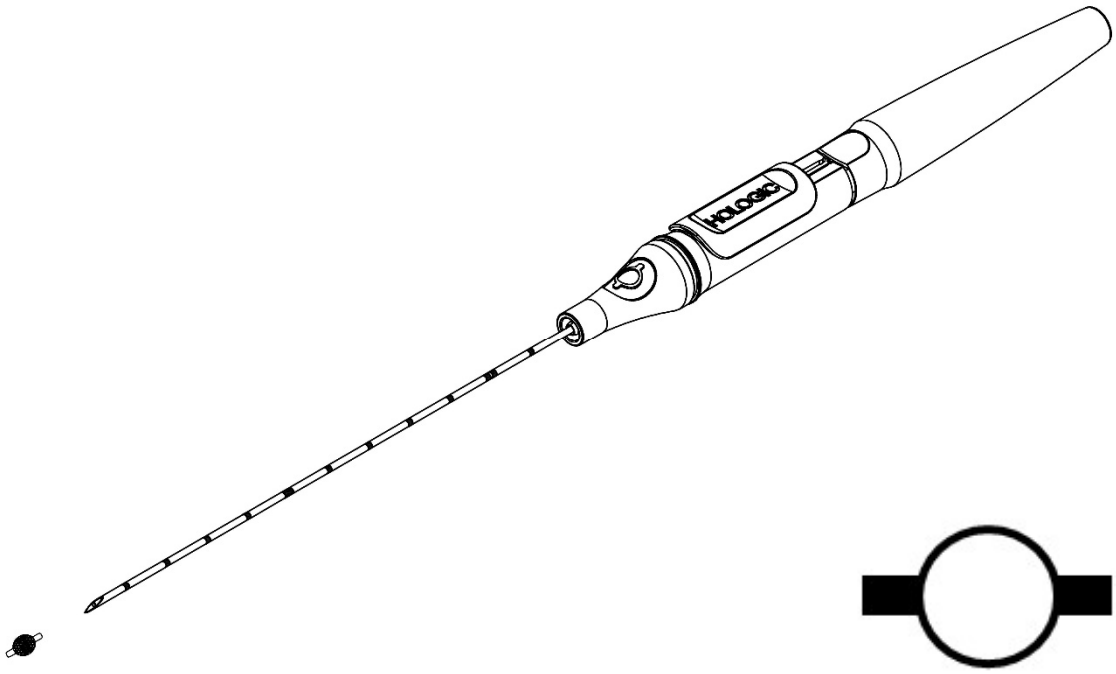
Tumark® Vision

REF 351230 351232



INSTRUCTIONS FOR USE OF THE DEVICE IN THE USA

HOLOGIC®

Article No.: 999926V5-US

INSTRUCTIONS FOR USE

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

Important Information:
Read the 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 device 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 breast tissue and axillary lymph nodes, following an open or a percutaneous procedure to radiographically mark the location of the surgical site. It is not indicated to be used with magnetic resonance imaging (MRI) techniques.

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.

Use environment:
The application takes place in a clinical environment (examination room in a hospital or specialist practice).

Performance characteristics:
- Visibility of the clip markers in X-ray, MRI and sonography procedures.
- Long-term stable marking of tissue by anchoring the clip marker in the target tissue.

Duration of use:
The clip marker of the *Tumark® Vision* is a permanent implant (> 30 days).

Potential adverse effects and complications not specifically related to the device but associated with surgical procedures in general can include:
Accidental intravascular placement with downstream embolization, implant migration, increased implant migration for clip marking in stereotactic procedure and after vacuum assisted biopsy, damage to nerves and vessels, puncture of breast implants, hypersensitivity/allergic reaction, foreign body reaction, inflammation, hematoma, compromised visibility in ultrasound imaging due to expansion delay of the clip marker, compromised visibility in ultrasound imaging due to lack of deployment of the vision marker, discomfort/pain, infections.

