

California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Exactech, Inc: AcuMatch XLE and Novation XLE Recall

Recall Date	Product Description	Recalling Firm	Recall Reason
02/12/2025	AcuMatch XLE Item Number / Product Description: 140-28-27 AM EHXL 0 ₂ LNR G 28MM 140-32-27 AM EHXL 0 ₂ LNR G 32MM 140-32-28 AM EHXL 0 ₂ LNR H 32MM 140-28-29 AM EHXL 0 ₂ LNR J 28MM 140-32-29AM EHXL 0 ₂ LNR J 32MM 140-36-29 AM EHXL 0 ₂ LNR J 36MM 140-32-30 AM EHXL 0 ₂ LNR K 32MM 140-36-30AM EHXL 0 ₂ LNR K 36MM 140-28-25 AM EHXL 0 ₂ LNR E 28MM 140-28-26 AM EHXL 0 ₂ LNR F 28MM 140-28-28 AM EHXL 0 ₂ LNR H 28MM 140-36-28 AM EHXL 0 ₂ LNR H 36MM 140-28-30 AM EHXL 0 ₂ LNR K 28MM 142-28-24 AM EHXL 15 ₂ LNR D 28MM 142-28-26 AM EHXL 15 ₂ LNR F 28MM 142-32-27 AM EHXL 15 ₂ LNR G 32MM 142-32-28 AM EHXL 15 ₂ LNR H 32MM 142-36-28 AM EHXL 15 ₂ LNR H 36MM 142-36-29 AM EHXL 15 ₂ LNR J 26MM 142-28-29 AM EHXL 15 ₂ LNR J 28MM 142-32-29 AM EHXL 15 ₂ LNR J 32MM 142-28-30 AM EHXL 15 ₂ LNR K 28MM 142-32-30 AM EHXL 15 ₂ LNR K 32MM 142-36-30	Exactech, Inc.	Due to the lack of the Ethylene Vinyl Alcohol (EVOH) barrier layer.

	AM EHXL 15₂ LNR K 36MM 142-28-25 AM EHXL 15₂ LNR E 28MM 142-28-27 AM EHXL 15₂ LNR G 28MM 142-28-28 AM EHXL 15₂ LNR H 28MM 144-28-28 AM EHXL EXT LNR H 28MM 144-28-29 AM EHXL EXT LNR J 28MM 144-28-25 AM EHXL EXTLNR E 28MM 144-28-26AM EHXL EXTLNR F 28MM 144-28-27 AM EHXL EXTLNR G 28MM 144-28-30 AM EHXL EXTLNR K 28MM 148-28-26 AM EHXL LAT LNR F 28MM 148-28-27 AM EHXL LAT LNR G 28MM 148-36-28 AM EHXL LAT LNR H 36MM 148-36-29 AM EHXL LAT LNR J 36MM 148-28-30 AM EHXL LAT LNR K 28MM 148-36-30 AM EHXL LAT LNR K 36MM 148-28-25AM EHXL LATLNR E 28MM 148-28-28 AM EHXL LATLNR H 28MM 148-28-29 AM EHXL LATLNR J 28MM All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment. Novation XLE Item Number / Product Description: 140-22-70 NV EHXL NTL LNR G00 22MM 140-28-50 NV EHXLNTRL LNR G0 28MM 140-28-51 NV EHXLNTRL LNR G1 28MM 140-28-52 NV EHXL NTRL LNR G228MM 140-32-51 NV EHXL NTRL LNR G132MM 140-32-52 NV EHXL NTRL LNR G232MM 140-32-53 NV		
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EHXL NTRL LNR G332MM 140-32-54 NV EHXLNTRL LNR G4 32MM 140-32-55 NV EHXLNTRL LNR G5 32MM 140-36-52 NV EHXLNTRL LNR G2 36MM 140-36-53 NV EHXL NTRL LNR G336MM 140-36-54 NV EHXLNTRL LNR G4 36MM 140-36-55 NV EHXLNTRL LNR G5 36MM 140-40-53 NV EHXLNTRL LNR G3 40MM 140-40-54 NV EHXLNTRL LNR G4 40MM 140-40-55 NV EHXLNTRL LNR G5 40MM 142-22-68 NV EHXL ALPLNR G00 22MM 142-22-70 NV EHXL LIPLNR G00 22MM 142-28-50 NV EHXL LIP LNR G0 28MM 142-28-51 NV EHXL LIP LNR G1 28MM 142-28-52 NV EHXL LIP LNR G2 28MM 142-28-60 NV EHXL ALIPLNR G0 28MM 142-28-61 NV EHXL ALIP LNR G1 28MM 142-28-62 NV EHXL ALIP LNR G2 28MM 142-32-51 NV EHXL LIP LNR G1 32MM 142-32-52 NV EHXL LIP LNR G2 32MM 142-32-53 NV EHXL