javelin®

TAILOR'S BUNION FIXATION SYSTEM

Surgical Technique Guide

NVISION™ biomedical technologies

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TAILOR'S BUNION FIXATION SYSTEM

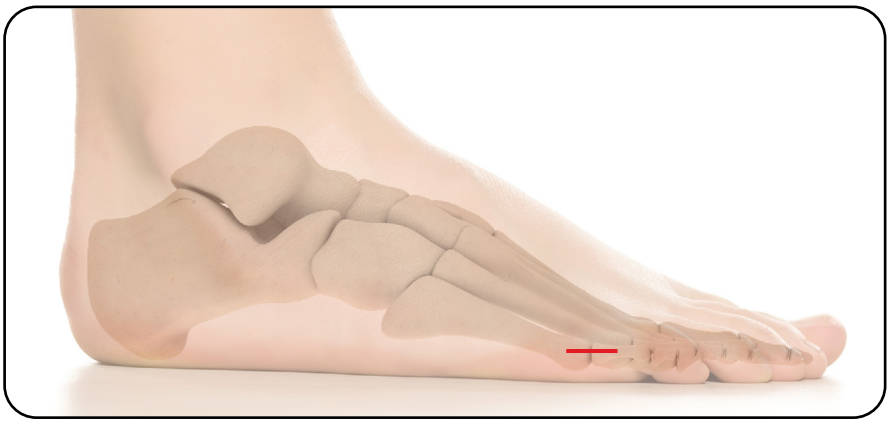
The Javelin® System provides a streamlined, comprehensive solution for Tailor's Bunion corrections. The system consists of an intramedullary titanium alloy plate and screws that provide stable fixation for 5th metatarsal bone fragments following a transverse osteotomy.

The plate's low-profile design enables the user to achieve maximum medial correction of the capital fragment. A targeting jig is provided in the system to allow for easy insertion of bi-cortical screws targeting the plate holes in the intramedullary canal.

Step 1 - Site Preparation

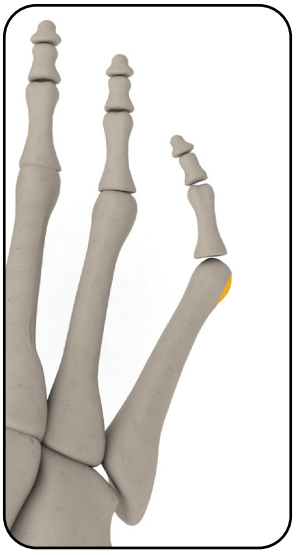
A. Incision

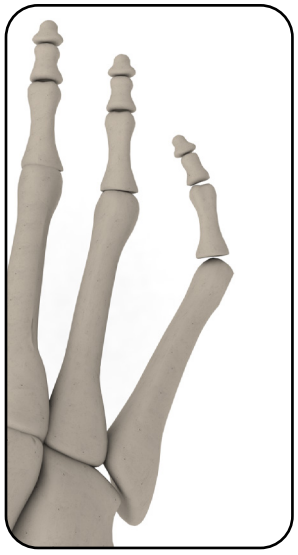
Using intraoperative fluoroscopy, make a 10mm-12mm longitudinal incision along the lateral aspect of the 5th metatarsal. The incision should grant access to the distal metaphyseal-diaphyseal junction of the 5th metatarsal.



B. Condylectomy

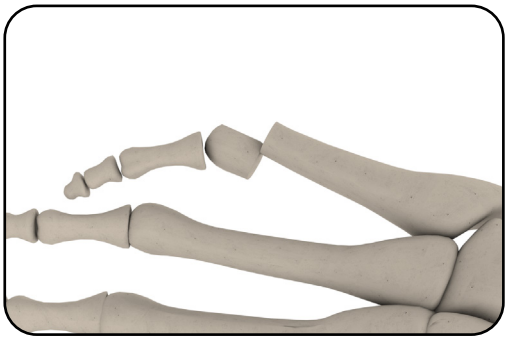
Perform a condylectomy of the lateral protuberance of the 5th metatarsal while keeping the plane of resection in alignment with the long axis of the body of the 5th metatarsal.

