

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

To: Healthcare Providers and Exactech Sales Representatives

Date: December 31, 2024

Subject: **Important Notice Regarding Voluntary Recall of Exactech Hip Devices**

Commercial Name: Exactech AcuMatch, Novation and Alteon XLE Hip Liners (see "Attachment A" for product specific information)

We are writing to inform you about a lot-specific voluntary recall of XLE hip liners manufactured from 2018 through August 2021. These devices were marketed as AcuMatch XLE, Novation XLE and Alteon XLE, cleared through 510(k)s K173583 Exactech® Novation® and AcuMatch® E-HXL Acetabular Liners and K182502 Alteon Acetabular Cup System.

Please refer to "Appendix 1" for specific information about the affected products.

Thank you for your attention to this matter. Please review the subsequent information and take the appropriate action as necessary.

Reason for Recalling the Units:

This voluntary recall involves specific hip polyethylene liner lots that were packaged without the ethylene vinyl alcohol (EVOH) layer in the innermost bag, which is required by our packaging standards. The issue was identified during a review of supplier-provided packaging material certifications. The EVOH layer is intended to mitigate the risk of oxidation, which can lead to device degradation over time. The affected lots were packaged using only Low-Density Polyethylene (LDPE) and Nylon, which does not meet our product specifications or regulatory standards.

Since the XLE liners were released in 2018, 33 adverse events have been reported: 27 required revision surgery, and 6 were resolved without surgical intervention.

This recall is being conducted out of an abundance of caution to ensure all devices in the field meet their intended packaging requirements.

Actions to be Taken:

- **Immediate Discontinuation:** Immediately discontinue use of all affected products.
- **Quarantine and Return:** Segregate and quarantine affected products and arrange for their return to Exactech. The "Recall Confirmation Form" section of this communication provides

product return instructions.

Clinical Guidance:

1. **Patient Monitoring:** Surgeons should regularly monitor patients with affected devices for potential risks such as device wear, failure, component cracking or fracture, new or worsening pain, bone loss and/or swelling, as per the instructions for use.
2. **Diagnostic Considerations:** Diagnostic imaging, such as X-rays, may be considered if device failure is suspected.
3. **Revision Considerations:** Revision of well-functioning devices is not recommended for patients.
4. **Resources:** Healthcare providers and patients with questions can access educational resources on our website exac.com/recall-information and use the device serial look-up tool.

We appreciate your understanding and assistance in managing this recall process. Should you have any questions or require further information, please do not hesitate to contact our team. Thank you for your continued support and commitment to patient care.

Reporting Information

1. **Exactech Reporting:** Please report any adverse reactions or other quality problems experienced with these products to complaints@exac.com
2. **FDA Medwatch Reporting:** Healthcare professionals and consumers are encouraged to report any adverse events or quality concerns related to this recall to the FDA through the Medwatch reporting system.
 - Online at FDA Medwatch Website or
 - Calling 1-800-FDA-0178.

Transmission of this Recall Notice:

This notice needs to be passed on to all those who need to be aware of it within your organization.

This recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

We apologize for the inconvenience and thank you for your cooperation in this effort.

Sincerely,



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

01/16/2025

Date

URGENT VOLUNTARY MEDICAL DEVICE RECALL

Date: December 31, 2024

Subject: **Important Notice Regarding Voluntary Recall of Exactech Hip Devices**

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 packagingrecall@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 A".

