Medicines & Healthcare products Regulatory Agency

DEVICE SAFETY INFORMATION (DSI)

M6-C Artificial Cervical Disc, Spinal Kinetics LLC: New monitoring requirements for the risk of osteolysis

DSI/2026/001

Specialisms: *Orthopaedics, General Practice*

DEVICE DETAILS

M6-C artificial Cervical Disc

AFFECTED LOT SERIAL NUMBERS

All devices (Refer to Field Safety Notice)

MANUFACTURED BY

Spinal Kinetics LLC, OrthoFix

Summary

The MHRA has conducted an assessment following reports of osteolysis and early device failure in the literature. The MHRA found that there was a delay in the manufacturer's communication of the risks of osteolysis, change in indications for use and updates to the product information to users and patients in the UK. Patients implanted with the M6-C artificial cervical disc should be informed of the risks of osteolysis, receive annual routine monitoring and discuss the need for further investigation and continued follow-up.

Advice for Healthcare Professionals:

Clinical follow-up recommendation:

- trusts/ hospitals should review local records to identify patients implanted with the M6-C device and invite them for active monitoring of their implant
- all identified patients should be contacted to inform them of the active monitoring programme and advised to contact their surgeon if they experience any new or unexpected symptoms
- patients that have the M6-C device implanted should be actively monitored for signs and symptoms of osteolysis.

- all patients should receive an anterior-posterior and lateral X-ray of the cervical spine on an annual basis that is reviewed clinically irrespective of whether they have symptoms
- follow the guidance from the British Association of Spine Surgeons
- if a patient has symptoms and/or osteolysis is suspected from their X-ray, further scanning such as CT or MRI will be required to evaluate the implant further. Appropriate follow-up should be adjusted based on an individual patient basis
- if a patient has osteolysis, surgeons should discuss the available options with them based on the clinical presentation of the patient. If revisional surgery is required, this should be carried out by a spinal surgeon with experience in revisional cervical spine surgery
- if hospitals need to prioritise patients for recall, patients with multi-level implantations of the M6-C device should be prioritised as the indications for use has been updated to exclude multi-level implantations

Advice for Healthcare Professionals to Provide to Patients:

- If you experience any new or unexpected symptoms including increasing neck pain, arm pain radiating from the neck, pins and needles in the hands or arm, weakness in the hands or arms electric type sensations into the arms or trunk on neck movements or weakness or loss of balance in their legs, speak to your implanting surgeon or the hospital where your surgery was performed in the first instance
- if you have had an M6-C device implanted, it is important you have had a recent X-ray in the last 12 months
- if you have had an M6-C device implanted, you should expect to be contacted by your surgeon or implanting hospital. There is no need to contact your surgeon or implanting hospital directly if you have no new or unexpected symptoms

Advice for Distributors:

- there is no advice for distributors related to this DSI

Explanation of identified safety issue

The M6-C artificial cervical disc is an intervertebral disc prosthesis intended to preserve the range of motion in the cervical spine when replacing a diseased native disc. Osteolysis is a recognised complication of cervical disc replacements. The MHRA have investigated a signal of osteolysis following concerns about the safety of the device raised in Yellow Card reports.

Published literature and case reports have described severe cases of osteolysis in patients with the M6-C device implanted resulting in complex revision surgeries including corpectomies (vertebrectomy). The literature also reports cases of symptomatic and asymptomatic osteolysis. In some cases, implant failure has been reported alongside osteolysis.

In 2020 the manufacturer Orthofix updated the Instructions for Use (IFU) in Australia regarding information on the consequences of osteolysis and to recommend routine monitoring of patients implanted with the device. In 2023, the UK IFU was updated to include the updated precautions. In August 2025, the manufacturer issued a Field Safety Notice (FSN) notifying users of these updates to the IFU that had not been communicated to users in the UK until this time.

The updated precautions included:

- *Routine long term clinical and radiographic monitoring of patients implanted with the M6-C is suggested to assess any changes in implant condition or surrounding anatomy. Changes in disc position, loss of height and peri-prosthetic bone loss may be indicative of onset of osteolysis. Peri-prosthetic osteolysis may result in neck pain and serious neurological sequelae including cervical spinal cord compression and quadriplegia.*

The FSN also highlighted that multi-level implantations had been removed from the indications for use.

Due to the risk of osteolysis, recall and monitoring of patients with the M6-C implant should be undertaken on an annual basis. The updated precautions, developed in association with the British Association of Spine Surgeons (BASS), constitutes a change in the current routine clinical practice for artificial cervical disc replacements. BASS have also published their own advisory notice about the monitoring requirements of the M6-C.

The Manufacturer discontinued the M6-C device in February 2025 and there are no remaining M6-C devices available for use on the UK market.

Reporting advice

Healthcare professionals should report incidents:

- in England and Wales to the Yellow Card website 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 Yellow Card website in accordance with your organisations medical device policies and procedures.

Additional information:

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

You can sign up to receive our monthly roundup of safety communications.

