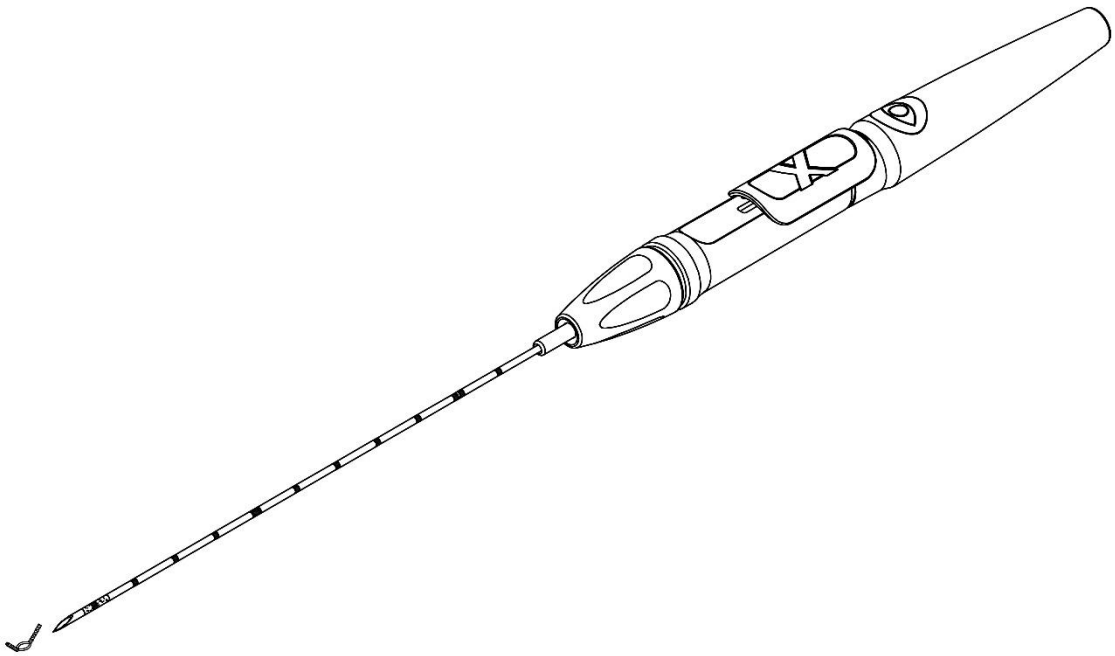
Tumark® Eye

REF 271510 271512



INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA

Article No.: 999835V6-US

SOMATEX®
MEDICAL TECHNOLOGIES GMBH

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA

CONTENT

EN - ENGLISH

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® Eye* 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® Eye* 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® Eye* 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® Eye* is not intended for use except as indicated above.
- The use of the *Tumark® Eye* 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 shall use the *Tumark® Eye*.
- 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 implanting a clip marker near a breast implant, handle with care to avoid puncturing the breast implant.
- The *Tumark® Eye* should only be used if the indicator on the packaging is green, only before the expiry date, and only if the packaging is unopened and undamaged. Product sterility can only be guaranteed if these criteria are met. If the indicator is not green, if the expiry date is exceeded, or if the packaging is damaged or opened before use, the product should not be used and the distributor or manufacturer, SOMATEX, should be contacted.
- The product is intended for single use only: DO NOT reuse or resterilize.
- When using a positioning needle, the *Tumark® Eye* must be checked for compatibility in advance. The bevelled *Tumark® Eye* cannula tip opening should protrude fully out of the positioning needle, and the user should be able to gauge this protrusion in order to be able to apply the clip marker safely and not place it too far into the tissue.

Precautions:
- The *Tumark® Eye* clip marker is made from a nickel-titanium alloy (Nitinol), which is why the product is contraindicated in patients with severe nickel allergy.
- Make sure that the slide button remains in the retracted position while the cannula is being put in position.
- The clip marker must be placed by pushing the slide button forward as far as possible to the stop position.
- There is risk of injury due to the sharp cannula tip. Use care especially when unpacking the cannula.
- The cannula of *Tumark® Eye* is NOT made of MRI-compatible metals. NOT suitable for MRI safety area. Danger of injury!
- Pay attention to the dimensions of the clip marker in relation to the size of the tissue area being marked (see Product Description).
- In rare cases the expansion of the clip marker may be delayed. Visibility in radiological imaging might be compromised until full expansion.
- **Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**

Information about materials used:
The implantable clip marker is made from a nickel-titanium alloy (Nitinol).

MRI Safety Information application system (cannula with handle):

MR unsafe

Unlike the clip marker, the *Tumark® Eye* cannula application device is not suitable for use in an MRI scanner.

MRI Safety Information clip marker:

MR
MR conditional

The clip marker is conditionally MR safe. A patient can safely undergo an MRI procedure with the clip marker under the following conditions:

- static magnetic field up to 3.0 Tesla with
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg.