LIP LNR G3 32MM 142-32-54 NV EHXL LIP LNR G4 32MM 142-32-55 NV EHXL LIP LNR G5 32MM 142-32-61 NV EHXL ALIP LNR G1 32MM 142-32-62 NV EHXL ALIP LNR G2 32MM 142-32-63 NV EHXL ALIP LNR G3 32MM 142-32-64 NV EHXL ALIP LNR G4 32MM 142-32-65 NV EHXL ALIP LNR G5 32MM 142-36-52 NV EHXL LIP LNR G2 36MM 142-36-53 NV EHXL LIP LNR G3 36MM 142-36-54 NV EHXL LIP LNR G4 36MM 142-36-55 NV EHXL LIP LNR G5 36MM 142-36-62 NV EHXL ALIP LNR G2 36MM 142-36-63 NV EHXL ALIP LNR G3 36MM		
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142-36-64 NV EHXL ALIP LNR G4 36MM 142-36-65 NV EHXL ALIP LNR G5 36MM 142-40-53 NV EHXL LIP LNR G3 40MM 142-40-54 NV EHXL LIP LNR G4 40MM 142-40-55 NV EHXL LIP LNR G5 40MM 142-40-63 NV EHXL ALIP LNR G3 40MM 142-40-64 NV EHXL ALIP LNR G4 40MM 142-40-65 NV EHXL ALIP LNR G5 40MM 146-22-70 NV EHXL LATLNR G00 22MM 146-28-51 NV EHXL LAT LNR G1 28MM 146-32-51 NV EHXL LAT LNR G1 32MM 146-32-52 NV EHXL LAT LNR G2 32MM 146-32-53 NV EHXL LAT LNR G3 32MM 146-32-54 NV EHXL LAT LNR G4 32MM 146-32-55 NV EHXL LAT LNR G5 32MM 146-36-52 NV EHXL LAT LNR G2 36MM 146-36-53 NV EHXL LAT LNR G3 36MM 146-36-54 NV EHXL LAT LNR G4 36MM 146-36-55 NV EHXL LAT LNR G5 36MM 146-40-53 NV EHXL LAT LNR G3 40MM 146-40-54 NV EHXL LAT LNR G4 40MM 146-40-55 NV EHXL LAT LNR G5 40MM 148-32-51 NV EHXL 10_ç LNR G1 32MM 148-36-52 NV EHXL 10_ç LNR G2 36MM 148-36-53 NV EHXL 10_ç LNR G3 36MM 148-36-54 NV EHXL 10_ç LNR G4 36MM 148-36-55 NV EHXL 10_ç LNR G5 36MM 148-40-53 NV EHXL 10_ç LNR G3 40MM 148-40-54 NV EHXL 10_ç LNR G4 40MM 148-40-55 NV EHXL 10_ç LNR G5 40MM All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip		
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	replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment.		
02/12/2025	Novation XLE Item Number / Product Description: 140-22-70 NV EHXL NTL LNR G00 22MM 140-28-50 NV EHXLNTRL LNR G0 28MM 140-28-51 NV EHXLNTRL LNR G1 28MM 140-28-52 NV EHXL NTRL LNR G228MM 140-32-51 NV EHXL NTRL LNR G132MM 140-32-52 NV EHXL NTRL LNR G232MM 140-32-53 NV EHXL NTRL LNR G332MM 140-32-54 NV EHXLNTRL LNR G4 32MM 140-32-55 NV EHXLNTRL LNR G5 32MM 140-36-52 NV EHXLNTRL LNR G2 36MM 140-36-53 NV EHXL NTRL LNR G336MM 140-36-54 NV EHXLNTRL LNR G4 36MM 140-36-55 NV EHXLNTRL LNR G5 36MM 140-40-53 NV EHXLNTRL LNR G3 40MM 140-40-54 NV EHXLNTRL LNR G4 40MM 140-40-55 NV EHXLNTRL LNR G5 40MM 142-22-68 NV EHXL ALPLNR G00 22MM 142-22-70 NV EHXL LIPLNR G00 22MM 142-28-50 NV EHXL LIP LNR G0 28MM 142-28-51 NV EHXL LIP LNR G1 28MM 142-28-52 NV EHXL LIP LNR G2 28MM 142-28-60 NV EHXL ALIPLNR G0 28MM 142-28-61 NV EHXL ALIP LNR G1 28MM 142-28-62 NV EHXL ALIP LNR G2 28MM 142-32-51 NV EHXL LIP LNR G1 32MM 142-32-52 NV EHXL LIP LNR G2 32MM 142-32-53 NV	Exactech, Inc.	Due to the lack of the Ethylene Vinyl Alcohol (EVOH) barrier layer.

