

# Instructions For Use



## Cleaning, Disinfection and Sterilization of Navigator Products

According to EN ISO 17664

## **GENERAL WARNINGS:**

Failure to obey to these warnings may cause permanent damage to the systems and/or lead to inadequate sterilization.

### **WARNING:**

The Probes and cables must be cleaned, disinfected and sterilized only by qualified personnel.

### **WARNING:**

Do not sterilize when the battery is inside the probe. Do not sterilize when the cap is missing or not tightened. Attempting to do so will cause permanent damage to the probe.

### **WARNING:**

Do not sterilize the Navigator Control Unit or immerse it in fluids. Attempting to do so will cause permanent damage to the Control Unit.

### **WARNING:**

Do not drop the Navigator probe. The reusable Navigator probe is a delicate surgical instrument. Mechanical shock can result in permanent damage to the probe.

### **WARNING:**

Reusable probes and reusable probe cables should only be sterilized by STERRAD NX Standard method.

### **WARNING:**

Do not use unapproved methods of sterilization such as ethylene oxide (ETO), gamma sterilization, steam autoclave or plazlyte sterilize. These sterilization methods have not been validated on the Navigator probe and cables and may cause permanent damage to them.

### **WARNING:**

The Co-Pilot device is a sterile single use item. Do not re-use or sterilize the Co-Pilot device. Discard the Co-Pilot device after single use.

### **WARNING:**

Failure to properly clean and disinfect the device prior to sterilization could lead to inadequate sterilization.

### **WARNING:**

Do not sterilize the battery and battery holder of the Pilot Wireless Probe. Sterilization of these units will cause permanent damage to them.

### **WARNING:**

The handling and storing of sterile probes and cables should be conducted per your facility's guidelines in packaging and storing sterile products.

### **WARNING:**

Do not scratch or abrade the probe when decontaminating. Scratching / abrading the probe will make future decontamination difficult, if not impossible.

### **WARNING:**

Follow universal, generally accepted practices when handling components that have come in contact with blood or tissue.

### **WARNING:**

The probe must be covered by a drape while in use to avoid cross contamination.

## Overview

This Instructions for Use describes the cleaning, disinfection, radioactive decontamination, and sterilization procedures of the Navigator Probes and corresponding cables.

Table 1 indicates the probes and cables that are eligible for cleaning, disinfection, radioactive decontamination, and sterilization.

Part Number	Description	Cleaning	Disinfection	Radioactive decont.	Sterilization
WP-9000-14	Wireless Pilot Probe, 14mm	YES	YES	YES	YES
SP-2A14-67	Standard Lymphatic Mapping Probe (cabled, 14mm, angled)	YES	YES	YES	YES
SP-2S14-67	Standard Lymphatic Mapping Probe (cabled, 14mm, straight)	YES	YES	YES	YES
SP-2S11-53	Superficial Head & Neck Probe (cabled, 11mm tip, straight)	YES	YES	YES	YES
SP-2S10-31	Laparoscopic Probe (cabled, 10mm tip, straight, 310mm shaft length)	YES	YES	YES	YES
SP-2S10-19	Laparoscopic Probe (cabled, 10mm tip, straight, 190mm shaft length)	YES	YES	YES	YES
SP-2S10-31D	Daniel Lung Probe (cabled, 10mm tip, angled, 310mm shaft length)	YES	YES	YES	YES
GP-4001-00	Cable for CdTe Probes	YES	YES	YES	YES
GP-6801-00	Co-Pilot, One Box of 12 Sterile Devices	NO	NO	YES	NO
SP-3075-00	12mm Lymphatic Mapping Probe (Csl, cabled, 12mm tip, angled)	YES	NO	YES	NO
PM-4000-20	Cable for 12mm SMX (Csl) Probes only	YES	NO	YES	NO
PM-0400-40	Gain Module (use with 12mm SMX Probes only)	NO	NO	NO	NO
GP-2800-00	Navigator GPS Control Unit	NO	NO	NO	NO
N2-9800-00	Navigator 2.0 Control Unit	NO	NO	NO	NO
N2-8000-01	Wireless Receiver for use with Wireless Pilot Probe	YES	NO	YES	NO
WP-8500-12	Wireless Pilot Probe Batteries	NO	NO	NO	NO
SP-1800-00	Top Gun II Collimator (Use with 14mm Probes only)	YES	YES	YES	NO

Table 1: Cleaning, Disinfection, Radioactive Decontamination and Sterilization of Navigator Components

## Procedure Steps

All probes and probe cables require cleaning and disinfection immediately after and immediately before use. The radioactive decontamination and sterilization procedures are optional. Follow these steps to ensure that cleaning and disinfection are done correctly.

