

URGENT: CUSTOMER NOTIFICATION/RECALL COMMUNICATION LETTER

Date: 07 Dec 2019 to: Alloplus

This letter is to inform you that Innovative Design Orthopaedics (IDO) is recalling the following:

Product Name	Class	Part number	Batch number
Verso Shoulder Stemmed Humeral X-Large	III	124563	A14097-A
Verso Shoulder Humeral Shell Small	III	124564	A14037-A
Verso Shoulder Humeral Shell Large	III	124566	A15003-A

Reason for recall

The recall has been initiated due to non-conformance raised by the notified body, BSI. According to BSI, company reporting regarding reprocessing of the coated implant parts was incomplete and inadequate.

IDO is not aware of any incidents and/or adverse events that resulted from use of the products identified in the table above.

Potential Risk

A potential risk may include compromise of the mechanical properties of the re-coated parts and residues of the reprocessing agent that may remain on the product.

Actions for customers:

- 1) Immediately examine your inventory and quarantine this product;
- 2) Immediately discontinue distribution of this product;
- 3) Notify to your National Competent Authority about the recall process;
- 4) Return the product identified in the table above to: Innovative Design Orthopaedics Limited
Main office address: 6 Brewery Court, High Street Theale, Reading, Berkshire RG7 5AJ UK.
- 5) If you may have further distributed this product, please identify those sites and notify them at once of this product recall. Your notification to your customers should include a copy of this recall notification letter;
- 6) Please complete and return the enclosed "Customer Recall Response Form" as soon as possible and email the form to: gadi.sonnino@idorth.com or orna@ad-or.com.

Your assistance is appreciated.

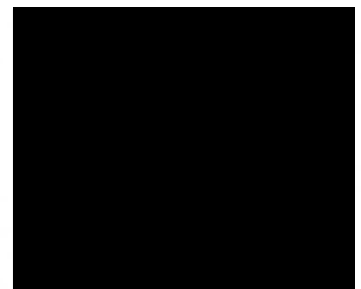
I apologize for any inconvenience this may cause you.

If you have any questions, please do not hesitate to contact us at:

T: +44(0)33020200840

F: +44(0)33020200841

E: info@idorth.com



CUSTOMER RECALL RESPONSE FORM

Please send completed response form to: gadi.sonnino@idorth.com or orna@ad-or.com

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Verso Shoulder Stemmed Humeral X-Large	III	124563	A14097-A
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- ☐ I have read and understand the sub-recall instructions provided in the Customer Notification/Recall Communication letter dated _____.
- ☐ I have checked my stock and have quarantined inventory consisting of _____ items.
- ☐ I have identified and notified to hospitals that were shipped and have communicated.
- ☐ I have identified and notified hospitals that were shipped this product and have communicated that we are conducting recall of this item.

Date of communication: _____

Method of communication: _____

Have there been any Adverse Events associated with removed product? ☐ Yes ☐ No

If yes, please explain: _____

Please Complete Contact Information for Person Completing Response	
Name:	
Title:	
Tel Number:	
Address:	
Date:	
Signature:	