
Urgent Field Safety Notice

Exactech Optetrak Asymmetric Hi-Flex Femoral Component, Sz 3, Left and Right
FSCA-identifier: 09302014
Type of action: Recall

Date: September 30th 2014

Attention: **All staff who may use or handle these devices**

Details on affected devices:

Catalog Number	Serial Range	Device Description
244-02-03	2925147 - 2925194	Optetrak Asymmetric Hi-Flex Femoral Component, Size 3, Left
244-03-03	2925246 - 2925293	Optetrak Asymmetric Hi-Flex Femoral Component, Size 3, Right

Description of Issue: Exactech has identified a portion of the products above as being incorrectly labeled. The outer and inner labeling incorrectly identifies the side designation for the device (i.e., Right as Left, or Left as Right). The correct part number is marked on the device itself.

Clinical Impact (Risk to Health): If the labeling error were to result in a device being implanted on the incorrect side, there are no anticipated adverse health consequences. The left and right Optetrak Hi-Flex PS femoral implants differ only in the anterior flange geometry. The inner patella groove, articulating surfaces, and implant fit to the underlying bone are the same.

Advice on action to be taken by the user:

- **Immediately cease distribution or use of these products.**
- **Extend this information to your accounts that may have this product in their possession.**
- **Verify whether you have any of the subject femoral components from the specified serial number ranges.**
- **Acknowledge receipt of this notice by faxing back the attached form.**
- **Return affected product as instructed on the attached form.**

Transmission of this Field Safety Notice:

This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.



2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

Contact reference person:

<<Name>>

National Distributor for Exactech affected devices:

<<Address>>

Thank you for your prompt attention to this matter. Though we do not believe that this issue has an impact on patient safety at this time, we are taking this action to ensure the health and safety of patients and the users of our products. Corrective actions of this type are collaborative efforts and require your participation to be effective. We regret any inconvenience that this action may cause, but we appreciate your understanding as we take action to ensure patient and customer satisfaction.

The undersigned confirms that this notice has been notified to the appropriate Regulatory Agency.

Darrell J. Kassner
Sr. Director, Regulatory Affairs
Exactech, Inc.

Attachment: Response form



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RESPONSE FORM - RECALL FAX NOTICE

Please check the appropriate box.

	I do not have any of the subject Optetrak [®] Hi-Flex [®] PS Femoral Implants. 244-02-03 (2925147 – 2925194) 244-03-03 (2925246 – 2925293)
	I have one or more of the subject Optetrak [®] Hi-Flex [®] PS Femoral Implants in my inventory and will be returning them to Exactech. 244-02-03 (2925147 – 2925194) number returning _____ 244-03-03 (2925246 – 2925293) number returning _____

Distributorship

Name and Title (Print)

Name (Signature)

Thank you in advance for your prompt attention to this matter. According to policy, please fax back this response form within 48 hrs of receipt of the notice and contact your Exactech representative to confirm quantities at your location and arrangements for product return and inventory restocking.

National Exactech representative

<<Name>>
<<Address>>
<<Contact>>