- **Before Use**, visually inspect probe and probe cable to ensure that it is free of contamination.
- **After Use**, Clean, Disinfect and Store Probe and Cable. Wipe down control unit and gain module (if available).
- Radioactive Decontamination Procedure – OPTIONAL
- Sterilization Procedure – OPTIONAL
- Place probe and cable in a sterile drape while in use.

<p><b>Preparation of probes and cables</b></p>	<p>Check the following in wired probes and respective cables:</p> <ol style="list-style-type: none"> <li>1. The cables are free of cracks or cuts</li> <li>2. The connectors of the probe and cable are completely dry.</li> <li>3. The cable is detached from the Probe and the Navigator Control Unit.</li> <li>4. (If available) The top gun collimator is removed from the Probe.</li> <li>5. The Co-Pilot device is removed from the probe and control unit, and discarded.</li> </ol> <p>Check the following in the Wireless Pilot probe:</p> <ol style="list-style-type: none"> <li>1. The battery is removed from the wireless Pilot Probe.</li> <li>2. The battery holder is inserted in the wireless Pilot Probe.</li> <li>3. The cap is securely tightened to the wireless Pilot Probe.</li> </ol>
<p><b>Cleaning</b></p>	<p>Equipment: Enzymatic Cleaner</p> <ol style="list-style-type: none"> <li>1. Rinse the outside surfaces of the probe with a brisk stream of</li> <li>2. lukewarm tap water (98 °F to 105 °F / 36.5 °C to 40.5 °C). Prepare enzymatic cleaner, suitable for surgical instruments, according to the manufacturer's recommendation. Wipe with soft cloth or sponge soaked in enzymatic cleaner. Repeat separately for collimator cleaning, if used.</li> <li>3. Visually inspect device(s) for contaminated areas.</li> <li>4. Repeat steps 1 &amp; 2 until visual inspection reveals instrument(s) is clean.</li> <li>5. Rinse equipment with a brisk stream of lukewarm tap water (98 °F to 105 °F / 36.5 °C to 40.5 °C) for 30-seconds.</li> </ol>
<p><b>Disinfection</b></p>	<p>Equipment: OPA high-level disinfectant</p> <ol style="list-style-type: none"> <li>1. Prepare Mixture according to manufacturer's instructions</li> <li>2. Immerse probe and cable completely for a minimum of 12 minutes at 68 °F (20 °C or higher), to destroy all pathogenic microorganisms. <i>Note that probes that are compromised can be damaged if detergent seeps into them.</i></li> <li>3. Rinse equipment with a brisk stream of lukewarm tap water (98 °F to 105 °F / 36.5 °C to 40.5 °C) for approximately 1 minute. Repeat rinse two additional times.</li> </ol>

<b>Drying</b>	Air-dry or dry with clean towel. Flush the probe connector with 70% isopropyl or ethyl alcohol, and then flush with air. Ensure that the connector ends of the probe and cable are completely dry before storing. The cable may take up to 24 hours to completely dry.
<b>Radioactive Decontamination</b>	<p>Equipment: Standard Nuclear Medicine Guidelines, Radiacwash™</p> <p>An increase in background counts may signal radioactive contamination of the probe or the environment. If a process of elimination shows the probe to be contaminated with radioactive material, the probe must be decontaminated.</p> <ol style="list-style-type: none"> <li>1. Decontaminate the probe using standard Nuclear Medicine Department techniques, which may involve washing the probe with a solution such as Radiacwash™.</li> <li>2. Ensure that all recesses, crevices, and mating surfaces are clean.</li> <li>3. Dispose of pads and cleaning solution in approved containers.</li> </ol>
<b>Sterilization</b>	<p>Equipment: STERRAD® NX</p> <ol style="list-style-type: none"> <li>1. Please refer to the manufacturer's instructions to properly conduct the sterilization procedure. The probe cable can be loosely coiled and then placed together with the probe.</li> <li>2. After the sterilization procedure is completed, handle and store the probes and cables per your facility's guidelines in packaging and storing sterile products.</li> </ol>
<b>Control Unit &amp; Gain Module</b>	If unclean, wipe Control Unit and Gain Module (if present) with a soft cloth moistened with mild soap and water. Dry with a soft cloth. Store the Control Unit and Gain Module in a clean, safe environment.



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