

# The New Standard of Care for Reprocessing of the Olympus® TJF-Q180V Duodenoscope: Terminal Sterilization Using the STERIZONE® VP4 Sterilizer

## STERIZONE VP4 Sterilizer

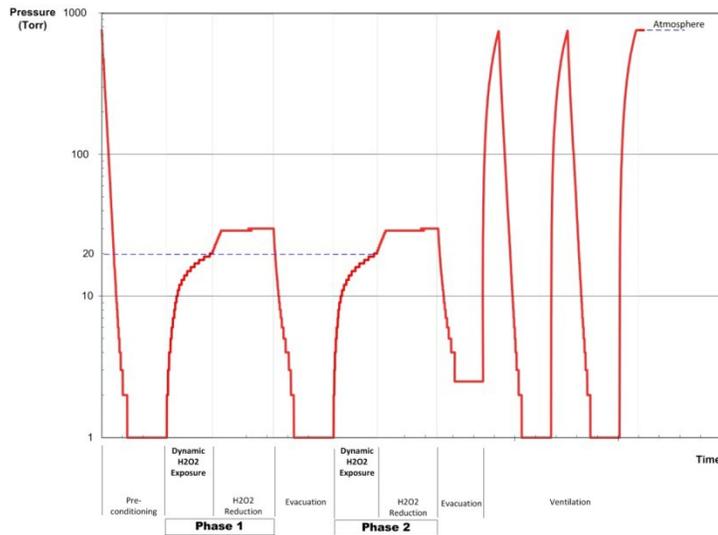
### How it works

**Single Cycle.** The STERIZONE VP4 Sterilizer offers a single preset sterilization cycle designed for the sterilization of a wide variety of loads consisting of general instruments, single, double or multi-channel flexible endoscopes, and rigid and semi-rigid channeled endoscopes.

**Dual Sterilants.** The STERIZONE VP4 Sterilizer uses dual sterilants, vaporized hydrogen peroxide ( $H_2O_2$ ) and ozone ( $O_3$ ), in a multiphase process, and is the only dual-sterilant sterilizer cleared for use in the United States.

#### Sterilization Process (Figure 1).

After a **preconditioning** step, which creates a vacuum inside the chamber, the first cycle phase is initiated with the **Dynamic  $H_2O_2$  exposure** step. During this step, a 50 weight-percent hydrogen peroxide solution (referred to as 125-280 Solution™) is injected at a fixed injection rate in vapor form into the sterilization chamber. The patented micro-pulsed injection (referred to as Dynamic Sterilant Injection System™) continues until a differential pressure set point of 19 Torr is reached. The total amount of hydrogen peroxide introduced into the sterilization



**Figure 1:** STERIZONE VP4 Sterilizer cycle graph corresponding to the two injection phases followed by evacuation and ventilation.

chamber, and thus the duration of the injection, varies depending on load composition, weight and temperature. The STERIZONE VP4 Sterilizer is the first sterilizer to automatically vary the amount of sterilant based on the load, and why a single cycle can be used to sterilize a wide variety of different loads.

A small amount of ozone is then added in the  **$H_2O_2$  reduction** step. The ozone reacts with residual hydrogen peroxide to form hydroxyl radicals. The formation of these hydroxyl radicals further enhances the overall lethality of the process. The ozone used in the process is generated within the sterilizer using oxygen. Oxygen required by the sterilizer can be supplied from a variety of sources, such as an oxygen concentrator or a portable oxygen cylinder.

The chamber is then subjected to a vacuum during the **evacuation** phase, which removes residual sterilant from the chamber. All microbial life is killed in the first phase. For additional

safety as required by regulations, the whole process is then repeated a second time for a complete second cycle. Then in the final **ventilation** phase, the system removes air to create a vacuum, and then returns to atmospheric pressure, repeating this process two times to safely remove residual sterilant from the chamber and the instrumentation.

**No toxic residues.** The STERIZONE VP4 Sterilizer produces no toxic residues, reducing risks to workers and potential patient health concerns. A user manual is provided and users must read, understand and follow the instructions provided in the manual.

More information about this sterilizer can be found in the STERIZONE VP4 Sterilizer Technical Monograph available at [tso3.com/sterizone](http://tso3.com/sterizone).