For any enquiries, please contact info@mhra.gov.uk

Stakeholder engagement:

- British Association of Spine Surgeons
- NHS England National Patient Safety team
- Getting It Right First Time (GIRFT)
- NHS England National Specialised Commissioning
- Incident Reporting & Investigation Centre (IRIC) for Scotland
- NHS Wales
- Department of Health (NI)
- National Institute for Health and Care Excellence (NICE)

References

Scott-Young, M., Rathbone, E. & Grierson, L. Midterm osteolysis-induced aseptic failure of the M6-C™ cervical total disc replacement secondary to polyethylene wear debris. *Eur Spine J* 31, 1273–1282 (2022). https://doi.org/10.1007/s00586-021-07094-7

Silva Tavares, J., Jácome Morgado, D., Seromenho Santos Nora, A. *et al.* Osteolysis after cervical disc arthroplasty with artificial cervical disc. *Eur Spine J* 34, 64–68 (2025). https://doi.org/10.1007/s00586-024-08585-z

Altorfer, F.C.S., Kelly, M.J., Avrumova, F., Zhu, J, Abjornson, C., Lebl, D.R. Reasons for Revision Surgery After Cervical Disk Arthroplasty Based on Medical Device Reports Maintained by the US Food and Drug Administration. Spine 49(20):p 1417-1425, October 15, 2024. | DOI: 10.1097/BRS.0000000000000506

Gonzalez D, Tang F, Khalifé M, Bitan F. Osteolysis of the Cervical Spine after M6-C Disk Replacement due to Allergy to Polycarbonate Urethane: A Case Report and Literature Review. HSS J. 2024 Aug 28:15563316241273745. doi: 10.1177/15563316241273745. Epub ahead of print. PMID: 39564410; PMCID: PMC11572286.

Blumenthal, S.L., Ohnmeiss, D.D., Courtois, E.C. *et al.* Treatment of failed cervical total disc replacements in a series of 53 cases and description of a management strategy. *Eur Spine J* 33, 3117–3123 (2024). https://doi.org/10.1007/s00586-024-08402-7

Häckel, S., Gaff, J., Pabbruwe, M. *et al.* Heterotopic ossification, osteolysis and implant failure following cervical total disc replacement with the M6-C™ artificial disc. *Eur Spine J* 33, 1292–1299 (2024). https://doi.org/10.1007/s00586-024-08129-5

Carrera DA, Ricks CB. Catastrophic delayed cervical arthroplasty failure: illustrative case. J Neurosurg Case Lessons. 2022 Mar 14;3(11):CASE21731. doi: 10.3171/CASE21731. PMID: 36209405; PMCID: PMC9379625.

Phayal G, Chiluwal A, Zavarella SM. Long-Term Complication of Three-Level Cervical Artificial Total Disc Replacement: A Case Report. Cureus. 2023 Jul 24;15(7):e42380. doi: 10.7759/cureus.42380. PMID: 37621799; PMCID: PMC10445663

Clohisy JCF, Abjornson C, Bauer TW, Baral E, Albert TJ. Delayed Failure of M6-C Cervical Disc Arthroplasty After Conversion of Adjacent Cervical Disc Arthroplasty to Fusion: A Case Report. JBJS Case Connect. 2023 Apr 18;13(2). doi: 10.2106/JBJS.CC.22.00788. PMID: 37071739.

Roschke E, von der Höh NH, Dietz A, Stingu CS, Gradistanac T, Henkelmann J, Heyde CE. A Rare Case of Wear Induced Complications after Cervical Disc Replacement. Z Orthop Unfall. 2022 Jun;160(3):324-328. English, German. doi: 10.1055/a-1340-0643. Epub 2021 Feb 18. PMID: 33601460.

Pingel A, Hoffmann CH, Scholz M, Kandziora F. Late Implant Failure in Cervical Disc Arthroplasty (M6-C, Spinal Kinetics) Causing Radiculopathy and Myelopathy. Z Orthop Unfall. 2022 Apr;160(2):207-212. English, German. doi: 10.1055/a-1286-5172. Epub 2020 Dec 9. PMID: 33296944.

Nunley P, Meyers A, Mangual-Perez D, Young E, Googe H, Armstrong I, Tran S, Stone M. Rates of Osteolysis for Commercially Available Cervical Disc Arthroplasty Devices in the United States: A Manufacturer and User Facility Device Experience Database Analysis. Int J Spine Surg. 2025 Oct 27;19(5):517-524. doi: 10.14444/8772. PMID: 40681342.

Bosh- García D, Gutiérrez R, Cisneros B, Cardona C, Montenegro, J, Nuñez J. The Efficacy of Second-Generation cervical Spine Arthroplasty: A 5 year Perspective. J Minim Invasive Spine Surg Tech 2024;9(Suppl 2):S117-S125. doi:https://doi.org/10.21182/jmisst.2024.01347

Phillips FM, Coric D, Sasso R, Lanman T, Lavelle W, Lauryssen C, Albert T, Cammisa F, Milam RA. Prospective, multicenter clinical trial comparing the M6-C compressible cervical disc with anterior cervical discectomy and fusion for the treatment of single-level degenerative cervical radiculopathy: 5-year results of an FDA investigational device exemption study. Spine J. 2024 Feb;24(2):219-230. doi: 10.1016/j.spinee.2023.10.020. Epub 2023 Nov 10. PMID: 37951477.