

# Surgeon or facility letterhead

## Important patient notice regarding Exactech knee replacement devices


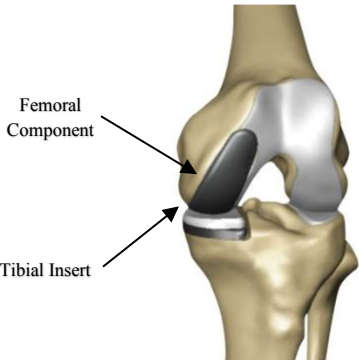
August 2, 2022

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 2004 and 2022, you received a specific type of partial or total knee replacement system 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 (i.e., plastic tibial insert) of the knee replacement device that you received and is communicating with surgeons and patients who have utilized this knee replacement model.

### Explanation of the recall:

<p>A standard total knee replacement has four parts:</p> <ol style="list-style-type: none"><li>1. The femoral component (this is the metal piece that attaches to your thigh bone, also known as your "femur")</li><li>2. The tibial tray (this is the metal piece that fits into your shin bone, also known as your "tibia")</li><li>3. The patellar component (this is the piece of plastic that fits onto your kneecap, also known as the patella)</li><li>4. The tibial polyethylene (plastic) insert (this is the plastic that fits between the femoral component and tibial component and acts as the new cushion or cartilage for your replaced knee joint)</li></ol>	
<p>A partial knee replacement has the primary parts illustrated in the figure to the right:</p> <ol style="list-style-type: none"><li>1. The partial femoral component (this is the metal piece that attaches to your thigh bone, also known as your "femur")</li><li>2. The partial tibial polyethylene (plastic) insert (this is the plastic that fits between the partial femoral component and tibial component and acts as the new cushion or cartilage for your partially replaced knee joint)</li></ol>	

During a recent review of its knee 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 the plastic insert prior to it being implanted in your knee. If a large amount of oxygen diffuses into the plastic insert while it's 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. Oxidation increases during the shelf life of the product and therefore 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.

Exactech has found that the tibial 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 knee 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 knee replacement and decide whether additional treatment is needed. Determination of whether the plastic is worn is accomplished by examining your knee in the office and obtaining x-rays. After this evaluation is complete, we will decide if additional treatment, including revision surgery, is necessary.

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Where available, the manufacturer has made us aware of which implant you received and the shelf life of that implant. From that information we can make the appropriate decisions regarding your future care.

## **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 knee swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in your knee, please call our office to schedule an evaluation. At this time, if your knee is functioning well and you have no pain and no symptoms, revision surgery is not recommended.

After we have examined your knee, Exactech and their medical reimbursement consultants, in collaboration with our office billing department, will contact you to arrange for appropriate remuneration for associated expenses.

## **What if I have more questions?**

Exactech is committed to patient safety and to providing necessary treatment information. The out-of-specification packaging issue has been rectified by Exactech, such that plastic inserts that are manufactured from this point forward conform to Exactech's packaging specifications.

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](mailto: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,