

19 June 2018

Attention to: Healthcare Institution
cc: Chairman Medical Board and relevant Head of Departments

MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION

RE: ZY5154 150cm Y Extension Tube Dual Check Valve <2068 Kpa300 – Lots 1711008 & 1712015

Dear Customer,

Imaxeon Pty Ltd, product owner of the above medical device, has been notified by the Wuxi Yeso-med, manufacturer of the device, to initiate a recall of two lots - 1711008 and 1712015 – which have experienced a number of complaints relating to leakage at the connector-tubing bond.

The product owner has advised that the affected lots be quarantined. Please confirm the quantity of tubes in your inventory.

O'Connor's will be in contact to arrange for the return and replacement of the affected product.

Kindly return the completed form as below via fax (+65 6470 3000) or email (enquiries@oconnors.wbl.com.sg).

We appreciate your cooperation and sincerely regret any inconvenience.

Yours Sincerely,



Stanley Yee
General Manager

On behalf of O'Connor's Singapore Pte Ltd

CUSTOMER RESPONSE FORM

Field Safety Corrective Action for ZY5154 150cm Y Extension Tube Dual Check Valve <2068 Kpa300 – Lots 1711008 & 1712015

Impacted Lots	Balance Quantity Unused
1711008	
1712015	

Customer/Institution Name:	
Contact Person Name/Title:	
Phone:	
Email:	
Address:	
Total Quantity:	
RGA #: (if returning product)	

Signature:

Date:



Product Recall Notification – ZY5154 – Lots 1711008 and 1712015

Dear Distributor,

Imaxeon has been notified by the Wuxi Yeso-med, manufacturer of the ZY5154 Extension Tube with Y-Connector that they are initiating a recall of two lots - 1711008 and 1712015 – which have experienced a number of complaints relating to leakage at the connector-tubing bond.

Please quarantine the product as advised, and confirm the quantity of tubes, both in your inventory, and at your customers inventory, where known.

Imaxeon Product Supply will be in contact to arrange for the return and replacement of the affected product.

Return the completed form to regulatory@imaxeon.com

We appreciate your cooperation and sincerely regret any inconvenience.



Derby Chang
QA Manager
Imaxeon Pty Ltd
15 June 2018

Distributor	
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	Qty at Distributor (ea)	Qty at Customer (ea)
1711008		
1712015		