SAMPLE PROCEDURE
Determining suitability of the V-PRO Sterilizer for low temperature sterilization of device inventory

Product Referenced:
V-PRO Sterilizers

This document contains a sample procedure for determining the suitability of the V-PRO® Low Temperature Sterilizers for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in Healthcare facilities. The procedures contained in this document are only intended to provide a foundation for developing specific policies and procedures for your facility. It is the responsibility of the health care facility to ensure compliance with applicable laws, regulations, standards, and industry recommended practices. The health care facility should seek expert advice and consultation for guidance with compliance issues. STERIS Corporation makes no representation, express or implied, with respect to this sample procedure’s compliance with local or federal laws, regulations, standards, or industry recommended practices. STERIS Corporation is not responsible for any loss, injury, damage, or claim arising from use of this document or the sample policies and procedures contained herein.

Title: Determining suitability of V-PRO maX 2, V-PRO maX, V-PRO 1 Plus, V-PRO 1 and V-PRO 60 Low Temperature Sterilizers for a device inventory.

Definitions:

Device list: Healthcare facility’s inventory of devices, limited in this case to only those that require low temperature sterilization.

Manufacturer’s written instructions for use (IFU): Written recommendations provided by the manufacturer of a device that provide instructions for operation and safe and effective processing (AAMI ST58:2013 2.38).


Procedure:

Follow the steps outlined below to determine the suitability of V-PRO Sterilizers for a particular medical device. The evaluation may occur either at the time of acquiring the sterilizer, when new medical devices are purchased, or when medical devices are loaned to the healthcare facility.
1. Obtain the device list to be reviewed. This list may be the existing device inventory currently reprocessed in low temperature sterilization, or new devices being added to the inventory. The source of this list may vary by facility, but it is commonly available from the Sterile Processing Department. See sample outline of a device list provided at the end of this sample procedure.

2. Complete analysis of the devices on the device list following one or more of the following methods:
   - Reviewing device Instructions for Use (Step 2.1.)
   - Using the STERIS Device Matrix (Step 2.2.)
   - Using an OEM interactive guide (Step 2.3.)

2.1. **Reviewing device Instructions for Use:**

   2.1.1. Obtain the current Indications for Use for the V-PRO Sterilizer. This information is available via the intranet on the page for each model of the V-PRO Sterilizer at: [https://www.steris.com/products/vaporized-hydrogen-peroxide-sterilizer](https://www.steris.com/products/vaporized-hydrogen-peroxide-sterilizer)

   2.1.2. Collect the current Instructions for Use documentation for each device on the device list (step 1.). If the device is an older model, there may be an updated version of the Instructions for Use available. The device manufacturer is the best resource for the latest Instructions for Use.

   NOTE: Online subscription Instructions for Use libraries may not always have the current version of the Instructions for Use and some device manufacturers do not allow their Instructions for Use to be posted on these sites.

   2.1.3. Review the sterilization recommendations on each Instruction for Use to determine if hydrogen peroxide gas sterilization is recommended. Record on the device list whether or not the device is compatible with hydrogen peroxide gas sterilization. If the Instructions for Use specifically states compatibility with V-PRO Sterilizers, record the sterilizer model and recommended cycle(s) on the device list.

   NOTE: Device manufacturers may have listed a brand of hydrogen peroxide gas sterilization, rather than the generic modality. Examples of hydrogen peroxide gas sterilization brands are STERRAD® and V-PRO Sterilizers.

   2.1.4. If the device has up to 3 lumens for rigid scopes or up to 2 lumens for flexible scopes, locate the length of the working channel for the device and the internal diameter. Record these measurements on the device list.
2.1.5. If the materials of the device are listed, record the materials on the device list. If the Instructions for Use indicates that hydrogen peroxide gas sterilization is a compatible sterilization modality it is not necessary to record the materials.

2.1.6. If the manufacturer’s Instructions for Use does not specifically state compatibility with the V-PRO Sterilizer(s) owned by the facility, compare the device’s information to the cycle claims for the V-PRO Sterilizer.

2.1.6.1. Check for Material Compatibility.

2.1.6.1.1. Does the Instructions for Use state the device is compatible with hydrogen peroxide gas sterilization? If yes, then the materials are compatible.

