



April 30, 2010

Re: **Compatibility of Olympus Small Diameter Flexible Endoscopes, Camera Heads and Accessories with the STERRAD[®] NX Sterilizer: Technical Information for Olympus Customers in the United States**

Dear Health Care Professional:

This letter provides information on the material and functional compatibility of Olympus small diameter flexible endoscopes, camera heads and accessories with the STERRAD[®] NX Sterilizer (STERRAD NX) manufactured by Advanced Sterilization Products (ASP), a Johnson & Johnson Company.

OLYMPUS SMALL DIAMETER FLEXIBLE ENDOSCOPES

Olympus is announcing the compatibility of the listed Olympus small diameter flexible endoscopes with STERRAD NX. Olympus flexible endoscopes that are compatible with STERRAD NX are identified by the presence of a white line on the control section (see figure below). Olympus flexible endoscopes that do not contain this identifying white line are NOT compatible with STERRAD NX. If you are uncertain if an Olympus small diameter flexible endoscope is compatible with STERRAD NX, please contact Olympus. Please note that the following statements apply only to STERRAD NX. The products listed below are not compatible with STERRAD 100NX.



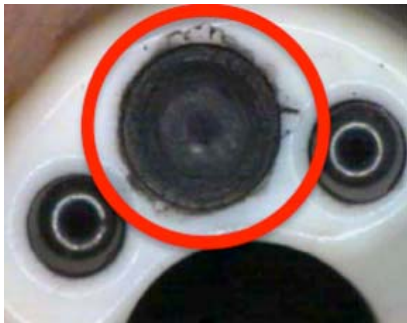
Compatible with limitation(s): The following statements apply only to Olympus small diameter flexible endoscopes with a white line present on the control section. This white line indicates that the device is compatible with STERRAD NX in accordance with the limitations stated below. Existing Olympus endoscopes for the models listed below that do not have a white line present on the control section are NOT compatible with STERRAD NX. Contact Olympus for information on upgrading older endoscopes to be compatible with STERRAD NX.

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Olympus has validated the material and functional compatibility of the listed Olympus endoscope models with a white line present on the control section following a minimum of 100 cycles in the STERRAD NX. Prior to 100 cycles in the STERRAD NX, cosmetic changes, such as discolorization of black anodized aluminum parts, may be observed. Following 100 cycles in the STERRAD NX, the listed models of Olympus small diameter flexible endoscopes with a white line on the control section may require a bending section or insertion tube replacement.

- BF-1T60
- BF-MP60
- BF-P60
- BF-XP60
- BF-MP160F
- BF-XP160F
- BF-1T180
- BF-1TQ180
- BF-P180
- BF-Q180
- BF-Q180-AC
- CHF-P60
- CYF-5
- CYF-5A
- CYF-V2
- CYF-V2R
- CYF-VA2
- ENF-V2
- ENF-VT2
- ENF-VQ
- LTF-V3
- LTF-VP
- LTF-VP-S
- LTF-VH
- LTF-160
- MAF-GM
- MAF-TM
- URF-P5
- URF-V

Materials of the flexible endoscope may be damaged or deteriorate after 100 cycles in the STERRAD NX. Olympus testing indicates that the adhesive around the distal end lens and bending section, the bending section cover, the coating of the insertion tube and universal cord, and the insertion tube itself may be damaged or deteriorate after 100 cycles in the STERRAD NX. Damage or deterioration from STERRAD NX reprocessing may add to preexisting damage/wear from prior use, accelerating the need for endoscope maintenance. Inspect the device according to the instructions provided in the Endoscope Manual prior to each use with specific attention to the materials listed above. Below are representative examples of material damage that may be observed after 100 cycles. If any damage or deterioration of the endoscope is observed, discontinue use of the endoscope and send it to Olympus for inspection and repair. Use of a damaged endoscope may pose a risk to patient safety.



Deterioration of adhesive around distal end lens



Bubbling of adhesive at bending section cover



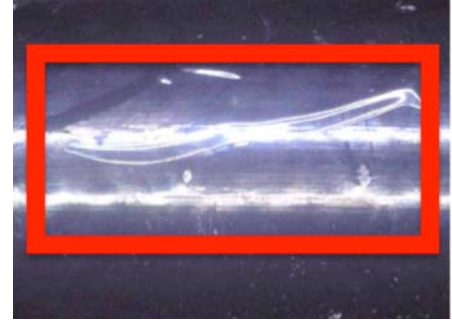
Cracking of bending section cover



Cracking of the insertion tube



Peeling of the universal cord tube coating



Detachment of insertion tube coating from surface

Not Compatible: All Olympus small diameter flexible endoscopes without the white line present on the control section are NOT compatible with STERRAD NX.

OLYMPUS CAMERA HEADS, VIDEO ADAPTERS/COUPLERS

Compatible: The following Olympus camera heads are compatible with STERRAD NX.

- OTV-S7H-1D/1N/1NA
- OTV-S7H-N/NA
- MAJ-554

Compatible with limitation(s): The following Olympus video products are compatible with STERRAD NX according to the specified limitations.

