

Instructions For Use





Sterilization of Navigator Surgical Gamma Probes

According to EN ISO 17664



Manufactured by:
Dilon Technologies, Inc.
12050 Jefferson Avenue
Suite 34
Newport News, VA 23606
USA
Phone: 1-844-DILONNAV



<p>PROBE MODEL: SP-2A14, 67, SP-2S14-67, SP-2S11-53, SP-2S10-31, SP-2S10-19, SP-2S10-31D, WP-9000-14; WP-9000-14S Only model numbers manufactured October 30, 2015, and later are sterilizable.</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 probes and cables, prior to cleaning and sterilization, 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: Ensure the following for wireless probes, wired probes, and cables:</p> <ol style="list-style-type: none"> 1. The probes are free of any damage. 2. The cables are free of cracks or cuts. 3. The connectors of the probe and cable are completely dry. 4. The cable is detached from the probe and the Navigator Control Unit. 5. (If available) The top gun collimator is removed from the probe.
<p>Cleaning</p>	<p>Equipment: Enzo[®] Enzymatic Detergent or equivalent enzymatic detergent</p> <p>Instructions:</p> <ol style="list-style-type: none"> 1. Prepare enzymatic cleaner, suitable for surgical instruments, according to the manufacturer's recommendation. 2. 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). Wipe with soft cloth or sponge soaked in enzymatic cleaner. Repeat separately for collimator cleaning, if used. 3. Visually inspect device(s) for contaminated areas. 4. Repeat steps 1 & 2 until visual inspection reveals instrument(s) is clean. 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. 6. Air-dry or dry with clean towel.
<p>Wireless Probe Battery</p>	<p>For wireless probe only:</p> <ol style="list-style-type: none"> 1. After cleaning of the wireless probe, and prior to each sterilization, insert a new CR2 DURACELL battery. 2. Ensure the cap is securely tightened to the Wireless Pilot Probe. The O-ring on the cap should not be visible.

Sterilization

Equipment:

Sterilization systems:

Follow the manufacturer's IFU for the sterilization system of your choice.

Wireless probe, wired probe, and cable:

- STERRAD® NX - Standard Cycle
- STERRAD® 100NX - Standard Cycle
- STERRAD® 100S - Short Cycle

- 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

- 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)

- STERIZONE® VP4 Sterilizer - Cycle 1

Additional methods for wireless probe and wired probe (not for use on cable):

- 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

Instructions:

1. After the sterilization procedure is completed, handle and store the probes and cables per your facility's guidelines in packaging and storing sterile products.
2. The wireless probe with battery inside has a two-week shelf life of storage and no use after sterilization.

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 the cable contains polyurethane.

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 of storage that is longer than two weeks, replace the battery and re-sterilize the probe.

(Optional)

Navigator Sterilization Trays

Navigator sterilization custom trays:

- Small Navigator Sterilization Tray. Size: 2.6" (6.6cm) x 12" (30.5cm) – Fits one probe. (Figure 1)
- Large Navigator Sterilization Tray. Size: 6.5" (16.5cm) x 18" (45.7cm) - Fits any probe size and a cable. (Figure 2)

Instructions:

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



Figure 1. Small Navigator Sterilization Tray

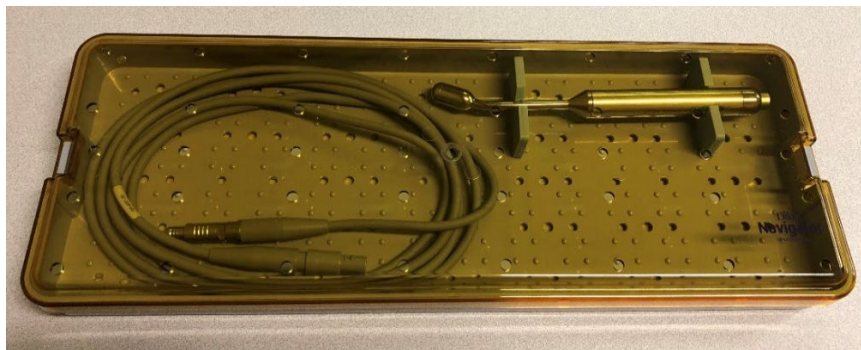


Figure 2. Large Navigator Sterilization Tray

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 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.