

*****URGENT VOLUNTARY MEDICAL DEVICE RECALL*****

To: Healthcare Providers and Exactech Sales Representatives

Date: August 15, 2025

Subject: **Voluntary Recall of Reverse Shoulder Humeral Liners (standard) — 320 & 322 Series**

Product: Exactech Equinox Reverse Shoulder Humeral Liners

Summary of Action

On August 15, 2025, Exactech, Inc. initiated a voluntary recall of units of the standard 320-38/42-00/03 and 322-38/42-00/03 series rTSA Humeral Liner products manufactured at Exactech's Sarasota, FL location. This action follows findings from an internal manufacturing review that identified a dimensional nonconformance affecting the articular surface position.

This recall applies only to the SKUs listed in the "Products Involved" table below. Out of an abundance of caution, Exactech is removing all affected units from distribution to ensure all products meet dimensional specifications.

Reason for Recall:

Root Cause

During an internal investigation and 100% inspection of in-process inventory, Exactech identified that certain reverse shoulder humeral liners have an articular surface positioned outside of the dimensional specification in the labelling. This deviation resulted from a manufacturing fixture that allowed the liner component to shift slightly out of alignment prior to backside machining.

Device Effect

Testing identified that the articular surface position in some liners may deviate by up to 0.0198 inches (0.5 mm). Computer simulation predicted this could slightly change contact locations with surrounding bone or soft tissue, resulting in small range of motion reductions (–0.5° abduction, –1° internal rotation, –1° external rotation, with similar increases in opposite directions).

This device nonconformity was identified through internal inspection, with no related complaints or adverse events reported.

Potential Clinical Impact

The observed shift in the articular surface position may alter the locations of impingement with the scapula or surrounding soft tissues, which may decrease active range of motion.

Product Involved: Equinoxe Reverse Shoulder Humeral Liners – Refer to “Appendix 1” for product information

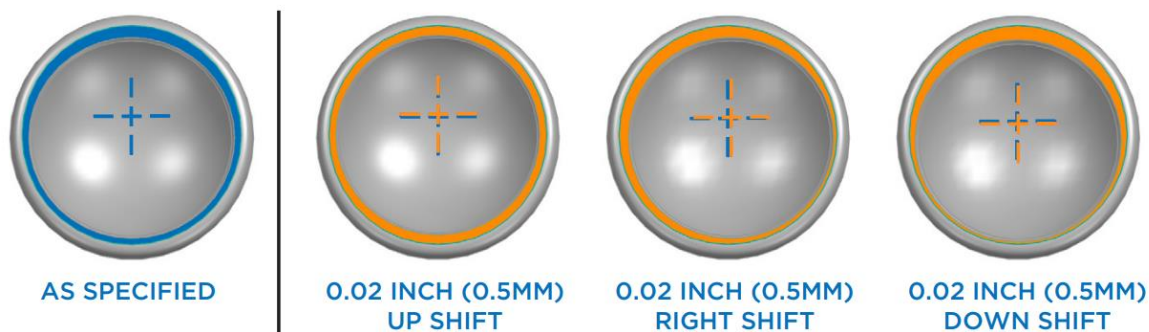
Item Number	Full Item Description
320-38-00	145-DEG PE 38MM HUM LINER +0
320-38-03	145-DEG PE 38MM HUM LINER +2.5
320-42-00	145-DEG PE 42MM HUM LINER +0
320-42-03	145-DEG PE 42MM HUM LINER +2.5
322-38-00	145-DEG PE 38MM HUM LINER +0
322-38-03	145-DEG PE 38MM HUM LINER +2.5
322-42-00	145-DEG PE 42MM HUM LINER +0
322-42-03	145-DEG PE 42MM HUM LINER +2.5

Action Required – Immediate Recall Steps:

1. **Healthcare providers** who have treated patients using the Exactech Equinoxe Humeral Liners subject to this recall should continue to follow those patients pursuant to the healthcare provider’s standard of care.
2. **Do Not Use / Quarantine** any of these products in your inventory.
3. **Segregate and return** unused units via prepaid packaging to Exactech.
4. **Complete the “Recall Confirmation Form”** confirming product return or on-hand inventory.
5. **Transmission of this Recall Notice:** This notice must be passed on to all who need to be aware within your organization and any locations the affected products has been transferred to. This recall has been reported to the U.S. FDA and will be reported to other regulatory authorities as required.

Resources: Healthcare providers and patients with questions can access educational resources on our website www.exac.com/recall-information and use the device serial look-up tool.

Representative Example of Observed Condition:



Reverse Humeral Liner surface shown 1) as specified and 2) with three possible manufacturing shifts of the center of rotation. Blue indicates specified center of rotation, orange indicates shifted position.

Reporting Information

1. **Exactech Reporting:** Please report any adverse reactions or other quality problems experienced with these products to complaints@exac.com or 1-800-392-2832
2. **Adverse Reactions or other quality problems can also be reported to FDA's Medwatch:**
 - a. Web: www.fda.gov/medwatch
 - b. Call 1-800-332-1088 or fax 1-800-332-0178

Sincerely,



Matthew Collins
Vice President, Global Quality Assurance
Exactech, Inc.
2320 NW 66th Ct.
Gainesville, FL 32653

15 August 2025

Date

URGENT VOLUNTARY MEDICAL DEVICE RECALL

Date: August 15, 2025

Subject: **Voluntary Recall of Reverse Shoulder Humeral Liners — 320 & 322 Series**

Recall Confirmation Form

It is important that you take the actions detailed in this Recall Notice and confirm that you have received information. Please complete and return this form to Exactech at humeralCORrecall@exac.com

Your reply is the evidence we need to monitor the dissemination of this notice.

Please check the appropriate boxes and sign.

- ☐ I acknowledge receipt of this recall notice and confirm that I fully understand the issue identified, the clinical impact, and all actions that will be required in accordance with this recall notices
- ☐ 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 listing "Attachment 1".

Date

Agency

Name (Print)

Signature

This form is to be returned to Exactech – Scan and email this form to humeralCORrecall@exac.com

Send affected products to:

Exactech
2320 NW 66th Ct
Gainesville, FL 32653

APPENDIX 1

Item Number	Product Description	510K #	UDI
320-38-00	REVERSE SHOULDER,38mm Humeral Liner,+0mm	K063569	10885862086655
320-38-03	REVERSE SHOULDER,38mm Humeral Liner,+2.5mm	K063569	10885862086662
320-42-00	REVERSE SHOULDER,42mm Humeral Liner,+0mm	K063569	10885862086693
320-42-03	REVERSE SHOULDER,42mm Humeral Liner,+2.5mm	K063569	10885862086709
322-38-00	REVERSE SHOULDER,38mm Humeral Liner,+0mm	K223833	10885862593832
322-38-03	REVERSE SHOULDER,38mm Humeral Liner,+2.5mm	K223833	10885862593849
322-42-00	REVERSE SHOULDER,42mm Humeral Liner,+0mm	K223833	10885862593917
322-42-03	REVERSE SHOULDER,42mm Humeral Liner,+2.5mm	K223833	10885862593924