

06 December 2022

To: Distributors

Subject: **URGENT MEDICAL DEVICE FIELD SAFETY NOTICE (REMOVAL)**

Zimmer, Inc. is conducting a voluntary medical device Field Safety Corrective Action (removal) related to the NexGen® Stemmed Option Tibial Components due to the clinically and statistically significant higher overall revision rates when these tibial components are used with either the Legacy® Posterior Stabilized (LPS) Flex or LPS Flex Gender Solutions Femoral (GSF) components as compared to other total knee arthroplasties in the United Kingdom National Joint Registry (UK NJR). Removing the NexGen Stemmed Option Tibial Component from inventory will prevent its future implantation with either the LPS Flex or LPS Flex GSF femoral components and mitigate the increased revision risk with these two specific combinations of tibial and femoral component.

You are receiving this letter because our records show that (1) you have unconsumed NexGen Stemmed Option Tibial Component inventory in your facility, (2) you have implanted the NexGen Stemmed Option Tibial component in combination with either the LPS Flex or LPS Flex GSF component, or (3) both. For your reference, the LPS Flex and LPS Flex GSF component part numbers are provided in Appendix 1.

Recalled Product: All NexGen® Complete Knee Solution Stemmed Nonaugmentable Option Tibial Components

Item Number	Device Identifier	Tibial Component Description
00-5986-037-01	00889024218833	NexGen Complete Knee Solution - Stemmed Nonaugmentable Tibial Component, Option Size 3
00-5986-037-02	00889024218840	NexGen Complete Knee Solution - Stemmed Nonaugmentable Tibial Component, Option, Size 4
00-5986-047-01	00889024218857	NexGen Complete Knee Solution - Stemmed Nonaugmentable Tibial Component, Option, Size 5
00-5986-047-02	00889024218864	NexGen Complete Knee Solution - Stemmed Nonaugmentable Tibial Component, Option, Size 6
00-5986-057-01	00889024218871	NexGen Complete Knee Solution - Stemmed Nonaugmentable Tibial Component, Option, Size 7
00-5986-057-02	00889024218888	NexGen Complete Knee Solution - Stemmed Nonaugmentable Tibial Component, Option, Size 8

In the recently published 19th Annual Report from the United Kingdom National Joint Registry (NJR), the NexGen Stemmed Option Tibial Component was found to have higher revision rates than the average revision rate of all other total knee replacements (TKRs) in the registry when paired with either the LPS Flex or LPS Flex GSF Option femoral components. More specifically, the NJR provided Zimmer Biomet with a variant report that showed the NexGen Stemmed Option Tibial Component, when combined with both the LPS Flex and LPS Flex GSF femoral components, had both a higher overall revision rate and revision rate for aseptic tibial loosening than other TKRs in the registry. For each femoral / tibial construct, the expected number of revisions was calculated using a Kaplan Meier log-rank analysis, stratified for patient gender, age-group, and year-cohort.

First, the NexGen TKR System utilizing the specific combination of the Stemmed Option Tibial Components with the LPS Flex femoral components (N=6,859) had a clinically and statistically significant increased cumulative revision risk compared to all other posterior stabilized TKRs (N=287,768) with a revision rate ratio (RRR = revised/expected revisions) of 1.73 (95% CI, 1.55-1.92) (p<0.001). Additionally, this combination had a clinically and statistically significant increased cumulative revision risk for aseptic tibial loosening compared to all other posterior stabilized TKRs with revision rate ratio of 3.49 (95% CI, 2.99-4.04) (p<0.001).

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Second, the NexGen TKR System utilizing the specific combination of the Stemmed Option Tibial Components with the LPS Flex GSF femoral components (N=3,571) had a clinically and statistically significant increased cumulative revision risk compared to all other posterior stabilized TKRs (N=287,768) with a revision rate ratio of 1.56 (95% CI, 1.33-1.82) ($p<0.001$). Additionally, this second combination had a clinically and statistically significant increased cumulative revision risk for aseptic tibial loosening compared to all other posterior stabilized TKRs with a revision rate ratio of 2.86 (95% CI, 2.26-3.58) ($p<0.001$).

