Technical Data Monograph

V-PRO® s2
Low Temperature Sterilization System

STERIS®

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1 Introduction

This Technical Data Monograph illustrates the principles of operation and demonstrates the safety and efficacy of the V-PRO s2 Low Temperature Sterilization System. The sterilizer's preprogrammed sterilization cycles operate at low pressure and temperature, suitable for processing medical devices without leaving toxic residues. The summary test data for microbicidal efficacy, material compatibility, and biocompatibility testing performed on the VPRO s2 Sterilization System are included.

The V-PRO s2 Sterilizer is designed to deliver maximum productivity by providing ease of use and maximum flexibility in the sterilization and infection control needs in a healthcare facility through:

- **Innovation**: The V-PRO s2 Sterilizer offers the Fast Cycle, smart cup technology, and an ergonomic hands-free door opening option to help with the fast-paced work environment of today. These features set the sterilizer apart from other sterilizers offered in the market today.
- **Assurance**: The V-PRO s2 Sterilizer has been specifically designed to provide effective and safe sterilization of a wide array of medical device technologies. Utilizing vaporized hydrogen peroxide in a highly controlled and proprietary system, the sterilizer is engineered to be safe on the high technology substrates used in medical devices by using and maintaining hydrogen peroxide concentration below 60%. Additionally, it is not necessary to incorporate additional energy into this unit, such as plasma, to reduce residual hydrogen peroxide because of the unique engineering and software features incorporated into this system.
- **Compliance**: The V-PRO s2 Sterilizer is specifically designed to meet the infection control, operational and quality needs of healthcare providers by maximizing throughput, compatibility and ease of use. By combining the needs of the healthcare provider and those of the medical device manufacturer, the VPRO s2 Sterilizer provides the highest assurance for compliance to standards and validation requirements.

STERIS combines the benefits of the V-PRO s2 Sterilizer with validation testing completed through specific and direct collaboration with medical device manufacturers. While the V-PRO s2 Sterilizer can be used safely and effectively within its claims, collaborative validation between STERIS and the medical device manufacturer provides additional assurance for the healthcare facility and the medical device manufacturer.

Indications for Use

The V-PRO s2 Low Temperature Sterilization System using VAPROX® HC Sterilant is intended for use in the terminal sterilization of properly prepared (cleaned, rinsed and dried) medical devices in Healthcare Facilities. The preprogrammed sterilization cycles operate at low pressure and low temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments and instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors.

The V-PRO s2 Sterilizer Non Lumen Cycle can sterilize:‡

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

‡ The validation studies were conducted using a validation load consisting of one instrument tray for a total weight of 25 lbs (11.3 kg).

The V-PRO s2 Sterilizer Fast Cycle can sterilize:‡

Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

- Single or dual channeled devices with stainless steel lumens that are ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (~16-9/64") in length
- Triple channeled devices with stainless steel lumens that are either:

  ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-53/64") in length
  ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length
  or
  ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

Non-lumened instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes.

‡ Validation testing for all lumen sizes was conducted using a maximum of eight (8) lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. Validation testing was conducted using a validation load consisting of one pouched instrument tray and two pouched devices outside of the tray with a total weight of 4.0 lbs (~1.8kg).

The V-PRO s2 Sterilizer Flexible Cycle can sterilize:@

One surgical flexible endoscope (such as those used in ENT, Urology and Surgical Care) or bronchoscope with light cord (if not integral to endoscope), mat, and additional load.

- The flexible endoscope may be a single or dual lumen device with lumens that are ≥ 1 mm ID and ≤ 990 mm in length.
- Additional load, up to 11 lb (5 kg) can include stainless steel lumens with the following dimensions
  - ≥ 2 mm (~5/64") ID and ≤ 400 mm (~15 3/4") in length
  - ≥ 0.76 mm (~1/32") ID and ≤ 233 mm (~9 11/64") in length
  - ≥ 1.0 mm (~3/64") ID and ≤ 254 mm (~10") in length

@ The validation studies were conducted using a validation load consisting of two instrument trays. One tray contained one flexible endoscope, with silicone mat, instrument organizers and light cord (if not integral to scope), and the second tray contained additional load and twelve (12) stainless steel lumens for a total load weight of 11 lbs (5 kg). Hospital loads should not exceed the maximum number of lumens validated by this testing.

The V-PRO s2 Sterilizer Lumen Cycle can sterilize: ^

Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

- Single or dual channeled devices with stainless steel lumens that are ≥ 0.77 mm (~1/32") internal diameter (ID) and ≤ 410 mm (16-9/64") in length
- Triple channeled devices with stainless steel lumens that are either:

  ≥ 1.2 mm (~3/64") ID and ≤ 275 mm (~10-53/64") in length
  ≥ 1.8 mm (~5/64") ID and ≤ 310 mm (~12-13/64") in length
  or
  ≥ 2.8 mm (~7/64") ID and ≤ 317 mm (12-31/64") in length

^ Validation testing for all lumen sizes was conducted using a maximum of twelve (12) stainless steel lumens per load. Hospital loads should not exceed the maximum number of lumens validated by this testing. The validation studies were performed using a validation load consisting of one instrument tray and two pouches for a total weight of 11 lbs (5.0 kg).

System Features

The principle features of the V-PRO s2 Low Temperature Sterilization System include:

- Large, easy to use touch screen control panel to initiate and monitor the validated sterilization cycles
- Free-standing, compact design
- Proprietary hydrogen peroxide based sterilant with RFID (Radio-frequency Identification) label which is provided in a multi-cycle container
- RFID reader for ease of tracking and documenting sterilant
- Foot sensor for hands-free loading of sterilizer
- Process monitoring and cycle documentation
- Automatic load aeration
- System designed for ease of use and maintenance
- Easy installation – no utilities save electricity required; no special venting required
- Specially designed conditioning phase that aids in removal of residual moisture. All loads should be thoroughly dried before packaging and placing into the sterilizer.

The V-PRO s2 Low Temperature Sterilization System consists of several components. These components include:

- The V-PRO® s2 Sterilizer
- VAPROX® HC Sterilant with RFID label
- Celerity™ 20 HP Biological Indicator
- VERIFY™ V24 Self-Contained Biological Indicator

- Celerity™ 20 HP Biological Indicator Challenge Pack
- VERIFY™ V24 Challenge Pack
- Verdoc™ Vaporized VH202 Record Card with Process Indicator
- V-PRO® and PRO-LITE™ Sterilization Trays, Instrument Organizers, and Silicone Mats
- Vis-U-All™ Low Temperature Sterilization Pouches and Tubing

2 V-PRO s2 Low Temperature Sterilization System: Principle of Operation

The V-PRO s2 Low Temperature Sterilization System uses Vaporized Hydrogen Peroxide or VHP to sterilize medical instruments. Prior to sterilization, cleaned and dried instruments are packaged in wrapped trays or Tyvek sterilization pouches that are specifically designed for use with the V-PRO s2 Sterilizer. The packaged instruments are placed on the sterilizer's two shelves and the sterilizer door is closed. The appropriate sterilization cycle based on load contents is selected to initiate the sterilization process.

