EXACTECH, INC
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URGENT MEDICAL DEVICE CORRECTION

August 2, 2022

To: Exactech Knee and Ankle Surgeons, Hospitals, Health Care Professionals

Description: Exactech Ultra-High Molecular Weight Polyethylene (UHMWPE) Knee and Ankle Polyethylene Inserts packaged in out-of-specification vacuum bags:

Dear Exactech Surgeon,

The purpose of this letter is to provide an important update on the status of our knee and ankle arthroplasty polyethylene inserts and the recall we initiated on August 31, 2021, and important recommendations for surgeons.

After extensive testing, we have confirmed that most of our inserts manufactured since 2004 were packaged in out-of-specification vacuum bags that are oxygen resistant but do not contain a secondary barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. **The use of these non-EVOH bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight 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 conventional UHMWPE, which, in conjunction with other surgical factors, can lead to both accelerated wear debris production and bone loss, and/or component fatigue cracking/fracture, all leading to corrective revision surgery.**

Exactech is now expanding the recall to include all knee and ankle arthroplasty polyethylene inserts packaged in non-EVOH bags **regardless of label or shelf life manufactured since 2004**. During the period between August 2021 and July 2022 knee and ankle devices packaged in non-EVOH bags have been shipped and implanted by surgeons.

The design of these systems has evolved over time, but the UHMWPE materials have been consistent. More specifically, all Exactech knee systems have had polyethylene inserts packaged in non-EVOH bags at various points during their respective market tenures. The original Optetrak Knee system, introduced in 1992, has shown statistically significant higher overall revision rates as compared to other TKA's in the Australian, United Kingdom and New Zealand registries.

The Australian Registry reported a total of 374 TKR revision procedures among 3,684 primary Optetrak TKRs with up to 14- to 20-years follow-up for each prosthesis combination. Every Exactech Optetrak TKR polyethylene component combination demonstrated statistically significant increased revision rates compared to other TKR systems (N=668,852) with at least one and a half years of follow-up with hazard ratios ranging from 1.84 to 5.85 ($p<0.001$)[1,4-7]. The United Kingdom Registry reported that the Exactech Optetrak TKR System utilizing the cruciate retaining femoral component (N=1,638) had statistically significant increased cumulative revision rates compared to all TKRs (N=1,145,052) at the 3, 5, 10, 13 and 15-year timepoints.[2] The New Zealand Registry reported a total of 63 TKR revision procedures among 661 primary Optetrak TKRs. The Optetrak TKR revision

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rate was 1.015/100 component years compared to all other primary TKRs (N=118,430) which had a revision rate of 0.48/100 component years and represented a statistically significant value greater than a two-fold increased revision rate.[3]

Additionally, the reasons for revision potentially associated with polyethylene wear (e.g., loosening, lysis, pain) were increased three- to seven-fold in the most used Exactech Optetrak TKR combination (Optetrak-PS/Optetrak) which had a total of 263 TKR revision procedures among 2,410 primary TKRs when compared to other TKRs in the Australian Registry[4]. The reasons for these increased revision diagnoses related to accelerated polyethylene wear may be related to the non-conforming packaging.

We are uncertain if the root cause of these Optetrak higher and earlier than expected revision rates are due only to the non-conforming vacuum bags. The uncertainty in assessing the root cause stems from the fact that the registry data of the Optetrak Knee System report outcomes for polyethylene components in both conforming and non-conforming packaging, and the registries do not contain packaging information.

Beginning in 2011 we transitioned from Optetrak to Optetrak Logic. The 2021 Australian Registry reported the following:
Logic CR – 621 implanted, 11 revised with a survivorship @ 5 years equal to 2.4% cumulative revision rate.
Logic PS – 611 implanted, 21 revised with a survivorship @ 5 years equal to 4.2% cumulative revision rate.
Yearly Cumulative % Revision of Primary TKR by Model (all diagnoses) @ 6 yrs., Logic PS & CR equal to 3.8%, All other manufacturers' total knee equal to 3.7%

Exactech ankle arthroplasty systems have been represented by one implant system, marketed since 2017, and known as the Vantage® Total Ankle system.

Oxidation increases during the shelf life of the product and therefore the risk to patients increases with the implantation of products with longer times on the shelf. Our analysis of reported complaints for revisions has shown that the risk of revision for polyethylene wear is greatest for patients who have polyethylene inserts that were on the shelf for greater than five years.

Please be advised that beginning in August 2021, Exactech recalled product with a labeled 8-year shelf-life that would have a shelf life of 5 years or greater as of August 31, 2022. Exactech is expanding the recall to include the remaining Exactech Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts in the field, regardless of shelf life, that were packaged in non-EVOH bags.

Exactech is advising surgeons to avoid implanting nonconforming devices. A list of product codes, product and description can be found at: https://www.exac.co.uk/recall-information. Your local Exactech Representative will work with you to remove non-EVOH devices from inventory.

For all patients historically implanted with polyethylene devices in non-EVOH bags, surgeons should maintain an appropriate index of suspicion for patients with any new or worsening pain, inability to bear weight, grinding or other noise, swelling, or instability in their knee. Note that registry data suggests that the reasons for revision related to accelerated UHMWPE wear in the most used prosthesis combination (Optetrak-PS/Optetrak) were increased 3- to 7-fold compared to all other TKR systems.[4] The reasons for these increased revision diagnoses related to accelerated polyethylene wear may be related to the non-EVOH packaging.

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In addition, Exactech recommends that surgeons closely monitor the affected knee and ankle patients for potential wear, osteolysis, and associated failure modes, regardless of polyethylene shelf-life and regardless of the time period that has elapsed since index arthroplasty. If a failed device is suspected, consider performing X-rays to further evaluate the device. Pre-emptive removal of non-painful, well-functioning Exactech knee and ankle 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 for painful arthritic knee and ankle joints 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 if available, polyethylene knee and ankle inserts that are packaged in conforming vacuum bags that contain the specified secondary EVOH oxygen barrier layer.

To assist you in communicating with your patients, Exactech is providing Knee and Ankle Patient Letter template and Frequently Asked Questions (FAQs) for you to send to your patients who have been implanted with Exactech knee and ankle devices packaged in non-conforming bags. We recommend surgeons customize the letter and send it to patients implanted with non-conforming devices. Additionally, Exactech is prepared to provide you (1) a list of all your knee and ankle arthroplasty patients who received devices in non-conforming bags, 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 or not that implanted device is non-conforming. Exactech website: https://www.exac.co.uk/recall-information

Additionally, Exactech has partnered with BroadSpire to assist patients with questions and certain out-of-pocket costs related to clinical follow-up and additional surgery that may be necessary. If you have any questions, please call at 01908 991163 or email BroadSpire directly at exactech.recall@crawco.co.uk.

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, packaging-bags@exac.com, or contact your local Exactech Representative if you wish to meet and we will arrange a time as soon as possible.

In conclusion, we would like to reiterate our sincere thanks for your support of Exactech over the years and for taking the time to read this note. We look forward to hearing from you.

Sincerely,

Darin Johnson, President
Sharat Kusuma, MD, FAAOS, Senior Vice President, and Chief Medical Officer

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