

# Medical Device Advisory



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## EXACTECH EQUINOXE SHOULDER SYSTEM WITH DEFECTIVE PACKAGING: OXIDATION RISKS

The Health Sciences Authority (HSA) would like to alert healthcare professionals about possible health risks associated with the Equinox Shoulder System joint replacement devices. These devices were manufactured by Exactech between 2004 and August 2021 and were packaged in defective bags.

### Background

Equinox Shoulder System are joint replacement devices used in skeletally mature adults with degenerative diseases or fractures of the glenohumeral joint, or revision surgery in cases of failed glenohumeral joint replacement. Such joint replacement devices typically include a plastic (polyethylene) articulating component.

### Risks of Increased Oxidation of Polyethylene Components

Some Equinox Shoulder System devices, manufactured between 2004 and August 2021, were packed in defective bags which had one missing oxygen barrier layer.

Elevated transmission of oxygen could occur from the external environment, leading to unintended oxidation of the polyethylene device component packaged within these defective bags. Early degradation of the polyethylene component can increase the risk of:

- early and excessive device wear,
- component fracture,
- device failure,
- new or worsening pain,
- bone loss,
- swelling in the affected area, or
- revision surgery as a result of these issues.

### Affected Equinox Shoulder Devices

Details of Equinox Shoulder System implants, packaged in defective bags and previously supplied for implantation of local patients, can be found below.

Catalogue Number	Device Description	Period of Manufacture
314-02-02	GLENOID, PEGGED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Small	Between 2004 and August 2021
314-02-13	GLENOID, PEGGED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Medium	
314-02-22	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 38, 41, 44, 47 head, Small, 8°, LEFT	

314-13-03	CAGE GLENOID, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Medium	
314-13-13	CAGE GLENOID, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Medium	
314-13-14	CAGE GLENOID, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Large	
320-36-00	REVERSE SHOULDER, 36mm Humeral Liner, +0mm	
320-36-03	REVERSE SHOULDER, 36mm Humeral Liner, +2.5mm	
320-38-00	REVERSE SHOULDER, 38mm Humeral Liner, +0mm	
320-38-03	REVERSE SHOULDER, 38mm Humeral Liner, +2.5mm	
320-38-10	REVERSE SHOULDER, 38mm Constrained Humeral Liner, +0mm	
320-38-13	REVERSE SHOULDER, 38mm Constrained Humeral Liner, +2.5mm	
320-42-00	REVERSE SHOULDER, 42mm Humeral Liner, +0mm	
320-42-10	REVERSE SHOULDER, 42mm Constrained Humeral Liner, +0mm	

### Recommendations for Healthcare Professionals

Healthcare professionals are advised not to implant any Equinox Shoulder Systems packaged in defective bags. See Appendix A for the full list of impacted devices.

Prophylactic removal of a well-functioning device from patients who are not experiencing new or worsening symptoms is not recommended.

Monitor patients implanted with affected Equinox Shoulder System devices that were manufactured between 2004 and August 2021, for potential device wear, failure, or bone loss. Where device failure is suspected, X-ray examination to further evaluate the patient and their implanted device should be considered.

Where necessary, discuss the benefits and risks of all relevant treatment options, including revision surgery, with your patients.

### Reporting of Adverse Events associated with Equinox Shoulder System

Healthcare professionals are reminded to report all adverse events (AE) and/or suspected AEs related to Equinox Shoulder System to the Medical Devices Cluster, Health Products Regulation Group, HSA at Tel: 6866 1048, or report online using the e-form below.



[AE Reporting e-Form](#)

Confirmation of the causality of the AE is not a prerequisite for reporting to HSA; as long as there is a suspicion that a medical device may be related to a serious adverse event, an AE report may be submitted.

Yours faithfully

MS WONG WOEI JIUANG  
ASSISTANT GROUP DIRECTOR  
MEDICAL DEVICES CLUSTER  
HEALTH PRODUCTS REGULATION GROUP  
HEALTH SCIENCES AUTHORITY

