URGENT FIELD SAFETY NOTICE – Precice Bone Transport System

Date: March 2023

Commercial Name: Precice Bone Transport System

Type of Action: Advisory Notice

NuVasive Specialized Orthopedics, Inc. (NSO) voluntarily issues this field safety notice (FSN) to provide a follow-up communication on the Precice Bone Transport System.

The following two communications were issued in 2021. The outcome of these communications was the removal of the device and the suspension of the EU MDD CE certificate.

- In February 2021, NSO recalled the Precice Bone Transport System (February 2021 Precice FSN).
- In April 2021, NSO notified healthcare providers that the EU MDD CE certificate was suspended (April 2021 - NSO Statement).

Updated Status for Precice Bone Transport

- The EU MDD CE certificate was reinstated by NSO's notified body in January 2023.
- Biocompatibility / biological and device risk assessments have been assessed and have been determined to be acceptable in the intended patient population.
- The Instructions for Use (IFU) document has been updated. The updated IFU can be found at www.nuvasive.com/eIFU.
- The Precice Bone Transport System is being made available again for use in select regions, following the prior stated activities.

Summary of the IFU changes:

IFU Section	Updated IFU Language
Intended Use	The Precice Bone Transport System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, malunions, nonunions, or bone transport of long bones in adults.

<table>
<tr><th>IFU Section</th><th>Updated IFU Language</th></tr>
<tr><td>Contraindications</td><td>Max Patient Weight Bearing:
<table>
<tr><th>Limb</th><th>Nail Diameter (mm)</th><th>Max. Patient Weight Bearing</th></tr>
<tr><td rowspan="3">Tibia</td><td>10.0</td><td>25lbs/11kg</td></tr>
<tr><td>11.5</td><td>125lbs/57kg</td></tr>
<tr><td>13.0</td><td>125lbs/57kg</td></tr>
<tr><td rowspan="3">Femur</td><td>10.0</td><td>25lbs/11kg</td></tr>
<tr><td>11.5</td><td>125lbs/57kg</td></tr>
<tr><td>13.0</td><td>125lbs/57kg</td></tr>
</table></td></tr>
<tr><td>Warnings</td><td>Bone transportation also involves soft tissues; it is important to allow the soft tissue to heal prior to the transport procedure and previous/current incision sites should be monitored.
Patients of the Precice Bone Transport System should not be implanted with more than two devices at a time and the patient’s weight should be a minimum of 50 lbs. Failure to follow these criteria may result in the described potential adverse events and complications described above.</td></tr>
<tr><td>Potential Adverse Events</td><td>Added a new section www.nuvasive.com/eIFU</td></tr>
</table>

Reasons for IFU Updates:

- Further informs end users regarding the target patient population based on current evidence.
- Provides additional clarity on device use to mitigate the likelihood of complications.
- Further clarifies the potential adverse events that can occur when using the device.

Clinical Impact:

NuVasive continues to monitor all post-market surveillance reports of adverse events as required by the regulations and laws in markets which it operates. To date, potential adverse events related to the original recall of the device have not been observed.

Recommended User Action:

This FSN details updates to the IFU document that physicians should consult prior to and during patient care of those being treated with the Precice Bone Transport System. This should be consulted for currently implanted and future potential Precice Bone Transport System patients.

- 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.
- Please review, complete, sign and return the attached Consignee Confirmation Form in accordance with the directions on the form (accompanying this FSN).
- The device is intended to be implanted for up to one year. For patients currently implanted beyond one year, or in patients weighing less than 50 pounds and/or with more than two devices implanted, their healthcare team should assess their treatment progression and consider removal of the nail(s) 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.

Additionally, this is a reminder to reference the existing language within the IFU, including but not limited to:

- The Precice Bone Transport System remains 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 is recommended to be removed after implantation time of no more than one year. Additional implantation duration may result in the described adverse events and complications described in the Warnings section of the IFU.
- The Precice Bone Transport System is contraindicated in patients in which the Precice Bone Transport nail would cross joint spaces or open epiphyseal growth plates.
- The Precice Bone Transport System is contraindicated in patients unwilling or incapable of following postoperative care instructions.
- The Precice Bone Transport System cannot withstand the stresses of full weight bearing.
- The Precice Bone Transport System is contraindicated in patients with metal allergies and sensitivities.
- Metallic implants can loosen, fracture, corrode, migrate, resulting in pain related to osteolysis.
- 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.

Transmission of this Field Safety Notice:

This notice needs to be passed on to all those within your organization who interact with the Bone Transport System.

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 24, 2023
Date

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Commercial Name: Precice Bone Transport System

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 March, 2023, Precice Bone Transport System FSN

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

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