Medicines & Healthcare products Regulatory Agency

MHRA Regulating Medicines and Medical Devices

20 January 2021

MHRA Reference: 2020/012/009/226/001

Device recall and supply suspended to the UK: All PRECICE Systems by NuVasive Specialized Orthopedics Inc.

NuVasive Specialized Orthopaedics, Inc. (NSO) has issued the attached Field Safety Notice (FSN) dated 20 January 2021.

NSO has undertaken voluntary action to recall and suspend the supply of all PRECICE Systems to the UK, while they are in the process of addressing the safety concerns identified by MHRA. These devices, therefore, will remain unavailable for supply until further notice.

The PRECICE system is a family of devices typically used to treat orthopaedic conditions associated with long bones and includes the following devices:

- PRECICE Intra-medullary Limb Lengthening Device
- PRECICE Short
- PRECICE Unyte
- PRECICE Freedom
- PRECICE Opty-line
- PRECICE Bone Transport
- PRECICE Stryde
- PRECICE Plate

All PRECICE System devices are affected by the following concerns:

1. Unknown long-term biological safety profile

The long-term safety of the PRECICE System family is unknown. Several biological endpoints have not been adequately assessed and others have failed to be considered, including chronic, reproductive and developmental toxicity, and carcinogenicity.

The manufacturer has been made aware of several adverse incidents potentially related to biological safety for the PRECICE STRYDE. This includes reports of pain and bony abnormalities at the interface between the telescoping nail segments. The manufacturer is investigating the issue and the root cause has yet to be confirmed.

2. Inappropriate use in children and adolescents

MHRA is aware that there has been widespread use of these devices in children and adolescents. The PRECICE System has not been validated for use in these patient groups.

MHRA does not believe the indications and contraindications provided by the manufacturer are suitably clear. The wording of the manufacturer's instructions for use could lead to inadvertent off-label use of this family of devices.

MHRA's recommendations

Due to the unknown risks of using the devices listed above, MHRA recommends the following:

- Do not implant any of the affected PRECICE System devices in the UK. A complete list of affected devices is attached.
- If you have any devices remaining on site, remove them from stock and return them to the manufacturer (NSO).
- Review and implement the manufacturer's clinical advice under the 'Recommended User Action' section in the FSN. Contact NSO for clarification of the clinical advice and recommended user actions, if required.
- 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.

Devices Safety and Surveillance Group
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