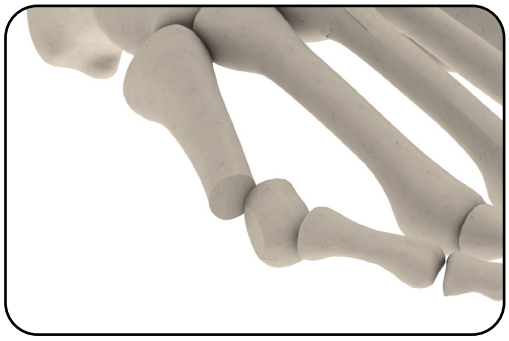




C. Osteotomy

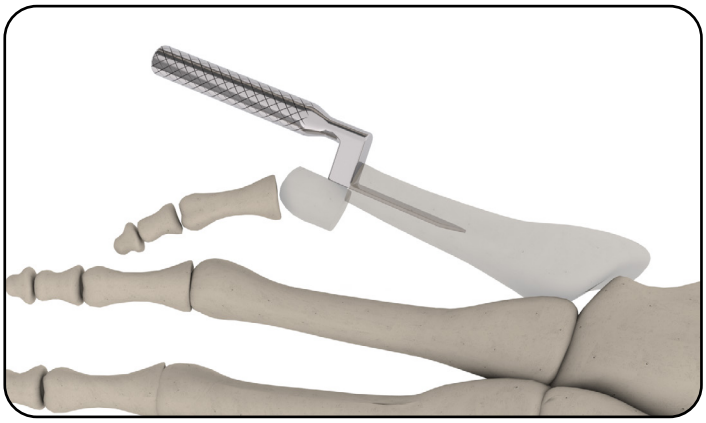
Perform a transverse 5th metatarsal osteotomy perpendicular to the long axis of the bone at the distal metaphyseal-diaphyseal junction. Then, shift the capital fragment medially to correct the Tailor's Bunion deformity.





Step 2 - Broaching

Insert broach retrograde in the intramedullary canal of the 5th metatarsal proximal fragment. Use the laser marks on the broach to determine implant length. Remove the broach axially along the path of entry.



Note: To maximize IM correction, insert broach in the intramedullary canal along the medial inner cortical wall of the fifth metatarsal. A broach extraction tool is provided in the set to be used if needed.

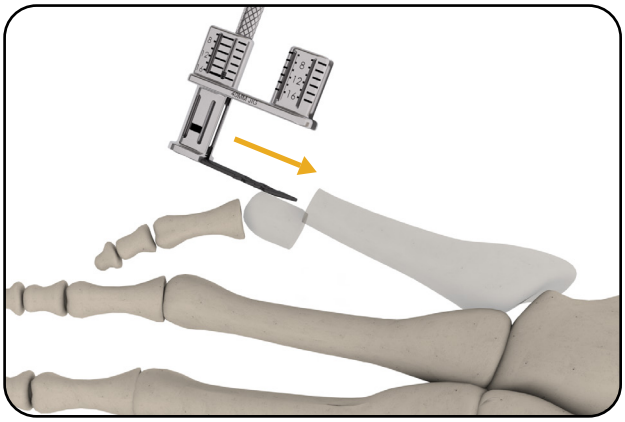
Step 3 - Implant Insertion

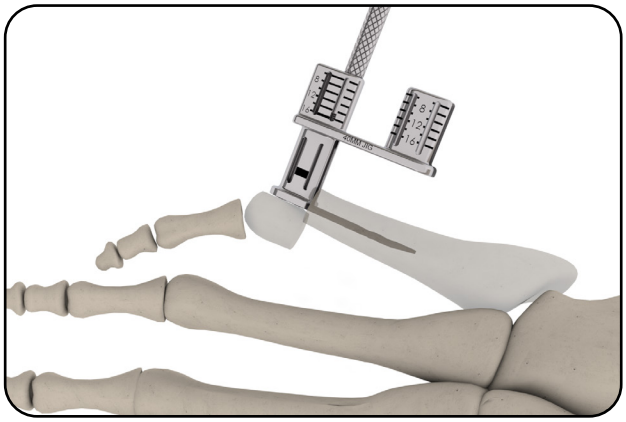
A. Plate/Jig Assembly

Assemble the plate/guide construct by placing the jig over the plate and inserting the threaded knob of the targeting guide into the 2nd most distal hole of the plate.

