Potential Biocompatibility Concerns with NuVasive Specialized Orthopedics' Precice Devices – Letter to Health Care Providers

July 8, 2021

The U.S. Food and Drug Administration (FDA) is informing health care providers about potential biocompatibility concerns associated with NuVasive Specialized Orthopedics' Precice devices made from stainless steel and titanium. The FDA is also providing health care providers with recommendations for monitoring patients with these devices, which include the following:

Stainless Steel (Biodur 108)-Based Precice Devices:

- Precice Bone Transport
- Precice Plate
- Precice Stryde

Titanium-Based Precice Devices:

- Precice Freedom
- Precice Intra-medullary Limb Lengthening (IMLL) Device
- Precice Short
- Precice Unyte

NuVasive is performing additional biocompatibility testing on materials used for all Precice devices against updated testing standards. NuVasive is also conducting a series of assessments of potential mechanical failures that may contribute to biocompatibility issues. The FDA has received reports of pain and changes in the surrounding bone and soft tissue in people implanted with the Precice Stryde device, which is stainless steel (Biodur 108)-based.

Recommendations

For **Stainless steel-based devices:**

- Stop implanting any new stainless steel-based Precice devices.
- Be aware that as of February 2021, NuVasive voluntarily removed from the U.S. market all stainless steel-based devices due to adverse events related to increased pain and bone changes. If you still have these products, please follow the actions provided by NuVasive

(https://www.nuvasive.com/wp-content/uploads/2021/02/NSO-Precice-FSN-United-States-Biodur.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

For **Titanium-based devices:**

- Be aware that NuVasive has initiated a voluntary recall (not a removal from the U.S. market) for these devices.
- Be aware that these devices are not being sold in the U.S. market due to a voluntary manufacturer ship hold (https://www.nuvasive.com/wp-content/uploads/2021/04/Company-statement_MAGEC-and-Precice-CE-Mark_09April2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) placed in April 2021.
- If you still have these products, please follow the recommendations provided by NuVasive (https://www.nuvasive.com/wp-content/uploads/2021/02/NSO-Precice-FSN-United-States-Titanium.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer).

Recommendations for **all Precice devices:**

- Follow U.S. labeling instructions:
  - Do not implant longer than the cleared implantation time of one year.
  - Follow weight-bearing instructions for Precice devices. These devices are either non-weight bearing or cannot withstand full weight bearing for the thigh bone (femur) and shin bone (tibia) applications.
  - Do not implant in people under 18 years of age.
- For patients implanted with these devices, check for changes in the surrounding bone and soft tissue during routine radiographic monitoring. When patients have increased pain or other unexpected symptoms, perform additional radiographs and physical examination, with special attention to the area surrounding the telescoping junction of the implant.
- At this time and based on currently available information, early removal of non-painful, well-functioning Precice devices from asymptomatic patients prior to one-year post implantation is not recommended. Decisions about removing or exchanging the Precice device should be made by health care providers in consultation with the patient or caregiver on a case-by-case basis.
- Report any adverse events or suspected events experienced with Precice devices to the FDA through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).

Background

Precice devices are implants intended for people age 18 years and over, to lengthen the limb, shorten or compress the limb, or transport segments of long bones. Precice devices include adjustable rods placed inside a patient, which are driven by an internal magnetic mechanism.

Stainless steel-based devices: The FDA has received reports describing pain and changes in surrounding bone and soft tissue in patients with the stainless steel-based Precice devices. These adverse events may be related to corrosion, wear, and previously unanticipated exposure of components that are undergoing biocompatibility testing. At this time, the FDA is uncertain if the root cause of these adverse events is due to the stainless-steel material or related to design features and materials common to all Precice devices.

Titanium-based devices: At this time, the FDA is not aware of reports of adverse events related to biocompatibility issues with titanium-based Precice devices. As NuVasive continues to investigate the root cause of issues with stainless steel-based Precice devices, the company is also looking into how those issues may relate to titanium-based devices.

On April 5, 2021, NuVasive posted a statement (https://www.nuvasive.com/wp-content/uploads/2021/04/Company-statement_MAGEC-and-Precice-CE-Mark_09April2021.pdf) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) informing health care providers of ongoing biocompatibility testing with Precice devices and placed a global ship hold for all Precice devices. See the Precice System Notices page (https://www.nuvasive.com/precicenotices/) (http://www.fda.gov/about-fda/website-policies/website-disclaimer) for all field safety notices for Precice devices.

Given the information available at this time, the FDA has no evidence that alters the currently understood benefits and risks of titanium-based Precice devices for the intended FDA-cleared patient population. If the health care team determines there is a time-urgent need for an available intramedullary lengthening device, the team should consider use on a case-by-case basis.

FDA Actions

The FDA is working with NuVasive to:

- Evaluate new testing results to address biocompatibility issues with these devices and collect additional data to better understand the risks to patients.
- Ensure patients with a Precice device continue to receive appropriate follow-up monitoring.

The FDA will continue to keep health care providers and the public informed as new or additional information becomes available.

Reporting Problems to the FDA

The FDA encourages health care providers to report any adverse events or suspected adverse events experienced with NuVasive Precice devices.

- Voluntary reports can be submitted through MedWatch, the FDA Safety Information and Adverse Event Reporting program (/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program/reporting-serious-problems-fda).
- Device manufacturers and user facilities must comply with the applicable Medical Device Reporting (MDR) regulations (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities).
- Health care personnel employed by facilities that are subject to the FDA's user facility reporting requirements (/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities) should follow the reporting procedures established by their facilities.

Prompt reporting of adverse events can help the FDA identify and better understand the risks associated with medical devices.

Contact Information

If you have questions about this letter, contact the Division of Industry and Consumer Education (/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) (DICE).