OLYMPUS

Date: August 26, 2014

URGENT: MEDICAL DEVICE RECALL

Attention: Surgical Department

Products: **Item Numbers:**
3345 - Everest BiCOAG® MOLly® Forceps, 5mm/45cm
3345PK - PKS™ MOLly® Forceps, 5mm/45cm
3640 - Everest BiCOAG® Macro-Jaw Forceps, 5mm/45cm
3640PK - PKS™ Macro-Jaw Forceps, 5mm/45cm
3844 – Everest BiCOAG® LP Scissors, 5mm/45cm
910010PK - PKS™ MOLly® Forceps, 5mm/45cm

Lots: All product manufactured before July 28, 2014. Affected product will have an expiration date earlier than August, 2017

Dear Health Care Practitioner:

Olympus America Inc. ("Olympus") has become aware of an issue that requires your attention. This letter pertains to the 45 centimeter length Gyrus ACMI MOLly Forceps, Macro-Jaw Forceps, and Scissors ("forceps") referenced above, which are supplied as single-use, sterile devices intended for the electrosurgical coagulation, mechanical grasping, and dissection of tissue during the performance of laparoscopic and general surgical procedures. Our records indicate that you have purchased forceps which are within the shelf life and manufacture date stated above.

Due to an anomaly in the packaging process, it is possible that a defective seal could be present 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 defective package seals. 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 Return Material Authorization ("RMA") in order to return the product at no charge to you. Olympus will issue a credit or replacement to your facility for any returned forceps/scissors.

OLYMPUS AMERICA INC.
3500 CORPORATE PARKWAY, P.O. BOX 610, CENTER VALLEY, PA 18034-0610
TELEPHONE (484) 896-5000

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

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