Medicines & Healthcare products Regulatory Agency

Device Safety Information (DSI)

Symbios ORIGIN® Posterior Stabilised Patient-Matched Total Knee Replacement Device: Risk of Early Revision (DSI/2024/005)

Device Details

ORIGIN is a patient-matched total knee replacement prosthesis available in posterior stabilised (PS) and cruciate retaining (CR) variants.

Affected catalogue and lot numbers: Refer to the Field Safety Notice (FSN) issued by the manufacturer for details on the affected devices.

Manufactured by: Symbios Orthopédie SA

Summary

The MHRA was alerted by Beyond Compliance and the UK National Joint Registry (NJR) to a significantly higher revision rate observed with the ORIGIN PS patient-matched total knee replacement. The ORIGIN PS variant, raised as a level 1 outlier, demonstrates a revision rate (per 100 patient years) that is at least two times higher than all other bicondylar knee replacements in the UK. This issue currently appears to be UK-specific as other international registries do not show the same increase in early revision surgeries.

The MHRA has conducted a review of all available evidence and has requested further investigation by the manufacturer. The root causes behind the UK revision procedures are yet to be fully established and the underlying reasons behind the differences between regions is yet to be understood.

As a precautionary measure, Symbios Orthopédie SA has initiated a voluntary suspension of all further sales and implantations, alongside a recall of all variants of the ORIGIN device family within the UK. This will be until such a time that further evidence is gathered and assessed.

The devices being recalled are outlined in the FSN issued by the manufacturer.

Risks associated with implantation of affected devices

For patients implanted with the ORIGIN PS variant, there is an increased risk of requiring an operation to replace the device. The NJR data extracted in March 2024 demonstrates a revision rate (per 100 patient years) that is at least two times higher than all other

bicondylar knee replacements in the UK. The data shows 8 revisions from 149 primary implantations over a period of approximately 6 years. Patients have undergone revisions for aseptic loosening, malalignment, stiffness and instability.

For patients implanted with the CR variant, there is no evidence to suggest an increased risk of revision, however the manufacturer has opted to expand the scope to include the entire ORIGIN device family as a precaution. The actions below are applicable to ALL variants.

Actions

Actions for healthcare professionals (particularly surgeons) and hospitals

- Follow the actions set out in the FSN.
- Identify patients implanted with the affected devices.
- Contact and inform patients that they should return for a follow up visit within 12 months and that they will soon be invited by the NJR to complete an evaluation of their knee joint replacement.
- Surgeons are encouraged to recognise that when interpreting post-operative x-rays for the ORIGIN, the insert may demonstrate variations in thickness, asymmetry or obliquity per design; as a patient-matched device, this interpretation may differ to more general total knee arthroplasty systems.
- There are specific reporting arrangements for healthcare professionals to follow in each region. Healthcare professionals should report incidents:
  - in England and Wales to the Yellow Card scheme or via the Yellow Card app
  - in Scotland to Incident Reporting & Investigation Centre (IRIC) and their local incident recording system
  - in Northern Ireland to the Northern Ireland Adverse Incident Centre and their local incident recording system

Actions for patients

- If you have been implanted with one of the affected knee implants, you should be contacted by the hospital that carried out your surgery with further information.
- If you experience any new or unexpected symptoms including pain, stiffness, or instability, please speak to your implanting surgeon or the hospital where your surgery was performed in the first instance or contact your GP if you have not yet been contacted by the hospital that carried out your surgery.
- Report any suspected or actual adverse incidents to the MHRA using the Yellow Card scheme website.

Additional information

You can sign up to receive email updates on alerts and device safety information from the MHRA.

Stakeholder engagement

National Joint Registry (NJR)
Interim Devices Working Group (IDWG)
Orthopaedic Data Evaluation Panel (ODEP)
Beyond Compliance
British Orthopaedic Association (BOA)

British Association for Surgery of the Knee (BASK)
NHS England National Patient Safety Team
NHS National Services Scotland
Northern Ireland Adverse Incident Centre

Medical Speciality

Orthopaedics

Published: 23/04/2024