exactech

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

352.377.1140
352.378.2617

URGENT FIELD SAFETY NOTICE
MEDICAL DEVICE RECALL

To: Exactech Sales Representatives

Date: April 18, 2024

Subject: **Important Notice Regarding Voluntary Recall of Exactech Patella Devices**

Commercial Name: Exactech Optetrak Patella (see "Attachment 1" for product specific information)

We are writing to inform you about a lot-specific voluntary recall of Patella devices manufactured from 2004 through August 2021.

Please refer to "Attachment 1" for specific information about the affected products.

Thank you for your attention to this matter. Please review the subsequent information and take the appropriate action as necessary.

Reason for Recalling the Units:

This voluntary recall involves Patella lots that were packaged without the specified ethylene vinyl alcohol (EVOH) layer. Between 2004 and August 2021, our packaging process utilized two different types of packaging materials: 1) Low Density Polyethylene (LDPE), Nylon, and EVOH, or 2) LDPE and Nylon without EVOH.

EVOH enhances oxygen permeation prevention, the presence of Nylon alone still provides a barrier that limits oxygen permeation, when implants are used within the prescribed shelf life. Despite this we are voluntarily recalling these lots as a precautionary measure, given the potential for oxidation-related issues.

Potential issues due to oxidation include accelerated device wear or failure, component cracking or fracture, new or worsening pain, bone loss, and/or swelling in the affected area, which could necessitate revision surgery.

Clinical Impact:

1. **Implantation Precaution:** Do not implant affected devices packaged in defective packaging.
2. **Patient Monitoring:** Surgeons should regularly monitor patients with affected devices for potential device wear, failure, component cracking or fracture, new or worsening pain, bone loss and/or swelling, as per the instructions for use.
3. **Diagnostic Considerations:** Consider performing X-rays to further evaluate the patient if there's suspected device failure.
4. **Revision Considerations:** Revision of well-functioning devices is not recommended for patients without new or worsening pain or symptoms.

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5. **Patient Resources:** Patients with questions can access educational resources on our website HERE and use the device serial look-up tool HERE to check if their implant is part of the recall.

Actions to be Taken

- Review this notification thoroughly.
- Immediately discontinue use and quarantine any affected product.
- Send all affected product back to Exactech as outlined in the attached "Recall Confirmation Form".

Reporting Information

1. **Exactech Reporting**: Please report any adverse reactions or other quality problems experienced with these products to complaints@exac.com.

Transmission of this Recall Notice:

This notice needs to be passed on to all those who need to be aware of it within your organization.

This recall was reported to the U.S. Food and Drug Administration and will be reported to other Competent Authorities, Notified Bodies, and Regulatory Authorities as required.

We apologize for the inconvenience and thank you for your cooperation in this effort.

Sincerely,

18 April 2024

Matthew Collins
Vice President, Global Quality Assurance
Exactech, Inc.
2320 NW 66th Ct.
Gainesville, FL 32653

Date

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Recall Confirmation Form

It is important that you take the actions detailed in this Recall Notice and confirm that you have received information. Please complete and return this form to Exactech at packagingrecall@exac.com.

Your reply is the evidence we need to monitor the dissemination of this notice.

Please check the appropriate boxes and sign.

☐ I acknowledge receipt of this recall notice and confirm that I fully understand the issue identified, the clinical impact, and all actions that will be required in accordance with this recall notices

☐ 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 product listing "Attachment 1".

_____ _____

Date **Agency**

_____ _____

Name (Print) **Signature**

This form is to be returned to Exactech – Scan and email this form to packagingrecall@exac.com.

Send affected products to:

Exactech Inc.
2320 NW 66th Ct
Gainesville, FL 32653
Attention Patella Recall

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ATTACHMENT 1

Part Number	Device Description	Device Identifier
200-02-26	THREE PEG PATELLA 26MM	10885862039576
200-02-29	THREE PEG PATELLA 29MM	10885862039583
200-02-32	THREE PEG PATELLA 32MM	10885862039590
200-02-35	THREE PEG PATELLA 35MM	10885862039606
200-02-38	THREE PEG PATELLA 38MM	10885862039613
200-02-41	THREE PEG PATELLA 41MM	10885862039620
200-03-26	ONE PEG PATELLA 26MM	10885862039637
200-03-29	ONE PEG PATELLA 29MM	10885862039644
200-03-32	ONE PEG PATELLA 32MM	10885862039651
200-03-35	ONE PEG PATELLA 35MM	10885862039668
200-03-38	ONE PEG PATELLA 38MM	10885862039675
200-03-41	ONE PEG PATELLA 41MM	10885862039682
200-05-23	INSET PATELLA 23MM	10885862039835
200-05-26	INSET PATELLA 26MM	10885862039842
200-05-29	INSET PATELLA 29MM	10885862039859
200-07-26	ADVANCED PATELLA 26MM 3 PEG IMPLANT	10885862314260
200-07-29	ADVANCED PATELLA 29M 3 PEG IMPLANT	10885862314277
200-07-32	ADVANCED PATELLA 32MM 3 PEG IMPLANT	10885862314284
200-07-35	ADVANCED PATELLA 35MM 3 PEG IMPLANT	10885862314291
200-07-38	ADVANCED PATELLA 38MM 3 PEG IMPLANT	10885862314307