March 3, 2009

Re: Compatibility of Olympus Products with the STERRAD® 50 and 100S Sterilizers: Information for Olympus Customers in the United States

Dear Health Care Practitioner:

This letter provides information on the material and functional compatibility of Olympus products with STERRAD® 50 and 100S Sterilizers manufactured by Advanced Sterilization Products (ASP), a Johnson & Johnson Company. For information regarding STERRAD® 50 and 100S Indications for Use and sterilization efficacy, please contact ASP.

OLYMPUS FLEXIBLE ENDOSCOPES

According to the Indications for Use in the United States, the STERRAD® 50 and 100S Sterilizers are not indicated for sterilization of Olympus flexible endoscopes with lumens in the United States. All Olympus flexible endoscopes with lumens fall outside the lumen restrictions indicated in the STERRAD® 50 and 100S Indications for Use. The lumen materials or dimensions of other Olympus medical products may also fall outside these restrictions. Please refer to the product instruction manual or contact Olympus regarding lumen specifications.

OLYMPUS SURGICAL ACCESSORIES

Compatible: The following Olympus surgical accessories are compatible with STERRAD® 50 and 100S Sterilizers:

<table>
<thead>
<tr>
<th>Product(s)</th>
<th>Model(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BAL Plug§</td>
<td>MH-192</td>
</tr>
<tr>
<td>ETO Cap</td>
<td>MB-156</td>
</tr>
<tr>
<td>Grasping Forceps</td>
<td>T 1079</td>
</tr>
<tr>
<td>Gas Supply Adapter</td>
<td>MAJ-1227</td>
</tr>
<tr>
<td>Lens Cleaning Sheath</td>
<td>MAJ-659/1345</td>
</tr>
<tr>
<td>Light Guide Adapter</td>
<td>MAJ-669/900/1413</td>
</tr>
<tr>
<td>Miniature Light Source</td>
<td>MAJ-524</td>
</tr>
<tr>
<td>Rechargeable Miniature Light Source</td>
<td>MAJ-922</td>
</tr>
<tr>
<td>Mouthpiece</td>
<td>MAJ-651</td>
</tr>
<tr>
<td>Scope Connecting Adapter for Microscope</td>
<td>MAJ-943</td>
</tr>
<tr>
<td>Sterilization Cap</td>
<td>MAJ-1538</td>
</tr>
<tr>
<td>Suction Valve†</td>
<td>MD-493</td>
</tr>
</tbody>
</table>

§BAL plug may become difficult to attach to endoscope following reprocessing in the STERRAD 50 and 100S Sterilizers

†Suction Valve Cover may become difficult to attach to the valve body following reprocessing in the STERRAD 50 and 100S Sterilizers.
OLYMPUS SMALL DIAMETER FLEXIBLE ENDOSCOPES

Compatible but with Cosmetic Changes: On the following models of Olympus small diameter flexible endoscope without lumens, 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.

The insertion tube may require replacement after 100 cycles due to degradation of the adhesive.

If these changes are acceptable, the following endoscopes and products may be processed in STERRAD® 50 and 100S Sterilizers:

- ENF-GP
- ENF-V
- ENF-V2
- ENF-VQ
- LTF-V2
- LTF-V3
- LTF-VH
- LTF-VP

Not Compatible or Use Restricted: The following endoscope models and surgical accessories are either NOT compatible with STERRAD® 50 and 100S Sterilizers or are restricted from use because their lumens or materials fall outside the STERRAD® 50 and 100S “Indications for Use”.

- AF-Series
- BF-Series
- CHF-Series
- CYF-Series
- ENF-Series (except ENF-GP, ENF-V/V2/VQ)
- GIF-N30 & GIF-N230
- HYF-Series
- LF-Series
- LTF-V
- LTF-160
- LTF-240
- PEF-V
- PF-Series
- URF-Series
- Lens Cleaning Sheath (MAJ-659/1345)
OLYMPUS RIGID ENDOSCOPES AND ACCESSORIES

Compatible but with Cosmetic Changes: The following rigid endoscopes and accessory products may be sterilized in the STERRAD® 50 and 100S Sterilizers. Cosmetic changes, such as the discoloration of anodized parts may be observed in less than 50 cycles. However, functional performance was still within product specifications after 400 cycles.

