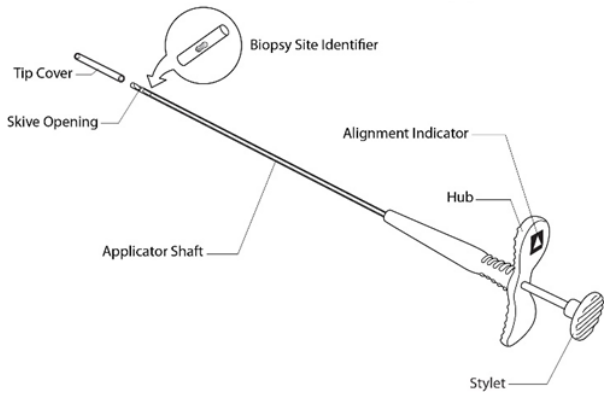
Mammotome® MammoStar™

biopsy site identifier



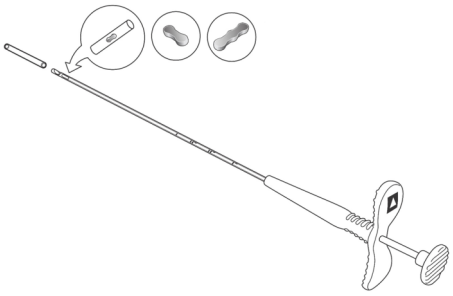
DEVICOR MEDICAL PRODUCTS, INC.

INSTRUCTIONS FOR USE - EN

INDICATIONS FOR USE

MammoSTAR is indicated for use to radiographically mark soft tissue at the surgical site during a surgical procedure or for future surgical procedures.

Illustration 1. Illustration and Nomenclature for MammoSTAR™ Biopsy Site Identifier



DEVICE DESCRIPTION

MammoSTAR Biopsy Site Identifier is a sterile, single patient use, pyrolytic carbon coated zirconium oxide discrete marker embedded in a glucan aspect that is visible on standard radiographs (x-ray, mammography, fluoroscopy, kV, and CT) as well as ultrasound, and Magnetic Resonance Imaging (MRI). MammoSTAR is placed into soft tissue during open, percutaneous, or endoscopic procedures to radiographically mark a surgical location.

The sideport MammoSTAR applicator shafts are marked with 1 depth indicator band. This band is used with Mammotome probes, except for Mammotome MR probes.

MammoSTAR rigid needle applicators are marked with depth indicator bands at 1 cm increments.

MammoSTAR is supplied pre-loaded in the delivery device.

CONTRAINDICATIONS

None known.

WARNINGS

Do not insert MammoSTAR into blood vessels.

PRECAUTIONS / UNDESIREABLE SIDE AFFECTS

- Only qualified physicians trained in minimally invasive biopsy techniques should use this device. Consult medical literature relative to techniques, complications, and hazards prior to performing any minimally invasive procedure.
- Minimally invasive instruments may vary in size from manufacturer to manufacturer. When minimally invasive instruments and accessories from different manufacturers are employed together and in conjunction with the MammoSTAR device in a procedure, **verify compatibility prior to initiation of the procedure**.
- Do not use in the presence of infection.
- MammoSTAR Biopsy Site Identifier is not recommended for use in patients with breast implants due to the risks of puncturing the implant capsule with the sharp device.

Product Code	Product Description	Gauge Size	Marker Shape	Glucan Aspect	Applicator	Deployment	Insertion
STAR0801	MammoSTAR Biopsy Site Identifier	8G	Barbell	Standard 2 mm x 17 mm	Flexible	Side Deploy	Probe
STAR0802	MammoSTAR Biopsy Site Identifier	8G	Tribell	Standard 2 mm x 17 mm	Flexible	Side Deploy	Probe
STAR1001	MammoSTAR Biopsy Site Identifier	10G	Barbell	Standard 2 mm x 17 mm	Rigid Needle	Distal Deploy	Direct
STAR1101	MammoSTAR Biopsy Site Identifier	11G	Barbell	Standard 2 mm x 17 mm	Flexible	Side Deploy	Probe
STAR1102	MammoSTAR Biopsy Site Identifier	11G	Tribell	Standard 2 mm x 17 mm	Flexible	Side Deploy	Probe
STAR1121	MammoSTAR Biopsy Site Identifier	11G	Barbell	Standard 2 mm x 17 mm	Rigid	Distal Deploy	Probe
STAR1401	MammoSTAR Biopsy Site Identifier	14G	Barbell	Standard 2 mm x 17 mm	Rigid Needle	Distal Deploy	Direct
STAR1402	MammoSTAR Biopsy Site Identifier	14G	Tribell	Standard 2 mm x 17 mm	Rigid Needle	Distal Deploy	Direct
STAR1403	MammoSTAR Biopsy Site Identifier	14G	Barbell	Petite 2 mm x 9 mm	Rigid Needle	Distal Deploy	Direct

