



November 30, 2021

Re: Availability of NuVasive Specialized Orthopedics Precice titanium device systems

Dear Surgeon Partners,

We are pleased to inform you the **U.S. voluntary ship hold on Precice Unyte and Precice Freedom has been lifted and these products are available for sale, effective immediately.**

U.S. product availability

The **Precice titanium device systems (Precice IMLL, Precice Short, Precice Unyte, and Precice Freedom) are available for sale in the U.S.** As previously shared, this decision was made after discussions between the U.S. Food and Drug Administration (FDA) and NuVasive Specialized Orthopedics (NSO), following a number of interactions over the last several months regarding available biocompatibility testing results, other available data, and the overall risks and benefits of the device.

The **Precice biodur device systems (Precice Stryde, Precice Bone Transport, and Precice Plate) were previously removed from the market** and remain unavailable. NSO continues to work with the U.S. FDA in review of these remaining products and will continue to keep you updated on product availability.

Updated Instructions for Use (IFU)

In addition, the Company updated the Precice Unyte and Precice Freedom IFU documents to align with the Precice IMLL and Precice Short IFU documents. These updates include:

- Clarity that the device is intended for use only in patients age 18 and older;
- No more than two (2) devices should be implanted at a time; and
- Patients should weigh 50 lbs. or more while undergoing treatment with the devices listed.

See the electronic IFU section on the NuVasive website—[click here](#)—to reference the updated IFU. As a reminder, please consult the IFU prior to and during a patient's treatment with the Precice titanium device systems.

Field Safety Notice (FSN)

NSO has issued an FSN in the U.S. to notify you and other healthcare providers of the Precice titanium device systems' IFU updates. You will receive the FSN via email and a copy will be inserted in the product shipping box. **Please review and acknowledge the FSN and return to NSO at your earliest convenience.**

This letter and the FSN is posted on our website for [Precice notices](#). Please reach out to your NSO representative with any questions—our team is here to support you and your patients.

Sincerely,

Kyle T. Malone

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NuVasive, Inc.

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