URGENT FIELD SAFETY NOTICE – PRECICE SYSTEM

Date: 01 Mar 2021

Commercial Name: Precice Intramedullary limb lengthening device (IMLL) Systems, including Precice Short (referred to in this notice as the Precice IMLL System)

Type of Action: Advisory Notice

Description of the Issue:

NuVasive Specialized Orthopedics, Inc is providing the Field Safety Notice (FSN) to inform healthcare providers of the following information:

> The Instructions for Use (IFU) for the Precice IMLL system has been updated to include the following Warnings:
>
> **Warnings: The PRECICE System has not been evaluated for biological safety in patients in relation to reproductive health or in patients under the age of 18 years of age.**

Information Pertinent to Biological Safety:

This device does not have the full complement of biological assessments as outlined in ISO 10993-1:2018 for all potential patients. The additional toxicological risk assessments being undertaken to close these gaps include carcinogenicity, chronic toxicity, developmental toxicity, and reproductive toxicity. Post-market data has not identified unexpected incidents related to biological safety with the Precice Short or IMLL systems. The generation of evidence to bridge the current gaps are ongoing with expected completion in Q2 2021.

Overview of the Precice System of devices:

The Precice IMLL system is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

Clinical Impact:

This notice alerts users to the updated IFU language. As previously discussed above, adverse events related to biological safety have not been identified in these patient populations.

The IFU should be consulted prior to and during patient treatment with the Precice IMLL device.

Recommended User Action:

- Review, complete, sign and return the attached Consignee Confirmation Form accompanying this notification in accordance with the directions on the form.
- If a patient has been previously implanted with a listed device and was under the age of 18, consultation may be warranted, at the discretion of the provider.
- If a patient has been previously implanted with a listed device and is pregnant, becomes pregnant, or intends to become pregnant, consultation may be warranted, at the discretion of the provider.
- Forward this notice to anyone in your facility that needs to be informed.
- Direct any additional manufacturer inquiries to FSNprecice@nuvasive.com
- Report to NSO any adverse effect or product complaints related to the use of these devices to FSNprecice@nuvasive.com, whether or not those adverse effects are related to this FSN.
- Download the Precice System eIFU from www.nuvasive.com/eIFU.

As a reminder, the following guidelines should be considered in all Precice System family patients, according to the Instructions for Use (IFU), including, but not limited to:

- The IFU should be consulted on an ongoing basis before and throughout patient treatment with Precice products.
- The Precice IMLL device is contraindicated in patients in which the Precice devices would cross joint spaces or open epiphyseal growth plates.
- The Precice IMLL device is contraindicated in patients unwilling or incapable of following postoperative care instructions.
- Precice IMLL device should be removed after an implantation period of no more than one year.
- Once the physician determines that the IMLL device has achieved its intended use and is no longer required, it is removed using standard surgical techniques.
- The Precice IMLL device cannot withstand the stressed of full weight bearing for tibia or femur applications. For humerus applications, patients should not bear any weight on the treated limb. Patients should utilize external support and/or restrict activities until consolidation occurs.
- The Precice family of devices are contraindicated for use in patients with metal allergies and sensitivities.
- Metallic implants can loosen, fracture, corrode, migrate, or cause pain.

- Smoking, chronic steroid use, and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect on the bone regenerate during the lengthening process.

Affected Devices:

Precice IMLL device. See attachment 1 for a list of SKUs.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those who need to be aware of within your organization.

This notice has been reported to all applicable regulatory authorities.

Matthew Collins
Vice President, Global Quality Assurance
101 Enterprise #100
Aliso Viejo, CA 92656

March 1, 2021
Date

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Type of Action: Advisory Notice

Consignee Confirmation Form

It is important that your organization takes the actions detailed in this FSN and confirms that you have received this FSN. Please complete and return this form to NSO per the instructions below.

Your organization's reply is the evidence we need to monitor the dissemination of this notice.

Customer Name: _____

Address: _____

_____

_____

_____

Phone: _____

(Information required for regulatory effectiveness check)

I acknowledge receiving and reading the 01 Mar 2021 Precice IMLL FSN

_____	_____	_____
Name/Title	**Signature**	**Date**
_____	_____	_____
NSO representative, if applicable	**Signature**	**Date**

This form is to be returned to NSO – Scan and email this form to FSNprecice@nuvasive.com