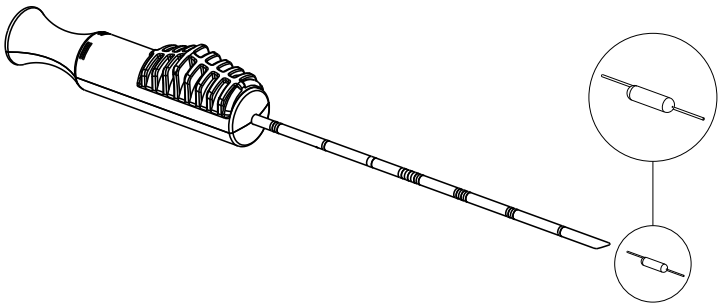
English

DELIVERY SYSTEM

INSTRUCTIONS FOR USE



DESCRIPTION

The SCOUT MD Console, SCOUT MD Multiple-use Guides (SCOUT MD Guide, SCOUT MD Access Guide), SCOUT MD Single-use Handpieces (SCOUT MD Single-Use Handpiece, SCOUT MD Access Single-use Handpiece) and SCOUT MD Delivery System (including SCOUT MD Reflector) are accessories to the SCOUT MD Surgical Guidance System. The SCOUT MD Reflector, when used in conjunction with the SCOUT MD Guides/Handpieces and SCOUT MD Console, can be used as a marker for the surgeon to follow in the excision of tissue.

The SCOUT MD Delivery System is a sterile, single use device. The delivery system consists of a plastic molded handle attached to a 16 GA introducer needle with the SCOUT MD Reflector preloaded inside. When the release button is actuated, the needle retracts into the handle thereby deploying the SCOUT MD Reflector.

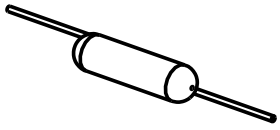
The SCOUT MD Reflector is 12 mm long (Standard Reflector A, B, C) or 8 mm long (Mini Reflector D) and is delivered through a 16 GA introducer needle. There are four (4) unique configurations of the SCOUT MD Reflector (A,B,C,D) each with a unique shape and radar signal. The SCOUT MD Reflector is designed to return a detectable signal within surrounding tissue when illuminated by the micro-impulse radar signal from the SCOUT MD Guide/Handpiece. In addition, the SCOUT MD Reflector is visible under ultrasound, MRI, and radiographic imaging. Refer to the SCOUT MD Console Operation Manual for other functional attributes.

INDICATIONS FOR USE

The SCOUT MD Reflector is intended to be placed percutaneously in soft tissue (>30 days) to mark a biopsy site or a soft tissue site intended for surgical removal. Using imaging guidance (such as ultrasound, MRI, or radiography) or aided by non-imaging guidance (SCOUT MD System) the SCOUT MD Reflector is located and surgically removed with the target tissue. The SCOUT MD System is intended only for the non-imaging detection and localization of the SCOUT MD Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.

CONTRAINDICATIONS

- The SCOUT MD Reflector is not intended for use in the heart, eyes, brain or spinal cord.
- The SCOUT MD Reflector should not be placed in a tissue site with clinical evidence of infection.



WARNINGS

- Persons with a known allergy to nickel-titanium (Nitinol) may suffer an allergic reaction to the SCOUT MD Reflector.
- FOR SINGLE PATIENT USE ONLY. Do not reuse, reprocess or re-sterilize. Reuse, reprocessing or re-sterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or re-sterilization may also create a risk of contamination of the device 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 the device may lead to injury, illness or death of the patient.
- DO NOT RESTERILIZE. After re-sterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or re-sterilization of the medical device increases the probability that the device will malfunction due to the potential adverse effects on components that are influenced by thermal and/or mechanical changes.
- Caution should be exercised with using the device on patients with prostheses so as to not puncture the prosthesis during placement.
- If any resistance is felt during advancement of the needle, carefully correct the orientation of the needle but never apply strong forces in order to overcome the obstacle.
- If the patient has an internal or external active cardiac implant, contact the cardiac implant manufacturer for instructions before using the SCOUT MD Surgical Guidance System. The micro-impulse radar signal may interfere with the intended function of the cardiac implant.
- Exercise caution when placing the SCOUT MD Reflector near the chest wall. Insert the SCOUT MD Delivery System parallel to the chest wall to avoid puncturing the chest wall during placement.
- DO NOT USE if the package is open or damaged. Sterility could be compromised.
- DO NOT USE the SCOUT MD Reflector and SCOUT MD Delivery System beyond the expiration date shown on the product label.
- The SCOUT MD Delivery System is not recommended for use inside the bore of the MRI magnet.

