ZIMMER BIOMET

23 January 2025

To: Hospitals
Subject: **URGENT MEDICAL DEVICE FIELD SAFETY CORRECTIVE ACTION (REMOVAL)**

Affected product: NexGen® Legacy® Constrained Condylar Knee (LCCK) Articular Surface with Locking Screw

See **Attachment 2 – Affected product list** for the affected batches.

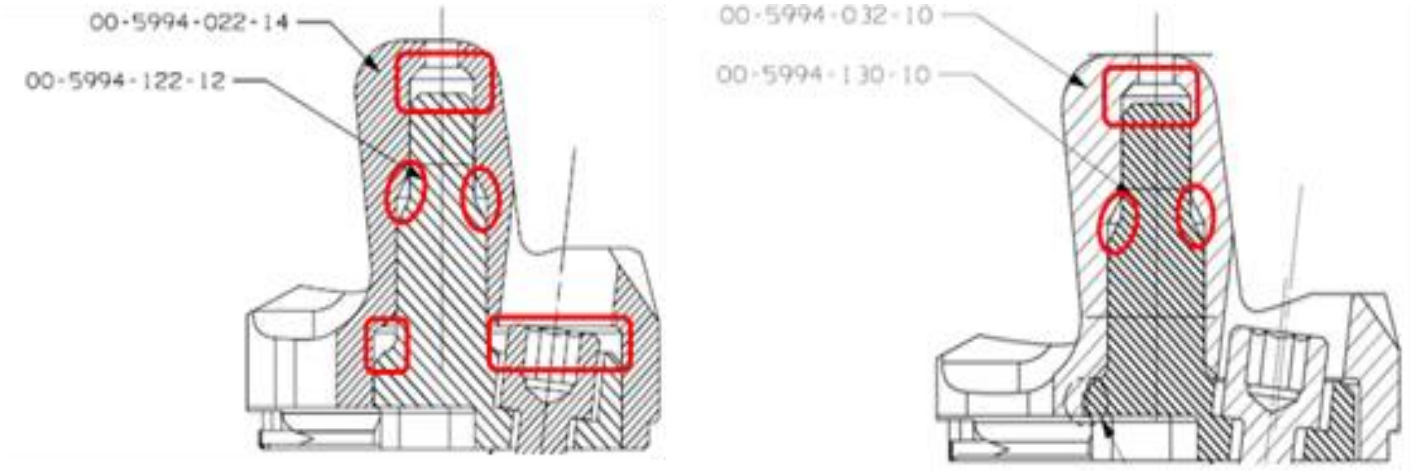

Figure 1: Layout illustrating the incorrect metal post position within the polyethylene articular surface.

Zimmer Inc. is conducting a batch specific medical device Field Safety Corrective Action (removal) for seven batches of the NexGen LCCK 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** above. To date, no product complaints have been 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 products were distributed between May 2024 and December 2024. Local distribution may differ.

Hospital responsibilities

1. Review this Field Safety Notice and ensure that affected personnel are aware of the contents.
2. Immediately locate and quarantine any affected product in your inventory. Your Zimmer Biomet sales representative may assist removing the affected product(s) from your facility.
3. If any affected product has been further distributed, provide your customers with this Field Safety Notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of acknowledgement** and send it to fieldaction.uk@zimmerbiomet.com. This form must be returned even if you do not have any affected product available for return.
5. Retain a copy of **Attachment 1 - Certificate of acknowledgement** with your records in the event of a compliance audit of your facility.
6. If you have further questions or concerns after reviewing this Field Safety Notice, please contact your local Zimmer Biomet representative.

Other information

This Field Safety Corrective Action was reported to all relevant Competent Authorities and Notified Bodies as required under the applicable regulations for Medical Devices per Regulation (EU) 2017/745 and guidance MDCG 2023-3. The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies. Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.uk@zimmerbiomet.com.

We would like to thank you for your co-operation in advance and regret any inconvenience caused by this Field Safety Corrective Action.

Sincerely,

Francis Moloney, VP QA/RC EMEA

ATTACHMENT 1 - Certificate of acknowledgement

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Field Safety Corrective Action reference number: ZFA 2024-00269
Affected product: NexGen® Legacy® Constrained Condylar Knee (LCCK) Articular Surface with Locking Screw

Do you have affected product in your facility?

☐ Yes, we currently have one or more affected products in our facility.

☐ No, we currently have no affected products in our facility.

Note: Any product not returned is considered dispositioned under your distributorship and unavailable for use.

Complete the table below for all affected products (to be) returned. If additional space is needed, please provide a spreadsheet and return it with this form. **Do not return products with other returns.**

Material number	Batch number	Quantity returned

Hospital acknowledgement

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

Printed name		**Title**	
Facility name		**Telephone number**	
Facility address		**Post code**	
City		**Country**	
Signature		**Signing date**	

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ATTACHMENT 2 - Affected product list

Material number:	00-5994-022-14
Material description:	NexGen LCCK Articular Surface with Locking Screw - Striped Purple/C,D - Height 14 mm
Batch number	**UDI number**
66602503	(01)00889024635647(17)290423(10)66602503
66520665	(01)00889024635647(17)290424(10)66520665
66881918	(01)00889024635647(17)290915(10)66881918
66949906	(01)00889024635647(17)291028(10)66949906

Material number:	00-5994-032-10
Material description:	NexGen LCCK Articular Surface with Locking Screw - Striped Yellow/E,F - Height 10 mm
Batch number	**UDI number**
66782843	(01)00889024635746(17)290624(10)66782843
66782840	(01)00889024635746(17)290625(10)66782840
66873137	(01)00889024635746(17)290828(10)66873137