APEX 3D™
TOTAL ANKLE REPLACEMENT

TIBIAL PEG PUNCH

AUXILIARY SURGICAL TECHNIQUE GUIDE

Exclusively foot & ankle
Paragon 28®

PRODUCT INFORMATION

The Paragon 28® APEX 3D™ Total Ankle Replacement System is a cemented, fixed bearing device comprised of a tibial component, a talar component and a Vitamin E Ultra-High Molecular Weight Polyethylene component. Implants are available in varying sizes and design configurations intended for both primary and revision applications. For additional information regarding Indications for Use, Contraindications, Warnings, Precautions, etc. please visit: https://www.paragon28.com/ifus/

CONTENTS

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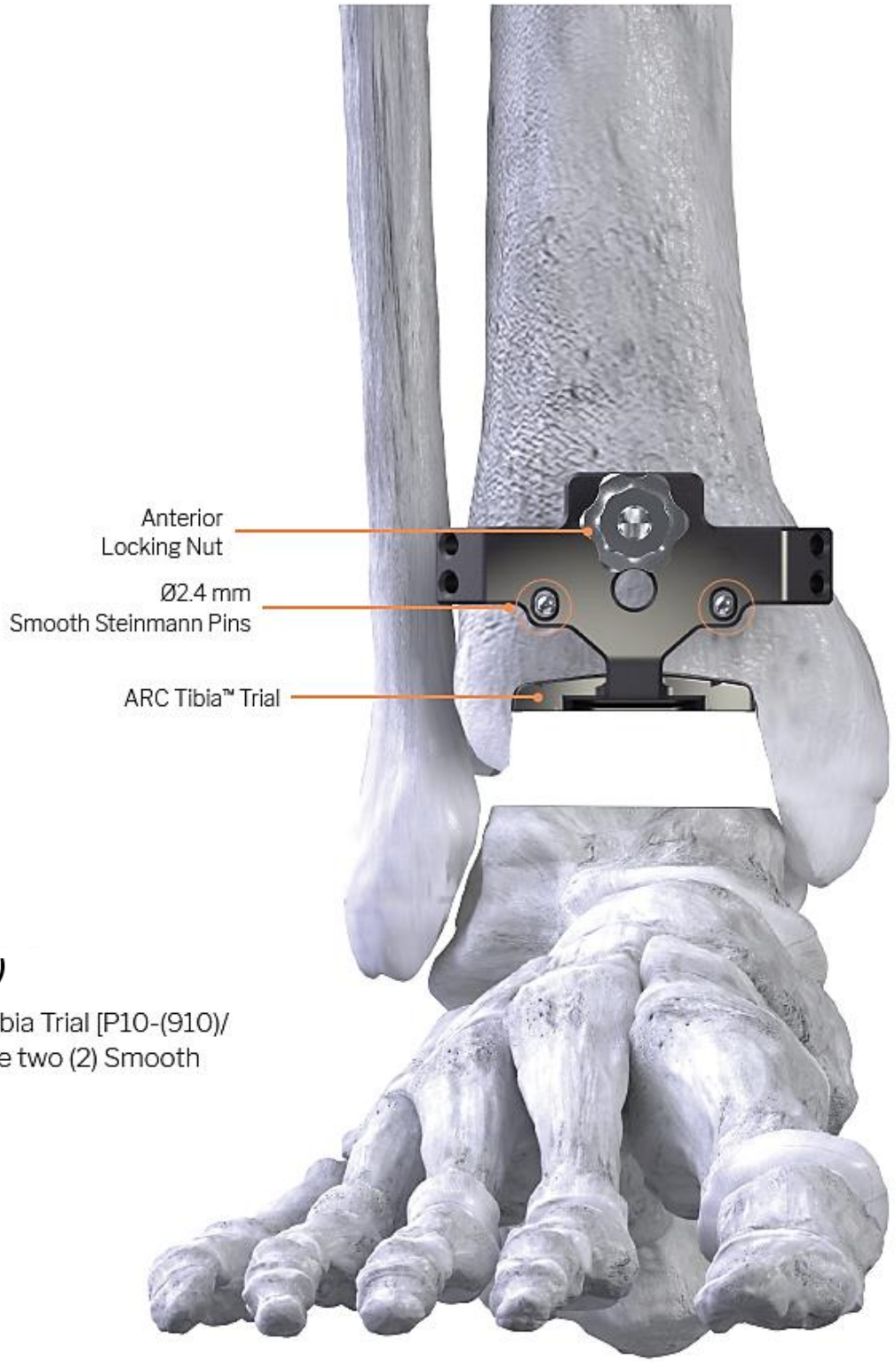
ACKNOWLEDGMENTS:
Contributing Surgeon Advisors, Paragon 28's Development Engineers, Clinical Researchers and Marketing Teams.

TIBIAL TRIALING



TIBIAL TRIAL POSITIONING

(Steps Applicable for Flat-Cut Option)

