exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA
352.377.1140
352.378.2617

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

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA
352.377.1140
352.378.2617

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.com/recall. 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.

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

exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA
352.377.1140
352.378.2617

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.com/recall.

Finally, Exactech has implemented third-party administrator (TPA) services 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.

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

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA
352.377.1140
352.378.2617

References

1. Australian Orthopaedic Association National Joint Replacement Registry: Hip, Knee & Shoulder. Annual Report 2021. Adelaide, Australia: AOA, 2021.
2. United Kingdom National Joint Registry: 18th Annual Report. Annual Report 2020. United Kingdom: United Kingdom National Joint Registry, 2021.
3. The New Zealand Joint Registry: Twenty-One Year Report. Annual Report 2020. New Zealand: New Zealand Joint Registry, 2020.
4. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-PS/Optetrak Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.
5. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-CR (cemented)/Optetrak-CR (cemented) Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.
6. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-PS/Optetrak-PS Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.
7. Australian Orthopaedic Association National Joint Replacement Registry: Optetrak-PS/Optetrak RBK Total Knee Investigation 2021. Adelaide, Australia: AOA, 2021.

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

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) inserts manufactured 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 tothe non-conforming packaging.

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.

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

exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

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.

4. Do surgeons need to revise all patients that currently have one of these inserts that were packaged in thebags 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 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), please see table A for more information.

exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

Table A

Language	Email	Telephone
French	exactech.recall@crawco.be	+32 80026327
Italian	exactech.recall@crawco.it	+39 0200704115
German	exactech.recall@crawco.de	49 (211) 54012549

7. Who at Exactech should I contact for additional information and assistance?

If patients have any questions regarding Exactech knee or ankle products, or if they know the serial number of their Exactech implant(s), please see table A for more information.

8. What is Exactech's recommendation on how to communicate with patients who might be at risk of early wearbut 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 regardingthis recall?

Yes. Patients can view the Dear Healthcare Professional Letter and patient letters on Exactech's website at: https://www.exac.com/recall. 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.

If patients have any questions regarding Exactech knee or ankle products, or if they know the serial number of their Exactech implant(s), please see table A for more information.

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

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.

exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

FSN Ref.: CRC2021-08-13-01 **FSCA Ref.: CRC2021-08-13-01**

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL

Date: **August 1, 2022**
For Attention of: **Exactech Agents, Representatives, and Distributors in Possession of Affected Products**
Affected Product: **Exactech Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts**
Contact details of local representative:

Name: Elliot Cintron
Email: elliot.cintron@exac.com
Phone: +41 79 955 2823
Address:
Hofgut,
3073 Guemligen – Switzerland

The purpose of this letter is to provide an important **update** on the status of all Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts. This Recall that was initiated on August 31, 2021, focused on product packaged in nonconforming bags labeled with an 8-year shelf life that would have shelf life of 5 years or greater as of August 31, 2022.

Exactech is now **expanding the Recall** to include all knee and ankle arthroplasty polyethylene inserts packaged in nonconforming bags **regardless of shelf life manufactured since 2004**.

Description of Issue: Exactech is recalling Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts packaged in vacuum bags that did contain a Nylon barrier, which does substantially limit oxygen transmission, but did not contain an additional oxygen barrier layer consisting of Ethylene Vinyl Alcohol (EVOH) as specified on the packaging drawing.

Exactech has confirmed through testing that most of our inserts manufactured 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 use of these non-conforming 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.

As of August 5, 2021, all polyethylene inserts manufactured by Exactech are being packaged in vacuum bags with EVOH to ensure adequate oxygen barrier properties and protection from oxidation of polyethylene inserts.

Clinical Impact: Use of these non-conforming bags may enable increased oxygen diffusion to the UHMWPE (ultra-high molecular weight polyethylene) insert, resulting in increased oxidation of the material relative to

exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

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.

Actions to be Taken by the USER:

In order to comply with applicable regulations and Exactech policies:

- **CAREFULLY REVIEW THIS RECALL NOTIFICATION** to ensure that you fully understand the issue identified, the recall strategy, and all actions required.
- **IMMEDIATELY IDENTIFY AND QUARANTINE** any of the subject devices in your inventory and/or customer's inventory listed on the Phase II Product Scope Listing (Attachment 1).
- **EXTEND THE DESCRIPTION OF ISSUE AND CLINICAL IMPACT** as described in the recall notification to your accounts that may have this product in their possession.
- In addition to this recall notification, **PLEASE FORWARD TO YOUR AFFECTED CUSTOMERS/SURGEONS** the attached
  1. Dear Healthcare Professional (DHCP) Letter,
  2. Patient Letter Template and
  3. Frequently Asked Questions (FAQs)
- **COMPLETE AND RETURN** the attached Recall Inventory Response Form to Exactech via email at recalls@exac.com within 15 business days of receipt of this notice.
- Please **REPORT** all device-related **SERIOUS INCIDENTS** to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.
- **WE ARE REQUIRING 100% EFFECTIVENESS FOR THIS RECALL.**

Our first concern is for the health and safety of patients and the users of our products. Actions of this type are collaborative efforts and require your participation to be effective.

Please complete and return the attached Recall Response Form to Exactech within the next 15 business days.

