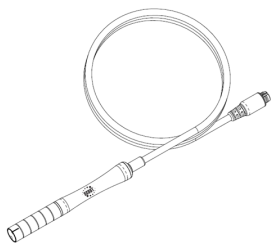


**HANDPIECE****INSTRUCTIONS FOR USE****DESCRIPTION**

The SCOUT® Surgical Guidance Console, SCOUT Handpiece and SCOUT Reflector are accessories to the SCOUT Surgical Guidance System. The SCOUT Handpiece is a sterile, single-use medical device that, when used with the SCOUT Console (available separately), provides control operations for detecting the SCOUT Reflector (available separately) within soft tissue.

The system employs micro-impulse radar and infrared (IR) light technology to detect the presence of the SCOUT Reflector, which is placed into soft tissue during a prior procedure. The SCOUT Console provides the Radar signal to the SCOUT Handpiece along with power for the infrared light source. The SCOUT Handpiece delivers the Radar signal and IR light into the soft tissue and in turn receives signals reflected back from the SCOUT Reflector. The SCOUT Console processes the reflected Radar signals to provide the physician an audible and visual indication when the SCOUT Reflector is detected.

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.

CONTRAINDICATIONS

- Not intended for connection to any other device or equipment. Only for use with the SCOUT Console and SCOUT Reflector.

WARNINGS

- SCOUT Handpiece contains sensitive electronic components. Do not crush or subject cable to tight bends.
- SCOUT Handpiece is designed for use only with the SCOUT Console and SCOUT Reflector.
- 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 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, reuse of the device may lead to degradation of the components and seals 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.
- SCOUT Handpiece operates by emitting infrared light from the distal end. Do not point an active SCOUT Handpiece at eyes.
- Do NOT use if the package is open or damaged.
- Use the SCOUT Handpiece prior to the expiry date shown on the product label.
- Electrical leakage risk: Non-hazardous voltage is present during normal SCOUT Handpiece use.
- 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.
- SCOUT Handpiece is shipped sterile and must not be re-sterilized.
- SCOUT Handpiece is for SINGLE USE only.
- After use, this product may be a potential biohazard. Dispose in accordance with your facility's biohazardous waste and/or electronic 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.
- SCOUT Handpiece is MR (Magnetic Resonance) Unsafe and should not be used in the MR environment.

NOTE

These instructions for the SCOUT Handpiece 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.

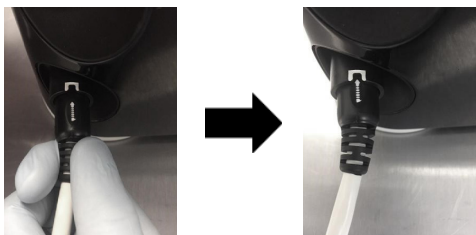
STORAGE

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

RECOMMENDED PROCEDURE**SETUP INSTRUCTIONS**

- Prepare the SCOUT Console for use (see details in Operation Manual).

- Remove the pouched SCOUT Handpiece from the outer carton.
- Open the outer pouch and transfer the sterile inner pouch containing the SCOUT Handpiece onto the sterile field using aseptic technique.
- Open the sterile inner pouch and remove the SCOUT Handpiece.
- Hand the connector end of the SCOUT Handpiece outside the sterile field.
- Connect the SCOUT Handpiece to the SCOUT Console, ensuring that the white arrow aligns with the white alignment notch on the SCOUT Console connector.



- Turn on the SCOUT Console and activate the SCOUT Handpiece (see details in the Operation Manual supplied with the SCOUT Console).

TESTING THE SCOUT HANDPIECE

- Place the distal end of the SCOUT Handpiece on the target of the SCOUT Handpiece Test Card.



- If the audible indicator sounds, then the SCOUT Handpiece is ready for use.
- If the audible indicator does not sound, replace the SCOUT Handpiece and test (see Operation Manual for additional troubleshooting steps).

USING THE SCOUT HANDPIECE

- Apply the distal end of the SCOUT Handpiece to the skin or soft tissue.
- Ensure that no air gaps are present between the distal end of the SCOUT Handpiece and tissue.
- When the SCOUT Handpiece detects the SCOUT Reflector, the numerical display on the SCOUT Console will adjust as the SCOUT Handpiece is placed closer to the SCOUT Reflector. In addition, the SCOUT Console will emit an audible feedback that increases in cadence.

REMOVING THE SCOUT HANDPIECE FROM THE SCOUT CONSOLE

- Once the procedure is complete, shut down the SCOUT Console (reference the Operation Manual for instructions).
- Remove the SCOUT Handpiece by pulling the connector straight out of the SCOUT Console while holding the SCOUT Console still.

SYMBOL	DESIGNATION
	Use By: YYYY-MM-DD
	Lot Number
	Catalog Number
	Sterilized Using Ethylene Oxide
	Do Not Use if Package is Damaged
	Single Use
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Do Not Re-sterilize
	Caution: Consult accompanying documents
	Date of Manufacture
	Medical Device
Sterile Package	Sterile Package
	Storage Temperature Range



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 Customer Service 1-800-356-3748



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