EXACTECH PTE LTD
UEN : 201315636E
10 JALAN KILANG
BT MERAH ENTERPRISE CENTRE
#03-01, SINGAPORE 159410
65 6273.0091
65 6273.1822

FIELD SAFETY NOTICE

5 December 2019

To Whom It May Concern,

Cc: Chairman Medical Board and relevant Head of Departments

Exactech Equinoxe Platform Fracture Stem

Exactech Pte Ltd, is issuing this letter to inform that the manufacturer has issued an Urgent Field Safety Notice (FSN), relating to 304-22-07 Equinoxe Platform Fracture Stem, 6.5mm, Right and 304-22-11 Equinoxe Platform Fracter Stem, 10.5mm Right

Details of Affected Device:

Catalog Number	Description	Serial Number
304-22-07	Equinoxe Platform Fracture Stem, 6.5mm, Right	All
304-22-11	Equinoxe Platform Fracture Stem, 10.5mm, Right	All

Description of Issue:

The implants are standard length fracture stems, but the translations on the outer label include the word “long” in all languages other than the original English version.

Clinical Impact (Risk to Health)

The likelihood of the surgical staff noticing that the stem is standard length (and not “long” as incorrectly noted in the translations) is very high for the following reasons:

There is a substantial length difference between the 6.5mm standard and long Fracture Stems; upon opening, it would be obvious to the surgeon and surgical staff that the stem was not a “long” length.

1. The labels on the side of the “long” stem clearly specify that they are a “Humeral Long Stem” and indicate the 200mm length in two locations; standard stems do not include these details.
2. Only the standard length stems are included in the Platform Fracture Stem Kit; the long stems must be ordered separately.

Advice on action to be taken by the user
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.

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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. (As appropriate)

Please transfer this notice to other organization on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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:[redacted], Fax: 65 6273 1822, events that are reported to Exactech Pte Ltd will be investigated.

Yours Sincerely,

[redacted]

Pua Fei San
Quality & Regulatory Affairs Manager

Enclosed:

1. Advisory Notice issued by Exactech Inc
2. Acknowledgment Form
3. Affected Outer Label

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ACKNOWLEDGEMENT FORM

Acknowledgement of Responsibility:

By signing below, I acknowledge that

i. I have received this notice and have reviewed the information in this Field Safety Notice
ii. all users have been informed of the notification (as appropriate)

Printed Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____

Contact Number: _____

Signature: _____ Date: _____