Surgeon or facility letterhead

Important patient notice regarding Exactech ankle replacement devices

August 2, 2022

Dear valued patient,

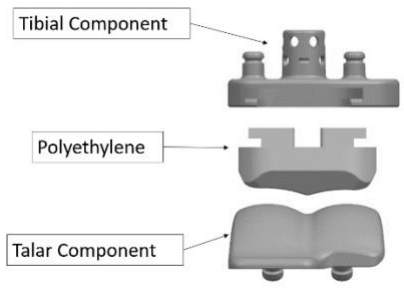
Because the safety and health of our patients is our top priority, we are writing to inform you that between the years of 2017 and 2022, you received a specific type of total ankle replacement that was manufactured by the orthopedic device company, Exactech, Inc, headquartered in Gainesville, Florida, USA.

Exactech, Inc. has recently implemented a recall of one component of the ankle replacement device that you received and is communicating with surgeons and patients who have utilized this ankle replacement model.

Explanation of the recall:

As shown in the diagram below, a standard ankle replacement has three parts:

1. The tibial component (this is the metal piece that attaches to your shin bone, also known as your "tibia")
2. The talar component (this is the metal piece that fits into your foot bone, also known as your "talus")
3. The polyethylene (plastic) insert (this is the plastic that fits between the tibial component and the talar component and acts as the new cushion or cartilage for your replaced ankle joint)



During a recent review of its ankle implant manufacturing process, Exactech learned that one of the packaging layers for the plastic insert has been out of specification and may allow oxygen from the air to diffuse into this plastic insert prior to it being implanted in your ankle. If a large amount of oxygen diffuses into the plastic insert while it is being stored and before it is implanted, this can lead to a process called oxidation, which can cause the plastic to wear out earlier than expected or to become damaged after it is implanted into the patient's body.

Exactech has found that the plastic insert in the out of specification bag can wear out earlier than expected in some patients. Premature wear of the plastic insert of your ankle replacement can lead to the need for additional surgery (also known as revision surgery). In those cases where the plastic has worn out earlier than expected or has been damaged, we will evaluate your ankle replacement and decide whether additional treatment is needed. Determination of whether the plastic is worn is accomplished by examining your ankle in the office and obtaining x-rays. After this evaluation is complete, we will decide if additional treatment, including revision surgery, is necessary.

What we are asking you to do:

If you are receiving this letter, we may contact you in the near future to return to our clinic for a checkup. We will examine your medical records and determine whether or not you need to be seen. Additionally, in advance of hearing from us, if you have been experiencing any new or worsening ankle swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in your ankle, please call our office to schedule an evaluation. At this time, if your ankle is functioning well and you have no pain and no symptoms, revision surgery is not recommended.

Exactech, Inc., as the manufacturer of the implant, is assisting us in ensuring that patients are contacted and followed up. Exactech is also assisting patients with certain out-of-pocket costs related to clinical follow-up and any additional surgery that may be necessary. After we have examined your ankle, Exactech and their medical reimbursement consultants, in collaboration with our office billing department, will contact you to arrange for appropriate remuneration for associated expenses.

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What if I have more questions?

Exactech will provide a Frequently Asked Questions document where you can find answers to some common questions, and 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.

Exactech has provided a Frequently Asked Questions (FAQ's) document where you can find answers to some common questions, and a searchable tool on Exactech website. The searchable tool will empower a patient to enter her/his implant serial number and check whether or not that implanted device is non-conforming. The Frequently Asked Questions (FAQ's), serial number look-up, and other information concerning the call and claims management process can be found on Exactech's 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.

Please also contact our office directly if you have questions.

Exactech considers patient safety their top priority. We appreciate your time and attention in reading this important notification.Our office will be in touch shortly to schedule a follow-up visit with you.

Most sincerely,