

FSN Ref.: CRC-00012

FSCA Ref.: CRC-00012

*****URGENT FIELD SAFETY NOTICE*****
MEDICAL DEVICE RECALL

Date: March 7, 2024
For Attention of: Exactech Agents, Representatives, and Distributors in Possession of Affected Products
Affected Product: Exactech's Equinox reverse Total Shoulder Arthroplasty (rTSA) and the anatomic Total Shoulder Arthroplasty (aTSA) UHMWPE humeral liners and glenoids that were packaged in non-conforming packaging.
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The purpose of this letter is to inform you that a **RECALL** is being performed by Exactech for the products in Appendix 1 section of this recall notice.

Description of Issue: Exactech's Equinox reverse Total Shoulder Arthroplasty (rTSA) and the anatomic Total Shoulder Arthroplasty (aTSA) UHMWPE humeral liners and glenoids that were packaged in non-conforming bags have been shipped and implanted since May 2005. The packaging of these affected UHMWPE humeral liners and glenoids are nonconforming as they do not meet the established packaging specification. They were packaged in vacuum bags that did not contain an additional oxygen barrier layer consisting of Ethylene Vinyl Alcohol (EVOH). Health Care Providers may not easily distinguish which polyethylene inserts are in nonconforming packaging, therefore Health Care Providers may have implanted these polyethylene inserts.

Exactech is recalling all remaining affected UHMWPE shoulder humeral liners and glenoids that have been packaged in non-conforming vacuum bags. Most hospitals' inventory currently includes both non-conforming and conforming devices. We advise surgeons to avoid implanting nonconforming devices. To assist sales agents to immediately identify nonconforming product in inventory locations, Exactech is providing a list of the nonconforming insert serial numbers affected by this recall notice (see Attachment A).

Clinical Impact: After extensive testing, we have recently confirmed that most of our affected UHMWPE shoulder products in scope manufactured since 2004 consisting of Exactech's Equinox reverse Total Shoulder Arthroplasty (rTSA) and the anatomic Total Shoulder Arthroplasty (aTSA) UHMWPE humeral liners and glenoids that were packaged in non-conforming bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH), that further augments oxygen resistance. The use of these non-conforming bags may enable increased oxygen diffusion to the

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UHMWPE (ultra-high molecular weight polyethylene) shoulder product, resulting in increased oxidation of the material relative to affected device packaged with the specified additional oxygen barrier layer. Over time, oxidation can potentially degrade the mechanical properties of conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.


Actions to be Taken by the USER:**In order to comply with applicable regulations and Exactech policies:**

- **CAREFULLY REVIEW THIS RECALL NOTIFICATION** to ensure that you fully understand the issue identified, the recall strategy, and all actions required.
- **IMMEDIATELY IDENTIFY AND QUARANTINE** any of the subject devices in your inventory and/or customer's inventory listed Product Scope Listing (Attachment A).
- **EXTEND THE DESCRIPTION OF ISSUE AND CLINICAL IMPACT** as described in the recall notification to your accounts that may have this product in their possession.
- **COMPLETE AND RETURN** the attached Recall Inventory Response Form to Exactech via email at recalls@exac.com.
- **WE ARE REQUIRING 100% EFFECTIVENESS FOR THIS RECALL.** For any items you need replaced, please submit a Restock Only order to Customer Service.
- Please **REPORT** all device-related **SERIOUS INCIDENTS** to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.

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.

Please complete and return the attached Recall Response Form to Exactech within the next 5 business days.

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Vice President - Quality Assurance

The relevant National Competent Authorities will be advised of the FSCA.

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*****URGENT FIELD SAFETY NOTICE RESPONSE FORM*****

Please check the appropriate box and complete as indicated.

- ☐ **I acknowledge** receipt of this Recall Notification **and confirm** that I fully understand the issue identified, the clinical impact, and all actions that will be required in accordance with this Recall Notice.
- ☐ **I agree to extend the description of this issue and clinical impact** as described in this notification to my accounts that may have this product in their possession.
- ☐ **I have completely identified and quarantined the affected devices**, as identified in the Product Scope Listing (Attachment A).

