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FREQUENTLY ASKED QUESTIONS (FAQs)

Date:	**August 10, 2022**
Attention:	**Exactech US Agents/Surgeons**
Product:	**Exactech moderately crosslinked and conventional UHMWPE Acetabular Hip Liners (CONNEXION GXL, ACUMATCH, MCS and NOVATION)**

1. **Why is Exactech communicating with surgeons?**
   It is the practice of Exactech to perform detailed analysis and inform our surgeon customers and patients as soon as possible when such observations are made. By analyzing post-market data, Exactech has become aware of certain conditions that may put certain patients at a higher risk of premature wear of the GXL and conventional UHMWPE acetabular liner.

2. **Is this a new recall of GXL?**
   No. Exactech issued an Urgent Dear Healthcare Professional (DHCP) communication in July, 2021 for Exactech Connexion GXL polyethylene acetabular liners that alerted surgeons to field observations of this liner exhibiting early linear and volumetric wear. Exactech has now identified an additional risk factor that was not known at the time of the prior DHCP communication; therefore, in the best interest of patient health and safety, we are:

   - Expanding the scope of the recall communication to include all surgeons who have implanted either GXL liners or certain nonconforming conventional UHMWPE liners since 2004. The previous letter included only surgeons that had implanted Connexion GXL liners between 2015 and 2021.
   - Expanding the patient follow-up guidance to include all patients who have received either a:
     i. GXL liner regardless of packaging materials and have not been examined in the past 12 months.
     ii. Conventional UHMWPE acetabular liners packaged in nonconforming packaging and have not been examined in the past 12 months.
   - Including information regarding the additional risk factor related to devices packaged in non-conforming packaging.

3. **Is Exactech removing the GXL or conventional UHMWPE liners from the field due to this issue?**
   In March 2018, Exactech received FDA clearance for our next generation of polyethylene highly crosslinked Vitamin E liners, XLE. Bench testing reveals that Exactech's new XLE liner does outperform the Connexion GXL liner in both volumetric wear and edge loading

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assessments. Therefore, in 2019, Exactech decided to transition GXL liners out of the US market and replace them with the new XLE liner. Thus, we expect there to be no or very limited GXL product in the US Market.

Exactech is removing all conventional UHMWPE liners that were packaged in a non-conforming bags.

4. **What are the factors that may increase my patients' risk of premature wear?**

For GXL Liners, this phenomenon appears to be more common when:

- The relative implant position of the acetabular and femoral components in either/both the coronal plane and the sagittal plane results in edge loading of the femoral head on the liner.
- The femoral and acetabular components have a high degree of combined anteversion. This can sometimes be seen in posterior approaches when surgeons antevert to avoid posterior dislocation and/or direct anterior approaches when the combined anteversion is higher.
- Patients have a higher activity level.
- The thinnest available acetabular liner is used with larger femoral heads (e.g. > 32mm head in a 48 mm cup or a 36mm head in a 52mm cup).

For both GXL and conventional UHMWPE liners, if the insert was packaged in a vacuum bag that is oxygen resistant but does not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance, there may be an increased risk of oxidation and early polyethylene wear.

5. **What does Exactech recommend?**

Exactech recommends that surgeons closely monitor the affected GXL and conventional polyethylene patients for early wear and / or early signs of lysis, regardless of packaging materials used with GXL, conventional polyethylene packaged in non-conforming bags, 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. metal artifact sparing 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 without significant osteolytic lesions 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

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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. 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.

6. Do I need to contact all of my patients?

Yes. We recommend contacting all of your patients who have received either a conventional polyethylene liner packaged in the nonconforming bags or GXL liner, regardless of packaging materials, by providing them the [patient letter document title/document number]. Exactech also recommends that surgeons perform follow-up examination on all affected GXL and conventional NC 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 with metal suppression techniques) 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.

