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*****URGENT DEAR HEALTHCARE PROFESSIONAL COMMUNICATION*****

11 August 2022

To: Surgeons, Hospitals, Health care professionals
Description: Exactech moderately crosslinked and conventional UHMWPE Acetabular Hip Liners (CONNEXION GXL, ACUMATCH, MCS and NOVATION)

Expanded Field Correction: US Specific

Product Family	US Clearance Date	Affected Devices Distributed in US
Acumatch GXL	September 2005	4422
MCS GXL	September 2005	238
Novation GXL	March 2007	33,654
Exactech All Polyethylene Cemented Cup	September 1996	37
Acumatch Conventional UHMWPE	November 1993	1,224
MCS Conventional UHMWPE	October 1993	28
NOVATION Conventional UHMWPE	July 2007	502

Product specific information is listed in Attachment 1

Dear Surgeon:

In July 2021, Exactech issued a worldwide Urgent Dear Healthcare Professional (DHCP) communication regarding Exactech Connexion GXL, moderately crosslinked polyethylene acetabular hip liners (link to Exactech website: https://www.exac.com/medical-professionals/recall-information/).The purpose of the July 2021 communication was to inform surgeons that Exactech had observed a higher-than-expected number of cases in which the Connexion GXL liner exhibited early linear and volumetric wear with associated periacetabular and proximal femoral osteolysis. Exactech also characterized some of the risk factors that were associated with early polyethylene wear, including the following:

1. Use of the thinnest available liner for a given acetabular shell (e.g. a 36mm inner diameter liner in a 52mm outer diameter acetabular shell)
2. A lateralized (+5mm) or face-changing liner.
3. Implantation of the femoral and acetabular components in such a way that edge loading between the femoral head and acetabular liner was occurring.

Exactech has identified an additional risk factor for premature wear that was not known at the time of the prior DHCP communication. GXL inserts manufactured since 2004 were packaged in out-of-specification (referred to hereafter as “non-conforming”) vacuum bags that are oxygen resistant but do not contain a secondary oxygen barrier layer known as ethylene vinyl alcohol (EVOH), which further

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augments oxygen resistance. **The use of these non-conforming bags may enable increased oxygen diffusion to the polyethylene insert resulting in increased oxidation of the material relative to inserts packaged with the specified additional oxygen barrier layer. Over time, oxidation can severely degrade the mechanical properties of the Connexion GXL polyethylene, which, in conjunction with other surgical factors, can lead to both accelerated wear and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

Since issuance of the July 2021 communication, Exactech has also learned that additional conventional (i.e. non-crosslinked) ultra-high molecular weight polyethylene acetabular liners were packaged in non-conforming vacuum bags. These conventional liners are identified in Attachment 1. These polyethylene liners differ from Connexion GXL in that they are composed of conventional, non-crosslinked ultra-high molecular weight polyethylene (hereafter referred to as UHMWPE). Like the Connexion GXL, these liners are susceptible to increased oxygen diffusion during shelf storage, with subsequent risks for component fatigue and damage after implantation.

The purpose of the current letter is to update surgeons regarding the implications of the packaging non-conformity on performance of the Connexion GXL and other conventional UHMWPE acetabular liners. In addition, this letter provides updates to patient management and follow-up recommendations since issuance of the July 2021 DHCP letter. (link to Exactech website for initial DHCP letter: https://www.exac.com/medical-professionals/recall-information/). Please make note of the following updates:

1. We are expanding the scope of the recall communication to include all surgeons who have implanted either GXL liners or nonconforming conventional UHMWPE liners since 2004. The previous letter included only surgeons that had implanted Connexion GXL liners between 2015 and 2021.
2. We are expanding the patient follow-up guidance to include all patients who have received either a:
    a. GXL liner regardless of packaging materials and have not been examined in the past 12 months.
    b. Conventional UHMWPE acetabular liners packaged in nonconforming packaging and have not been examined in the past 12 months.
3. Patient management instructions, including X-rays and other diagnostic workup instructions, remain the same as identified in the prior letter.
4. Exactech has already provided many US surgeons with personalized lists of their Connexion GXL patients; however, those lists did not include patients that had index surgery prior to 2015, nor did they include conventional UHMWPE patients. We are now providing surgeons with full lists of both patient groups.
5. This communication relates ONLY to Exactech Connexion GXL and conventional UHMWPE acetabular liners sold in the US. Exactech's highly crosslinked, vitamin E infused polyethylene liner, known as Alteon® XLE Liner, is not affected by this recall.

