MHRA Device Safety Information

Reference: MDSI2405 **Issued:** 23 April 2024 **Review Date:** 23 April 2025

Symbios ORIGIN® Posterior Stabilised Patient-Matched Total Knee Replacement Device: Risk of Early Revision

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency on 23 April 2024. The original webpage can be accessed here.

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. Devices are being recalled as outlined in the FSN issued by the manufacturer.

Action for healthcare professionals (particularly surgeons) and hospitals

1. Direct this notice to all appropriate managers, staff and users.
2. Follow the actions set out in the FSN.
3. Identify patients implanted with the affected devices.
4. 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.
5. 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.
6. Healthcare professionals in Scotland should report any incidents to local incident recording systems and Incident Reporting & Investigation Centre (IRIC).

For information only: action MHRA has recommended for others

MHRA has recommended the following actions for patients:

1. 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.
2. 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.
3. Report any suspected or actual adverse incidents to the MHRA using the Yellow Card scheme website.

Background Information

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 in this alert are applicable to ALL variants.

Equipment details

Manufacturer name:	Symbios Orthopédie SA
Brand name:	ORIGIN
Device name:	Posterior Stabilised Patient-Matched Total Knee Replacement Device
LOT numbers:	Refer to the Field Safety Notice (FSN) issued by the manufacturer for details on the affected devices.

Enquiries - manufacturer or supplier contact details

Symbios UK Ltd, Unit 2, Silverdown Office Park, Fair Oak Close, Clyst Honiton, Exeter, Devon EX5 2UX United Kingdom

Phone: +44 1 392 365 884

Suggested onward distribution (may not include all affected departments)

Orthopaedics
Operating Departments
Device Managers
Health & Safety
Risk Management

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

Information about IRIC

Incident Reporting & Investigation Centre (IRIC), Facilities Division, NHSScotland Assure 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.

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