

Freedom of Information Act Request

Under the Freedom of Information Act, I would like to request the following information:

I am a journalist working for BBC Radio 4, writing to request information under the Freedom of Information Act 2000

On 15 February 2023, the Medical and Healthcare Regulatory Agency (MHRA) issued a notice advising of the withdrawal of all All NexGen Complete Knee Solution Stemmed Nonaugmentable Option Tibial Components made by Zimmer Biomet.

<https://mhra.gov.filecamp.com/s/d/uNEoJ8FNw6hgKvPL>

This was followed by an MHRA notice issued on 15th February 2023 stating that there was a higher revision rate for NexGen knee replacements compared to other knee replacements.

They identified 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.

<https://gbr01.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.gov.uk%2Fdru-g-device-alerts%2Fnexgen-knee-replacement-affected-patients-should-be-offered-additional-follow-up%23risk-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&data=05%7C02%7Cd.wraith%40nhs.net%7Cf137e7dc758f4dd664a708ddab474d40%7C37c354b285b047f5b22207b48d774ee3%7C0%7C0%7C638855044909264306%7CUnknown%7CTWFpbGZsb3d8eyJFbXB0eU1hcGkiOnRydWUsIlYiOiIwLjAuMDAwMCIsIlAiOiJXaW4zMjIsIkFOIjojIiwFb3IjOiIldUIjoyfQ%3D%3D%7C0%7C%7C%7C&sdata=yFi7Y8ZHWVYPM%2B9IAQIcJKhwtpqNT%2BEeTV%2BSGNW4W%2FI%3D&reserved=0>

The MHRA advised the patients should be offered additional follow-up.

I would like to request the following information under the Freedom of Information Act 2000

From the 15th February 2023 until 13 June 2025:

1. How many patients has your Trust identified that have been implanted with the affected devices? **None**
2. How many of these patients have been notified about this recall? N/A
3. How many of these patients have received a follow up consultation? N/A
4. How many of these patients have received revision surgery? N/A
5. How many of these patients are awaiting revision surgery? N/A

If you are not satisfied with the handling of your request, you have the right to request an internal review. Requests for an internal review should be submitted within 40 working days from the date of this response, and should be addressed to d.wraith@nhs.net.

Our Ref: 387
June 2025

If you remain dissatisfied after the internal review, you have the right to appeal to the Information Commissioner's Office (ICO). The ICO can be contacted at:

Information Commissioner's Office
Wycliffe House
Water Lane
Wilmslow
Cheshire
SK9 5AF
Tel: 0303 123 1113
Website: <https://ico.org.uk/make-a-complaint/>