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Background and synthesis of worldwide clinical data regarding Exactech Connexion GXL and conventional hip polyethylene:

Over the past ~20 years, Exactech has marketed and sold two varieties of hip polyethylene that are affected by this recall: 1) Conventional UHMWPE, 2) Connexion GXL moderately cross linked polyethylene:

1. **Connexion GXL** liner was first released for broad commercialization in 2005. This acetabular insert is the only Exactech product that is manufactured using a "moderate" cross linking process (i.e. two split doses of 25 kGy of gamma irradiation). This process was initially designed to optimize the mechanical properties of fracture resistance with the crosslinking benefits of reduced polyethylene wear. Our analysis shows that this moderately cross-linked material, which is unique to the Connexion GXL liner, is inherently more susceptible to oxidation and polyethylene wear in the hip versus modern, highly crosslinked Vitamin E polyethylene liners. This susceptibility is heightened when it is packaged in non-conforming bags, which allow increased oxygen diffusion.

   Published worldwide registry data on the Connexion GXL acetabular liner (e.g. United Kingdom and Australian joint registries) contain insufficient sample sizes to enable any conclusions regarding clinical performance. However, Exactech is aware of three peer-reviewed publications regarding early wear and osteolysis of the Connexion GXL liner. These publications have helped Exactech elucidate which Connexion GXL patients are at risk for early failures [1], [2], [3].
   These articles have collectively identified 19 patients that experienced medium-term failure of Connexion GXL liners. The failure rates of the Connexion GXL liner in these series range from 1%-3.2% at ~ 5 years. The articles propose that surveillance of Connexion GXL patients is warranted. The average time to revision in these three papers was ~ 5 years. While it appears that most patients with premature wear have symptoms of hip and / or groin pain, we have also observed that premature wear and lysis can occur in asymptomatic patients.
2. **Exactech conventional polyethylene.** Unlike the GXL liner, evidence of premature wear in the conventional polyethylene liners was not identified in literature or registries at the time of this recall. However, the effects of the non-conforming packaging on the conventional polyethylene liner are not fully known due to insufficient long-term clinical data. Given that some manufacturing lots of our conventional polyethylene were packaged in non-conforming bags, and the fact that this polyethylene is not antioxidant stabilized, (e.g. with vitamin E), conventional polyethylene devices in non-conforming packaging are included in the current recall / field action.

RECOMMENDATIONS REGARDING PATIENT FOLLOW-UP AND MANAGEMENT:

Exactech recommends that surgeons closely monitor the affected GXL and conventional polyethylene patients for early wear and / or early signs of lysis:

- For GXL, regardless of packaging materials and regardless of the time period that has elapsed since index arthroplasty.

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- For conventional polyethylene, in non-conforming packaging and regardless of the time period that has elapsed since index arthroplasty.

Exactech also recommends that surgeons perform follow-up examination on all affected GXL and conventional polyethylene patients who have not been seen in over 12 months. Suggested follow-up includes a routine clinical hip exam and x-rays, including standing AP pelvis, cross-table lateral, and sitting/functional lateral. These x-rays will assess the relative alignment of the acetabular and femoral components and should identify edge loading. Additional three-dimensional imaging (i.e. computed tomography or magnetic resonance imaging) should also be utilized by surgeons to better characterize lytic defects, based on the surgeon's discretion. Other diagnostic workup for failed total hip arthroplasty, including serology and hip aspiration should also be used at the surgeon's discretion. **Pre-emptive removal of non-painful, well-functioning Exactech hip devices from asymptomatic patients is not recommended**. Decisions about removing or exchanging the device should be made by health care providers in consultation with the patient or caregiver on a case-by-case basis. As part of shared decision-making, discuss the benefits and risks of all relevant treatment options with your patients. For patients who exhibit premature polyethylene wear, the surgeon should consider revision surgery per their clinical judgment. If the surgeon desires to perform an isolated polyethylene exchange, Exactech can provide new Vitamin E infused (XLE liner) polyethylene hip inserts, for AcuMatch and Novation acetabular liners only. The surgeon should also use his/her discretion to determine whether revision of the entire acetabular construct (i.e. outer metal shell and polyethylene liner) is warranted.

In addition to providing surgeons with lists of all their affected GXL and/or conventional polyethylene patients since 2004, Exactech is providing surgeons with two draft letters directed at patients who have been implanted with Exactech GXL hip devices. We recommend that surgeons customize the letter and send it to patients. Alternatively, Exactech is prepared to send these letters to your patients or provide administrative assistance with these mailings. We may contact you separately about your willingness to participate in a voluntary program to provide Exactech with statistics on patient follow-up per a new FDA Patient Science and Engagement Program. Exactech is also prepared to provide you (1) a list of all your patients' identification to assist in clinical follow-up efforts, (2) a frequently asked questions page online to assist you, and (3) a tool on Exactech's website that will empower a patient to enter her/his implant serial number and confirm whether that implanted device is non-conforming.

