ZIMMER BIOMET

February 8, 2023

To: Risk Managers and Surgeons

Subject: ZFA 2022-00240 NexGen Option Tibia Recall Notification

Zimmer Biomet is conducting a voluntary medical device recall 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).

The accompanying recall letter was originally issued on December 6, 2022 to surgeons and hospitals that had implanted the NexGen Option Tibia in combination with the LPS Flex or LPS Flex GSF component after October 2012 based on the 10-year shelf-life expiration period of the implants. After additional review, the recall strategy was amended to expand the recall notification to surgeons and hospitals that have record of implanting this combination prior to October 2012 regardless of the duration of the implantation.

You are receiving this notification because you have implanted a NexGen Option Tibia in combination with the LPS Flex or LPS Flex GSF component prior to October 2012 according to our records. We request that you review the accompanying recall notice and follow the instructions included in the risk manager and surgeon responsibilities identified on page 3 of the notice.

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

Sincerely,

Stephanie Leppo
Quality Associate Director

ZIMMER BIOMET

February 8, 2023 (updated from previously issued on December 6, 2022)

To: Risk Managers and Surgeons

Subject: **URGENT MEDICAL DEVICE RECALL**

Zimmer Biomet is conducting a voluntary medical device recall 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) ($p<0.001$).

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 patients, 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 recall 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		
Long range health consequences (injuries or illness) that may result from use of or exposure to the product issue.	Most Probable	Highest Severity
	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.

Risk Manager Responsibilities:

1. Review this notification and ensure that affected personnel are aware of the contents.
2. If you have affected product at your facility, assist your Zimmer Biomet sales representative and quarantine all affected product. Your Zimmer Biomet sales representative will remove the affected product from your facility.
3. If the product has been further distributed, provide your customers with the recall notice and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com. This form shall be returned even if you do not have affected products at your facility.
5. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
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.

Surgeon Responsibilities:

1. Review this notification for awareness of the contents.
2. It is recommended that for patients implanted with the NexGen Stemmed Option Tibial Component with either the LPS Flex or LPS Flex GSF Femoral Components, maintain an appropriate index of suspicion for patients with any new pain, inability to bear weight, swelling or instability of the knee. The UK NJR data suggests that tibial component loosening is a key cause of the increased TKR revisions. If your patient experiences any new pain or other symptoms related to the TKR, it is recommended that additional clinical and/or radiographic follow-up is completed.
3. If an impacted patient would like additional information pertaining to the recall, or if you would like to provide them a resource with a plain language description of the recall, please direct them to the Zimmer Biomet website at the following URL or provide them with a copy of the plain language description provided in Appendix 2: https://www.zimmerbiomet.com/en/products-and-solutions/specialties/knee/nexgen-complete-knee-solution.html#10-Info
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to CorporateQuality.PostMarket@zimmerbiomet.com.
5. Retain a copy of the acknowledgement form with your recall records in the event of a compliance audit of your facility's documentation.
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 medical device 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.

- 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 or 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 also 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

ZIMMER BIOMET

ATTACHMENT 1- Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

Affected Product: NexGen Complete Knee Solution Stemmed Nonaugmentable Option Tibial Components

Field Action Reference: ZFA 2022-00240

Please check one as applicable:

☐ Hospital Facility ☐ Surgeon

Do you have affected product in your facility?
(Hospital Facility Only: Please mark the appropriate response.)

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

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

By signing below, I acknowledge that the required actions have been taken in accordance with this recall notice.

Printed Name: _____ **Signature:** _____

Title: _____ **Telephone:** ( ) ____-_____ **Date:** ____/____/____

Facility Name: _____

Facility Address: _____

City: _____ **State:** _____ **ZIP:** _____

Note: This form will be returned to Zimmer Biomet before this action is closed for your account. It is important that you complete this form and email a copy to CorporateQuality.PostMarket@zimmerbiomet.com or fax to 574-373-3589 or 574-373-5097.