## Reprocessing the Olympus® TJF-Q180V Duodenoscope

The effective reprocessing of duodenoscopes is known to be challenging due to the device's design complexity, including long, narrow lumens and a forceps elevator mechanism. Multiple duodenoscope related patient infections have been published, despite adherence to the device manufacturer's reprocessing instructions [1,2,3,4,5]. As a result, many healthcare facilities are seeking a solution for terminal sterilization of duodenoscopes because it offers a significantly greater margin of safety than the current standard of care using high-level disinfection. Efficient terminal sterilization of long, complex, multi-channel flexible endoscopes that fall within certain dimensions, such as the Olympus® TJF-Q180V duodenoscope (see claims at [tso3.com](http://tso3.com)) is now possible with the STERIZONE VP4 Sterilizer.

In 2015, the STERIZONE VP4 Sterilizer was approved in Canada and Europe for the sterilization of multichannel flexible endoscopes. In June 2016, the FDA cleared the following endoscope claims:

*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.*

These indications for use were validated with data described in regulatory filings as Load #9. Validation for this Load #9 was performed with a colonoscope, the worst-case device sterilized in the sterilizer.

In May 2018, the STERIZONE VP4 Sterilizer received an additional clearance for long, complex, multi-channel flexible endoscopes that fall within certain dimensions. This application was supported by validation data for the Olympus® TJF-Q180V duodenoscope. A summary of the data submitted to the FDA in connection with this clearance has been published in the American Journal of Infection Control, 2019[6]. See **Figure 2** for an example of the Olympus® TJF-Q180V.



**Figure 2:** Olympus® EVIS EXERA II TJF-Q180V duodenoscope.

This document also provides a high-level summary of the validation data for sterilization of the Olympus<sup>®</sup> EVIS EXERA II TJF-Q180V duodenoscope in the STERIZONE VP4 Sterilizer that was submitted as part of the May 2018 FDA clearance.

## Sterility validation in the STERIZONE VP4 Sterilizer

Comprehensive sterilization validation testing was completed for the Olympus<sup>®</sup> EVIS EXERA II TJF-Q180V duodenoscope in the STERIZONE VP4 Sterilizer. The validation studies included:

- Demonstration of the  $10^{-6}$  Sterility Assurance Level (SAL)
- Simulated Use Validation
- Clinical In-Use Validation.

All methods were validated and in accordance with FDA guidance [7]. Testing was performed using a minimum of three replicates.

### Demonstration of $10^{-6}$ Sterility Assurance Level

The sterilization of the Olympus<sup>®</sup> EVIS EXERA II Duodenovideoscope TJF-Q180V in the STERIZONE VP4 Sterilizer was validated with a half-cycle approach, commonly referred to as “overkill”.

**Objective:** Validate the sterility assurance level (SAL) of the sterilizer with a specific device, in this case for sterilization of a duodenoscope.

**Test Methods:** The half-cycle method consists of inoculating the duodenoscope with at least  $10^6$  CFU (Colony Forming Units) of the most resistant microorganism, and by demonstrating no growth following a sterilization half cycle. In this case, no growth indicates a 6-log reduction of the bacterial inoculum at the half-cycle. Extending this to a complete cycle will achieve a 12-log reduction of the test microorganism. This demonstrates a sterility assurance level of  $10^{-6}$  that is required to claim terminal sterilization.

The microorganism used for this test was the *Geobacillus stearothermophilus* spore, which is recognized as the most resistant microorganism to oxidative sterilization processes, such as hydrogen peroxide and ozone. *G. stearothermophilus* spores are far more resistant to sterilization processes than viruses (lipid and nonlipid), fungi or mycobacteria, other vegetative spores and spore-forming bacteria, and multi-drug resistant organisms (MDROs).

As per testing guidelines, the half-cycle was performed with no washing steps after inoculating the device with resistant spores and then allowing the suspension to dry. The loads were conditioned to represent the worst-case sterilization conditions at a temperature of 79°F, which produces the shortest sterilant exposure in the STERIZONE VP4 Sterilizer. Following completion of the half cycle, the inoculated sites, which consisted of the elevator recess, the air and water channels (distal and umbilical sections), the suction channel and the instrument channel, were sampled for detection of viable microorganisms.

**Results:** All test results demonstrated sterilization of the Olympus<sup>®</sup> EVIS EXERA II Duodenovideoscopes TJF-Q180V using a half-cycle validation approach in the STERIZONE VP4 Sterilizer, confirming a sterility assurance level of  $10^{-6}$ . See **Table 1**.

