

July 24, 2014

Re: **Compatibility of Olympus Small Diameter Flexible Endoscopes, Camera Heads and Accessories with the STERRAD® NX Sterilizer: 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 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. For information regarding STERRAD® NX sterilization cycles, sterilization efficacy and Indications for Use, please contact ASP.

OLYMPUS SMALL DIAMETER FLEXIBLE ENDOSCOPES

Olympus is announcing the compatibility of the listed Olympus and Gyrus ACMI small diameter flexible endoscopes with STERRAD NX. Olympus flexible endoscopes that are compatible with STERRAD NX 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 STERRAD NX, please contact Olympus or visit the Interactive Reprocessing Guide at www.olympusconnect.com. Contact Olympus for information on upgrading older endoscopes to be compatible with STERRAD NX.



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

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Page 1 of 8



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 STERRAD[®] NX[®] Sterilization System. For example, the engraving fill material used to mark Gyrus ACMI instrumentation may be damaged by the STERRAD[®] NX[®] Sterilization System. Although this damage is generally defined as cosmetic, the material may be removed by the sterilization process.

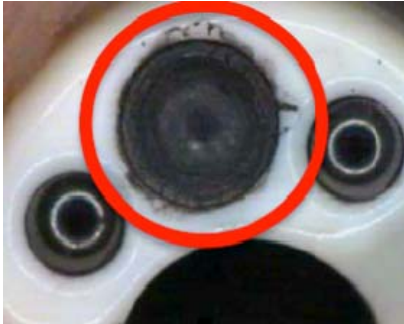
Type	Model(s)
BF	1T60/MP60/P60/XP60 MP160F/XP160F 1T180/1TQ180/P180/Q180/Q180-AC H190*/Q190*/1TH190*/P190*/XP190*
CHF	P60
CYF	V2/VA2/V2R/VH*/VHA*/VHR* 5/5A/5R
ENF	V2/VT2/VQ/V3*/VH*
LTF	160 V3 VH/VP/VP-S S190-5*/S190-10* 190-10-3D*
MAF	GM TM
URF	P5/ P6/P6R V/V2*/V2R*
DUR	D/ DBA/8ULTRA/8ULTRA-BA/8/8BA/8E/8EBA
AUR	7
ACN	2T/2TBA
ICN	2/2BA

*Although these Olympus models are compatible with sterilization in the STERRAD NX, they do not contain a white line on their control section.

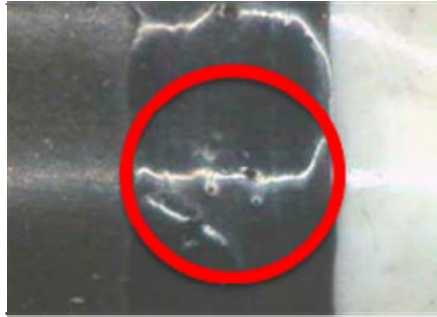
Materials of the flexible endoscope may be damaged or deteriorate after 100 cycles in the STERRAD NX. Olympus testing indicates that the adhesive around the distal end lens and bending section, the bending section cover, the coating of the insertion tube and universal cord, and the insertion tube itself 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.

Examples of possible damage to endoscopes:



Deterioration of adhesive around distal end lens



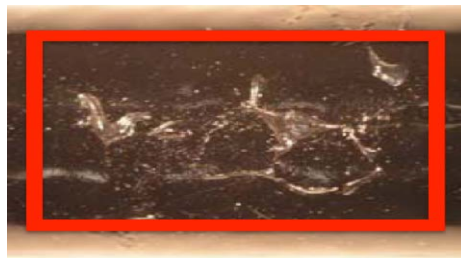
Bubbling of adhesive at bending section cover



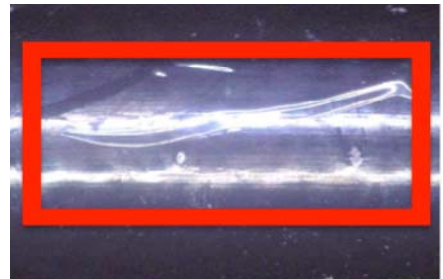
Cracking of bending section cover



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 that are either listed as not compatible in their respective reprocessing manuals or are listed as not compatible on the Interactive Reprocessing Guide at www.olympusconnect.com. 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 STERRAD NX, please contact Olympus or visit the Interactive Reprocessing Guide at www.olympusconnect.com

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OLYMPUS CAMERA HEADS, VIDEO ADAPTERS/COUPLERS

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

- OTV-SC (MAJ-554)
- OTV-S6H-N/D/1N/1D/NA/1NA
- OTV-S7H-N/NA/1D/1N/1NA/D-6M
- CH-S190-XZ-E/Q
- OTV-S7ProH-FD

Compatible with limitation(s): The following Olympus video adapters/couplers 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	When reprocessed more than 100 cycles, the surface of the camera cable may become tacky and require replacement. Inspect prior to use.
CH-S190-08-LB OTV-S7H-1D-L08E OTV-S7H-D-L08E	Camera Head	Although discoloration of the switches and black anodized aluminum parts may be observed, the functional performance is maintained.

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
- 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/Q/S

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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
MB-156	ETO Cap
MAJ-1538	Sterilization Cap
MAJ-1545	Scope ID Tag
MAJ-2079	Rigid Sheath
MAJ-2081	Sealing Cap
MAJ-2092	Forceps/Irrigation Plug

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.

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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 Dilator
MAJ-659	Lens Cleaning Sheath
MAJ-1537	
MAJ-579	Biopsy Valve
MD-495	
MD-51	Suction Valve Holder
MB-884	Syringe Plug
MAJ-1214	Water-resistant Cap
MAJ-1345	Lens cleaning sheath for LTF-V3
MH-507	Channel-opening cleaning brush
MAJ-1077	Suction cleaning adapter
MAJ-1219	
MAJ-222	
BW-15B	Channel cleaning brush
BW-7B	
BW-20T	
BW-9Y	

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 product has been repaired by such a facility, please contact the repair facility directly for compatibility information.

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

Certain components of the Olympus flexible endoscopes listed above as “compatible with cosmetic changes” will deteriorate over time with repeated reprocessing in the STERRAD NX. Specifically, the endoscope’s epoxy adhesives will deteriorate with repeated use. The following inspection procedure should be followed prior to each use to detect deterioration of the adhesives, objective lens and light guide lens.

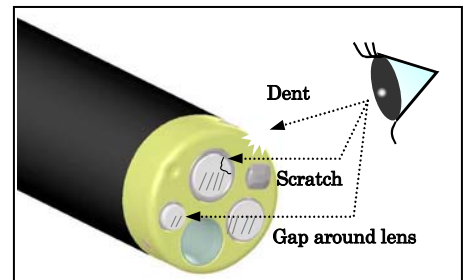
WARNING

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 and poses a risk to patient safety.

1. Wipe the surface of the lens 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.



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.

Functional damage to Gyrus ACMI instruments which is deemed to have been caused by use of the STERRAD[®] NX[®] Sterilization System **will** be covered under Gyrus ACMI’s Limited Express Warranty when such damage has been identified.

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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”.

When sterilizing a compatible flexible endoscope in a STERRAD NX 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 STERRAD NX. For those endoscopes that require an ETO Cap, 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. (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 STERRAD NX Sterilizers

STERILIZATION EFFICACY

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

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

Sincerely,

A handwritten signature in black ink, reading "Mary Ann Drosnock".

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