

NuVasive Specialized Orthopedics

PRECICE SYSTEM: Fast Distractor

INSTRUCTIONS FOR USE

Product Description:

The NuVasive Specialized Orthopedics **PRECICE System: Fast Distractor** is an optional, sterile, single-use distractor that may be used during the PRECICE surgical procedure to pre-distract the PRECICE nail, prior to implantation.

Intended Use:

The PRECICE Fast Distractor is intended to be used with the PRECICE System. The PRECICE System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones.

The PRECICE Fast Distractor can be used to pre-distract the PRECICE nail to a desired length, prior to implantation. The PRECICE Fast Distractor serves as an optional tool, providing surgeons the ability to adjust the length of the PRECICE nail prior to implantation. After pre-distracting the PRECICE nail, the PRECICE Fast Distractor may also be used to retract the PRECICE nail, prior to implantation.

Precautions:

- The PRECICE Fast Distractors are supplied sterile and are for single-use only. The Fast Distractor has not been tested to be cleaned or sterilized for multiple uses. If the Fast Distractor 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 if the sterile pouch has been damaged or is open.
- Do not pre-distract the PRECICE nail to its maximum potential distraction length (stroke). The maximum pre-distraction length must be 5 mm less than the maximum PRECICE nail stroke length.
- Before using the PRECICE Fast Distractor, remove and discard all protective packaging materials.
- Please refer to the manufacturer's Instructions for Use for the O.R. drill with regard to the recommended duty cycle.

Table 1: Model Numbers and Description

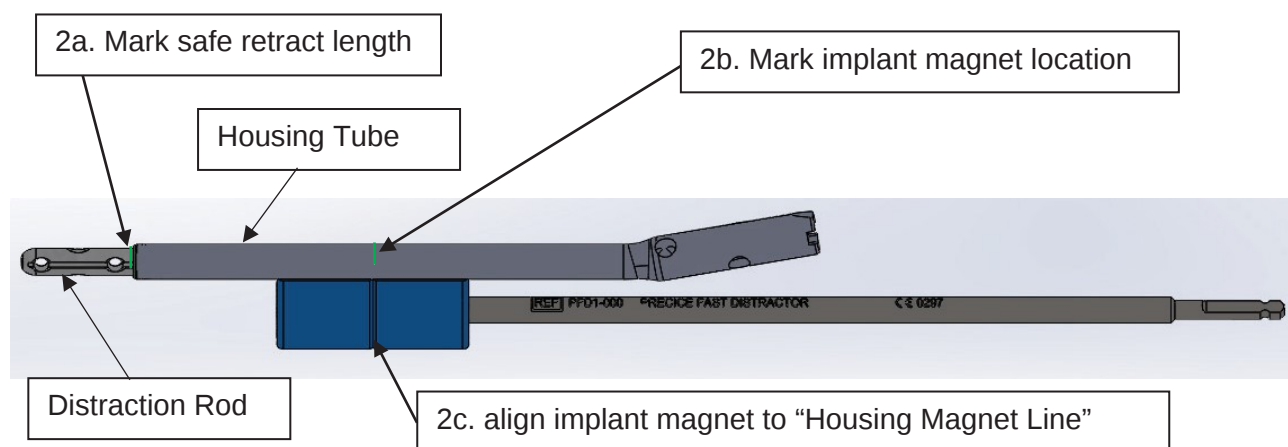
Sterile, Single-Use, Fast Distractor	Model Number	Description
	PFD1-000	PRECICE Fast Distractor

Fast Distractor 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.

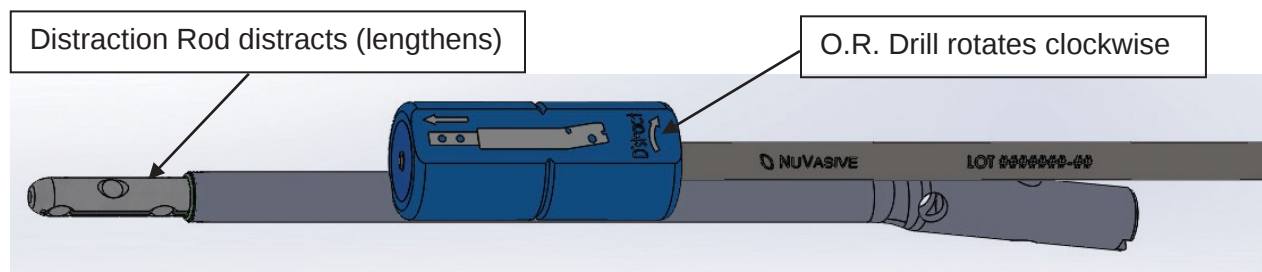
General Procedure for PRECICE Fast Distractor for use with PRECICE System Nails:

1. Ensure that the PRECICE Fast Distractor is in its original package.
2. It is recommended to mark the PRECICE nail with a sterile marker prior to pre-distracting the nail:
 - a. Place a mark on the distraction rod of the PRECICE nail near the housing tube (see 2a in the figure below) prior to pre-distracting the nail. This is used to mark the original position of the distraction rod and to aid in visualizing the distraction direction and safe retraction length.
Caution: Do not retract past this line to avoid potential implant jamming!
 - b. Identify the location of the magnet in the PRECICE nail by sliding the Fast Distractor along the shaft of the nail. There will be an attraction between the magnets within each device then mark its location (see 2b in the figure below).



3. Place the identified magnet location of the PRECICE nail onto the PRECICE Fast Distractor "Housing Magnet Line" (see 2c in the above figure) with the distraction rod pointing away from the O.R. drill with AO attachment, while maintaining standard sterile technique. Caution: the PRECICE Fast Distractor will magnetically attract and self-align to the magnet in the PRECICE nail.

4. Hold the PRECICE nail onto the Fast Distractor Housing, 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 drill counter clockwise to retract (shorten) the PRECICE nail. Do not retract the PRECICE nail more than the amount it was distracted (lengthened).



5. Frequently measure the PRECICE nail until the desired length is achieved. The distraction rate depends on the O.R. drill speed. Refer to the table below for drill speed and distraction rate examples:

Drill Speed	Approximate Distraction Rate
1500 rpm	7 mm / minute
750 rpm	3.5 mm / minute

Implantation Procedure

Refer to the PRECICE System's Instructions for Use for the implantation procedure with regard to the PRECICE nail.

PRECICE Fast Distractor



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 PRECICE Fast Distractor
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	Refer to 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.



NuVasive Netherlands B.V.

Jachthavenweg 109A
1081 KM Amsterdam
The Netherlands
Phone: +31 20 72 33 000

0297



NuVasive Specialized Orthopedics

Valley Forge Business Center
2560 General Armistead Avenue
Audubon, PA 19403
USA
Customer Service:
Phone 1-866-GLOBUS1 (OR)
1-866-456-2871
Fax 1-866-GLOBUS3 (OR)
1-866-456-2873

Australian Sponsor

Life Healthcare Pty Ltd.
Level 8, 15 Talavera Road
North Ryde NSW 2113
Australia



NuVasive Switzerland GmbH

c/o Domenghini & Partners AG

Falkengasse 3

6004 Luzern, Switzerland



UK Responsible Person:

NuVasive UK Limited

Suite B, Ground Floor, Caspian House

The Waterfront, Elstree Herts

United Kingdom

 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.