B. Plate Intramedullary Insertion

Insert the plate retrograde into the intramedullary canal until the targeting guide stops on the distal aspect of the proximal osteotomy fragment. If necessary, persuade the construct by impacting the flat distal surface of the targeting guide.

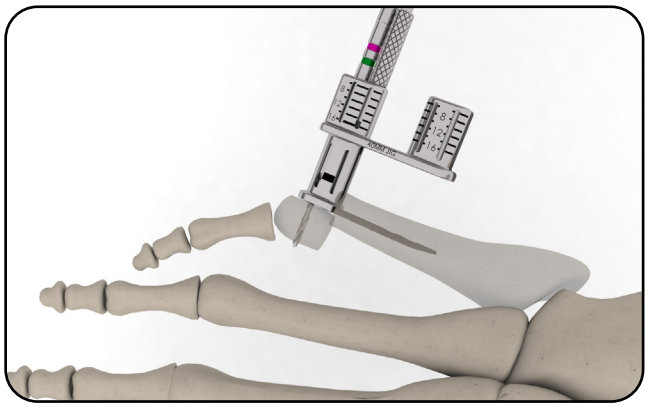


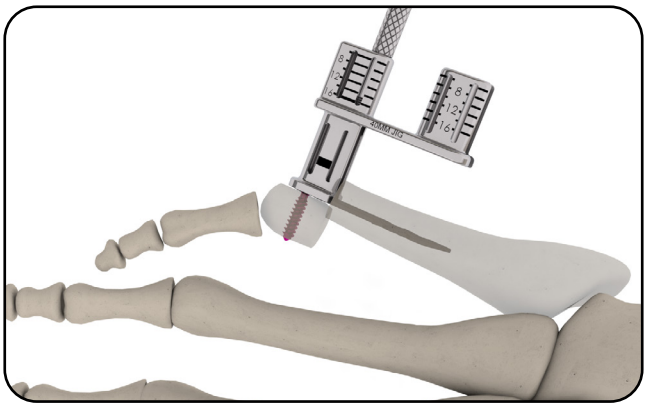


Step 4 - Drill / Screw

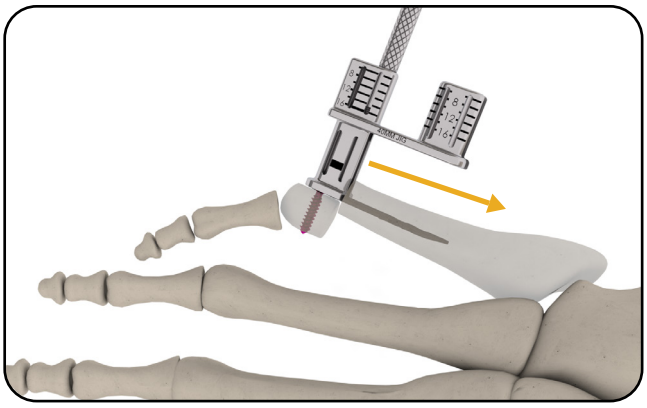
A. Most Distal Screw Insertion

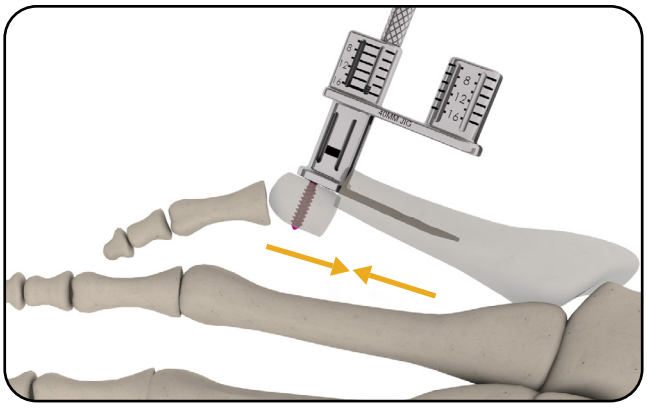
Drill the most distal screw hole and select screw length by using the drill depth indicator on the targeting guide. If necessary, use the system's depth gauge to measure screw length by placing it through the targeting guide. Use the screw inserter to insert the most distal plating screw.