Date

Agency

Name (Print)

Signature

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

Send affected products to:

Exactech
2320 NW 66th Ct
Gainesville, FL 32653
Attention XLE Recall

APPENDIX 1

Version or Model	Device Description	Brand Name	Device Identifier
140-28-25	AM EHXL 0°LNR E 28MM	AcuMatch XLE	10885862537973
140-28-26	AM EHXL 0°LNR F 28MM	AcuMatch XLE	10885862537980
140-28-27	AM EHXL 0° LNR G 28MM	AcuMatch XLE	10885862537997
140-28-28	AM EHXL 0°LNR H 28MM	AcuMatch XLE	10885862538000
140-28-29	AM EHXL 0° LNR J 28MM	AcuMatch XLE	10885862538017
140-28-30	AM EHXL 0°LNR K 28MM	AcuMatch XLE	10885862538024
140-32-27	AM EHXL 0° LNR G 32MM	AcuMatch XLE	10885862538031
140-32-28	AM EHXL 0° LNR H 32MM	AcuMatch XLE	10885862538048
140-36-28	AM EHXL 0°LNR H 36MM	AcuMatch XLE	10885862538079
142-28-24	AM EHXL 15° LNR D 28MM	AcuMatch XLE	10885862538123
142-28-25	AM EHXL 15°LNR E 28MM	AcuMatch XLE	10885862538130
142-28-26	AM EHXL 15° LNR F 28MM	AcuMatch XLE	10885862538147
142-28-27	AM EHXL 15°LNR G 28MM	AcuMatch XLE	10885862538154
142-28-28	AM EHXL 15°LNR H 28MM	AcuMatch XLE	10885862538161
142-28-29	AM EHXL 15° LNR J 28MM	AcuMatch XLE	10885862538178
144-28-25	AM EHXL EXTLNR E 28MM	AcuMatch XLE	10885862538260
144-28-26	AM EHXL EXTLNR F 28MM	AcuMatch XLE	10885862538277
144-28-27	AM EHXL EXTLNR G 28MM	AcuMatch XLE	10885862538284
144-28-28	AM EHXL EXT LNR H 28MM	AcuMatch XLE	10885862538291
144-28-29	AM EHXL EXT LNR J 28MM	AcuMatch XLE	10885862538307
144-28-30	AM EHXL EXTLNR K 28MM	AcuMatch XLE	10885862538314
148-28-25	AM EHXL LATLNR E 28MM	AcuMatch XLE	10885862538321
148-28-26	AM EHXL LAT LNR F 28MM	AcuMatch XLE	10885862538338
148-28-27	AM EHXL LAT LNR G 28MM	AcuMatch XLE	10885862538345
148-28-28	AM EHXL LATLNR H 28MM	AcuMatch XLE	10885862538352

Version or Model	Device Description	Brand Name	Device Identifier
148-28-29	AM EHXL LATLNR J 28MM	AcuMatch XLE	10885862538369
140-32-29	AM EHXL 0° LNR J 32MM	AcuMatch XLE	10885862538055
140-32-30	AM EHXL 0° LNR K 32MM	AcuMatch XLE	10885862538062
140-36-29	AM EHXL 0° LNR J 36MM	AcuMatch XLE	10885862538086
140-36-30	AM EHXL 0° LNR K 36MM	AcuMatch XLE	10885862538093
142-28-30	AM EHXL 15° LNR K 28MM	AcuMatch XLE	10885862538185
142-32-27	AM EHXL 15° LNR G 32MM	AcuMatch XLE	10885862538192
142-32-28	AM EHXL 15° LNR H 32MM	AcuMatch XLE	10885862538208
142-32-29	AM EHXL 15° LNR J 32MM	AcuMatch XLE	10885862538215
142-32-30	AM EHXL 15° LNR K 32MM	AcuMatch XLE	10885862538222
142-36-28	AM EHXL 15° LNR H 36MM	AcuMatch XLE	10885862538239
142-36-29	AM EHXL 15° LNR J 26MM	AcuMatch XLE	10885862538246
142-36-30	AM EHXL 15° LNR K 36MM	AcuMatch XLE	10885862538253
148-28-30	AM EHXL LAT LNR K 28MM	AcuMatch XLE	10885862538376
148-36-28	AM EHXL LAT LNR H 36MM	AcuMatch XLE	10885862538383
148-36-29	AM EHXL LAT LNR J 36MM	AcuMatch XLE	10885862538390
148-36-30	AM EHXL LAT LNR K 36MM	AcuMatch XLE	10885862538406
01-030-40-0022	ALT XLE LNRNTRL G0 22	Alteon XLE	10885862549433
01-030-40-0122	ALT XLE LNRNTRL G1 22	Alteon XLE	10885862549440
01-030-40-0128	ALT XLE LNR NTRL G1 28	Alteon XLE	10885862549457
01-030-40-0222	ALT XLE LNRNTRL G2 22	Alteon XLE	10885862549464
01-030-40-0228	ALT XLE LNR NTRL G2 28	Alteon XLE	10885862549471
01-030-42-0128	ALT XLE LNREXTCOV G1 28	Alteon XLE	10885862549792
01-030-42-0228	ALT XLE LNR EXTCOV G2 28	Alteon XLE	10885862549815
01-030-46-0022	ALT XLE LNR+5 LAT G0 22	Alteon XLE	10885862550453

