Non Lumen Cycle
- Non-lumened rigid and semi-rigid endoscopes
- Non-lumened flexible endoscopes
- Stainless steel or Titanium diffusion-restricted spaces

Lumen Cycle
- Single or Dual Stainless Steel Lumen Devices
  - ≥ 0.77 mm internal diameter (ID) and ≤ 410 mm in length (L)
- Triple Stainless Steel Lumen Devices
  - ≥ 1.2 mm ID and ≤ 275 mm L
  - ≥ 1.8 mm ID and ≤ 310 mm L
  - ≥ 2.8 mm ID and ≤ 317 mm L

Flexible Cycle
- Single or Dual Lumen Devices
  - ≥ 1 mm ID and ≤ 390 mm L
- Polyethylene (PE)/PTFE (Teflon®) Tubing*
  - ≥ 1 mm ID and ≤ 4,000 mm L

Examples of Representative Devices
Refer to the complete Indications for Use and validation loads on the reverse side.

INSIDE LUMEN DIAMETERS
- 0.77 mm 0.030 inches 2.3 French
- 1.0 mm 0.039 inches 3.0 French
- 2.0 mm 0.078 inches 6.0 French
- 3.0 mm 0.118 inches 9.0 French
- 4.0 mm 0.157 inches 12.0 French

LUMEN LENGTHS
- 0 mm
- 50 mm
- 100 mm
- 150 mm
- 275 mm
- 310 mm
- 317 mm
- 410 mm

Pictorial representation of device measurements are approximate and for reference only.

*Tubing claims have not been reviewed by the Food and Drug Administration
The V-PRO 60 Low Temperature Sterilization System, with VAPROX® HC Sterilant, is a vaporized hydrogen peroxide sterilizer intended for use in the terminal sterilization of cleaned, rinsed and dried reusable metal and nonmetal medical devices used in Healthcare facilities. The pre-programmed sterilization cycles (Lumen Cycle, Non Lumen Cycle, and Flexible Cycle) operate at low pressure and low temperature and are thus suitable for processing medical devices sensitive to heat and moisture.

<table>
<thead>
<tr>
<th>Sterilizer Cycle</th>
<th>Indications for Use</th>
<th>Total Load</th>
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| **Lumen Cycle**  | - Instruments with diffusion-restricted spaces such as the hinged portion of forceps and scissors  
- Non-lumened devices including non-lumened rigid and semi-rigid endoscopes  
- Medical devices, including single, dual and triple channeled rigid and semi-rigid endoscopes, with the following configurations:
  1. Single or dual lumen devices with stainless steel lumens that are $\geq 0.77$ mm ($\sim 1/32"$) internal diameter (ID) and $\leq 410$ mm ($16-9/64"$) in length  
  2. Triple lumen devices with stainless steel lumens that are:
     - $\geq 1.2$ mm ($\sim 3/64"$) ID and $\leq 275$ mm ($\sim 10-55/64"$) in length  
     - $\geq 1.8$ mm ($\sim 5/64"$) ID and $\leq 310$ mm ($\sim 12-13/64"$) in length  
     - $\geq 2.8$ mm ($\sim 7/64"$) ID and $\leq 317$ mm ($12-31/64"$) in length | 11 lbs (5.0 kgs) and 12 Lumens |
| **Non Lumen Cycle** | - Non-lumened devices including non-lumened rigid, semi-rigid and flexible endoscopes and non-lumened devices with stainless steel or titanium diffusion-restricted spaces such as the hinged portion of forceps and scissors. | 12 lbs (5.4 kgs) |
| **Flexible Cycle** | - One flexible surgical endoscope or bronchoscope with a light cord (if not integral to endoscope) and mat without any additional load. The flexible endoscope may be a:
  - Single or dual lumen device with lumens that are $> 1$ mm ($\sim 3/64"$) ID and $< 990$ mm ($38-63/64"$) in length | NA |

a The validation studies for all lumen configurations were conducted using a maximum of twelve (12) 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 with instrument organizers and mat and two pouches for a total weight of 11 lbs (5.0 kg).

b The validation studies were performed using a validation load consisting of one instrument tray with instrument organizers and mat and one pouch for a total weight of 12 lbs (5.4 kg).

c The validation studies were conducted with one flexible endoscope, packaged into a tray with silicone mat, instrument organizers and light cord (if not integral to scope) and no additional load.

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