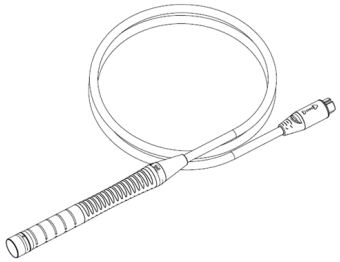
English

GUIDE

INSTRUCTIONS FOR USE



DESCRIPTION

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

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 or biopsy site prior to the procedure. The SCOUT Console provides the Radar signal to the Handpiece along with power for the infrared light source. The SCOUT Multiple-use Handpiece delivers the Radar signal and IR light into the soft tissue or biopsy site and in turn receives signals reflected back from the SCOUT Reflector. The SCOUT Console processes the reflected Radar signals to provide the physician with an audible and visual indication when the SCOUT Reflector is detected.

INDICATIONS FOR USE

SCOUT

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.

CLEANING AND DISINFECTION

HANDLING THE HANDPIECE

•Avoid dropping, impact, or abrasion to handpieces. Careless handling can result in damaged infrared lights, damaged internal circuitry, cracked housings, and cable or system connector damage. Do not use handpieces with cracked or damaged housings, shaft, strain relief or cable assemblies as these issues may increase cross-contamination risks and compromise electrical safety features of the handpiece.
•Use care to avoid excessive twisting, pulling, pinching, or kinking of handpiece cable assemblies. When transporting handpieces, maintain control of cables and system connectors and use protective accessories if possible.
•Prevent introduction of foreign objects or moisture in the system connector assembly. Do not apply excessive force on any component of the system connector.
•Do not allow prolonged exposure to excessive moisture or immersion of handpieces in any liquid other than liquid recommended in this user manual.
•Avoid rapid and extreme temperature changes as well as lengthy exposure to direct sunlight or a strong ultraviolet light source.

HANDPIECE INSPECTION

Before use, inspect the following areas of the handpiece:
•Handpiece body including the shaft, handle: inspect for cracks, abrasions, or evidence of impact.
•Strain relief and cable assembly: check for cracks, cuts, tears, abrasion, kinking or crushing.
•System connector: check for foreign objects, broken latches, or bent pins and shielding.
•Cable assembly: check for discoloration or inflexibility of the handpiece cable or strain-relief.

HANDPIECE CLEANING AND LOW LEVEL DISSINFECTING

These generalized cleaning instructions are indicated for use with SCOUT Multiple-use Handpieces. Cleaning is the removal of all visible soil or contaminants from the handpiece. All handpieces must be cleaned after every use and is an essential step before disinfection is attempted.

1.After every procedure, ensure that any obvious contaminants are completely wiped off the handpiece.
2.Use a moistened soft cloth or wipe (CaviWipes®) to remove any remaining contaminants or gross debris that remain on the handpiece or cable. Do not re-use cloths or wipes. Disinfectant wipes should be used in accordance with the manufacturer's instructions. Merit Medical is not responsible for damage incurred during the cleaning process for products in which no material compatibility evaluation has been conducted.
Note: CaviWipes have been tested for compatibility with the SCOUT Multiple-use Handpiece.
3.For use as a low-level disinfectant, use a second CaviWipe wipe to thoroughly wet the surface. For best results, the surface should remain visibly wet for 3 minutes at room temperature (68°F/20°C)
4.Use a lint-free soft and clean dry cloth or wipe to thoroughly dry the handpiece and cable.

Notes: Cleaning products other than those described in the previous section (CaviWipes) should be as close to neutral PH as possible. Any, cleaning or disinfectant products containing concentrations surfactants, methanol, ethanol, benzyl or methyl alcohol, bleach, methyl or ethyl paraben, polyethylene glycol, mineral oil, lubricant oil, oil based lotions, acetone, ammonia, anhydrous ammonia, iodine, iodine compounds, acids with 5PH or lower may damage or discolor the handpiece. The use of any type of brush is not recommended as bristles may damage the distal end of the handpiece. Ultrasonic cleaning is not approved for SCOUT Multiple-use Handpieces.

Warning: Disinfectant wipes and topical spray products are not FDA-cleared, high-level disinfectants. These products do not provide adequate protection should the handpiece become cross-contaminated or in contact with unhealthy or non-intact skin.

HIGH LEVEL DISINFECTING

The following provides instructions for performing high level disinfection of SCOUT Multiple-use Handpiece with Cidex® OPA.

1.Clean the handpiece and cable according to the procedures in the "Handpiece Cleaning and Low-Level Disinfecting" section.
2.Ensure minimum effective concentration (MEC) of the Cidex OPA using Cidex OPA test strips.
3.Equilibrate a water bath of Cidex OPA to 20°C.
4.Immerse the handpiece into the Cidex OPA as shown in the image. Do not immerse the connector, cable, or cable strain relief. Ensure all air bubbles are removed from the surface of the handpiece with a syringe filled with the disinfectant to remove all air bubbles.
5.Allow the handpiece to soak for 12 minutes.
6.Thoroughly rinse the handpiece by immersing in pure water (PURW), agitating and allowing to set for a minimum of 1 minute.
7.Repeat the previous step two more times for a total of 3 rinses using a fresh batch of PURW each time.
8.Dry the handpiece using a sterile lint-free cloth.

The following provides instructions for performing high level disinfection of SCOUT Multiple-use Handpiece with the Nanosonics® Trophon® EPR System.

