



July 24, 2014

Re: **Compatibility of Olympus Small Diameter Flexible Endoscopes, Camera Heads and Accessories with the DUO Cycle in STERRAD® 100NX Sterilizers: 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 DUO Cycle in STERRAD® 100NX Sterilizers manufactured by Advanced Sterilization Products (ASP), a Johnson & Johnson Company for use in the United States market. The DUO Cycle of STERRAD 100NX was specifically developed to decrease potential damage to sensitive materials. For information regarding STERRAD® 100NX sterilization cycles, sterilization efficacy and Indications for Use, please contact ASP.

OLYMPUS SURGICAL ACCESSORIES

Compatible: The following Olympus surgical accessories are compatible with DUO Cycle in the STERRAD® 100NX Sterilizers:

Product(s)	Model(s)
ETO Cap	MB-156
Light Guide Adapter	MAJ-1413
Mouthpiece	MA-651
Sterilization Cap	MAJ-1538
Cap	MH-364
BAL Plug [§]	MH-192
Gas Supply Adaptor [•]	MAJ-1227
Rechargeable Miniature Light Source	MAJ-922
Cylinder Plug [‡]	MAJ-1940
Scope ID Tag	MAJ-1545

[§]BAL plug may become difficult to attach to endoscope following reprocessing. In this event, replace with a new MH-192.

[•]After 100 cycles the battery holder cover and/or buckle may break. Inspect the 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. If any damage or deterioration is observed, discontinue use of this product and replace with a new one.

[‡] 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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OLYMPUS SMALL DIAMETER FLEXIBLE ENDOSCOPES

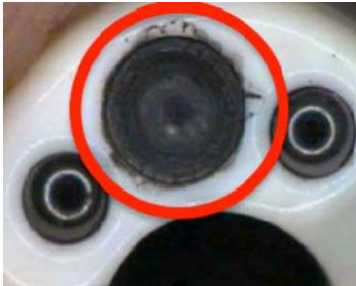
Olympus flexible endoscopes that are compatible with the DUO Cycle in the STERRAD 100NX are either listed as compatible in their respective reprocessing manuals or can be identified by the presence of a white line on the control section (see figure below). Not all compatible models will contain the white line on the control section. If you are uncertain if an Olympus small diameter flexible endoscope is compatible with the STERRAD 100NX DUO Cycle, please contact Olympus or visit the Interactive Reprocessing Guide at www.olympusconnect.com.



Compatible but with Cosmetic Changes: On the following models of Olympus small diameter flexible endoscopes, the surface of the adhesive on the bending section and the adhesive around the distal lenses became rough in less than 100 cycles. In addition, there was discoloration of anodized parts in less than 50 cycles. However, the functional performance of the instruments was still within the product specification after 100 cycles. If you intend to sterilize the following Olympus flexible endoscopes in the DUO Cycle of the STERRAD[®] 100NX, inspect the endoscope according to the procedure listed below prior to each use. The insertion tube may require replacement after 100 cycles due to adhesive degradation. 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.

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[®] 100NX[®] Sterilization System DUO Cycle. For example, the engraving fill material used to mark Gyrus ACMI instrumentation may be damaged by the STERRAD[®] 100NX[®] Sterilization System DUO Cycle. Although this damage is generally defined as cosmetic, the material may be removed by the sterilization process.

Examples of possible damage:



Deterioration of adhesive around distal end lens



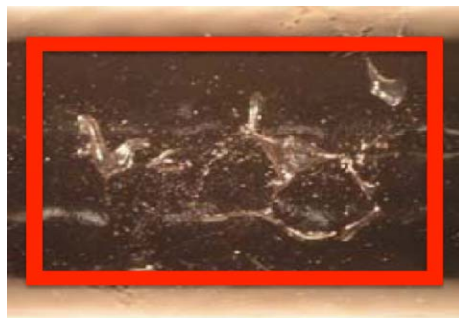
Bubbling of adhesive at bending section cover



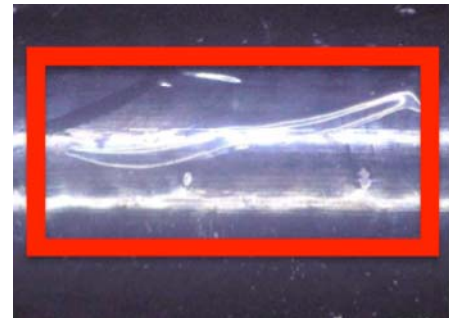
Cracking of bending section cover



Cracking of the insertion tube



Peeling of the universal cord tube coating



Detachment of insertion tube coating from surface



If these changes are acceptable, the following endoscopes and products may be processed in the DUO Cycle of the STERRAD® 100NX Sterilizers:

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 100NX DUO cycle, they do not contain a white line on their control section.

OLYMPUS VIDEO CAMERA SYSTEMS AND ACCESSORIES

Compatible: Olympus camera heads and video adapters for the following camera systems are compatible with DUO Cycle in STERRAD® 100NX Sterilizers:

- OTV-SC (MAJ-554)
- OTV-S6H-N/D/1N/1D/NA/1NA/1D-L08E³/D-L08E³
- OTV-S7ProH-HD-L08E¹
- OTV-S7ProH-FD
- OTV-S7H-N/NA/1D/1N/1NA/D-6M
- Video Adapters AR-T10EA (A4210A) / AR-T10SA (A4212A) / AR-T10QA (A4214A) / AR-T12EA (A4211A) / AR-T12SA (A4213A) / AR-T12QA(A4215A)²
- CH-S190-XZ-E/Q
- CH-S190-08-LB³

1When reprocessed more than 100 cycles by 100NX DUO Cycle, the surface of camera cable may become tacky and require replacement. Inspect prior to each use.

2When reprocessed in the 100NX, product life may be reduced. Inspect thoroughly before use. If any irregularity is observed on the adhesive joints or soldered parts of the endoscope, do not use.

3 Although discoloration of the switches and black anodized aluminum parts may be observed, the functional performance is maintained.

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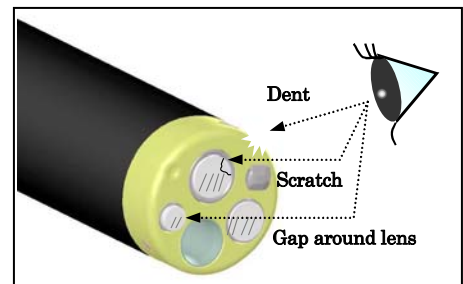
Inspecting Olympus Flexible Endoscopes for Deterioration of the Adhesives, Objective Lens and Light Guide Lens:

Certain components of the Olympus flexible endoscopes listed above as “compatible with cosmetic changes” will deteriorate over time with repeated reprocessing in the STERRAD 100NX. 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.



NON-OLYMPUS REPAIRS

Olympus cannot guarantee that any product repaired by a non-Olympus facility will be compatible with STERRAD 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 STERRAD® 100NX® Sterilization System DUO Cycle **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 STERRAD 100NX 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 100NX. 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 100NX 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 100NX 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® 100NX Sterilizers, contact your local Olympus sales representative or Technical Support at 1-800-387-0437. Thank you.

Sincerely,

A handwritten signature in blue ink that reads "Mary Ann Drosnock".

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