



Date: August XX, 2016

URGENT: MEDICAL DEVICE RECALL

Attention: Surgical Risk Management Department

Products: TS100S - Tubeset Standard Diego Elite

Lots: JC590857, JC590858, JC594867, JC598903, JC598911, JC598913, JC984883, JC984886, JC594866, JC597337, JC598915, JC601077, JC984882, JC984885

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 is recalling all packages of the above Diego Elite Tubesets due to a potential problem with the internal drive shaft that may cause it to become disengaged, stopping the blade from spinning.

Olympus has not received any complaints relating to drive shaft disengagement. However we are conducting that 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 xxx-xxx-xxxx 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 xxx-xxx-xxxx 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.

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

xxx-xxx-xxxx or at E-MAIL@olympus.com for any additional information concerning this matter.

Sincerely,

Signature Block