
Urgent Field Safety Notice**Exactech Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit****FSCA-identifier: 11012016****Type of action: Field Advisory**

Date: October 17, 2016

Attention: **All staff who may use or handle these devices****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 also be advised that there is a potential for the screw head to fall into the wound site.

Details of the affected devices:

Catalog Number	Serial Ranges	Device Description
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	Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit

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.**

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:

Tina O'Brien

National Distributor for Exactech affected devices:

Exactech UK
Grosvenor House
Prospect Hill
Redditch
B97 4DL
United Kingdom

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.



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 Equinox Reverse Shoulder Fixed Angle Torque Defining Screw Kit (REF 320-20-00).

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 and contact your Exactech representative to confirm quantities at your location.

Exactech representative

Tina O'Brien
Exactech UK
Grosvenor House
Prospect Hill
Redditch
B97 4DL
United Kingdom
phone: +44 1527 591 555
email: tina.obrien@exac.co.uk