Version or Model	Device Description	Brand Name	Device Identifier
01-030-46-0128	ALT XLE LNR+5 LAT G1 28	Alteon XLE	10885862550477
01-030-48-0128	ALT XLE LNR10° FC G1 28	Alteon XLE	10885862550811
01-030-40-0232	ALT XLE LNR NTRL G2 32	Alteon XLE	10885862549488
01-030-40-0322	ALT XLE LNR NTRL G3 22	Alteon XLE	10885862549495
01-030-40-0328	ALT XLE LNR NTRL G3 28	Alteon XLE	10885862549501
01-030-40-0332	ALT XLE LNR NTRL G3 32	Alteon XLE	10885862549518
01-030-40-0422	ALT XLE LNR NTRL G4 22	Alteon XLE	10885862549532
01-030-40-0428	ALT XLE LNR NTRL G4 28	Alteon XLE	10885862549549
01-030-40-0432	ALT XLE LNR NTRL G4 32	Alteon XLE	10885862549556
01-030-40-0436	ALT XLE LNR NTRL G4 36	Alteon XLE	10885862549563
01-030-40-0522	ALT XLE LNR NTRL G5 22	Alteon XLE	10885862549570
01-030-40-0528	ALT XLE LNR NTRL G5 28	Alteon XLE	10885862549587
01-030-40-0532	ALT XLE LNR NTRL G5 32	Alteon XLE	10885862549594
01-030-40-0536	ALT XLE LNR NTRL G5 36	Alteon XLE	10885862549600
01-030-40-0622	ALT XLE LNR NTRL G6 22	Alteon XLE	10885862549624
01-030-40-0628	ALT XLE LNR NTRL G6 28	Alteon XLE	10885862549631
01-030-40-0632	ALT XLE LNR NTRL G6 32	Alteon XLE	10885862549648
01-030-40-0636	ALT XLE LNR NTRL G6 36	Alteon XLE	10885862549655
01-030-40-0640	ALT XLE LNR NTRL G6 40	Alteon XLE	10885862549662
01-030-40-0722	ALT XLE LNR NTRL G7 22	Alteon XLE	10885862549679
01-030-40-0728	ALT XLE LNR NTRL G7 28	Alteon XLE	10885862549686
01-030-40-0732	ALT XLE LNR NTRL G7 32	Alteon XLE	10885862549693
01-030-40-0736	ALT XLE LNR NTRL G7 36	Alteon XLE	10885862549709
01-030-40-0740	ALT XLE LNR NTRL G7 40	Alteon XLE	10885862549716
01-030-40-0822	ALT XLE LNR NTRL G8 22	Alteon XLE	10885862549723