**Table 1. TJF-Q180V Half-Cycle Validation Results in the STERIZONE VP4 Sterilizer.**

Test sites	Microorganism contamination type	Results
Elevator recess		Pass
Air/water channels	1.0 – 2.5 x 10 <sup>6</sup> CFU of <i>G. stearothermophilus</i> spores	Pass
Suction channel		Pass
Instrument channel		Pass

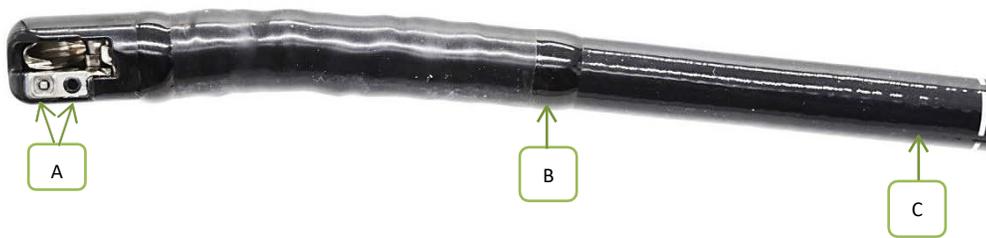
### Simulated Use Validation

The sterilization of the Olympus® EVIS EXERA II Duodenovideoscope TJF-Q180V in the STERIZONE VP4 Sterilizer was also validated with a simulated use method.

**Objective:** Validate the sterilization of the duodenoscope under worst-case, simulated-use conditions.

**Test Methods:** When performing this simulated use validation study, the most resistant microorganism known to the sterilization process is mixed with a soil containing organic and inorganic components designed to mimic clinical soils. Tests were performed by directly inoculating duodenoscopes with at least 10<sup>6</sup> CFU of the *G. stearothermophilus* spores mixed with 5% fetal bovine serum and 400 ppm hard water and left to dry overnight. The inoculated duodenoscopes were then placed in compatible sterilization containers and reprocessed in the STERIZONE VP4 sterilization cycle.

This simulated use study was conducted with duodenoscopes that were repeatedly reprocessed in the STERIZONE VP4 Sterilizer prior to testing. The inoculation sites and load conditions were the same as the those previously identified in the half-cycle validation, with the addition of three sites where adhesives are used to join or secure materials (e.g., adhesive that joins bending rubber to insertion tube). These additional sites (**Figure 3**) were selected because adhesives are known to be susceptible to possible degradation from repeated reprocessing based on available literature [8]. Again, to simulate worst case conditions, the cleaning step was omitted prior to sterilization.



**Figure 3.** Picture of the distal end and additional inoculation sites on the Olympus® EVIS EXERA II TJF-Q180V duodenoscope (adhesives around the light source and camera objective lenses, the bending section adhesive, and the insertion tube).

After inoculation, the duodenoscopes were conditioned to worst-case temperature (79°F) and then sterilized. Following processing in STERIZONE VP4 Sterilizer, test sites were then sampled for detection of viable microorganisms.

**Results:** All testing was performed under worst-case conditions and demonstrated sterilization of the Olympus<sup>®</sup> EVIS EXERA II Duodenovideoscopes TJF-Q180V in the STERIZONE VP4 Sterilizer. See **Table 2**.

**Table 2.** TJF-Q180V Simulated-Use Validation Results in the STERIZONE VP4 Sterilizer.

Test sites	Microorganism contamination type	Results
Elevator recess		Pass
Air/water channels		Pass
Suction channel		Pass
Instrument channel	1.0 – 2.5 x 10 <sup>6</sup> CFU of <i>G. stearothersophilus</i> spores mixed with organic and inorganic soils	Pass
Light source and camera lens adhesives		Pass
Flexible section adhesive		Pass
Insertion tube		Pass

### Clinical In-Use Validation

The sterilization of the Olympus<sup>®</sup> EVIS EXERA II Duodenovideoscope TJF-Q180V in the STERIZONE VP4 Sterilizer was also validated under clinical in-use conditions.

**Objective:** Validate sterilization of the Olympus<sup>®</sup> TJF-Q180V when reprocessed in a healthcare facility using the STERIZONE VP4 Sterilizer.

