

Instructions For Use



Sterilization of Navigator Gamma Probes

According to EN ISO 17664



Manufactured by:
Dilon Technologies, Inc.
12050 Jefferson Avenue
Suite 340
Newport News, VA 23606
USA
Phone: 1-844-DILONNAV



Authorized European Representative:
AG Medical
Route de l'Orme,
Parc des Algorithmes - Imm. "Homère"
91190 Saint-Aubin
France
<http://ag-medical.com/>



<p>PROBE MODEL: WP-9000-14, SP-2A14, 67, SP-2S14-67, SP-2S11-53, SP-2S10-31, SP-2S10-19, SP-2S10-31D, WP-9000-14S</p> 	<p>CABLE MODEL: GP-4001-00</p> 	<p>TOP GUN COLLIMATOR MODEL: SP-1800-00</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>PREPARATION STEPS:</p> <p>Navigator 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>Navigator Wireless 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>Enzol[®] Enzymatic Detergent or equivalent enzymatic detergent</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. The cable may take up to 24 hours to completely dry.

<p>Sterilization</p>	<p>Equipment:</p> <p style="text-align: center;">Sterilization systems:</p> <p>For probe or 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>For 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 style="text-align: center;">Sterilization trays (optional):</p> <p>Small Navigator Sterilization Tray. Size: 2.6" (6.6cm) x 12" (30.5cm) – Fits one probe. (Figure 1)</p> <p>Large Navigator Sterilization Tray. Size: 6.5" (16.5cm) x 18" (45.7cm) - Fits all probe sizes and cable. (Figure 2)</p>
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Sterilization
(Continued)

Instructions:

1. Place probe and cable (including optional top gun collimator) on a sterilization tray



Figure 1. Small Sterilization Tray



Figure 2. Large Navigator Sterilization Tray

2. 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.
3. After the sterilization procedure is completed, handle and store the probes and cables per your facility's guidelines in packaging and storing sterile products.
4. The wireless probe with battery inside has a two-week shelf life after sterilization.

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.

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.