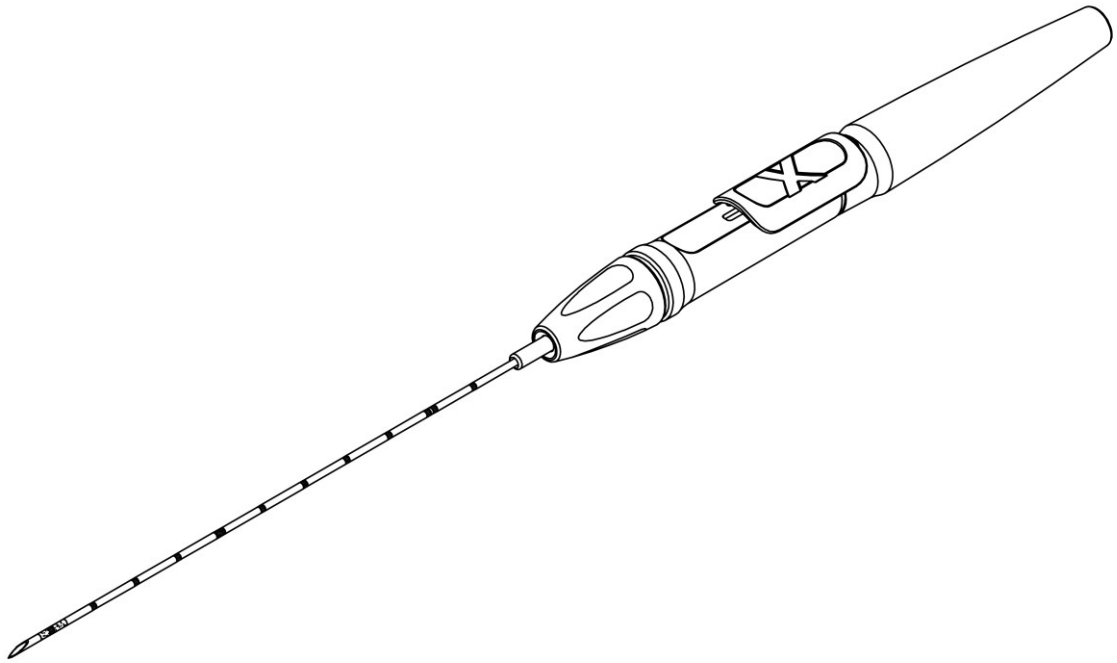
TUMARK® Professional X-Shape

REF 351210 351212

TUMARK® Professional Q-Shape

REF 351220 351222



INSTRUCTIONS FOR USE

Article No.: 999927V1

CE 0482

SOMATEX® MEDICAL TECHNOLOGIES GMBH

INSTRUCTION FOR USE

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 Tumark® Professional is unsafe and can result in life threatening or severe injury to the patient or user and to damage or malfunction of the device.

Indications:
The Tumark® Professional is intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. It is indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. It is not indicated to be used with magnetic resonance imaging (MRI) techniques.

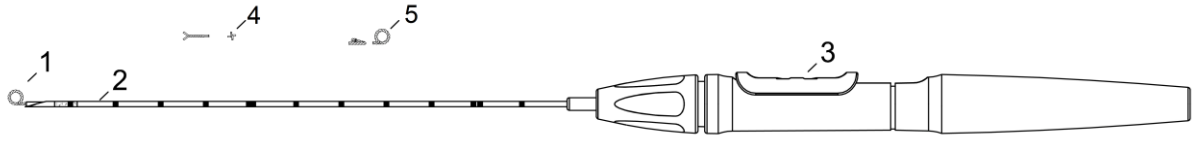
Purpose of the Device:
The Tumark® Professional serves for marking of soft breast tissue which ensures radiographical and radiological visibility using ultrasound and mammography and therefore lesion localization at a later date. The marker may be implanted to mark the location of a biopsy sampling point or the location of a removed tumor. In addition, it may be implanted in lesions prior to or during chemotherapy.

Contraindications:
- The Tumark® Professional is not intended for use except as indicated above.
- The use of the Tumark® Professional system is contraindicated in patients who suffer from a severe nickel allergy.

Warnings:
- Only qualified physicians with knowledge, experience and training in percutaneous soft tissue marking should use the Tumark® Professional.
- 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 Tumark® Professional tissue site marking system is only sterile if the indicator is green, if used before the expiration date and if package is unopened and undamaged. DO NOT use if indicator is not green, after the expiration date or if package is open or damaged.
- Single patient use only. DO NOT reuse or resterilize.

