



STERIZONE® VP4 STERILIZER

QUICK REFERENCE DATA SHEET CANADA AND EUROPE

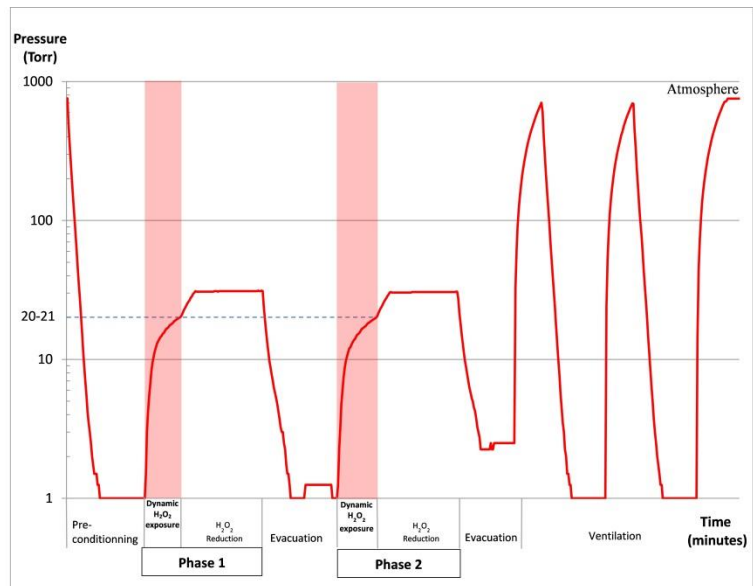


The **STERIZONE® VP4 Sterilizer** is a general purpose low-temperature sterilizer designed to sterilize reusable medical devices up to a maximum load of 75 lb using one single preset cycle. Unlike fixed cycle H₂O₂ sterilization systems, the STERIZONE® VP4 Sterilizer can sterilize a wider range of instruments 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

STERIZONE® VP4 STERILIZER

QUICK REFERENCE DATA SHEET CANADA AND EUROPE

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

Type of Device	Approved Geometries	Load Restrictions
Single and dual channel flexible endoscopes: <ul style="list-style-type: none"> • Bronchoscope • Cystoscope • Ureteroscope • Uretero-rensocope • Nephroscope • Hysteroscope • ENT flexible endoscopes 	$\geq 1 \text{ mm ID} \times \leq 989 \text{ mm length}$	\leq up to 5 channels /cycle Single and double lumen flexible endoscopes have been validated <ul style="list-style-type: none"> • 3 single channel flexible endoscopes or • 2 double channel flexible endoscopes and 1 channel flexible endoscope
Multi- channel flexible endoscopes without elevator guide-wire mechanism: <ul style="list-style-type: none"> • Colonoscopes • Gastrosopes Multi- channel flexible endoscopes with elevator guide-wire mechanism: <ul style="list-style-type: none"> • Olympus® EVIS EXERA II Duodenovideoscope TJF-Q180V 	Multi- channel flexible endoscopes without elevator guide-wire mechanism: <ul style="list-style-type: none"> $\geq 1.45 \text{ mm ID} \times \leq 3500 \text{ mm length}$ $\geq 1.2 \text{ mm ID} \times \leq 1955 \text{ mm length}$ 	No more than 8 channels per cycle Only 1 multi-channel flexible endoscope packaged in a compatible container, placed on the lower shelf of the loading rack without any additional load, has been validated
Rigid instruments w/ channels (Single and dual channels, rigid and semi-rigid): <ul style="list-style-type: none"> • Rigid ureteroscopes • Resectoscopes and resectoscopes sheath • Thoracosopes • Rigid hysteroscopes • Trocars • Suction cannulas 	Stainless steel lumens: <ul style="list-style-type: none"> $\geq 0.7 \text{ mm ID} \times \leq 500 \text{ mm length}$ $\geq 2.0 \text{ mm ID} \times \leq 575 \text{ mm length}$ 	≤ 15 channels load/cycle Only single and dual channeled devices have been validated.
General Instruments: <ul style="list-style-type: none"> • Nonlumened endoscopes • Cameras • Fiber optic light cables • Electrophysiology cables • Stainless steel surgical instruments 	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.	Maximum load should not exceed 75 lb, including a maximum individual package weight of 25 lb per shelf

¹ Device configuration claims for sterility are list in the Canadian Medical Device License number 37796. Check the manufacturer's instructions before loading any item into the STERIZONE® VP4 Sterilizer. TSO₃ offers sterility and functional compatibility studies to the manufacturer of medical devices to meet validation requirements for *instructions for use* inclusion for sterilization.

STERIZONE® VP4 STERILIZER
QUICK REFERENCE DATA SHEET CANADA AND EUROPE

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.
- Mixed flexible, lumen, and nonlumen loads can be processed at one time. This capability, along with the ability to process up to 75 lb in one cycle improves the ability to process instrument sets 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.

Please refer to the STERIZONE® VP4 user manual for indication for use and for safety consideration.