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: **July 19, 2022**
For Attention of: **Exactech Agents, Representatives, and Distributors in Possession of Affected Products**
Affected Product: **Exactech Knee Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts**
Contact details of local representative: **Name: Ivonne Tiemissen**
Email: ivonnetiemissen@oudshoornbv.com
Phone: +31 412 63 24 00
Address: Oudshoorn Surgical Technics
Wethouder van Eschstraat 38
Oss, The Netherlands 5342 AT

The purpose of this letter is to provide an important **update** on the status of all Knee 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 arthroplasty polyethylene inserts packaged in nonconforming bags **regardless of shelf life manufactured since 2004**.

Description of Issue: Exactech is recalling Knee 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

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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.

Best regards,

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recalls@exac.com

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

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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.***