



November 15, 2021

Re: Availability of NuVasive Specialized Orthopedics Precice IMLL and Short

Dear Surgeon Partners,

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

All remaining Precice titanium products (Precice Unyte and Precice Freedom) remain on a voluntary ship hold at this time, but the product is targeted for return to market the week of November 29, 2021. 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 IMLL and Precice Short IFU document to 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 system.

Field Safety Notice (FSN)

NSO previously issued a U.S. FSN to notify you and other healthcare providers of the Precice IMLL and Precice Short IFU updates. You should have received the FSN via email and a copy will be inserted in all product packaging. **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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