NUVASIVE

URGENT FIELD SAFETY NOTICE – Precice Unyte, and Precice Freedom

Date: December 6, 2021

Commercial Name: Precice Unyte, and Precice Freedom trade names

Type of Action: Advisory Notice

NuVasive Specialized Orthopedics, Inc. (NSO) voluntarily issues this Field Safety Notice (FSN) to inform healthcare providers of the following, in follow-up from the prior Feb 2021 Precice FSN and April 2021 - NSO Statement communications:

1. This notice of updates to our Instructions for Use (IFU) documents. These updates include:
    a. Clarifying that the device is intended for use only in adults.
    b. That no more than 2 devices should be implanted at a time, and
    c. Patients should weigh 50 lbs or more while undergoing treatment the devices listed.

The following updates have been made to our IFUs located at www.nuvasive.com/eIFU. We recommend users with existing inventories maintain this FSN as a reference document.

IFU Section	Updated IFU Language (in bold)
Intended Use **(Unyte)**	……. pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones **in adults**.
Intended Use **(Freedom)**	……. lengthening of the residual limb of the femur **in adults.**
Warnings	Patients ……. **should not be implanted with more than two devices at a time and the patient's weight should be a minimum of 50 lbs**.

Reasons for IFU Updates:

- These changes are a follow up to the prior communications:

- Feb 2021 Precice FSN and April 2021 - NSO Statement

- These updates clarify the instructions regarding the target patient population based on the latest scientific evidence.

Clinical Impact:

NuVasive continues to monitor all post-market surveillance data relating to the Precice Unyte and Precice Freedom device systems. To date, there have been no reports of toxicological harms identified. Additional biological assessments are ongoing to determine whether there are potential toxicological risks to patients under 50 lbs or for patients with more than two implanted devices. Until that testing is completed, the use of Precice Unyte and Precice Freedom are not recommended for patients under 50 lbs or with more than 2 implanted devices.

Recommended User Action:

This FSN provides information regarding updates to our IFUs for Precice Unyte and Precice Freedom. The updated IFU's provide greater clarity on the conditions for use and should be consulted (www.nuvasive.com/eIFU) prior to and during patient care of those being treated with Precice Unyte and Precice Freedom devices.

- The IFU should be consulted on an ongoing basis before and throughout patient treatment.
- An NSO representative will be contacting your office or you to help with any questions or concerns.
- Acknowledgement of these changes is critical. Please review, complete, sign and return the attached Consignee Confirmation Form in accordance with the directions on the form (accompanying this notification).
- For patients currently weighing less than 50 pounds and/or with more than two devices implanted should consult their healthcare team for assessment of their treatment progression and consider removal of nails promptly at the end of treatment. Following this recommended action can minimize the potential for implantation risks while also minimizing the risks associated with repetitive surgical interventions and sub-optimal conversion to alternative therapies mid-treatment.

The following recommendations should be considered when using any of the Precice devices in accordance to the respective device IFU (Precice Unyte and Precice Freedom) including, but not limited to:

- The Precice Unyte and Precice Freedom nails remain implanted until bone consolidation has been completed. Once the physician determines that the nail has achieved its intended use and is no longer required, it is removed using standard surgical techniques.
- Device should be removed after implantation time of no more than one year.
- The Precice Unyte and Precice Freedom devices are contraindicated in patients in which the nail would cross joint spaces or open epiphyseal growth plates.
- The Precice Unyte and Precice Freedom devices are contraindicated in patients unwilling or incapable of following postoperative care instructions.
- The Precice Unyte and Precice Freedom nails cannot withstand the stresses of full weight bearing for tibia and femur applications.
- The Precice Unyte and Precice Freedom 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/drug use and the use of other anti-inflammatory drugs have been determined to affect bone healing and could potentially have an adverse effect of the bone regenerate during the lengthening process. Additionally, patients should be evaluated for narcotic dependencies associated with pain management.

In the event of adverse reactions or quality problems are experienced with the use of this product, the consignee may report this information to NuVasive at complaints@nuvasive.com, and the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

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 all applicable regulatory authorities.

[redacted]

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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 December 6, 2021 Precice Unyte, and Precice Freedom 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