

Smith & Nephew, Inc.
1450 Brooks Road
Memphis, TN 38116
USA

1-901-396-2121
1-800-821-5700
www.smith-nephew.com



Urgent Medical Device Recall Notice
R-2018-24

May 29, 2018

<Insert Address>

This letter is to inform you that Smith & Nephew Inc., have voluntarily initiated a field action to remove a group of VISIONAIRE LIGHTWEIGHT ALIGNMENT RODS due to a manufacturing error. The diameter of the rod is oversized, preventing mating with the VISIONAIRE Alignment Connector.

Please see product details below:

Product Number	Description	Batch Number
71440302	VISIONAIRE LIGHTWEIGHT ALIGNMENT ROD	17HCL0003F
		17HCL0006E
		17HCL0004E
		17HCL0005E

Shipment Date: December 8, 2017 through April 20, 2018

Potential Risk of Use of the Product

The alignment rod will not mate with the VISIONAIRE connector. A backup device is used to perform the alignment verification. The backup device is a standard drop rod instrument that is readily available; therefore, the risk of an adverse health consequence is low.

Required Actions:

- Please follow the instructions on the attached Response Form.

Enclosure: Response Form



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PLEASE COMPLETE ALL ITEMS AND RETURN WITHIN 5 DAYS OF RECEIPT

Required Actions:

1. Please inspect your inventory and locate any devices from the listed product and batch numbers on the first page of this Field Action Notification, and quarantine them immediately.
 - a. If you are a distributor, you must notify your customers of the field action and ensure that these actions are carried out.
2. If you have no product to return, please put an X in the appropriate location below.
3. If you have product to return, please list the batch numbers and quantities of each batch that you are returning in the appropriate boxes below.
4. Complete the remainders of the form sign and send to FieldActions@smith-nephew.com or fax to 901-566-7975.

Please Note – even if you have no product to return, this form must be completed, signed and returned.

5. Once the form is received by Smith & Nephew, you will be sent a Return Authorization (RA) number.

If you have any questions or concerns regarding this recall please contact FieldActions@smith-nephew.com.

No Product to Be Returned

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Product Part Number	Batch Number (List Specific Batch #'s to be Returned)	Quantity of Units to be Returned

We hereby confirm that we are aware of this Medical Device Field Action and it has been communicated within our organization.

Printed Name (required): _____ Title: _____

Signature (required): _____ Date (required): ____/____/____

Email: _____ Telephone: (____) _____ - _____

S&N Account Number: _____ RA Number (S&N use only): _____

Name of Organization(s) Covered by Response: _____

Return affected product to: Smith & Nephew | Attn: Global Field Actions | Building G, 1450 Brooks Rd. East| Memphis, TN 38116