HUGH JAMES

NexGen Knees

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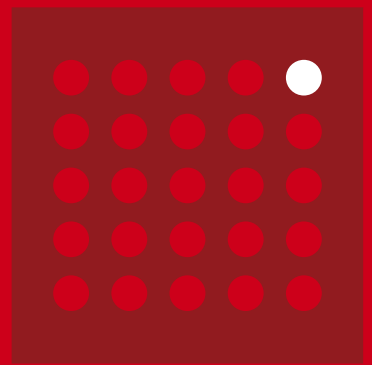


NexGen knee prostheses

- **Including the ‘NexGen Complete Knee Solution Stemmed Nonaugmentable Tibial Component, Option (Product Number: 5986)**

- **used in combination with a NexGen Legacy Posterior Stabilized and a NexGen articular surface component. The NexGen Complete Knee Solution**

Recall

- **Tibial Component was the subject of a voluntary recall on 6 December 2022,**
- **The recalled tibial component is one of a number of separate components which form the knee replacement prosthesis.**
- **Each knee replacement prosthesis consists of a tibial component, a femoral component and an articular surface component. In some cases, a patella component is also inserted.**

Defendants

- Manufacturer producer
- Zimmer Inc
- Zimmer GmBH

- Importer producer
- Zimmer Biomet UK Limited is an importer of some of the NexGen components into the European Union and into the United Kingdom.
- Zimmer International Logistics GmbH,
- Biomet Global Supply Chain Centre BV, Zimmer Biomet UK Ltd

The defect?

- The products put patients at risk of a distinctive, device-specific mode of failure,
- consisting of the rotational movement between the superior surface of the tibial tray and the insert, leading to debonding of the tibial component from the tibial cement mantle and abrasive damage.
- This mode of failure is not seen in standard cemented posterior stabilised implants.
- This is a distinctive, device-specific type of harm that would not have happened with a normally performing device.

Pleaded case

- (i) Patients suffered a distinctive, device-specific mode of failure
- (debonding of the tibial component from the tibial cement mantle and abrasive damage)
- (ii) in the alternative, the revision rate ratio was unacceptably high,
- (iii) there was an informational defect
- in that patients and surgeons were not warned of the device-specific mode of failure,
- nor of the unacceptably high revision rate,
- (iv) there was a failure to respond appropriately to the National Joint Registry's concerns about the product raised in 2015.

Product history

- **Previous version of the NexGen Complete Knee Solution stemmed tibial component was marketed in or around 1995.**
- **2012, the next version**
- **17 June 2015 the National Joint Registry ("NJR") "*notified Zimmer and the MHRA that the NexGen High Flex Knee had been found to be a level 1 outlier.***
- ***Our investigation suggested this was due to tibial loosening in combination with the option tibial stem and posterior stabilisation."***

NJR

- **4 March 2021 the NJR, wrote to Mr Daniel Tilbury, Complaints and Vigilance Supervisor, Biomet UK Limited.**

- **Having conducted an *"analysis based on implant bespoke reports and the presumed codes"*, the *"clear indications"* were that**

- ***"the cruciate retaining versions were doing better than expected, whilst the LPS were doing worse.***

- ***This particularly reaches significance with the LPS Flex Option with tibial loosening being confirmed as the leading factor."***

- ***March 2020, Keohane, Power, Cullen, O'Neill and Masterson* published a single-cohort study *(Keohane 2020)* :**
- ***"High rate of tibial debonding and failure in a popular knee replacement: a cause for concern."***
- ***"we would not expect this level of implant failure from a surgeon who had no previous significant issues with aseptic loosening using a different prosthetic."***

