Impact

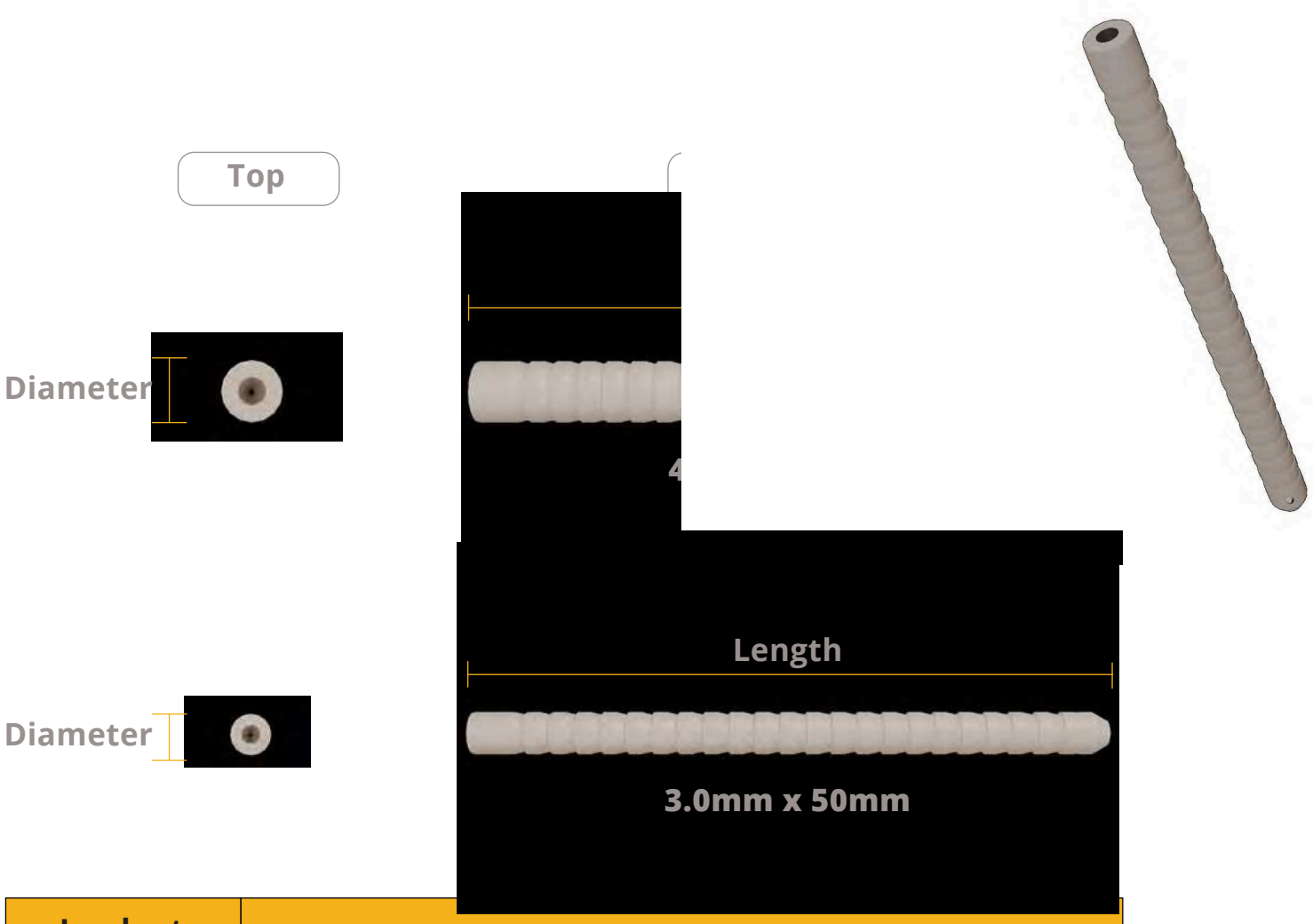
NVISION
BIOMEDICAL TECHNOLOGIES™

Product Sizes Available

Ø3.0: 50mm
Ø4.0: 50mm

The Impact Fusion Grade PEEK Nail System is an advanced non-metal fixation solution designed to optimize the alignment and stabilization of bone fractures, osteotomies, and arthrodesis. The Impact nail implants are crafted from a compound of PEEK and hydroxyapatite to promote osteoconduction. The nails are cannulated for precise k-wire guidance, and incorporate a tantalum bead at the distal tip to serve as a depth marker on imaging to ensure surgical accuracy.

The system is versatile, offering a range of diameters and lengths to suit various clinical applications. Each nail is trimmable; a measured nail cutter is included to trim pre-implantation, or a nail may be trimmed in situ post-implantation as needed.



