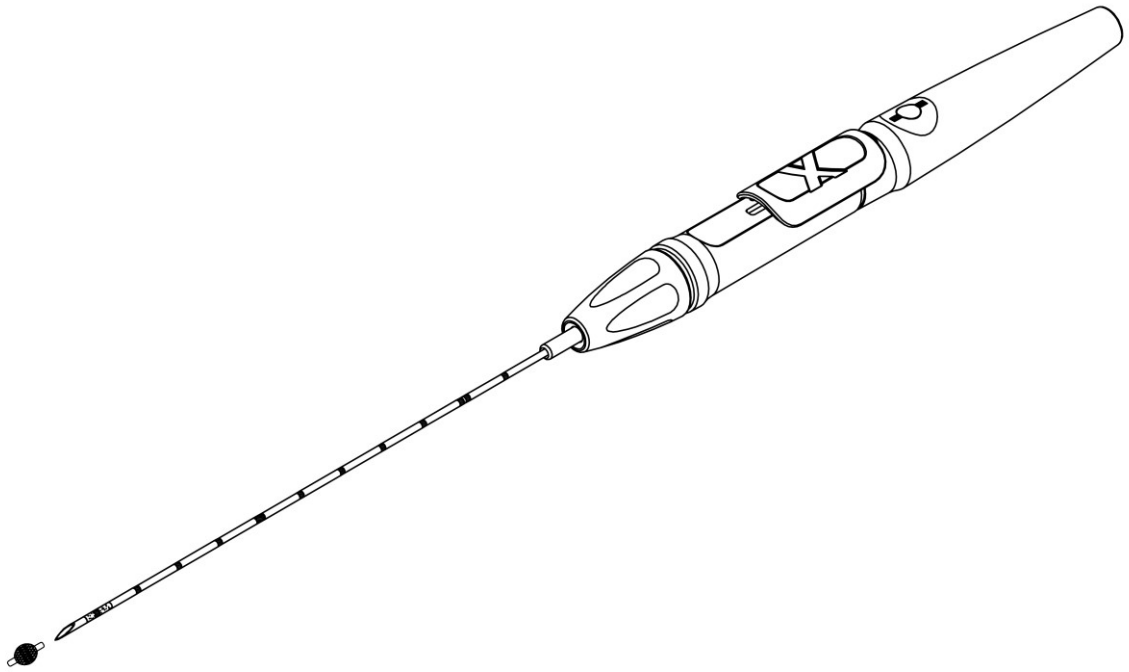
Tumark® Vision

REF *351230* *351232*



INSTRUCTIONS FOR USE

Article No.: 999926V1

CE 0482

SOMATEX® MEDICAL TECHNOLOGIES GMBH

INSTRUCTIONS FOR USE

Read instructions before use ***Keep for future reference***

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® Vision 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® Vision 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.

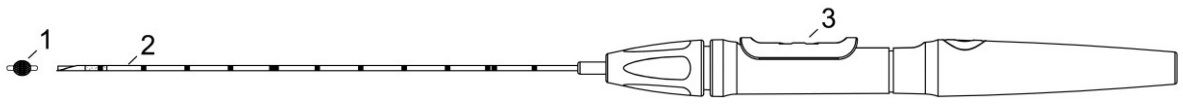
Purpose of the Device:
The Tumark® Vision serves for marking of soft breast tissue which ensures radiographical and radiological visibility using ultrasound and mammography and therefore lesion localization at a later date. The marker may be implanted to mark the location of a biopsy sampling point or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

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

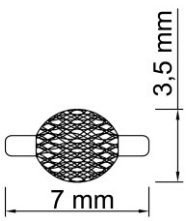
Warnings:
- Only qualified physicians with knowledge, experience and training in percutaneous soft tissue marking should use the Tumark® Vision.
- This manual does not include descriptions or instructions for surgical techniques. It is the responsibility of the physician performing any procedure to determine the appropriateness of the procedure to be performed and of the use of this device and to determine the specific technique for each patient.
- DO NOT use the system in patients with breast implants.
- The Tumark® Vision tissue site marking system is only sterile if the indicator on the package 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® Vision 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 marker has a spherical shape. The clip shape is labelled on the handle.



Schematic illustration



Dimensions of clip marker

Behaviour of the clip marker in Magnetic Resonance Imaging (MRI):
The Somatex Tumark® Vision as an application system for clip markers is not suitable for use in MRI.
The clip marker itself, which has already been placed inside a patient, can be exposed to a magnetic field of up to 3.0 Tesla, for example in follow-up examinations. With regard to interaction (displacement) there are no increased risks to a patient with a Tumark Vision® clip marker implant.

The behaviour of the clip marker in MRI was tested under the following conditions (not clinically):
- Static magnetic field of 1.5 Tesla and 3.0 Tesla
- Gradient field of 542 Gauß/cm max.

The temperature increase of the Tumark® Vision clip marker was assessed as *not clinically significant*.

The non-clinical testing was performed with 1.5 Tesla on a MRI of type *Magnetom Avanto (Siemens Medical, Erlangen, Germany)* with *Numaris 4, syngo MR B17* software. The clip marker image artefact amounted to 4.3 mm during the spin echo sequence and 5.2 mm during the gradient echo sequence.
The non-clinical testing was performed with 3 Tesla on a MRI of type *Magnetom Skyra (Siemens Medical, Erlangen, Germany)* with *Numaris 4, syngo MR D13* software. The clip maker image artefact amounted to 5.2 mm during the spin echo sequence and 5.8 mm during the gradient echo sequence.

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

Directions for Use:
1. Prior to opening the pack, 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 the area around it with sterile drapes if required.
3. Locate the target area by using appropriate imaging systems. Note that the Tumark® Vision cannula is not useable for MR imaging systems. Consider the size of the clip marker in relation to the area to be marked (see picture *Dimensions of clip marker*).
4. Pull the protective tube from the cannula hub with a twisting movement.
5. Puncture the target area with the cannula (2) and insert the cannula into the tissue. The puncture depth can be measured by the marks on the cannula when the cannula tip is being positioned.
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 to stop position.
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-sterilisation 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 sterilisation 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.

SYMBOLS

	**Consult instructions for use**
	**Article number**
	**Lot / Batch number**
	**Date of manufacture**
	**Manufacturer**
	**Use-by date**
	**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**
	**MR unsafe (concerns only cannula)**
	Green indicator: Product is sterilized

INFO

Ordering:

REF	Ø	L
351230	1.2 mm / 18 G	100 mm
351232	1.2 mm / 18 G	120 mm

Manufactured by:
SOMATEX Medical Technologies GmbH
Rheinstr. 7d
14513 Teltow
GERMANY

Tel.: + 49 (0) 30 319 82 25-00
Fax: + 49 (0) 30 319 82 25-99
service@somatex.com
www.somatex.com