**Appendix A: Affected Equinox Shoulder System devices manufactured between 2004 and August 2021**

<b>Catalogue Number</b>	<b>Device Description</b>
314-01-02	GLENOID, KEELED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Small
314-01-03	GLENOID, KEELED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Medium
314-01-04	GLENOID, KEELED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Large
314-01-12	GLENOID, KEELED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Small
314-01-13	GLENOID, KEELED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Medium
314-01-14	GLENOID, KEELED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Large
314-01-15	GLENOID, KEELED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Extra Large
314-02-02	GLENOID, PEGGED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Small
314-02-03	GLENOID, PEGGED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Medium
314-02-04	GLENOID, PEGGED, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Large
314-02-12	GLENOID, PEGGED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Small
314-02-13	GLENOID, PEGGED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Medium
314-02-14	GLENOID, PEGGED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Large
314-02-15	GLENOID, PEGGED, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Extra Large
314-02-22	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 38, 41, 44, 47 head, Small, 8°, LEFT
314-02-23	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 41, 44, 47, 50 head, Medium, 8°, LEFT
314-02-24	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 44, 47, 50, 53 head, Large, 8°, LEFT
314-02-25	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 44, 47, 50, 53 head, Extra Large, 8°, LEFT
314-02-32	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 38, 41, 44, 47 head, Small, 8°, RIGHT
314-02-33	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 41, 44, 47, 50 head, Medium, 8°, RIGHT
314-02-34	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 44, 47, 50, 53 head, Large, 8°, RIGHT
314-02-35	GLENOID, POSTERIOR AUGMENT, PEGGED, CEMENTED, Mates with 44, 47, 50, 53 head, Extra Large, 8°, RIGHT
314-04-22	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 12°, LEFT
314-04-23	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 12°, LEFT
314-04-24	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 12°, LEFT
314-04-25	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 12°, LEFT
314-04-32	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 12°, RIGHT
314-04-33	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 12°, RIGHT
314-04-34	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 12°, RIGHT
314-04-35	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 12°, RIGHT
314-06-22	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 16°, LEFT
314-06-23	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 16°, LEFT
314-06-24	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 16°, LEFT

314-06-25	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 16°, LEFT
314-06-32	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 38, 41, 44, 47 head, FOR CEMENTED USE ONLY, Small, 16°, RIGHT
314-06-33	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 41, 44, 47, 50 head, FOR CEMENTED USE ONLY, Medium, 16°, RIGHT
314-06-34	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Large, 16°, RIGHT
314-06-35	GLENOID, POSTERIOR AUGMENT, PEGGED, Mates with 44, 47, 50, 53 head, FOR CEMENTED USE ONLY, Extra Large, 16°, RIGHT
314-13-02	CAGE GLENOID, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Small
314-13-03	CAGE GLENOID, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Medium
314-13-04	CAGE GLENOID, CEMENTED, Mates with 38, 41, 44 head, alpha curvature, Large
314-13-13	CAGE GLENOID, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Medium
314-13-14	CAGE GLENOID, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Large
314-13-15	CAGE GLENOID, CEMENTED, Mates with 47, 50, 53 head, beta curvature, Extra Large
314-13-22	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 38, 41, 44, 47 head, Left, Small
314-13-23	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 41, 44, 47, 50 head, Left, Medium
314-13-24	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 44, 47, 50, 53 head, Left, Large
314-13-25	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 44, 47, 50, 53 head, EXTRA LARGE, Left
314-13-32	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 38, 41, 44, 47 head, Right, Small
314-13-33	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 41, 44, 47, 50 head, Right, Medium
314-13-34	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 44, 47, 50, 53 head, Right, Large
314-13-35	CAGE GLENOID, POSTERIOR AUGMENT, CEMENTED, Mates with 44, 47, 50, 53 head, EXTRA LARGE, Right
320-36-00	REVERSE SHOULDER, 36mm Humeral Liner, +0mm
320-36-03	REVERSE SHOULDER, 36mm Humeral Liner, +2.5mm
320-36-10	REVERSE SHOULDER, 36mm Constrained Humeral Liner, +0mm
320-36-13	REVERSE SHOULDER, 36mm Constrained Humeral Liner, +2.5mm
320-38-00	REVERSE SHOULDER, 38mm Humeral Liner, +0mm
320-38-03	REVERSE SHOULDER, 38mm Humeral Liner, +2.5mm
320-38-10	REVERSE SHOULDER, 38mm Constrained Humeral Liner, +0mm
320-38-13	REVERSE SHOULDER, 38mm Constrained Humeral Liner, +2.5mm
320-40-00	Humeral Liner
320-40-03	Humeral Liner
320-40-10	Constrained Humeral Liner
320-40-13	Constrained Humeral Liner
320-42-00	REVERSE SHOULDER, 42mm Humeral Liner, +0mm
320-42-03	REVERSE SHOULDER, 42mm Humeral Liner, +2.5mm
320-42-10	REVERSE SHOULDER, 42mm Constrained Humeral Liner, +0mm
320-42-13	REVERSE SHOULDER, 42mm Constrained Humeral Liner, +2.5mm
320-44-00	Humeral Liner
320-44-03	Humeral Liner
320-44-10	Constrained Humeral Liner
320-44-13	Constrained Humeral Liner
320-46-00	REVERSE SHOULDER, 46mm Humeral Liner, +0mm
320-46-03	REVERSE SHOULDER, 46mm Humeral Liner, +2.5mm
320-46-10	REVERSE SHOULDER, 46mm Constrained Humeral Liner, +0mm
320-46-13	REVERSE SHOULDER, 46mm Constrained Humeral Liner, +2.5mm