Originally posted October 27, 2021
Updated November 10, 2021

Re: Update on NuVasive Specialized Orthopedics Precice titanium device system CE certificate

Dear Surgeon Partners,

We are pleased to inform you the **CE certificate has been reinstated for the NuVasive Specialized Orthopedics (NSO) Precice titanium device system, inclusive of Precice IMLL, Precice Unyte, Precice Opty-Line, Precice Short, and Precice Freedom, effective immediately.**

The CE certificate for the Precice biodur device system (Precice Stryde, Precice Bone Transport, and Precice Plate) remains temporarily suspended and under assessment as NSO works through a similar review process with its notified body, DQS Medizinprodukte GmbH (DQS). **All sales of the Precice biodur device system remain on hold.**

Product availability outside the United States

Currently, NSO has prioritized the return to market of Precice IMLL and is working through and/or assessing the return of the remaining Precice titanium device system products. At this time, **only Precice IMLL and Precice Short are available for sale outside of the United States and product availability will differ by country.** NSO continues to work with local regulatory bodies on any country-specific requirements to reintroduce the Precice titanium device system to a respective region. Please speak with your NSO representative on the status of product availability in your country.

Extensive product review

The CE certificate reinstatement was supported by an extensive review by DQS that included an assessment of clinical evidence, technical documentation, and biocompatibility testing results.

Updated Instructions for Use (IFU)

In addition, the Company updated the Precice IMLL and Precice Short IFU document. 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 has issued an FSN outside of the United States to notify you and other healthcare providers of the Precice IMLL and Precice Short IFU updates and the CE certificate reinstatement. You will receive 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
Vice President, Clinical, Medical, & Regulatory Affairs
NuVasive, Inc.

Matthew Collins
Vice President, Global Quality Assurance
NuVasive, Inc.