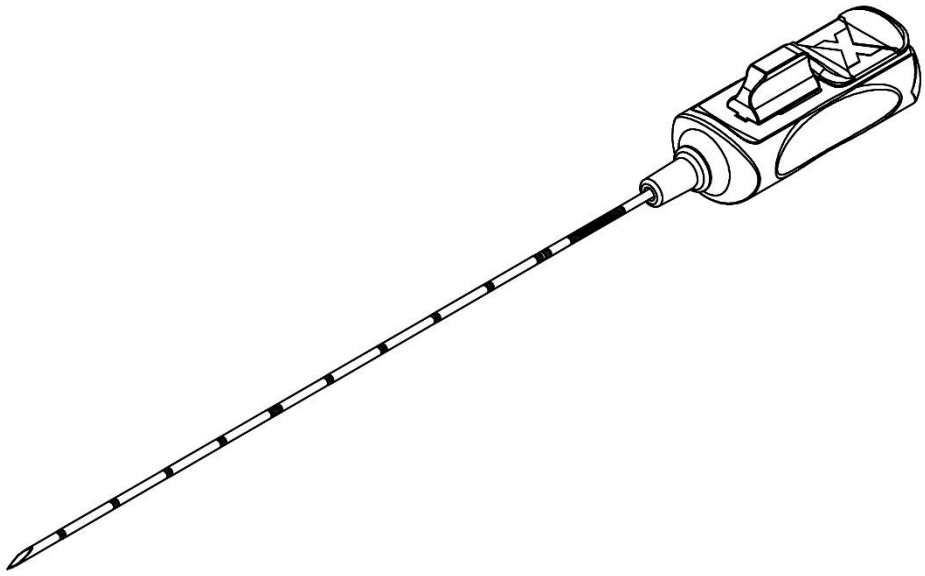
Tumark® MRI

REF 601570

INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA



INSTRUCTIONS FOR USE

Article No.: 999885V9-US

SOMATEX®
MEDICAL TECHNOLOGIES GMBH

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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® MRI* 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® MRI* 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 location in breasts tissue following an open or percutaneous procedure. It is intended to be used with magnetic resonance imaging (MRI) techniques.

Purpose of the Device:
The *Tumark® MRI* serves for marking of soft breast tissue which ensures visibility using magnetic resonance imaging (MRI) techniques 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® MRI* is only intended for the use indicated above.
- The use of the *Tumark® MRI* 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® MRI*.
- Only qualified physicians with knowledge, experience and training in MR Imaging should use the *Tumark® MRI* in Magnetic Resonance Imaging (MRI) procedures.
- 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® MRI* should only be used 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 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® MRI* must be checked for compatibility in advance. The bevelled *Tumark® MRI* 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.
- Note that the size of the image artifact depends on the sequence and the orientation towards the B_0 field. Therefore the actual position of the cannula tip may differ from the position of the artifact tip.

Precautions:
- The *Tumark® MRI* 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.
- 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 law (USA) 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).
- The cannula is made from an alloy of cobalt and chrome.

MRI Safety Information:

MR
MR conditional

The *Tumark® MRI* is conditionally MR safe. A patient can safely undergo an MRI procedure with the application system (cannula with handle) and the clip marker under the following conditions:
- static magnetic field of **1.5 Tesla** and **3.0 Tesla** with
- theoretically estimated maximum – averaged across the whole body – specific absorption rate (whole body averaged SAR) of 2 W/kg for scanning of 20 minutes.

Non-clinical tests were performed on the following systems:

- 3 Tesla Siemens Magnetom Trio (Siemens Medical, Erlangen, Germany) MRI with Software Numaris 4, syngo MR (Version "B15, N4_VB15A_LATEST_20070519_P12"),
- 1.5 Siemens Magnetom Avanto (Siemens Medical, Erlangen, Germany) MRI with Software Numaris 4, syngo MR (Version "B13, N4_VB13A_LATEST_20060607_P29").

Under the scanning conditions defined above, it is expected that the *Tumark® MRI* will produce the following maximum HF-conditional temperature rise after 20 minutes of continuous scanning:

- **Application system with 1.5 Tesla: 1.41 °C (2 W/kg SAR)**
- **Application system with 3.0 Tesla: 1.07 °C (2 W/kg SAR)**
- **Clip Marker with 1.5 Tesla: <1 °C (2 W/kg SAR)**
- **Clip Marker with 3.0 Tesla: <1 °C (2 W/kg SAR).**

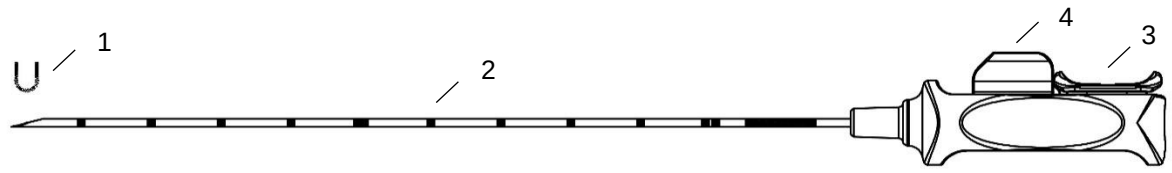
Under the scanning conditions defined above, it is expected that the *Tumark® MRI* will produce the following maximum image artefacts:

- Application system with 1.5 Tesla: 13.4 mm spin echo sequence, 8.9 mm gradient echo sequence
- Application system with 3.0 Tesla: 52.1 mm spin echo sequence, 47.8 mm gradient echo sequence
- Clip Marker with 1.5 Tesla: 7.1 mm spin echo sequence, 6.5 mm gradient echo sequence
- Clip Marker with 3.0 Tesla: 9.0 mm spin echo sequence, 6.5 mm gradient echo sequence.

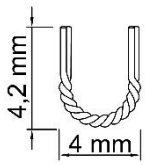
Do not expose the implanted clip marker to unconventional and non-standardized MRI techniques other than the ones listed above, because it has NOT BEEN TESTED for that purpose.

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 marker clip can be placed using one hand by pushing the slide button on the plastic handle forward (3) once the fixing clip (4) has been removed. 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 U- shape (1).



schematic representation



dimensions of clip marker

Directions for Use:

1. Before opening, make sure that the packaging is not already open or damaged 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. Locate the target area by using appropriate MR imaging systems.
4. Open the packaging and remove the product from packaging.
5. Remove the fixing clip (4) from the handle and remove the cannula protection hose by twisting it from the base.
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. Confirm the needle placement with appropriate MR imaging systems. If necessary correct the placement.
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:
Keep away from sunlight and heat.
Store in a dry area at a temperature of 5 – 30 °C / 41 – 86 °F.

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**
	**Catalogue number**
	**Lot / Batch code**
	**Date of manufacture**
	**Manufacturer**
	**Use-by date**
	**Sterilized by ethylene oxide**
	**Sterile barrier system with protective packaging outside**
	**Double sterile barrier system**
	**Do not reuse**
	**Do not resterilize**
	**Do not use if package is damaged**
	**Temperature limit**
	**Not made with natural rubber latex**
	**Keep away from sunlight and heat**
	**Keep dry**
	**MR conditional**
	**Medical Device**
L	**Length**
Ø	**Diameter**

INFO

Ordering:

REF	Ø	L	Name
601570	18 G / 1.20 mm	120 mm	Tumark® MRI

Manufactured by:
SOMATEX Medical Technologies GmbH
Kaiserin-Augusta-Allee 112/113
10553 Berlin
Germany

SOMATEX®
MEDICAL TECHNOLOGIES GMBH