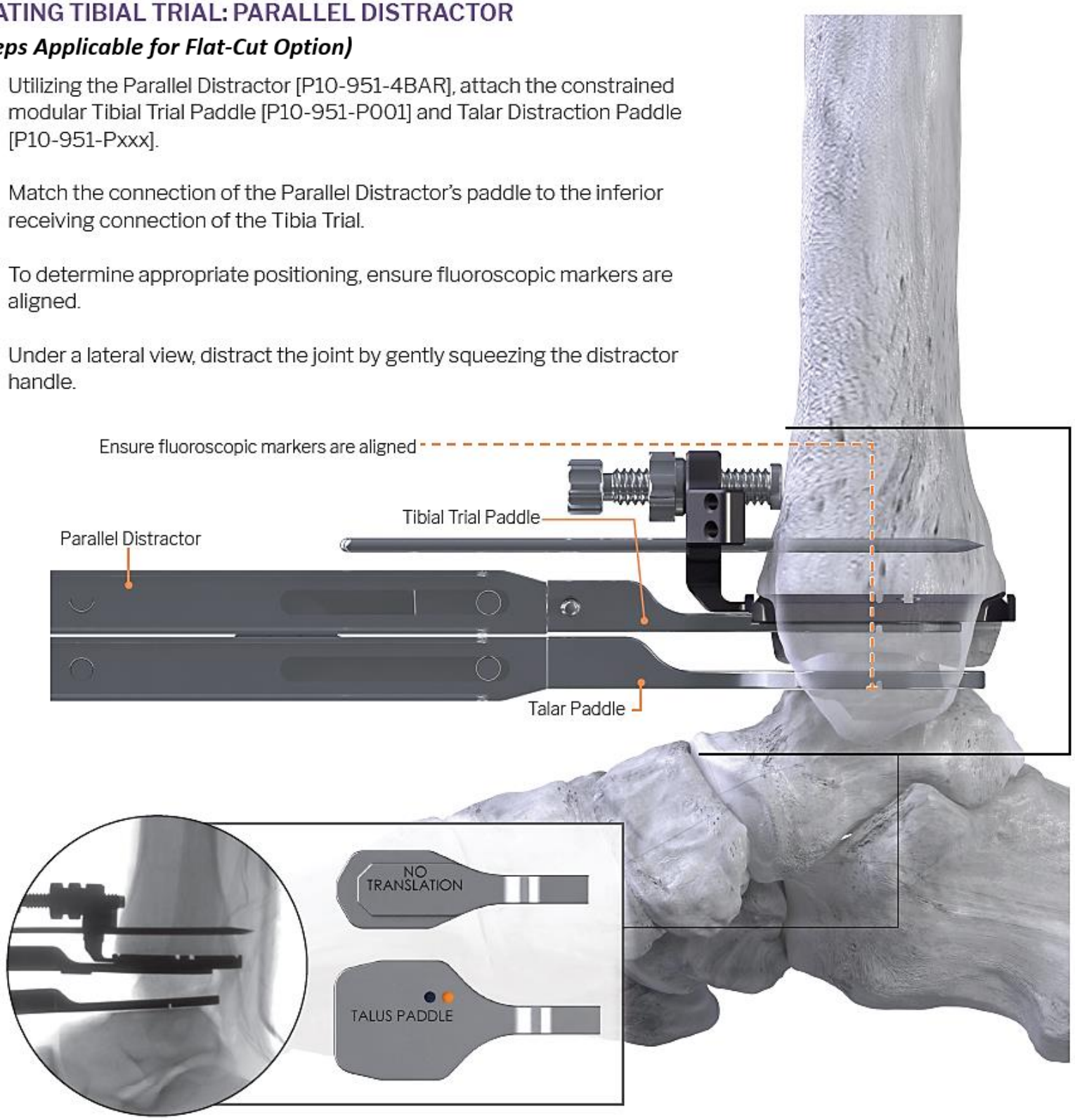
- Utilizing the size matched ARC Tibia Trial [P10-(910)/(911)-TBxx], by hand, slide over the two (2) Smooth Steinmann Pins already in place.

TIBIAL TRIALING

SEATING TIBIAL TRIAL: PARALLEL DISTRACTOR

(Steps Applicable for Flat-Cut Option)

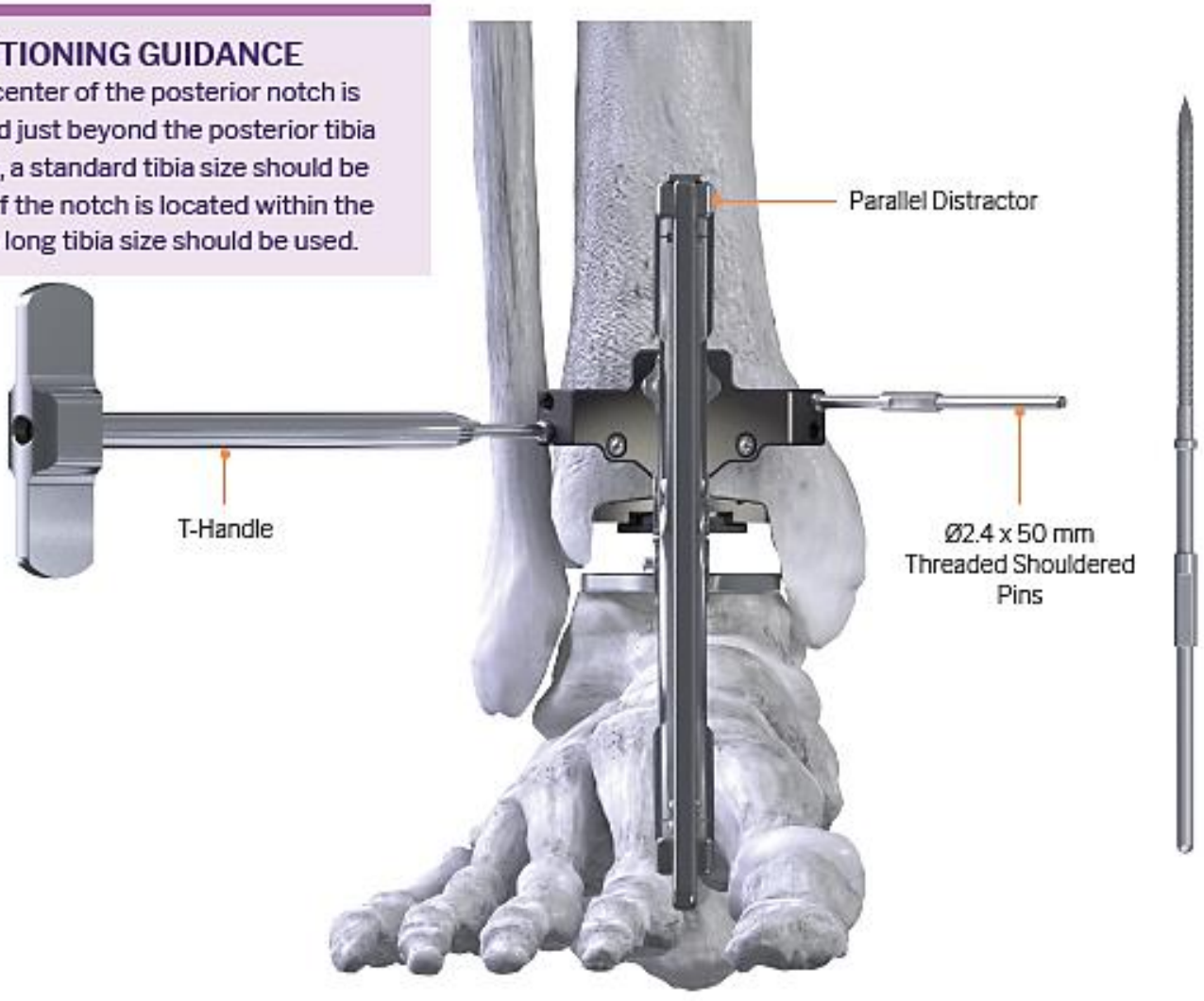
- Utilizing the Parallel Distractor [P10-951-4BAR], attach the constrained modular Tibial Trial Paddle [P10-951-P001] and Talar Distraction Paddle [P10-951-Pxxx].
- Match the connection of the Parallel Distractor's paddle to the inferior receiving connection of the Tibia Trial.
- To determine appropriate positioning, ensure fluoroscopic markers are aligned.
- Under a lateral view, distract the joint by gently squeezing the distractor handle.