Note: Compression can be generated between osteotomy fragments by impacting the proximal flat distal surface of the targeting guide before inserting the proximal screws.

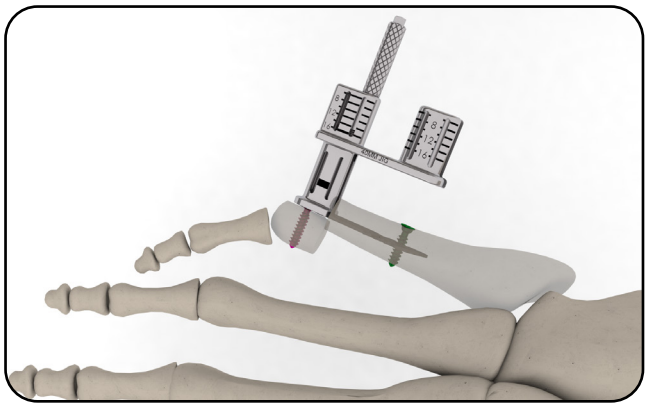


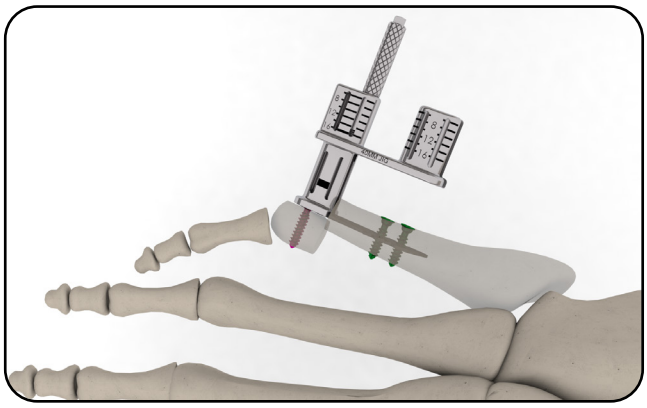


Note: Forceps or elevators can be used to press the capital fragment against the plate when drilling and inserting the most distal screw to provide stability. Additionally, a k-wire can be inserted through the cannulated plate inserter into the capital fragment to help prevent rotation.

B. Proximal Screw Insertion

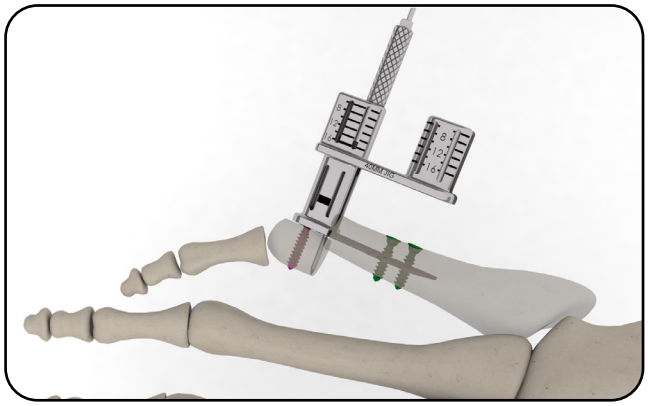
Use a blade to make a percutaneous incision to insert the proximal screws flush with the lateral aspect of the 5th metatarsal. Repeat **Step 4 A** for the most proximal screw hole and the second most proximal screw hole.

