numbers:

Article Number	Size	Name
271880	20G/0.95 x 50 mm	Tuloc Premium
271881	20G/0.95 x 90 mm	Tuloc Premium
271883	20G/0,95 x 120 mm	Tuloc Premium

Symbols:

SYMBOLS	EXPLANATION
	Read instruction before use
	Order number
	LOT / Batch number
	Date of manufacture
	Manufacturer
	Expiration date
	Sterilized using ethylene oxide
	Sterile barrier system with protective packaging outside
	Double sterile barrier system
	Do not reuse
	Do not resterilize
	Do not use damaged goods
	Temperature limit
	Not made with natural rubber latex
	Keep away from sunlight and heat
	Keep dry

Manufactured by:
SOMATEX Medical Technologies GmbH
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Germany