DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190103

Device Name
V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems

Indications for Use *(Describe)*
The V-PRO 1, V-PRO 1 Plus and V-PRO maX Low Temperature Sterilization Systems using VAPROX HC Sterilant are 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 temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle.

The V-PRO 1 Plus and V-PRO maX Sterilizers' 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 two instrument trays for a total weight of 50 lbs (22.7 kg).

The V-PRO maX Sterilizer's Flexible Cycle can sterilize:
Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:
1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either:
• A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length
• Or two lumens with:
- One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
  - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).
And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length.
†† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).
2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. †† The flexible endoscope may contain either:
• A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
• Or two lumens with:
One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
- And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length.
†† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).

The V-PRO 1, V-PRO 1 Plus and V-PRO maX Sterilizers' Lumen Cycle can sterilize:
†Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:
• Single channeled devices with a stainless lumen that is ≥ 0.77 mm ID and ≤ 500 mm in length

• Single channeled devices with a stainless lumen that is ≥ 1.8 mm ID and ≤ 542 mm in length
• Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
• Triple channeled devices with stainless lumens that are either
≥ 1.2 mm ID and ≤ 275 mm in length
≥ 1.8 mm ID and ≤ 310 mm in length or
≥ 2.8 mm ID and ≤ 317 mm in length

† Validation testing for all lumen sizes was conducted using a maximum of 20 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 two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

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510(k) Number *(if known)*
K190103

Device Name
V-PRO maX 2 Low Temperature Sterilization Systems

Indications for Use *(Describe)*
The V-PRO maX 2 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 temperature, suitable for processing medical devices without leaving toxic residues.

Each Cycle can sterilize non-lumened instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors. Only stainless steel or titanium diffusion-restricted spaces should be processed in the Non Lumen Cycle and Fast Non Lumen Cycle.

The 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 two instrument trays for a total weight of 50 lbs (22.7 kg).

The Fast 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 pouched instrument tray for a total weight of 11 lbs (5 kg).

The Flexible Cycle can sterilize:
Single or dual lumen surgical flexible endoscopes (such as those used in ENT, Urology and Surgical Care) and bronchoscopes in either of the two configurations:

1. Two flexible endoscopes with a light cord (if not integral to endoscope) and mat with no additional load.* The flexible endoscopes may contain either:
• A single lumen that is ≥ 1 mm internal diameter (ID) and ≤ 1050 mm in length
• Or two lumens with:
  - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
  - And the other lumen that is ≥ 1 mm ID and ≤ 850 mm in length
* The validation studies were conducted with two flexible endoscopes, each packaged into a tray with silicone mat and light cord (if not integral to endoscope).

2. One flexible endoscope with a light cord (if not integral to endoscope) and mat and additional non-lumened instruments. †† The flexible endoscope may contain either:
• A single lumen that is ≥ 1 mm ID and ≤ 1050 mm in length
• Or two lumens with:
  - One lumen that is ≥ 1 mm ID and ≤ 990 mm in length
  - And the other lumen is ≥ 1 mm ID and ≤ 850 mm in length.
†† The validation studies were conducted with a flexible endoscope in a tray with silicone mat and light cord (if not integral to endoscope). Also included in the load were an additional instrument tray and one pouch for a total weight of 24 lbs (11 kg).

The Lumen Cycle can sterilize:
†Medical devices (including single, dual and triple channeled rigid and semi-rigid endoscopes) with the following configurations:

- Single channeled devices with a stainless lumen that is ≥ 0.77 mm ID and ≤ 500 mm in length
- Single channeled devices with a stainless lumen that is ≥ 1.8 mm ID and ≤ 542 mm in length
- Dual channeled devices with stainless lumens that are ≥ 0.77 mm ID and ≤ 527 mm in length
- Triple channeled devices with stainless lumens that are either:
  ≥ 1.2 mm ID and ≤ 275 mm in length
  ≥ 1.8 mm ID and ≤ 310 mm in length
  or
  ≥ 2.8 mm ID and ≤ 317 mm in length

† Validation testing for all lumen sizes was conducted using a maximum of 20 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 two instrument trays and two pouches for a total weight of 19.65 lbs (8.9 kg).

Type of Use *(Select one or both, as applicable)*

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