- Though rare, hypersensitivity, immune response or foreign body reaction are possible with use of MammoSTAR markers. As with any implanted device, the implant site should be monitored for any sign of irritation or reaction following the surgical procedure.
- Infection is a possible adverse reaction as a result of any surgical procedure. Physicians should monitor patient to ensure no sign of infection following procedure.
- The MammoSTAR device is supplied sterile in a sealed package and is intended for single use only. Reprocessing, resterilization or reuse of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of this device may lead to injury, illness or death of the patient. Carefully examine each unit to verify that neither the contents nor the sterile package has been damaged in shipment. **DO NOT USE** if damaged.
- **Do not re-sterilize**. This may damage and/or distort contents which may result in patient injury, illness or death.
- Unless the packaging is damaged, the MammoSTAR device will remain sterile until used or expired.
- After use, device may be potential biohazard. Handle accordingly and dispose of in accordance with accepted medical practice and applicable local, state and federal requirements (USA).

POSSIBLE ADVERSE EVENTS

Possible adverse reactions (e.g., infection) that may be associated with the use of the MammoSTAR Biopsy Site Identifier are similar to those associated with the use of other marking devices. The patient should be counseled to report adverse events to the treating physician. **Physicians should report device-related adverse events to Devicor Medical Products at 1-877-926-2666.**

MR SAFETY INFORMATION

MR CONDITIONAL

MammoSTAR delivery devices are not compatible with MRI delivery. While the MammoSTAR devices may be used in the MRI environment they will not be used during the actual MR imaging. The patient will be moved out of the MR System and then the delivery device will be used to place the marker. As such, they will not be exposed to an MR imaging procedure or RF heating.

MR This Marker is MR Conditional

Non-clinical testing demonstrated that the Marker is MR Conditional. A patient with this device can be scanned safely, immediately after placement under the following conditions:

- Static magnetic field of 3-Tesla or less
- Maximum spatial gradient magnetic field of 36,000-Gauss/cm (extrapolated) or less
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 4-W/kg for 15 minutes of scanning (i.e., per pulse sequence)
- First Level Controlled Operating Mode of operation for the MR system

MRI-Related Heating

In non-clinical testing the Marker produced the following temperature rise during MRI performed for 15-min of scanning (i.e., per pulse sequence) in a 3-Tesla MR system (3-Tesla/125-MHz, Excite, HDx, Software 14X.M5, General Electric Healthcare, Milwaukee, WI):

MR system reported, whole body averaged SAR	2.9-W/kg
Calorimetry measured values, whole body Averaged SAR	2.7-W/kg
Highest temperature change	1.5 °C
Temperature scaled to whole body averaged SAR of 4-W/kg	2.1 °C

Artifact Information

MR image quality may be compromised of the area of interest is in the exact same area or relatively close to the position of the marker. Therefore, optimization of MR imaging parameters to compensate for the presence of this device may be necessary. The maximum artifact size (i.e., as seen on the gradient echo pulse sequence) extends approximately 5-mm or less relative to the size and shape of the marker.

Artifact size is dependent on the type of pulse sequence used for imaging (larger for gradient echo pulse sequences and smaller for spin echo pulse sequences), the frequency encoding direction (larger if the frequency encoding direction is parallel to the device and smaller if it is perpendicular to the device), and the size of the field of view. Positional errors and artifacts on MR images will be smaller for MR systems with lower static magnetic field strengths using the same imaging parameters as those operating at higher static magnetic field strengths.

INSTRUCTIONS FOR USE

Verify compatibility of all minimally invasive instruments and accessories prior to use (refer to **Precautions).**

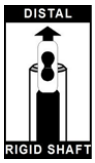
MammoSTAR delivery devices are not compatible with MRI delivery (refer to **MRI Safety Info).**

