



ΕΛΛΗΝΙΚΗ ΔΗΜΟΚΡΑΤΙΑ

ΥΠΟΥΡΓΕΙΟ ΥΓΕΙΑΣ

ΕΘΝΙΚΟΣ ΟΡΓΑΝΙΣΜΟΣ ΦΑΡΜΑΚΩΝ

Διεύθυνση Ελέγχου Παραγωγής και Κυκλοφορίας Προϊόντων

Τμήμα Ελέγχου Κυκλοφορίας

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Χολαργός 18/4/2024

Αρ.Πρωτ.: 34781,44615

ΠΡΟΣ: OPTIMUM ORTHOPAEDICS S.A.

Δρόσου 10

Τ.Κ. 145 64 Ν. Κηφισιά

ΘΕΜΑ: Ανάκληση των Ιατροτεχνολογικών προϊόντων Exactech Equinox Shoulder UHMWPE (Exactech's Equinox reverse Total Shoulder Arthroplasty (rTSA) και Anatomic Total Shoulder Arthroplasty (aTSA) UHMWPE), του συνημμένου πίνακα της κατασκευάστριας εταιρείας Exactech Inc.

Κατασκευαστής: Exactech Inc.

Διάθεση στην Ελληνική αγορά: OPTIMUM ORTHOPAEDICS S.A.

ΑΠΟΦΑΣΗ

Έχοντας υπόψη:

1. Το άρθρο 6, παρ.ΙΙ εδ.8 του Ν. 1316/83 (ΦΕΚ 3 Α') «Ίδρυση, οργάνωση και αρμοδιότητες του Ε.Ο.Φ.», όπως αντικαταστάθηκε με το άρθρο 25 του Ν. 3730/2008 (ΦΕΚ 262 Β').
2. Την υπ' αριθ. FSCA CRC-00012, MDSS Ref. 24-049 CMDR επείγουσα ειδοποίηση ασφαλείας του κατασκευαστή Exactech Inc (αρ. πρωτ. ΕΟΦ 34781/21-3-2024).

ΑΠΟΦΑΣΙΖΟΥΜΕ

Την ανάκληση των Ιατροτεχνολογικών προϊόντων Exactech Equinox Shoulder UHMWPE (Exactech's Equinox reverse Total Shoulder Arthroplasty (rTSA) και Anatomic Total Shoulder Arthroplasty (aTSA) UHMWPE) του συνημμένου πίνακα λόγω μη συμμορφούμενης συσκευασίας. Η Exactech ανακαλεί όλες τις εναπομείνουσες συσκευασίες που έχουν κατασκευαστεί από το 2004, καθώς δεν πληρούν τις καθιερωμένες προδιαγραφές συσκευασίας, με αποτέλεσμα την δυνητική υποβάθμιση του προϊόντος.

Η παρούσα απόφαση αποτελεί προληπτικό μέτρο με σκοπό να ενισχύσει την εθελοντική ανάκληση στην οποία έχει προβεί η εταιρεία.

Η εταιρεία OPTIMUM ORTHOPAEDICS S.A., ως διανομέας του προϊόντος στην Ελλάδα, οφείλει να επικοινωνήσει άμεσα με τους αποδέκτες του και να αποσύρει τους συγκεκριμένους κωδικούς από την αγορά.

Τα παραστατικά της ανάκλησης πρέπει να τηρούνται για διάστημα τουλάχιστον πέντε (5) ετών και να τίθενται υπόψη του ΕΟΦ, εφόσον ζητηθούν.

Ο ΠΡΟΕΔΡΟΣ ΔΣ/ΕΟΦ

Ε. ΜΑΝΩΛΟΠΟΥΛΟΣ

ΣΥΝΗΜΜΕΝΑ

Πίνακας προϊόντων

ΕΣΩΤΕΡΙΚΗ ΔΙΑΝΟΜΗ

Τμήμα Ελέγχου Κυκλοφορίας

Τμήμα Υλικοεπαγρύπνησης

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
314-02-33	GLENOID, POSTERIOR AUGMENT,PEGGED, CEMENTED,Mates with 41, 44, 47, 50 head, Medium, 8°,RIGHT	10885862175106

Version or Model	Device Description	Device Identifier
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

Version or Model	Device Description	Device Identifier
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

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