Table 1. Summary of RRRs of NexGen Stemmed Option Tibia variants compared non-NexGen PS knees
(Derived from UK NJR's Variant Report, dated March 2022)

NexGen Femoral Variants in Combination with the Stemmed Option Tibial Component (N)	All Other NJR Knees (Comparator, N)	Cumulative Revision Type	RRR/Relative Risk (95%CI)	P value
LPS Flex (6,859)	PS non-NexGen knees (287,768)	Overall	1.73 (1.55-1.92)	$p<0.001$
LPS Flex GSF (3,571)	PS non-NexGen knees (287,768)	Overall	1.56 (1.33-1.82)	$p<0.001$
LPS Flex (6,859)	PS non-NexGen knees (287,768)	ATL	3.49 (2.99-4.04)	$p<0.001$
LPS Flex GSF (3,571)	PS non-NexGen knees (287,768)	ATL	2.86 (2.26-3.58)	$p<0.001$

Footnote:

- LPS Flex: NexGen Stemmed Option Tibial Components combined with LPS Flex Option femoral components and LPS Flex Std bearings
- LPS Flex GSF: NexGen Stemmed Option Tibial Components combined with LPS Flex GSF Option femoral components and LPS Flex Std bearings
- PS: Posterior Stabilized
- LPS: Legacy Posterior Stabilized
- ATL: aseptic tibial loosening
- Revision Types: cumulative "overall" revisions or revisions due to ATL
- RRR: For each femoral/tibial construct, the revision rate ratio (RRR) is calculated by dividing the number of revisions by the number of expected revisions. The expected number of revisions was calculated using a Kaplan Meier log-rank analysis, adjusted for patient gender, age-group, and year-cohort.
- Relative Risk: ratio between cumulative revision rates for the NexGen variants and that of the Comparator over the entire follow-up times.
- 95% CI: 95% confidence interval

The full UK NJR annual report is publicly available and can be accessed at <https://reports.njrcentre.org.uk> with information about the NexGen Stemmed Option Tibial Component located on page 357. As you follow and advise your customers, please be aware that the cumulative revision rate (for all reasons) for the NexGen Stemmed Option Tibia Component is less than 10% at 10 years. Zimmer Biomet will continue to monitor product performance and investigate this Field Safety Notice issue along with associated clinical performance data.

For patients who require revision of the specific combination of the NexGen Stemmed Option Tibia Component with the LPS Flex or LPS Flex GSF Option femoral components, the patient may experience the potential long-range health risks described in the table below:

Risks		
	Most Probable	Highest Severity
Long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Patient may experience minor or moderate pain or ache, minor or moderate range of motion limitation, swelling or edema, minor or moderate tissue damage, and decreased joint function.	Loss of fixation or non-integration and product failure occurs, such as tibial loosening, leading to surgical intervention. Revision TKR may result in major perioperative complications. Limb length discrepancy and moderate pain or ache, tissue damage and range of motion limitation may occur.

Our records indicate that you may have received one or more of the affected products. The affected units were distributed between October 2012 and October 2022.

Your Responsibilities:

1. Review this Field Safety Notice 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 fieldaction.cis@zimmerbiomet.com. This form must be returned even if you do not have affected products available to return in your territory.
 - b. Include a hardcopy of **Attachment 1** in each carton of your return shipment for immediate processing.
 - c. Mark “RECALL” on the outside of the returned cartons
4. If an impacted consignee would like additional information pertaining to the Field Safety Notice, or if you would like to provide them a resource with a plain language description of the Field Safety Notice, please direct them to the Zimmer Biomet website at the following URL: <https://www.zimmerbiomet.eu/en/products-and-solutions/specialties/knee/nexgen-complete-knee-solution.html#10-Info>.
5. Retain a copy of your **Inventory Return Certification Form** 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 Field Safety Notice, please contact your Zimmer Biomet representative. Alternatively, your questions may be emailed to fieldaction.qscc@zimmerbiomet.com.

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Other Information

This Field Safety Notice was reported to all relevant Competent Authorities and the related Notified Body as required under the applicable regulations for Medical Devices as per MEDDEV 2.12-1 in Europe.

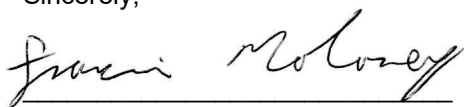
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.cis@zimmerbiomet.com or to your local Zimmer Biomet contact.

Please be aware that the names of user facilities notified are routinely provided to the Competent Authorities for audit purposes.

The undersigned confirms that this Field Safety Notice has been delivered to the appropriate Regulatory Agencies.