Side Port Delivery

REF

STAR0801
STAR0802
STAR1101
STAR1102

1. Inspect the MammoSTAR device package to ensure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.
2. Using standard aseptic technique, remove the MammoSTAR device from the package. **REMOVE THE TIP COVER**. Inspect the device to ensure it has not been damaged, kinked, or bent.
3. It is recommended to clear the probe of any remaining diagnostic tissue or fluids prior to marker insertion or deployment.
4. Retract the specimen cutter/collection tube from the MAMMOTOME Biopsy probe per instructions for use of the probe. Prior to retracting the cutter/collection tube the needle can be pulled back up to 1 cm.
5. When placement of the MammoSTAR Biopsy Site Identifier is desired, place the MammoSTAR applicator into the Mammotome Biopsy probe. Advance MammoSTAR until the colored depth band on the MammoSTAR shaft is aligned with the distal edge of the Mammotome tissue collection chamber.
   CAUTION: If significant resistance is met during the advancement of the MammoSTAR prior to reaching the colored depth indicator band, remove the marker to inspect the integrity of the distal tip of the marker device, and repeat insertion. Take a new marker device if damage is present.
   CAUTION: Do not insert beyond appropriate band or tip damage may occur.
6. The MammoSTAR side deploy device is marked with an arrow on the hub to indicate the deployment position. Align the arrow on the hub with the center of the aperture of the biopsy device.
7. Grasp the tissue marker handle and, using firm, but gentle force, advance the plunger forward completely until it contacts the finger tabs on the handle to deploy the biopsy site identifier into the biopsy cavity.
   Note: Ensure the alignment indicator on the tissue marker handle ALWAYS remains in the position corresponding with the probe's sample aperture orientation.
   CAUTION: If excessive resistance is met during deployment, check the alignment of the MammoSTAR applicator shaft as specified in step 6.
   CAUTION: Due to its absorbent characteristics, the MammoSTAR glucan portion may swell with extended exposure to tissue fluids increasing the force to deploy. Deploy in a timely manner. If the marker is unable to deploy, remove and replace with a new device.
8. After deployment, release pressure from the plunger to allow the spring to retract the plunger.
9. Rotate the outer cannula of the biopsy device 180 degrees.
10. Verify the deployment and proper position of the marker prior to removal of the device with the appropriate imaging modality. Slowly remove the biopsy device and the MammoSTAR device as one unit.
    - **CAUTION:** The tip of the MammoSTAR applicator shaft may shear when the marker applicator is removed independently from the probe. The probability of tip shear can increase as a result of the following:
    - Improper deployment of the marker from a failure to align the MammoSTAR applicator as specified;
    - Inserting the marker beyond the appropriate color depth indicator band;
    - Diagnostic tissue remaining in biopsy probe needle aperture during marker insertion and deployment.
11. Dispose of the device properly.
12. Confirm final marker position with desired imaging.



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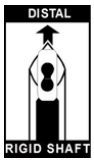
STAR1121



REF

STAR1401
STAR1402
STAR1403
STAR1001

Distal Delivery

1. Inspect the MammoSTAR device package to ensure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.
2. Using standard aseptic technique, remove the MammoSTAR device from the package. **REMOVE THE TIP COVER**. Inspect the device to ensure it has not been damaged, kinked or bent.
3. When placement of the MammoSTAR Biopsy Site Identifier is desired, advance the device to the targeted site using the 1 cm markings on the device shaft as guides (when applicable). Locate the target area using appropriate imaging technique.
4. Completely advance the plunger forward to release the MammoSTAR Biopsy Site Identifier from the device.
   CAUTION: Due to its absorbent characteristics, the MammoSTAR glucan portion may swell with extended exposure to tissue fluids increasing the force to deploy. Deploy in a timely manner. If the marker is unable to deploy, remove and replace with a new device.
5. Verify the deployment and proper position of the marker prior to removal of the device with the appropriate imaging modality.
6. With the plunger completely advanced, rotate applicator and slowly remove the MammoSTAR device.
7. Dispose of the device properly.
8. Confirm final marker position with desired imaging.

HOW SUPPLIED STERILE R

MammoSTAR Biopsy Site Identifier device is individually packaged and supplied ten (10) packages to a box.

STORAGE

There are no special storage instructions for the MammoSTAR device. Prior to use, the product should be at room temperature, 15 °C - 32 °C (60 °F - 90 °F).

WARRANTY

The manufacturer warrants that reasonable care has been used in the design and manufacture of this device. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness. Handling and storage of this device as well as factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond the manufacturer's control directly affect the device and the results obtained from its use. The manufacturer's obligation under this warranty is limited to the replacement of this device and the manufacturer shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this device. The manufacturer neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this device.

Prices and specifications are subject to change without notice.

MammoSTAR is a registered trademark of Devicor Medical Products, Inc.

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Saint Paul, Minnesota 55110 USA

Devicor Medical Products, Inc.
1-877-926-2666
mammotome.com

DEVICOR® MEDICAL PRODUCTS, INC.

QTY Quantity (EN)

LOT Batch Code (EN)

REF Catalog number (EN)

Use by Date (EN)

Manufacturer and Date of Manufacture (YYYY-MM-DD) (EN)

Consult Instructions for Use (EN)

Do not use if package is damaged (EN)

℞ Only By prescription (EN)

Do not re-use (EN)

Single Sterile Barrier System (EN)

STERILE R Sterilized using irradiation (EN)

MR MR Conditional (EN)

MD Medical Device (EN)

Distributor (EN)

Importer (EN)

Compatible With (EN)

Do not re-sterilize (EN)

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