The four V-PRO s2 Sterilizer Cycles (Non Lumen Cycle, Fast Cycle, Flexible Cycle and Lumen Cycle) operate similarly with the primary differences being variances in hold times and pressure set points. As noted in the Indications for Use section, each cycle has specific claims with regards to the types of medical devices and amount of load that may be sterilized within the cycle. Uses other than as specified and described in these Indications for Use are not recommended, may not be effective in Sterilization and may not be safe.

Each sterilizer cycle consists of three phases: Condition, Sterilize and Aeration. Figures 1-4 show the set points for the critical cycle parameters

- CONDITION —This cycle phase consists of the reservoir filling and a vacuum pulse to remove air and moisture from the chamber. When setpoint is reached, the load is tested for acceptable moisture content. If content is acceptable, the cycle proceeds (filtered, dry air is introduced to setpoint). If not, the Condition pulse repeats with a timed vacuum pulse. This phase is ordered by the control. Condition phase elements are shown as #s 1, 2 and 3 in Figures 1-4.
- STERILIZE — This cycle phase consists of a series of pulses, two to four depending upon the specific cycle (Table 1). For all sterilant injections, the sterilizer automatically vaporizes the correct amount of liquid hydrogen peroxide from the multiple-cycle VAPROX HC Sterilant cup. Each pulse consists of the following steps: vacuum pulled to setpoint (Pre-Injection Pressure); VAPROX HC Sterilant vapor drawn into chamber; hold for programmed time (Post-Injection Hold); filtered air introduced to setpoint; hold for programmed time (Post-Transition Hold); deep vacuum pulled to setpoint in preparation for the next injection of sterilant. The 1st and 3rd pulses of the Non Lumen, Flexible and Lumen Cycles and the 1st and 2nd pulses of the Fast Cycle, have a prime injection where sterilant is injected while the sterilizer vacuum actively evacuates the chamber. There is no set exposure time for the prime injection. Sterilize phase elements are shown as #s 4 through 8 in Figures 1-4.

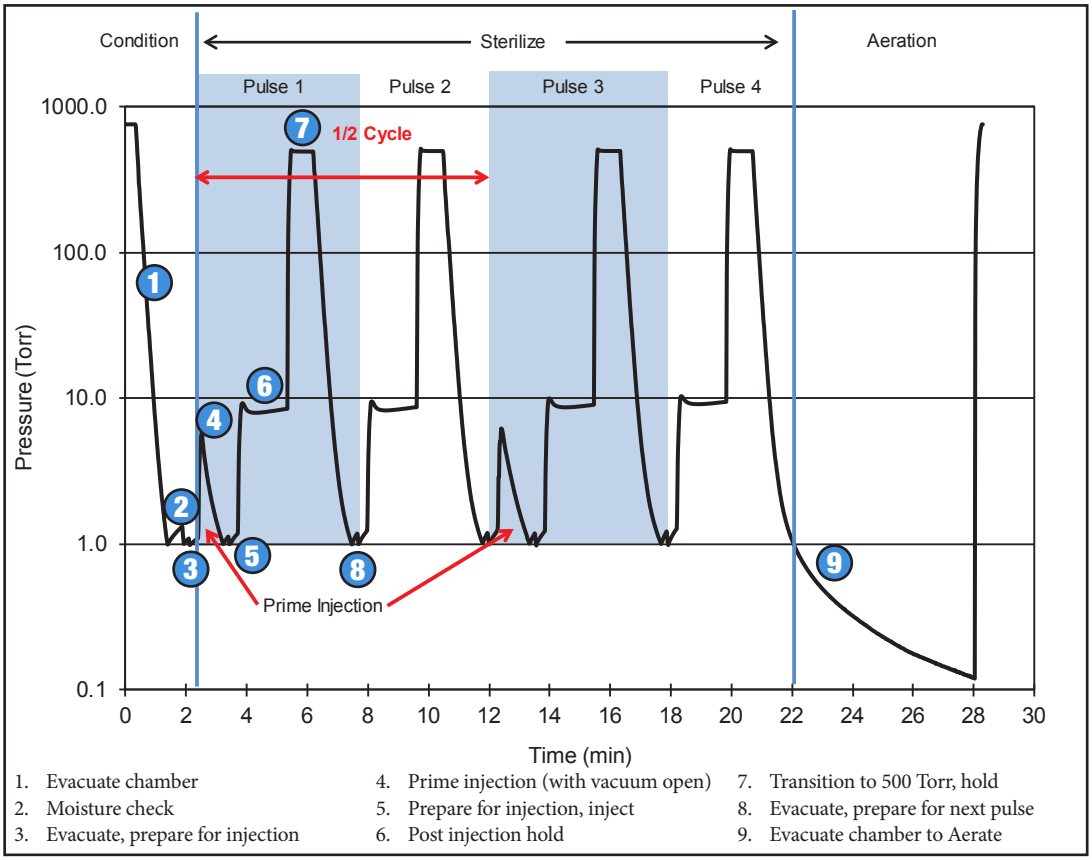
Table 1. Sterilization Phase Cycle Parameters

Sterilize Phase	Cycle			
	Non Lumen	Fast	Flexible	Lumen
Sterilize Pulses	4	2	4	4
Pre-Injection Pressure	1.0 Torr	1.0 Torr	0.4 Torr	0.4 Torr
Post-Injection Hold	1 minute 30 seconds	2 minutes 45 seconds	1 minute 30 seconds	6 minutes
Post-Transition Hold	45 seconds	1 minute	45 seconds	2 minutes

- AERATION — This cycle phase consists of pulling a vacuum to setpoint and continuing to evacuate for the programmed time. This phase is ordered by the control to reduce chamber vapor concentration. The chamber VHP is exhausted through a catalytic converter that decomposes the VHP to water and oxygen. No special venting is required for operation of the V-PRO s2 Sterilizer. Once Aeration phase is complete, chamber pressure is brought to atmospheric level and the chamber door unlocks. Condition phase is shown as #9 in Figures 1-4.

