



December 1, 2009

**Statement on Olympus Endoscope Sterile Efficacy in STERRAD® NX™ System**

ASP's responsibility, as the sterilization device manufacturer, is to assess sterile efficacy based on existing materials and lumen claims for STERRAD® Systems. ASP follows sterilization validation under ISO 14937: 2000 *Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices, including Technical Corrigendum 1: 2003* and AAMI TIR No.12-2004, "Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Device Manufacturers."

Medical device manufacturers are responsible under EN ISO 17664: 2004: *Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices*, to provide their customers with instructions for sterilization that meet the functionality requirements for their devices. Please contact Olympus regarding the functional and material compatibility of Olympus devices with STERRAD® NX™ Sterilization System.

This letter is to confirm, as of this date, that the following Olympus endoscopes can be effectively sterilized in the STERRAD® NX™ Advanced Cycle using a STERRAD® approved container or tray and based on specifications provided by Olympus Corporation that meet material and lumen claims for achieving sterile efficacy:

Olympus Model	Product Code	Lumen Dimensions	Notes
Flexible Cystoscope	CYF-5	2.4mm x 640mm	Must have white identification line for STERRAD NX Please note Olympus special Instructions as posted
Flexible Cystoscope	CYF-5A	2.4mm x 640mm	As above
Flexible Video-Cystoscope	CYF-V2	2.2mm x 615mm	As above
Flexible Video-Cystoscope	CYF-VA2	2.2mm x 615mm	As above
Flexible Ureteroscope	URF-P5	1.2mm x 835mm <sup>1</sup>	As above
Flexible Video-Ureteroscope	URF-V	1.2mm x 825mm	As above
Flexible Choledochoscope	CHF-P60	2.2mm x 615mm	As above
Videolaryngoscope	ENF-V2	No Channel	As above
Videolaryngoscope	ENF-VT2	2.0mm x 365mm	As above
Videolaryngoscope	ENF-VQ	No Channel	As above
Pleurascope	LTF-160	2.8mm x 505mm	As above
Pleurascope	LTF-V3	No Channel	As above
Pleurascope	LTF-VP	No-Channel	As above
Pleurascope	LTF-VP-S	No-Channel	As above
Pleurascope	LTF-VH	No-Channel	As above

33 Technology Drive, Irvine, CA 92618 Tel: (800) 595-0200 Fax: (949) 581-5997

ADVANCED STERILIZATION PRODUCTS

Division of Ethicon, Inc.  
a Johnson & Johnson company



Fiber Bronchoscope	BF-1T60	3.0mm x 835mm	As above
Fiber Bronchoscope	BF-P60	2.2mm x 835mm	As above
Fiber Bronchoscope	BF-MP60	2.0mm x 835mm	As above
Fiber Bronchoscope	BF-XP60	1.2mm x 835mm	As above
Portable Bronchoscope	MAF-TM	2.6mm x 835mm	As above
Portable Bronchoscope	MAF-GM	1.5mm x 835mm	As above
Video Bronchoscope	BF-MP160F	2.0mm x 835mm	As above
Video Bronchoscope	BF-XP160F	1.2mm x 835mm	As above
Video Bronchoscope	BF-1T180	3.0mm x 835mm	As above
Video Bronchoscope	BF-1TQ180	2.8mm x 835mm	As above
Video Bronchoscope	BF-P180	2.0mm x 835mm	As above
Video Bronchoscope	BF-Q180	2.0mm x 835mm	As above
Video Bronchoscope	BF-Q180AC	2.0mm x 835mm	As above

This letter is to confirm, as of this date, that the following Olympus medical devices can be effectively sterilized in the STERRAD<sup>®</sup> NX<sup>™</sup> standard cycle using a STERRAD<sup>®</sup> approved container or tray and based on specifications provided by Olympus Corporation that meet material and lumen claims for achieving sterile efficacy:

VISERA Camera Head	OTV-S7H-1D	No Channel	
VISERA Camera Head	OTV-S7H-1N	No Channel	
VISERA Camera Head	OTV-S7H-1NA	No Channel	
VISERA Camera Head	OTV-S7N-N	No Channel	
VISERA Camera Head	OTV-S7H-NA	No Channel	
OTV-SC Camera Head	OTV-SC	No Channel	
Light Guide Adapter	MAJ-1413		
Mouthpiece	MA-651		
CAP	MH-364		
Gas Supply Adapter	MAJ-1227		
BAL Plug	MH-192		
Autoclavable Video Adapter	AR-T10EA		Specified limitations**
Autoclavable Video Adapter	AR-T10QA		Specified limitations**
Autoclavable Video Adapter	AR-T10SA		Specified limitations**
Autoclavable Video Adapter	AR-T12EA		Specified limitations**
Autoclavable Video Adapter	AR-T12QA		Specified limitations**
Autoclavable Video Adapter	AR-T12SA		Specified limitations**

\*\* STERRAD<sup>®</sup> NX<sup>™</sup> reprocessing may reduce product life. Inspect prior to each use. If any irregularity is observed, discontinue use and replace with a new unit.

<sup>1</sup> URF-P5 flexible ureteroscope must have white indicator mark on control handle indicating NX compatible. Models without this mark have a lumen length which is outside the STERRAD<sup>®</sup> NX<sup>™</sup> lumen claims