

06 December 2022

To: Hospitals and Surgeons

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).

MASTER maintained electronically in Document Control System; printed document is an UNCONTROLLED COPY unless identified as controlled by Document Control

For Internal Use Only PROPRIETARY & CONFIDENTIAL

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 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. Local deployment may differ.

Hospital Responsibilities:

1. Review this Field Safety Notice 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 Field Safety Notice for hospitals and ensure documentation.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.eire@zimmerbiomet.com. This form shall be returned even if you do not have affected products at your facility.
5. Retain a copy of the **Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
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.gsc@zimmerbiomet.com.

Surgeon Responsibilities:

1. Review this Field Safety Notice 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 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 or provide them with a copy of the plain language description provided in Appendix 2: <https://www.zimmerbiomet.eu/en/products-and-solutions/specialties/knee/nexgen-complete-knee-solution.html#10-Info>.
4. Complete **Attachment 1 – Certificate of Acknowledgement** and send to fieldaction.eire@zimmerbiomet.com.
5. Retain a copy of the **Certificate of Acknowledgement Form** with your Field Safety Corrective Action records in the event of a compliance audit of your facility's documentation.
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.gsc@zimmerbiomet.com.

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.

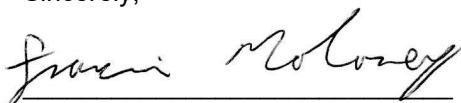
Please keep Zimmer Biomet informed of any adverse events associated with this product or any other Zimmer Biomet product by emailing per.ie@zimmerbiomet.com or to your local Zimmer Biomet contact.

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 - Certificate of Acknowledgement

IMMEDIATE RESPONSE REQUIRED – TIME SENSITIVE ACTION NEEDED

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

Please return the completed form to your Zimmer Biomet contact person or by e-mail to:
fieldaction.eire@zimmerbiomet.com

Regarding the parts:

A thorough search has been performed for the affected products and the below are available for return. Please provide a spreadsheet with the return of this form if the below table has not enough space to list all products.

| Item Number | Lot Number | Quantity Returned |
|-------------|------------|-------------------|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |

All products that are not available (for return) have been implanted or used: Yes No Unknown

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

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.

Hospital Facility Surgeon *(Please check one as applicable)*

Printed Name: _____ **Signature:** _____

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

Facility Name: _____

Facility Address: _____

City: _____ **Country:** _____ **ZIP:** _____

Note: This form must 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 fieldaction.eire@zimmerbiomet.com.

MASTER maintained electronically in Document Control System; printed document is an UNCONTROLLED COPY unless identified as controlled by Document Control

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

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

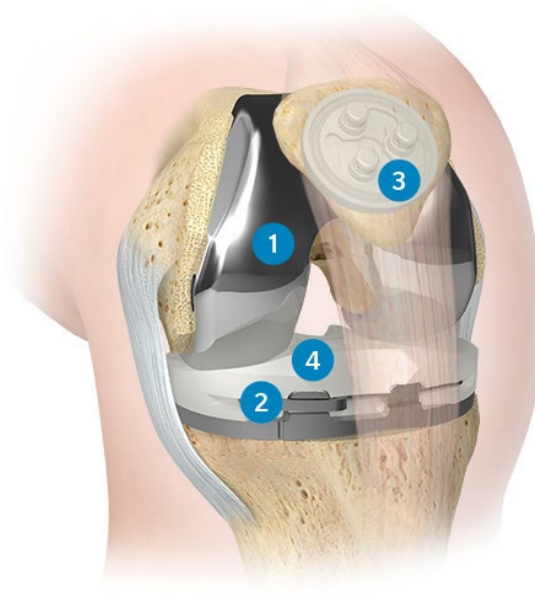
| Item Number | Device Identifier | Description |
|----------------|-------------------|-----------------------------|
| 00-5964-012-01 | 00889024569157 | LPS-FLEX OPTION FEMORAL B-L |
| 00-5964-012-02 | 00889024569164 | LPS-FLEX OPTION FEMORAL B-R |
| 00-5964-013-01 | 00889024569171 | LPS-FLEX OPTION 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 |

MASTER maintained electronically in Document Control System; printed document is an UNCONTROLLED COPY unless identified as controlled by Document Control

For Internal Use Only PROPRIETARY & CONFIDENTIAL

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, Inc.
- More specifically, Zimmer, Inc. is conducting a voluntary medical device Field Safety Corrective Action 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).



MASTER maintained electronically in Document Control System; printed document is an UNCONTROLLED COPY unless identified as controlled by Document Control

For Internal Use Only PROPRIETARY & CONFIDENTIAL

- Zimmer, Inc. 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 Field Safety Notice 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 |

MASTER maintained electronically in Document Control System; printed document is an UNCONTROLLED COPY unless identified as controlled by Document Control

For Internal Use Only PROPRIETARY & CONFIDENTIAL

- 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 knee products should be directed to fieldaction.gsc@zimmerbiomet.com.
- 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 product should be directed to per.ie@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.

MASTER maintained electronically in Document Control System; printed document is an UNCONTROLLED COPY unless identified as controlled by Document Control

For Internal Use Only PROPRIETARY & CONFIDENTIAL