TIBIAL TRIALING

POSITIONING GUIDANCE

If the center of the posterior notch is located just beyond the posterior tibia cortex, a standard tibia size should be used. If the notch is located within the tibia, a long tibia size should be used.



TIBIAL TRIAL – SIZING EVALUATION

- Under a lateral fluoroscopic view determine tibia implant length.
- With the Parallel Distractor loosely retracted in position, fine tune the anterior position of the tibial trial by adjusting the AP positioning bolt.
- Once appropriate positioning has been achieved, secure the Tibial Trial's position by advancing the anterior locking nut until flush against trial.

SURGICAL NOTE:

It is recommended to use a long tibial size if uncertain whether the posterior tibial cortex is located within the notch of the trial or not. Full anterior/posterior coverage with minimal overhang is preferred.

SECURE TIBIAL TRIAL

(Steps Applicable for Flat-Cut Option)

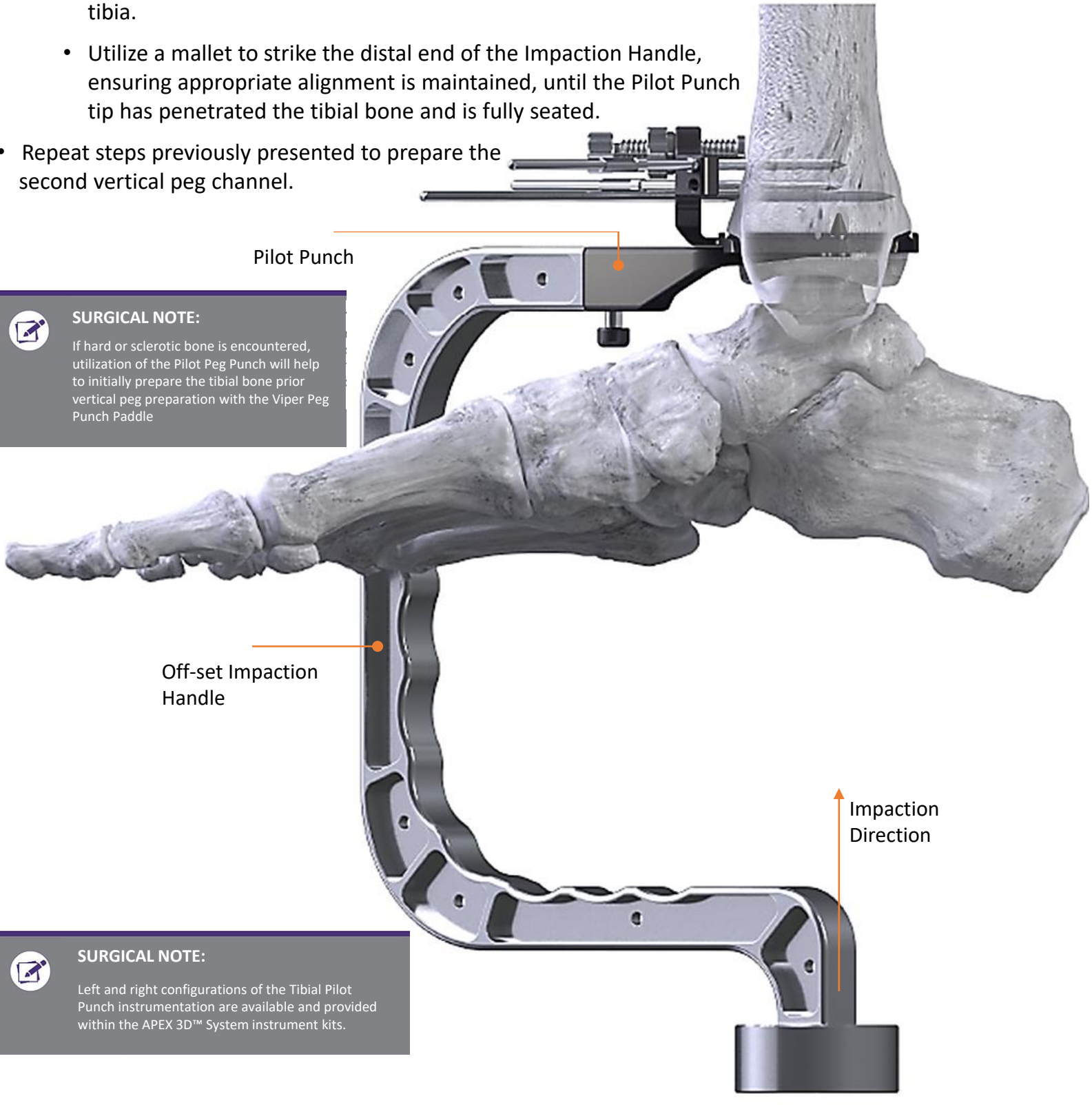
- By hand, place two (2) Ø2.4 mm x 50 mm Threaded Shouldered Pins into a set of the offset converging pin holes located on the medial and lateral aspect of the Tibial Trial.
- Ensure that either both laser marked pin holes are used together, or non-laser marked pin holes are used together.
- Connect to power and advance stopping before the shoulder engages the trial. (DO NOT FULLY SEAT UNDER POWER)
- By hand, secure the pin against trial using the provided T-Handle.
- Remove the Distractor, re-check Tibial Trial position under lateral fluoroscopy to confirm position and fit.

