URGENT FIELD SAFETY NOTICE

PRECICE INTRAMEDULLARY LIMB LENGTHENING DEVICE (IMLL), PRECICE SHORT, PRECICE UNYTE, AND PRECICE FREEDOM

Date: 20 Feb 2021

Commercial Name: The following Precice System devices:

Precice Intramedullary limb lengthening device (IMLL), Precice Short, Precice Unyte, and Precice Freedom. All lots affected

Type of Action: Advisory Notice

NuVasive Specialized Orthopedics, Inc (NSO) voluntarily issues this Field Safety Notice (FSN) to inform healthcare providers of the following information:

Description of the Issue:

NSO is notifying that the products outlined in the commercial section above are not indicated for use in individuals under the age of 18 years old.

Information Pertinent to Biological Safety:

These devices do 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 have not identified unexpected incidents related to biological safety with the Precice IMLL, Short, Precice Unyte, or Precice Freedom systems. The generation of evidence to bridge the current gaps are ongoing with expected completion in Q2 2021.

Information related to potential patient populations:

These devices are not indicated for use in individuals younger than 18 years of age.

Developmental toxicity analyses have not been performed on these devices.

Reproductive toxicity analyses have not been performed on these devices.

- Updates to the IFU are being pursued to provide end-user clarity and will be communicated as appropriate.
- Additional biological endpoints for use in potential patient populations are underway with expected completion Q2 2021. Relevant communication will be made as appropriate.

Overview of the Precice System of devices:

The Precice System of devices, collectively, is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones. The Precice Freedom System is indicated for lengthening of the residual limb of the femur.

Clinical Impact:

This notice is being done out of an abundance of caution as NSO completes:

- The additional assessments of developmental and reproductive toxicity.

Actions to be taken customer/User:

- An NSO representative will be contacting your office or you to help with any questions or concerns.
- 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.
- Adverse reactions or quality problems are experienced with the use of these products, you may report these directly to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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.
- These Precice family of devices are contraindicated in patients in which the Precice devices would cross joint spaces or open epiphyseal growth plates.
- These Precice family of devices are contraindicated in patients unwilling or incapable of following postoperative care instructions.
- Precice System devices should be removed after an implantation period of no more than one year.
- Once the physician determines that the Precice/Short/Freedom/Unyte System has achieved its intended use and is no longer required, it is removed using standard surgical techniques.
- These Precice System devices are either non-weight bearing or cannot withstand the full weight-bearing for tibia or femur applications.
- These 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 Intramedullary limb lengthening device (IMLL), Precice Short, Precice Unyte, and Precice Freedom.

See attachment 1 for a list of SKUs.

NUVASIVE

Transmission of this Field Safety Notice:

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

This notice has been reported to the FDA.

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

Feb 22, 2021
Date

URGENT FIELD SAFETY NOTICE

PRECICE INTRAMEDULLARY LIMB LENGTHENING DEVICE (IMLL), PRECICE SHORT, PRECICE UNYTE, AND PRECICE FREEDOM

Date: 02 Feb 2021

Commercial Name: Precice System, including the following marketed devices:

Precice Intramedullary limb lengthening device (IMLL), Precice Short, Precice Unyte, and Precice Freedom.

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 120 Feb 2021 Precice System 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