8. Can Exactech provide me with a listing of my affected patients?

Yes. Exactech has included a listing of all of your affected GXL and nonconforming conventional liner UHMWPE patients, based on information submitted into our invoicing system at the time of the implantation. We have provided all of the information that we have available for each patient.

9. Can Exactech assist me in sending the letters or reimburse my costs to contact my patients?

Yes. We recognize the significant administrative burden that managing the recall may impose on physician practices, including analyzing and organizing patient records to identify those patients included in the recall; drafting and sending correspondence to those patients; scheduling follow-up visits; transmitting records to Broadspire as needed, and numerous other tasks. Exactech has worked with a leading law firm and healthcare valuation firm to establish an independent fair market value for these recall-related tasks so that Exactech can ethically and compliantly reimburse physician practices for these administrative tasks, which are otherwise not reimbursable by a third-party payor and would not have otherwise been incurred by physician practices.

Additionally, Exactech has provided a patient letter template to assist in communicating with your patients.

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Lastly, in an effort to reducing the time spent by physician practices answering routine questions from patients regarding the recall, Exactech has established both a website and telephone hotline to provide patients with answers. The hotline currently features a pre-recorded message of frequently asked questions, as well as the ability to request a call back from an HCP to answer additional questions.

Please go to https://www.exac.com/medical-professionals/recall-information/ for more information on these programs.

10. Do I need to revise all of my patients that currently have GXL or conventional UHMWPE liners?

No. **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. Only patients with diagnostic evidence, found during routine clinical exam and x-rays, of edge loading components, early asymmetric polyethylene wear, and early signs of lysis, should be considered for revision to the XLE liner. Bench testing reveals that Exactech's new XLE liner does outperform previous liners in both volumetric wear and edge loading assessments.

11. For patients who currently have a GXL liner and need revision, how can I find out whether their existing acetabular component will accept the new XLE highly crosslinked liner?

XLE liners are available for revision with AcuMatch Cup and Novation Crown Cup Systems.

12. For patients who need a revision, is there any assistance that Exactech can provide for out-of-pocket costs to the patient?

Yes. We will reimburse patients whose implants are included in the recall for certain out-of-pocket expenses related to visiting their surgeon. These expenses might include copays, deductibles, and reasonable travel expenses associated with seeing the surgeon who performed their primary surgery. Please go to https://www.exac.com/medical-professionals/recall-information/ for more information.

13. What information can Exactech provide as to the changes that have been made from the legacy GXL liner to the updated XLE highly crosslinked liner? Is Exactech confident this new liner will perform better in those patients who have had failures with the legacy GXL liner?

- The new XLE liner, which was introduced in 2019 is highly crosslinked with 100kGy of gamma irradiation and also Vitamin E infused.
- In our bench testing data, the new XLE liner has lower wear and equivalent fracture resistance when compared with the GXL liner.

14. Who at Exactech should I contact for additional information and assistance?

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Please contact Exactech BroadSpire at 888-912-0403 or send us an email to mailto:GXL@exac.com.

15. **Does Exactech have a website or information page where I can direct patients who want more information regarding this recall?**
    Please go to https://www.exac.com/medical-professionals/recall-information/ for more information about this recall and Exactech's programs.

16. **What if I identify a patient with problems related to excessive or premature prosthesis liner wear?**
    Please report any cases of excessive or premature prosthesis liner wear to your local Exactech Agent. They can help you order a replacement liner for the revision. Additionally, they will report the liner wear and revision to Exactech's Post Market Quality department for investigation, potential reporting to the FDA (MDR), and continuous monitoring.

17. **What if I have at-risk patients who have relocated, moved away, and/or are lost to follow-up?**
    Exactech's first concern is for the health and safety of patients and the users of our products. Exactech is working to be open and transparent regarding this issue. Exactech is notifying the FDA regarding their findings and this communication to surgeons with patients who may be at higher risk for premature wear. The FDA will post this information on its public website: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts. Additionally, Exactech plans to post this information on its website at: https://www.exac.com/medical-professionals/recall-information/