[OPTIONAL] TIBIAL VERTICAL PEG PREPARATION

TIBIAL VERTICAL PEG PREPARATION – PILOT PUNCH

(Steps Applicable for Flat-Cut Option)

- Connect the Tibial Pilot Peg Punch to the Off-set Impaction Handle.
- Insert the Pilot Punch by sliding the vertical tip posteriorly until it aligns with either the medial or lateral Tibial Trial peg holes.
- Under a lateral fluoroscopic view:
    - Confirm Pilot Punch arm is perpendicular to the long axis of the tibia.
    - Utilize a mallet to strike the distal end of the Impaction Handle, ensuring appropriate alignment is maintained, until the Pilot Punch tip has penetrated the tibial bone and is fully seated.
- Repeat steps previously presented to prepare the second vertical peg channel.



SURGICAL NOTE:

If hard or sclerotic bone is encountered, utilization of the Pilot Peg Punch will help to initially prepare the tibial bone prior vertical peg preparation with the Viper Peg Punch Paddle

SURGICAL NOTE:

Left and right configurations of the Tibial Pilot Punch instrumentation are available and provided within the APEX 3D™ System instrument kits.

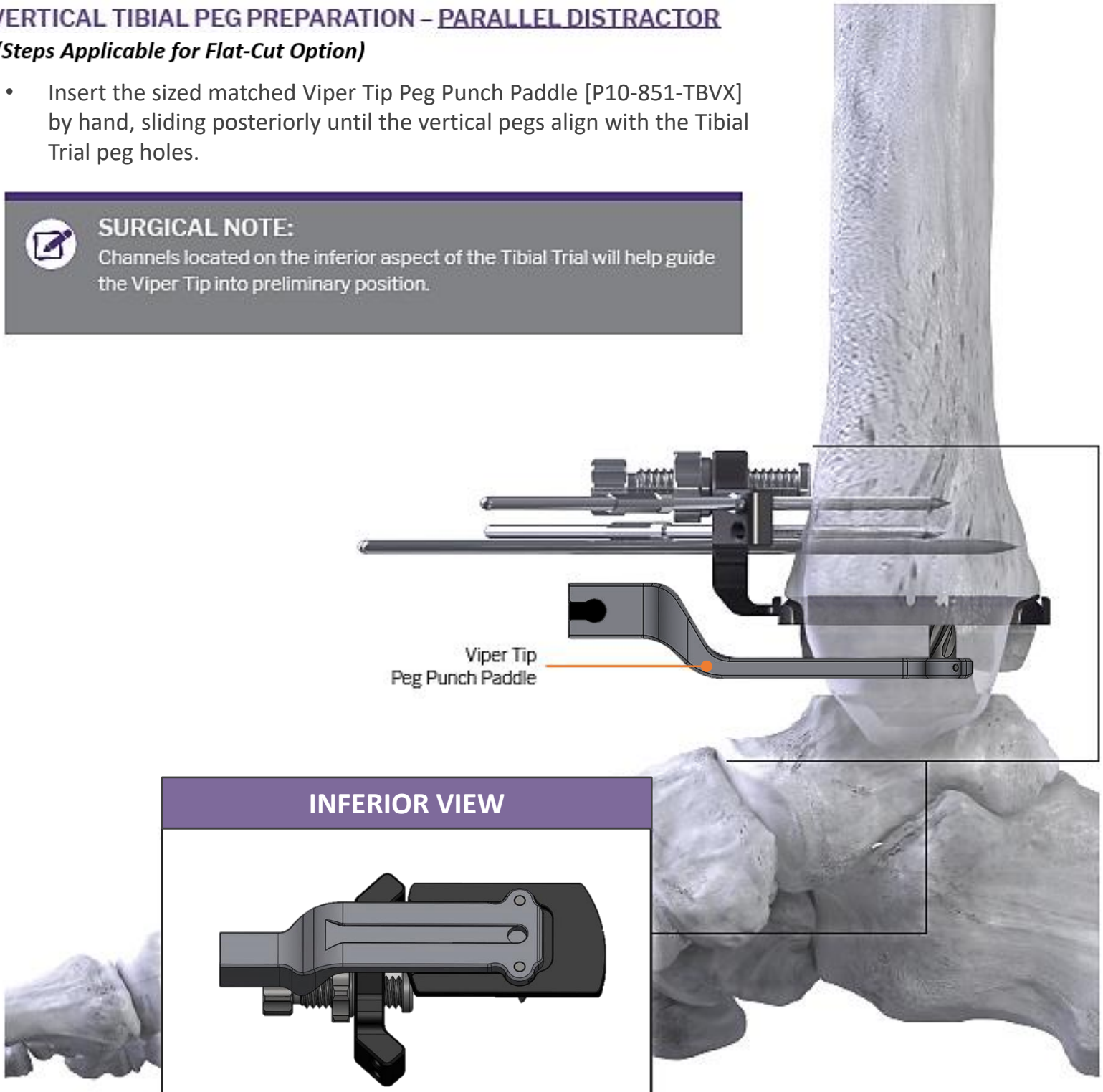
TIBIAL VERTICAL PEG PREPARATION

VERTICAL TIBIAL PEG PREPARATION – PARALLEL DISTRACTOR

(Steps Applicable for Flat-Cut Option)

- Insert the sized matched Viper Tip Peg Punch Paddle [P10-851-TBVX] by hand, sliding posteriorly until the vertical pegs align with the Tibial Trial peg holes.