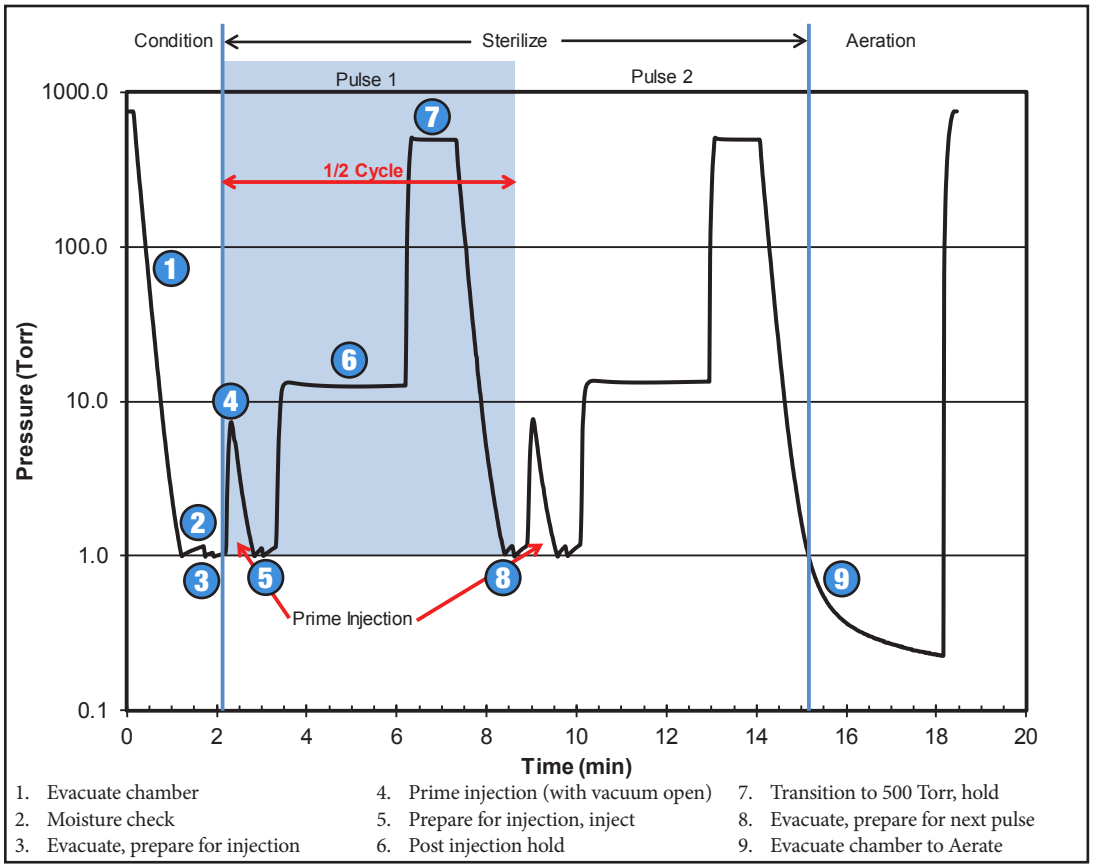
At completion of the sterilization cycle, the load is removed and can be immediately used or stored prior to use.

Figure 1. Pressure Graph of V-PRO s2 Sterilizer Non Lumen Cycle



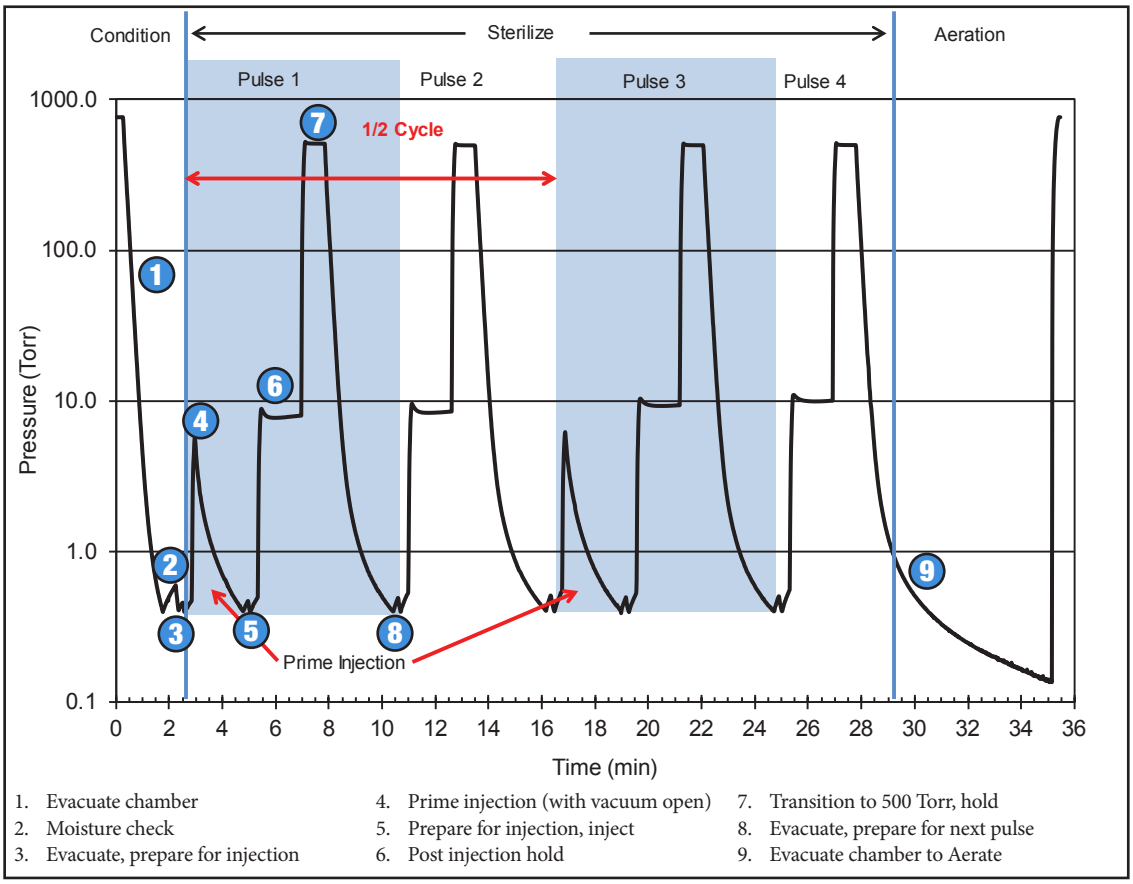
1. Evacuate chamber
2. Moisture check
3. Evacuate, prepare for injection
4. Prime injection (with vacuum open)
5. Prepare for injection, inject
6. Post injection hold
7. Transition to 500 Torr, hold
8. Evacuate, prepare for next pulse
9. Evacuate chamber to Aerate