Implant	
PP-30-50	Cannulated PEEK Pin, 3.0mm Diameter x 50mm Long
PP-40-50	Cannulated PEEK Pin, 4.0mm Diameter x 50mm Long

3.0mm Diameter Inserter

4.0mm Diameter Inserter

K-Wire Depth Gauge

K-Wire 1.4mm x 150mm Diameter Single Trocar

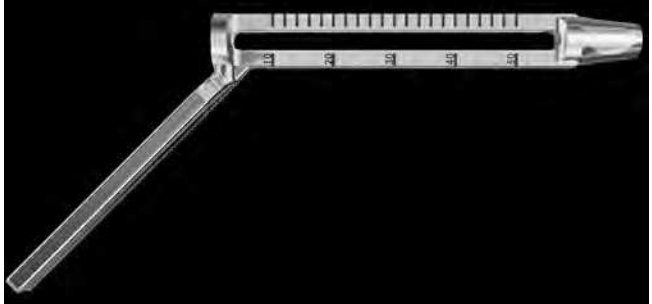
2.0mm Extraction Drill

Removal Slap Hammer

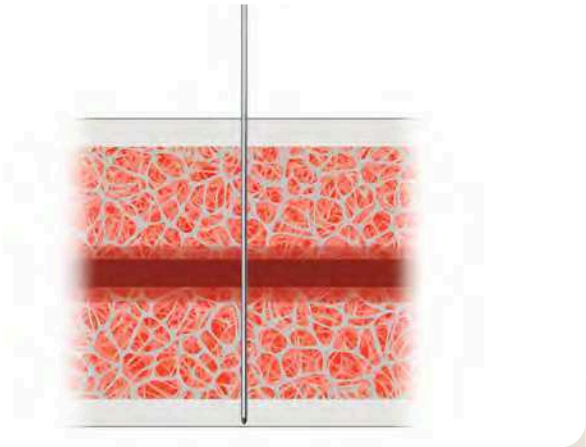
3.0mm Nail Cutter

3.0mm Drill Depth Gauge

4.0mm Drill Depth Gauge



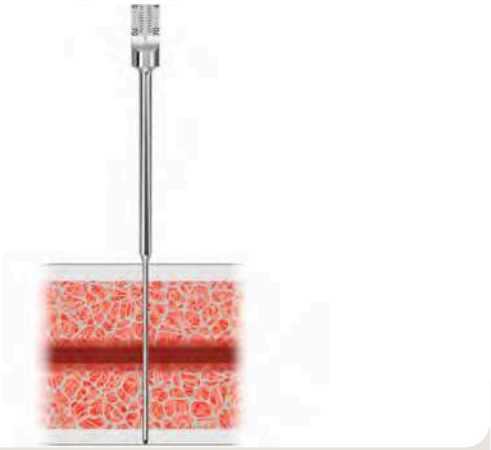
Surgical Technique



1

Insert K-Wire

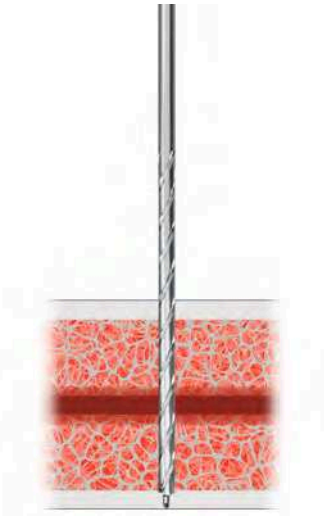
Insert the k-wire across fracture/osteotomy site until the distal trocar tip penetrates the far cortex or until desired depth is achieved. Verify correct placement using fluoroscopy.



2

Measure

Slide the depth gauge over the k-wire down to the bone and measure for appropriate nail length.



3

Drill

Slide appropriate cannulated drill over the k-wire based on the nail diameter to be used. Drill to the desired depth or through the far cortex to facilitate bi-cortical fixation. Drill guide can be used to verify measurement depth.

4A

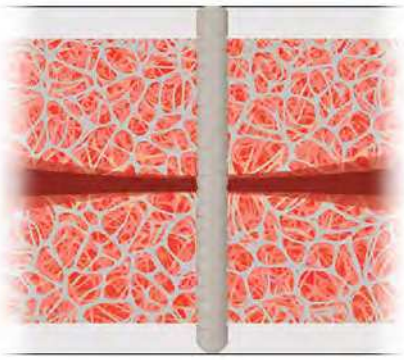
Customizing Nail Length Pre-Insertion

Nails can be cut to a desired length utilizing the tabletop cut guide as needed. Select the required diameter nail and insert the distal tip with the marker bead into the cut guide to the desired length on the guide. Trim the nail through the cut guide using a sagittal saw. The nail retained in the cut guide is now cut to the desired length and ready to be implanted.

4B

Customizing Nail Length Post-Insertion

Nails may also be trimmed to the appropriate length after insertion. After inserting the nail into the desired position, any length of nail extending beyond the surface of the bone may be trimmed flush with the bone utilizing a standard sagittal saw.



5

Nail Insertion

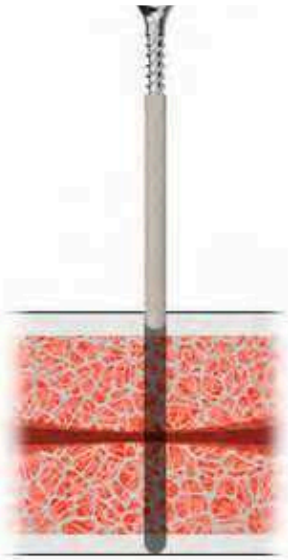
Insert the indicated nail over the k-wire with the corresponding inserter. Impact the nail into the bone until the desired depth is achieved. Confirm placement of nail with fluoroscopy. Remove inserter and kwire.

