



STERIZONE® VP4 STERILIZER QUICK REFERENCE DATA SHEET- USA

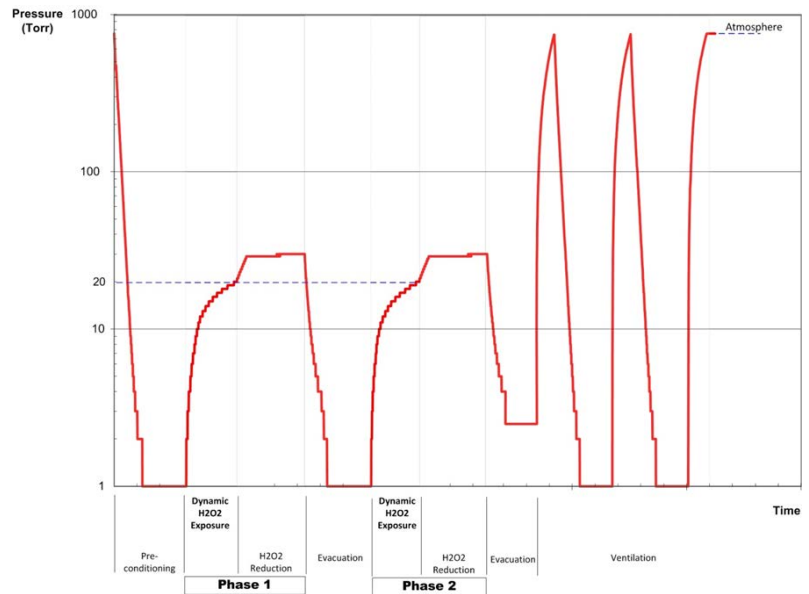
The **STERIZONE® VP4 Sterilizer** is a general purpose low-temperature sterilizer designed to sterilize reusable medical devices up to a maximum load of 75 lb using one single preset cycle. Unlike fixed cycle H₂O₂ sterilization systems, the STERIZONE® VP4 Sterilizer can sterilize a wider range of instruments and load configurations. The STERIZONE® system uses a *Dynamic Sterilant Delivery System™* that delivers H₂O₂ through microburst injections to adapt the total amount of hydrogen peroxide introduced to the composition (surface area, weight and temperature) of the sterilizer load.



The single cycle STERIZONE® VP4 Sterilizer process cycle time range is between 46 and 60 minutes, based on the load configuration. The second step of the cycle phase is the H₂O₂ reduction step. During this step, a set concentration of ozone is injected into the chamber to break down and reduce the residual hydrogen peroxide. Additionally, the result of the chemical reaction between the hydrogen peroxide and ozone forms hydroxyl radicals, which add to the lethality of the process.



Sterilize reusable medical devices up to a maximum load of 75 lb using one single cycle



Cycle Graph

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Within the approved sterilization claims for the USA market, the following instruments have been validated¹ by TSO₃ for use in the STERIZONE® VP4 Sterilizer:

Type of Device	Approved Geometries	Load Restrictions
<p>Single or double channel flexible endoscopes Such as:</p> <ul style="list-style-type: none"> • Ureteroscopes • Bronchoscopes • Cystoscopes • Hysteroscope • Nephroscope • ENT flexible endoscopes 	<p>≥ 1 mm ID x ≤ 989 mm length</p>	<p>No more than 5 channels per cycle</p> <p>Up to 3 packaged single channel flexible endoscope in the presence of other packaged medical devices.</p> <p style="text-align: center;">or</p> <p>Up to 2 doubled channel and 1 single channel flexible endoscope per load</p>
<p>Rigid instruments w/ channels including single and double channel, rigid and semi-rigid endoscopes and rigid tubing Such as:</p> <ul style="list-style-type: none"> • Resectoscopes and resectoscopes sheath • Thoracoscopes • Trocars • Rigid ureteroscopes • Rigid hysteroscopes • Suction cannulas 	<p>Stainless steel lumens: ≥0.7 mm ID x ≤500 mm length ≥2.0 mm ID x ≤575 mm length</p>	<p>≤ 15 channels load/cycle in the presence of other packaged medical devices.</p>
<p>Multi-channel flexible endoscope Such as:</p> <ul style="list-style-type: none"> • Colonoscope • Gastroscope 	<p>≥ 1.2 mm ID x ≤ 1955 mm length ≥ 1.45 mm ID x ≤ 3500 mm length</p>	<p>No more than 1 multichannel flexible endoscope packaged in a compatible container placed on the lower shelf without any additional load.</p> <p>Up to 4 channels per endoscope (such as working, air, water, etc.) (excluding umbilical tubes)</p>
<p>General Instruments: Such as:</p> <ul style="list-style-type: none"> • Nonlumened endoscopes • Stainless steel surgical instruments • Cameras • Fiber optic light cables • Electrophysiology cables 	<p>Combined load of nonlumened endoscopes and nonlumened instruments which may include stainless steel diffusion-restricted areas such as the hinged portion of scissors or forceps.</p>	<p>Maximum load should not exceed 75 lb, including a maximum individual package weight of 25 lb per shelf</p>

¹Device configuration claims for sterility and demonstrated compatibility are listed in the 510(k) applications K141163 and K153689. TSO₃ will refer hospitals to contact the medical device manufacturer if there is no published data on approval for specific devices for use in the STERIZONE® VP4 Sterilizer. TSO₃ offers sterility and functional compatibility studies to meet validation requirements for *instructions for use* inclusion for sterilization.

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Example of compatible materials		
<ul style="list-style-type: none"> • Aluminium • Viton • Brass • LCP • Nylon • Polycarbonate • Silicone 	<ul style="list-style-type: none"> • PEEK • Ultem • Polyethylene • PMMA • POM • PPO (Noryl) • PPSU (Radel) 	<ul style="list-style-type: none"> • Polypropylene • Polystyrene • Teflon • Polyurethane • PVC • Stainless steel • Titanium
Example of non-compatible materials		
<ul style="list-style-type: none"> • Tissue packaging • Paper pockets • Tie wraps (Ties nylon - wraps) • P-touch adhesive labels 	<ul style="list-style-type: none"> • Adhesive nitrocellulose paper (masking tape) • Metallized paper 	<ul style="list-style-type: none"> • Liquid (aqueous or not) • Natural rubber • Latex • Wood • Textile fabrics

Devices that should NOT be processed in STERIZONE® VP4 Sterilizer:

- Devices that cannot withstand a vacuum
- Implants, unless approved by the manufacturer
- Glass or plastic ampules

Summary

- The STERIZONE® VP4 Sterilizer offers advancement in low-temperature sterilization that provides the hospital increased efficiency in volume processing at a lower cost.
- The STERIZONE® VP4 Sterilizer offers the simplicity of a single dynamic cycle that adjusts the H₂O₂ delivery to meet the load configuration/weight.
- The STERIZONE® VP4 Sterilizer has been validated to process some complete instrument sets in a single cycle.
- Mixed* loads including flexible, lumen, and non-lumen devices can be processed at the same time. This capability, along with the ability to process up to 75 lb. in one cycle allows the sterilization of full instrument sets rather than rather than individual instruments.
- The 1 Torr preconditioning phase removes excess moisture to reduce cycle disruption.
- Compatibility has been demonstrated over a wide range of products enabling a greater selection of processing options for the hospital.
- The multiple pulse microburst injection of H₂O₂ provides greater assurance of sterility over a greater range of load configurations than a fixed injection sterilization system.

**The multi-channeled endoscope such as colonoscope and gastroscope with up to 4 channels per endoscope has been validated to be sterilized alone, without any additional load.*

Please refer to the STERIZONE® VP4 user manual for indications for use and for safety considerations.