INBONE® II
Total Ankle System

SURGICAL TECHNIQUE SUPPLEMENT
TIBIAL REAMING SPECIFICATION

WRIGHT™

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SURGICAL TECHNIQUE SUPPLEMENT

Tibial Reaming Specification

Contents

Wright recognizes that proper surgical procedures and techniques are the responsibility of the medical professional. The following guidelines are furnished for information purposes only. Each surgeon must evaluate the appropriateness of the procedures based on his or her personal medical training, experience, and patient condition. Prior to use of the system, the surgeon should refer to the product Instructions For Use package insert (145283) for additional warnings, precautions, indications, contraindications and adverse effects. Instructions For Use package inserts are also available by contacting the manufacturer. Contact information can be found on the back of this surgical technique and the Instructions For Use package inserts are available on wmt.com under the link for Prescribing Information.

Please contact your local Wright representative for product availability.

Product Information

chapter 1

Through the advancement of partial and total joint replacement, the surgeon has been provided with a means of restoring mobility, correcting deformity, and reducing pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from a variety of materials and that any joint replacement system, therefore, cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system, including the implant/bone interface, will not be as strong, reliable, or durable as a natural human joint.

Ankle joint replacement components consist of a talar dome, a talar stem that attaches to the talar dome with a Morse Taper, a tibial platform, a tibial stem assembly consisting of between two and eight component pieces that attaches to the tibial platform with a Morse Taper, and an UHMWPE component. Components are available in a variety of sizes and design configurations intended for both primary and revision applications.

In using joint prostheses, the surgeon should be aware of the following:

The correct selection of the prosthesis is extremely important. The potential for success in joint replacement is increased by selection of the proper size, shape, and design of the prosthesis. Joint prostheses require careful seating and adequate bone support. Surgeons are encouraged to use their best medical judgment when choosing the proper implant size regardless of the endosteal area of the bone. Surgeons must be familiar with the applicable operative techniques and instructions for use for each implant system.

In selecting patients for total joint replacements, the following factors can be critical to the eventual success of the procedure:

1. **Patient's weight.** An overweight or obese patient can produce high loads on the prosthesis, which can lead to failure of the prosthesis. This becomes a major consideration when the patient is small boned and a small size prosthesis must be used.
2. **Patient's occupation or activity.** If the patient is involved in an occupation or activity, which includes substantial walking, running, lifting, or muscle strain, the resultant forces can cause failure of the fixation or the device, or both. The prosthesis will not restore function to the level expected with normal healthy bone, and the patient should not have unrealistic functional expectations.
3. **Condition of senility, mental illness, or alcoholism.** These conditions, among others, may cause the patient to ignore certain necessary limitations and precautions in the use of the prosthesis, leading to failure or other complications.
4. **Foreign body sensitivity.** Where material sensitivity is suspected, appropriate tests should be made prior to material selection or implantation.

Indications and Contraindications

chapter 2

Intended Use

The INBONE® Total Ankle is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint.

Indications

INBONE®Total Ankle Replacement

Total ankle arthroplasty is intended to give a patient limited mobility by reducing pain, restoring alignment and replacing the flexion and extension movement in the ankle joint. Total ankle arthroplasty is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

The ankle prosthesis is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: The ankle prosthesis is intended for cement use only.

Contraindications

Absolute contraindications include:

1. Osteomyelitis;
2. Excessive bone loss at the ankle joint site;
3. Steroid use;
4. Infection at the ankle site or infections at distant sites that could migrate to the ankle;
5. Sepsis;
6. Muscular atrophy;
7. Dementia;
8. Vascular deficiency in the ankle joint;
9. Skeletally immature patients (patient is less than 21 years of age at the time of surgery);
10. Cases where there is inadequate neuromuscular status (e.g., prior paralysis, fusion and/or inadequate abductor strength), poor bone stock, poor skin coverage around the joint which would make the procedure unjustifiable;
11. neuropathic joints;
12. hepatitis or HIV infection;
13. excessive loads as caused by activity or patient weight;
14. female of childbearing age, for whom a negative pregnancy test is not obtained; and,
15. neurological or musculoskeletal disease that may adversely affect gait or weight-bearing.

Conditions presenting increased risk of failure include:

1. uncooperative patient or patient with neurologic disorders, incapable of following instructions;
2. marked bone loss, severe osteoporosis, or revision procedures for which an adequate fit of the prosthesis cannot be achieved;
3. metabolic disorders that may impair bone formation;
4. osteomalacia; and,
5. poor prognosis for good wound healing (e.g., decubitus ulcer, end-stage diabetes, severe protein deficiency and/or malnutrition).

