MHRA Device Safety Information

Reference: MDSI2303 **Issued:** 15 February 2023 **Review Date:** 15 February 2024

Zimmer Biomet NexGen Knee replacement: affected patients should be offered additional follow up

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 15 February 2023. The original webpage can be accessed here.

Summary

The National Joint Registry (NJR) has identified that both the NexGen® Stemmed Option Tibial Components, when paired with either the Legacy® Posterior Stabilized (LPS) Flex Option Femoral or the LPS Flex Gender Solutions Femoral (GSF) Option Femoral, had a higher overall revision rate and a higher revision rate for aseptic tibial loosening compared to the average revision rate of all other total knee replacements in the UK NJR.

Actions for hospitals/surgeons

1. Follow the actions set out in the FSN.
2. Identify patients implanted with the affected devices.
3. Contact affected patients to inform them of the issue and offer clinical follow up with an orthopaedic surgeon. Patients may require a revision surgery. Radiographic assessment should be undertaken in patients presenting with any symptoms associated with their total knee replacement. Priority should be given to patients who:
   - have reported pain, inability to bear weight, developed a limp, swelling or instability of the knee;
   - have not had a follow-up appointment in the last two years;
   - have not had a satisfactory X-ray in the last 2 years.
4. Inform patients that they should contact their implanting hospital if they are experiencing any new pain/symptoms relating to their knee replacement in the future.
5. Report any suspected or actual adverse incidents involving these devices to your local management system and to IRIC.

Equipment details

NexGen® Stemmed Option Tibial Components when paired with either the Legacy® Posterior Stabilized (LPS) Flex Option Femoral or the LPS Flex Gender Solutions Femoral (GSF) Option Femoral.

See Field Safety Notice (FSN) for affected product codes.

All patients who have been implanted with these specific combinations of components are affected.

NexGen is manufactured by Zimmer Biomet.

Background

The National Joint Registry (NJR) has identified that both the NexGen® Stemmed Option Tibial Components, when paired with either the Legacy® Posterior Stabilized (LPS) Flex Option

Femoral or the LPS Flex Gender Solutions Femoral (GSF) Option Femoral, had a higher overall revision rate and a higher revision rate for aseptic tibial loosening compared to the average revision rate of all other total knee replacements in the UK NJR (table 1). Additional follow up should be offered to all patients implanted with these specific combinations of components.

Table 1. Summary of RRRs of NexGen Stemmed Option Tibia variants compared All Other NJR 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)	Revision Type	RRR/Relative Risk (95%CI)	P value
LPS Flex (6,859)	All other NJR TKR (1,193,124)	Overall	2.04 (1.83-2.26)	$p < 0.001$
LPS Flex GSF (3,571)	All other NJR TKR (1,193,124)	Overall	1.85 (1.58-2.16)	$p < 0.001$
LPS Flex (6,859)	All other NJR TKR (1,193,124)	ATL	5.41 (4.64-6.28)	$p < 0.001$
LPS Flex GSF (3,571)	All other NJR TKR (1,193,124)	ATL	4.49(3.55-5.62)	$p < 0.001$

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
- 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

A standard total knee replacement has 4 parts. These include the femoral component, tibial tray, patellar component, and the polyethylene insert. The manufacturer, Zimmer Biomet, has issued a FSN to recall all NexGen Stemmed Option Tibial Components that have not been implanted.

Risk associated with the NexGen® Stemmed Option Tibial Components when paired with either the Legacy® Posterior Stabilized (LPS) Flex Option Femoral or the LPS Flex Gender Solutions Femoral (GSF) Option Femoral

For patients implanted with the affected device combination, there is an increased risk of needing an operation to replace their original implanted knee replacement (table 1). The UK NJR data

suggests that tibial loosening is a key cause of the increased total knee replacement revisions for these specific combinations. Tibial loosening could typically present as new pain in the knee joint or limping. In rare cases tibial loosening may be asymptomatic.

The NJR has provided all hospitals with a list of affected patients recorded in the Registry with this combination. For Scotland this will be co-ordinated by health boards.

All affected patients should be offered clinical follow up and examination as outlined in the Actions section.

Suggested onward distribution

Orthopaedics	Device Managers	Risk Management
Operating Departments	Health & Safety	

Stakeholder engagement

- British Association for Surgery of the Knee (BASK)
- British Orthopaedic Association (BOA)
- Incident Reporting and Investigation Centre (IRIC), NHS National Services Scotland
- National Joint Registry (NJR)
- NHS England - National Patient Safety Team
- Welsh Government

Enquiries

Enquiries and adverse incident reports should be addressed to:

Incident Reporting & Investigation Centre (IRIC)
NHS National Services Scotland
Tel: 0131 275 7575 Email: nss.iric@nhs.scot

Accessibility: Please contact us using the above details if you are blind or have a sight impairment and would like to request this alert in a more suitable format.

IRIC remit: general information about adverse incidents, safety alerts and IRIC's role can be found in CEL 43 (2009), *Safety of Health, Social Care, Estates and Facilities Equipment: NHS Board and Local Authority Responsibilities,* issued 30 October 2009.

Report an incident: Information on how to report an adverse incident

NHS National Services Scotland is the common name for the Common Services Agency for the Scottish Health Service https://www.nss.nhs.scot/