



December 1, 2021

## NuVasive statement on Precice titanium device system availability

As outlined in [our Field Safety Notice](#) on November 30, 2021, NuVasive Specialized Orthopedics (NSO), a subsidiary of NuVasive, has lifted the U.S. voluntary ship hold on the Precice titanium device systems (Precice IMLL, Precice Short, Precice Unyte, and Precice Freedom) and **these products are available for sale in the U.S., effective immediately**. This decision was made after discussions between the U.S. Food and Drug Administration (FDA) and 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 U.S. FDA has updated their [prior communication](#), stating:

*“The FDA believes it is in the best interest of patients to make titanium-based Precice devices available in the United States. At this time, the overall benefits of the devices outweigh the known risks for on-label use with the updated labeling, compared to alternative treatments.”*

In addition, the CE certificate has been reinstated for the Precice titanium device systems and product availability and sale outside the U.S. will differ by country.

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