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA
352.377.1140
352.378.2617

FSN Ref.: CRC2021-08-13-01	FSCA Ref.: CRC2021-08-13-01

Best regards,

Kate Jacobson (Aug 1, 2022 14:24 EDT)

Kate Jacobson
Director Quality Systems and Compliance
Exactech, Inc.
2320 NW 66th Court
Gainesville, FL 32653
800.392.2832
recalls@exac.com

The relevant National Competent Authorities have been advised of the FSCA.

exactech

EXACTECH, INC
2320 NW 66th Court
Gainesville, FL 32653
USA

352.377.1140
352.378.2617

FSN Ref.: CRC2021-08-13-01 **FSCA Ref.: CRC2021-08-13-01**

URGENT FIELD SAFETY NOTICE RESPONSE FORM

Please check the appropriate box and complete as indicated.

☐ **I acknowledge** receipt of this Recall Notification **and confirm** that I fully understand the issue identified, the recall strategy, and all actions required in accordance with Phase II.

☐ **I agree to extend the description of this issue and clinical impact** as described in this notification to my accounts that may have this product in their possession.

☐ **I have completely identified and quarantined the affected devices,** as identified in the Phase II Product Scope Listing (Attachment 1).

_____ _____

Date Agency

_____ _____

Name (Print) Name (Signature)

Thank you for your prompt attention to this matter. Please complete and return this response form to recalls@exac.com ***within 15 business days of receipt.***

Swiz_Updated FSN_Exactech_7.11.2022_Clean

Final Audit Report 2022-08-01

Created:	2022-08-01
By:	Priyanka Pistolwala (priyanka.pistolwala@exac.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAIhQi7JyLaDYi28JrD7OF-ekgGuU5hp7K

"Swiz_Updated FSN_Exactech_7.11.2022_Clean" History

Document created by Priyanka Pistolwala (priyanka.pistolwala@exac.com)
2022-08-01 - 2:56:11 PM GMT- IP address: 70.171.41.205

Document emailed to Kate Jacobson (kate.jacobson@exac.com) for signature
2022-08-01 - 2:56:31 PM GMT

Document e-signed by Kate Jacobson (kate.jacobson@exac.com)
Signature Date: 2022-08-01 - 6:24:23 PM GMT - Time Source: server- IP address: 50.89.230.53

Agreement completed.
2022-08-01 - 6:24:23 PM GMT

Surgeon or facility letterhead

Important patient notice regarding Exactech knee replacement devices

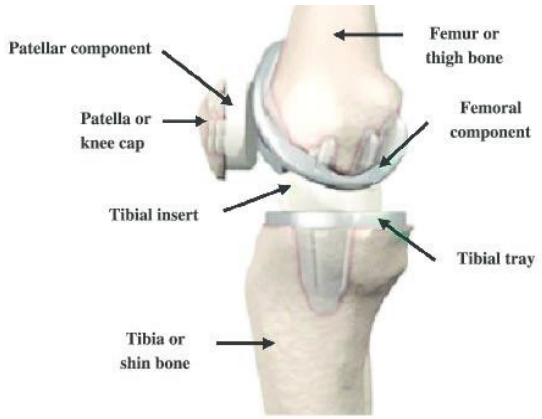
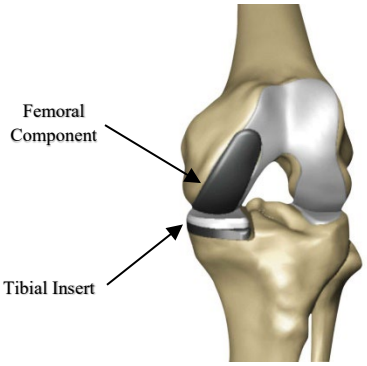
August 2, 2022

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 and2022, 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:

A standard total knee replacement has four parts: 1. The femoral component (this is the metal piece that attaches to your thigh bone, also known as your "femur") 2. The tibial tray (this is the metal piece that fits into your shin bone, also known as your "tibia") 3. The patellar component (this is the piece of plastic that fits onto your kneecap, also known as the patella) 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)	
A partial knee replacement has the primary parts illustrated in the figure to the right: 1. The partial femoral component (this is the metal piece that attaches to your thigh bone, also known as your "femur") 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)	

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 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. 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

Surgeon or facility letterhead

additional treatment, including revision surgery, is necessary.

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, orany 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 billingdepartment, 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.com/recall.

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 or email BroadSpire directly at the following:

Language	Email	Telephone
French	exactech.recall@crawco.be	+32 80026327
Italian	exactech.recall@crawco.it	+39 0200704115
German	exactech.recall@crawco.de	49 (211) 54012549

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,

Surgeon or facility letterhead

Important patient notice regarding Exactech ankle replacement devices

August 2, 2022

Dear valued patient,

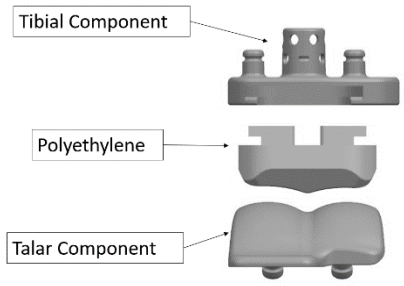
Because the safety and health of our patients is our top priority, we are writing to inform you that between the years of 2017 and 2022, you received a specific type of total ankle replacement that was manufactured by the orthopedic device company, Exactech, Inc, headquartered in Gainesville, Florida,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

Surgeon or facility letterhead

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.com/recall.

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 or email BroadSpire directly at the following:

Language	Email	Telephone
French	exactech.recall@crawco.be	+32 80026327
Italian	exactech.recall@crawco.it	+39 0200704115
German	exactech.recall@crawco.de	49 (211) 54012549

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,