Non-clinical tests were performed on the following systems:

- 1.5 Tesla Siemens Magnetom Avanto (Siemens Medical, Erlangen, Germany) MRI with software Numaris 4, syngo MR (Version "B13, N4_VB13A_LATEST_20060607_P29"),
- 3 Tesla Siemens Magnetom Skyra (Siemens Medical, Erlangen, Germany) MRI with software Numaris 4, syngo MR (Version "D11, N4_VB11D_LATEST_20110129_P3").

Under the scanning conditions defined above, it is expected that clip marker of *Tumark® Eye* will produce the following maximum RF-related temperature rise:

- at 1.5 Tesla: < 1.0 °C (2 W/kg SAR) after 20 min of continous scanning,
- at 3.0 Tesla: < 1.0 °C (2 W/kg SAR) after 20 min of continous scanning.

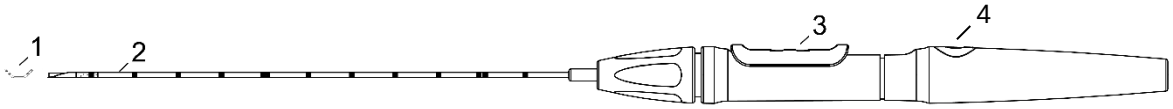
Under the scanning conditions defined above, it is expected that clip marker of *Tumark® Eye* will produce the following image artefacts:

- at 1.5 Tesla: 3.4 mm spin echo sequence; 3.8 mm gradient echo sequence,
- at 3.0 Tesla: 3.7 mm spin echo sequence; 3.9 mm gradient echo sequence.

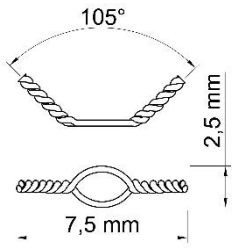
Do not expose the implanted *Tumark® Eye* clip marker to unconventional and non-standardized MRI-techniques other than the ones listed above, because it has NOT BEEN TESTED for that purpose.

Product Description:

This is a sterile product for single use only and consists of a non-absorbable nickel-titanium clip marker (1), an introducer cannula (2), and a plastic handle. When new and unopened, the clip marker is contained within the cannula. The cannula tip is bevelled to help insertion, has markings 1 cm apart for measuring the depth of penetration, and a textured surface behind the cannula tip. The handle is equipped with a slide button (3) which allows one handed placement of the marker by pressing it forward. A safety catch system prevents the slide button from inadvertently moving forward and therefore prevents premature deployment of the marker. The clip marker has a circular shape with lateral protruding ends. The symbol of the clip marker shape is depicted on the handle (4).



schematic representation



dimensions of the eye marker

Directions for Use:

1. Before opening, make sure that the packaging is not already open or damaged, that the indicator on the packaging is green, and that it is within the expiry date.
2. Disinfect the puncture area and cover the area around it with sterile drapes if required.
3. Use suitable imaging methods (ultrasound, mammography) to identify the target area. NOTE: the *Tumark® Eye* cannula is not suitable for the MRI safety zone.
4. Open the packaging and remove the product from packaging.
5. Remove the cannula protection hose from the outer cannula by twisting.
6. Use the cannula (2) to puncture the target area, and insert into the tissue. The depth of insertion can be read from the markings on the cannula when positioning the cannula tip.
7. Check the position of the cannula tip using suitable imaging techniques, and adjust if appropriate.
8. Place the clip marker (1) by pushing the slide button (3) forward as far as it will go.
9. Verify and record the position of the clip marker (1).
10. Remove the cannula (2).
11. Treat the wound.

12. After use: dispose the application device properly, following internal guidelines if appropriate; however, at least one suitable container intended for contaminated cannulas should be provided to ensure safe disposal.

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 dry and cool area at a temperature of 5 – 30 °C / 41 °F – 86 °F.
Keep away from sunlight and heat.

Any serious events that occur in relation to the product should be reported to SOMATEX as well as the competent national authority.

SYMBOLS

	ENGLISH
	Consult instructions for use
REF	Catalog number
LOT	Lot / Batch code
	Date of manufacture
	Manufacturer
	Use-by date
STERILE EO	Sterilized by ethylene oxide
	Do not reuse
	Do not resterilize
	Do not use if the package is damaged
	Temperature limit
	Single sterile barrier system with protective packaging outside
	Single sterile barrier system
	Not made with natural rubber latex
	Keep away from sunlight and heat
	Store in a dry place
	MR unsafe (concerns only cannula)
	MR conditional
MD	Medical Device
●	Green indicator: Product is sterilized
L	Length
Ø	Diameter

INFO

Ordering:

REF	Ø	L
271510	1.2 mm / 18 G	100 mm
271512	1.2 mm / 18 G	120 mm

Manufactured by:
SOMATEX Medical Technologies GmbH
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Germany

SOMATEX®
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