



Date: January XX, 2017

URGENT: MEDICAL DEVICE RECALL

Attention: Health Care Practitioner

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 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 assessed the risk and determined that there is minimal risk to patients or users should the affected product continue to be utilized, and no risk to patients who may already have been treated with affected product. 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.

What does this mean for you as an Olympus customer?

1. An Olympus representative will work with your supply team to identify and exchange affected inventory you may have in your warehouse. Any further use of any affected product you have needs to be ceased.
2. Olympus will issue a credit or replacement to your facility for any product with the above lot numbers.
3. Please note on the enclosed reply form that you have received this information and return it to the Olympus representative.

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