

Date: 29 April 2015

## URGENT: MEDICAL DEVICE RECALL

Action Identifier Number: **202**

Type of Action: **Recall**

Affected Products: **TS101DC - Tubeset Declog Diego Elite**  
**TS100S - Tubeset Standard Diego Elite**

Affected Lot Numbers: All products manufactured before April 2015 including lot ranges listed below;

- **TS101DC: XX803643 to XX922827**
- **TS100S: XX757969 to XX920343**

Dear Customer,

Olympus has become aware of an issue that requires your attention. This letter pertains to the Olympus Tubesets for Diego Elite, 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 Tubesets.

Olympus are recalling all packages of the above Diego Elite Tubesets due to compromises in sterile packaging that may allow a breach of the package's sterile barrier and may compromise the sterility of the product. The breach may not be easily seen.

Olympus has not received any complaints of injury associated with compromised sterile packaging. However, it is possible that use of non-sterile product may introduce microbes and increase the potential for postoperative infection. Accordingly, if one or more of your patients have undergone a procedure using this product, you must make a determination as to what, if any, medical actions are necessary regarding such patients.

**Action to be taken by the user:**

1. Cease any further use of the affected devices.
2. Call Olympus Customer Services (01702 616333) to obtain a Return Materials Authorisation number. This will allow the product to be returned to Olympus KeyMed free of charge.
3. Return affected devices for the attention of Stephen Luck.  
  
Olympus KeyMed Olympus KeyMed  
Goods in 4  
The Cordwainers  
Southend on Sea  
SS2 5RU
4. Complete and return the attached reply form by 10 May 2015. Note that even if there is none of the affected inventory present in your stock, you are still required to complete and return the enclosed reply form.
5. Pass this notice to all those who need to be made aware within your organisation, or to any organisation where the potentially affected devices have been transferred.

We appreciate your cooperation and apologise for any inconvenience this may cause and we replace any affected product returned to us. If you have any questions, please do not hesitate to contact your customer service representative.

Yours Sincerely,

ROBERT GRIGGS  
General Manager – Quality Management and Regulatory Affairs

Enc. Reply Form

Date: 29 April 2015

**URGENT: FIELD SAFETY NOTICE REPLY FORM**

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

Mr Robert Griggs – General Manager – Quality Management and Regulatory Affairs

E-Mail: [robert.griggs@olympus.co.uk](mailto:robert.griggs@olympus.co.uk)

**Important Field Safety Notice information concerning;****TS101DC - Tubeset Declog Diego Elite****TS100S - Tubeset Standard Diego Elite**

Dear Sir

We confirm that the following

☐ Affected devices are currently held at this site and we shall be returning them,

Model	Quantity Shipped	Lot Number

or,

☐ We confirm that we have used all quantities of the affected devices we have purchased from Olympus and no will be returned.

Name: \_\_\_\_\_

Hospital \_\_\_\_\_

Department: \_\_\_\_\_

Signature \_\_\_\_\_

Date \_\_\_\_\_