OLYMPUS IRELAND
KeyMed House, Calmount Park, Ballymount, Dublin 12
Telephone: (01) 426 0100
e-mail: info@olympus.ie website: www.olympus.ie

20 February 2017

URGENT: MEDICAL DEVICE RECALL NOTICE
Action Identifier Number: **240**
Type of Action: **Recall**

Affected product:

TS100S – Olympus Diego Elite Tubeset, Standard
TS101DC – Olympus Diego Elite Tubeset, Declog

Affected Lot numbers:

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 Customer

Olympus has become aware of an issue with the above Olympus Tubesets for Diego Elite ("tubeset"), 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 utilised. There is 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 field.

Action to be taken by the end-user:

1. Pass this notice to all those within your facility who need to be made aware of its contents;

2. Cease any further use of affected products, remove them from your inventory and quarantine them until they are returned to Olympus;

3. Olympus will issue a credit or replacement to your facility for any product with the above lot numbers. If your preference is for a replacement, an Olympus representative will work with your supply team to identify and exchange affected product you may have in your inventory.

4. Please confirm you have received this information by completing and returning the attached Medical Device Recall Notice Reply Form.

We appreciate your cooperation and apologise for any inconvenience this may cause. If you have any questions or would like further information, please do not hesitate to contact the Olympus Helpdesk on 01 426 0100.

Yours Sincerely

Robert Griggs

Quality and Regulatory Affairs General Manager

Enc. Medical Device Recall Notice Reply Form

Date: 20 February 2017

URGENT: MEDICAL DEVICE RECALL NOTICE REPLY FORM

Affected product:

TS100S – Olympus Diego Elite Tubeset, Standard
TS101DC – Olympus Diego Elite Tubeset, Declog

Affected Lot numbers:

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

Please send the completed and signed reply form by post, fax or a digitally scanned e-mail to:

Ms Lynette Moran – Office Manager: Olympus Ireland
Email: info@olympus.ie
Fax: 01 426 0123

Dear Ms Moran

We confirm we have received your Medical Device Recall Notice on the Diego Elite Tubesets referenced above and understand that we need to return any products in our inventory.

We have (please tick as applicable):

☐ Checked our inventory and no longer have any of the above products.

☐ Checked our inventory and will be sending back the following number of Tubesets: _____

Name and Job Title: _____

Hospital name: _____

Address: _____

_____

City: _____ Post Code: _____