SURGICAL NOTE:
Channels located on the inferior aspect of the Tibial Trial will help guide the Viper Tip into preliminary position.



INFERIOR VIEW

Viper Tip / Tibial Trial Connection

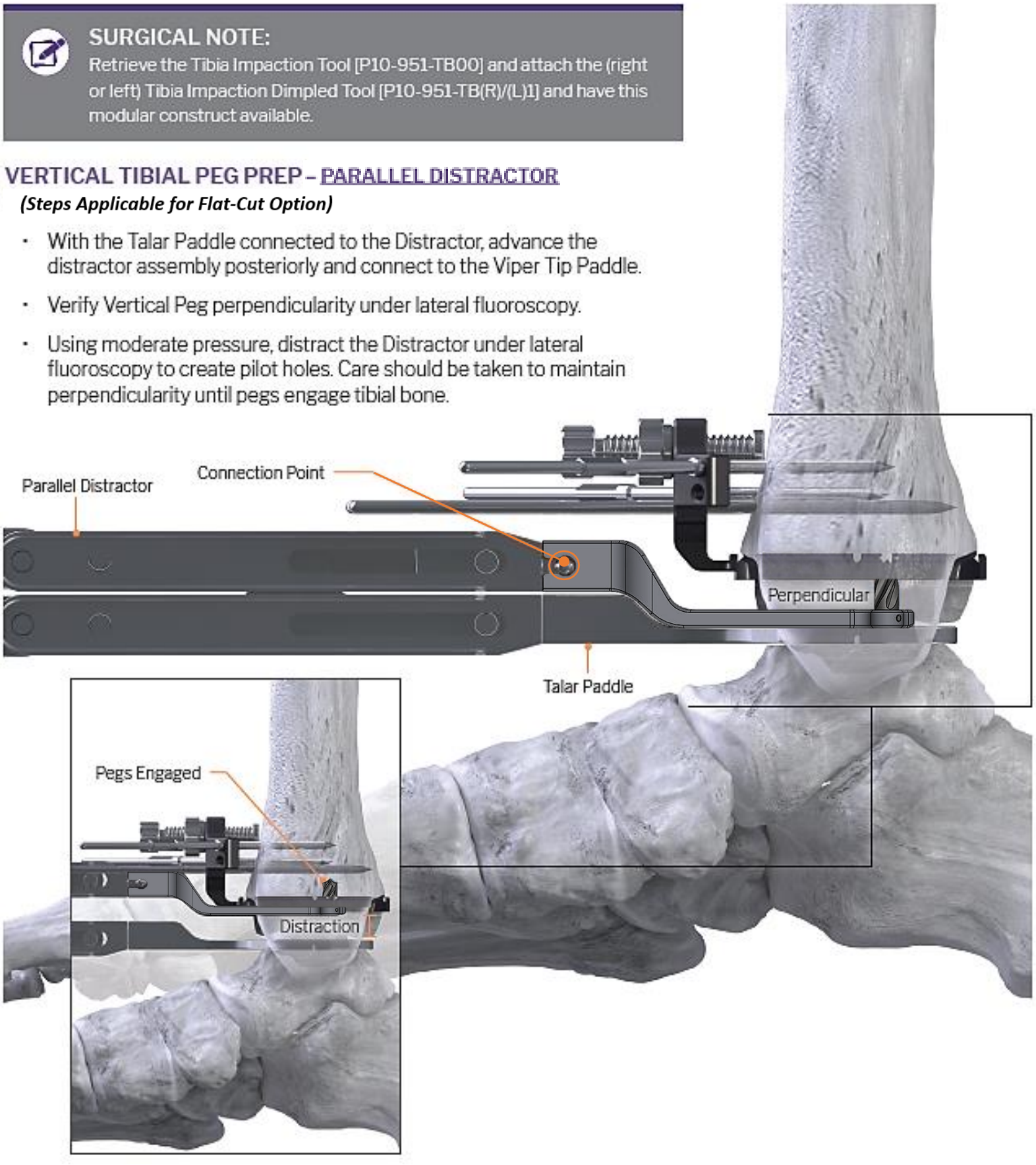
TIBIAL VERTICAL PEG PREPARATION

SURGICAL NOTE:
Retrieve the Tibia Impaction Tool [P10-951-TB00] and attach the (right or left) Tibia Impaction Dimpled Tool [P10-951-TB(R)/(L)1] and have this modular construct available.

VERTICAL TIBIAL PEG PREP – PARALLEL DISTRACTOR

(Steps Applicable for Flat-Cut Option)

- With the Talar Paddle connected to the Distractor, advance the distractor assembly posteriorly and connect to the Viper Tip Paddle.
- Verify Vertical Peg perpendicularity under lateral fluoroscopy.
- Using moderate pressure, distract the Distractor under lateral fluoroscopy to create pilot holes. Care should be taken to maintain perpendicularity until pegs engage tibial bone.

