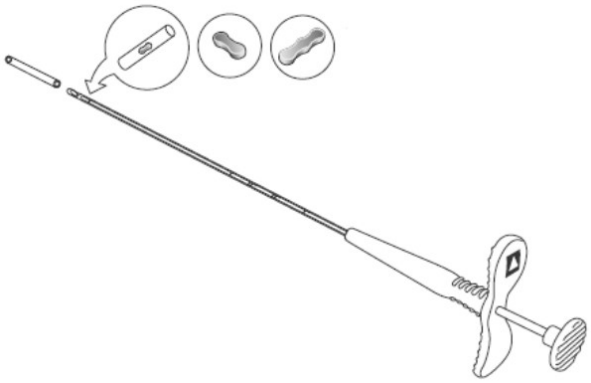
Mammotome® MammoStar™
biopsy site identifier



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.

DEVICE DESCRITPION

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.

Product Code	Product Description	Gauge Size	Marker Shape	Glucan Aspect	Applicator	Deployment	Insertion
STAR0831	MammoSTAR Biopsy Site Identifier	8G	Barbell	Standard 2 mm x 17 mm	Semi-Flexible	Side Deploy	Probe
STAR0832	MammoSTAR Biopsy Site Identifier	8G	Tribell	Standard 2 mm x 17 mm	Semi-Flexible	Side Deploy	Probe
STAR0833	MammoSTAR Biopsy Site Identifier	8G	Barbell	Petite 2 mm x 9 mm	Semi-Flexible	Side Deploy	Probe
STAR1031	MammoSTAR Biopsy Site Identifier	10G	Barbell	Standard 2 mm x 17 mm	Semi-Flexible	Side Deploy	Probe
STAR1032	MammoSTAR Biopsy Site Identifier	10G	Tribell	Standard 2 mm x 17 mm	Semi-Flexible	Side Deploy	Probe
STAR1033	MammoSTAR Biopsy Site Identifier	10G	Barbell	Petite 2 mm x 9 mm	Semi-Flexible	Side Deploy	Probe

The MammoSTAR applicator shafts are marked with 6 depth indicator bands: 3 for use with the sample management system ON the probe (solid band lines marked with numbered longitudinal stripe in corresponding gauge color) and 3 for use with the sample management system OFF (solid band marked in corresponding gauge colors) (See Illustration 2). Each depth indicator band is used to indicate depth confirmation of the applicator device when using Mammotome Revolve Biopsy Probes.

Illustration 1: Illustration and Nomenclature for MammoStar Biopsy Site Identifier

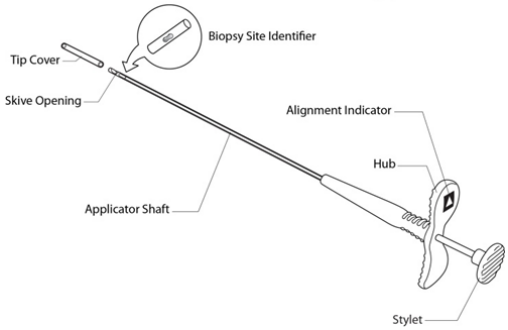
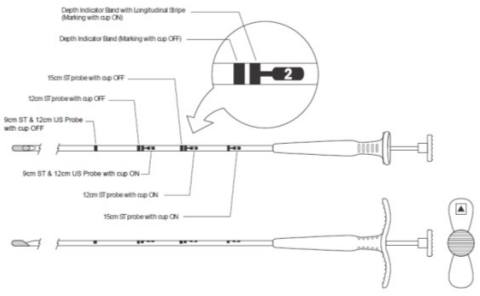


Illustration 2: MammoStar Applicator Shaft Depth Indicator Bands



The MammoSTAR Biopsy Site Identifiers are designed for use with Mammotome revolve Biopsy Probes. At the completion of percutaneous breast biopsy procedure, the MammoSTAR Tissue Marker is deployed into the biopsy site through the probe. After deployment, a spring retracts the plunger leaving the marker in place.

MammoSTAR Biopsy Site Identifiers are supplied pre-loaded in the delivery device.

CONTRAINDICATIONS

None known.

WARNINGS

Do not insert MammoSTAR into blood vessels.

PRECAUTIONS / UNDESIRABLE SIDE EFFECTS

- 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 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.
- Though rare, hypersensitivity, immune response or foreign body reaction are possible with the 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, or resterilization or reuse of the 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 or distort contents.
- 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.**

MRI 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**).