EHXL LIP LNR G3 32MM 142-32-54 NV EHXL LIP LNR G4 32MM 142-32-55 NV EHXL LIP LNR G5 32MM 142-32-61 NV EHXL ALIP LNR G1 32MM 142-32-62 NV EHXL ALIP LNR G2 32MM 142-32-63 NV EHXL ALIP LNR G3 32MM 142-32-64 NV EHXL ALIP LNR G4 32MM 142-32-65 NV EHXL ALIP LNR G5 32MM 142-36-52 NV EHXL LIP LNR G2 36MM 142-36-53 NV EHXL LIP LNR G3 36MM 142-36-54 NV EHXL LIP LNR G4 36MM 142-36-55 NV EHXL LIP LNR G5 36MM 142-36-62 NV EHXL ALIP LNR G2 36MM 142-36-63 NV EHXL ALIP LNR G3 36MM 142-36-64 NV EHXL ALIP LNR G4 36MM 142-36-65 NV EHXL ALIP LNR G5 36MM 142-40-53 NV EHXL LIP LNR G3 40MM 142-40-54 NV EHXL LIP LNR G4 40MM 142-40-55 NV EHXL LIP LNR G5 40MM 142-40-63 NV EHXL ALIP LNR G3 40MM 142-40-64 NV EHXL ALIP LNR G4 40MM 142-40-65 NV EHXL ALIP LNR G5 40MM 146-22-70 NV EHXL LATLNR G00 22MM 146-28-51 NV EHXL LAT LNR G1 28MM 146-32-51 NV EHXL LAT LNR G1 32MM 146-32-52 NV EHXL LAT LNR G2 32MM 146-32-53 NV EHXL LAT LNR G3 32MM 146-32-54 NV EHXL LAT LNR G4 32MM 146-32-55 NV EHXL LAT LNR G5 32MM 146-36-52 NV EHXL LAT LNR G2 36MM 146-36-53 NV EHXL LAT LNR G3 36MM 146-36-54 NV EHXL LAT LNR G4 36MM 146-36-55 NV EHXL LAT LNR G5 36MM 146-40-53 NV EHXL LAT LNR		
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	G3 40MM 146-40-54 NV EHXL LAT LNR G4 40MM 146-40-55 NV EHXL LAT LNR G5 40MM 148-32-51 NV EHXL 10¿ LNR G1 32MM 148-36-52 NV EHXL 10¿ LNR G2 36MM 148-36-53 NV EHXL 10¿ LNR G3 36MM 148-36-54 NV EHXL 10¿ LNR G4 36MM 148-36-55 NV EHXL 10¿ LNR G5 36MM 148-40-53 NV EHXL 10¿ LNR G3 40MM 148-40-54 NV EHXL 10¿ LNR G4 40MM 148-40-55 NV EHXL 10¿ LNR G5 40MM All Exactech Hip Systems are indicated for use in skeletally mature individuals undergoing primary surgery for hip replacement due to osteoarthritis, rheumatoid arthritis, osteonecrosis, post-traumatic degenerative problems of the hip, and for treatment of proximal femoral fractures where prosthetic replacement is determined by the surgeon as the preferred treatment		
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Recall Class	Product Identification	Distribution	Affected Dates
II	Item Number / Product Description/ UDI-DI code: 140-28-27 AM EHXL 0¿ LNR G 28MM 10885862537997 140-32-27 AM EHXL 0¿ LNR G 32MM 10885862538031 140-32-28 AM EHXL 0¿ LNR H 32MM 10885862538048 140-28-29 AM EHXL 0¿ LNR J 28MM 10885862538017 140-32-29 AM EHXL 0¿ LNR J 32MM 10885862538055 140-36-29 AM EHXL 0¿ LNR J 36MM 10885862538086 140-32-30 AM EHXL 0¿ LNR K 32MM 10885862538062 140-36-30 AM EHXL 0¿ LNR K 36MM 10885862538093 140-28-25 AM	803 units were distributed in California	December 2024 and Prior

