

Title: TriMark Patient Information Leaflet**Instruction for Healthcare Institution or Provider**

1. This product is supplied with the manufacturer's patient implant card and information leaflet.
2. Follow the manufacturer's instruction, complete the patient implant card.
3. Provide the manufacturer's patient implant card and information leaflet to the patient.
4. Additionally, provide this Australian patient information leaflet to the patient.

Product Number	Description	UDI
TRIMARK TD 1309	Trimark TD 13-09	05420045503277
TRIMARK TD 1312	Trimark TD 1312	05420045503284
TRIMARK TD 13MR	Trimark TD 13MR	05420045503291
TRIMARK TD 3609	Trimark TD 3609	05420045503307
TRIMARK TD 3612	Trimark TD 3612	05420045503314
TRIMARK-EVIVA-10	Trimark Biopsy Marker for use with Eviva 10 cm, 1st Shape	05420045503550
TRIMARK-EVIVA-13	Trimark Biopsy Marker for use with Eviva 13 cm, 1st Shape	05420045503574
TRIMARK-EVIVA-2S-10	Trimark Biopsy Marker for use with Eviva 10 cm, 2nd Shape	05420045503567
TRIMARK-EVIVA-2S-13	Trimark Biopsy Marker for use with Eviva 13 cm, 2nd Shape	05420045503581
TRIMARKTD-2S-13-09	Trimark TD 13-09 2nd shape	05420045503321
TRIMARKTD-2S-13-MR	Trimark TD 13MR 2nd shape	05420045503345
TRIMARKTD-2S-36-09	Trimark TD 3609 2nd shape	05420045503352
TRIMARKTD-2S-36-12	Trimark TD 3612 2nd shape	05420045503369

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Intended Purpose

The ATEC TriMark biopsy site marker system is intended to be used to mark an open or percutaneous biopsy site to radiographically mark the location of the biopsy site.

The Biopsy Site Markers are used following breast biopsy procedures performed with ATEC breast biopsy system. The markers provide the user with the ability to mark permanently the location of the cavity where the breast biopsy was performed.

The markers are placed at the biopsy site under stereotactic, ultrasound, or magnetic resonance imaging (MRI) guidance, depending on which type of biopsy device is used. Radiographic marking allows physicians to locate biopsy cavities should a follow-up lumpectomy or re-biopsy be necessary.

Instructions For Use

TriMark biopsy site marker is intended to be used only by physicians trained in open or percutaneous biopsy procedures.

Intended Performance and Side Effects

The measurable objectives / outcomes for evaluation of performance are accurate localization defined by minimal migration rates as well as visibility on ultrasound and x-ray. These outcomes should be similar to or better than similar devices.

Side Effects can include:

- Pain
- Seroma
- Inflammation
- Blunt trauma
- Hematoma
- Hemorrhage/Bleeding/Blood loss/Minor vascular injury
- Infection
- Hypersensitivity/Allergic reaction
- Foreign body reaction
- Tissue damage
- Marker migration
- Perforation
- Needle Stick/Puncture
- Scar Tissue
- Sepsis

Residual Risks

The risks associated with these devices have been reduced to an acceptable level.

Warnings about risks that could arise from the interaction of the device with other equipment and precautions and other measures that, because of those risks, should be taken by the patient or a health professional.

- There are possible adverse reactions when an object is implanted in the body. It is the responsibility of the physician to evaluate any risk or benefit prior to the use of this device.
- Potential complications of marker clip placement consist of pain, seroma formation, inflammation, bruising, hematoma, hemorrhage, infections, hypersensitivity or allergic reaction, soft tissue damage, misdiagnosis (due to marker clip migration), perforation or scar tissue.
- The ATEC TriMark deployment device is not recommended for use within the bore of an MRI magnet.
- The ATEC TriMark biopsy site marker system is not recommended for use in patients with breast implants.
- The ATEC TriMark procedure should be performed only by physicians having adequate training and familiarity with this procedure. Consult medical literature relative to techniques, complications, and hazards prior to performance of any minimally invasive procedure.