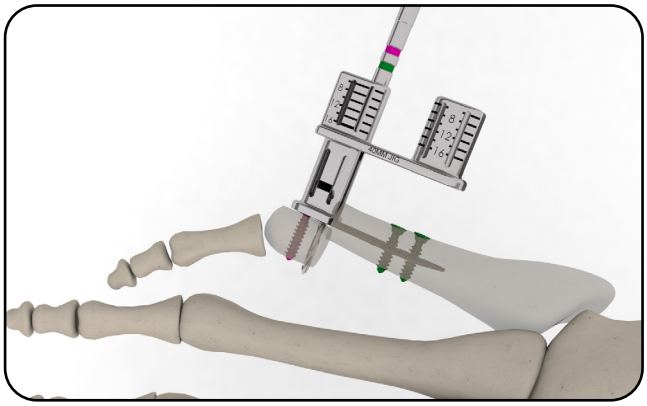




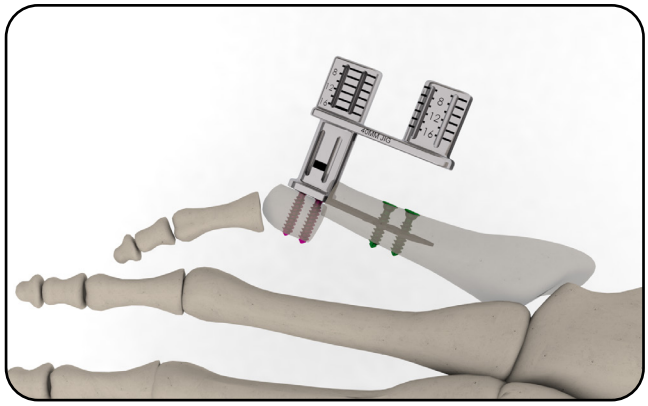
C. Second Most Distal Screw Insertion

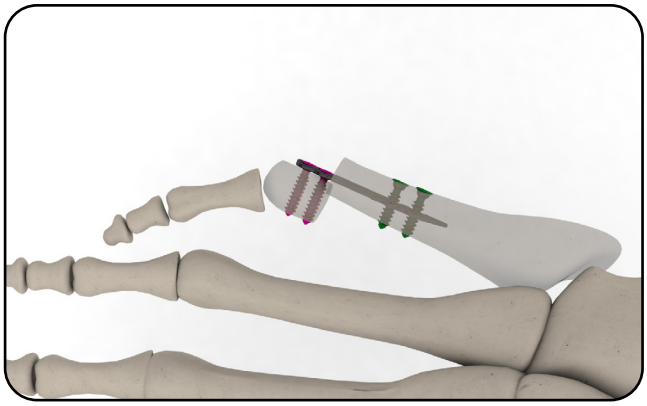
Use the k-wire to drill through the cannula of the knurled plate inserter to prepare the last screw hole, then remove the k-wire and jig and freehand the last screw.





Note: The knurled plate inserter can be removed to hold the jig in place and allow drilling for the second most distal hole.





Indications for Use
The Javelin® Tailor's Bunion Fixation System is indicated for stabilization and fixation of fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the foot (such as 5th metatarsal osteotomies for the correction of Tailor's Bunion). The system may be used in both adults and adolescent (13-21 years of age) patients.

Contraindications
Prior to using the Javelin Tailor's Bunion Fixation 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.

Warnings
- The patient must be cautioned, preferably in writing, about the use, limitations, and potential adverse effects of this device including the possibility of delayed union, non-union, device or treatment failure as a result of loose fixation and/or loosening, stress, excessive activity, or weight bearing or load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.
- The patient should be informed about the importance of following the prescribed post-operative rehabilitation protocol and to understand the possible limitations in activities of daily living. The patient must be warned that failure to follow postoperative care instructions may cause the implant or treatment to fail.
- For safe effective use of the implant, the surgeon must be thoroughly familiar with the surgical technique for the device, implant, and associated instruments. Potential failures of the Tailor's Bunion Fixation System may include delayed union, non-union, loosening of fixation, stress fractures of the bones, or incomplete healing as a result of excessive activity, overloading or noncompliance to post-operative rehabilitation.
- The device is not designed to withstand the stress of weight bearing, load bearing, or excessive physical activity. Device breakage may occur when the implant is subjected to excessive loading associated with delayed union or nonunion. Improper insertion of the device during implantation may also increase the possibility of loosening, or migration.
- The Javelin Tailor's Bunion Fixation 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 Javelin Tailor's Bunion Fixation System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
- DO NOT reuse any of Javelin Tailor's Bunion Fixation System implantable components. Reuse may compromise the structural integrity of the plate and screws and/or lead to failure, which may result in patient injury.

