



OLYMPUS AMERICA INC.

ENDOSCOPE GROUP
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TECHNICAL BULLETIN

January 31, 2001

Re: **Compatibility of Olympus Flexible Endoscopes and Ancillary Products with Rapicide™ High Level Disinfectant and Sterilant**

Dear Olympus Customer,

Olympus has recently completed a study of the compatibility of Olympus flexible endoscopes and ancillary products with Rapicide™ High Level Disinfectant and Sterilant - a new glutaraldehyde-based germicide from MediVators, Inc. (Eagan, MN)¹. MediVators, Inc. has also recently completed a study of the compatibility of Olympus/MediVators cleaning and disinfecting products with Rapicide™.

The conclusion of these studies is that the **Olympus endoscopes and the Olympus/MediVators products listed below are compatible with Rapicide™ when used according to label directions.**

GI ENDOSCOPES

Simulated-use exposure of Olympus GI endoscopes to Rapicide™ used in accordance with label directions demonstrated that these endoscopes are materially and functionally compatible. No cosmetic effects from the exposure were noted.

The described test results are applicable to the following endoscope models:

EVIS Videoscopes	OES Fiberscopes
<u>GIF/CF/PCF/JF/TJF/SIF</u>	<u>GIF/CF/PCF/JF/TJF/SIF</u>
100/200-Series	10-Series
130/230-Series	20-Series
140/240-Series	30-Series
160-Series	40-Series
OSF-V60	OSF-3
	PJF-7.5
	SIF-SW

The following accessories were tested and are also compatible:

Splinting Tube for SIF:	ST-S2
Splinting Tube for CF/PCF:	ST-C3/C5/C6/C8

ULTRASOUND ENDOSCOPES and PROBES

Simulated-use exposure of Olympus Ultrasound Endoscopes to Rapicide™ used in accordance with label directions demonstrated that these endoscopes are functionally compatible. A minor cosmetic effect to the glue on the distal end and the glue on the bending section of the endoscopes was observed.

¹Olympus tested Lot No. 35399. Rapicide™ and MediVators™ are trademarks of MediVators, Inc.

Simulated-use exposure of Olympus Ultrasound Probes to Rapicide™ produced no functional or cosmetic changes.

The described test results are applicable to the following models:

Ultrasound Endoscopes	Ultrasound Probes
<hr/> GF/JF/CF Models UM20/30-Series UM200-Series UM130/230-Series UM240-Series GF-UC30P MH-908	<hr/> UM Models UM-2R/3R/4R UM-G20-29R UM-S20-20R UM-BS20-26R UM-S30-25R UM-S30-20R

BRONCHOSCOPES

Simulated-use exposure of Olympus Bronchoscopes to Rapicide™ used in accordance with label directions demonstrated that these endoscopes are functionally compatible. After extended exposure to Rapicide™ a slight wrinkling of the black covering on the light-guide tube was noted when the tube was coiled tightly. However, no functional problems or other damage was observed.

The described test results are applicable to the following endoscope models:

EVIS Videoscopes	OES Fiberscopes
<hr/> BF Models 160-Series 200-Series 240-Series	<hr/> BF Models 10-Series 20-Series 30-Series 40-Series

SURGICAL / SPECIALTY ENDOSCOPES

Simulated-use exposure of the following endoscopes to Rapicide™ used in accordance with label directions demonstrated that these endoscopes are functionally compatible. After extended exposure to Rapicide™ a slight wrinkling of the black covering on the light-guide tube was noted when the tube was coiled tightly. However, no functional problems or other damage was observed.