Date_____
Agency_____
Name (Print)_____
Name (Signature)

Thank you for your prompt attention to this matter. Please complete and return this response form to recalls@exac.com **within 5 business days of receipt.**

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Appendix 1: Recall Scope Product Table

Version or Model	Device Description	Device Identifier
314-01-02	GLENOID,KEELED, CEMENTED,Mates with 38, 41, 44 head, alpha curvature, Small	10885862084408
314-01-03	GLENOID,KEELED, CEMENTED,Mates with 38, 41, 44 head, alpha curvature, Medium	10885862084415
314-01-04	GLENOID,KEELED, CEMENTED,Mates with 38, 41, 44 head, alpha curvature, Large	10885862084422
314-01-12	GLENOID,KEELED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Small	10885862084439
314-01-13	GLENOID,KEELED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Medium	10885862084446
314-01-14	GLENOID,KEELED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Large	10885862084453
314-01-15	GLENOID,KEELED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Extra Large	10885862084460
314-02-02	GLENOID,PEGGED, CEMENTED,Mates with 38, 41, 44 head, alpha curvature, Small	10885862084477
314-02-03	GLENOID,PEGGED, CEMENTED,Mates with 38, 41, 44 head, alpha curvature, Medium	10885862084484
314-02-04	GLENOID,PEGGED, CEMENTED,Mates with 38, 41, 44 head, alpha curvature, Large	10885862084491
314-02-12	GLENOID,PEGGED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Small	10885862084507
314-02-13	GLENOID,PEGGED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Medium	10885862084514
314-02-14	GLENOID,PEGGED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Large	10885862084521
314-02-15	GLENOID,PEGGED, CEMENTED,Mates with 47, 50, 53 head, beta curvature, Extra Large	10885862084538
314-02-22	GLENOID, POSTERIOR AUGMENT,PEGGED, CEMENTED,Mates with 38, 41, 44, 47 head, Small, 8°,LEFT	10885862175052
314-02-23	GLENOID, POSTERIOR AUGMENT,PEGGED, CEMENTED,Mates with 41, 44, 47, 50 head, Medium, 8°,LEFT	10885862175069
314-02-24	GLENOID, POSTERIOR AUGMENT,PEGGED, CEMENTED,Mates with 44, 47, 50, 53 head, Large, 8°,LEFT	10885862175076
314-02-25	GLENOID, POSTERIOR AUGMENT,PEGGED, CEMENTED,Mates with 44, 47, 50, 53 head, Extra Large, 8°,LEFT	10885862175083
314-02-32	GLENOID, POSTERIOR AUGMENT,PEGGED, CEMENTED,Mates with 38, 41, 44, 47 head, Small, 8°,RIGHT	10885862175090

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Version or Model	Device Description	Device Identifier
314-02-33	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 41, 44, 47, 50 head, Medium, 8°, RIGHT	10885862175106
314-02-34	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 44, 47, 50, 53 head, Large, 8°, RIGHT	10885862175113
314-02-35	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 44, 47, 50, 53 head, Extra Large, 8°, RIGHT	10885862175120
314-04-22	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 12°, LEFT	10885862199553
314-04-23	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 12°, LEFT	10885862199560
314-04-24	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 12°, LEFT	10885862199577
314-04-25	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 12°, LEFT	10885862199584
314-04-32	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 12°, RIGHT	10885862198495
314-04-33	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 12°, RIGHT	10885862198501
314-04-34	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 12°, RIGHT	10885862198518
314-04-35	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 12°, RIGHT	10885862198525
314-06-22	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 16°, LEFT	10885862228307
314-06-23	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 16°, LEFT	10885862228314
314-06-24	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 16°, LEFT	10885862228321
314-06-25	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 16°, LEFT	10885862228338
314-06-32	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 16°, RIGHT	10885862228345
314-06-33	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 16°, RIGHT	10885862228352

