



July 24, 2014

Re: **Compatibility of Olympus and Gyrus ACMI Small Diameter Flexible Endoscopes, Camera Heads and Accessories with the Amsco® V-PRO® Sterilizers: Technical Information for Olympus and Gyrus ACMI Customers in the United States**

Dear Health Care Professional:

This letter provides information on the material and functional compatibility of Olympus and Gyrus ACMI products with the Amsco® V-PRO® maX, Amsco® V-PRO 1 Plus and Amsco® V-PRO 1 Sterilization Systems manufactured by Steris Corporation (Mentor, OH) for users in the United States. The V-PRO maX system is a low temperature vaporized hydrogen peroxide sterilization processing program that allows users to choose between three cycles: a Flexible Cycle, a Lumen Cycle, and a Non Lumen Cycle. The V-PRO 1 Plus Sterilizer has two cycles: a Lumen Cycle and a Non Lumen Cycle. The V-PRO 1 Sterilizer has one cycle which is the identical to the Lumen Cycle in the other V-PRO Sterilizers. Please note that specific instruments require specific cycles. For information regarding cycle parameters or for information regarding V-PRO sterilization efficacy and Indications for Use, please contact STERIS Corporation.

#### OLYMPUS SMALL DIAMETER FLEXIBLE ENDOSCOPES

Olympus flexible endoscopes that are compatible with the V-PRO maX (Non Lumen or Flexible Cycles) and V-PRO 1 Plus (Non Lumen Cycle) systems are either listed as compatible in their respective reprocessing manuals or can be identified by the presence of a white line on the control section (see figure below). Not all compatible models will contain the white line on the control section. If you are uncertain if an Olympus small diameter flexible endoscope is compatible with the V-PRO maX or V-PRO 1 Plus system, please contact Olympus or visit the Interactive Reprocessing Guide at [www.olympusconnect.com](http://www.olympusconnect.com). The Interactive Reprocessing Guide is located under the Resources tab.



**Compatible with Limited Exposure:** On the following models of Olympus small diameter flexible endoscopes, the insertion tube may require replacement after 100 cycles of exposure due to adhesive degradation. When sterilizing the following Olympus flexible endoscopes in the V-PRO maX or V-PRO 1 Plus systems, inspect the endoscope following the inspection procedure described later in this document prior to each use.

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For Gyrus ACMI products, the compatibility results are based on the completion of a minimum number of sterilization cycles, and may not be representative of actual use. Cosmetic and/or functional damage may occur in the V-PRO maX or V-PRO 1 Plus system. For example, the engraving fill material used to mark Gyrus ACMI instrumentation may be damaged by the V-PRO maX or V-PRO 1 Plus system<sup>®</sup>. Although this damage is generally defined as cosmetic, the material may be removed by the sterilization process.

If the described compatibility limitations are acceptable, the following endoscopes and products may be processed in the **Flexible Cycle** in the V-PRO maX sterilization system:

Type	Model(s)
BF	1T60/MP60/P60/XP60 MP160F/XP160F 1T180/1TQ180/P180/Q180/Q180-AC H190*/Q190*/1TH190*/P190*/XP190*
CHF	P60 V
CYF	V2/VA2/V2R/VH*/VHA*/VHR* 5/5A/5R
ENF	V2/VT2/VQ/V3*/VH*
LTF	160/260 V3 VH/VP/VP-S S-190-5*/S-190-10*/190-10-3D*
MAF	GM TM
URF	P5/ P6/P6R V/V2*/V2R*
DUR	DUR-D/ DBA/8ULTRA/8/8BA/8E/8EBA
AUR	7/735
ACN	2T/2TBA
ICN	2/2BA

\*Although these Olympus models are compatible with sterilization in the V-PRO maX Flexible Cycle, they do not contain a white line on their control section.

If the described compatibility limitations are acceptable, the following endoscopes and products may be processed in the **Non Lumen Cycle** in the V-PRO maX and V-PRO 1 Plus sterilization systems:

Type	Model(s)
ENF	V2/ VQ/V3*/VH*
LTF	V3 VH/VP/VP-S S-190-5/S-190-10*/190-10-3D*

\*As described above, these scopes do not have a white line indicating compatibility.

