

## FIELD SAFETY NOTICE

29 June 2017

To Whom It May Concern,

### Exactech LPI Fit Tibial Tamp Head

Exactech Pte Ltd, is issuing this letter to inform that the manufacturer has issued an Advisory Notice, relating to the use of the LPI Fit Tibial Tamp Head, 213-75-01.

#### Details of Affected Device:

Device Description	Catalog Number	Lot Number
LPI Fit Tibial Tamp Head	213-75-01	37166002 44944004 44944005 44944006 48073010 48073011 48073012 49036017 51180004 51180005 51180006 51180008 51754031 51754032 51754033 51754034 59743001 61872001 61872002

#### Background/Description of Problem

Exactech has updated the surgical techniques for implantation of Logic Fit tray to clarify the proper technique and instrumentation to remove the tamp assembly from the bone, i.e., to include a caution statement about the potential for instrument breakage if the tamp handle / guide is misused by impacting in retro-grade.

The updated surgical techniques, Lit# 712-25-31 revD and 712-29-30 rev B, can be found on the Exactech website ([www.exac.com](http://www.exac.com)) or can be obtained by contacting Customer Service at Exactech Pte Ltd, 10 Jalan Kilang, Sime Darby Enterprise Centre, #03-01, Singapore 159410, 65-6273 0091 or Fax 65-6273 1822.

**Clinical Impact (Risk to Health)**

Exactech Inc, US, has received reports of instrument breakage; to date, there have been no confirmed reports of a broken instrument piece left in a patient and no reports of a revision associated with this issue.

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

Healthcare professionals are advised to do the following:

- Review the updated surgical 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.

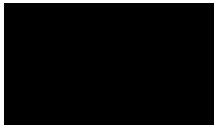
**Transmission of this Field Safety Notice**

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.

**Reporting of Adverse Event**

You are advised to report any adverse events and/or suspected adverse reactions associated with these devices to Ms Pua Fei San at Tel: 65 6273 0091, Email: [feisan.pua@exac.com.sg](mailto:feisan.pua@exac.com.sg), Fax: 65 6273 1822, events that are reported to Exactech Pte Ltd will be investigated.

Yours Sincerely,



**Pua Fei San**

Quality & Regulatory Affairs Specialist

Enclosed:

1. Advisory Notice issued by Exactech Inc
2. Acknowledgment Form
3. Surgical Technique 712-25-31 rev D
4. Surgical Technique 712-29-30 rev B

Copy:

Chairman of Medical Boards  
Head of Departments - Orthopedics

## FIELD SAFETY NOTICE

### ACKNOWLEDGEMENT FORM

Acknowledgement of Responsibility:

By signing below, I acknowledge that

- i. I have received this notice and have reviewed the updated operative techniques
- ii. all users have been informed of the notification

Printed Name: \_\_\_\_\_

Title: \_\_\_\_\_

Hospital Name: \_\_\_\_\_

Hospital Address: \_\_\_\_\_

Contact Number: \_\_\_\_\_

Signature: \_\_\_\_\_

Date: \_\_\_\_\_

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