

URGENT FIELD SAFETY NOTICE

Date: 03 November 2016
Subject Device: Exactech Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit
Attention: Exactech Equinox Users

Please be advised that the manufacturer of Exactech Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit, has issued an Advisory Notice, relating to the use of the Torque Defining Screw Kit.

Details of Affected Device:

Device Description	Catalog Number	Serial Range
Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit	320-20-00	4410696-4410819 4415393-4415492 4418789-4418888 4422658-4423007 4423542-4423591 4424509-4424558 4458153-4458252 4458303-4458352 4461732-4461806 4464592-4464691 4467733-4467824 4471099-4471298 4485494-4485543 4488224-4488260 4504738-4504987 4513150-4513199 4513250-4513299 4517116-4517215 4519806-4520005 4533291-4533390 4542043-4542092

Description of Issue:

When the Torque Defining Screw is tightened to the torque required to disengage the screw head, the screw head will disengage as expected, but it may not be retained in the Torque Defining Screwdriver.

Clinical Impact (Risk to Health):

This may cause a delay in surgery of less than 1 minute due to the need to pick up the screw head that was not retained by the driver. Surgeons should be advised that there is a potential for the screw head to fall into the wound site.

The issue has no impact on patient safety at this time. Action was taken to ensure the health and safety of patients and users of our products.

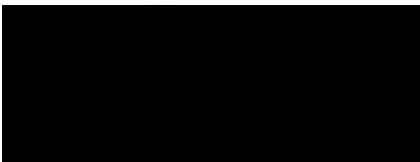
Advice on action to be taken by user:

Our record has shown that you have received the device with the affected serial number. This notice must be forwarded to all those who need to be aware within your organization.

Actions Required by User:

1. Please complete the Acknowledgement Form with the Serial Number and Quantity of the affected units in your possession.
2. Please sign the Acknowledgement Form and return it back to Exactech Pte Ltd via email (wahida.abdulrazak@exac.com.sg) or fax at **6273 1822**. Alternatively, you may submit the completed form to your local Exactech Representative.
3. Please do not remove the affected items from the premises. The use of the affected device has no safety impact to the final user or the patient.
4. This notice needs to be passed on to all those who needs to be aware within your organization.
5. Please maintain awareness on this notice.

Please contact your local representative for any questions pertaining to this Field Safety Notice. Thank you for your prompt attention to this matter.



Wahida Abdul Razak (Ms)
Quality Affairs & Regulatory Affairs Manager
Exactech Pte Ltd
Email: wahida.abdulrazak@exac.com.sg
Mobile: 65 81251535

*Enclosed.
Advisory Notice by Exactech Inc.*



FIELD SAFETY NOTICE

ACKNOWLEDGEMENT FORM

DEVICE DESCRIPTION: Exactech Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit			
CATALOG NUMBER	SERIAL NUMBER	Tick	QUANTITY (PC)
320-20-00	4422749		
	4458203		
	4458344		

Acknowledgement of Responsibility:

By signing below, I acknowledge that

- i. the quantity(s) and serial number (s) of Exactech Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit detailed in this notification are listed above and
- ii. all users have been informed of the notification.

Printed Name: _____

Title: _____

Hospital Name: _____

Hospital Address: _____

Contact Number: _____

Signature: _____ Date: _____