OLYMPUS

Date: October 21, 2014

URGENT: MEDICAL DEVICE RECALL

Attention: OR Manager, Surgery Department
Risk Management Department

Products: 006889-901 Disposable Dual Incision, 8 mm, 32 cm Falope-Ring Band Applicator Kit (8/PK)
005280-901 Disposable Dual Incision, 8 mm, 32 cm Falope-Ring Band Applicator Kit w/8mm Trocar / Cannula (8/PK)

Lots: Various – All product manufactured between September 22, 2009 and September 22, 2014. The product will have an expiration date between September 22, 2014 and September 22, 2019.

Dear Health Care Practitioner:

Olympus America Inc. ("Olympus") is recalling all packages of Falope-Ring® Band Applicator kits ("Falope Kit") due to compromises in sterile packaging that could be associated with bacterial contamination that might lead to patient infection. Olympus has received complaints of alleged infection associated with defective package seals.

This letter pertains to the Gyrus ACMI Disposable Falope Kit referenced above, which are supplied as single-use, sterile devices intended for female sterilization (permanent contraception). Our records indicate that you have purchased affected Falope Kit(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.

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 for you to 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.

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

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

OLYMPUS

Olympus Disposable Falope-Ring Band Applicator Kit Recall

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005280-901 Disposable Dual Incision, 8 mm, 32 cm Falope-Ring Band Applicator Kit w 8 mm Trocar / Cannula (8/PK)

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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 Name: (Please do not abbreviate)

_____

Address:

_____

City:

_____

State:

_____ Postal Code: _____

Your Name: _____

Your Phone number: _____

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

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