Exactech®
Surgeon focused. Patient driven.™

GLOBAL HEADQUARTERS
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FREQUENTLY ASKED QUESTIONS
KNEE AND ANKLE RECALL

1. Why is Exactech communicating with surgeons and patients?

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. After extensive testing, we have confirmed that most of our total knee replacements (TKR), partial knee replacements (PKR), and total ankle replacements (TARs) with polyethylene (plastic) components and insertsmanufactured 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 barrier layer containing ethylene vinyl alcohol (EVOH) that further augments oxygen resistance. The TKR and TAR manufactured by Exactech and packaged in non-conforming bags may be associated with the following risks:

1. Statistically significant higher and earlier than expected revision rates in Optetrak TKR
2. Increased risk of polyethylene (plastic) wear, and
3. Potential development of osteolysis (bone loss) in the first-generation Optetrak TKR
4. The reasons for revision potentially associated with polyethylene wear (e.g., loosening, lysis, pain) were increased three- to seven-fold in the Optetrak TKR when compared to other TKRs, and may be related to the non-conforming packaging.

Polyethylene wear can initiate a variety of clinical issues to include device loosening, device fracture, mechanical failure, pain, bone loss or recurrent swelling in the affected area.

2. Is Exactech removing the knee and ankle inserts from the field due to this issue?

Yes, Exactech is recalling all total knee, partial knee, and ankle devices with plastic inserts packaged in the non-conforming bags with the missing layer of EVOH.

3. What does Exactech recommend to surgeons?

We advise surgeons to avoid implanting non-conforming devices. We have also provided surgeons with a draft letter to their patients who have implanted Exactech knee and ankle devices packaged in non-conforming bags. We strongly recommend surgeons discuss and send the letter to their affected patients. For all patients implanted with polyethylene devices in non-conforming 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 or ankle. 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.

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4. Do surgeons need to revise all patients that currently have one of these inserts that were packaged in the bags not containing the extra layer of EVOH?

No. Pre-emptive removal of non-painful, well-functioning Exactech knee and ankle devices from asymptomatic patients is not recommended.

5. How can surgeons determine if they have any of these inserts in their inventory?

Surgeons will be provided with a list of product codes; product description and serial numbers can be found at: https://www.exac.com/recall. Surgeons' local sales agent will identify non-conforming devices and remove it from each surgeon's inventory. We will work to provide each surgeon with complete sets of conforming inserts as quickly as possible.

6. How can patients determine if they have one of these inserts implanted in them?

Exactech will be providing a searchable tool on Exactech website that will empower a patient to enter her/his implant serial number and confirm whether or not that serial number is non-conforming.

Most patients may not know what brand of TKR, PKR, or TAR insert that was used in their procedure or the serial number that could be used to identify inserts that are the subject of this recall. Patients should therefore contact their implanting surgeon first to determine what type of implant they have. Exactech will be providing surgeons with serial numbers and the necessary patient identifiers such that surgeons can identify and contact those patients who have Exactech implants affected by the recall. Exactech will be providing surgeons with a draft letter to their patients who have implanted Exactech knee and ankle devices packaged in non-conforming bags. With this information provided, surgeons will be able to contact their patients and determine appropriate level and intensity of follow-up based on individual patient risk assessment. If patients have any questions regarding Exactech knee or ankle products, or if they know the serial number of their Exactech implant(s), they can call the Exactech- Broadspire hotline directly at the following United States phone number: +1 888 912 0403.

7. 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.

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8. 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?

Exactech is providing surgeons with a patient letter that they can edit and send to their patients. Exactech is encouraging surgeons to communicate with their affected patients and inform those with serial numbers on the searchable website. Additionally, Exactech has implemented third-party administrator services (TPA) to assist patients with out-of-pocket costs and claims management related to this recall. Information regarding these services can be found on the Exactech website at: https://www.exac.com/recall

9. Does Exactech have a website or information page where patients who want more information regarding this recall?

Yes. Patients can view the Dear Healthcare Professional Letter and patient letters on Exactech's website at: https://www.exac.com/medical-professionals/product-safety-alert/. In addition, Exactech will be providing a searchable tool on Exactech's website that will empower a patient to enter her/his implant serial number and confirm whether or not that serial number is non-conforming.

More information is also available via email at: packaging-bags@exac.com or by calling us at 1.888.892.5635

10. What if a surgeon identifies a patient with problems related to excessive or premature prosthesis wear?

Please report any cases of excessive or premature prosthesis wear to your local Exactech Agent. They can help you order a replacement for the revision. Additionally, they will report the wear and revision to Exactech's Post Market Quality department for investigation, potential reporting to the FDA (MDR), and continuous monitoring.

11. What if a surgeon has 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 and will offer a searchable tool on our website to empower patients to determine if they have received non-conforming products.

Additionally, Exactech plans to post this information on its website at: https://www.exac.com/recall