Precautions:
- Make sure that the slide-button does not change its backward position while placing the cannula.
- The marker must be placed by pushing the slide-button forward as far as possible.
- Cannula tip is sharp. Use care especially while unpacking the cannula.
- **Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**

Device Description:
The Tumark® Professional is a sterile, single use, preloaded tissue site marking system consisting of a non-absorbable nickel-titanium marker (1), an introducer cannula (2) and a plastic handle. The introducer cannula is designed with a beveled tip for convenient introduction, 1 cm depth marks and an ultrasound enhancement on the distal end to aid in cannula placement. The handle is equipped with a slide-button (3) which allows for a one handed placement of the marker by pressing it forward. A safety catch system prevents the slide-button to inadvertently move forward and therefore prevents a premature deployment of the marker. The clip markers for the Tumark® Professional are available in two different shapes: X-shape (4) and Q-shape (5). Instruments loaded with an X-shaped clip show the X on the handle. Instruments loaded with a Q-shaped clip show the Q on the handle.
For details please refer to order numbers.



Behaviour of the clip marker in Magnetic Resonance Imaging (MRI):
The Somatex Tumark® Professional, as applier of a clip marker, is not suitable for use in MRI, while the clip marker itself, which has already been placed in a patient, can be exposed to a magnetic field of up to 3.0 tesla, for instance in follow-up examinations. With regard to the interactions of the clip marker with the magnetic field (dislocation, heating), there are no additional dangers or risks to a patient with incorporated Tumark® Professional, clip marker in an MRI with 3.0 tesla or less.

The implanted clip marker itself can be subjected to an MRI procedure under the following conditions without any risk:

X-shape:

- Static magnetic field of 3.0 tesla or less
- Gradient field of 542 Gauss / cm or less
- Maximum whole-body average SAR (Specific Absorption Rate) of 2 W/kg at scan duration of 20 minutes.

In a non-clinical test with a 3 tesla Magnetom Trio (Siemens Medical, Erlangen, Germany) MRT using the Numaris 4, syngo MR software, the image artefact of the clip marker amounted to 2,7 mm while using a spin echo sequence, whereas 3,7 mm in case of gradient echo sequence.

Q-shape:

- Static magnetic field of 3.0 tesla or less
- Gradient field of 542 Gauss / cm or less
- Maximum whole-body average SAR (Specific Absorption Rate) of 2 W/kg at scan duration of 20 minutes.

In a non-clinical test with a 3 tesla Magnetom Trio (Siemens Medical, Erlangen, Germany) MRT using the Numaris 4, syngo MR software, the image artefact of the clip marker amounted to 4,7 mm while using a spin echo sequence, whereas 4,0 mm in case of gradient echo sequence.

Do not expose the implanted clip marker of the Tumark® Professional to other unconventional and non-standardized MRI-techniques than the ones listed above, because it has NOT BEEN TESTED for that purpose.

Directions for Use:

1. Prior to opening the package, make sure that the indicator on the package is green and that the package has not been opened and/or damaged. In addition, check the sterilization expiration date.
2. Disinfect the puncture area and cover it with sterile drapes.
3. Locate the target area by using appropriate imaging systems. Note that the Tumark® Professional is not useable in MR imaging systems.
4. Pull the protective tube away from the cannula hub with a twisting movement.
5. Puncture the target area with the cannula (2) and insert the cannula into the breast. The depth marks can assist you while positioning the cannula to the target.
6. Confirm the needle placement with appropriate imaging systems. If necessary correct the placement.
7. Place the marker (1) by firmly pushing the slide-button (3) forward as far as possible.
8. Confirm and document the location of the marker (1).
9. Remove the cannula (2).
10. Treat the wound.
11. After the procedure, please ensure the appropriate disposal of the cannula (2) in the proper cannula container.

Warning:

The company SOMATEX does not assume any liability for the use of this product or its components in case of re-sterilization or reuse. This product may not be reused after a single application. The quality of the materials, coats and adhesive joints could degrade. Safe use is not guaranteed any longer. The product that is already used once is not designed for the required cleaning and sterilization processes. The sterility of the reprocessed disposable products is therefore not guaranteed. The risk of unwanted injuries and infections, especially cross-infections between patient and medical staff inappropriately increases.

Storage Instructions:

Store in a dark, dry (humidity 30% - 65%) place with a temperature between 41° - 86° F (5° – 30°C).

SYMBOLS

	**Consult instructions for use**
REF	**Article number**
LOT	**Lot / Batch number**
	**Date of manufacture**
	**Manufacturer**
	**Use-by date**
STERILE EO	**Sterilized by ethylene oxide**
	**Single use only**

	**Do not resterilize**
	**Do not use if the package is damaged**
	**Temperature limit**
	**Not made with natural rubber latex**
	**Keep away from sunlight and heat**
	**Store in a dry place**
	**Green indicator: Product is sterilized**

INFO

Ordering:

REF	Ø	L	Name
351210	18 G / 1.20 mm	100 mm	Tumark® Professional X-Shape
351212	18 G / 1.20 mm	120 mm	Tumark® Professional X-Shape
351220	18 G / 1.20 mm	100 mm	Tumark® Professional Q-Shape
351222	18 G / 1.20 mm	120 mm	Tumark® Professional Q-Shape

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