

Instructions For Use



Cleaning and Sterilization of Navigator Gamma Probes

According to EN ISO 17664

<p>PROBE MODEL: WP-9000-14, SP-2A14, 67, SP-2S14-67, SP-2S11-53, SP-2S10-31, SP-2S10-19, SP-2S10-31D</p> 	<p>CABLE MODEL: GP-4001-00</p> 
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<p>Preparation of probes and cables</p>	<p>WARNING: To avoid permanent damage of the Navigator Control Unit, do not sterilize the Navigator Control Unit or immerse it in fluids.</p> <p>WARNING: To avoid permanent damage of the probe and cables, prior to cleaning, sterilization or disinfection, always inspect them for cracks, wear or other damages.</p> <p>WARNING: To avoid permanent damage to the wireless probe, do not clean with the battery cap open or not securely tightened.</p> <p>Check the following in wired probes and respective cables:</p> <ol style="list-style-type: none"> 1. The cables are free of cracks or cuts 2. The connectors of the probe and cable are completely dry. 3. The cable is detached from the Probe and the Navigator Control Unit. 4. (If available) The top gun collimator is removed from the Probe. <p>Check the following in the Wireless Pilot probe:</p> <ol style="list-style-type: none"> 1. (Optional) A new CR2 DURACELL battery is inserted in the Wireless Pilot Probe. 2. The cap is securely tightened to the Wireless Pilot Probe. The O-ring on the cap should not be visible.
<p>Cleaning</p>	<p>Equipment:</p> <p>Enzymatic Cleaner</p> <p>Instructions:</p> <ol style="list-style-type: none"> 1. Rinse the outside surfaces of the probe with a brisk stream of 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. 2. Visually inspect device(s) for contaminated areas. 3. Repeat steps 1 & 2 until visual inspection reveals instrument(s) is clean. 4. 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. Do not exceed 60°C. 5. 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.

OPTION 1. Sterilization

<p>Sterilization</p>	<p>Equipment:</p> <p>Probe and Cable:</p> <p>STERRAD® NX - Standard Cycle STERRAD® 100NX - Standard Cycle STERRAD® 100S - Short Cycle</p> <p>STERIZONE® VP4 Sterilizer - Cycle 1</p> <p>Steris V-PRO® 1 Plus - Non-Lumen Cycle Steris V-PRO® maX - Non-Lumen Cycle Steris V-PRO® 60 - Non-Lumen Cycle Steris V-PRO® maX - Flexible Cycle</p> <p>Steris System 1E® (US use only) Steris System 1® (International use Only) Steris System 1® Express (International use Only) Steris System 1® Plus (International use Only)</p> <p>Probe Only (not for use on cable):</p> <p>Steris V-PRO® 1 - Standard Cycle Steris V-PRO® 1 Plus . Lumen Cycle Steris V-PRO® maX . Lumen Cycle Steris V-PRO® 60 . Lumen Cycle</p> <p>WARNING: To avoid permanent damage of the cable, do not process the cable in the V-PRO 1 Standard Cycle or the VPRO-1 Plus, VPRO maX, or V-PRO 60 Lumen Cycles because it contains polyurethane.</p>
	<p>Instructions:</p> <ol style="list-style-type: none"> 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. 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. 3. The wireless probe with battery inside has a two-week shelf life after sterilization. <p>WARNING: Do not exceed the two-week shelf life after sterilization for a wireless probe with battery inside. A wireless probe with a shelf life longer than two weeks may not function properly due to a drained battery. If the probe has a shelf life longer than two weeks, replace the battery and re-sterilize the probe.</p>

OPTION 2. High Level Disinfection

High Level Disinfection	<p>Equipment:</p> <p>OPA high-level disinfectant</p>
	<p>Instructions:</p> <ol style="list-style-type: none"> 1. Prepare Mixture according to manufacturer's instructions 2. Immerse probe and cable completely for a minimum of 12 minutes at 68°F (20°C or higher), to destroy all pathogenic microorganisms. 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. Air-dry or dry with clean towel. Do not exceed 60°C. 4. 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. 5. The wireless probe with battery inside has a two-week shelf life after disinfection. <p>WARNING: To avoid health hazards, comply with the disinfectant manufacturer's instructions.</p> <p>WARNING: Do not exceed the two-week shelf life after disinfection for a wireless probe with battery inside. A wireless probe with a shelf life longer than two weeks may not function properly due to a drained battery. If the probe has a shelf life longer than two weeks, replace the battery and re-sterilize the probe.</p>

NOTE: The instructions provided above have been validated by the medical device manufacturer as being capable of preparing the Navigator probe for re-use. It remains the responsibility of the facility to ensure that the probes and cables have been properly cleaned, disinfected and sterilized. This requires validation and routine monitoring of the process. Any deviation by the facility from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.



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