Precautions
- Protect the Javelin Tailor's Bunion Fixation System's implantable components against scratching or nicking. Such stress concentration can lead to implant failure.
- Before using the Javelin Tailor's Bunion Fixation System, inspect all implants and instruments for wear, disfiguration and physical damage. If evidence of wear, disfiguration or physical damage is found, DO NOT use and contact your local Nvision representative or the Nvision Customer Care Department.
- DO NOT permanently implant the Nvision K-Wires; they are only intended to be used for provisional fixation and guidance.
- Do not mix implant components from different manufacturers for metallurgical, biomechanical and functional reasons.
- DO NOT use screw lengths that will excessively protrude through the far cortex as it may result in soft tissue irritation.
- Implants and instruments are to be treated as sharps.
- The benefits from implant surgery may not meet the patient's expectations or may deteriorate over time, requiring revision surgery to replace the implant or to carry out alternative procedures. Note: To maintain traceability of the Javelin Tailor's Bunion Fixation System implantable components, record each of the respective components LOT numbers in the patient records post implantation.

Potential Adverse Events
Possible adverse effects associated with Javelin Tailor's Bunion Fixation System 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 Biomedical Technologies products but are in principle observed with any implant. Promptly inform Nvision Biomedical Technologies as soon as complications occur in connection with implants or surgical instruments used. In the event of premature failure of an implant in which a causal relationship with its geometry, surface quality, or mechanical stability is suspected, please provide Nvision Biomedical Technologies with explant(s) in a cleaned, disinfected, and sterile condition. Nvision cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of osseous implant bed in the case of implants, incorrect indication or surgical technique, or with any incorrect patient information and consequent incorrect patient behavior.

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

Notes

Notes

ORDERING INFORMATION

javelin®
TAILOR'S BUNION FIXATION SYSTEM

Plates

Part Number	Description
TB-30-4	30mm long plate
TB-40-4	40mm long plate

Locking Screws

Part Number	Description
TB-24-06L	2.40mm dia. 6mm long
TB-24-08L	2.40mm dia. 8mm long
TB-24-10L	2.40mm dia. 10mm long
TB-24-12L	2.40mm dia. 12mm long
TB-24-14L	2.40mm dia. 14mm long
TB-24-16L	2.40mm dia. 16mm long
TB-30-06L	3.00mm dia. 6mm long
TB-30-08L	3.00mm dia. 8mm long
TB-30-10L	3.00mm dia. 10mm long
TB-30-12L	3.00mm dia. 12mm long
TB-30-14L	3.00mm dia. 14mm long
TB-30-16L	3.00mm dia. 16mm long

Non-locking Screws

Part Number	Description
TB-24-06N	2.40mm dia. 6mm long
TB-24-08N	2.40mm dia. 8mm long
TB-24-10N	2.40mm dia. 10mm long
TB-24-12N	2.40mm dia. 12mm long
TB-24-14N	2.40mm dia. 14mm long
TB-24-16N	2.40mm dia. 16mm long
TB-30-06N	3.00mm dia. 6mm long
TB-30-08N	3.00mm dia. 8mm long
TB-30-10N	3.00mm dia. 10mm long
TB-30-12N	3.00mm dia. 12mm long
TB-30-14N	3.00mm dia. 14mm long
TB-30-16N	3.00mm dia. 16mm long

Instruments

Part Number	Description
TB-1000T-DR24	Drill for 2.4mm screw
TB-1000T-DR30	Drill for 3.0mm screw
TB-1000T-JG30	30mm Targeting Jig Drill Guide
TB-1000T-JG40	40mm Targeting Jig Drill Guide
TB-1000T-JGIN	Targeting Jig Plate Inserter
TB-1000T-BRCH	Broach
TB-1001T-DPG	Depth Gauge
TB-1000T-ISRT	Screw Inserter
TB-1000T-MLT	Slotted Mallet
TB-1000T-PLX	Plate Extractor
TB-1000T-BRX	Broach Extractor
CSRW-1000T-320	Kwire Trocar 1.0mm x 150mm
HAN-1000T-AOSM	AO Handle, Small

Nvision™ biomedical technologies

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