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*****URGENT DEAR HEALTHCARE PROFESSIONAL COMMUNICATION*****

6th March 2024

To: Surgeons, Hospitals, Health Care Professionals

Description: Exactech Equinoxe Shoulder reverse total shoulder (rTSA) UHWMPE and anatomic total shoulder (aTSA) UHMWPE devices that were packaged in non-conforming packaging.

US Specific

Product specific information is listed in Attachment 1

Dear Surgeon:

On January 16, 2024, the FDA issued a Safety Communication regarding the Equinoxe reverse total shoulder (rTSA) and the anatomic total shoulder (aTSA) devices that were packaged in nonconforming packaging.

To eliminate confusion and concern in the market, Exactech is now proceeding with a recall and removal of these devices as recommended by FDA. A table with all affected parts is included in Attachment 1 below. Conforming product is available, and we do not anticipate any disruption in your service as we perform this removal.

The FDA Safety Communication (linked here) listed possible health risks associated with Exactech Equinoxe anatomic glenoids and reverse humeral liners manufactured between 2004 and August 2021, which were packaged in packaging without one of the oxygen barrier layers that further protect the devices against oxidation. **Oxidation can lead to faster device wear or failure, device component cracking or fracture, new or worsening pain, bone loss, and/or swelling in the affected area.** Any of these outcomes could result in the need for revision surgery.

In the Safety Communication, FDA recommended that Health Care Providers **do not implant any Equinoxe Shoulder Systems packaged in defective bags. FDA does not recommend removal of well-functioning Equinoxe Shoulder Systems from patients who do not have any new or worsening pain or symptoms.**

Surgeons should monitor patients who have implanted affected devices “for potential device wear, failure, or bone loss” and should “consider performing X-rays to further evaluate the patient and their implanted device if you suspect a failed device.”

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Surgeons are encouraged to discuss revision surgery with patients who may have worsening pain or joint weakness that is potentially attributable to the device based on a clinical examination, on a case-by-case basis. As a part of shared decision-making, discuss the benefits and risks of all relevant treatment options with your patients.

For any patients who come to you with questions, you can point them to an educational resource we are hosting on our website that outlines the facts about this recall (linked here). We also have a device serial look-up tool (linked here) that patients can use to understand if they have implants that were packaged in nonconforming packaging.

Actions to be Taken:

- **Review this communication thoroughly.**
- **Contact your local Exactech Representative** if you have any questions regarding this communication.
- Your local agent will help to determine which anatomic glenoid and reverse humeral liner components are affected and should be removed from inventory.

Our first concern is for the health and safety of patients and the users of our products. Actions of this type are collaborative efforts and require your participation to be effective.

If it is helpful, we would appreciate the opportunity to set up a conference call/WebEx with you and our corporate leadership team to discuss any questions you have about this recall.

In conclusion, we would like to reiterate our sincere thanks for your support of Exactech over the years. We look forward to hearing from you.

Sincerely,

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ATTACHMENT 1

Product Line Number	Product Line Description	Total Affected Units Sold (US) (2004-2.15.2024)
Equinoxe aTSA Devices		
314-01-0X	EQUINOXE GLENOID, KEELED ALPHA	854
314-01-1X	EQUINOXE GLENOID, KEELED BETA	989
314-02-0X	EQUINOXE GLENOID, PEGGED ALPHA	4054
314-02-1X	EQUINOXE GLENOID, PEGGED BETA	5035
314-02-2X	EQUINOXE POST AUG GLENOID, LEFT	527
314-02-3X	EQUINOXE POST AUG GLENOID, RIGHT	672
314-04-2X	EQUINOXE POST AUG GLENOID, LEFT 12	37
314-04-3X	EQUINOXE POST AUG GLENOID, RIGHT, 12	41
314-06-2X	EQUINOXE POST AUG GLENOID, LEFT, 16	131
314-06-3X	EQUINOXE POST AUG GLENOID, RIGHT, 16	193
314-13-0X	EQUINOXE CAGE GLENOID, ALPHA	10306
314-13-1X	EQUINOXE CAGE GLENOID, BETA	12434
314-13-2X	EQUINOXE CAGE GLENOID, POST AUG, LEFT	3209
314-13-3X	EQUINOXE CAGE GLENOID, POST AUG, RIGHT	3731
Equinoxe rTSA Devices		
320-36-0X	EQUINOXE 145-DEG PE 36MM HUM LINER	9434
320-36-1X	EQUINOXE 145-DEG PE 36MM CONST HUM LINER	803
320-38-0X	EQUINOXE 145-DEG PE 38MM HUM LINER	41398
320-38-1X	EQUINOXE 145-DEG PE 38MM CONST HUM LINER	3225
320-40-0X	EQUINOXE 145-DEG PE 40MM HUM LINER	2826
320-40-1X	EQUINOXE 145-DEG PE 40MM CONST HUM LINER	437
320-42-0X	EQUINOXE 145-DEG PE 42MM HUM LINER	19262
320-42-1X	EQUINOXE 145-DEG PE 42MM CONST HUM LINER	2354
320-46-0X	EQUINOXE 145-DEG PE 46MM HUM LINER	1839
320-46-1X	EQUINOXE 145-DEG PE 46MM CONST HUM LINER	440