URGENT RECALL NOTIFICATION

PRECICE STRYDE, PRECICE PLATE AND PRECICE BONE TRANSPORT

Date: 20 Feb 2021

Commercial Name: Precice Stryde, Precice Plate, Bone Transport – All lots.

Type of Action: Advisory Notice and Voluntary Product Removal

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

Description of the Issue:

There have been several reports of adverse events potentially related to biological safety in one of the device systems listed above (Precice Stryde), which are currently under investigation. The events include reports of pain and bony abnormalities at the interface between the telescoping nail segments. The root cause has yet to be confirmed, though preliminary explant analyses suggest the issues are not of a biological safety origin.

Information Pertinent to Biological Safety:

The Precice devices included in this notice 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.

- The generation of evidence to bridge the current gaps are ongoing with expected completion in Q3 2021.

Information related to potential patient populations:

The Precice Stryde and Precice Bone Transport devices are not indicated for use in individuals younger than 18 years of age.

As stated in the IFU, the Precice Plate device is indicated for use in pediatrics and in small stature adults.

Biological assessments for all potential patient populations in the device systems may not have been made.

- Updates to the IFU are being pursued to provide end-user clarity and will be communicated as appropriate.
- Additional information on the outcome of those assessment or otherwise will communicated as appropriate.
- The devices will not be available for use until further notice.

Overview of the Precice System of devices:

The Precice Stryde and Bone Transport System of devices, are intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

The Precice Plate device is indicated for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, and non-unions of long bones, in pediatric and small stature adult patients.

Clinical Impact:

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

- Investigations into the adverse events reported in Precice Stryde.
    - It should be noted that we are not aware of similar adverse events in the Precice Plate and Precice Bone Transport systems
- The additional testing being performed related to biological safety

Patients who are currently planned to receive these devices or are between staged surgical interventions / along a continuum of treatment or care with the use of affected devices may be impacted. Clinicians responsible for care should consider alternative arrangements for treatment during this time and contact FSNprecice@nuvasive.com with any questions.

Actions to be taken by the customer/user:

- An NSO representative will be contacting your office or you to provide instructions for the ***return of any Precice Stryde, Plate, or Bone Transport device***.
- ***Do not implant Precice Stryde, Plate, or Bone Transport*** until further notice.
- Review, complete, sign and return the attached Consignee Confirmation Form accompanying this notification in accordance with the directions on the form.
- The Precice Stryde, Plate, and Bone Transport will not be available until further notice.

- Prophylactic removal of functioning devices is not recommended. Instead, any treatment decisions should be made by the physician in consultation with the patient and/or family.
- For any patients, assessment of any symptoms, via consultation, and radiography should be made to determine if pain and abnormal bony changes might be present, as described above.
    - If so, then clinical care decisions should be made at the discretion of the healthcare team, in consultation with the patient and any other relevant decision makers.
- If a patient has been previously implanted with the 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 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 Stryde, Plate, and Bone Transport.
- Precice Stryde and Bone Transport are contraindicated in patients in which the devices would cross joint spaces or open epiphyseal growth plates.
- Precice Stryde, Bone Transport, and Plate are contraindicated in patients unwilling or incapable of following postoperative care instructions.
- Precice Stryde, Bone Transport, and Plate should be removed after an implantation period of no more than one year.
- Precice Stryde and Bone Transport cannot withstand the stresses of full weight-bearing for tibia or femur applications.
- Precice Plate is not designed to withstand the stresses of weight bearing. For humeral applications, patients should limit use of the treated limb and should not stress or bear weight on the treated limb unless instructed by a physician.

- Precice Stryde, Bone Transport, and Plate 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 Stryde, Plate, and Bone Transport. 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 it within your organization.

The content within 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 SYSTEM

Date: 20 Feb 2021

Commercial Name: Precice Stryde, Precice Plate, Precice Bone Transport

Type of Action: Advisory Notice and Voluntary Product Removal

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 20 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