Information to be conveyed to the patient:
- Physician is responsible for informing the patient about any potential residual risks and undesirable side-effects
- Product is contraindicated in patients with nickel allergy

Clinical benefit:
The device has a positive impact on patient management by enabling directed imaging during follow-up procedures and radiotherapy which ultimately delivers the direct clinical benefit to the patient.

Warnings:

- Only qualified physicians with knowledge, experience and training in percutaneous soft tissue marking and axillary lymph nodes 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.
- Ensure a sterile environment and aseptic way of working! Failure in sterile handling can lead to infections.
- When implanting a clip marker near a breast implant, handle with care to avoid puncturing the breast implant.
- The products should only be used if the indicator on the packaging is green, only before the expiration 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 expiration date is exceeded, or if the packaging is damaged or opened before use, the product should not be used.
- The product is intended for single use only: DO NOT reuse or resterilize. The quality of the materials, coats and adhesive joints could degrade. The product that is already used once is not designed for the required cleaning and sterilization processes. Sterility of the reprocessed disposable products and safe use are therefore not guaranteed. The risk of unwanted injuries and infections, especially cross-infections between patient and medical staff inappropriately increases. The company SOMATEX does not assume any liability for the use of this product or its components in case of re-sterilization or reuse.
- When using a positioning needle, the *Tumark® Vision* must be checked for compatibility in advance. The bevelled 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.
- Care must be taken, when marking axillary lymph nodes in particular, NOT to trap nearby blood vessels with the clip marker and not to damage a nearby nerve.
- If the clip marker, which was placed in the area of the axillary lymph nodes, cannot be found again, it is important to identify and ensure its location.
- When marking axillary lymph nodes there is a potential risk of introducing the clip marker into the venous system and embolising downstream.
- After setting, the clip marker can migrate depending on the strength of the target tissue. It is recommended to check and observe the position of the clip marker.
- Before using the products, a nickel allergy must be excluded for the patient and they must be advised of possible allergic reactions. An allergy test can be performed on the patient in advance.
- The marker **application system** is **NOT** suitable for deployment under **MRI**.
- Patients with implanted clip markers can undergo MRI imaging.
- The cannulas are NOT made of MRI-compatible metals. NOT suitable for MRI safety area. Danger of injury!

Precautions:

- Make sure that the slider does not change its backward position while placing the cannula.
- The clip marker must be placed by pushing the slider 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 device description).
- In rare cases the expansion of the clip marker may be delayed. Visibility in radiological imaging might be compromised until full expansion.
- The frequency and periods of monitoring after clip marker implantation are determined by the physician.

- **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) with the % mass fractions of the individual elements according to ASTM F2063: Nickel 54.5 to 57.0 %; Carbon ≤ 0.04 %; Copper ≤ 0.01 %; Chromium ≤ 0.01 %; Hydrogen ≤ 0.005 %; Iron ≤ 0.05 %; Niobium ≤ 0.025 %; Nitrogen ≤ 0.005 %; Oxygen ≤ 0.04 %; Titanium is roughly equal to the difference between 100 % and the sum of the aforementioned mass fractions of the other elements.

MRI Safety Information application system:

MR unsafe

The *Tumark® Vision* as an application system for clip markers is **not** suitable for use in MRI.

MRI Safety Information clip marker:

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
- maximum spatial field gradient of 8,100 G/cm (81 T/m)
- maximum force product of 339,000,000 G^2/cm (339 T^2/m)
- theoretically estimated maximum whole body averaged (WBA) specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode).

Non-clinical tests were performed on the following systems to determine image artefacts:

- 1.5 Tesla Philips Achieva dStream (Philips Healthcare, Best, The Netherlands) MRI with Software 5.4.1\5.4.1.2
- 3.0 Tesla Philips Ingenia (Philips Healthcare, Best, The Netherlands) MRI with Software 5.3.1\5.3.1.3

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

- at 1.5 Tesla: 5.4 °C (2 W/kg SAR) RF-related temperature increase after 15 min of continuous scanning,
- at 3.0 Tesla: 5.1 °C (2 W/kg SAR) RF-related temperature increase after 15 min of continuous scanning.