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&RA EMEA



ATTACHMENT 1 - Inventory Return Certification Form

IMMEDIATE RESPONSE REQUIRED –TIME SENSITIVE ACTION NEEDED

Affected Product: NexGen Complete Knee Solution Stemmed Nonaugmental Option Tibial Components
Field Safety Corrective Action Reference: ZFA2022-00240

Country: _____ **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 GmbH
Biomet Global Supply Chain Center B.V.
Hazeldonk 6530 - Dock 20
Breda 4836 LD, Netherlands

This is the final return for the entire territory. An exhaustive search has been performed for the affected products.	Check one of the following:	
	Yes <input type="checkbox"/>	No <input type="checkbox"/>

All products that are not available for return will be considered as dispositioned on your location, and therefore, physically unavailable unless otherwise specified.

☐ Credit my account

☐ Send a Replacement

Item Number	Lot Number	Quantity Returned

Complete this table for all affected items returned or provide a spreadsheet with the return of this form if the above table does not have enough space. **Please do not return affected product with other returns.**

Certificate of Acknowledgement

By signing below, I acknowledge that I have received, read, and understand the contents of this Field Safety Notice 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 fieldaction.cis@zimmerbiomet.com.

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Appendix 1: LPS Flex or LPS Flex GSF Component Item Numbers (For Reference Only)

These products are **NOT** required to be returned.

Item Number	Device Identifier	Description
00-5964-012-01	00889024569157	LPS-FLEX OPTION FEMORAL B-L
00-5964-012-02	00889024569164	LPS-FLEX OPTION FEMORAL B-R
00-5964-013-01	00889024569171	LPS-FLEX OPTION FEMORAL C-L
00-5964-013-02	00889024569188	LPS-FLEX OPTION FEMORAL C-R
00-5964-013-51	00889024001077	LPS-FLEX OPTION FEMORAL C-L
00-5964-013-52	00889024001084	LPS-FLEX OPTION FEMORAL C-R
00-5964-014-01	00889024569195	LPS-FLEX OPTION FEMORAL D-L
00-5964-014-02	00889024569201	LPS-FLEX OPTION FEMORAL D-R
00-5964-014-51	00889024001091	LPS-FLEX OPTION FEMORAL D-L
00-5964-014-52	00889024001107	LPS-FLEX OPTION FEMORAL D-R
00-5964-015-01	00889024405080	LPS-FLEX OPTION FEMORAL E-L
00-5964-015-02	00889024563919	LPS-FLEX OPTION FEMORAL E-R
00-5964-015-51	00889024001114	LPS-FLEX OPTION FEMORAL E-L
00-5964-015-52	00889024001121	LPS-FLEX OPTION FEMORAL E-R
00-5964-016-01	00889024563926	LPS-FLEX OPTION FEMORAL F-L
00-5964-016-02	00889024563933	LPS-FLEX OPTION FEMORAL F-R
00-5964-016-51	00889024001138	LPS-FLEX OPTION FEMORAL F-L
00-5964-016-52	00889024001145	LPS-FLEX OPTION FEMORAL F-R
00-5964-017-01	00889024563940	LPS-FLEX OPTION FEMORAL G-L
00-5964-017-02	00889024563957	LPS-FLEX OPTION FEMORAL G-R
00-5964-017-51	00889024001152	LPS-FLEX OPTION FEMORAL G-L
00-5964-017-52	00889024001169	LPS-FLEX OPTION FEMORAL G-R
00-5764-013-51	00889024192218	LPS-FLEX GSF OPT SZ C-L
00-5764-013-52	00889024192225	LPS-FLEX GSF OPT SZ C-R
00-5764-014-51	00889024192232	LPS-FLEX GSF OPT SZ D-L
00-5764-014-52	00889024192249	LPS-FLEX GSF OPT SZ D-R
00-5764-015-51	00889024192256	LPS-FLEX GSF OPT SZ E-L
00-5764-015-52	00889024192263	LPS-FLEX GSF OPT SZ E-R
00-5764-016-51	00889024192270	LPS-FLEX GSF OPT SZ F-L
00-5764-016-52	00889024192287	LPS-FLEX GSF OPT SZ F-R
00-5764-017-51	00889024192294	LPS-FLEX GSF OPT SZ G-L
00-5764-017-52	00889024192300	LPS-FLEX GSF OPT SZ G-R

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