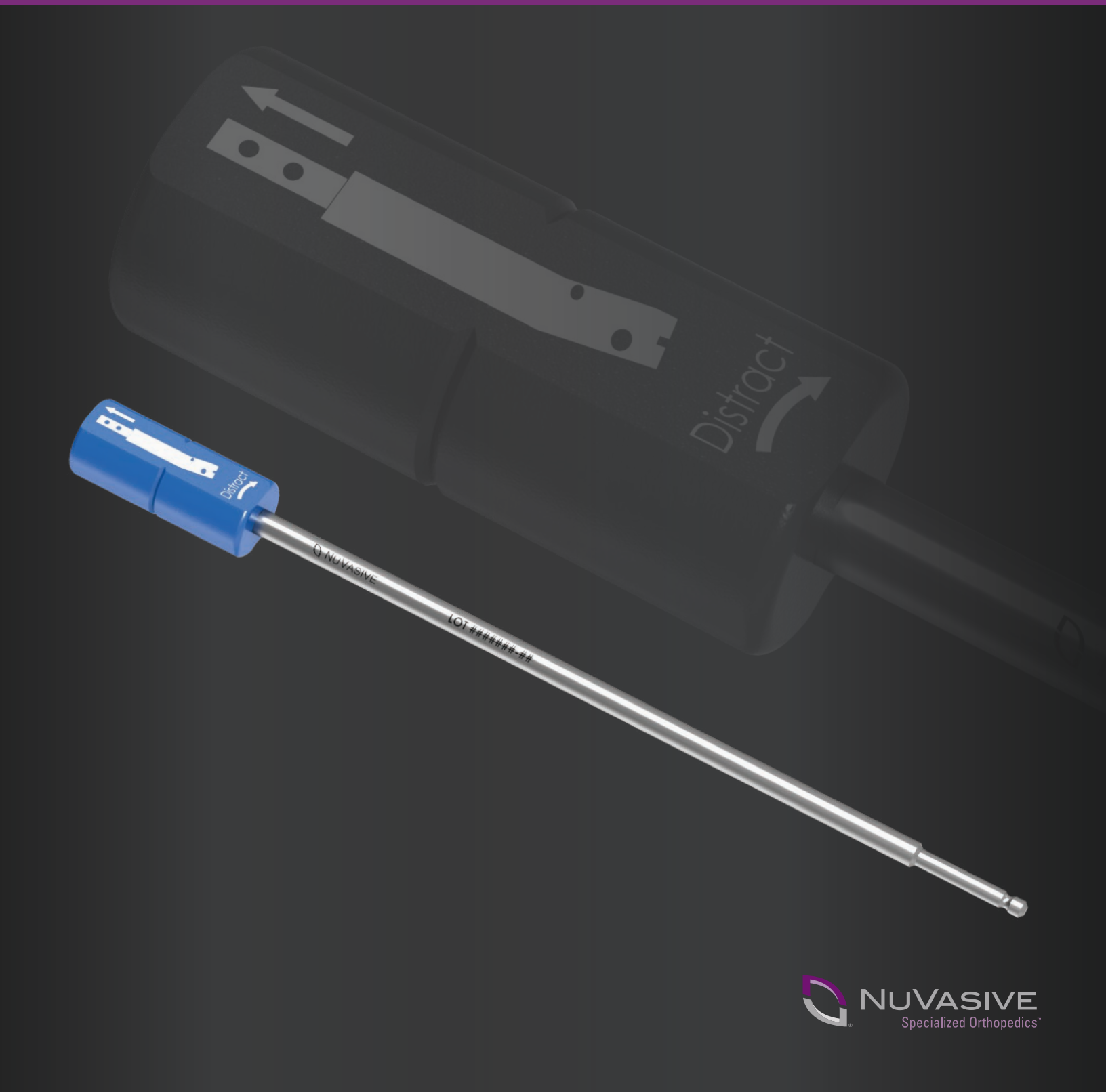
PRECICE®

ADJUSTABLE SOLUTIONS
FOR ORTHOPEDICS

PRECICE® Fast Distractor



NuVasive
Specialized Orthopedics™

PRECICE®

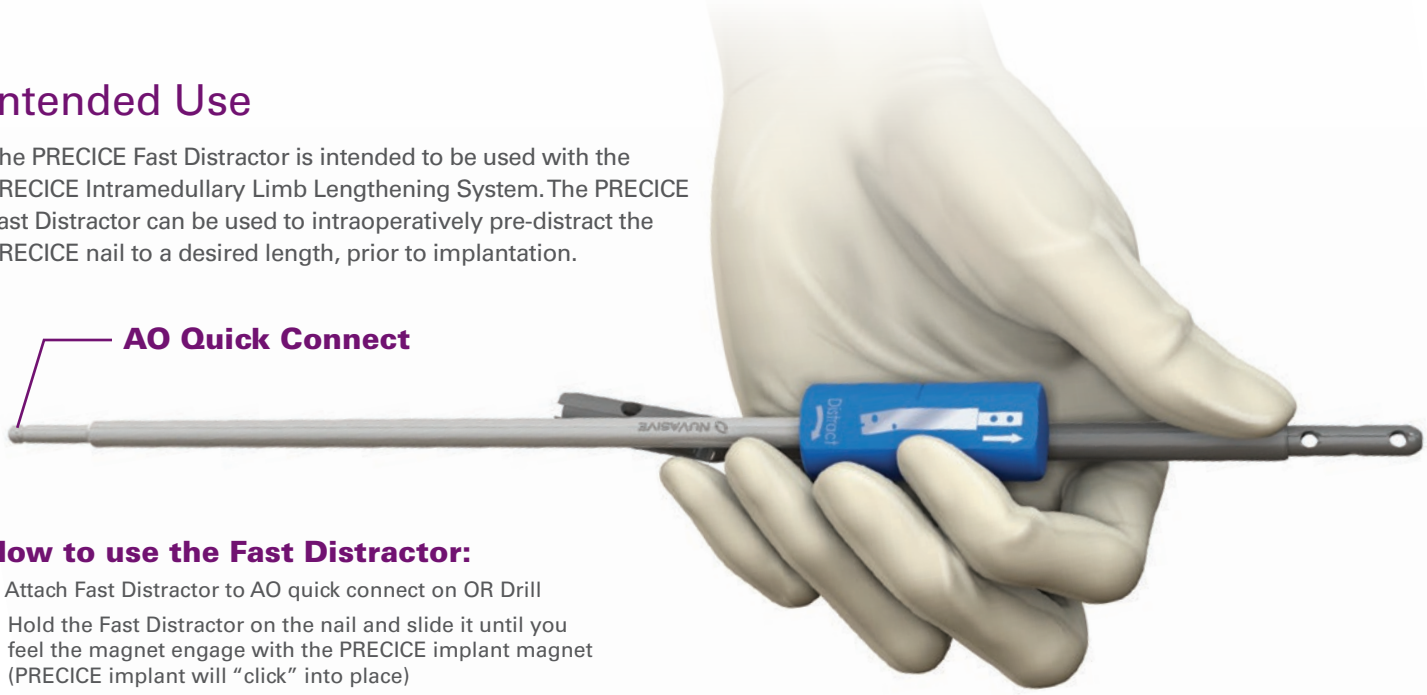
ADJUSTABLE SOLUTIONS FOR ORTHOPEDICS

The NuVasive Specialized Orthopedics,™ Inc. 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 Intramedullary Limb Lengthening System. The PRECICE Fast Distractor can be used to intraoperatively pre-distract the PRECICE nail to a desired length, prior to implantation.



How to use the Fast Distractor:

1. Attach Fast Distractor to AO quick connect on OR Drill
2. Hold the Fast Distractor on the nail and slide it until you feel the magnet engage with the PRECICE implant magnet (PRECICE implant will "click" into place)
3. Ensure drill is in the forward position (Clockwise - Do not retract)
4. Cradle the fast distractor and nail in your hand
5. Start slowly and allow the drill to rotate freely (do not block it by holding too tightly)
6. Use a ruler to confirm the proper distraction amount has been achieved

Model Number Description

Sterile, Single-Use, Fast Distractor PFD1-000 PRECICE Fast Distractor

Drill Speed Approximate Distraction Rate

- 1,500 rpm, 7mm/minute
- 750 rpm, 3.5mm/minute

Precautions:

- The PRECICE Fast Distractor is supplied sterile and is 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 5mm 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.

NUVASIVE Specialized Orthopedics™

For more information about this product, please contact your local sales representative.

101 Enterprise, Suite 100 | Aliso Viejo, CA 92656 Phone: 949-837-3600 | Fax: 949-837-3664

CE 0297