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- This device should be used only by physicians trained in open or percutaneous biopsy procedures.
- The ATEC TriMark biopsy site marker should be deployed into the cavity created during the biopsy procedure. Deployment into tissue outside of the biopsy cavity is not recommended.
- If the deployment device is difficult to insert or remove from the biopsy device do not apply excessive force. Excessive force may cause damage or breakage of the deployment device which may result in a portion of the deployment device being left behind in the patient. If the deployment device cannot be easily removed from the biopsy device, remove the deployment device and the biopsy device as one unit.
- Marker position relative to established landmarks may change under mammography upon subsequent breast compressions.
- The ATEC TriMark biopsy site marker is not intended to be repositioned or recaptured after deployment.
- Excess hematoma within the biopsy cavity can lead to marker adhesion to the deployment device, increasing the risk of marker drag out.
- Care should be taken to avoid damaging the cannula. Avoid operator or instrument contact with the ATEC TriMark biopsy site marker or the distal end of the deployment device.
- The implanted ATEC TriMark biopsy site marker is magnetic resonance imaging (MRI) conditional. The implanted ATEC TriMark biopsy site marker presents no additional risk to patient or operator from magnetic forces, torque, heating, induced voltages, or movement, but it may affect MRI image quality.
- Minimally invasive instruments and accessories manufactured or distributed by companies not authorized by Hologic, Inc., may not be compatible with the ATEC TriMark biopsy site marker system. Use of such products may lead to unanticipated results and possible injury to the user or patient.
- Instruments or devices which come into contact with bodily fluids may require special disposal handling to prevent biological contamination.
- Following the insertion of the marker deployment device, the console should NOT be put into the "Biopsy" mode.
- Dispose of all opened instruments whether used or unused.
- Do not resterilize and/or reuse the ATEC TriMark biopsy site marker system. Resterilization and/or reuse may compromise the integrity of the instrument. This may lead to potential risks of failure of the device to perform as intended, and/or cross-contamination associated with using inadequately cleaned and sterilized devices.
- If deployment guide is not used for 36-09 or 36-12 devices, damage may occur to the deployment device, resulting in device malfunction.

Post Implantation

- Biopsy Site Markers are implanted sterile, they serve no other function but as a Marker, there are no preventative examination or monitoring required.
- Biopsy Site Markers are permanent implants that do not have end of life, no near end of life precaution or action is required.

Materials and SubstancesImplantable Device

Model	Permanent Material/Composition (%mass/mass)
TRIMARKTD-2S-13-09	Titanium Grade II per ASTM F67-13:
TRIMARKTD-2S-13-12	Nitrogen, max.....0.03
TRIMARKTD-2S-36-09	Carbon, max.....0.08
TRIMARKTD-2S-36-12	Hydrogen, max.....0.015
TRIMARKTD-2S-13-MR	Iron, max.....0.30
	Oxygen, max.....0.25
	Titanium.....balance (99.32%)
TRIMARK TD 1309	Titanium Sponge Powder per ASTM F1580-18:
TRIMARK TD 1312	Nitrogen, max.....0.02

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TRIMARK TD 3609	Carbon, max.....0.03
TRIMARK TD 3612	Hydrogen, max.....0.03
TRIMARK TD 13MR	Iron, max.....0.15
	Oxygen, max.....0.40
	Aluminum, max.....0.05
	Silicon, max.....0.04
	Chlorine, max.....0.20
	Titanium.....balance (99.08%)

Deployment Device

The TriMark deployment devices contain stainless steel and therefore may contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from stainless steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. A device specific evaluation has determined that the presence of Cobalt does not present a risk within the clinical use of this device.

Reporting of Incidents

Any serious incident that occurs in relation to the device should be reported to the manufacturer and to the Therapeutic Goods Administration at <https://www.tga.gov.au/reporting-problems>.



250 Campus Drive, Marlborough, MA 01752 USA | +1.508.263.2900 | Hologic.com

Australian Sponsor

Hologic (Australia and New Zealand) Pty Ltd
PO Box 1971 Macquarie Centre NSW 2113

Email: australia@hologic.com
Tel: 1800 264 073

Reference IFUs:

- ATEC TriMark AW-23561-002
- TriMark for Eviva AW-23540-002