English

SCOUT Bx™ DELIVERY SYSTEM

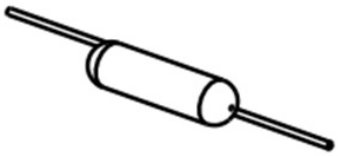
INSTRUCTIONS FOR USE

DESCRIPTION

The SCOUT® Console, SCOUT Handpiece and SCOUT Reflector are components of the SCOUT Surgical Guidance System. The SCOUT® Reflector and SCOUT Bx 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/INTENDED PURPOSE

Using SCOUT Bx Delivery System, 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 or a 15 GA rigid cannula. 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.

SCOUT Bx DELIVERY SYSTEM

The SCOUT Bx delivery system consists of a plastic molded handle and 15 GA rigid cannula. The SCOUT Reflector is preloaded inside the delivery system. When the deployment plunger is actuated, the SCOUT reflector is deployed through the distal end of the device.

BIOPSY DEVICE COMPATIBILITY

The SCOUT Bx delivery system has been designed to be compatible with the following Hologic® biopsy devices and accessories:

•Eviva® 0913-20

•Eviva 1213-20

•BREV09 (20mm aperture)

•ATEC® ILS 0914-20

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.

CLINICAL BENEFITS

The intended clinical benefit of the SCOUT Surgical Guidance System is accurate marker placement and lesion localization to facilitate target tissue excision.

KEY PERFORMANCE CHARACTERISTICS

The SCOUT Reflector, through radar guidance, is able to be detected to a depth of 60mm with an accuracy of +/- 1mm.

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 delivery system carefully correct the orientation of the device but never apply strong forces in order to overcome the obstacle.
• 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 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 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 Bx 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)).
• Reflector placement within a hematoma or fibroadenoma could affect the sensitivity of the system.
• 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 Bx delivery system is shipped sterile and must not be re-sterilized.
• The SCOUT Reflector and SCOUT Bx 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 Bx delivery system is MR Conditional.
• The SCOUT Bx delivery system is not recommended for use within the bore of the magnet.
• 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.

POTENTIAL COMPLICATIONS

The SCOUT reflector provides an important means of treating patients requiring soft tissue cancer surgery, however, the potential exists for serious complications including, but not limited to, the following:

Potential Reflector Complications

• Additional procedure

• Allergic reaction

• Device migration

• Foreign body non vascular

• Infection

• Inflammation

• Pulmonary event

• Soft tissue injury

• Tract seeding

NOTES

These instructions for the SCOUT Reflector and SCOUT Bx 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.

For a copy of this device's current European Summary of Safety and Clinical Performance (SSCP), please go the European database on medical devices (Eudamed), where it is linked to the basic UDI-DI. https://ec.europa.eu/tools/eudamed.

STORAGE

Where applicable, please refer to the label for specific storage conditions.

RECOMMENDED PROCEDURE EVIVA 0913-20 /1213-20, and BREV09 (20mm aperture) or ATEC ILS 0914-20

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 biopsy device from the introducer sheath.
3. Place the SCOUT Bx delivery system through the hub of the introducer sheath and advance until the delivery handle is seated firmly against the introducer hub.

Note: For use with ATEC ILS 0914-20, attach the MRI spacer onto the SCOUT Bx delivery system and firmly seat against the deployment handle. Place the delivery system through the hub of the introducer sheath and advance until the deployment handle/spacer assembly is seated firmly against the introducer hub.

4. Deploy the SCOUT Reflector by depressing the deployment plunger forward until it latches onto the handle. The reflector deployment window will turn orange when fully deployed and latched into place.

5. Verify deployment and accurate placement of the SCOUT Reflector with the appropriate imaging modality prior to removal of the device.
Note: For use with the ATEC ILS 0914-20, remove the delivery system prior to shuttling the patient back into the bore of the magnet.
6. Remove the SCOUT Bx delivery system and introducer sheath from the breast and properly dispose in accordance with acceptable medical practices and applicable local, state, and federal laws and regulations.
7. Confirm final placement of the SCOUT Reflector using the preferred imaging technique. A two- view mammogram is recommended.
8. The SCOUT Handpiece and SCOUT Console can also be used to confirm SCOUT Reflector detection and placement.

REMOVAL

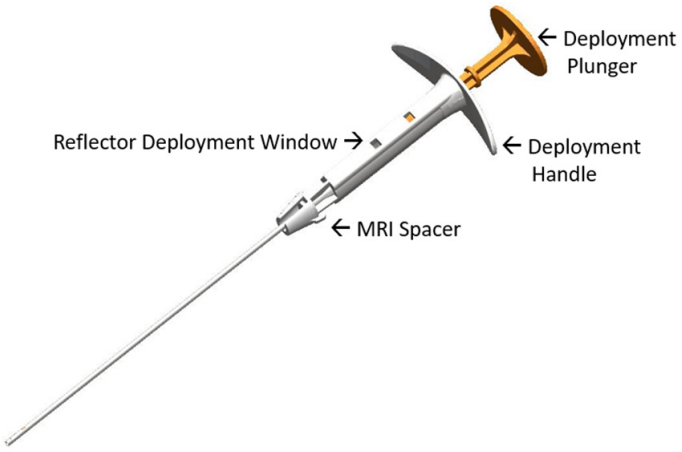
1. Determine the proximity of the SCOUT Reflector by using the SCOUT Handpiece and SCOUT Surgical Console, and/or by using imaging guidance (x-ray or ultrasound).

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.



SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
LOT	Lot Number
REF	Catalog Number
STERILE EO	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
2	Single Use
Rx ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Do Not Re-sterilize
	Caution
	Date of Manufacture
MD	Medical Device.
	Single Sterile Barrier System
	Non-Pyrogenic
	Manufacturer
EC REP	Authorized Representative in European Community
UDI	Unique Device Identifier
	Consult Instructions for Use

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.

MR

MRI Safety Information

SCOUT Bx Delivery System may be safely used in an MR Scanner room under the following conditions. Failure to follow these conditions may result in injury to patient and users.
The SCOUT Bx Delivery System must not be brought inside an MRI system bore and must be at least 1 foot away from the edge of the scanner bore.

Device Name	Scout Bx Delivery System
Static Magnetic Field Strength (B0)	3.0T or less
Maximum Spatial Field Gradient	4.6 T/m (460 gauss/cm)
RF Excitation	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.
RF Transmit Coil Type	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.
Operating Mode	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.
Maximum Whole-Body SAR	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.
Maximum Head SAR	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.
Scan Duration	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.
MR Image Artifact	Not Applicable. The device must not be brought into an MR bore and must be at least 1 foot away from the edge of the MR bore.

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