2.1.6.1.2. If the Instructions for Use does not specify compatibility with hydrogen peroxide gas sterilization, then determine if the device is made of the following compatible materials (if so the device is materially compatible with V-PRO Sterilizers).
**Plastics**
Delrin® (polyoxymethylene, POM) †
EVA (ethylene vinyl acetate)
Kratom Polymers (styrenic block copolymer, SBC)
Neoprene (polychloroprene) †
Noryl (polyphenylene ether and polystyrene)
Nylon (polyamide) †
PMMA (polymethyl methacrylate)
Polycarbonate
PEEK (polyether ether ketone)
Polyethylene
Polypropylene
Polyurethane
PVC (polyvinyl chloride)
Radel® (polyphenylsulfone) †
Santoprene (thermoplastic vulcanizates, TPVs)
Silicone
Teflon® (polytetrafluoroethylene, PTFE)
Ultem® Polymers (polyetherimide, PEI)

**Ceramics and others**
Alumina (Al2O3)
Diamond
Glass
Ruby
Sapphire
Silicon Nitride (Si3N4)
Zirconium Nitride (ZrN)

**Zirconia (ZrO2 with or without Y2O3)**

**Metals**
Aluminum
Brass
Cobalt Chrome
Alloy
Copper ††
Gold
Nitinol
Platinum
Silver
Stainless Steel †††
Titanium †††

**Coatings**
Aluminum Titanium Nitride (AlTiN)
Aluminum Titanium Nitride Chromium Nitride (AlTiN CrN)
Diamond Like Carbon (DLC)
Titanium Nitride (TiN)
Titanium Nitride Titanium Carbonitride (TiN TiCN)
Tungsten carbide (WC)

1. Delrin and Teflon are registered trademarks of the DuPont Corporation.
2. KRATON Polymers is a registered trademark of KRATON Polymers U.S. L.L.C.
3. ULTEM Polymers is a registered trademark of the SABIC Innovative Plastics IP BV.
4. Radel is a registered trademark of Solvay Advanced Polymers LLC.
† May have limited life after repeated sterilization.
†† When used in power or electrical connections.
††† Non Lumen Cycle should NOT be used to sterilize mated surface configurations other than stainless steel and titanium.
2.1.6.1.3. Record on the device list’s “Lumen measurements or materials listed in Instructions for Use” column whether or not the device is materially compatible.

2.1.6.2. Check for Sterilization Claims

2.1.6.2.1. If the device has any lumens or working channels, compare the information recorded in step 2.1.4. to the length and inner diameter specification provided in the indications for use for each V-PRO Sterilizer cycle (step 2.1.1.). The device must fall within the listed lumen claims to be compatible with the cycle.

2.1.6.3. If a device is materially compatible (2.1.6.1.) and within the sterilization lumen claims (2.1.6.2.), then identify which cycle to use and record the identified V-PRO Sterilizer model and cycle on the device list.

2.1.6.3.1. Non Lumen: If the device does not have a lumen or working channel. Devices with a stainless steel or titanium diffusion restricted space such as the hinged portion of forceps and scissors may also be processed.

2.1.6.3.2. Flexible: If the device is a flexible scope AND has a working channel.

2.1.6.3.3. Lumen: If the device has a stainless steel lumen

NOTE: Non Lumen devices may also be processed in the Flexible and Lumen Cycles.

2.2. Reviewing devices based on STERIS Device Matrix:

2.2.1. Log onto the internet and go to the STERIS Device Matrix located at https://www.steris.com/products/devicematrix/.

2.2.2. Individually enter each device model # in the search box, or search by OEM.

2.2.3. Record the appropriate V-PRO Sterilizer and cycles listed in the matrix on the device list.

2.2.4. If a device is not found in the matrix, submit a question to the STERIS Device Testing team via the “Contact Us” section on the STERIS
Device Matrix at [http://www.steris.com/products/devicematrix/](http://www.steris.com/products/devicematrix/) (see picture below). STERIS will follow up to assist in determining if the device is materially compatible and within the claims for V-PRO Sterilizers.

2.3. **Reviewing particular OEM devices based on their interactive guides:**

2.3.1. Go to the OEM’s reprocessing guide, such as Olympus Connect’s Interactive Reprocessing Guide.

2.3.2. Search for each device for that OEM and record the appropriate V-PRO Sterilizer and cycles on the device list.

3. **Using the completed device list:**

3.1. Save the completed device list for the V-PRO Sterilizers with the Instructions for Use or other appropriate location based on the healthcare facility. Information from this device list should be accessible to employees operating the V-PRO Sterilizer.

3.2. If desired, update healthcare facility’s instrument tracking or workflow management system with the V-PRO Sterilizer model and cycles for the device inventory.
<table>
<thead>
<tr>
<th>Device</th>
<th>Model #</th>
<th>Manufacturer</th>
<th>Compatible with hydrogen peroxide gas sterilization?</th>
<th>Lumen measurements or materials listed in Instructions for Use</th>
<th>V-PRO Sterilizer and Cycle</th>
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