April 23, 2010

Olympus Statement Concerning STERIS System 1
Additional Information

As a follow up to the Olympus America Inc. statement published on December 23, 2009 concerning the FDA's actions with respect the STERIS System 1 (SS1), Olympus Winter & Ibe GmbH (Olympus) and Olympus America Inc. (OAI) would like to advise you of the following additional information.

FDA

As noted in our December 23, 2009 statement, the FDA has posted several documents regarding the SS1 matter. These documents can be found at http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm194411.htm. The documents include a transcript of the conference call with healthcare facilities hosted by the FDA on December 10, 2009, a "Questions and Answers" document, and a document listing legally marketed alternative sterilization methods to replace the SS1. If you haven't done so already, we strongly urge you to review the documents posted by the FDA in order to get a more complete understanding of this situation.

Among other things, the FDA states in these documents that STERIS Corporation (STERIS) has significantly modified the SS1, and that the FDA has not approved or cleared this modified product. Accordingly, the FDA has not determined whether the SS1 is safe or effective for its labeled claims, including claims that it sterilizes medical devices.

In a letter dated February 22, 2010 to endoscope manufacturers that have devices labeled for use with the SS1, the FDA states:

> *"If your devices are labeled for use with the SS1, you should revise your labeling to correct these violations as soon as possible by removing all statements indicating that your devices may be reprocessed with the SS1 and by specifying only legally-marketed reprocessing devices. FDA anticipates that you should be able to do this within one year."*

The FDA's letter also recommends that endoscope manufacturers take additional actions. A copy of this letter may be found through the link indicated above.

Olympus has identified a number of devices that list the SS1 as verified for material compatibility; please see list on the following page. In accordance with the FDA's direction, Olympus has removed references to the SS1 for these devices' Instructions for Use. The updated Instructions for Use, which list other reprocessing methods verified for material compatibility, are available on the Olympus Connect customer portal (www.olympusconnect.com).

Olympus looks forward to partnering with you to meet your reprocessing needs as you work to ensure the safety of your patients and staff. Please contact your local Olympus representative at 800-848-9024 or visit www.olympusamerica.com for more information on reprocessing alternatives to STERIS System 1.

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The following Instructions for Use manuals can be accessed by visiting www.OlympusConnect.com, selecting the “Product Support” button, and then selecting “Instruction Manuals.”

Instructions for Use Title	**New Document Number, Version**
Working Elements: A4744, A4745	7.035.526 6.3_02/10
Arthroscopy Trocars: A00507A, A7515, A7516, A7517, A7518, A7519, A7520, A70950A, A70951A, A70954A, A70955A, A70959A, A70970A, A70971A, A70974A, A70975A, A70976A, A70977A, A70978A, A70979A, WA00508A, WA70949A, WA70951B, WA70952A, WA70953A, WA70990A, WA70991A, WA70992A, WA70993A, WA70994A, WA70995A	7.045.876 12.1_02/10
Working Elements, Guiding Tubes: A00561A, A00562A, A22061A, A22063A, A22065A, WA22066A, WA22067A	7.049.876 13.4_02/10
Video Ureteroscope, Attachment, Sealing Cap: WS1672/1, WA00395A, WA00387A	W7.051.519 1.1_02/10
Telescope: WS1746/1	W7.051.529 1.3_02/10
Working Elements: WA22366A, WA22367A	W7.051.776 2.7_02/10
Needle for Fascia Closure: WA51203A	W7.051.816 3.1_02/10
Telescope (Laryngoscope): WA96100A, WA96105A	W7.051.906 2.1_02/10
Sinuscopes: WA96200A, WA96201A, WA96202A, WA96203A, WA96204A, WA96205A, WA96206A, WA96208A	W7.051.926 1.3_02/10

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