Figure 2. Pressure Graph of V-PRO s2 Sterilizer Fast Cycle



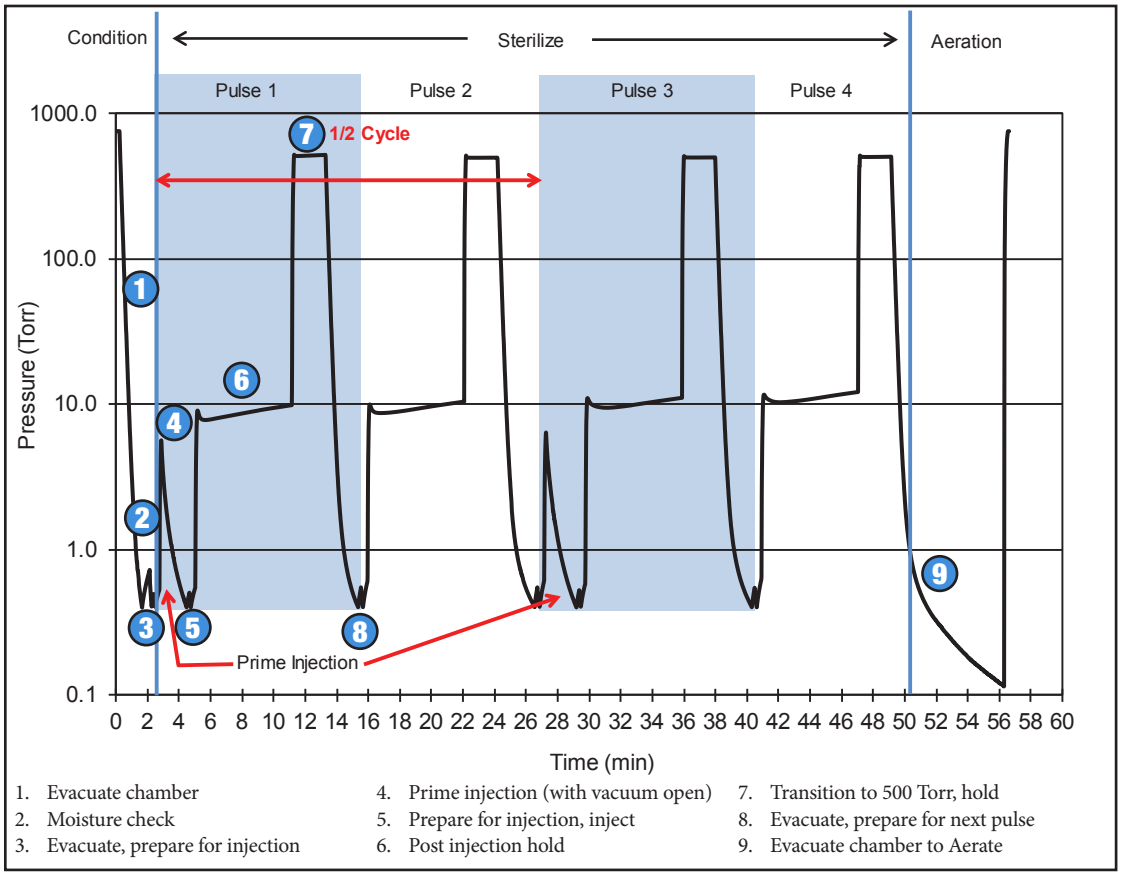
1. Evacuate chamber
2. Moisture check
3. Evacuate, prepare for injection
4. Prime injection (with vacuum open)
5. Prepare for injection, inject
6. Post injection hold
7. Transition to 500 Torr, hold
8. Evacuate, prepare for next pulse
9. Evacuate chamber to Aerate

Figure 3. Pressure Graph of V-PRO s2 Sterilizer Flexible Cycle



1. Evacuate chamber
2. Moisture check
3. Evacuate, prepare for injection
4. Prime injection (with vacuum open)
5. Prepare for injection, inject
6. Post injection hold
7. Transition to 500 Torr, hold
8. Evacuate, prepare for next pulse
9. Evacuate chamber to Aerate

Figure 4. Pressure Graph of V-PRO s2 Sterilizer Lumen Cycle



1. Evacuate chamber
2. Moisture check
3. Evacuate, prepare for injection
4. Prime injection (with vacuum open)
5. Prepare for injection, inject
6. Post injection hold
7. Transition to 500 Torr, hold
8. Evacuate, prepare for next pulse
9. Evacuate chamber to Aerate

3 Consumables

Sterilant

VAPROX HC Sterilant is a proprietary, 59% liquid hydrogen peroxide sterilant that is contained in a multi-cycle cup with RFID label. The sealed cup is placed into the sterilizer's cup interface and the door is closed. The sterilizer confirms that the sterilant cup is within its expiration date prior to automatically opening the sterilant cup. The sterilant cup has been engineered for safe and easy handling.

Sterility Assurance and Sterile Packaging

The Celerity™ and VERIFY® biological and chemical indicator products and STERIS Tyvek Packaging have been designed and validated for use with the V-PRO Low Temperature Sterilization processes. Each product is designed to meet applicable International Standards. Only use products that have been validated for the V-PRO s2 Low Temperature Sterilization System. Failure to do so may result in a non-sterile device.

Equipment Control

Celerity™ and VERIFY® Equipment Control Products monitor the critical performance characteristics of the sterilization process. As part of any Sterility Assurance Program, these products confirm that the equipment used is functioning correctly. Biological indicators such as the VERIFY V24 Self-Contained Biological Indicator offer a fast means of weekly or daily microbial monitoring while test packs such as the VERIFY Biological Indicator Challenge Pack for Vaporized VH2O2 Sterilization Processes provide assurance following installation, relocation or major repair.

Load Control

The V-PRO s2 Low Temperature Sterilization System provides cycle printouts for verification of critical performance parameters. A place is provided for the cycle reviewer's initials or signature.

Biological indicators such as the VERIFY V24 Self-Contained Biological Indicator or Celerity 20 HP Biological Indicator may also be used to monitor and release loads.

Pack Control

Chemical Indicator strips such as the Celerity HP Chemical Indicator confirm that sterilant can penetrate the packs to be sterilized. Each indicator provides the last check prior to use of the device. The indicator strips are designed to fit in sterilization pouches or trays.

Process Control and Record Keeping

A variety of external process indicators, record cards, record envelopes and logs are available for use with the V-PRO s2 Low Temperature Sterilization System. These items are used to prevent the mix up of sterilized items by labeling the packs prior to processing and to ensure complete documentation of sterilization processes.

4 Performance Evaluations

Microbicidal Efficacy Testing

STERIS Corporation conducted tests to validate the microbicidal efficacy of the V-PRO s2 Low Temperature Sterilization System's four sterilization cycles. The following summarizes the test data demonstrating that the V-PRO s2 Sterilizer and VAPROX HC Sterilant are effective.