Model	Description	Limitation(s)
AR-T10EA AR-T10QA AR-T10SA	Video Adapter	STERRAD NX reprocessing may reduce product life. Inspect prior to each use. If any irregularity is observed, replace with a new unit.
AR-T12EA AR-T12QA AR-T12SA	Video Adapter	
OTV-S7ProH- HD-L08E	Camera Head	

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Not compatible: The following Olympus camera heads and video adapters/couplers are NOT compatible with STERRAD NX.

Cameras

- MH-972D/N/I
- MH-973D/N/I
- OTV-S6H-1F
- OTV-S6H-1L
- OTV-S7H-1D-F08E/L08E
- OTV-S7H-FA-E/Q
- OTV-S7H-1FA-E
- OTV-S7H-1NA-10E/12E/12Q
- OTV-S7H-NA-10E/12E/10Q/12Q
- OTV-S7H-VA
- OTV-S7ProH-HD-10E/10Q/12E/12Q
- OTV-SP1H-N-12E/12Q
- OTV-SP1H-NA-12E/12Q
- MAJ-387I

Video Adapters/Couplers

- A10-T1/T2
- AR-FX08E
- AR-LX08E
- AR-T10/10E/10Q/10S
- AR-T12/12E/12Q/12S
- AR-TF08E
- AR-TL08E
- AR-TL12S
- AR-TZ2
- AR-SX12E/12Q/12S
- AR-ZX20
- MH-999E
- MH-999Q
- MH-999S

OLYMPUS SURGICAL ACCESSORIES

Compatible: The following Olympus surgical accessories are compatible with STERRAD NX.

Model	Description
MAJ-1413	Light Guide Adapter
MA-651	Mouthpiece
MH-364	Cap
MAJ-1227	Gas Supply Adapter

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Compatible with limitation(s): The following Olympus surgical accessories are compatible with STERRAD NX according to the specified limitations.

Model	Description	Limitation(s)
MH-192	BAL plug	May be difficult to attach to the endoscope after 50 cycles. In this event, replace with a new MH-192.
MAJ-922	Rechargeable Miniature Light Source	After 100 cycles, the light source may malfunction. Specifically, the battery holder cover and/or buckle may break. Inspect the light source's battery holder cover and buckle for damage, and confirm that the battery holder cover is attached firmly by the buckle according to the Instruction Manual prior to each use. If any damage or deterioration is observed, discontinue use of the light source and replace with a new light source.
MAJ-1940	Cylinder Plug	May be difficult to attach to the endoscope after 50 cycles. In this event, replace with a new MAJ-1940.

Not compatible: The following Olympus surgical accessories are either NOT compatible or have not been tested to determine compatibility with STERRAD NX.

Model	Description
MAJ-524	Miniature Light Source
MD-493	Suction Valve
MAJ-207	
MAJ-669	Light Guide Adapter
MAJ-900	
MAJ-943	Scope connecting adapter for microscope
SH-1	Surgical telescope holder
MAJ-891	Forceps/Irrigation Plug
T1079	Grasping forceps
MAJ-1379	Trocar Introducer for LTF 5mm scope
MAJ-1235	Injection Adapter
ST-U1	Ureteroscope Sheath Director
MAJ-659	Lens Cleaning Sheath
MAJ-1537	
MAJ-579	Biopsy Valve
MD-495	

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NON-OLYMPUS REPAIRS

Olympus products listed as compatible with STERRAD NX are constructed of advanced materials with improved durability against oxidizing sterilization processes. Olympus cannot guarantee that products repaired by a non-Olympus facility will be compatible with STERRAD NX. As a result, this compatibility statement is invalid for products repaired by a non-Olympus facility. Moreover, if a device is repaired by a non-Olympus facility, the corresponding product warranty may be voided. In the event that your products 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. Olympus will honor the terms of the warranty stated in the respective product manuals even if damage is the result of reprocessing with STERRAD NX, in accordance with proper reprocessing guidelines.

CAUTIONS

- Flexible endoscopes with multiple lumens should NOT be reprocessed with STERRAD® NX Sterilizer since these devices fall outside of the current “Indications for Use”.
- Gas sterilization of some endoscopes requires the attachment of an ETO cap. If an ETO cap is required for ETO sterilization, attach the ETO cap for STERRAD sterilization. See the endoscope’s manual to determine if an ETO cap is required. For those endoscopes that require an ETO cap to vent the endoscope, attach the ETO cap prior to reprocessing in the STERRAD Sterilizer. Failure to attach the ETO Cap prior to reprocessing in the STERRAD sterilizer will result in expansion and rupturing of the bending section cover when a vacuum is drawn in the sterilization chamber.
- Always use an appropriate sterilization tray approved for use with the STERRAD NX Sterilizer.

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STERILIZATION EFFICACY

Testing performed by Olympus only evaluated the material and functional compatibility of Olympus products with the STERRAD NX sterilizer. ASP has confirmed sterilization efficacy of the listed Olympus products. Visit the STERRAD Sterility Guide at www.sterradsterilityguide.com to verify that your Olympus device falls within STERRAD Systems cleared claims for sterility.

If you have any questions regarding the compatibility of Olympus products with the STERRAD NX Sterilizer, contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024. Thank you.

Sincerely,

A handwritten signature in black ink, appearing to read "Bradley J. Catalone". The signature is fluid and cursive, with a long horizontal stroke extending to the right.

Bradley J. Catalone, Ph.D.
Director of Clinical Affairs

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