WARNING: This device is not intended for subtalar joint fusion or subtalar joint impingement. Please carefully evaluate the anatomy of each patient before implantation.

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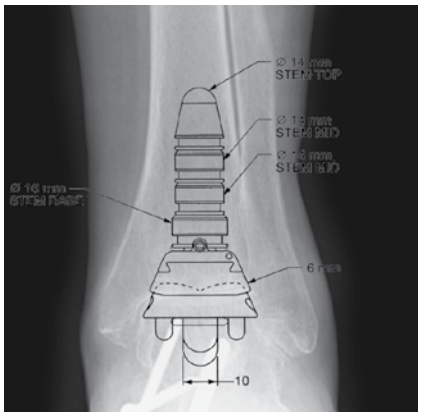
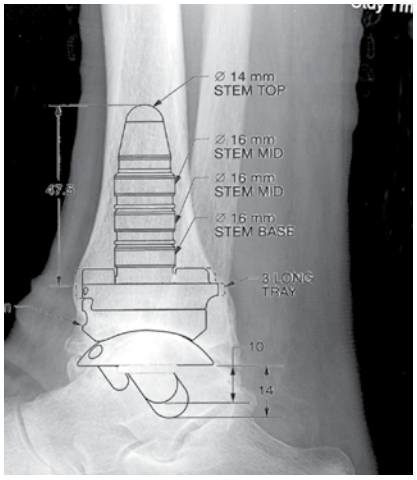
Preoperative Planning

chapter 3





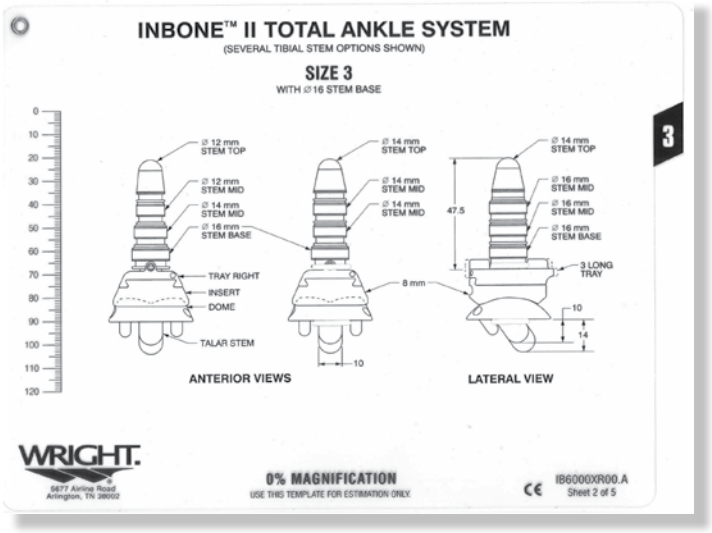
Templating is highly recommended

Introduction: In certain instances a surgeon may desire additional tibial fixation beyond the 4 stem pieces. There are potential risks with using additional tibial fixation, including periprosthetic fracture in areas where the tibial canal narrows or increased endosteal drilling occurs. Additionally, the ability to fit greater than 4 stem pieces in the tibia without cortical wall disruption is limited. Based on an anthropometric analysis, the top 4 stem pieces will often only fit within the IM canal in smaller configurations (i.e. 12 or 14mm midpieces and 12mm top pieces). If the surgeon believes that the benefit of additional fixation provided by using more than 4 tibial stem pieces outweighs the risk of weakening and potentially fracturing the tibia, the surgeon should proceed with caution, following these instructions.

Use X-ray templates to preoperatively assess the appropriate size, position, and number of tibial stem pieces. This templating may offer intraoperative guidance for component selection.

Radiographic overlays for the INBONE® II Total Ankle System are available in 0% and 10% magnification, and represent both the AP and Lateral profile of the prosthesis. Additional overlays are also available for tibial stem constructs up to eight stems.

CAUTION: Preoperative templating is intended for estimation purposes only. Final component size and position should be determined intraoperatively through direct visualization under fluoroscopic assistance.



