2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

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

URGENT FIELD SAFETY NOTICE

MEDICAL DEVICE RECALL

Date:	**September 15, 2021**
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 labeled with an 8-year shelf life**
Contact details of local representative:	[redacted]

The purpose of this letter is to inform you that a RECALL is being performed by Exactech for all Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts labeled with an 8-year shelf life. See Attachment 1 – Phase 1 Product List for details of affected products reported to be in your inventory.

Description of Issue: Exactech is recalling Exactech Knee and Ankle Ultra-High Molecular Weight Polyethylene (UHMWPE) inserts labeled with an 8-year shelf life. These inserts were 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.

Use of vacuum bags without an EVOH layer may result in elevated transmission of oxygen to the UHMWPE insert packaged therein which can potentially result in increased oxidation of the material relative to inserts packaged with EVOH over time.

As a result of extensive packaging material and UHMWPE insert testing by Exactech, data indicate that product within scope of this recall still performs as intended if implanted within 5 years of manufacture.

As of August 5, 2021, all products manufactured by Exactech are being packaged in EVOH vacuum bags to ensure adequate oxygen barrier properties and protection from oxidation of polyethylene inserts throughout the 8-year shelf life.

Clinical Impact: Exposure to oxygen over time can allow oxidation of the UHMWPE implant leading to a reduction of mechanical properties, which may ultimately require revision of the implant (UHMWPE Component); however, Exactech's testing and risk assessment confirms that the Nylon bags without the EVOH oxygen barrier properties perform similarly to Nylon bags with the EVOH oxygen barrier through 5 years of shelf life.

Actions Being Taken by Exactech: Exactech will be removing all Knee and Ankle UHMWPE products labeled with an 8-year shelf life and not packaged in EVOH/Nylon bags. This will be performed in a phased approach over the next 12 months, per the strategy outlined in Table 1 below. At this time, only UHMWPE products labeled with an 8-year shelf life are affected. There are no other Exactech UHMWPE products impacted by this recall (e.g. those products already labeled with a 5-year shelf life).

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

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

Table 1: 12-Month Recall Strategy

Phase I:	Immediately return all knee and ankle UHMWPE devices labeled with an 8-year shelf life that will be 5 years old or older by 08/31/2022 not packaged in EVOH/Nylon bags (See Attachment 1 - Phase I Product List).
Phase II:	Between 05/31/2022 to 08/31/2022 recall all remaining knee and ankle UHMWPE devices labeled with an 8-year shelf life not packaged in EVOH/Nylon bags (A new Recall Notification and Phase II Product Scope will be provided at the beginning of Phase II).

In addition to this Recall Notification, please inform your accounts that Exactech plans to provide a Dear Healthcare Professional (DHCP) letter to all Global Offices and Distributors to be forwarded to the end-users (surgeons) when local language translations become available.

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 Attachment 1 – Phase 1 Product List.
  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, **and inform your accounts** that Exactech plans to provide a Dear Healthcare Professional (DHCP) letter to all Global Offices and Distributors to be forwarded to the end-users (surgeons) when local language translations become available.
- **COMPLETE AND RETURN** the attached Recall Inventory Response Form and Attachment 1 – Phase I Product List 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.

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.

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 352-378-2617

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

Best regards,

[redacted]

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

2320 NW 66TH COURT
GAINESVILLE, FL 32653

352-377-1140
FAX 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.

☐ **I have identified and quarantined the affected devices**, as identified in Attachment I - Phase I Product List (Attachment 1) and have attached it to this response.

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

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.***