CAUTIONS

- This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of SCOUT Reflector placement. Please read all information carefully.
- Federal law restricts this device to sale by or on the order of a physician (21 CFR
- §801.109(b)(1)).
- Handle in a manner that will prevent accidental contamination.
- DO NOT USE if the device is damaged.
- DO NOT USE SCOUT MD Delivery System if it is in the unlocked position when taken out of the package.
- After use, this product may be a potential biohazard. Dispose in accordance with your facility's biohazardous waste procedures.
- MR Conditional. The implanted SCOUT MD Reflector and SCOUT MD Delivery System can be used in the MRI environment; see MRI use information in the chart below.
- The SCOUT MD Delivery System is not recommended for use within the bore of the magnet.
- The SCOUT MD System is intended to provide surgical guidance without the use of a localization wire. If the clinician places a localization wire in addition to the SCOUT MD Reflector, the localization wire may impact the performance of the SCOUT MD Reflector. To minimize this impact, consider the following:
  - Place the localization wire posterior to the SCOUT MD Reflector.
  - After placing the localization wire, confirm that the SCOUT MD Reflector can be detected from the skin surface with SCOUT MD Guide/Handpiece.
- Avoid placing the SCOUT MD Reflector within a hematoma as this may impact detection capability.

PRECAUTIONS

- The Reflector has been studied in the breast and axilla but use in other anatomical locations has not been well established.

ADVERSE REACTIONS / POTENTIAL COMPLICATIONS

The SCOUT MD Delivery System provides an important means of treating patients requiring soft tissue cancer surgery, however, the potential exists for serious complications or an additional procedure, including, but not limited to foreign body reaction, device migration, infection, inflammation, soft tissue injury, bleeding, nerve damage, or pneumothorax.

KEY PERFORMANCE CHARACTERISTICS

The SCOUT MD Reflector, through radar guidance, can be detected to a depth of 60mm with an accuracy of ±1mm (up to 50mm).

NOTE

These instructions for the SCOUT MD Reflector and SCOUT MD Delivery System are NOT meant to define or suggest any medical or surgical technique. The individual physician is responsible for the proper procedure and techniques to be used with this product.

STORAGE

Store the SCOUT MD Delivery System in a clean and dry area, away from direct sunlight.