Keohane follow up

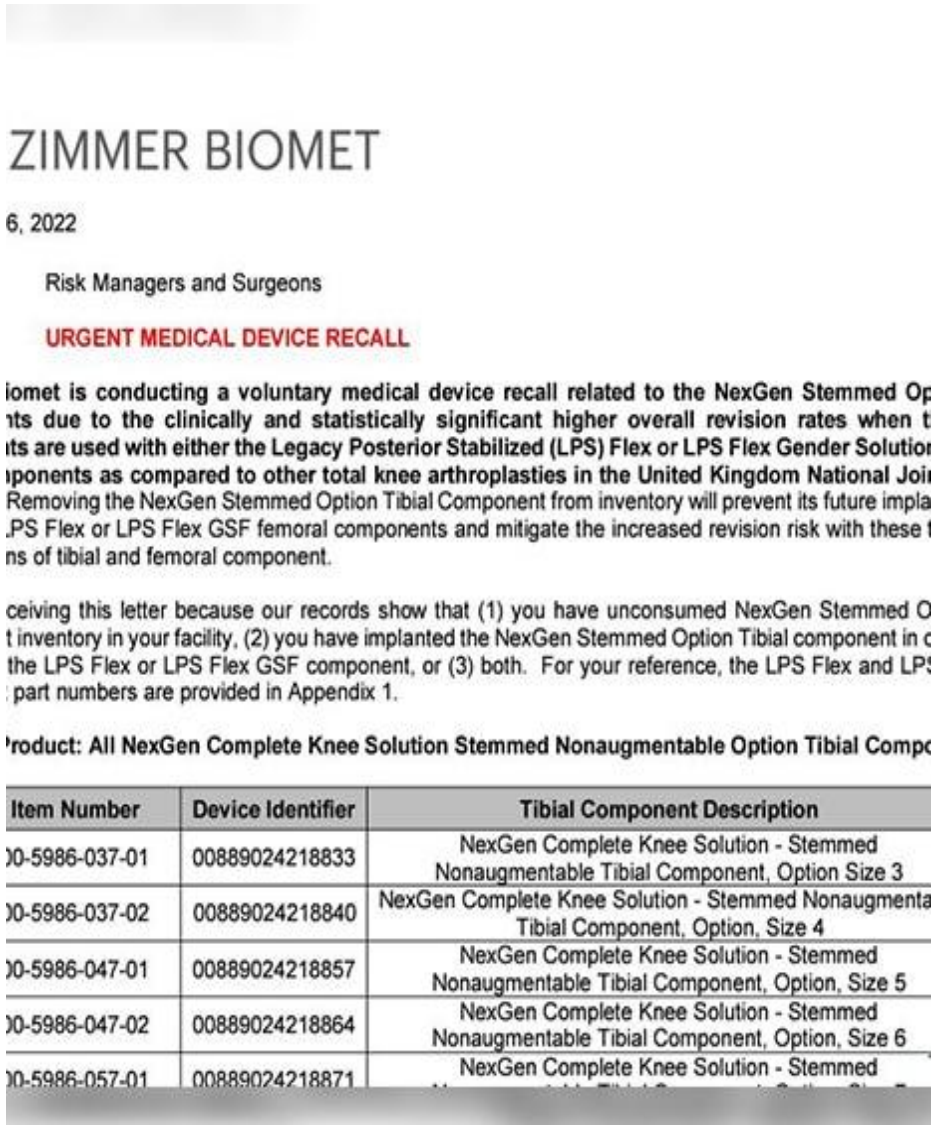
- June 2022, a follow-up review was published by Keohane, Sheridan and Masterson:
- *“High rate of tibial debonding and failure in a popular knee replacement”*
- *Between 2013 and 2016, 352 Zimmer NexGen Complete Knee Solution TKAs were performed on 331 patients.*

- *62 TKAs had been revised to date, giving an*
- *“all-cause revision rate of 17.6% at a minimum of five years.”*
- *59 revisions were for aseptic loosening of the tibial component (16.7%).*

- **The paper concluded*:***
- ***“while overall, we believe in conclusion that early aseptic loosening is multifactorial in nature,***
- ***the significantly high aseptic revision rate, as seen by an experienced fellowship-trained arthroplasty surgeon, has led us to believe that there is a fundamental issue with this NexGen implant design.***
- ***Continued implant surveillance and rigorous review across all regions using this particular implant is warranted based on the concerning findings described here.***
- ***If universally alarming findings are noted in future, an implant recall may be necessary in future.”***

Recall

- **6 December 2022 Zimmer Biomet issued an *"urgent medical device recall"* addressed to Risk Managers and Surgeons.**
- ***"Zimmer Biomet is conducting a voluntary medical device recall related to the NexGen Stemmed Option Tibial Components***
- ***due to the clinically and statistically 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).***



ZIMMER BIOMET

6, 2022

Risk Managers and Surgeons

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ns of tibial and femoral component.

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

roduct: All NexGen Complete Knee Solution Stemmed Nonaugmentable Option Tibial Compo

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 Nonaugmenta 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

Recall

- ***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.”***

Recall

- The recall notice cites NJR statistics of March 2022 which were said to demonstrate a clinically and statistically increased risk for aseptic tibial loosening (ATL), with a revision rate ratio ("RRR") of

- 3.49 (when combined with LPS Flex) or of

- 2.86 (when combined with LPS Flex GSF) in comparison with non-NexGen PS knees.

- The overall revision rate was increased, with an RRR of 1.73 (with LPS Flex) and 1.56 (with LPS Flex GSF) in comparison with non-NexGen PS knees.

MHRA Device safety alert

- 15 February 2023 MHRA issued a Device Safety Information notice in relation to the Tibial Components when combined with LPS Flex NexGen Femoral Variant or LPS Flex GSF NexGen Femoral Variant.
- Cited NJR statistics of March 2022 which demonstrated a clinically and statistically increased risk for ATL with a revision rate ratio (“RRR”) of 5.41 (when combined with LPS Flex) or
- of 4.49 (when combined with LPS Flex GSF) in comparison with all other NJR knees.
- In addition, the overall revision rate was increased, with an RRR of 2.04 (with LPS Flex) and 1.85 (with LPS Flex GSF) in comparison with all other NJR knees.
- The Device Safety Information notice provided for actions including identification and follow-up of all patients implanted with the affected devices.

The Comparator

- **A prosthesis with the same method of fixation, namely an alternative cemented posterior stabilised implant with a fixed polyethylene bearing.**

- **Expected longevity of the comparator would be 25 – 30 years (in patients under the age of 55 years) or for life (in patients over the age of 55 years).**

High Court Directions

- 59 cases in the High Court of England and Wales
- Case management conference 18 May 2026
- Managed by Senior Master Cook

- Stay all cases but serve records and summary
- Barge case to plead out
- CMC February 2027 for
- Lead case selection and evidence directions

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Watch this space!

Mark Harvey
Cardiff and London