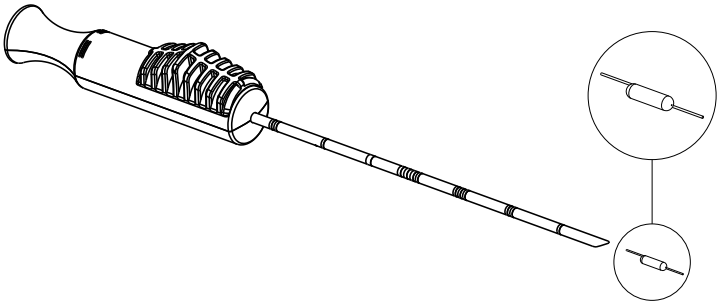
English

REFLECTOR AND DELIVERY SYSTEM

INSTRUCTIONS FOR USE

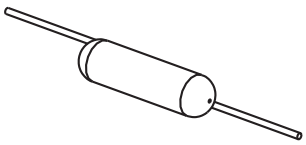


DESCRIPTION

The SCOUT® Surgical Guidance Console, SCOUT Handpiece and SCOUT Reflector are accessories to the SCOUT Surgical Guidance System. The SCOUT® Reflector and SCOUT Delivery System is a sterile, single use device composed of a SCOUT Reflector preloaded in a delivery system. The SCOUT Reflector, when used in conjunction with the SCOUT Handpiece and SCOUT Console, can be used as a guide for the surgeon to follow in the excision of tissue. The SCOUT Reflector is visible using ultrasound and radiography.

INDICATIONS FOR USE

The SCOUT 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 System) the SCOUT Reflector is located and surgically removed with the target tissue. The SCOUT System is intended only for the non-imaging detection and localization of the SCOUT Reflector that has been implanted in a soft tissue biopsy site or a soft tissue site intended for surgical removal.



SCOUT Reflector

The SCOUT Reflector is approximately (12 mm long - Standard or 8 mm long - Mini) and is delivered through a 16 GA needle. The SCOUT Reflector is designed with features that make it reflective to the micro-impulse radar signal of the SCOUT Handpiece. As a result, the SCOUT Reflector returns a detectable signal compared to surrounding tissue when illuminated by the SCOUT Handpiece. Signal strength is directly related to the SCOUT Reflector depth. Refer to the SCOUT Console Operation Manual for the detection range. The optimal technique for detecting the SCOUT Reflector with the SCOUT Handpiece includes placing the patient in the supine position. The SCOUT Reflector is visible under ultrasound, MRI, and radiographic imaging.

Delivery System

The SCOUT Delivery System consists of a plastic molded handle and 16 GA introducer needle. The SCOUT Reflector is preloaded inside the needle. When the release button is actuated, the needle retracts into the handle thereby deploying the SCOUT Reflector.

CONTRAINDICATIONS

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

WARNINGS

- 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.
- Exercise caution when placing the SCOUT Reflector near the chest wall. Insert the SCOUT Delivery System parallel to the chest wall so as to not puncture the chest wall during placement.
- The device has been designed for SINGLE PATIENT, SINGLE USE only. Reusing this medical device bears the risk of cross-patient contamination as medical devices – particularly those with long and small lumina, joints, and/or crevices between components – are difficult or impossible to clean once body fluids or tissues with potential pyrogenic or microbial contamination have had contact with the medical device for an indeterminable period of time. The residue of biologic material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications. In addition, the reuse of the device may lead to degradation of the components thereby increasing the probability that the device will malfunction.
- DO NOT RESTERILIZE. After resterilization, 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 resterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.
- Do NOT use if the package is open or damaged.
- Use the SCOUT Reflector and SCOUT Delivery System prior to the expiry date shown on the product label.
- If the patient has an internal or external active cardiac implant, contact the cardiac implant manufacturer for instructions before using the SCOUT Surgical Guidance System. The micro-impulse radar signal may interfere with the intended function of the cardiac implant.

CAUTIONS

- Federal law restricts this device to sale by or on the order of a physician (21 CFR §801.109(b)(1)).
- 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.
- The SCOUT Reflector and SCOUT Delivery System is shipped sterile and must not be resterilized.
- The SCOUT Reflector and SCOUT Delivery System is for SINGLE USE only.
- After use, this product may be a potential biohazard. Dispose in accordance with your facility's biohazardous waste procedures.
- Handle in a manner that will prevent accidental contamination. Do not use a device that is damaged. Do not use any device if the package is opened or damaged.
- The implanted SCOUT Reflector is MR Conditional.
- The SCOUT Delivery System is MR Unsafe and should not be used in the MR environment.
- The SCOUT System is intended to provide surgical guidance without the use of a localization wire. There may be instances where the user may opt for placement of a localization wire in addition to the SCOUT Reflector. Placement of a localization wire may impact the performance of the SCOUT System. To minimize this impact, consider the following when placing the localization wire:
- Place the localization wire posterior to the SCOUT Reflector.
- After placing the localization wire, confirm that the SCOUT Reflector can be detected from the skin surface.
- Persons with a known allergy to nickel-titanium (Nitinol) may suffer an allergic reaction to the Reflector.

