Device Safety Information (DSI)

NuVasive Specialized Orthopedics (NSO) PRECICE Titanium Systems: UK Suspension Lifted, DSI 2023/006

Devices 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)

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.

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.

Risk 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.

Actions

Actions for health care 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 healthcare institution's local incident reporting system and/or your national incident reporting authority as appropriate: England, Scotland, Northern Ireland, Wales.

Actions for patients

- If you have been waiting for surgery during the period of the UK suspension of these devices, you are likely to be contacted by your medical team to discuss the options now available to you.
- If you have a device implanted and you experience any pain or other problems associated with the implant, please speak to your implanting surgeon/ hospital in the first instance or contact your GP if you have been discharged from their care.
- If you have not yet had the device implanted, you may be invited to participate in post-market clinical follow-up activities. MHRA strongly recommends patient involvement to ensure the safety and effectiveness of the device can continue to be stringently monitored.
- 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

Spinal Expert Advisory Group (SEAG)
British Orthopaedic Association (BOA)
NHS England Patient Safety Team
Devolved Administrations