Exactech is advising surgeons to avoid implanting nonconforming devices. A list of product codes, product description and serial numbers can be found at: https://www.exac.com/medical-professionals/recall-information/. Your Exactech agent will work with you to remove non-conforming devices from inventory.

FDA has been notified of this recall.

Exactech is committed to reimbursing your patients for their out-of-pocket expenses associated with the recall and have engaged a third-party administrator, Broadspire, to process these claims. Additionally, Exactech has engaged orthopedic nurses who can answer live questions from patients regarding the GXL and/or conventional liners and premature wear. The phone number for both of

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these resources is 888-912-0403. Information regarding these services can be found on the Exactech website at: https://www.exac.com/medical-professionals/recall-information/.

If it is helpful, we would appreciate the opportunity to set up a conference call / WebEx with you and our corporate leadership team to discuss the issues around this recall, the TPA services, provision of patient lists and management, drafted letters to patients, or any other questions in greater detail. Please correspond with the email address, gxl@exac.com, or call us at 1.888.912.0403 if you wish to meet and we will arrange a time as soon as possible.

Actions to be Taken:

- **Review this communication thoroughly.**
- **Contact your local Exactech Representative** if you have any questions regarding this communication.
- **Provide letters to your patients informing them of the issue and to return for observation if not seen in the past 12 months. Exactech can assist you with these communications.**
- **Your local agent will help to determine which liners are affected and should be removed from inventory. Please note that our records indicate there are no GXL liners in US field inventory.**

Our first concern is for the health and safety of patients and the users of our products. Actions of this type are collaborative efforts and require your participation to be effective.

Sincerely,

Sharat Kusuma, MD, FAAOS
Chief Medical Officer
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References:

1. Early Polyethylene Failure in a Modern Total Hip Prosthesis: A Note of Caution; Thomas, Parvataneni, Vlasak, and Gray; The Journal of Arthroplasty, 35, 2020, 1297-11302
2. Early Failure of Modern Moderately Cross-Linked Polyethylene Acetabular Liner; Kahlenberg, Menken, Ranawat, and Rodriguez; Arthroplasty Today, 6, 2020, 224-226
3. Unexpected Wear of a Moderately Crosslinked Polyethylene in Total Hip Arthropolasty; Yakkanti, Ocksrider, Patel, Kolevar, Moore, Rimnac, Kraay, Wright, Baral, Robinson; Abstract for AAOS (future publication)

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ATTACHMENT 1

Product Information:

Product Line Number	Product Line Description	Total Affected Devices Distributed (US)
Acumatch GXL Acetabular Liners		
130-28-2X	ACUMATCH GXL 0 DEGREE 28MM ACETABULAR LINER	61
130-32-2X	ACUMATCH GXL 0 DEGREE 32MM ACETABULAR LINER	154
130-36-2X	ACUMATCH GXL 0 DEGREE 36MM ACETABULAR LINER	125
132-28-2X	ACUMATCH GXL 15 DEGREE 28MM ACETABULAR LINER	800
132-28-3X	ACUMATCH GXL 15 DEGREE 28MM ACETABULAR LINER	1
132-32-2X	ACUMATCH GXL 15 DEGREE 32MM ACETABULAR LINER	1747
132-32-3X	ACUMATCH GXL 15 DEGREE 32MM ACETABULAR LINER	6
132-36-2X	ACUMATCH GXL 15DEG LINER 36MM	1144
132-36-3X	ACUMATCH GXL 15DEG LINER 36MM	5
134-28-2X	ACUMATCH GXL 28MM EXTENDED COVERAGE LINER	151
134-28-3x	ACUMATCH GXL 28MM EXTENDED COVERAGE LINER	1
138-28-2X	ACUMATCH GXL 15 DEGREE +5 LATERALIZED 28MM ACETABULAR LINER	84
138-36-27	ACUMATCH GXL 15 DEGREE +5 LATERALIZED 38MM ACETABULAR LINER	1
138-39-28	ACUMATCH GXL 15 DEGREE +5 LATERALIZED 36MM ACETABULAR LINER	97
138-36-29	ACUMATCH GXL 15 DEGREE +5 LATERALIZED 36MM ACETABULAR LINER	45
MCS GXL Acetabular Liners		
104-28-4X	MCS GXL 5/15 DEGREE 28MM ACETABULAR LINER	92
104-32-XX	MCS GXL 5/15 DEGREE 32MM ACETABULAR LINER	114
104-36-XX	MCS GXL 5/15 DEGREE 36MM ACETABULAR LINER	24
900-02-1X	MCS CUSTOM GXL ACETABULAR LINER	6
900-02-5X	MCS CUSTOM GXL ACETABULAR LINER	2
Novation GXL Acetabular Liners		
130-28-5X	NOVATION GXL NEUTRAL 28MM ACETABULAR LINER	1434
130-32-5X	NOVATION GXL NEUTRAL 32MM ACETABULAR LINER	6679
130-36-5X	NOVATION GXL NEUTRAL 36MM ACETABULAR LINER	9806
130-40-XX	NOVATION GXL NEUTRAL 40MM ACETABULAR LINER	754
132-28-5X	NOVATION GXL LIPPED 28MM ACETABULAR LINER	812
132-32-5X	NOVATION GXL LIPPED 32MM ACETABULAR LINER	4188