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

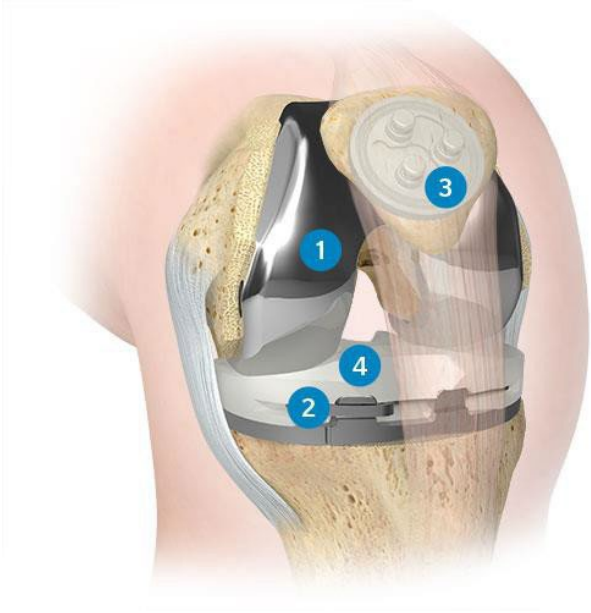
These products are NOT required to be returned.

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

Appendix 2: Important Patient Information Regarding
NexGen Stemmed Option Tibial Components when used with the Legacy Posterior Stabilized (LPS) Flex or LPS Flex Gender Solutions Femoral (GSF) Components

- This information is for patients who received a specific type of total knee replacement that was manufactured by Zimmer Biomet.
- More specifically, Zimmer Biomet is conducting a voluntary medical device recall related to the **NexGen Stemmed Option Tibial Components** ("Option Tibial Components") due to the clinically important higher overall revision rates when these tibial components are used with either the LPS Flex or LPS Flex GSF femoral components as compared to other total knee arthroplasties in the United Kingdom National Joint Registry. For your reference, the item list for the affected Option Tibial Components is provided in Table 1. You may refer to your health care provider or surgery center to obtain your operation implant information records to identify the item numbers.
- To be clear, the LPS Flex and LPS Flex GSF femoral components are not being recalled. Nevertheless, the item list for these products can be found in Table 2.
- Standard total knee replacement has four parts (see Diagram below):

    1. The femoral component (the product that attaches to your thigh bone);
    2. The tibial tray (the product that fits into your shin bone). **This is the recalled part**;
    3. The patellar component (the product that fits onto your kneecap); and
    4. The polyethylene insert (the product that fits between the femoral component and tibial component and acts as the new cartilage for your replaced knee joint).



- Zimmer Biomet voluntarily made the decision to remove the Option Tibial Components. Recent joint registry data from the United Kingdom (https://reports.njrcentre.org.uk) noted that the Option Tibial Components, particularly when paired with either the LPS Flex or LPS Flex GSF femoral components, had higher revision rates than the average revision rate of all other total knee replacements in the registry. More specifically, the NJR provided Zimmer

Biomet with a variant report that showed the Option Tibial Components, when combined with both the LPS Flex and LPS Flex GSF femoral components, had both a clinically important higher overall revision rate and a clinically important revision rate for aseptic tibial loosening than other total knee replacements in the registry.

- The UK NJR data suggests that tibial loosening is a key cause of the increased total knee replacement revision for the Option Tibial Components when paired with either the LPS Flex or LPS Flex GSF femoral components. Tibial loosening would typically present as new pain in the knee joint.

- The fact that a patient has a knee component within the scope of this recall does not necessarily mean that the knee component is not functioning well or needs to be replaced.

- Removal of any knee arthroplasty when a patient is not experiencing any symptoms is not recommended.

- Patients implanted with the Option Tibial Components used with either the LPS Flex or LPS Flex GSF femoral components who are not experiencing new or worsening symptoms, should continue normal follow-up with their surgeon or health care provider.

- If you have been experiencing any new pain, inability to bear weight, swelling or instability of the knee, it is recommended that you follow-up with your surgeon or another health care provider for further investigation of the cause of the pain, which could include implant factors as well as patient factors (age, sex, body habitus, activity level, etc.), surgical factors (technique, alignment, cement placement, etc.), and postoperative rehabilitative factors.

- Table 1: The item list for the Option Tibial Components can be found here. These are the recalled products.

Item Number	Device Identifier	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

- Table 2: The item list for the LPS Flex and LPS Flex GSF femoral components can be found here. These products are not recalled.

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

- Questions regarding the Option Tibial Components or any other Zimmer Biomet's knee products should be directed to the Zimmer Biomet Customer Service Team at 574-371-3071.

- Complaints related to the Option Tibial Components when used with either the LPS Flex or LPS Flex GSF femoral components or any other Zimmer Biomet knee products can be reported to Zimmer Biomet's Post-Market Surveillance Department at product.experience@zimmerbiomet.com for investigation, potential regulatory reporting and continuous monitoring.

- Patient health and safety are top priorities at Zimmer Biomet. We appreciate your time and attention in reading this important notification.