OLYMPUS

Date: February 7, 2017

URGENT: MEDICAL DEVICE RECALL

Attention: Surgical Risk Management Department

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

Lots: JC621742, JC626143, JC626144, JC626145, JC627148, JC627149, JC631662, JC631663, JC631664, JC632250, JC632251, JC632256, JC632257, JC632258, JC632259, JC632260, JC632261, JC632262, JC632263, JC632264, JC632265, JC632266, JC632267, JC632268, JC633647, JC633648, JC633649, JC633654, JC633655, JC633656, JC633664, JC633665, JC633666, JC984886, PWO-303239, PWO-303401A, PWO-303401B, PWO-303401C, RWK2-JC625880, RWK2-JC625881, RWK-JC625880, RWK-JC625881, RWK-JC625882

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 a problem with the internal drive shaft that may cause it to become disengaged, stopping the blade from spinning.

Olympus has not received any reports of injuries relating to drive shaft disengagement. However we are conducting this action out of an abundance of caution and to ensure the quality of the product in the field.

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 Materials Authorization in order to return the product at no charge to you. Olympus will issue a credit or replacement to your facility for any returned product.
3. Please note on the enclosed Reply Form that you have received this information.
4. Fax the completed Reply Form to Olympus Regulatory Affairs Department at (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 Affairs & Quality Assurance

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