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Product Line Number	Product Line Description	Total Affected Devices Distributed (US)
132-32-6X	NOVATION GXL LIPPED ANTERIOR 32MM ACETABULAR LINER	21
132-36-5X	NOVATION GXL LIPPED 36MM ACETABULAR LINER	4694
132-36-6X	NOVATION GXL LIPPED ANTERIOR 36MM ACETABULAR LINER	15
132-40-XX	NOVATION GXL LIPPED 40MM ACETABULAR LINER	688
136-28-XX	NOVATION GXL +5 LATERALIZED 28MM ACETABULAR LINER	9
136-32-XX	NOVATION GXL +5 LATERALIZED 32MM ACETABULAR LINER	413
136-36-XX	NOVATION GXL +5 LATERALIZED 36MM ACETABULAR LINER	2268
136-40-XX	NOVATION GXL +5 LATERALIZED 40MM ACETABULAR LINER	175
138-32-XX	NOVATION GXL 10° FACE CHANGING 32MM ACETABULAR LINER	413
138-36-5X	NOVATION GXL 10° FACE CHANGING 36MM ACETABULAR LINER	1172
138-40-XX	NOVATION GXL 10° FACE CHANGING 40MM ACETABULAR LINER	110
Exactech All Polyethylene Cemented Acetabular Cup		
106-22-XX	ALL POLY CEMENTED CUP 22MM	15
106-28-XX	ALL POLY CEMENTED CUP 28MM	14
106-32-XX	ALL POLY CEMENTED CUP 32MM	8
Acumatch Conventional UHMWPE		
130-28-XX	ACUMATCH 0 DEGREE ACETABULARLINER 28MM	8
132-22-XX	ACUMATCH 15 DEGREE ACETABULAR LINER 22MM	1
132-28-XX	ACUMATCH 15 DEGREE ACETABULAR LINER 28MM	246
132-32-XX	ACUMATCH 15 DEGREE ACETABULAR LINER 32MM	657
132-36-XX	ACUMATCH 15 DEGREE ACETABULAR LINER 36MM	121
134-28-XX	ACUMATCH EXTENDED COVERAGE ACETABULARLINER 28MM	14
138-28-XX	ACUMATCH LATERALIZED ACETABULAR LINER 28MM	8
138-36-XX	ACUMATCH +5MM LATERALIZED ACETABULARLINER 15 DEG 36MM	7
144-28-XX	ACUMATCH 0 DEGREE CONSTRAINED ACETABULAR LINER 28MM	29
144-32-XX	ACUMATCH 0 DEGREE CONSTRAINED ACETABULARLINER 32MM	133
MCS Conventional UHMWPE		

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Product Line Number	Product Line Description	Total Affected Devices Distributed (US)
146-28-XX	MCS 0 DEGREE CONSTRAINED ACETABULAR LINER 28 MM	16
146-32-XX	MCS 0 DEGREE CONSTRAINED ACETABULAR LINER 32 MM	7
900-01-93	CUSTOM MCS ACETABULAR LINER +0 22MM	2
900-01-94	CUSTOM MCS ACETABULAR LINER +5 LATERALIZED 22MM	3
MCS Conventional UHMWPE		
134-28-4X	NOVATION CONSTRAINED ACETABULAR LINER 28MM	83
134-32-XX	NOVATION CONSTRAINED ACETABULAR LINER 32MM	187
134-36-XX	NOVATION CONSTRAINED ACETABULAR LINER 36MM	232