Exactech
Surgeon focused. Patient driven.™

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FREQUENTLY ASKED QUESTIONS (FAQs)

Date: June 24, 2021
Attention: Exactech US Agents/Surgeons
Product: GXL Liners for Novation, Acumatch and MCS systems

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 UHWPE acetabular liner.

2. Is Exactech removing the GXL liner from the field due to this issue?
   No, Exactech is not recalling the GXL liner. Overall, the GXL Acetabular liner is considered safe and effective and performs as intended. However, in March 2018, Exactech received FDA approval for our next generation of polyethylene highly crosslinked Vitamin E liners, XLE. Therefore, in 2019, Exactech decided to transition GXL liners out of the US market in favor of the XLE liner. Thus, at this time, the GXL liner has been transitioned entirely out of the US market. Bench testing reveals that Exactech's new XLE liner does outperform the Connexion GXL liner in both volumetric wear and edge loading assessments.

3. What are the factors that may increase my patients' risk of premature wear?
   This phenomenon appears to be more comment 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).

4. What does Exactech recommend?
   Exactech's recommendation for surgeons is that GXL patients who are less than six (6) years from index surgery and who have not been seen in over 12 months return to the office/clinic for a routine clinical 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. For patients with edge loading components, early asymmetric polyethylene wear, and early signs of lysis, the surgeon should consider revising the GXL liner to Exactech's latest generation HXLPE, Vitamin E liner, if possible.

5. Do I need to revise all of my patients that currently have GXL liners?
   No. 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 the Connexion GXL liner in both volumetric wear and edge loading assessments. Again, worldwide data shows that the percentage of patients who have premature wear is less than 1% out of nearly 90,000 implanted devices.

6. 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?

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

7. 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.

8. Who at Exactech should I contact for additional information and assistance?
   Please contact Exactech's Chief Medical Officer:
   Sharat Kusuma, MD
   Phone: 800.382.2832
   Email: sharat.kusuma@exac.com

   Dr. Kusuma is a board-certified and hip/knee arthroplasty fellowship-trained orthopedic surgeon that has both the clinical experience and product knowledge to assist you.

9. What is Exactech's recommendation on how to communicate with patients who might be at risk of early wear but who need to return to the office for another follow-up visit?
   Please explain that while the GXL acetabular liner is safe and effective, Exactech has identified certain implant factors that may place them at a higher risk for premature wear of their GXL acetabular liner and that it is important that they come in for an examination and x-rays to properly and thoroughly evaluate the status of their implant.

10. Does Exactech have a website or information page where I can direct patients who want more information regarding the GXL liner?
    Patients can view the Dear Healthcare Professional Letter on Exactech's website at:
    https://www.exac.com/medical-professionals/

11. What if I identify a patient with problems related to excessive or premature GXL 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.

12. 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/