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**Urgent Field Safety Notice**

Exactech Equinoxe Modular and Non-Modular Pilot Tip Reamers

**FSCA-identifier: 05232017-03**

**Type of action: Field Advisory**

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Date: May 23, 2017

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

**Description of Issue:**

Exactech has updated the surgical technique for implantation of the Equinoxe Platform Shoulder System to clarify the proper technique for use of the Pilot Tip Reamers, i.e., to include a caution statement that the surgeon should avoid applying a bending force to the pilot tip reamer and should avoid using the reamer to retract the humeral head, as this may result in instrument breakage.

The updated surgical techniques, Lit# 718-01-30 rev J, can be found on the Exactech website ([www.exac.com](http://www.exac.com)) or can be obtained by contacting Customer Service at Exactech, Inc., 2320 NW 66th Court, Gainesville, FL 32653-1630 USA, (800) 392-2832, or FAX (352) 378-2617.

**Clinical Impact (Risk to Health):**

Exactech has received reports of instrument breakage, which may result in a broken instrument piece left in a patient.

**Details of the affected devices:**

Catalog Number	Device Description	Lot
321-25-01, 321-25-38, 321-25-42, 321-25-46 321-45-01, 321-45-38, 321-45-42, 321-45-46 321-05-01, 321-05-38, 321-05-42, 321-05-46	Equinoxe Modular and Non-Modular Pilot Tip Reamers	All Lots

**Advice on action to be taken by the user:**

- Review the updated operative techniques.
- Extend this information to your accounts that may have this product in their possession.
- Acknowledge receipt of this notice by completing and returning the attached form.

**Transmission of this Field Safety Notice:**

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

**Contact reference person:**

YS Yoo

**National Distributor for Exactech affected devices:**

Exactech PTE, Ltd

10 Jala Kilang

Sime Darby Enterprise Center, 03-01

Singapore 159410

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.



Graham Cuthbert  
Manager, Regulatory Affairs  
Exactech, Inc.

Attachment: Response form

## RESPONSE FORM - FIELD ADVISORY NOTICE

I have received this notice and will extend it to my accounts that may have the affected Exactech Equinoxe Modular and Non-Modular Pilot Tip Reamers (REF 321-25-01, 321-25-38, 321-25-42, 321-25-46, 321-45-01, 321-45-38, 321-45-42, 321-45-46, 321-05-01, 321-05-38, 321-05-42, 321-05-46).

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Distributorship

\_\_\_\_\_  
Name and Title (Print)

\_\_\_\_\_  
Name (Signature)

Thank you in advance for your prompt attention to this matter. According to policy, please return this completed response form via fax or email within 48 hrs of receipt of the notice.

Exactech representative

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Singapore 159410  
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