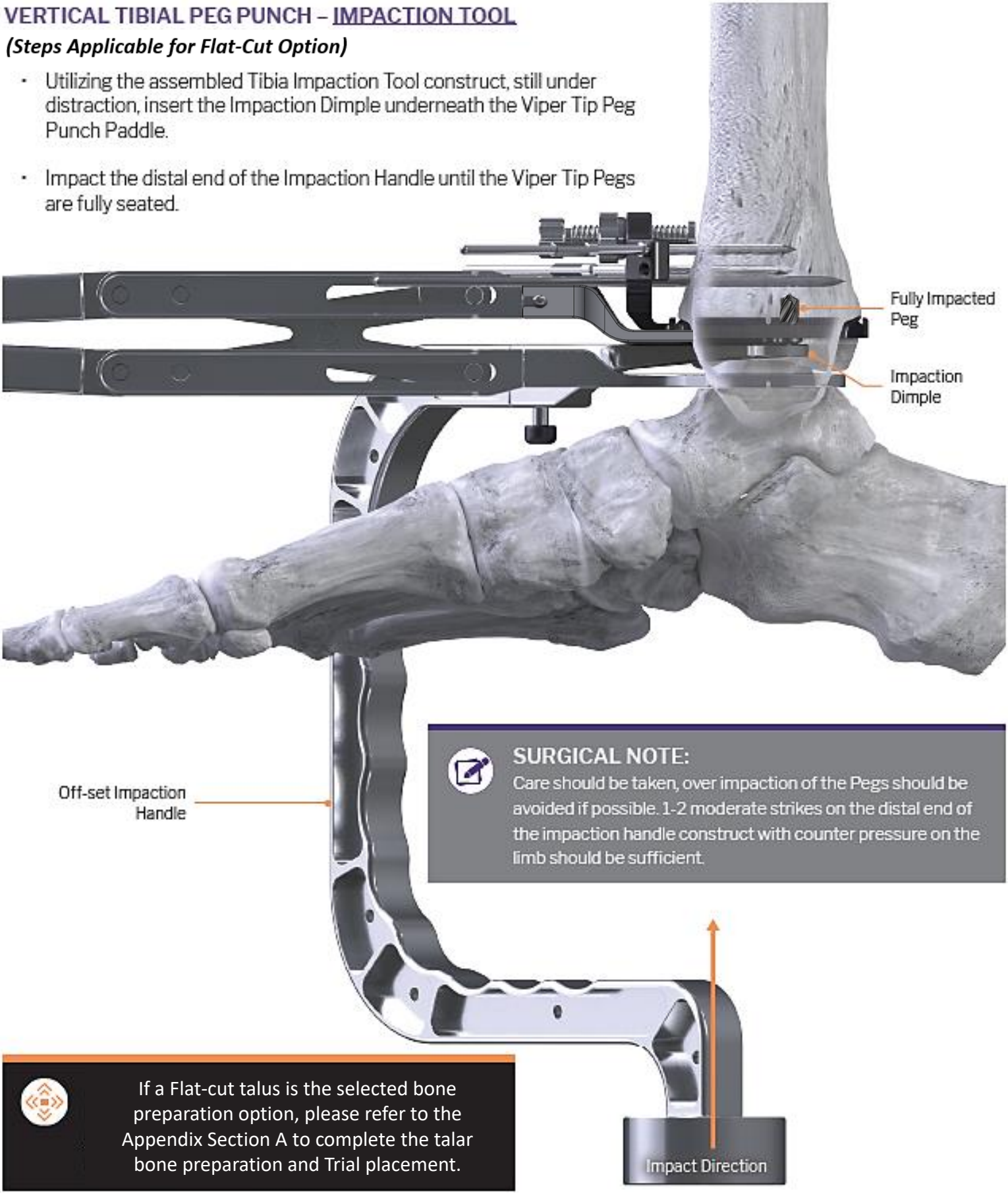


TIBIAL VERTICAL PEG PREPARATION

VERTICAL TIBIAL PEG PUNCH – IMPACTION TOOL

(Steps Applicable for Flat-Cut Option)

- Utilizing the assembled Tibia Impaction Tool construct, still under distraction, insert the Impaction Dimple underneath the Viper Tip Peg Punch Paddle.
- Impact the distal end of the Impaction Handle until the Viper Tip Pegs are fully seated.



SURGICAL NOTE:
Care should be taken, over impaction of the Pegs should be avoided if possible. 1-2 moderate strikes on the distal end of the impaction handle construct with counter pressure on the limb should be sufficient.

If a Flat-cut talus is the selected bone preparation option, please refer to the Appendix Section A to complete the talar bone preparation and Trial placement.

BONE PREPARATION, TRIALING, & IMPLANTATION

Subsequent steps for talar bone preparation, trialing and full APEX 3D™ Total Ankle Replacement construct implantation can be found in section 7 of the APEX 3D Surgical Technique Guide (P10-STG-0001).

[ALTERNATIVE OPTION] – TIBIAL VERTICAL PEG PREPARATION - OFFSET IMPACTION PEG PUNCH

VERTICAL TIBIAL PEG PREPARATION

(Steps Applicable for Flat-Cut Option)