NOTE

These instructions for the SCOUT Reflector and SCOUT 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.

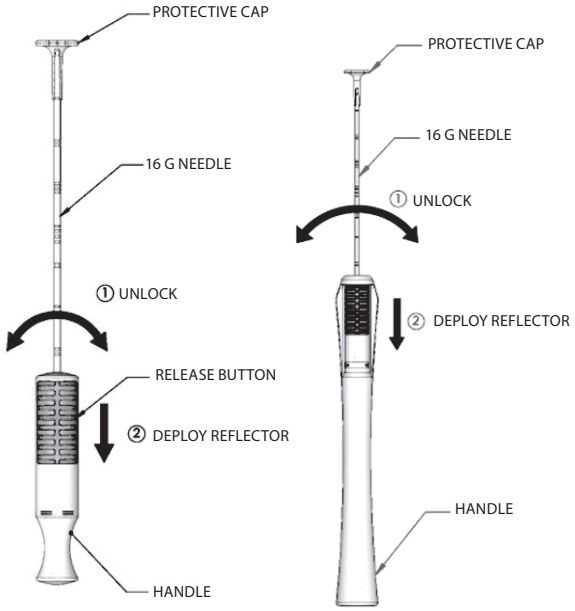
STORAGE

- Store at -20° to 60°C (-4° to 140°F), 10% to 95% relative humidity, non-condensing.

RECOMMENDED PROCEDURE

DELIVERY

1. Inspect the package for damage and expiration date. If undamaged and unexpired, open the package and transfer the product onto the sterile field using aseptic technique.
2. Remove the protective cap.
3. Locate the desired SCOUT Reflector placement location (center of tumor or within 1-2 mm from closest boundary of the tumor or biopsy site) for deployment using the preferred imaging technique (ultrasound or x-ray).
4. Determine the skin entry site.
5. Percutaneously advance the SCOUT Delivery System needle into the tissue toward the target.
6. Confirm needle placement with appropriate imaging technique. If necessary, reposition the needle and reconfirm placement.
   - Depth marks on the needle are for general reference only. Placement is to be based on imaging.
7. Unlock the SCOUT Delivery System by rotating the release button clockwise or counter clockwise ❶. A purple indicator will be visible when the device is unlocked.
8. While maintaining the position of the delivery system handle, firmly slide the release button proximally ❷ to deploy the SCOUT Reflector. The SCOUT Reflector is deployed once the release button covers the purple indicators proximal to the button.
9. Remove the needle and confirm placement of the SCOUT Reflector using the preferred imaging technique. A two view mammogram is recommended.
10. The SCOUT Handpiece and SCOUT Console can also be used to confirm SCOUT Reflector detection and placement.



REMOVAL

1. Determine the proximity of the SCOUT Reflector by using the SCOUT Handpiece and SCOUT Surgical Console, and/or by using imaging guidance (x-ray or ultrasound).
2. Perform an excision of the intended tissue using the SCOUT Handpiece and SCOUT Surgical Console or imaging (x-ray or ultrasound) for guidance.
3. Using the SCOUT Handpiece and SCOUT Surgical Console or imaging (x-ray or ultrasound), confirm the SCOUT Reflector is present in the excised specimen.

PATIENT IMPLANT CARD

If implant card is required, please follow the instructions below. The healthcare provider must place the peel tabs from the label of the implanted SCOUT Reflector 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.

	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 reflector may be safely scanned under the following conditions. Failure to follow these conditions may result in injury.

Device Name	SCOUT Reflector
Static Magnetic Field Strength (B0)	3.0T or less
Maximum Spatial Field Gradient	20 T/m (2,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
Operating Mode	Normal Operating Mode or First Level Controlled Operating Mode
Maximum Whole-Body SAR	Up to 4 W/kg
Maximum Head SAR	Up to 3.2 W/kg
Scan Duration	Up to 4 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.

The reflector may move and/or induce pain when exposed to strong spatial field gradient in the scanner.

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