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## OLYMPUS AND GYRUS ACMI SURGICAL ACCESSORIES

**Compatible:** The following Olympus and Gyrus ACMI surgical accessories are compatible with the **Flexible** Cycle in the V-PRO maX sterilization system with the following caveats.

Product	Model	Compatibility
Miniature light source	MAJ-524	YES
Rechargeable miniature light source	MAJ-922	YES
Suction valve	MAJ-207	After 150 cycles, the button on the MAJ-207 may be difficult to operate. Inspect prior to use. If this occurs, replace with a new MAJ-207.
Mouthpiece	MA-651	YES
Biopsy valve	MAJ-579	YES
Biopsy valve	MD-495	YES
BAL valve	MH-192	YES
Gas supply adapter	MAJ-1227	YES
Light guide adapter	MAJ-1413	YES
Forceps/Irrigation plug (Isolated type)	MAJ-891	YES
Air supply tube	MAJ-1196	YES
Water-resistant Cap	MAJ-1214	YES
Injection adapter	MAJ-1235	YES
Sterilization cap	MAJ-1538	YES
ETO cap	MB-156	YES
Cap	MH-364	YES
Cylinder Plug	MAJ-1940	YES
Trocar Introducer for LTF 5mm Scope	MAJ-1379	YES
Digital Hysteroscope CF Sheath	IDH-4S	YES
CyberWand USL Advanced Transducer	CW-USLTA	YES
Sealing cap	MAJ-2081	YES
Forceps Irrigation Plug	MAJ-2092	After 150 cycles, the MAJ-2092 may be difficult to attach to an endoscope. Inspect prior to use. If this occurs, replace with a new MAJ-2092.

**Compatible:** The following Gyrus ACMI products and surgical accessories are compatible with the **Lumen** Cycle in the V-PRO maX sterilization system.

Product	Model	Compatibility
Universal Stopcock, Luer Lock	75U	YES
Nipple Luer, Male	94C	YES
Adapter	98-0340	YES
Light Post Adapter, Wolf	98-0341	YES
Lightpost Adapter, M3 Gold, Wolf	98-0759	YES
Light Post Adapter, M3, Storz/Olympus	98-0760	YES
Monopolar Active Cord, Bovie/ValleyLab Generators	C650-129A	YES
Self Sealing Seals 5FR (pkg 6) - Silicone, Green, for up to 5 Fr	CS-G5	YES
ACMI Seal Kit (0-7FR), 12/Box - Silicone, Green, for up to 7 Fr	CS-G7	YES