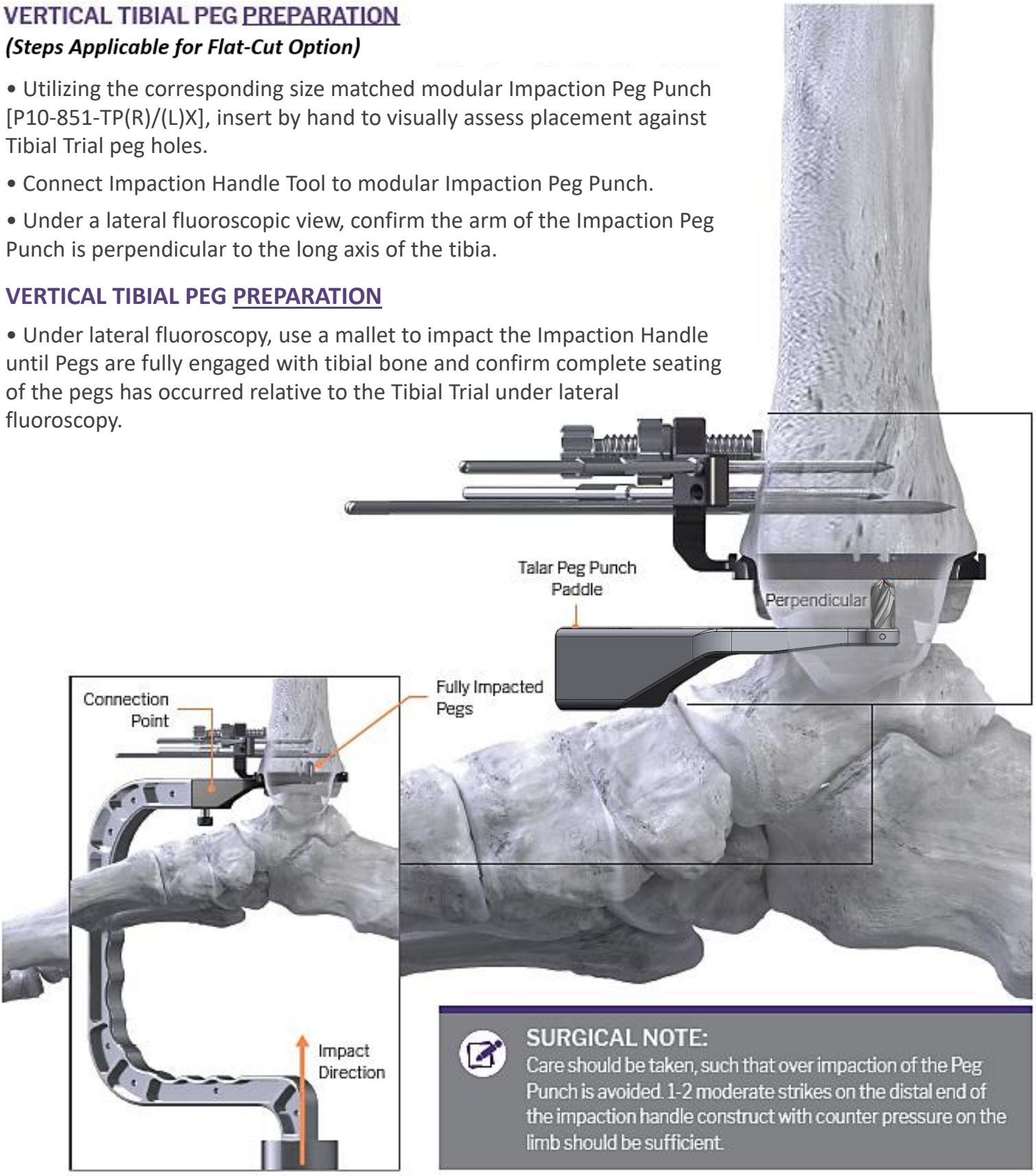
• Utilizing the corresponding size matched modular Impaction Peg Punch [P10-851-TP(R)/(L)X], insert by hand to visually assess placement against Tibial Trial peg holes.

• Connect Impaction Handle Tool to modular Impaction Peg Punch.

• Under a lateral fluoroscopic view, confirm the arm of the Impaction Peg Punch is perpendicular to the long axis of the tibia.

VERTICAL TIBIAL PEG PREPARATION

• Under lateral fluoroscopy, use a mallet to impact the Impaction Handle until Pegs are fully engaged with tibial bone and confirm complete seating of the pegs has occurred relative to the Tibial Trial under lateral fluoroscopy.



SURGICAL NOTE:
Care should be taken, such that over impaction of the Peg Punch is avoided. 1-2 moderate strikes on the distal end of the impaction handle construct with counter pressure on the limb should be sufficient.

SURGICAL NOTE:
Left and right configurations of the Tibial Peg Punch instrumentation are available and provided within the APEX 3D™ System instrument kits.

Refer to www.paragon28.com/ifus for the complete and most current instructions for use document.

INDICATIONS FOR USE

The APEX 3D™ Total Ankle Replacement System is indicated as a total ankle replacement in primary surgery for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis. Revision surgery for these patients is also indicated for patients with sufficient bone stock present. In the United States, components are intended for cemented use only.

CONTRAINDICATIONS

Use of the APEX 3D™ Total Ankle Replacement System is contraindicated in cases of inflammation, cases of active or suspected sepsis/infection and osteomyelitis; or in patients with certain metabolic diseases.
All applications that are not defined by the indications are contraindicated. In addition, surgical success can be adversely affected by:

- Acute or chronic infections, local or systemic
- Any mental or neuromuscular disorder that could result in an unacceptable risk of failure at the time of fixation or complications in post-operative treatment (e.g. dementia, senility, alcoholism)
- Corpulence; an overweight or corpulent patient can strain the prosthesis to such a degree that stabilization or prosthesis failure can occur
- Excessive loads as caused by activity or patient weight
- Female of childbearing age, for whom a negative pregnancy test is not obtained
- Steroid use
- Inadequate neuromuscular status (e.g. prior paralysis, neuropathy, neuropathic joint, fusion and/or inadequate abductor strength)
- Muscular atrophy
- Osteomyelitis
- Poor bone stock, poor skin coverage, or excessive bone loss around the joint which would make the procedure unjustifiable
- Sepsis
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery)
- Suspected or documented metal allergy or intolerance
- Musculoskeletal disease that may adversely affect gait or weightbearing
- Neurologic disorder/instability and non-compliance that may adversely affect gait or weight bearing
- Vascular deficiency in the ankle joint

Other medical or surgical pre-conditions that could compromise the potentially beneficial procedure, such as:

- Congenital abnormalities
- Immunosuppressive pathologies
- Increased sedimentation rates that cannot be explained by other pathologies
- Marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Metabolic disorders that may impair bone formation
- Osteomalacia
- Poor prognosis for good wound healing
- Presence of tumors
- Increased leukocyte (WBC) count
- Pronounced left shift in the differential leukocyte count
- Uncooperative patient or patient with neurological disorders, incapable of following instructions

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS

IN ANY SURGICAL PROCEDURE, THE POTENTIAL FOR COMPLICATIONS AND ADVERSE REACTIONS EXIST. THE RISKS AND COMPLICATIONS WITH THESE PROSTHETIC COMPONENTS INCLUDE:

- Asymptomatic, progressive bone resorption (osteolysis) due to foreign body reaction to particulate matter (See Important Physician Information section for more information)
- Sensitivity, allergy or other reactions to prosthetic component materials
- Peripheral neuropathies or nerve damage resulting in pain or numbness of the affected limb
- Loosening or migration of the prosthetic components
- Subluxation or dislocation of the prosthetic components with resulting reduction in range of movement
- Bending, disassembly and/or breakage of the prosthetic components
- Fractures resulting from unilateral joint loading
- Fatigue fracture of the prosthetic components as the result of trauma, strenuous activity, improper alignment, incomplete implant seating, or duration of service
- Bone fracture by trauma or excessive loading, particularly in the presence of poor bone stock
- Drop in blood pressure intra-operatively due to the use of bone cement
- Thrombosis, embolism, or myocardial infarction
- Wound hematoma and delayed wound healing
- Acute post-operative wound infections and late infections with possible sepsis
- Pain, a feeling of malaise or abnormal sensations due to the prosthetic components