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

- at 1.5 Tesla: 5.0 mm spin echo sequence; 5.0 mm gradient echo sequence;
- at 3.0 Tesla: 5.3 mm spin echo sequence; 5.7 mm gradient echo sequence.

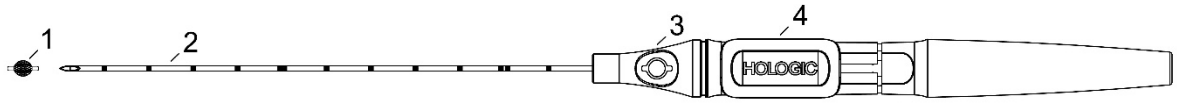
Do not expose the implanted clip marker to unconventional and non-standardized MRI techniques other than the ones listed above, because it has NOT BEEN TESTED for that purpose.

Device description:

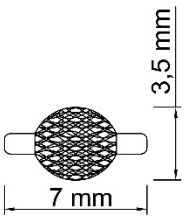
The product is a sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker (1), an introducer cannula (2) and a plastic handheld applier with deployment mechanism.

The cannula tip is bevelled to help insertion, has markings 1 cm apart for orientation regarding the depth of penetration, and a textured surface behind the cannula tip. The handle is equipped with a slide-button (4) which allows for a one handed placement of the clip 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 clip marker. After pushing out of the cannula, the clip marker expands and takes its final shape.

The clip marker has a spherical shape. The symbol of the clip marker shape is depicted on the handle (3).



Schematic illustration



Dimensions of clip marker

Device Preparation and Use:

1. Prior to use, ensure that the sterilization indicator is green and that the packaging has not been opened and / or damaged. Do not use the product if the packaging or the product appears to have been comprised. Check the sterilization expiration date. Do not use the product if it has expired.
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 that the marker **application system** is **NOT** suitable for deployment under **MRI**.
   - Consider the size of the clip marker in relation to the area to be marked (see picture *dimensions of clip marker*).
4. Open the packaging and remove the product from the 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. Deploy the marker by advancing the slider forward **as far as possible to the stop position.** After pushing out of the cannula, the clip marker expands and takes its final shape.
9. Verify and record the position of the clip marker.
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.
13. The clip marker is designed to remain permanently in the tissue. If it marks a conspicuous lesion, it is customary to also remove the clip marker with explantation of the lesion.
14. If it is necessary to remove the clip due to a medical diagnosis, the clip must be localized in advance with an imaging method and, in the case of deeper clips, marked with a marking wire so that the clip marker can then be surgically removed. The final explantation procedure is the responsibility of the physician.
15. Disposal of the clip marker: After the explantation, the clip marker can be properly disposed together with the explanted tissue as a contaminated explant.

Storage Instructions:

Store in a dry place, keep away from sunlight and heat (temperature of 5 – 30 °C / 41 °F – 86 °F).

SYMBOLS

	Caution
	Consult instructions for use
	Catalogue number
	Batch code
	Date of manufacture
	Manufacturer
	Expiration date
	Sterilized by ethylene oxide
	Medical Device
	Do not reuse
	Do not resterilize
L	Length

	Do not use if package is damaged
	Non-sterile protective packaging with the sterile barrier system inside
	Sterile barrier system / sterile packaging
	Green indicator: `Product is sterilized`
	Temperature limit
	Not made with natural rubber latex
	Keep away from sunlight and heat
	Store in a dry place
	MR unsafe (concerns only cannula)
	MR conditional (concerns only clip marker)
	Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician
Ø	Diameter

ORDERING

REF	Name	Diameter	Length
351230	Tumark® Vision	18G / 1.20 mm	100 mm
351232	Tumark® Vision		120 mm

HOLOGIC®

Distributed by:
Hologic, Inc.
250 Campus Drive
Marlborough, MA 01752 USA
Phone: 877-371-4372
email: mammosupport@hologic.com
www.hologic.com

SOMATEX Medical Technologies GmbH
Hohenzollerndamm 150 / 151
14199 Berlin
Germany

999926V5-US