Removal

1

Extraction Drill

Insert appropriate extraction drill (2.0mm for 3.0-4.0mm implants) into the cannulation of the nail. The drill should engage the entire length of the implant.



2

Slap Hammer

Once the drill is fully inserted, disconnect the drill from the handle or power and attach the slap hammer using the AO connect. Engage the slap hammer to gradually persuade the implant out of the bone.

INDICATIONS FOR USE

The Impact PEEK Union Nail System is indicated for maintenance of alignment and fixation of bone fractures, osteotomies, arthrodeses or bone grafts in the presence of appropriate additional immobilization (e.g. rigid fixation implants, cast, brace).

DEVICE DESCRIPTION

The Impact PEEK Union Nail System represents a cutting-edge fixation device crafted from advanced HA Enhanced PEEK. The system is versatile, offering a range of lengths and diameters to suit various clinical needs, and features a cannulated design for precise k-wire guidance. Additionally, it integrates tantalum pins to ensure optimal imaging visibility, enhancing surgical accuracy and outcomes.

Contraindications:

Prior to using the Impact PEEK Union Nail System, ensure that none of the following patient conditions are present: active or latent infection, sepsis, osteoporosis, insufficient quantity or quality of bone and/or soft tissue, material sensitivity (if sensitivity is suspected, tests are performed prior to implantation), or patients who are unwilling or incapable of following post-operative care instructions. These devices are not intended for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.

Warnings and Precautions:

- Re-operation to remove or replace implants may be required at any time due to medical reasons or device failure. If tive action is not taken, complica
- Use of an undersized implant in areas of high functional stresses may lead to implant fracture and failure.
- Plates and screws, wires, or other appliances of dissimilar metals should not be used together in or near the implant site.
- The implants are intended for single use only. Explanted implants shall not be reused.
- Instruments and K-wires are to be treated as sharps.
- Do not use other manufacturers' instruments or implants in conjunction with the Impact PEEK Union Nail System.

MR (Magnetic Resonance) Safety Information:

The Impact PEEK Union Nail System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the Impact PEEK Union Nail System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Potential Adverse Events:

Possible adverse effects associated with implants are infection, pain, stiffness, discomfort, or abnormal sensations and nerve or soft tissue damage due to the use of an implant or due to surgical trauma. The implant may break due to excessive activity, prolonged loading, incomplete healing, or excessive force on the implant during insertion. Metal sensitivity or histological or allergic or adverse foreign body reaction resulting from implantation of a foreign material may occur. Nerve or soft tissue damage, necrosis of the tissue or inadequate healing may result from the presence of an implant or due to surgical trauma.

Disclaimers

This publication details recommended procedures for using Nvision Biomedical Technologies' devices and instruments. It offers guidance but, as with any such technical guide, each surgeon must consider the particular needs of each patient and make appropriate adjustments when and as required. A workshop training is recommended prior to the first surgery. Please remember that the compatibility of different product systems has not been tested unless specified otherwise in the product labeling. For additional information please refer to the instructions for use (IFU) delivered with each implant. The surgeon must discuss all relevant risks, including the finite lifetime. All possible complications listed are not typical of Nvision Biomed-

Additional Information

CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician. This brochure describes the surgical technique used by Nvision Biomedical Technologies development surgeons. As the manufacturer of this device, Nvision Biomedical Technologies does not practice medicine and does not recommend this product or any specific surgical technique for use on any individual patient. The surgeon who performs any implant procedure is responsible for determining the appropriate product(s) and utilizing the appropriate technique(s) for said implantation in each individual patient.

For further information, please contact the Customer Service Department at:

Nvision Biomedical Technologies
4590 Lockhill Selma
San Antonio, TX 78249

Ordering Information

3.0mm Diameter Implant

Part Number	Description
PP-30-50	Cannulated PEEK Pin, 3.0mm Diameter x 50mm Long Assembly

4.0mm Diameter Implant

Part Number	Description
PP-40-50	Cannulated PEEK Pin, 4.0mm Diameter x 50mm Long Assembly

Instruments

Part Number	Description
PP-1001T-300	3.0mm Diameter Inserter
PP-1000T-300	3.0mm Diameter Drill
PP-1000T-DEP34	K-Wire Depth Gauge
KWIRE-14-150S	K-Wire 1.4mm x 150mm Diameter Single Trocar
PP-1000T-301	3.0 Drill Depth Gauge
PP-1001T-CUT3	Nail Cutter - 3.0mm Diameter
PP-1001T-400	4.0mm Diameter Inserter
PP-1000T-400	4.0mm Diameter Drill
PP-1000T-401	4.0 Drill Depth Gauge
PP-1001T-CUT4	Nail Cutter - 4.0mm Diameter
PP-1000T-200	2.0mm Extraction Drill
PP-1001T-SLAP	Removal Slap Hammer

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