Version or Model	Device Description	Brand Name	Device Identifier
01-030-40-0828	ALT XLE LNR NTRL G8 28	Alteon XLE	10885862549730
01-030-40-0832	ALT XLE LNR NTRL G8 32	Alteon XLE	10885862549747
01-030-40-0836	ALT XLE LNR NTRL G8 36	Alteon XLE	10885862549754
01-030-40-0840	ALT XLE LNR NTRL G8 40	Alteon XLE	10885862549761
01-030-42-0232	ALT XLE LNR EXTCOV G2 32	Alteon XLE	10885862549822
01-030-42-0328	ALT XLE LNR EXTCOV G3 28	Alteon XLE	10885862549846
01-030-42-0332	ALT XLE LNR EXTCOV G3 32	Alteon XLE	10885862549853
01-030-42-0428	ALT XLE LNR EXTCOV G4 28	Alteon XLE	10885862549884
01-030-42-0432	ALT XLE LNR EXTCOV G4 32	Alteon XLE	10885862549891
01-030-42-0436	ALT XLE LNR EXTCOV G4 36	Alteon XLE	10885862549907
01-030-42-0528	ALT XLE LNR EXTCOV G5 28	Alteon XLE	10885862549921
01-030-42-0532	ALT XLE LNR EXTCOV G5 32	Alteon XLE	10885862549938
01-030-42-0536	ALT XLE LNR EXTCOV G5 36	Alteon XLE	10885862549945
01-030-42-0628	ALT XLE LNR EXTCOV G6 28	Alteon XLE	10885862549976
01-030-42-0632	ALT XLE LNR EXTCOV G6 32	Alteon XLE	10885862549983
01-030-42-0636	ALT XLE LNR EXTCOV G6 36	Alteon XLE	10885862549990
01-030-42-0640	ALT XLE LNR EXTCOV G6 40	Alteon XLE	10885862550002
01-030-42-0728	ALT XLE LNR EXTCOV G7 28	Alteon XLE	10885862550026
01-030-42-0732	ALT XLE LNR EXTCOV G7 32	Alteon XLE	10885862550033
01-030-42-0736	ALT XLE LNR EXTCOV G7 36	Alteon XLE	10885862550040
01-030-42-0740	ALT XLE LNR EXTCOV G7 40	Alteon XLE	10885862550057
01-030-42-0828	ALT XLE LNR EXTCOV G8 28	Alteon XLE	10885862550071
01-030-42-0832	ALT XLE LNR EXTCOV G8 32	Alteon XLE	10885862550088
01-030-42-0836	ALT XLE LNR EXTCOV G8 36	Alteon XLE	10885862550095
01-030-42-0840	ALT XLE LNR EXTCOV G8 40	Alteon XLE	10885862550101

Version or Model	Device Description	Brand Name	Device Identifier
01-030-46-0232	ALT XLE LNR+5 LAT G2 32	Alteon XLE	10885862550507
01-030-46-0332	ALT XLE LNR+5 LAT G3 32	Alteon XLE	10885862550538
01-030-46-0432	ALT XLE LNR+5 LAT G4 32	Alteon XLE	10885862550576
01-030-46-0436	ALT XLE LNR+5 LAT G4 36	Alteon XLE	10885862550583
01-030-46-0532	ALT XLE LNR+5 LAT G5 32	Alteon XLE	10885862550613
01-030-46-0536	ALT XLE LNR+5 LAT G5 36	Alteon XLE	10885862550620
01-030-46-0632	ALT XLE LNR+5 LAT G6 32	Alteon XLE	10885862550668
01-030-46-0636	ALT XLE LNR+5 LAT G6 36	Alteon XLE	10885862550675
01-030-46-0640	ALT XLE LNR+5 LAT G6 40	Alteon XLE	10885862550682
01-030-46-0736	ALT XLE LNR+5 LAT G7 36	Alteon XLE	10885862550729
01-030-46-0740	ALT XLE LNR+5 LAT G7 40	Alteon XLE	10885862550736
01-030-46-0836	ALT XLE LNR+5 LAT G8 36	Alteon XLE	10885862550774
01-030-46-0840	ALT XLE LNR+5 LAT G8 40	Alteon XLE	10885862550781
01-030-48-0232	ALT XLE LNR 10° FC G2 32	Alteon XLE	10885862550842
01-030-48-0332	ALT XLE LNR 10° FC G3 32	Alteon XLE	10885862550873
01-030-48-0436	ALT XLE LNR 10° FC G4 36	Alteon XLE	10885862550927
01-030-48-0532	ALT XLE LNR 10° FC G5 32	Alteon XLE	10885862550958
01-030-48-0536	ALT XLE LNR 10° FC G5 36	Alteon XLE	10885862550965
01-030-48-0632	ALT XLE LNR 10° FC G6 32	Alteon XLE	10885862551009
01-030-48-0636	ALT XLE LNR 10° FC G6 36	Alteon XLE	10885862551016
01-030-48-0640	ALT XLE LNR 10° FC G6 40	Alteon XLE	10885862551023
01-030-48-0736	ALT XLE LNR 10° FC G7 36	Alteon XLE	10885862551061
01-030-48-0740	ALT XLE LNR 10° FC G7 40	Alteon XLE	10885862551078
01-030-48-0836	ALT XLE LNR 10° FC G8 36	Alteon XLE	10885862551115
01-030-48-0840	ALT XLE LNR 10° FC G8 40	Alteon XLE	10885862551122