Sterility Assurance Level (SAL) Testing

A SAL of 10^{-6} was established for the V-PRO s2 Sterilization System by performing ½ cycle testing using inoculated test articles to simulate medical instruments under worst-case sterilization conditions.

Worst Case Test Conditions:

Most Resistant Organism:

STERIS conducted vaporized hydrogen peroxide (VHP) resistance testing under greatly reduced exposure conditions with a variety of organisms (Table 2) and bacterial endospores (Table 3) to identify the most resistant organism to VHP.

Table 2. Microbial Resistance to VHP*

Test Organism	Log of Recovered Population at Exposure Time (min)			
	0	1	2	5
***Geobacillus stearothermophilus* spores, ATCC 7953**	**5.8**	**4.5**	**4.6**	**3.8**
Mycobacterium terrae, ATCC 15755	5.9	5.2	4.2	†
Staphylococcus aureus, ATCC 6538	5.0	4.4	2.1	†
Pseudomonas aeruginosa, ATCC 15442	5.7	3.2	0.8	†
Salmonella choleraesuis, ATCC 10708	5.3	4.4	0.8	†
Aspergillus niger spores, ATCC 6275	5.1	2.6	†	†
Klebsiella pneumoniae, ATCC 4352	4.2	3.2	†	†
Trichophyton mentagrophytes spores, ATCC 18748	5.4	2.9	†	†

* Exposure to 1.8 g/min VHP in a $0.6m^3$ Isolator

† No organism recovered

Table 3. Bacterial Spore D-Values*

Test Organism	D-Value (seconds)
***Geobacillus stearothermophilus* spores, ATCC 7953**	**42.3**
Bacillus subtilis spores, ATCC 19659	18.7
Clostridium sporogenes spores, ATCC 3584	15.6
Bacillus circulans spores, ATCC 4513	14.4
Bacillus cereus spores, ATCC 12826	9.9

* Exposure to 1.8 g/min VHP in a $0.6m^3$ Isolator

Conclusion:

Geobacillus stearothermophilus endospores are the most resistant organism and therefore were used to validate the V-PRO s2 Low Temperature Sterilization System's SAL and microbicidal efficacy.

Sterilizer Load

The SAL microbial tests were conducted in the presence of a validation load designed specifically for each V-PRO s2 Sterilizer cycle to provide a worst-case challenge with respect to chamber load.

The validation load for the Non Lumen Cycle was composed of :

- One validation tray either double-wrapped or double-pouched containing instruments including non-lumened general medical instruments, non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened instruments with diffusion-restricted areas for a total weight of 25 lbs (11.3 kg).

The validation load for the Fast Cycle was composed of:

- One double-pouched validation tray and two medical devices double-pouched separately with eight stainless steel lumens for a total load weight of ≥ 4.0 lbs (~1.8 kg).

The validation load for the Flexible Cycle was composed of:

- Two validation trays either double-wrapped or double-pouched with a total load weight of ≥ 11.0 lbs (5.0 kg).
- The two validation trays contained the flexible endoscope load and the mixed device load with twelve stainless steel lumens.

The validation load for the Lumen Cycle was composed of:

- One wrapped validation tray with twelve stainless steel lumens and two double-pouched devices with a total weight of ≥ 11 lbs (5.0 kg).

V-PRO s2 Sterilizer ½ Cycle

For the SAL studies, ½ Cycle evaluation was conducted. For the Non Lumen, Lumen, and Flexible Cycles, the ½ Cycle consisted of a moisture check/conditioning phase, 2 sterilization pulses, and an aeration phase (see Figures 1-4). This exposes the test articles to ½ the amount of vaporized hydrogen peroxide (2 sterilization pulses vs. 4 for a full cycle) for ½ of the total sterilant exposure time. For the Fast Cycle, the ½ Cycle consisted of a moisture check/conditioning phase, 1 sterilization pulse, and an aeration phase. As described for the Non Lumen, Lumen, and Flexible Cycles, reducing the sterilization pulses exposes the test articles to ½ the amount of vaporized hydrogen peroxide for ½ of the total sterilant exposure time.

Medical instrument worst-case material coupons (Table 4 and 6), mated configuration medical instrument coupons (Table 5), stainless steel lumens (Table 6 and 7), or Teflon lumens (Table 7) were challenged with 10^6 *Geobacillus stearothermophilus* spores and dried. The test articles were placed within the validation load and exposed to a V-PRO s2 Sterilizer Non Lumen ½ Cycle, Fast ½ Cycle, Flexible ½ Cycle or Lumen ½ Cycle. After exposure, the test articles were cultured and the number sterile versus number tested determined. All medical instrument materials, mated configuration materials and lumens were sterile after exposure to a V-PRO s2 Sterilizer ½ Cycle (Tables 4-8).

Table 4. V-PRO s2 Sterilizer Non Lumen ½ Cycle Microbicidal Efficacy Evaluation: Worst-Case Medical Instrument Materials

Trial	# Sterile/# Tested	
	Double Wrapped Tray	Double Tyvek Pouch
1	3/3	3/3
2	3/3	3/3
3	3/3	3/3

Table 5. V-PRO s2 Sterilizer Fast ½ Cycle Microbicidal Efficacy Evaluation: Mated Instrument Materials

Material	Coupon Pairs Sterile/Pairs Tested*	
	Non Lumen Cycle	Fast Cycle
PEEK	3/3	3/3
Delrin	3/3	3/3
Ultem	3/3	3/3
Radel	3/3	3/3
Noryl	3/3	3/3

* Tests conducted in Non Lumen and Fast Cycles qualifies sterilization in the Flexible and Lumen Cycles.

