

Precice Fast Distractor Max

Product Description:

The NuVasive Specialized Orthopedics **Precice Fast Distractor Max** is an optional, sterile, single-use instrument used to adjust implanted Precice System Nails. The Fast Distractor Max is intended for intraoperative use, and is designed to adjust Precice System Nails through specified tissue gaps.

Intended Use:

The Precice Fast Distractor Max is intended to be used with the Precice Systems. The Precice Fast Distractor Max can be used to adjust the distraction rod of Precice System nails intraoperatively through tissue gaps to a desired length.

Warnings:

- The Fast Distractor Max has not been tested to be cleaned or sterilized for multiple uses. If the Fast Distractor Max is used more than once, the device may not be sterile and could cause a serious infection and may not function as intended.
- **Do not** re-sterilize the device.
- **Do not** use the Fast Distractor Max if the sterile seal has been damaged or is open. Damaged package or product should be returned to NuVasive Specialized Orthopedics.
- Take caution not to place metallic instrumentation in close proximity to the Fast Distractor Max.
- **Do not** place the Fast Distractor Max directly on the nail's housing tube. Using the Fast Distractor Max in direct contact with the implant may jam the nail's internal mechanism.
- The Fast Distractor max is not implantable. Do not insert the Fast Distractor Max under soft tissue to adjust the implant.
- **Do not** compress the Fast Distractor Max on the soft tissue. When in use, pressure applied to the outer sleeve of the Fast Distractor Max may impede the internal magnet's rotation.
- **Do not** adjust the Precice nail if the soft-tissue gap (gap between nail and Fast Distractor Max) is lower than the specified minimum gaps listed in Table 1 below. The Precice Fast Distractor Max is intended to adjust Precice nails within the range of maximum and minimum gaps shown in Table 1.

Table 1: Precice Fast Distractor Max Nail Soft-Tissue Gap Ranges

Nail Type	Nail Diameter	Limb	Minimum Allowable Soft-Tissue gap for Adjustment	Maximum Allowable Soft-Tissue gap for Adjustment
Precice	12.5	Femur	38mm	70mm
	10.7			62mm
	8.5			55mm
	12.5	Tibia	6.4mm	16mm
	10.7			
	8.5			
	8.5	Humerus (225-300mm)	38mm	55mm
		Humerus (165-210mm)	6.4mm	25mm

Nail Type	Nail Diameter	Limb	Minimum Allowable Soft-Tissue gap for Adjustment	Maximum Allowable Soft-Tissue gap for Adjustment
Precice Stryde	13.0	Femur	38mm	70mm
	11.5			62mm
	10.0			55mm
	13.0	Tibia	6.4mm	16mm
	11.5			
	10.0			
Precice Bone Transport	13.0	Femur	38mm	70mm
	11.5			62mm
	10.0			55mm
	13.0	Tibia	6.4mm	16mm
	11.5			
	10.0			
Precice Ankle Salvage	13.0	Tibia	6.4mm	25mm
	11.5			
	10.0			

- **Do not** use the Fast Distractor Max to fully retract or distract the nail to/beyond its total stroke limit. Over-retracting or distracting the implant may jam the internal mechanism.
- Before using the Precice Fast Distractor Max, remove and discard all protective packaging materials.
- Please refer to the package label for the expiration date of the Fast Distractor Max. Packages or products outside of their expiration date should not be used and should be returned to NuVasive Specialized Orthopedics.
- The Fast Distractor Max may heat up after extended use. If the device heats up, stop using the device and allow the device to cool prior to using the device again.

Fast Distractor Max Procedure:

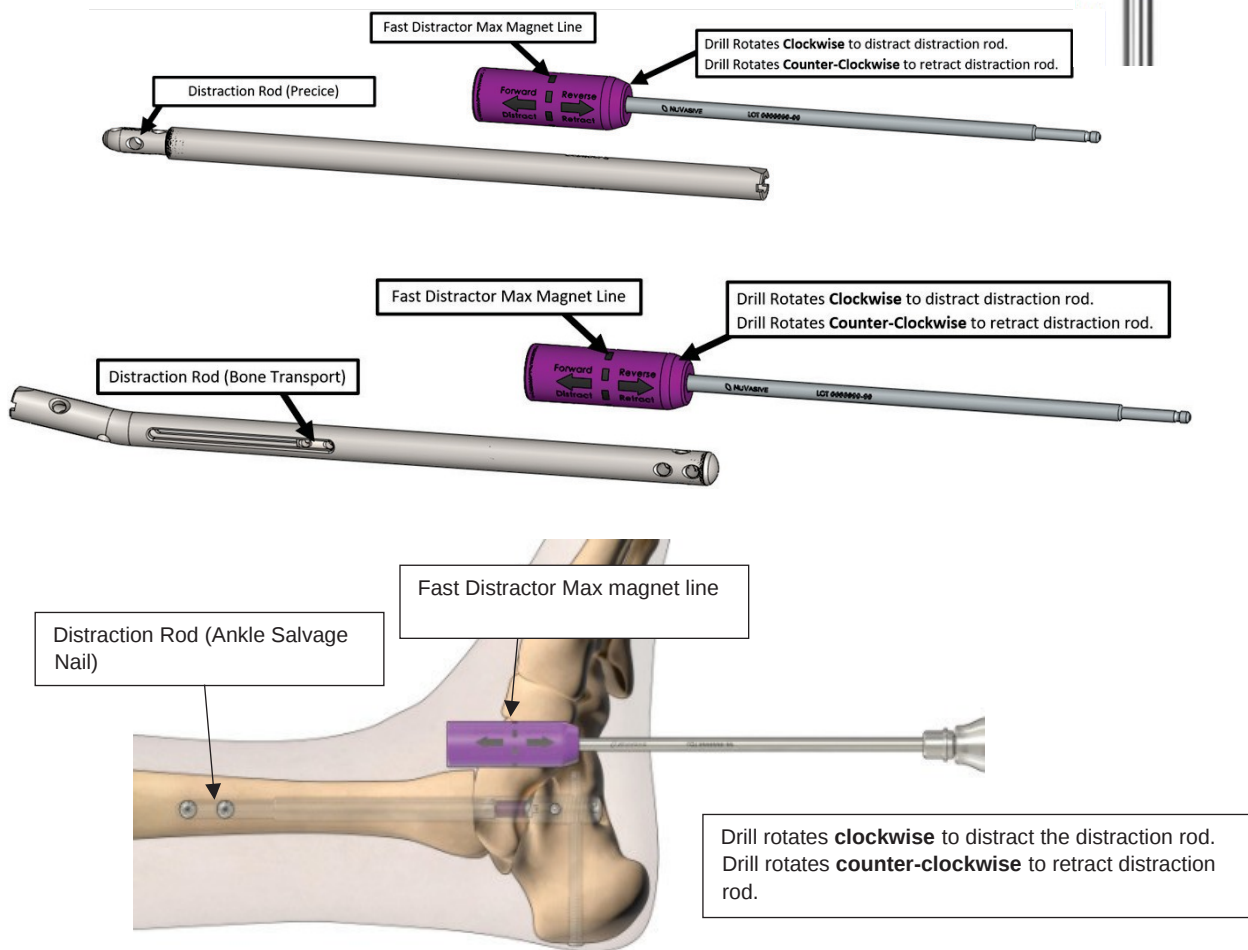
For optimal results, careful pre-operative diagnosis and planning, meticulous intraoperative planning and extended postoperative care by experienced orthopedic surgeons are essential. Prior to use, the surgeon should be specifically trained in the use of the NuVasive Specialized Orthopedics, Precice® System, to ultimately facilitate correct selection and implantation of the Precice nail.

General Procedure for Precice Fast Distractor Max for use with Precice System Nails:

1. Use imaging to identify the center of the magnet within the nail's housing body. Mark the skin at this site with a surgical marker.

2. Attach the Fast Distractor Max to an OR drill and align the dashed black center line of the Fast Distractor Max magnet over the skin-marked location. Confirm that the “Forward” arrow is pointing towards the distraction rod end of the nail and that the barrel of the Fast Distractor Max is positioned parallel to the nail’s housing body.

Warning: Do not use the Fast Distractor Max to fully retract or distract the nail to/beyond its total stroke limit. Over-retracting or distracting the implant may jam the internal mechanism.



3. Hold the Precice Fast Distractor Max over the nail magnet location, rotate **clockwise** with an O.R. drill rated up to 1500 rpm, with the distraction rod pointing away from the drill. This will cause the nail to distract (lengthen). Rotate the O.R. drill **counter-clockwise** to retract (shorten) the Precice nail.

Note: The Fast Distractor Max is intended to adjust the distraction rod without screw fixation of the Precice System Nail. In cases where Precice Ankle Salvage nails are inserted and affixed to the bone with screw fixation, the Fast Distractor Max can be used to achieve bone alignment and apposition by reducing gaps in between bone segments.

4. Observe the Precice nail until the desired distraction rod position is achieved. The distraction rate depends on the drill speed. Refer to the table below for drill speed and distraction rate examples:

Drill Speed	Distraction Rate
1500 rpm	7mm / min
650 rpm	3mm / min

Implantation Procedure:

Warning: The Fast Distractor Max is not implantable. Do not insert the Fast Distractor Max under soft tissue. Refer to the Precice System Technique Guide for the nail implantation procedure.

Disposal:

Please return used Precice Fast Distractor Max to NuVasive Specialized Orthopedics following instructions provided. Please call 1-866-GLOBUS1 (OR)1-866-456-2871 to obtain instructions or if you have any questions.

Precice Fast Distractor Max:



Table 2: Model Number and Description

Sterile, Single-Use Fast Distractor Max	Model Number	Description
	PFD2-000	Precice Fast Distractor Max

Symbols Definition:

Symbol	Definition
	Unsafe in Magnetic Resonance Imaging (MRI) Environments
	The PRECICE Fast Distractor is for Single-Use Only, Do not re-use
	Do not use if package is damaged or sterile barrier is broken
	Do not attempt to re-sterilize the Fast Distractor Max
 Rx Only/	Federal (US) law restricts the sale of this device for use by or on the order of a physician.
	Manufactured By
	Manufactured Date
	Model Number
	Lot Number
 www.globusmedical.com/eifu	See Instructions For Use www.globusmedical.com/eifu
	Expiration Date
	Sterilized using irradiation
	Authorized European Representative
	This product has met European Union health, safety, and environmental requirements, which ensure consumer and workplace safety.


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Prescription only

This product, and the use thereof, may be covered by one or more of the following U.S. and/or international patents: US 7,981,025, US 8,057,472, US 8,197,490, US 8,343,192, US 8,382,756, US 8,419,734, US 8,449,543, US 8,734,488, US 8,808,163, CN 101917918, EP 2,114,258. Other US and international patents pending. This product is licensed to the customer for single use only. Any re-sterilization or subsequent re-use is an unlicensed use and therefore constitutes patent infringement.