Date: April XX, 2015

URGENT: MEDICAL DEVICE RECALL

Attention: Surgical Risk Management Department

Products: TS101DC - Tubeset Declog Diego Elite
TS100S - Tubeset Standard Diego Elite

Lots: Lot numbers JC929332 and below for product TS100S and JC924165 and below for product TS101DC

Dear Health Care Practitioner:

Olympus has become aware of an issue that requires your attention. This letter pertains to the Olympus Tubesets for Diego Elite, ("tubeset") referenced above, which are supplied as single-use, sterile devices intended to provide irrigation and suction when used with the Diego elite system. Our records indicate that you have purchased affected tubeset(s).

Olympus America Inc. ("Olympus") is recalling all packages of the above Diego Elite Tubesets due to compromises in sterile packaging that may allow a breach of the package's sterile barrier and may compromise the sterility of the product. The breach may not be easily seen.

Olympus has not received any complaints of injury associated with compromised sterile packaging. However, it is possible that use of non-sterile product may introduce microbes and increase the potential for postoperative infection. Accordingly, if one or more of your patients have undergone a procedure using this product, you must make a determination as to what, if any, medical actions are necessary regarding such patients.

Olympus requires you to take the following action:

1. Immediately cease any further use of any affected product you have, remove it from your inventory and quarantine it until it is shipped back to us.
2. Call your Olympus customer service representative at 1-888-524-7266 to obtain a Returned Goods Authorization so that you may return the product with no charge to you. Olympus will issue a credit or replacement to your facility for any returned product.
3. Please note on the enclosed questionnaire that you have received this information.
4. Fax the completed questionnaire to 484-896-7128 regardless of whether you have any affected inventory at your facility.

In addition, if you may have further distributed this product, please identify your customers, notify them at once of this product recall, and appropriately document your notification process. Your notification to your customers may be enhanced by including a copy of this recall notification letter.

This recall is being made with the knowledge of the U.S. Food and Drug Administration ("FDA"), so it is important for you to document in writing all of your actions regarding this recall as they may be audited by the FDA.

Olympus regrets any inconvenience from this recall and fully appreciates your prompt cooperation in addressing this situation. Please do not hesitate to contact me directly at 484-896-5688 or at laura.storms@olympus.com for any additional information concerning this matter.

Sincerely,

Laura Storms
V.P., Regulatory/Clinical Affairs & Quality Assurance