Table 6. V-PRO s2 Sterilizer Fast ½ Cycle Microbicidal Efficacy Evaluation: Stainless Steel Lumens and Worst-Case Medical Instrument Material

Lumen Size (ID x Length mm)	# Sterile/# Tested
0.77 x 410	3/3
2.8 x 317	3/3
1.2 x 275	3/3
1.8 x 310	3/3
Worst-Case Material Coupons	9/9

Table 7. V-PRO s2 Sterilizer Flexible ½ Cycle Microbicidal Efficacy Evaluation: Flexible Endoscope and 11 lb. Mixed Load

Lumen Size (ID x Length mm)	Lumen Material	# Lumens Sterile/# Tested
1.0 x 1000	Teflon	9/9
2.0 x 400	Stainless Steel	3/3
0.76 x 233	Stainless Steel	3/3
1.0 x 254	Stainless Steel	3/3

Table 8. V-PRO s2 Sterilizer Lumen ½ Cycle Microbicidal Efficacy Evaluation: Stainless Steel Lumens

Lumen Configuration	Lumen Size (ID x Length mm)	# Sterile/# Tested					
		Wrapped Tray			Double Tyvek Pouch		
		Trial 1	Trial 2	Trial 3	Trial 1	Trial 2	Trial 3
Dual	0.77 x 410	3/3	3/3	3/3	1/1	1/1	1/1
	1.1 x 410	3/3	3/3	3/3	**		
Triple	1.2 x 275	2/2	2/2	2/2	1/1	1/1	1/1
	1.8 x 310	1/1	1/1	1/1	1/1	1/1	1/1
Triple	(2x1.5)* x 285	1/1	1/1	1/1	**		
	1.8 x 300	1/1	1/1	1/1			
	2.8 x 317	1/1	1/1	1/1	1/1	1/1	1/1

* Crescent shaped lumen
** Not evaluated

Conclusion:
All of the medical instrument materials, mated device materials and lumens challenged with 10^6 *Geobacillus stearothermophilus* spores were sterile after exposure to a V-PRO s2 Sterilizer Non Lumen ½ Cycle, Fast ½ Cycle, Flexible ½ Cycle and Lumen ½ Cycle, as applicable, thereby establishing an SAL of 10^{-6} for the V-PRO s2 Low Temperature Sterilization System.

Modified Total End Point Kill (VHP Dose Evaluation)

Testing was performed to demonstrate ½ Cycle efficacy and a modified total kill endpoint for the V-PRO s2 Sterilizer cycles under worst-case sterilization conditions. The test is termed *modified* total kill endpoint because the parameter varied is the concentration of vaporized hydrogen peroxide (amount of sterilant injected) rather than the traditional method of varying exposure time. The standard VAPROX HC Sterilant injection weight and reduced injection weights of sterilant were evaluated. The number of sterile test articles versus number tested at each concentration was determined.

The V-PRO s2 Sterilizer Non Lumen Cycle evaluation was conducted with the worst-case challenge material to VHP sterilization. The inoculated and dried worst-case challenge material coupon test articles were placed within the ≥25 lb validation load under ½ Cycle conditions. All worst-case material coupons were sterile at the normal sterilant concentration of 10.3 mg/L VHP as well as at the lower concentration of 5.9 mg/L VHP (Table 9).

Table 9. V-PRO s2 Sterilizer Non Lumen ½ Cycle VHP Dose Evaluation

VHP Concentration* (mg/L)	# Sterile Coupons /# Tested
1.4	0/9
2.8	7/9
5.9	9/9
10.3	9/9

* Calculated Chamber Concentration

For the V-PRO s2 Sterilizer Fast Cycle, stainless steel lumens (from Table 6) were evaluated as part of a ≥4 lb validation load under ½ Cycle conditions. All lumens were sterile at the normal sterilant concentration of 10.3 mg/L VHP as well as at the lower concentration of 5.9 mg/LVHP (Table 10).

Table 10. V-PRO s2 Sterilizer Fast ½ Cycle VHP Dose Evaluation

VHP Concentration* (mg/L)	# Sterile Coupons /# Tested
1.4	0/12
2.8	3/12
5.9	12/12
10.3	12/12

* Calculated Chamber Concentration

The V-PRO s2 Sterilizer Flexible Cycle was evaluated using inoculated test articles identified in Table 7. Testing was conducted within a ≥ 11 lb validation load containing a flexible endoscope and stainless steel lumens under ½ Cycle conditions. All lumens were sterile at the normal sterilant concentration of 10.3 mg/L VHP as well as at the lower concentration of 5.9 mg/L VHP (Table 11).

Table 11. V-PRO s2 Sterilizer Flexible ½ Cycle VHP Dose Evaluation

VHP Concentration* (mg/L)	Test Article	# Sterile Lumens/# Tested
0.6	Teflon lumens	0/9
	Stainless steel lumens	0/9
2.8	Teflon lumens	8/9
	Stainless steel lumens	4/9
5.9	Teflon lumens	9/9
	Stainless steel lumens	9/9
10.3	Teflon lumens	9/9
	Stainless steel lumens	9/9

* Calculated Chamber Concentration

The V-PRO s2 Sterilizer Lumen Cycle was evaluated using the inoculated stainless steel lumen test articles described in Table 8 within a ≥11 lb validation under ½ Cycle conditions. All lumens were sterile at the normal sterilant concentration of 10.3 mg/L VHP as well as at the lower concentrations of 5.9 mg/L (Table 12).

Table 12. V-PRO s2 Sterilizer Lumen ½ Cycle VHP Dose Evaluation

VHP Concentration* (mg/L)	# Sterile Lumens /# Tested
0.6	3/36
2.8	34/36
5.9	36/36
10.3	36/36

* Calculated Chamber Concentration

Conclusion:
The V-PRO s2 Sterilizer Non Lumen, Fast, Flexible and Lumen Cycles effectively kill 10^6 *G. stearothermophilus* spores, the most resistant organism to VHP, in a ½ Cycle evaluation at concentrations below the normal minimum injected concentration of 10.3 mg/L VHP.

AOAC Sporicidal Test Evaluation

AOAC sporicidal carrier testing was performed *in situ* to demonstrate the sporicidal efficacy of the V-PRO s2 Low Temperature Sterilization System. The test uses two types of test organisms (spores of *Clostridium* and *Bacillus*), in the presence of test soil, on two different porous surface carrier types (penicylinders and sutures). Testing was performed as defined in the Official Methods of Analysis of the AOAC International Association of Official Analytical Chemists, 2013, AOAC Official Method 966.04, "Sporicidal Activity of Disinfectants". It is required that a combination of at least 720 carriers are tested and all are required to demonstrate the absence of growth following exposure and incubation. Data is shown for the Non Lumen Cycle (Table 13); however, AOAC sporicidal efficacy has been established for all sterilization cycles of the V-PRO s2 Sterilizer: Fast, Flexible and Lumen Cycles.

Table 13. V-PRO s2 Sterilizer Non Lumen Cycle AOAC Sporicidal Carrier Evaluation

Carrier	#Sterile/#Tested			
	21 Days		≥ 24 Days (post heat-shock)	
	1° Tube	2° Tube	1° Tube	2° Tube
Bacillus subtilis penicylinder	180/180	180/180	180/180	180/180
Bacillus subtilis suture loop	180/180	180/180	180/180	180/180
Clostridium sporogenes penicylinder	180/180	180/180	180/180	180/180
Clostridium sporogenes suture loop	180/180	180/180	180/180	180/180
Total	**720/720**	**720/720**	**720/720**	**720/720**

Conclusion:
The V-PRO s2 Low Temperature Sterilization System effectively kills bacterial endospores when evaluated by the AOAC carrier method. VAPROX HC Sterilant is sporicidal.