- A-Cords
- Attachments
- Autoclavable Ureteroscopes
- Bridges
- Compact Uretero-Renoscopes
- Electrodes
- Forceps, Optical
- Hand Instruments, 3-9 Fr., Flexible/Semiflexible
- Irrigation Rings
- HF-Cables
- HF Electrodes, Flexible
- HF-Resection Electrodes
- Knives
- Light Guide Adapters, Mechanical
- Light Guide Adapters, Optical
- Light Guide Cables, Standard
- Obturators
- OP Telescopes, Autoclavable
- Sealing Caps and Sealing Rings
- Sheaths, Cystoscope and Resection
- Suction/Irrigation Instruments
- Telescopes, Autoclavable
- Trocar Tubes
- Trocar Spikes
- Ureteroscopes, Autoclavable
- Working Elements, Monopolar, Bipolar, for Knives or Probes
- Working Inserts with Albarran Lever
- Working Inserts with or without Working Channel
- Video Adapters, Autoclavable
- Video Telescopes, Autoclavable
- Verress Needles

It is necessary to confirm the dimensions of any channels/lumens to ensure that they fall within the current lumen restrictions listed in the STERRAD® 50 and 100S Sterilizer “Indications For Use”. Also, disassemble the instruments, if applicable, and open all stopcocks prior to sterilization. When sterilizing Olympus rigid endoscopes and accessories using the STERRAD® 50 and 100S Sterilizers, use an appropriate sterilization tray for the STERRAD® 50 and 100S Sterilizer. Contact ASP for further information on compatible sterilization trays.

Not Compatible or Use Restricted: The following products are either NOT compatible or are restricted from use with STERRAD® 50 and 100S Sterilizers because their lumens or materials fall outside the STERRAD® “Indications for Use”:

- Non-autoclavable Telescopes
- Bladder syringes
- Probes with Plugs
- Chrome-plated instruments
- Plastic Instrument Sterilization Trays
OLYMPUS VIDEO CAMERA SYSTEMS AND ACCESSORIES

Compatible: Olympus camera heads and video adapters for the following camera systems are compatible with STERRAD® 50 and 100S Sterilizers:

- Image Track-H
- OTV-SC (MAJ-554)
- OTV-S5 Series¹
- OTV-S6H-FA-E/S/Q and OTV-S6H-FA-E
- OTV-S6H-N/D/1N/1D/NA/NA
- OTV-S7Pro-H-FD
- OTV-S7Pro-H-D-10E/10Q/12E/12Q
- OTV-S7H-FA-E/Q and OTV-S7H-1FA-E
- OTV-S7H-N/NA/1D/1N/1NA/D-6M
- OTV-S7H-NA-10E/12E/10Q/20Q and OTV-S7H-1NA-10E/12E/12Q
- OTV-S7H-VA
- OTV-SX2 Series (MAJ-387I/387N)
- OTV-SP1-1H-N-12E/12Q and OTV-SP1-1H-NA-12E/12Q
- Video Adapters AR-FX08E/LX08E²
- Video Adapters AR-T1/T2²
- Video Adapters AR-TZ2/TF08E/TL08E/TL12S²
- Video Adapters AR-T10EA/T10SA/T10QA/T12EA/T12SA/T12QA
- Video Couplers MH-999E/999Q/999S³

¹Models with a silver threaded adapter connector on camera mount are compatible. Models with a black threaded adapter connector on camera mount are not compatible.

²Listed models with a silver coupler connector are compatible with cosmetic changes. Listed models with a black coupler connector are not compatible. Contact Olympus for additional details.

³Listed models with a silver attachment are compatible.

Compatible but with Cosmetic Changes: After less than 50 cycles the anodized parts of the following products showed some discoloration. However the functional performance of the instruments was still within the product specification up to 600 cycles. If these changes are acceptable, these products may be processed in STERRAD® 50 and 100S Sterilizers:

- OTV-S6H-1F/1L
- OTV-S7H-1D-F08E/L08E

Not Compatible: The Olympus camera heads and video adapters for the following camera systems are NOT compatible with STERRAD® 50 and 100S Sterilizers:

- Video Adapters A10-T1/T2
- OTV-S2
- OTV-S3
- OTV-S4
- OTV-SE
- OTV-SX
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.

CAUTIONS

- Flexible endoscopes with channels should NOT be reprocessed with STERRAD® 50 and 100S Sterilizers since these instruments fall outside of the current “Indications for Use”.
- When sterilizing a compatible flexible endoscope without channels in a STERRAD® 50 and 100S Sterilizer, follow the instructions in the Endoscope or Reprocessing Manual for ETO sterilization to determine if the endoscope requires an ETO cap. 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. (See endoscope instruction manual for additional details regarding the use of the ETO Cap).
- Always use the appropriate sterilization tray approved for use with STERRAD® 50 and 100S Sterilizers.

STERILIZATION EFFICACY

Olympus’ testing only evaluated the material and functional compatibility of Olympus products with STERRAD® 50 and 100S Sterilizers. Olympus has not tested nor confirmed the ability of STERRAD® 50 and 100S Sterilizers to sterilize Olympus products. Please contact ASP directly regarding all questions pertaining to sterilization efficacy and lumen restrictions.

If you have any questions regarding the compatibility of your Olympus endoscopy products with STERRAD® 50 and 100S Sterilizers, contact your local Olympus sales representative or the Olympus Technical Assistance Center at 1-800-848-9024. Thank you.

Sincerely,

Olympus