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Product	Model	Compatibility
CIRCON Blind Seal Kit - Silicone, Red, Blind	CS-RB	YES
CIRCON Blind Seal Kit - 6-12fr	CS-B612	YES
USA Elite System Cystourethroscope Sheath, 17 Fr, Red	E117-S	YES
USA Elite System Cystourethroscope Sheath, 21 Fr, Orange	E121-S	YES
USA Elite System Cystourethroscope Sheath, 23 Fr, Yellow	E123-S	YES
USA Elite System Cystourethroscope Sheath, 25 Fr, Green	E125-S	YES
Cystourethroscope Visual Obturator	E161	YES
Cystourethroscope Visual Obturator	E163	YES
Cystourethroscope Stationary Deflector	E164	YES
M3-Gold Autoclavable Telescope, 4mm, 0deg	M3-0A	YES
M3-Gold Autoclavable Telescope, 4mm, 110deg	M3-110A	YES
M3-Gold Autoclavable Telescope, 4mm, 12deg	M3-12A	YES
M3-Gold Autoclavable Telescope, 4mm, 30deg	M3-30A	YES
M3-Gold Autoclavable Telescope, 4mm, 70deg	M3-70A	YES
Gynecology Autoclavable Telescope , 2.7mm, 12deg	G27L-12A	YES
Gynecology Autoclavable Telescope, 27mm, 30deg	G27L-30WA	YES
USA CF Diagnostic Hysteroscope - working channel = .044 inches = 1.11mm = 3.3 Fr	GY5-CFH	YES
USA CF Operative Hysteroscope System - 7mm OD with 2.3 mm (7 fr) working channel	GY7-CFH	YES
CF Operative Bridge/Obturator, 2.3MM Channel	GYB-7	YES
USA Series CF Outer Sheath, 7mm	GYC-7	YES
USA Office Diagnostic Hysteroscope	GYD15	YES
Operative Hysteroscope Bridge	GYNE-BR	YES
Operative Hysteroscope Bridge	GYO-6	YES
SlimLine Operative Hysteroscope Inner Sheath/Bridge	GY275L-B	YES
SlimLine CF System, 5.5MM	GY275L-CFH	YES
SlimLine Diagnostic Sheath, 3.5MM	GY275L-DS	YES
SlimLine Outer Sheath	GY275L-S	YES
Kit, SlimLine Visual	GY275L-VK	YES
SlimLine Visual Obturator	GY275L-VO	YES
Protective Telescope Sheath	TEL-SH	YES
Bagley Semi-rigid Ureteroscope, 33cm	MR-6A	YES
Bagley Semi-rigid Ureteroscope ,43cm	MR-6LA	YES
SlimLine Semi-Rigid Ureteroscope, 42cm	MRO-742A	YES
SlimLine Semi-rigid Ureteroscope 33cm	MRO-733A	YES
SlimLine Pediatric Ureteroscope, 15cm	MRO-715A	YES
45° Autoclavable Fiberoptic Lightguide	G93-45	YES
Autoclavable Fiberoptic Lightguide	G93	YES
Sealing Cap	MAJ-2081	YES
Rigid Sheath	MAJ-2079	YES

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**Compatible:** The following Olympus surgical accessories are compatible with the **Non Lumen** Cycle in the V-PRO maX or V-PRO 1 Plus sterilization systems.

Product	Model	Compatibility
Miniature light source	MAJ-524	YES
Rechargeable miniature light source	MAJ-922	YES
Mouthpiece	MA-651	YES
BAL valve	MH-192	YES
Water-resistant Cap	MAJ-1214	YES
Sterilization cap	MAJ-1538	YES
ETO cap	MB-156	YES
Cap	MH-364	YES
Cylinder Plug	MAJ-1940	YES
Sealing Cap	MAJ-2081	YES

### OLYMPUS VIDEO CAMERA SYSTEMS AND ACCESSORIES

**Compatible:** Olympus camera heads and video adapters for the following camera systems are compatible with the **Flexible, Lumen, and Non Lumen** Cycles in the V-PRO maX, V-PRO 1 Plus and V-PRO 1 systems with the following caveats:

Product	Model	Compatibility
OTV-S7 series	OTV-S7H-1D	YES
	OTV-S7H-1D-L08E	Although discoloration of black anodized aluminum parts may occur, functional performance is maintained.
	OTV-S7H-1N	YES
	OTV-S7H-1NA	Although discoloration of the boot may occur, functional performance is maintained.
	OTV-S7H-D-6M	YES
	OTV-S7H-D-L08E	Although discoloration of black anodized aluminum parts may occur, functional performance is maintained.
	OTV-S7H-N	YES
	OTV-S7H-NA	Although discoloration of the boot may occur, functional performance is maintained.
OTV-S7Pro series	OTV-S7ProH-FD	YES
	OTV-S7ProH-HD-L08E	Although discoloration of the button and the black anodized aluminum parts may occur, functional performance is maintained.
190 series	CH-S190-08-LB	Although discoloration of switches and anodized aluminum parts may be observed, the functional performance is maintained.
	CH-S190-XZ-E/Q	Although discoloration of boot and/or switches may be observed, the functional performance is maintained.

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**Compatible:** The following Gyrus ACMI camera heads are compatible with the **Flexible** Cycle in the V-PRO maX sterilization system.