Medical Instrument Testing

STERIS Corporation conducted tests to validate the V-PRO s2 Low Temperature Sterilization System's ability to sterilize medical instruments. The following summarizes the test data demonstrating that the V-PRO s2 Sterilizer and VAPROX HC Sterilant are effective under simulated worst-case use and clinical use conditions.

- Simulated Use Evaluation

  Worst-case medical instruments with regard to size and features that are challenging to sterilize, were inoculated with 10^6 *G. stearothermophilus* spores with 5% fetal bovine serum and 300 ppm AOAC hard water. Lumened devices were inoculated at the center of the device lumen. The inoculated and dried medical instruments were processed through V-PRO s2 Sterilizer Non Lumen, Fast, Flexible or Lumen Cycle with each cycle's validation load. After exposure, the medical instrument sites were sampled and evaluated for growth of the test organism. The number of sterile devices tested versus the number of devices tested was determined (Tables 14, 15, and 16). All devices were sterile under worst-case simulated use conditions.

Table 14. V-PRO s2 Sterilizer Non Lumen and Fast Cycle Simulated Use Evaluation

Medical Instrument	Inoculation Site	Non Lumen Cycle #Sterile/#Tested	Fast Cycle #Sterile/#Tested
Cavity Clip	Surface	3/3	3/3
Surgical Scissors	Hinge (Mated Surface)	3/3	3/3
Ureteroscope	0.77mm ID x 410 mm length lumen	*	3/3

* Stainless steel lumen device evaluation was not performed for Non Lumen Cycle

Table 15. V-PRO s2 Sterilizer Flexible Cycle Simulated Use Evaluation

Medical Instrument	Lumen Type and Size (ID x Length mm)	# Sterile / # Tested
Dual Channel Ureterorenoscope	Teflon: 1.0 x 990 & 1.0 x 850	3/3 3/3
Dual Channel Cystoureteroscope	Stainless Steel: 0.76 x 233 & 1.0 x 254	3/3 3/3
Needle	Stainless Steel: 2.0 x 400	3/3

Table 16. V-PRO s2 Sterilizer Lumen Cycle Simulated Use Evaluation

Medical Instrument	Lumen Size (ID x Length mm)	# Sterile / # Tested
Dual Channel Ureteroscope	0.77 x 410	3/3
Hysteroscope (triple channel)	1.2 x 275	3/3
	1.8 x 310	3/3
Sheath (triple channel)	2.8 x 317	3/3

Conclusion:
The V-PRO s2 Low Temperature Sterilization System utilizing VAPROX HC Sterilant reproducibly sterilizes worst-case medical instruments challenged with high levels of the most resistant organism to VHP, *G. stearothermophilus* spores, in the presence of organic and inorganic challenge.

- Clinical Use Evaluation

  The V-PRO s2 Low Temperature Sterilization System sterilization cycles were evaluated in a clinical setting with medical instruments that had been used in clinical procedures. The instruments were cleaned, dried, packaged and exposed to either the Non Lumen, Fast, Flexible or Lumen Cycle. After exposure, selected medical instrument sites (surface sites or device lumens) were sampled and evaluated for growth of organisms. The number of sterile instrument sites versus the number of instrument sites tested was determined. All instruments were sterile under clinical use conditions (Tables 17, 18, 19, and 20).

Table 17. V-PRO s2 Sterilizer Non Lumen Cycle Clinical Use Evaluation

Medical Instrument	Selected Site	# Sterile / # Tested
Surgical Scissors	Hinge	3/3
Tourniquet	Surface	3/3
Syringe	Surface	3/3
Non-Lumened Flexible Endoscope	Insertion Tube	3/3

Table 18. V-PRO s2 Sterilizer Fast Cycle Clinical Use Evaluation

Medical Instrument	Selected Site	# Sterile / # Tested
Syringe	Surface	3/3
Surgical Scissors	Hinge	3/3
Dual Channel Ureteroscope	0.77 mm ID x 410 mm length lumen 1.1 mm ID x 410 mm length lumen	3/3

Table 19. V-PRO s2 Sterilizer Flexible Cycle Clinical Use Evaluation

Medical Instrument	Lumen Size (ID x Length mm)	# Sterile / # Tested
Cystoureteroscope	Stainless Steel: 0.76 x 233 Stainless Steel: 1.0 x 254	3/3 3/3
Ureteroscope	Stainless Steel: 1.8 x 408	3/3
Flexible Dual Channel Ureterorenoscope	Teflon: 1 x 990 Teflon: 1 x 850	3/3 3/3

Table 20. V-PRO s2 Sterilizer Lumen Cycle Clinical Use Evaluation

Medical Instrument	Lumen Size (ID x Length mm)	# Sterile / # Tested
Dual Channel Ureteroscope	0.77 x 410 1.1 x 410	3/3 3/3
Triple Channel Hysteroscope or Sheath	1.2 x 275 1.2 x 275 1.8 x 310 or 1.8 x 300 2.8 x 317 2.0 x 1.5* x 285	3/3 3/3 3/3 3/3 3/3 3/3

* Crescent shaped lumen

Conclusion:
The V-PRO s2 Sterilizer Non Lumen, Fast, Flexible and Lumen Cycles utilizing VAPROX HC Sterilant reproducibly sterilize clinically used medical instruments.

Overall Conclusions of Microbicidal Efficacy Evaluations

STERIS Corporation has validated the microbicidal efficacy of the V-PRO s2 Low Temperature Sterilization System:

- VHP (vaporized hydrogen peroxide) or hydrogen peroxide gas is a well-recognized antimicrobial with efficacy shown against viruses, bacteria, fungi (molds and yeasts), protozoa and bacterial spores. Bacterial spores, and in particular *Geobacillus stearothermophilus* spores, are known to be the most resistant organisms to VHP.
- A SAL of 10^{-6} has been established through ½ Cycle testing and modified total end point kill analysis, in accordance with ISO EN 14937.
- The system passed the AOAC Sporicidal Test, considered to be the most challenging sporicidal efficacy test internationally.
- Simulated and Clinical use testing has shown that instruments are sterile when processed in the V-PRO s2 Sterilizer utilizing VAPROX HC Sterilant.

5 Materials Compatibility

The V-PRO s2 Sterilizer process is compatible with a wide range of medical instruments and materials. STERIS Corporation performed medical instrument materials compatibility evaluations to ensure that the V-PRO s2 Low Temperature Sterilization System is safe for medical instruments. Representative medical instruments composed of a variety of materials were subjected to fifty (50) V-PRO s2 Low Temperature Sterilization Lumen Cycles (worst-case, longest sterilant exposure) with functional evaluations performed before and after the tests. Table 21 lists the materials and type of instruments evaluated for material compatibility.

