



Date: August 31, 2016

URGENT: MEDICAL DEVICE REMOVAL

Attention: Surgical Risk Management Department

Affected Products: TS100S - Tubeset Standard Diego Elite

Lots: JC590857
JC590858
JC594867
JC598903
JC984883
JC984886

Dear Health Care Practitioner:

Olympus is implementing a product removal action for the above-identified lots of the TS100S Tubesets for Diego Elite ("tubesets"). Please discontinue use of the affected products.

These tubesets are supplied as single-use, sterile devices intended to provide irrigation and suction when used with the Diego Elite system. The Diego Elite is intended for cutting, coagulation, drilling, debriding and removal of bone, and soft and hard tissue in general Ear, Nose & Throat, Sinus/Rhinology/Nasopharyngeal/Laryngology and Head & Neck procedures.

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.

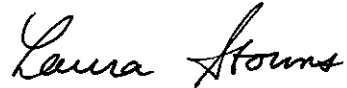
Olympus has not received any complaints relating to drive shaft disengagement to date. However we are conducting this action to ensure the quality of the product in the field.

Our records indicate that you have purchased affected tubesets. 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 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 return the enclosed questionnaire and note 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 regrets any inconvenience from this action 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,

A handwritten signature in cursive script that reads "Laura Storms".

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

Enc.