Product	Model	Compatibility
Invisio MegaPixel Direct Coupler Camera Head	IMP -1330	YES
Invisio MegaPixel Right Angle Camera Head with Swivel	IMP-1340	YES
Invisio MegaPixel Direct Coupler Camera Head	IMP-1370	YES
Invisio MegaPixel Right Angle Camera Head	IMP-1375	YES

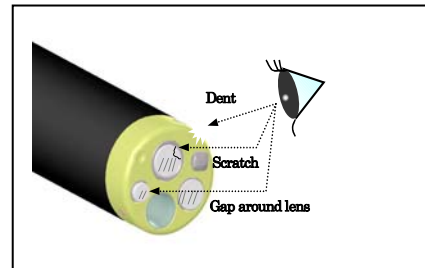
## Inspecting Olympus Flexible Endoscopes for Deterioration of Adhesives, Objective Lens and Light Guide Lens:

Certain components of Olympus flexible endoscopes listed as “Compatible with Limited Exposure” will deteriorate over time with repeated reprocessing in the V-PRO systems. Specifically, the epoxy adhesives used on the distal tip of the endoscope will deteriorate with repeated exposure to V-PRO cycles. The following inspection procedure should be followed prior to each sterilization and use of the endoscope to detect deterioration of the adhesives, objective lens and light guide lens.

**WARNING:** Endoscope users must inspect the equipment according to the following procedure before use. If any abnormality is observed, stop using the equipment and send it to Olympus for repair. Using a damaged endoscope may cause the lens to detach from the endoscope, and poses a risk to patient safety.

1. Wipe the surface of the lenses with a lint-free cloth.
2. Inspect the distal end of the endoscope, specifically the objective and light guide lenses, to determine if there are any chips or scratches on the lenses, or any missing adhesive or gaps in the adhesive surrounding the lenses. Do not use an endoscope with missing or deteriorated adhesive.
3. Check that the endoscopic image is not foggy.

**WARNING:** If the endoscopic image appears foggy during a patient examination, immediately withdraw the endoscope from the patient. Using an endoscope with a foggy image may cause patient injury.





## **NON-OLYMPUS REPAIRS**

Olympus cannot guarantee that any product repaired by a non-Olympus facility will be compatible with the V-PRO Sterilization Systems. Moreover, if a product is repaired by a non-Olympus facility, the corresponding product warranty may be voided. In the event that your equipment has been repaired by such a facility, please contact the repair facility directly for compatibility information.

## **WARRANTY**

Nothing contained in this letter alters, extends, or modifies in any way the authorized Olympus warranty applicable to each device or instrument.

Functional damage to Gyrus ACMI instruments which is deemed to have been caused by use of the V-PRO systems will be covered under Gyrus ACMI's Limited Express Warranty when such damage has been identified.

## **CAUTIONS**

When sterilizing a compatible flexible endoscope in a V-PRO Sterilizer, refer to the endoscope's instruction manual for information regarding how to prepare the endoscope for gas sterilization. If the endoscope requires an ETO cap to vent the endoscope for ETO sterilization, it will require the same ETO cap for sterilization in the V-PRO Sterilizers. For those endoscopes that require an ETO cap, attach the ETO cap to the endoscope prior to reprocessing in the V-PRO Sterilizer. Failure to attach the ETO Cap prior to reprocessing in the V-PRO sterilizer will result in expansion and rupturing of the bending section cover when a vacuum is drawn in the sterilization chamber. (Refer to the appropriate endoscope instruction manual for additional details regarding the use of the ETO Cap).

Always use the appropriate sterilization tray approved for use with the V-PRO Sterilization System.

## **STERILIZATION EFFICACY**

Olympus' testing has only evaluated the material and functional compatibility of Olympus and Gyrus ACMI products with the V-PRO Sterilization Systems. Olympus has not tested nor confirmed the ability of V-PRO Sterilizers to sterilize Olympus and Gyrus ACMI products. Please contact STERIS Corporation directly regarding all questions pertaining to sterilization efficacy and each V-PRO Sterilizer's Indications for Use.

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If you have any questions regarding the compatibility of your Olympus products with V-PRO Sterilizers contact your local Olympus sales representative or Technical Support at 1-800-387-0437. Thank you.

Sincerely,

A handwritten signature in black ink that reads "Mary Ann Drosnock". The signature is written in a cursive style.

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