The PRECICE® System is composed of an implantable intramedullary nail, locking screws, reusable instruments, and a hand-held External Remote Controller (ERC). The PRECICE nail is a sterile single use device that is surgically implanted using the instruments and locking screws. The ERC is used daily after implantation to non-invasively lengthen or shorten the implant to a prescribed length. The PRECICE System is intended for limb lengthening, open and closed fracture fixation, pseudoarthrosis, mal-unions, non-unions, or bone transport of long bones. Contraindications include infection or pathologic conditions of bone such as osteopenia which would impair the ability to securely fix the device, metal allergies and sensitivities, patients whose distance from the surface of the treated limb to the intramedullary canal is greater than 51 mm for the 10.7 and 12.5 mm diameter implants or greater than 38 mm for the 8.5 mm diameter implant, patients with an irregular bone diameter that would prevent insertion of the PRECICE nail, patients in which the PRECICE nail would cross joint spaces or open epiphyseal growth plates, patients in which there is an obliterated medullary canal or other conditions that tend to retard healing such as blood supply limitations, peripheral vascular disease or evidence of inadequate vascularity, patients unwilling or incapable of following postoperative care instructions, patients weighing in excess of 114 kg for the 10.7 and 12.5 mm diameter implants (models A-G, H, J, K, U, V, and X) or weighing in excess of 57 kg for the 8.5 and 10.7 mm diameter implants models (A-G, H, J, K, U, N, M ,P, Q, V, and X). The implantable device is only to be used by a trained licensed physician. Please refer to the PRECICE IMLL System instructions for use for complete Important Safety Information. **Caution: Federal law restricts this device to sale by or on the order of a physician.**

18-NUVA-0319