**Test Methods:** During this study, trained healthcare personnel executed the recommended cleaning procedure in conjunction with the Olympus<sup>®</sup> TJF-Q180V instructions for use (IFU) on clinically soiled duodenoscopes from patient procedures.

Hospital-owned duodenovideoscopes were used during clinical procedures and assessed for their sterility after processing in the STERIZONE VP4 Sterilizer. Study endoscopes were not in new condition, exhibiting visible signs of wear, like ridges on the insertion tube and cracks in the bending section. After the ERCP procedure, manual cleaning of the tested devices was performed by the hospital sterile processing department personnel according to their internal reprocessing procedure, which complies with the endoscope manufacturer instructions for cleaning. No automated endoscope reprocessor (AER) or high-level disinfection step was performed prior to terminal sterilization. The tested endoscopes were then packaged in compatible containers and reprocessed according to the STERIZONE VP4 Sterilizer indications for use. Following sterilization, the duodenoscopes were sampled for viable microorganisms under aseptic conditions. Samples from all channels, the elevator recess and the insertion tube surface were obtained from each clinically used duodenoscope.

**Results:** All clinical testing demonstrated sterilization of the Olympus® EVIS EXERA II Duodenovideoscopes TJF-Q180V in the STERIZONE VP4 Sterilizer. See **Table 3**.

**Table 3.** TJF-Q180V Clinical In-Use Validation Results in the STERIZONE VP4 Sterilizer.

Recovery site	Microorganism contamination type	Results
Elevator mechanism		Pass
Air/water channels	Aerobic and anaerobic bacteria plus yeast and molds, as found in a routine ERCP procedure	Pass
Suction channel		Pass
Instrument channel		Pass
Insertion tube		Pass

## Compatibility validation

The compatibility of the Olympus® EVIS EXERA II Duodenovideoscopes TJF-Q180V for sterilization in the STERIZONE VP4 was validated by simulated reprocessing.

**Objective:** Demonstrate the compatibility of the Olympus® TJF-Q180V when reprocessed in a healthcare facility using the STERIZONE VP4 Sterilizer.

**Test methods:** The duodenoscopes were repeatedly reprocessed, including complete manual cleaning between each sterilization cycle. The manufacturer’s recommended inspection was performed following each cycle, including a leak test. Additionally, a modified leak test was performed while applying additional force to the elevator forceps, which was designed to provide additional challenge to the elevator mechanism seal. The duodenoscope maintained functionality after multiple sterilization cycles and no leakage was detected at the elevator forceps.

Furthermore, the integrity of the distal end cap seals following repeated reprocessing was evaluated because damage to these seals could lead to liquid ingress and cross-contamination that would not be detected during a standard leak test. Two different methods were performed, including an optical detection method (fluorescent probe method) and a biological detection method (blood and egg yolk soil method). See **Table 4**. Both methods demonstrated that no liquid ingress occurred under the distal cap, indicating that the distal end seals remained intact following repeated cycling in the STERIZONE VP4 Sterilizer.

**Results:** Collectively, these compatibility studies demonstrated the compatibility of the Olympus® TJF-Q180V when reprocessed using the STERIZONE VP4 Sterilizer. No additional failure modes were observed that were not detectable by the manufacturer’s recommended inspection.

**Table 4.** TJF-Q180V Liquid Ingress Results after repeated processing in the STERIZONE VP4 Sterilizer.

Detection method	Number of duodenoscopes	Results
Optical (fluorescent probe)	2	No liquid ingress detected
Biological (blood and egg yolk soil)	3	No liquid ingress detected

In general, sterilization processes are harsher on endoscope materials than high-level disinfection and users may observe an increased frequency of repair. The duodenoscope manufacturer's IFUs for visual, tactile and functional inspection of the duodenoscope between each cycle should be followed. Materials known to degrade quicker during reprocessing, such as adhesives at the distal end and the bending section, should be carefully inspected in accordance with professional guidelines using lighted magnification. Preventive maintenance recommended by the duodenoscope manufacturer should be performed.

## Clinical recommendations

Before sterilization of the Olympus® TJF-Q180V duodenoscope in the STERIZONE VP4 Sterilizer:

- **Clean** the endoscope according to the manufacturer's instruction for use and professional guidelines.
- **Dry** the endoscope properly, including all internal channels.
- **Package** the duodenoscope in either a rigid sterilization container or a wrapped tray compatible with hydrogen peroxide-ozone sterilization.
- **Load** one duodenoscope per cycle, on the bottom shelf of the STERIZONE Loading Rack, following the STERIZONE VP4 Sterilizer instructions for use.

