exactech

EXACTECH, INC
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URGENT VOLUNTARY MEDICAL DEVICE RECALL

To: Surgeons, Hospitals, Health Care Professionals

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)

Dear Surgeon,

We are writing to inform you about a lot-specific voluntary recall of Patella devices manufactured from 2004 through August 2021. These devices were marketed as Optetrak and cleared through 510(k): K932690, K933610 and K160484.

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.

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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.
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.
- Contact your Exactech Representative. Your local agent will help determine if you have any remaining affected product and remove from your inventory.

Our utmost priority is ensuring patient safety and achieving effective outcomes for users of our products. Collaborative efforts are essential for the success of actions like this, and your participation is crucial.

We are committed to addressing any potential concerns promptly and transparently. If you have any questions or would benefit from further information, please inform us and we can arrange a meeting with our corporate leadership team. This will provide an opportunity to discuss any inquiries regarding this recall at packagingrecall@exac.com.

Reporting Information

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

2. **FDA Medwatch Reporting**: Healthcare professionals and consumers are encouraged to report any adverse events or quality concerns related to this recall to the FDA through the Medwatch reporting system.

    - Online at FDA Medwatch Website or
    - Calling 1-800-FDA-0178.

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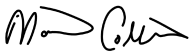
Transmission of this Recall Notice:

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,



18th April, 2024

Matthew Collins
Vice President, Global Quality Assurance
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Exactech, Inc.
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Date

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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