ZIMMER BIOMET

January 6, 2025

To: Distributors, Sales Representatives, and Distributor Operation Managers

Subject: **URGENT MEDICAL DEVICE RECALL - REMOVAL**

Affected Product: NexGen LCCK Legacy Articular Surface with Locking Screw

Item Number	Item Description	Lot Number	UDI Number
00-5994-022-14	NexGen LCCK Legacy Articular Surface with Locking Screw - Striped Purple/C,D - Height 14 mm	66602503	(01)00889024635647(17)290423(10)66602503
00-5994-022-14		66520665	(01)00889024635647(17)290424(10)66520665
00-5994-022-14		66881918	(01)00889024635647(17)290915(10)66881918
00-5994-022-14		66949906	(01)00889024635647(17)291028(10)66949906
00-5994-032-10	NexGen LCCK Legacy Articular Surface with Locking Screw - Striped Yellow/E,F - Height 10 mm	66782843	(01)00889024635746(17)290624(10)66782843
00-5994-032-10		66782840	(01)00889024635746(17)290625(10)66782840
00-5994-032-10		66873137	(01)00889024635746(17)290828(10)66873137

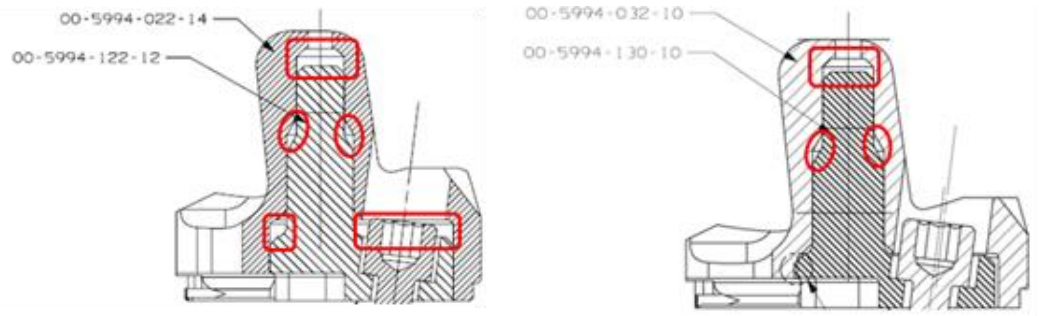

Figure 1: Layout illustrating the incorrect metal post position within the polyethylene articular surface

Zimmer Biomet is conducting a lot specific medical device recall removal for seven lots of the NexGen LCCK Legacy Articular Surface with Locking Screw products. It was identified internally that two commingle events occurred where the metal support post within the polyethylene articular surface was assembled incorrectly for three units within the scope. The non-conforming units were assembled with a metal support post that is shorter than expected, leading to a portion of the polyethylene spine being unsupported, as shown in red circles in Figure 1. There have been no complaints received.

Risks		
Describe immediate health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	None
Describe long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	None	Polyethylene wear/fracture resulting in adverse local tissue reaction (ALTR), requiring surgical intervention

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between May 2024 and December 2024.

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Your Responsibilities

1. Review this notification and ensure that affected team members are aware of the contents.
2. Immediately locate and quarantine affected product in your inventory.
3. Immediately return all affected product from your distributorship and from affected hospitals within your territory.
    a. Complete **Attachment 1 – Inventory Return Certification Form** for each return and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form must be returned even if you do not have affected products available to return in your territory.
    b. For International Returns, request an IRA by emailing zimmerbiometintlirarequests@zimmerbiomet.com
    c. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
    d. Mark "RECALL" on the outside of the returned cartons.
4. Return the **Additional Accounts** form to CorporateQuality.PostMarket@zimmerbiomet.com.
    a. Review the list of hospitals included with the email notification sent to your facility, which includes a list of hospitals that have already been notified of this recall.
    b. Identify whether there are any additional hospitals with unconsumed products that Zimmer Biomet has *not* notified and list these accounts on the Additional Accounts form. Please provide the form in **Excel format**.
    c. If there are no additional accounts to notify, please indicate that there are no additional accounts, or indicate "None" or "NA" on the form.
5. Retain a copy of your Inventory Return Certification and product return forms for your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this notice, please call customer service at 574-371-3071 between 8:00 am and 5:00pm EST, Monday through Friday. Calls received outside of call center operating hours will receive a voicemail prompt or be transferred to an on-call representative in the event of an emergency. Alternatively, your questions may be emailed to CorporateQuality.PostMarket@zimmerbiomet.com.

Other Information

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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA:

- Med Watch Reporting: Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's Med Watch Adverse Event Reporting program either online, by mail, or by fax.
- Online: www.fda.gov/medwatch/report.htm
- Call: 1-800-332-1088 to request a reporting form
- Mail: Use postage paid, pre-addressed form FDA 3500, available at: www.fda.gov/MedWatch/getforms.htm
- Fax: 1-800-FDA-0178

Under 21 CFR 803, manufacturers are required to report any serious injuries where a product has contributed or may have contributed to the event. Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing product.experience@zimmerbiomet.com.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes. Your urgent cooperation is needed. The undersigned confirms that this notice has been delivered to the appropriate Regulatory Agencies.

Thank you for your assistance. We regret any inconvenience caused by this recall.

Sincerely,

Stephanie Leppo
Quality Associate Director

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ATTACHMENT 1 - Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: NexGen LCCK Legacy Articular Surface with Locking Screw **ZFA Number:** ZFA 2024-00269

Territory Number: _____ **Account Number:** _____

Account Name: _____

Account Address: _____

Please return the affected product to the appropriate address below with a spreadsheet containing item number, lot number, and quantity:

Zimmer Biomet
Product Service Department
ATTN: RECALLS
1777 West Center Street
Warsaw, IN 46580

OR

Zimmer GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530
Dock 20
Breda 4836 LD, Netherlands

	Check one of the following:	
This is the final return for the entire territory. **An exhaustive search has been performed for the affected products.**	**Yes** ☐	**No** ☐

Note: Any product not returned or found in your territory is considered consumed and unavailable for use.

☐ **Credit My Account** ☐ **Send a Replacement**

Item Number	Lot Number	UDI Number	Quantity Returned

Complete this table for all affected items returned. If additional space is needed, please provide a spreadsheet and return it to CorporateQuality.PostMarket@zimmerbiomet.com with this form.

Certificate of Acknowledgement:

By signing below, I acknowledge that I have received, read, and understand the contents of this recall communication. All required activities are complete or are being completed.

Printed Name: _____ **Signature:** _____

Title: _____ **Tel:** ( ) _____ **Ext.** _____ **Date:** _____

Note: This form and affected product must be returned to Zimmer Biomet before this action is considered closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com.

Please do not return affected product with other returns.