Version or Model	Device Description	Brand Name	Device Identifier
140-22-70	NV EHXL NTL LNR G00 22MM	Novation XLE	10885862537225
140-28-50	NV EHXLNTRL LNR G0 28MM	Novation XLE	10885862537232
142-22-68	NV EHXL ALPLNR G00 22MM	Novation XLE	10885862537546
142-22-70	NV EHXL LIPLNR G00 22MM	Novation XLE	10885862537386
142-28-50	NV EHXL LIP LNR G0 28MM	Novation XLE	10885862537393
142-28-60	NV EHXL ALIPLNR G0 28MM	Novation XLE	10885862537553
146-22-70	NV EHXL LATLNR G00 22MM	Novation XLE	10885862537751
140-28-51	NV EHXLNTRL LNR G1 28MM	Novation XLE	10885862537249
140-28-52	NV EHXL NTRL LNR G228MM	Novation XLE	10885862537256
140-32-51	NV EHXL NTRL LNR G132MM	Novation XLE	10885862537263
140-32-52	NV EHXL NTRL LNR G232MM	Novation XLE	10885862537270
140-32-53	NV EHXL NTRL LNR G332MM	Novation XLE	10885862537287
140-32-54	NV EHXLNTRL LNR G4 32MM	Novation XLE	10885862537294
140-32-55	NV EHXLNTRL LNR G5 32MM	Novation XLE	10885862537300
140-36-52	NV EHXLNTRL LNR G2 36MM	Novation XLE	10885862537317
140-36-53	NV EHXL NTRL LNR G336MM	Novation XLE	10885862537324
140-36-54	NV EHXLNTRL LNR G4 36MM	Novation XLE	10885862537331
140-36-55	NV EHXLNTRL LNR G5 36MM	Novation XLE	10885862537348
140-40-53	NV EHXLNTRL LNR G3 40MM	Novation XLE	10885862537355
140-40-54	NV EHXLNTRL LNR G4 40MM	Novation XLE	10885862537362
140-40-55	NV EHXLNTRL LNR G5 40MM	Novation XLE	10885862537379
142-28-51	NV EHXL LIP LNR G1 28MM	Novation XLE	10885862537409
142-28-52	NV EHXL LIP LNR G2 28MM	Novation XLE	10885862537416
142-28-61	NV EHXL ALIP LNR G1 28MM	Novation XLE	10885862537560
142-28-62	NV EHXL ALIP LNR G2 28MM	Novation XLE	10885862537577