The described test results are applicable to the following endoscope models:

Series	Models
ENF-Series	P3, P4, T3, L3, XP
LF-Series	2, P, T, DP, TP, GP
CHF-Series	CB30, P20Q
URF-Series	P2, P3
CYF-Series	2, 3, 4, 4A, 200
HYF-Series	P, XP, 1T

VIDEO CAMERAS & ADAPTERS

The following Olympus video products are materially and functionally compatible with Rapicide™ when used according to label directions:

- OTV-S6H Series Cameras
- AR Series Video Adapters
- MH-999 Video Coupler

CLEANING AND DISINFECTING PRODUCTS

MediVators, Inc. has determined that the following Olympus/MediVators Products are compatible with Rapicide™:

- Olympus DSD Endoscope Disinfector by MediVators
- Olympus MV-2 Disinfector by MediVators (heated disinfectant reservoir required)
- Olympus MV-1 Disinfector by MediVators (heated disinfectant reservoir required)
- CLM-1087 Liquid Chemical Germicide Transfer Pump
- Filters for Olympus/MediVators Products²

It is necessary to use the "Liquid Chemical Germicide Change-Over Procedure for Olympus/MediVators Products" when changing an automated reprocessor to a new liquid chemical germicide. This procedure should be followed when changing from one chemical to another (e.g., ortho-phthalaldehyde to glutaraldehyde), as well as when changing from one brand of chemical to another (e.g., Glutaraldehyde Brand X to Glutaraldehyde Brand Y). Please contact the Olympus Endoscopy Customer Care Center at (800) 848-9024 to request a copy of the procedure.

Rapicide™ is intended for reuse at concentration levels above the minimum recommended concentration (MRC) of 1.5% glutaraldehyde for a period of time not to exceed 28 days. DO NOT RELY SOLELY ON DAYS IN USE to determine its potency. The concentration of Rapicide™ during its use-life must be verified using chemical indicator strips to determine that at least the minimum recommended concentration of 1.5% glutaraldehyde is present. Studies have shown that 60 reuse cycles have been attained in MediVators disinfectors under controlled laboratory conditions. However, the specific number of cycles that can be performed before the MRC is reached is dependent on individual reprocessing conditions and must therefore be determined for each clinical situation.

Rapicide™ is not approved for manual use and should only be used in an automated endoscope reprocessor.

The KeyMed AutoDisinfector has not been tested for compatibility with Rapicide™.

² Compatible Filters for Olympus/MediVators Products:

MF01-0011	Aldehyde/Oxidizing Chemical-Compatible DSD Disinfectant Filter
MF01-0012	DSD Aldehyde/Oxidizing Chemical-Compatible 0.2 Micron Water Filter
MF01-0013	DSD Aldehyde/Oxidizing Chemical-Compatible 0.2 Micron High Sediment Concentration Water Filter
MF01-0014	Replacement 1.0 Micron Pre-Filter Cartridge for DSD and MV-1/MV-2 Water Filtration Systems
MF01-0015	Replacement 0.45 Micron Water Filter for DSD Water Pre-Filtration System
CF01-0007	Replacement Filter Kit for CLM 5001 and CLM 5002V Water Filtration System (Containing CF01-0017 and CF01-0018)
CF01-0017	Replacement 1.0 Micron Prefilter Cartridge for 5001 and 5002V Water Filtration System
CF01-0018	Replacement 0.2 Micron Bacterial Retention Filter Cartridge for MV-1/MV-2 and 5001/5002V Water Filtration Systems
CLM-1076	Water Filtration System for MV-1 and MV-2 (Includes Housing & Filters)
MK01-0033	DSD Water Filtration System (Includes Housing and Filter)

NOTE: Please contact the Olympus Endoscopy Customer Care Center at (800) 848-9024 to request a copy of a description of the proper procedure for using Rapicide™ to periodically high-level disinfect the 0.2 micron filter and water supply lines to the disinfector.

ELEVATED TEMPERATURES

Rapicide™ is compatible with Olympus equipment when reprocessing is performed at the label-specified temperature of 35°C / 95°F. Olympus will not accept responsibility for instrument damage attributed to the use of Rapicide™ if the product is heated above this temperature.

SAFETY AND GERMICIDAL EFFICACY

For additional information regarding the safety and germicidal efficacy of Rapicide™ High Level Disinfectant and Sterilant, please contact MediVators Inc. at (800) 537-7324 or (651) 405-1661.

NON-OLYMPUS REPAIRS

Olympus cannot guarantee that any product repaired by a non-Olympus facility will be compatible with Rapicide™. 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 them directly for compatibility information.

WARRANTY

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