MHRA Device Safety Information

Reference: MDSI2306 **Issued:** 12 April 2023 **Review Date:** 12 April 2024

NuVasive Specialized Orthopedics (NSO) PRECICE Titanium Systems: UK Suspension Lifted

This is a copy of web content published by the Medicines & Healthcare products Regulatory Agency (MHRA) on 12 April 2023. The original webpage can be accessed here.

Summary

The MHRA has conducted a thorough assessment of technical and biological safety information provided by NSO and is satisfied that the PRECICE Titanium subset of devices (**Intra-Medullary Limb Lengthening (IMLL), Short, Unyte and Freedom)** can now be used in adults in the UK. NSO has agreed to meet a set of conditions to effectively monitor the long-term biological safety of the devices.

Please note: the CE marks for PRECICE Biodur systems (Bone Transport, Stryde and Plate) have NOT been reinstated and these devices remain suspended from the UK market.

Actions for healthcare professionals

- PRECICE Titanium systems: Intra-Medullary Limb Lengthening (IMLL), Short, Unyte and Freedom can now be appropriately selected for use in surgery.
- Follow the actions set out in the manufacturer's FSN.
- The PRECICE devices should only be implanted in accordance with the Manufacturer instructions For Use.
- Report any suspected or actual adverse incidents involving these devices through your local risk management system and to IRIC.

Equipment details

PRECICE Titanium Systems – Intra-Medullary Limb Lengthening (IMLL), Short, Unyte and Freedom.

Affected lot numbers/serial numbers: refer to FSN for affected devices.

Manufactured by NuVasive Specialized Orthopedics (NSO)

Risks involved with using affected product

All PRECICE System devices were affected by the following concerns as identified in the previous device recall notification dated 20 January 2021 ref: 2020/012/009/226/001

1. Unknown long-term biological safety profile

The MHRA conducted an extensive review of the PRECICE system of devices which found that there was insufficient information to confirm the long-term safety of PRECICE as per the intended use. NSO has now provided sufficient evidence to address this concern as set out below:

The long-term safety of unintended exposure to internal components and the leaching of hazardous chemicals was unknown. Extractable and leachable testing in worst case scenario, without the end cap, has been performed. This evaluation is considered acceptable and scientifically justified and is no longer a concern.

The long-term safety of exposure to metal wear debris was not sufficiently evaluated. NSO has since conducted testing to better define this risk but there remain some gaps in the evidence regarding safety. The MHRA has therefore requested NSO to conduct a post-market clinical follow up study to proactively monitor the risk of exposure to metal wear debris in patients who have these devices implanted. The MHRA will continue to review and assess the safety of the device on an ongoing basis.

2. Inappropriate use in children and adolescents

Despite children and adolescents being the main patient group, these devices have not been validated by NSO for use in these populations. The PRECICE devices should only be implanted in accordance with the Manufacturer instructions For Use. Any use of this device in non-adult populations is considered 'off-label' use'.

Stakeholder engagement

- Spinal Expert Advisory Group (SEAG)
- British Orthopaedic Association (BOA)
- NHS England Patient Safety Team
- Incident Reporting and Investigation Centre (IRIC)
- Devolved Administrations

Suggested onward distribution

Orthopaedics	Device Managers	Risk Management
Operating Departments	Health & Safety	

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/