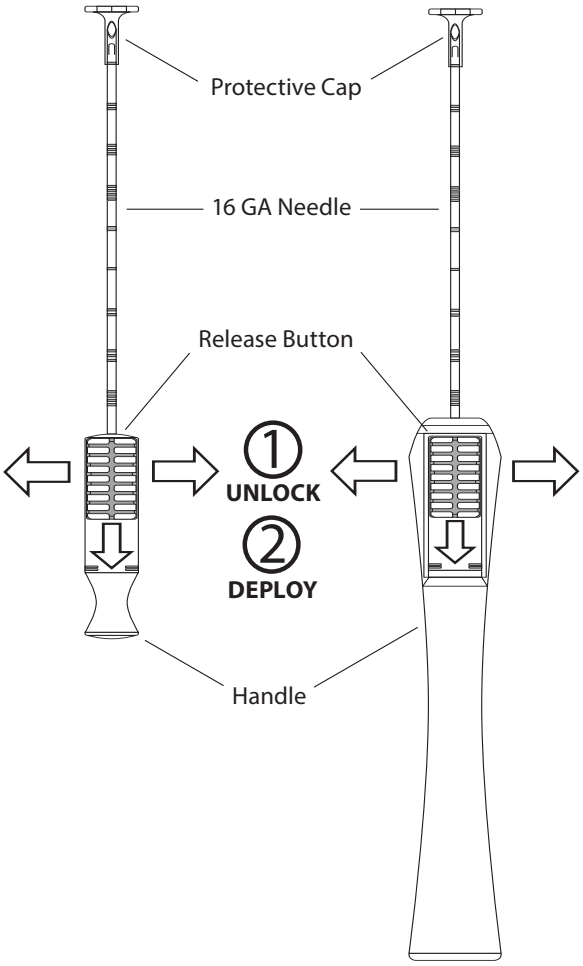
SCOUT MD REFLECTOR

DELIVERY

1. Inspect the package for damage and expiration date. DO NOT USE if damaged or expired.
2. Open the package and transfer the product onto the sterile field using aseptic technique.
3. Remove the white protective cap.
4. While using a preferred imaging technique (ultrasound, MRI or radiography), locate the desired SCOUT MD Reflector placement location at the center of tumor or within 1-2 mm from closest boundary of the tumor or biopsy site.
5. Determine the skin entry site and percutaneously advance the SCOUT MD Delivery System needle into the tissue toward the target.
   NOTE: Depth marks on the needle are for reference only. Placement is to be based on imaging.
6. Confirm needle placement with appropriate imaging technique. If necessary, reposition the needle tip and reconfirm placement.
7. Unlock the SCOUT MD Delivery System by rotating the Release Button clockwise or counter-clockwise. A purple indicator to the side will be visible when the device is unlocked.
8. Maintain handle position while retracting the Release Button proximally to deploy the SCOUT MD Reflector. The Release Button covers the proximal purple marks when fully deployed.

   NOTE: when the Release Button is retracted, the needle will be drawn back into the handle, deploying the SCOUT MD Reflector.
9. Remove the needle and confirm placement of the SCOUT MD Reflector using the preferred imaging technique. A two-view mammogram is recommended when deployed in breast tissue.
10. The SCOUT MD Guide/Handpiece and SCOUT MD Surgical Guidance Console can also be used to confirm SCOUT MD Reflector detection and placement.

11. Appropriately dispose the delivery device per institution protocol for a potentially biohazardous and sharp device.
NOTE: When initially placed into localization mode, the SCOUT MD system is capable of simultaneously detecting up to four uniquely coded reflectors, identified on the display screen by shape as well as the identification letters A, B, C, D. If multiple reflectors of the same code (e.g. A, A) are placed in the tissue, the system will detect the one that is in closest proximity to the SCOUT MD Guide/Handpiece.



SCOUT REFLECTOR REMOVAL AND TISSUE EXCISION

1. Determine the location of the SCOUT MD Reflector by using the SCOUT MD Surgical Guidance System and/or by using imaging guidance.
2. Excise the intended tissue to be removed using the SCOUT MD Surgical Guidance System or imaging for guidance.
3. Using the SCOUT MD Surgical Guidance System or specimen imaging, confirm the SCOUT MD Reflector is present in the excised specimen.

PATIENT IMPLANT CARD

The healthcare provider must place the peel tabs from the label of the implanted SCOUT MD Delivery System on the Patient Implant Card, complete the card with the information specific to the patient/implant procedure, and supply the patient with the completed Patient Implant Card.

SYMBOL	DESIGNATION
	Use by date: YYYY-MM-DD
LOT	Lot number
REF	Catalog number
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use If Package is Damaged and Consult Instruction for Use
	Single use
℞ ONLY	Caution:Federal (USA) law restricts this device to sale by or on the order of a physician.
	Do not resterilize
	Caution
	Date of Manufacture: YYYY-MM-DD
MD	Medical Device
	Single Sterile Barrier System
	Consult Instructions for Use For electronic copy scan QR code, or go to www.merit.com/ifu and enter IFU ID. For printed copy, call U.S.A. or EU Customer Service

MR

MRI Safety Information

A person implanted with SCOUT MD Reflector may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	SCOUT MD Reflector
Static Magnetic Field Strength (B0)	1.5T or 3.0T
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode
Maximum Whole-Body SAR	2 W/kg
Maximum Head SAR	3.2 W/kg
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks.
MR Image Artifact	The presence of this implant may produce an image artifact.

NOTE: The delivery system for the Scout MD Reflector is MR Unsafe and should not be brought into the MR Scanner room.

MERIT MEDICAL®

www.merit.com

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