EHXL 0¿LNR E 28MM 10885862537973 140-28-26 AM EHXL 0¿LNR F 28MM 10885862537980 140-28-28 AM EHXL 0¿LNR H 28MM 10885862538000 140-36-28 AM EHXL 0¿LNR H 36MM 10885862538079 140-28-30 AM EHXL 0¿LNR K 28MM 10885862538024 142-28-24 AM EHXL 15¿ LNR D 28MM 10885862538123 142-28-26 AM EHXL 15¿ LNR F 28MM 10885862538147 142-32-27 AM EHXL 15¿ LNR G 32MM 10885862538192 142-32-28 AM EHXL 15¿ LNR H 32MM 10885862538208 142-36-28 AM EHXL 15¿ LNR H 36MM 10885862538239 142-36-29 AM EHXL 15¿ LNR J 26MM 10885862538246 142-28-29 AM EHXL 15¿ LNR J 28MM 10885862538178 142-32-29 AM EHXL 15¿ LNR J 32MM 10885862538215 142-28-30 AM EHXL 15¿ LNR K 28MM 10885862538185 142-32-30 AM EHXL 15¿ LNR K 32MM 10885862538222 142-36-30 AM EHXL 15¿ LNR K 36MM 10885862538253 142-28-25 AM EHXL 15¿LNR E 28MM 10885862538130 142-28-27 AM EHXL 15¿LNR G 28MM 10885862538154 142-28-28 AM EHXL 15¿LNR H 28MM 10885862538161 144-28-28 AM EHXL EXT LNR H 28MM 10885862538291 144-28-29 AM EHXL EXT LNR J 28MM 10885862538307 144-28-25 AM EHXL EXTLNR E 28MM 10885862538260 144-28-26 AM EHXL EXTLNR F 28MM 10885862538277 144-28-27 AM EHXL EXTLNR G 28MM 10885862538284 144-28-30 AM		
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EHXL EXTLNR K 28MM 10885862538314 148-28-26 AM EHXL LAT LNR F 28MM 10885862538338 148-28-27 AM EHXL LAT LNR G 28MM 10885862538345 148-36-28 AM EHXL LAT LNR H 36MM 10885862538383 148-36-29 AM EHXL LAT LNR J 36MM 10885862538390 148-28-30 AM EHXL LAT LNR K 28MM 10885862538376 148-36-30 AM EHXL LAT LNR K 36MM 10885862538406 148-28-25 AM EHXL LATLNR E 28MM 10885862538321 148-28-28 AM EHXL LATLNR H 28MM 10885862538352 148-28-29 AM EHXL LATLNR J 28MM 10885862538369 Item Number / Product Description/ UDI-DI code: 140-22-70 NV EHXL NTL LNR G00 22MM 10885862537225 140-28-50 NV EHXLNTRL LNR G0 28MM 10885862537232 140-28-51 NV EHXLNTRL LNR G1 28MM 10885862537249 140-28-52 NV EHXL NTRL LNR G228MM 10885862537256 140-32-51 NV EHXL NTRL LNR G132MM 10885862537263 Serial Numbers: 6594943 6970850 6595376 6595380 6858220 6858230 6973123 6594924 6970840 6595383 6595385 6595381 6970835 6970838 6970842 6595922 6510276 6973139 140-32-52 NV EHXL NTRL LNR G232MM 10885862537270 140-32-53 NV EHXL NTRL LNR G332MM 10885862537287 140-32-54 NV EHXLNTRL LNR G4 32MM 10885862537294 140-32-55 NV EHXLNTRL LNR G5 32MM 10885862537300 140-36-52 NV EHXLNTRL LNR G2 36MM		
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10885862537317 Serial Numbers: 6558356 6422337 6631675 6504196 6631677 6631695 6631712 6844304 6631689 6631699 6631725 6558360 6844285 6844298 6844281 6348961 6504177 6504195 6504202 6504204 6631686 6844321 140-36-53 NV EHXL NTRL LNR G336MM 10885862537324 Serial Numbers: 6600076 6600101 6600054 6600057 6600093 140-36-54 NV EHXLNTRL LNR G4 36MM 10885862537331 140-36-55 NV EHXLNTRL LNR G5 36MM 10885862537348 140-40-53 NV EHXLNTRL LNR G3 40MM 10885862537355 Serial Numbers: 6510314 6510327 140-40-54 NV EHXLNTRL LNR G4 40MM 10885862537362 140-40-55 NV EHXLNTRL LNR G5 40MM 10885862537379 142-22-68 NV EHXL ALPLNR G00 22MM 10885862537546 142-22-70 NV EHXL LIPLNR G00 22MM 10885862537386 142-28-50 NV EHXL LIP LNR G0 28MM 10885862537393 142-28-51 NV EHXL LIP LNR G1 28MM 10885862537409 142-28-52 NV EHXL LIP LNR G2 28MM 10885862537416 142-28-60 NV EHXL ALIPLNR G0 28MM 10885862537553 142-28-61 NV EHXL ALIP LNR G1 28MM 10885862537560 142-28-62 NV EHXL ALIP LNR G2 28MM 10885862537577 142-32-51 NV EHXL LIP LNR G1 32MM 10885862537423 142-32-52 NV EHXL LIP LNR G2 32MM 10885862537430 142-32-53 NV EHXL LIP LNR G3 32MM 10885862537447 142-32-54 NV EHXL LIP LNR G4 32MM 10885862537454 142-32-55 NV		
