

STERIZONE® VP4 STERILIZER

INDICATIONS FOR USE

The STERIZONE VP4 Sterilizer is intended for use in terminal sterilization of cleaned, rinsed, and dried metal and non-metal reusable medical devices in health care facilities.

The single pre-set cycle of the STERIZONE VP4 Sterilizer uses hydrogen peroxide and ozone. The injection of vaporized hydrogen peroxide is followed by the injection of ozone, which reacts with residual hydrogen peroxide to form hydroxyl radicals.

Sterilization efficacy was demonstrated using a representative sample of one or more device types and packaging, in nine separate validation loads, as described in **Table 1**. The load to be processed should be maintained between 20°C to 26°C (68°F to 78°F). The total load weight shall not exceed 75 lb, inclusive of the containers/packaging weight but excluding the 25 lb loading rack.

Table 1. Description of the nine validation loads

Validation load #	Load description	Load weight ¹
1	<p>Validation load #1 consisted of general medical instruments, representing the following geometries:</p> <ul style="list-style-type: none"> • Clamp • Serrated surface • Box-lock • Handle • Button • Pivot hinge • Stopcock <p>Type of packaging used: wrapped plastic tray, including silicone mats and brackets, and pouch. General medical instruments were spread out over three trays, six pouches and one wrapped instrument.</p>	11 lb
2	<p>Validation load #2 consisted of general medical instruments, representing the following geometries:</p> <ul style="list-style-type: none"> • Gliding mechanism • Hinges and screws • Serrated surface • Luer-Lok™ • Spring • Rigid non-lumen scopes <p>Type of packaging used: wrapped plastic and aluminum tray, including silicone mats and brackets, rigid aluminum container and pouch. General medical instruments were spread out over one container, three trays, and six pouches.</p>	20 lb
3	<p>Validation load #3 consisted of three single channel flexible endoscopes (ureteroscope) with inside diameter of 1.0 mm and length of 850 mm, packaged individually in wrapped trays or containers, including appropriate silicone brackets or mats. Eight general medical instruments, each packaged in a pouch, were added.</p>	23 lb

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Validation load #	Load description	Load weight ¹
4	<p>Validation load #4 consisted of up to 15 rigid or semi-rigid channeled instruments in the presence of other packaged medical devices. Three double channel semi-rigid endoscopes (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm) were packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. Additional rigid channeled instruments or stainless steel rigid lumens were added to each package. Two additional general medical instruments, each packaged in a pouch, were added.</p>	19 lb
5	<p>Validation load #5 consisted in two single channel flexible endoscopes; one ureteroscope with inside diameter of 1.0 mm and length of 850 mm, and a bronchoscope with inside diameter of 1.8 mm and length of 830 mm, and one double channel semi- rigid endoscope (ureteroscope – 0.7 mm × 500 mm and 1.1 mm × 500 mm), packaged individually in wrapped trays or containers including appropriate silicone brackets or mats. No additional item was added.</p>	21 lb
6	<p>Validation load #6 consisted of general medical instruments, representing the following geometries:</p> <ul style="list-style-type: none"> • Distal end (swivel parts) • Hinge with screw • Cannula <p>General medical instruments packaged in one aluminum sterilization container.</p>	9 lb
7	<p>Validation load #7 consisted of general medical instruments, representing the following geometries:</p> <ul style="list-style-type: none"> • Box-lock hinge • Pivot hinge • Luer-Lok™ <p>General medical instruments, spread out over three aluminum sterilization containers, each weighting 25 lb.</p>	75 lb
8	<p>Validation load #8 consisted of two double channel flexible endoscopes (ureteroscope) with inside diameter of 1 mm and lengths of 850 and 989 mm; and one single channel flexible endoscope (ureteroscope) with inside diameter of 1 mm and length of 850 mm, packaged individually in wrapped plastic sterilization trays, including appropriate silicone brackets or mats.</p>	16 lb
9	<p>Validation load #9 consisted of one multi-channel flexible endoscope, with no more than 4 channels (Video Colonoscope), with inside diameters of 1.2 or more and lengths of 1955 mm or less, or 1.45 or more and lengths of 3500 mm or less; packaged in aluminum sterilization container.</p>	17 lb

¹Excluding the 25 lb loading rack