POTENTIAL COMPLICATIONS AND ADVERSE REACTIONS (CONTINUED)

- Inadequate range of motion due to improper selection or positioning of components or periarticular calcification
- Temporary and protracted functional neurological perturbation
- Corrosion with localized tissue reaction and pain
- Bone loss due to stress shielding
- Secondary necrosis of the talus

All possible complications listed here are not typical of Paragon 28®, Inc. products but in principle, may be observed with any total joint replacement implant. Promptly inform Paragon 28®, Inc. as soon as complications occur in connection with the 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 Paragon 28®, Inc. with the explant(s) in a cleaned, disinfected and sterile condition. Paragon 28®, Inc. cannot accept any other returns of used implants. The surgeon is held liable for complications associated with inadequate asepsis, inadequate preparation of the osseous implant bed in the case of implants, incorrect indication or surgical technique or incorrect patient information and consequent incorrect patient behavior

WARNINGS AND PRECAUTIONS

- This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.
- The surgeon should discuss with the patient prior to surgery possible risks, precautions, warnings, consequences, complications, and adverse reactions associated with the surgical procedure and implantation of the device.
- Improper selection, placement, positioning, and fixation of the prosthetic components may result in unusual stress conditions and a subsequent reduction in service life of the prosthetic component.
- Periodic, long-term follow-up is recommended to monitor the position and state of the prosthetic components, as well as the condition of the adjoining bone.
- Re-operation to remove or replace prosthetic components may be required at any time due to medical reasons or device failure If corrective action is not taken, complications may occur.
- Patients need to be informed regarding expectations pertaining to performance and limitations following surgery. The prosthesis does not replace normal bone, has a finite service life, and future revision surgeries may be necessary. Protection of the prosthesis from full weight bearing is needed until adequate fixation and healing is achieved. Certain activities and loading trauma should be limited to prevent unreasonable stresses that could lead to breaking or damage of the prosthetic components.
- Do not attempt a surgical procedure with faulty, damaged or suspect instruments or implants. Inspect all components preoperatively to assure utility.
- Never modify an implant.
- The implants and guide wires are intended for single use only.
- Instruments and implants are to be treated as sharps.
- Do not implant the instruments.
- **Do not use other manufacturer's instruments or implants in conjunction with the APEX 3D™ Total Ankle Replacement Device.**
- **Do not re-sterilize the APEX 3D™ Total Ankle Replacement Implants or Instruments.**

IMPORTANT PHYSICIAN INFORMATION

BONE RESORPTION IS A NATURAL CONSEQUENCE OF TOTAL JOINT ARTHROPLASTY DUE TO CHANGES IN BONE REMODELING PATTERNS. BONE REMODELING IS MEDIATED BY THE CHANGES IN STRESS DISTRIBUTION CAUSED BY IMPLANTATION. EXTENSIVE RESORPTION AROUND THE PROSTHESIS MAY LEAD TO IMPLANT LOOSENING AND FAILURE. IT IS GENERALLY AGREED THAT OSTEOLYSIS IS THE RESULT OF LOCALIZED FOREIGN-BODY REACTION TO PARTICULATE DEBRIS GENERATED BY CEMENT, METAL, UHMWPE, AND CERAMIC. REGARDING THE ETIOLOGY, IT HAS BEEN HYPOTHESIZED THAT PARTICULATE DEBRIS GENERATED BY THE COMPONENTS OF A PROSTHESIS MIGRATE INTO THE SYNOVIAL CAVITY AND THE BONE-IMPLANT INTERFACE, WHERE THEY RECRUIT MACROPHAGES AND STIMULATE PHAGOCYTIC ACTION. THE DEGREE OF RECRUITMENT IS DETERMINED BY THE SIZE, DISTRIBUTION AND AMOUNT OF PARTICULATE DEBRIS (RATE OF DEBRIS GENERATION). THE PHAGOCYTIC ACTION RESULTS IN THE RELEASE OF CYTOKINES AND INTERCELLULAR MEDIATORS (IL-1, 2, PE2) WHICH ENCOURAGE OSTEOCLASTIC BONE RESORPTION. CLINICAL AND BASIC RESEARCH IS CONTINUING IN ORDER TO PROVIDE SCIENTIFIC BASIS FOR THE CAUSES OF THIS PHENOMENON AND THE POTENTIAL WAYS TO REDUCE ITS OCCURRENCE. OSTEOLYSIS CAN BE ASYMPTOMATIC AND THEREFORE ROUTINE PERIODIC RADIOGRAPHIC EXAMINATION IS VITAL TO PREVENT ANY SERIOUS FUTURE COMPLICATION. PRESENCE OF FOCAL LESIONS THAT ARE PROGRESSIVE MAY NECESSITATE REPLACEMENT OF THE PROSTHETIC COMPONENT(S).

MR SAFETY INFORMATION

THE APEX 3D™ TOTAL ANKLE REPLACEMENT 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 APEX 3D™ TOTAL ANKLE REPLACEMENT SYSTEM IN THE MR ENVIRONMENT IS UNKNOWN. MR SCANNING OF A PATIENT WHO HAS THIS DEVICE MAY RESULT IN PATIENT INJURY.

APEX 3D™
TOTAL ANKLE REPLACEMENT

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DISCLAIMER

The purpose of the APEX 3D™ Total Ankle Replacement System Surgical Technique Guide is to demonstrate the use of the APEX 3D™ Total Ankle Replacement System. Although various methods can be employed for this procedure, the fixation options demonstrated were chosen for simplicity of explanation and demonstration of the unique features of our device. Federal law (U.S.A.) restricts this device to sale and use by, or on order of, a physician.