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314-06-34	GLENOID,POSTERIOR AUGMENT, PEGGED,Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 16°,RIGHT	10885862228369
314-06-35	GLENOID,POSTERIOR AUGMENT, PEGGED,Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 16°,RIGHT	10885862228376
314-13-02	CAGE GLENOID, CEMENTED,Mates with 38, 41, 44 head, alpha curvature,Small	10885862172679
314-13-03	CAGE GLENOID, CEMENTED,Mates with 38, 41, 44 head, alpha curvature,Medium	10885862172686
314-13-04	CAGE GLENOID, CEMENTED,Mates with 38, 41, 44 head, alpha curvature,Large	10885862172709
314-13-13	CAGE GLENOID, CEMENTED,Mates with 47, 50, 53 head, beta curvature,Medium	10885862172693
314-13-14	CAGE GLENOID, CEMENTED,Mates with 47, 50, 53 head, beta curvature,Large	10885862172716
314-13-15	CAGE GLENOID, CEMENTED,Mates with 47, 50, 53 head, beta curvature,Extra Large	10885862172723
314-13-22	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 38, 41, 44, 47 head, Left, Small	10885862196163
314-13-23	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 41, 44, 47, 50 head, Left, Medium	10885862196170
314-13-24	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 44, 47, 50, 53 head, Left, Large	10885862200983
314-13-25	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 44, 47, 50, 53 head, EXTRA LARGE,Left	10885862200990
314-13-32	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 38, 41, 44, 47 head, Right, Small	10885862201003
314-13-33	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 41, 44, 47, 50 head, Right, Medium	10885862201010
314-13-34	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 44, 47, 50, 53 head, Right, Large	10885862201027
314-13-35	CAGE GLENOID,POSTERIOR AUGMENT, CEMENTED,Mates with 44, 47, 50, 53 head, EXTRA LARGE,Right	10885862201034
320-36-00	REVERSE SHOULDER,36mm Humeral Liner,+0mm	10885862086617
320-36-03	REVERSE SHOULDER,36mm Humeral Liner,+2.5mm	10885862086624
320-36-10	REVERSE SHOULDER,36mm Constrained Humeral Liner,+0mm	10885862086631

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Version or Model	Device Description	Device Identifier
320-36-13	REVERSE SHOULDER,36mm Constrained Humeral Liner,+2.5mm	10885862086648
320-38-00	REVERSE SHOULDER,38mm Humeral Liner,+0mm	10885862086655
320-38-03	REVERSE SHOULDER,38mm Humeral Liner,+2.5mm	10885862086662
320-38-10	REVERSE SHOULDER,38mm Constrained Humeral Liner,+0mm	10885862086679
320-38-13	REVERSE SHOULDER,38mm Constrained Humeral Liner,+2.5mm	10885862086686
320-40-00	Humeral Liner	10885862535030
320-40-03	Humeral Liner	10885862535047
320-40-10	Constrained Humeral Liner	10885862535054
320-40-13	Constrained Humeral Liner	10885862535061
320-42-00	REVERSE SHOULDER,42mm Humeral Liner,+0mm	10885862086693
320-42-03	REVERSE SHOULDER,42mm Humeral Liner,+2.5mm	10885862086709
320-42-10	REVERSE SHOULDER,42mm Constrained Humeral Liner,+0mm	10885862086716
320-42-13	REVERSE SHOULDER,42mm Constrained Humeral Liner,+2.5mm	10885862086723
320-46-00	REVERSE SHOULDER,46mm Humeral Liner,+0mm	10885862086730
320-46-03	REVERSE SHOULDER,46mm Humeral Liner,+2.5mm	10885862086747
320-46-10	REVERSE SHOULDER,46mm Constrained Humeral Liner,+0mm	10885862086754
320-46-13	REVERSE SHOULDER,46mm Constrained Humeral Liner,+2.5mm	10885862086761