Insert here desired letterhead, or Exactech letterhead, or BOTH

July 2022

Dear valued patient,

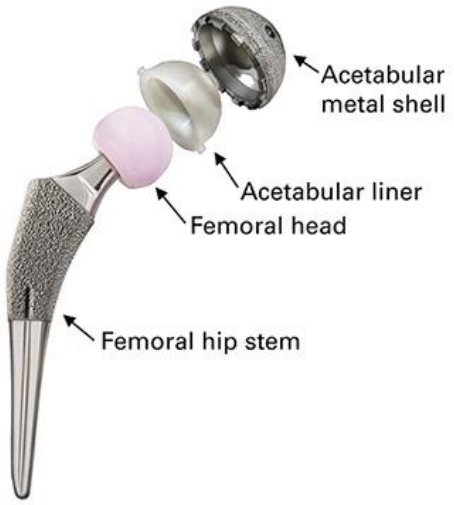
Because the safety and health of our patients is our top priority, we are writing to inform you of a medical device recall that may involve your hip implant and may require you to visit your surgeon for a follow-up evaluation if you are experiencing any new or worsening symptoms or pain (e.g., buttock pain, thigh pain, groin pain, and knee pain around the hip implant). Between the years of 2004 and 2021, you received a specific type of total hip replacement that was manufactured by the orthopedic device company, Exactech, Inc, headquartered in Gainesville, Florida, USA.

Exactech, Inc. has recently implemented a recall of the polyethylene plastic component of your hip replacement device that you received and is communicating with surgeons and patients who have utilized this device.

Explanation of the Issue:

As shown in the diagram below, most standard hip replacements contain four critical parts:

1. Acetabular metal shell (this is the metal “socket” that goes into your native hip socket)
2. Acetabular liner (plastic / polyethylene) liner (this is the new “cushion” that replaces the damaged cartilage).
3. Femoral head (this is the new ball of your hip joint, usually made of ceramic or metal).
4. Femoral hip stem (this is the component that fits into your thigh bone and secures the new ball).



During a recent review of its hip implant manufacturing process, Exactech learned that these polyethylene inserts can potentially become oxidized prior to and after implantation into the body. Oxidation is a natural chemical process that occurs when materials are exposed to the oxygen in the ambient air. In the case of these Exactech hip polyethylene inserts, the oxidation levels in the plastic are higher than desired. If a large amount of oxidation takes place prior to and after the plastic liner is implanted into the patient’s hip joint, it 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 recently observed that in a small percentage of patients, the plastic liner has worn out earlier than expected. Premature wear of the plastic insert of your hip 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 hip replacement and decide whether additional treatment is needed. Determination of whether the plastic is worn is accomplished by examining your hip 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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What we are asking you to do:

If you are receiving this letter, we may contact you soon to return to our clinic for a checkup. We will examine your medical records and determine whether you need to be seen. Additionally, in advance of hearing from us, if you have been experiencing any new or worsening hip swelling, pain while walking, inability to bear weight, grinding or other noise, instability, or any new symptoms of clicking in your implanted hip, please call our office to schedule an evaluation. While Exactech data indicates that most patients with premature wear appear to have symptoms of hip and / or groin pain, we have also observed that in some patients, premature wear of the plastic and damage to the bone may occur without the patient experiencing symptoms. At this time, if your hip 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 ensuring that all patients implanted with one of the identified implants are contacted and, if needed, followed up with their physician. Exactech is also assisting patients with certain out-of-pocket costs related to clinical follow-up and any additional surgery that may be necessary.

Exactech has engaged third-party administrator (TPA) services with Broadspire to assist patients with out-of-pocket costs and claims management related to this recall. Additional information regarding these services can be found on the Exactech website at: https://www.exac.com/recall.

Upon receipt of this letter, and prior to calling our office, we would request that you first call Broadspire at the following phone number 1.888.912.0403. This first phone call will allow you to accomplish a few critical items prior to being seen in our office:

1. You will be able to establish a Broadspire claim number that will facilitate rapid reimbursement of any out of pocket costs related to your follow up office visits.
2. This Broadspire extension also provides access to a patient hotline that enables access to live orthopaedic nurses who can answer additional questions regarding the hip implant liner and premature wear.

What if I have more questions?

Exactech is committed to patient safety and to providing necessary treatment information. If you have any additional questions regarding Exactech knee products or manufacturing, please call Exactech directly at the following United States phone number +1.888.912.0403.

Please also visit their website where they have posted FAQ's and other information concerning the recall and the Broadspire claims management process. Be sure to click on the Hip tab (not Knee/Ankle).

https://www.exac.com/medical-professionals/recall-information/

Please also contact our office directly at [XXX-XXX-XXXX] if you have questions.

We at [INSERT HERE PRACTICE NAME] consider patient safety and excellent patient outcomes our 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,

Dr. [INSERT HERE SURGEON NAME]

[INSERT HERE PRACTICE NAME]