February 19, 2014

URGENT: MEDICAL DEVICE RECALL

Attention: OR Manager, Surgery Department
           Risk Management Department

Products: 006889-901 Disposable Falope-Ring Band Kit, Disposable Dual Incision, 8 mm, 32 cm, without 8 mm Trocar / Cannula (8 / pack)
          005280-901 Disposable Falope-Ring Band Kit, Disposable Dual Incision, 8 mm, 32 cm, with 8 mm Trocar / Cannula (8 / pack)

Lots: MK761655, MK764022, MK767655, MK526401

Dear Health Care Provider:

Olympus Corporation of the Americas ("Olympus") has become aware of an issue that requires your attention. This letter pertains to the Gyrus ACMI Disposable Falope-Ring® Band Applicator Kit, ("Falope Kit") referenced above, which are supplied as single-use sterile devices. The Disposable Falope-Ring Band Applicator Kits are intended for female sterilization (permanent contraception). Our records indicate that you have purchased Disposable Falope Kit(s) from an affected lot(s).

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 or 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 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
Olympus Disposable Falope-Ring Band Applicator Kit Recall

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I have received the recall information on the Olympus Disposable Falope-Ring Band Applicator Kits referenced above and understand that I need to inspect my inventory, discontinue use of any affected product and return any affected product in my inventory.

I have:

    ______ checked my inventory and no longer have this product in inventory

    ______ checked my inventory, and have the following number of affected products: ______

Facility: __________________________________________________________

Address: __________________________________________________________

City: ____________________________ State: _____________ Postal Code: ______

Your Name: _______________________________________________________

Your Phone number: _______________________________________________

Please fax this completed reply form to Olympus at (484) 896-7128