Table 21. Material Compatibility

Materials	Instrument Evaluated	Cosmetic Change	Functionality
PLASTICS			
Delrin	Defibrillator	None	Pass
EVA	Slide for Cannula Tubing	Slight yellowing	Pass
Kraton	Pediatric Tuohy Borst Adapter	None	Pass
Neoprene	Neoprene Rubber Tubing	None	Pass
Noryl	STERIS V-PRO Sterilization Tray	None	Pass
Nylon	Resectoscope Sheath ID ring	Fading	Pass
PMMA	Contact	None	Pass
Polycarbonate	Nebulizer	None	Pass
PEEK	Endoscope	None	Pass
Polyethylene	Piston Syringe with Thumb Control Ring	None	Pass
Polypropylene	STERIS V-PRO Sterilization Tray	None	Pass
Polystyrene	Non-vented Luer Dispenser Tip Cap	None	Pass
Polyurethane	Flexible Endoscope	None	Pass
PVC	Nebulizer	None	Pass
Radel	Adapter for STERIS SYSTEM 1	None	Pass
Santoprene	Mouthpiece	None	Pass
Silicone	High Frequency Cord	None	Pass
Teflon (PTFE)	Resectoscope Working Element	None	Pass
Ultem	Instrument Tray	None	Pass
METALS			
Aluminum	Wide Field Vitrectomy Lens	Loss of black color	Pass
Brass	Bridge Adapter	None	Pass
Cobalt Chromium	Rod	None	Pass
Copper	Tongue Scraper	Color change	Pass
Gold	Forceps	None	Pass
Nitinol	Vascular Dilator	None	Pass
Platinum	Kimura Spatula	None	Pass
Silver	Garrett Vascular Dilator	None	Pass
Stainless Steel	Telescope	None	Pass
	Forceps		
Titanium	Knife	Fading	Pass

Table 21. Material Compatibility (continued)

Materials	Instrument Evaluated	Cosmetic Change	Functionality
CERAMICS AND OTHERS			
Alumina	Surgical Knife Blade	None	Pass
Diamond	Knife	None	Pass
Glass	Telescope	None	Pass
Sapphire/Ruby	Knife	None	Pass
Silicon Nitride	Surgical Blade	None	Pass
Zirconium Nitride	Forceps	None	Pass
Zirconium Oxide with Yttrium Oxide	Surgical Knife Blade	None	Pass
COATINGS			
Aluminum Titanium Nitride	Forceps	None	Pass
Aluminum Titanium Nitride/ Chromium Nitride	Forceps	None	Pass
Diamond Like Coating	Forceps	None	Pass
Titanium Nitride	Forceps	None	Pass
Titanium Nitride/Titanium Carbonitride	Forceps	None	Pass
Tungsten Carbide	Forceps	None	Pass

* See Operator Manual for specific information on compatible materials. Some grades of Nylon, Delrin, and Radel devices may have limited life after repeated sterilization.

Conclusion:
Exposure to numerous cycles in the V-PRO s2 Sterilizer does not significantly affect the appearance or functionality of most medical instruments.

6 Safety

The toxicology of hydrogen peroxide (H_20_2) is well understood in the scientific literature. A thorough risk assessment of hydrogen peroxide was completed in 2003 by the European Union. The by-products from hydrogen peroxide sterilization, formed upon decomposition are water (H_2O) and oxygen gas (O_2).

$$2\ H_2O_2 \longrightarrow 2\ H_2O + O_2$$

These by-products do not present toxicity concerns to the user. There are three conditions under which the V-PRO s2 Sterilizer user or patients could potentially be exposed to hydrogen peroxide. Safeguards are in place to prevent these potential exposures.

Exposure to Liquid Hydrogen Peroxide

Under normal conditions of use, the sterilizer operator is not exposed to the contents of the VAPROX HC Sterilant cup (59% hydrogen peroxide). The liquid hydrogen peroxide used for gaseous hydrogen peroxide sterilization is packaged within a sealed cup to minimize interaction of the user with the sterilant liquid. The user cannot access the sterilant without physically damaging the cup. A Safety Data Sheet (SDS) is provided to advise the user on safe handling practices.

Exposure to Hydrogen Peroxide Vapors

The user places a sealed, vented sterilant cup into the sterilizer. The sterilizer automatically dispenses and injects hydrogen peroxide into the low pressure chamber. At the end of each sterilization pulse, hydrogen peroxide vapor is removed from the chamber through

a catalytic converter which converts the hydrogen peroxide into water and oxygen. To confirm this, the environment around the sterilizer was monitored under worst-case simulated use conditions for acceptable VHP levels during typical sterilization cycle conditions. In a reduced ventilation requirement (less than 10 air exchanges per hour), the hydrogen peroxide level at the user breathing zone was >20 times lower than the OSHA hydrogen peroxide gas Time Weighted Average (TWA) limit of 1 ppm..

Exposure to Hydrogen Peroxide on Medical Instruments or Packaging

Biocompatibility testing was conducted for commonly used medical device materials after sterilization in the V-PRO s2 Sterilizer to verify effective removal of residuals. As part of the testing, cytotoxicity screening evaluations were conducted. Cytotoxicity is an extremely sensitive methodology that can identify a material as causing a positive cytotoxic response even though that material has an established history of safe clinical use. Therefore, the results obtained after processing in the V-PRO s2 Sterilizer were compared to those obtained using a similar technology that has been in clinical use for over fifteen years. In addition to cytotoxicity evaluations, ocular irritation, acute systemic toxicology, intracutaneous irritation and blood compatibility evaluations were performed. The results from these tests demonstrate that items processed in the V-PRO s2 Sterilization System do not have their innate biocompatible characteristics altered or compromised.

In accordance with ISO EN 10993-17 *Biological evaluation of medical devices- Part 17: Establishment of allowable limits for leachable substances*, a risk analysis was conducted, and safe levels of residual hydrogen peroxide were established. A risk assessment completed by the European Commission (2003) was used as the primary source document for this assessment. The V-PRO s2 Sterilization System was shown to reduce the levels of residues on representative medical devices (the same devices as used for the cytotoxicity evaluation) and common packaging materials to well below the established residue limits (11 to >65 fold lower than the allowable residue limit for internal tissue contact and > 100 fold lower than the allowable residue limit for dermal contact established in accordance with ISO 10993-17) proving that the V-PRO s2 Sterilizer effectively eliminates toxic process residuals.

Conclusion:
The sterilization process of the V-PRO s2 Sterilizer is safe for the environment, safe for the patient, and safe for the user.

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