Version or Model	Device Description	Brand Name	Device Identifier
142-32-51	NV EHXL LIP LNR G1 32MM	Novation XLE	10885862537423
142-32-52	NV EHXL LIP LNR G2 32MM	Novation XLE	10885862537430
142-32-53	NV EHXL LIP LNR G3 32MM	Novation XLE	10885862537447
142-32-54	NV EHXL LIP LNR G4 32MM	Novation XLE	10885862537454
142-32-55	NV EHXL LIP LNR G5 32MM	Novation XLE	10885862537461
142-32-61	NV EHXL ALIP LNR G1 32MM	Novation XLE	10885862537584
142-32-62	NV EHXL ALIP LNR G2 32MM	Novation XLE	10885862537591
142-32-63	NV EHXL ALIP LNR G3 32MM	Novation XLE	10885862537607
142-32-64	NV EHXL ALIP LNR G4 32MM	Novation XLE	10885862537614
142-32-65	NV EHXL ALIP LNR G5 32MM	Novation XLE	10885862537621
142-36-52	NV EHXL LIP LNR G2 36MM	Novation XLE	10885862537478
142-36-53	NV EHXL LIP LNR G3 36MM	Novation XLE	10885862537485
142-36-54	NV EHXL LIP LNR G4 36MM	Novation XLE	10885862537492
142-36-55	NV EHXL LIP LNR G5 36MM	Novation XLE	10885862537508
142-36-62	NV EHXL ALIP LNR G2 36MM	Novation XLE	10885862537638
142-36-63	NV EHXL ALIP LNR G3 36MM	Novation XLE	10885862537645
142-36-64	NV EHXL ALIP LNR G4 36MM	Novation XLE	10885862537652
142-36-65	NV EHXL ALIP LNR G5 36MM	Novation XLE	10885862537669
142-40-53	NV EHXL LIP LNR G3 40MM	Novation XLE	10885862537515
142-40-54	NV EHXL LIP LNR G4 40MM	Novation XLE	10885862537522
142-40-55	NV EHXL LIP LNR G5 40MM	Novation XLE	10885862537539
142-40-63	NV EHXL ALIP LNR G3 40MM	Novation XLE	10885862537676
142-40-64	NV EHXL ALIP LNR G4 40MM	Novation XLE	10885862537683
142-40-65	NV EHXL ALIP LNR G5 40MM	Novation XLE	10885862537690
146-28-51	NV EHXL LAT LNR G1 28MM	Novation XLE	10885862537768

Version or Model	Device Description	Brand Name	Device Identifier
146-32-51	NV EHXL LAT LNR G1 32MM	Novation XLE	10885862537775
146-32-52	NV EHXL LAT LNR G2 32MM	Novation XLE	10885862537782
146-32-53	NV EHXL LAT LNR G3 32MM	Novation XLE	10885862537799
146-32-54	NV EHXL LAT LNR G4 32MM	Novation XLE	10885862537805
146-32-55	NV EHXL LAT LNR G5 32MM	Novation XLE	10885862537812
146-36-52	NV EHXL LAT LNR G2 36MM	Novation XLE	10885862537829
146-36-53	NV EHXL LAT LNR G3 36MM	Novation XLE	10885862537836
146-36-54	NV EHXL LAT LNR G4 36MM	Novation XLE	10885862537843
146-36-55	NV EHXL LAT LNR G5 36MM	Novation XLE	10885862537850
146-40-53	NV EHXL LAT LNR G3 40MM	Novation XLE	10885862537867
146-40-54	NV EHXL LAT LNR G4 40MM	Novation XLE	10885862537874
146-40-55	NV EHXL LAT LNR G5 40MM	Novation XLE	10885862537881
148-32-51	NV EHXL 10° LNR G1 32MM	Novation XLE	10885862537898
148-36-52	NV EHXL 10° LNR G2 36MM	Novation XLE	10885862537904
148-36-53	NV EHXL 10° LNR G3 36MM	Novation XLE	10885862537911
148-36-54	NV EHXL 10° LNR G4 36MM	Novation XLE	10885862537928
148-36-55	NV EHXL 10° LNR G5 36MM	Novation XLE	10885862537935
148-40-53	NV EHXL 10° LNR G3 40MM	Novation XLE	10885862537942
148-40-54	NV EHXL 10° LNR G4 40MM	Novation XLE	10885862537959
148-40-55	NV EHXL 10° LNR G5 40MM	Novation XLE	10885862537966