1. Ensure the tissue marker being used is the correct type for the selected gauge needle and Mammotome revolve Biopsy Probe.

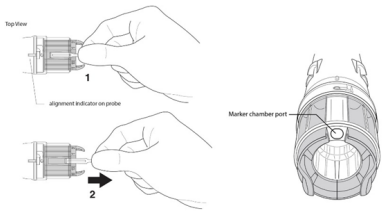
2. Inspect the MammoSTAR device package to ensure that the package integrity has not been compromised. The product is sterile through the expiration date unless the seal is broken.
3. Using standard aseptic technique, remove the MammoSTAR device from the package. **REMOVE THE TIP COVER.** Inspect the device to ensure it has not been damaged, kinked or bent.
4. It is recommended to clear the probe of any remaining diagnostic tissue or fluids prior to marker insertion and deployment.
5. Retract the cutter from the Mammotome revolve Biopsy Probe.

   Note: Ensure probe sample aperture is fully open for marker placement. If the variable aperture setting is being used on the Mammotome revolve Biopsy System, it must be changed to the full aperture setting for marker placement.

   Note: Prior to marker deployment, the biopsy probe can be pulled back up to 1 cm.
6. **If the sample management system is ON**, remove the marker port plug from the marker chamber port (See Illustration 3).
7. Place the MammoSTAR applicator into the Mammotome revolve Biopsy Probe Marker Chamber Port. Advance the MammoSTAR Device until the appropriate colored depth indicator band on the MammoSTAR applicator is aligned with the proximal edge of the specimen management system (See Illustration 5).

   Note: Ensure alignment indicator in the probe is aligned with the marker chamber port for proper tissue marker insertion (See illustration 3).

Illustration 3: Remove Marker Chamber Port Plug



If the specimen management system is OFF, be sure to insert the applicator into the larger opening at the proximal end of the probe (See Illustration 4). Advance the MammoSTAR applicator until the appropriate colored depth indicator band on the MammoSTAR shaft is aligned with the proximal end of the probe body (See Illustration 4).

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 consider conducting a "clear probe" before inserting a new marker device.

CAUTION: Do not insert beyond appropriate band or tip damage may occur. See Illustrations 4 & 5 for proper seating of the tissue marker with the sample management system ON and OFF.

Illustration 4: Tissue Marker Insertion Alignment with Sample Management System OFF

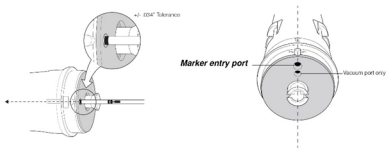
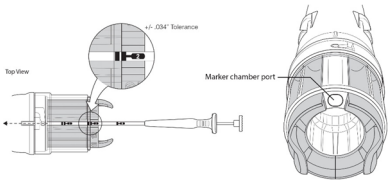


Illustration 5: Tissue Marker Depth Seating with Sample Management System ON



8. Position alignment indicator on the MammoSTAR handle and the longitudinal stripe on the MammoSTAR shaft with the position relative to the Mammotome revolve probe's sample aperture orientation.

CAUTION: DO NOT activate the probe cutter or other clinical functions while a marker is inserted in the probe. Take care to completely remove the marker out of the probe before activating any of the holster's clinical functions.

CAUTION: Failure to align the MammoSTAR applicator as specified may result in improper deployment of the biopsy site identifier.

CAUTION: Do not activate vacuum. Vacuum is not required for marker deployment.

9. 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 8.

   CAUTION: Due to its absorbent characteristics, the MammoSTAR Biopsy Site Identifier 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.
10. After deployment, release pressure from the plunger to allow spring to retract plunger away from the finger tabs on the handle.
11. Rotate the Mammotome revolve probe body or thumbwheel 90 to 180 degrees to position the sample aperture away from the deployed biopsy site identifier.
12. 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 with 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 the biopsy probe needle aperture during marker insertion and deployment.
13. Dispose of the device properly.
14. 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.

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

Quantity (EN)

Batch Code (EN)

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)

By prescription (EN)


Do not re-use (EN)


Single Sterile Barrier System (EN)

Sterilized using irradiation (EN)

MR Conditional (EN)

Medical Device (EN)


Distributor (EN)


Importer (EN)


Compatible With (EN)


Do not re-sterilize (EN)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