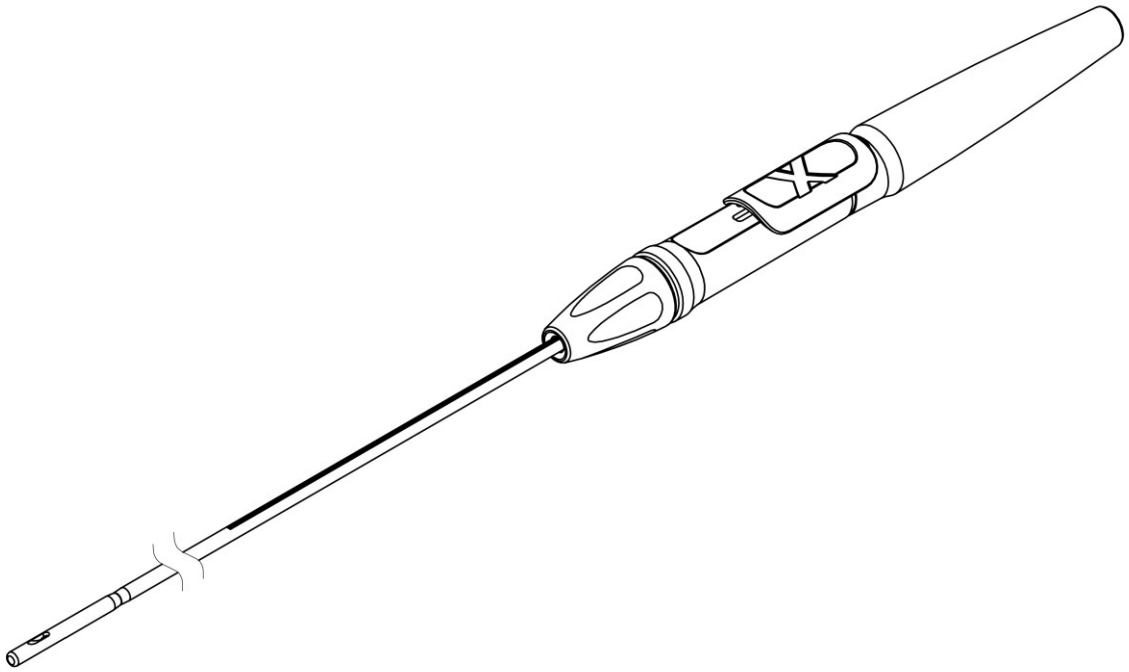
Tumark Flex for ATEC®

REF *351250* *351252*



INSTRUCTIONS FOR USE

Article No.: 999929V1

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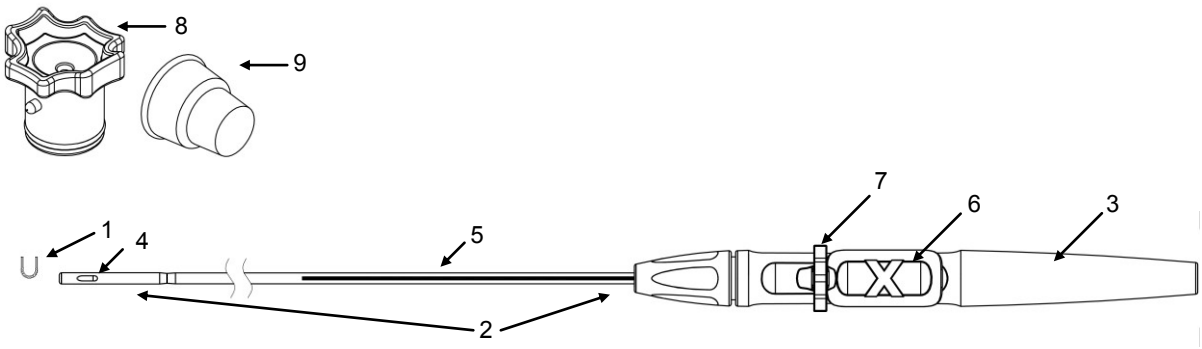
SOMATEX® MEDICAL TECHNOLOGIES GMBH



Instructions for use

Tumark Flex for ATEC®

Clip Marker System compatible with the vacuum assisted biopsy system ATEC® from Hologic®

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® Flex is intended for radiographically and radiologically percutaneous marking of soft tissue, especially breast tissue, via a clip marker.
The Tumark® Flex is not indicated to be used with magnetic resonance imaging (MRI) techniques.

Contraindications:
The clip marker of Somatex® Tumark® Flex contains nickel and should therefore not be used in case of a known nickel allergy.
The device is not intended for use except as indicated above.

Product description:
Somatex® Tumark Flex for ATEC® is a sterile disposable product, which consists of a pre-loaded Nitinol clip marker (1), a guide tube (2) and a handle (3) with ejection mechanism. The guide tube is composed of a tube section, a distal ramp (4) made of surgical steel with an opening for releasing the clip marker and a marking line (5), which shows the orientation of the ejection port for the clip marker. The handle is provided with a slider (6) by means of which the clip can be released, after the black fixation clip (7) is removed. The clip marker is situated in the distal ramp. The contents of delivery include insertion means (8) and a stopper (9) for the sampling container.
Tumark Flex for ATEC® can be used together with, e.g. ultrasound and stereotactic X-ray imaging procedures.