IB6000XR00 INBONE® II Total Ankle X-ray Template 0% Magnification
IB6000XR10 INBONE® II Total Ankle X-ray Template 10% Magnification
IB9000XR00 INBONE® Long Stem X-ray Template 0% Magnification
IB9000XR10 INBONE® Long Stem X-ray Template 10% Magnification

Reaming Specifications

chapter 4

Tibia reaming should only occur after joint space cuts have been made. Patient anatomy should dictate the size and number of stems used. For complete surgical steps, please reference the following techniques:

FA180-308 INBONE® Total Ankle System

FA093-210 INBONE® II Total Ankle System

FA359-512 PROPHECY® INBONE® Total Ankle System

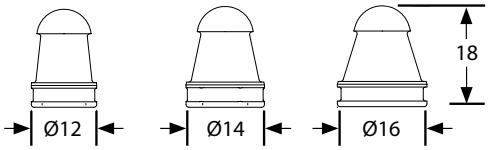
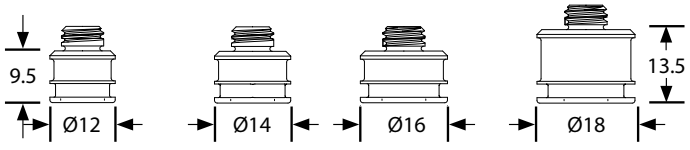
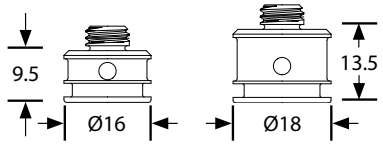
Use the same size reamer as the desired Tibial Top and Mid Stem implants. It is recommended to ream for 2mm press fit on Tibial Base Stem if possible. For instance, if the Tibial Base Stem is a 16mm, the Reamer size will be 14mm.

CAUTION: When reaming the tibial canal, use flouroscopy to view endosteal drilling. If you feel or hear cortical chatter, stop immediately.

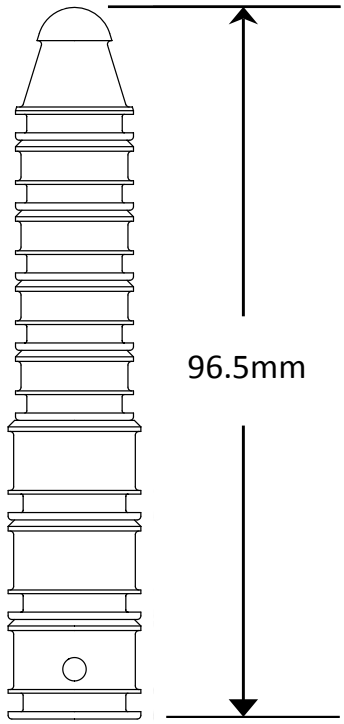
CAUTION: Overstuffing the tibial canal when implanting the Tibial Top and Mid Stems may increase the risk of periprosthetic fracture.

It is recommended to ream the tibia to a depth that is approximately 5mm greater than the total stem construct height. Individual stem component heights can be found in **| TABLE 1.**

Units = mm

IMPLANT	OPTIONS	
 Top Stem (Diameter)		
 Mid Stem (Diameter)		
 Base Stem (Diameter)		Exclusive Fit Size #2, #3 - 16mm only Size #4, #5, #6 - 18mm only

| TABLE 1: Stem Component Specifications



| FIGURE 1: Maximum length 8 piece construct

Tibial Tray sizes 2 and 3 can only utilize the 16mm base and up to a 16mm mid stem piece. Therefore, total stem construct height will be a minimum of 27.5mm when no Mid Stem pieces are used and a maximum of 84.5mm when 6 Mid Stem pieces are used. Stem height should be based on patient anatomy.

Tibial Tray sizes 4 through 6 can only utilize the 18mm base and up to an 18mm Mid Stem piece. Therefore, total stem construct height will be a minimum of 31.5mm when no Mid Stem pieces are used and a maximum of 112.5mm if six 18mm Mid Stem pieces are used. Stem height should be based on patient anatomy.

CAUTION: Because current instrumentation only allows for a maximum reaming depth of 100mm, when implanting sizes 4-6, it is recommended that the number of 18mm Mid Stem pieces be limited as follows:

7 piece construct – limit to four 18mm Mid Stems for a total construct height of 95mm.

8 piece construct – limit to two 18mm Mid Stems for a total construct height of 96.5mm. **| FIGURE 1**

Explant Information

To remove the components, small osteotomes, power saws, or other surgical instruments may be used to disrupt the bone-cement interface. Care must be exhibited to save remaining bone stock as well as to prevent fracture. Once the components have been removed, rongeurs or small osteotomes as well as other surgical instruments may be used to remove the remaining cement.

Postoperative Management

Postoperative care is the responsibility of the medical professional.

Notes

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