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EHXL LIP LNR G5 32MM 10885862537461 142-32-61 NV EHXL ALIP LNR G1 32MM 10885862537584 Serial Numbers: 7040076 6842549 6554448 6596005 6554464 6554458 6866177 6596019 6554457 6595993 6503270 142-32-62 NV EHXL ALIP LNR G2 32MM 10885862537591 142-32-63 NV EHXL ALIP LNR G3 32MM 10885862537607 142-32-64 NV EHXL ALIP LNR G4 32MM 10885862537614 142-32-65 NV EHXL ALIP LNR G5 32MM 10885862537621 142-36-52 NV EHXL LIP LNR G2 36MM 10885862537478 142-36-53 NV EHXL LIP LNR G3 36MM 10885862537485 142-36-54 NV EHXL LIP LNR G4 36MM 10885862537492 142-36-55 NV EHXL LIP LNR G5 36MM 10885862537508 142-36-62 NV EHXL ALIP LNR G2 36MM 10885862537638 Serial Numbers: 6831997 6679288 6831980 7032226 6679275 6831983 6335167 6832001 6555554 7032248 6679286 6679321 6831992 6927281 142-36-63 NV EHXL ALIP LNR G3 36MM 10885862537645 142-36-64 NV EHXL ALIP LNR G4 36MM 10885862537652 142-36-65 NV EHXL ALIP LNR G5 36MM 10885862537669 142-40-53 NV EHXL LIP LNR G3 40MM 10885862537515 142-40-54 NV EHXL LIP LNR G4 40MM 10885862537522 142-40-55 NV EHXL LIP LNR G5 40MM 10885862537539 142-40-63 NV EHXL ALIP LNR G3 40MM 10885862537676 Serial Numbers: 6452595 142-40-64 NV EHXL ALIP LNR G4 40MM 10885862537683 142-40-65 NV EHXL ALIP LNR G5		
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40MM 10885862537690 146-22-70 NV EHXL LATLNR G00 22MM 10885862537751 146-28-51 NV EHXL LAT LNR G1 28MM 10885862537768 146-32-51 NV EHXL LAT LNR G1 32MM 10885862537775 146-32-52 NV EHXL LAT LNR G2 32MM 10885862537782 146-32-53 NV EHXL LAT LNR G3 32MM 10885862537799 146-32-54 NV EHXL LAT LNR G4 32MM 10885862537805 146-32-55 NV EHXL LAT LNR G5 32MM 10885862537812 146-36-52 NV EHXL LAT LNR G2 36MM 10885862537829 146-36-53 NV EHXL LAT LNR G3 36MM 10885862537836 146-36-54 NV EHXL LAT LNR G4 36MM 10885862537843 146-36-55 NV EHXL LAT LNR G5 36MM 10885862537850 146-40-53 NV EHXL LAT LNR G3 40MM 10885862537867 Serial Numbers: 6602255 6602261 6602265 6602268 6602269 6602270 6602272 6602256 6602263 6602267 6602277 6602257 6602258 6602273 146-40-54 NV EHXL LAT LNR G4 40MM 10885862537874 146-40-55 NV EHXL LAT LNR G5 40MM 10885862537881 148-32-51 NV EHXL 10¿ LNR G1 32MM 10885862537898 148-36-52 NV EHXL 10¿ LNR G2 36MM 10885862537904 148-36-53 NV EHXL 10¿ LNR G3 36MM 10885862537911 148-36-54 NV EHXL 10¿ LNR G4 36MM 10885862537928 148-36-55 NV EHXL 10¿ LNR G5 36MM 10885862537935 148-40-53 NV EHXL 10¿ LNR G3 40MM 10885862537942 148-40-54 NV EHXL 10¿ LNR G4 40MM 10885862537959 148-40-55 NV		
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	EHXL 10¿ LNR G5 40MM 10885862537966		
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For additional information, please visit this [FDA Website AcuMatch XLE](#) and this [FDA Website Novation XLE](#).