Behaviour of the clip marker in Magnetic Resonance Imaging (MRI):
Somatex® Tumark Flex for ATEC® is not suitable for use in MRI.
However, the clip marker placed in the 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 Flex for ATEC® clip marker in an MRI with 3.0 tesla or less.
The clip marker of Tumark Flex for ATEC® can be subjected to an MRI procedure under the following conditions without any risk:

- Static magnetic field of 3.0 tesla or less
- Gradient field of 360 Gauss / cm or less
- Maximum whole-body average SAR (Specific Absorption Rate) of 2 W/kg at scan duration of 20 minutes.

The use of unconventional and non-standardised MRI-techniques is not checked for the clip marker of Tumark Flex for ATEC© and should therefore not be used.

The behaviour of the clip marker in MRI has not been clinically tested under the following conditions:
The clip marker of Tumark Flex for ATEC® experiences an increase in temperature of less than 0.61 °C at a maximum whole-body average SAR of 2 W/kg, determined by calorimetric measurement at an MRI scan duration of 20 minutes in a 3 tesla Magnetom Trio (Siemens Medical, Erlangen, Germany) MRI with the Numaris 4, syngo MR software.
In a non-clinical test with a 3 tesla Magnetom Trio (Siemens Medical, Erlangen, Germany) MRI using the Numaris 4, syngo MR software, the image artefact of the clip marker amounted to 7.1 mm while using a spin echo sequence, whereas 6.5 mm in case of gradient echo sequence.

Recommended handling for use with the ATEC® biopsy needle:

1. Prior to use, ensure that the packing is not opened and / or damaged. Check the sterilisation expiry date.
2. Take the biopsy sample according to the instructions of the device manufacturer and ensure that the ATEC® needle is completely free from any tissue residues.
3. Set the console to the "setup" or lavage mode.
4. Retract the cut tissue piece / removal needle according to the usage instructions for Hologic ATEC®, until the tissue sample chamber is accessible. Ensure that the cutting device of the ATEC® needle is completely retracted.
5. Rotate the ATEC® needle into the position, in which the clip has to be released from the biopsy sample chamber.
    - The clip marker is released at the distal end of the biopsy sample chamber. Retract the needle by 5 mm if the clip marker has to be released at the centre of the biopsy site.
6. Remove the filter chamber from the proximal end of the handheld insertion tool.
7. Separate the tissue filter from the filter chamber and close the filter chamber using the stopper (9).
8. Remove the magenta-coloured insertion means (8) from the packing and attach it to the filter clamp of the handheld tool: Insert the insertion means into the filter chamber and turn the insertion means until the end-stop.
9. Remove Tumark Flex for ATEC® from the packaging under sterile conditions and then discard the protective tube.
10. Insert the guide tube into the ATEC® needle with the help of insertion means.
    - Push the Tumark Flex for ATEC® carefully until the end-stop. The distal end of Tumark Flex for ATEC® must definitely be in contact with the distal end of the biopsy chamber.
11. The black marking line on the guide tube shows the direction of ejection of the clip marker from the ramp. Align the Tumark Flex for ATEC® in the preferred position for the ejection of the clip marker.
    Important: The eject port (4) of the Tumark Flex for Atec® and the biopsy chamber of the Atec® needles must always be aligned (2). Therefore, before administering the marker, check that the black mark (5) on the Tumark Flex for Atec® is correctly aligned to the biopsy sample chamber of the Atec® needle. Otherwise, the marker can be removed with the biopsy cannula. The Tumark Flex for Atec® can also get jammed in the Atec® needle.
12. Discard the black fixation clip at the slider. Apply the clip marker by pushing the slider at the handle until the end stop. Then, completely pull back the slider once again. The Tumark Flex for ATEC® must be in the preferred position during the entire procedure.
13. Remove the unloaded Tumark Flex for ATEC® together with the ATEC® needle from the tissue.
14. After treatment, the Tumark Flex for ATEC® and the ATEC® needle have to be properly disposed in a suitable container.

Warnings:

- These instructions for the Tumark Flex for ATEC® do NOT have the purpose of defining or proposing medical or surgical methods. The concerned physician is responsible for the selection of the suitable procedures and methods relating to this product.
- Tumark Flex for ATEC® clip marker should not be used in patients with breast implants.
- The physician must decide whether a biopsy should be carried out in patients with blood coagulation disorders or those under treatment with anticoagulants.
- Tumark Flex for ATEC® has been manufactured for single use only. The nickel / titanium (Nitinol) marker preloaded in the distal section of the needle is non-absorbable and meant for single use only.
- 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.
- Single patient use only. DO NOT reuse or resterilize.

Precautions:

- Keep the black fixation clip at the slider until application to avoid unintended release of the clip marker.
- The marker must be placed by pushing the slide-button forward as far as possible.
- **Caution: Federal (USA) Law restricts this device to sale by or on the order of a physician.**

Storage instructions:

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

Reorder Information:

Article number	Name	Description
351250	Tumark Flex for ATEC® 12G	Guidance system for use with Hologic ATEC® 12G needle
351252	Tumark Flex for ATEC® 9G	Guidance system for use with Hologic ATEC® 9G needle

Symbols:

SYMBOLS	EXPLANATION
	**Consult instructions before use**
	**Article number**
	**LOT / Batch number**
	**Manufacturer**
	**Manufacturing date**
	**Use-by date**
	**Sterilized by ethylene oxide**
	**Single use only**
	**Do not resterilize**
	**Do not use if package is damaged**
	**Temperature limit**
	**Not made with natural rubber latex**

Manufactured by:
SOMATEX Medical Technologies GmbH
Rheinstrasse 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