1.Clean the handpiece and cable according to the procedures in the "Handpiece Cleaning and Low-Level Disinfecting" section.
2.Place the handpiece into the Trophon EPR as shown.
3.Follow the Trophon EPR manufacturer's instructions for performing the standard cycle.
4.Remove the handpiece using minimal contact after the cycle is complete.
5.Dry the handpiece as necessary using a sterile lint-free cloth.
6.Visually inspect the handpiece and ensure any disinfectant residue present is removed.
7.The handpiece is ready for use or storage.

STERILIZATION

The following provides instructions for performing sterilization of the SCOUT Multiple-Use Handpiece with the Advanced Sterilization Products STERRAD® System and Steris V-PRO®Low Temperature Sterilization Systems.
Testing was performed in accordance with AAMI TIR No.12-2010 guidelines, "Designing, Testing and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."

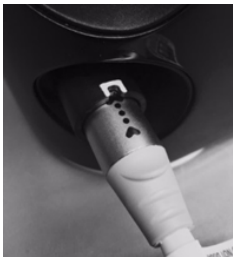
Sterilization can be performed in:			
STERRAD System	STERRAD 100S	STERRAD NX	STERRAD 100NX
Cycle	Short	Standard	Standard

Please refer to the STERRAD System User's Guides for general reprocessing instructions, including proper cleaning, and drying, and packaging information prior to reprocessing any medical device in a STERRAD System.

Sterilization can be performed in:				
STERIS System	V-PRO® maX Low Temperature Sterilization System	V-PRO® maX 2 Low Temperature Sterilization System	V-PRO® 60 Low Temperature Sterilization System	V-PRO® s2 Low Temperature Sterilization System
Cycle	Lumen or Non Lumen or Flexible Cycle	Lumen or Non Lumen or Flexible or Fast Non Lumen Cycle	Lumen or Non Lumen or Flexible Cycle	Lumen or Non Lumen or Flexible or Fast Cycle

Devices must be cleaned, rinsed, and dried in accordance with the instruction for use of the sterilizers. Refer to STERIS Operator Manual for proper operation of the unit and cycle selection.

RECOMMENDED PROCEDURE



SETUP INSTRUCTIONS

•Prepare the SCOUT Console for use (see details in Operation Manual).
•Connect the SCOUT Multiple-use Handpiece to the Console, ensuring that the white dots align and are facing upwards.
•Turn on the SCOUT Console and activate the Handpiece (see details in the Operation Manual supplied with the Console).

TESTING THE HANDPIECE

•Place the distal end of the Handpiece on the target of the Handpiece Test Card.
•If the audible indicator sounds, then the Handpiece is ready for use.
•If the audible indicator does not sound, replace the Handpiece and test (see Operation Manual for additional troubleshooting steps).

USING THE HANDPIECE

•Insert the Multiple-use Handpiece into the sterile sheath.
Note: SCOUT® Guide Sheath SH-01 has been tested for compatibility with the SCOUT Guide.
•Apply the sheathed Handpiece tip to skin or soft tissue.
•Ensure that no air gaps are present between the Handpiece tip and tissue.
•When the Handpiece detects the Reflector, the Console will emit an audible feedback that increases in cadence. In addition, the numerical display on the Console will adjust as the Handpiece is placed closer to the Reflector.
•After completion of procedure, remove the Multiple-use Handpiece from the sheath, dispose of sheath.

REMOVING THE HANDPIECE

•Once the procedure is complete, shut down the Console (reference the Operation Manual for instructions).
•Remove the Handpiece by pulling the connector straight out of the Console while holding the Console still.
•Clean and Disinfect the Multiple-use Handpiece and store with SCOUT Console.

CONTRAINDICATIONS

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

WARNINGS

•SCOUT Multiple-use Handpiece contains sensitive electronic components. Do not crush or subject cable to tight bends.
•SCOUT Multiple-use Handpiece is designed for use only with the SCOUT Console and SCOUT Reflector.
•Handpiece operates by emitting infrared light from the distal end of the Handpiece. Do not point an active Handpiece at eyes.
•Cross-contamination risk: Handpieces with cracks, abrasions or tears may harbor dangerous contaminants or tear protective sheaths used with the handpieces. Do not use handpieces with any signs of damage.
•Electrical leakage risk: Non-hazardous voltage is present during normal handpiece use.
•If the patient has an internal or external active cardiac implant, contact the cardiac implant manufacturer for instructions before using the SCOUT system. The micro-impulse radar signal may interfere with the intended function of the cardiac implant.
•Do NOT use if the package is open or damaged.

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 Reflector placement.
•SCOUT Multiple-use Handpiece is shipped non-sterile.
•After use, this product may be a potential biohazard. Clean and disinfect following the procedures described above.
•Handle in a manner that will prevent accidental contamination. Do not use a device that is damaged.
•Handpiece is MR (Magnetic Resonance) Unsafe and should not be used in the MR environment.
•Only use the covers or sheaths recommended. Other covers or sheaths may impact the ability of the handpiece to detect the Reflector.

NOTE

These instructions for the SCOUT Multiple-use 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

•Store at -20° to 60° C (-40° to 104° F), 10% to 95% relative humidity, non-condensing.

SYMBOL	DESIGNATION
LOT	Lot Number
REF	Catalog Number
	Do Not Use if Package is Damaged
NON STERILE	Non-Sterile
℞ ONLY	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Caution: Consult accompanying documents
MD	Medical Device
	"For European Union (EU) States, this symbol indicates 'Not for general waste.' Dispose of in accordance with the waste electronic & electrical equipment (WEEE) directive."

MERIT MEDICAL®

www.merit.com

Manufactured For:
Merit Medical Systems, Inc.
6 Journey, Suite 125
Aliso Viejo, CA 92656 USA
Customer Service 1-800-356-3748