High-level disinfection is not necessary prior to terminal sterilization in the STERIZONE VP4 Sterilizer.

The TSO<sub>3</sub> clinical team is available to support the implementation and provide guidance on best practices for endoscope sterilization in healthcare facilities. Contact [info@tso3.com](mailto:info@tso3.com) or call 1-844-833-0003.

## Conclusions

The STERIZONE VP4 Sterilizer was successfully validated for the terminal sterilization of the Olympus® EVIS EXERA II TJF-Q180V duodenoscope. Tests were performed under simulated worst-case conditions and clinical in-use conditions. All data and results from this study were reviewed and cleared by the FDA. The STERIZONE VP4 Sterilizer is 510(k) cleared in the U.S. for the terminal sterilization of long, complex multi-channel flexible endoscopes that fall within certain dimensions, and directly supported by testing of the Olympus® EVIS EXERA II TJF-Q180V duodenoscope.

The STERIZONE VP4 Sterilizer is an effective and efficient method of sterilization that can be central to an effective infection control strategy. Since 2017, the STERIZONE VP4 Sterilizer is being successfully adopted for sterilization of the Olympus® TJF-Q180V duodenoscope by a growing number of hospitals around the world to elevate the standard of care and provide enhanced safety for patients.

STERIZONE®



## References

1. Muscarella LF. Risk of transmission of carbapenem-resistant Enterobacteriaceae and related “superbugs” during gastrointestinal endoscopy. *World J Gastrointest Endosc.* 2014 Oct 16;6(10):457–74.
2. Wendorf KA, Kay M, Baliga C, Weissman SJ, Gluck M, Verma P, et al. Endoscopic retrograde cholangiopancreatography-associated AmpC Escherichia coli outbreak. *Infect Control Hosp Epidemiol.* 2015 Jun;36(6):634–42.
3. Epstein L, Hunter JC, Arwady MA, Tsai V, Stein L, Gribogiannis M, et al. New Delhi metallo- $\beta$ -lactamase-producing carbapenem-resistant Escherichia coli associated with exposure to duodenoscopes. *JAMA.* 2014 Oct 8;312(14):1447–55.
4. Lyon J. Maker of Duodenoscopes Under Scrutiny Again. *JAMA.* 2017 May 9;317(18):1826.
5. Humphries RM, Yang S, Kim S, Muthusamy VR, Russell D, Trout AM, et al. Duodenoscope-Related Outbreak of a Carbapenem-Resistant Klebsiella pneumoniae Identified Using Advanced Molecular Diagnostics. *Clin Infect Dis Off Publ Infect Dis Soc Am.* 2017 Oct 1;65(7):1159–66.
6. Molloy-Simard V, Lemyre J-L, Martel K, Catalone B, Elevating the standard of endoscope processing: Terminal sterilization of duodenoscopes using a hydrogen peroxide-ozone sterilizer, *Am J Infect Control.* 2019 Mar 47;3:243-250.
7. FDA Infection control devices branch. Guidance on Premarket Notification [510(k)] Submissions for - Sterilizers Intended for Use in Health Care Facilities.
8. Murray P. Preventable Tragedies: Superbugs and How Ineffective Monitoring of Medical Device Safety Fails Patients. 2016 Jan.

STERIZONE<sup>®</sup>

© 2018-2019, TSO<sub>3</sub> Inc. All rights reserved for all countries. The TSO<sub>3</sub> logo and STERIZONE<sup>®</sup> are registered trademarks of TSO<sub>3</sub> Inc. The Inukshuk logo below is also a trademark of TSO<sub>3</sub> Inc. Olympus<sup>®</sup> is a registered trademark of Olympus Corporation, Olympus America Inc., and/or their affiliates. The STERIZONE VP4 Sterilizer is patented in the US under US Pat. 9,101,679; 9,474,815; 9,480,763; 9,480,765 and 9,814,795. Other patent applications pending. Corresponding patents granted or pending in other countries. This document references device claims only approved for use in the United States of America as of the date of the publication (April 2019).



OUR MISSION: A STERILE DEVICE FOR EVERY PATIENT.