Integra®
Cadence® Total Ankle System

SURGICAL TECHNIQUE
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Indications

The Integra® Cadence® Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint.

The Integra® Cadence® Total Ankle System is indicated for use to treat:

- systemic arthritis of the ankle (e.g. rheumatoid arthritis, hemochromatosis)
- primary arthritis (e.g. degenerative disease)
- secondary arthritis (e.g. post-traumatic, avascular necrosis, if minimally 2/3 of the talus is preserved)

Integra® Cadence® Total Ankle System is also indicated for revision surgeries following failed total ankle replacement and non-union/mal-union of ankle arthrodesis, provided sufficient bone stock is present.

NOTE: In the United States, this device is intended for cemented use only.

NOTE: Outside the United States, this device is intended for cemented or cementless use.

Contraindications

The Integra® Cadence® Total Ankle System is contra-indicated for:

- Active infection
- Skeletally immature
- Pregnancy
- Suspected or documented metal allergy or intolerance
- Severe avascular necrosis of the talus/tibia
- Severe malalignment or instability that is not surgically correctable
- Neurological or musculoskeletal disease that may adversely affect gait or weight bearing
- Participation in activities that may exert excessive loading on joint area and prosthesis
- Inadequate neuromuscular status (e.g., prior paralysis, neuropathy)
- Poor bone stock, poor skin coverage, or excessive bone loss around the joint which would make the procedure unjustifiable
- Obesity
- Steroid use

The following conditions present an increased risk of failure:

- Severe osteoporosis; marked bone loss or revision procedures for which an adequate fit of the prosthesis cannot be achieved
- Osteomalacia
- Metabolic disorders
- Demonstrates physiological or anatomical anomalies
- Undergoing immunosuppressive therapy
- Malignancy/local bone tumors
- Compromised wound healing
- History of mental illness/instability and non-compliance
- History of drug abuse and/or addiction

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

The Integra® Cadence® Total Ankle System is designed to treat ankle arthritis through replacement of the ankle joint with a prosthesis, thereby reducing pain, restoring alignment, and allowing for movement at the replaced joint.

The prosthesis is composed of a tibial tray, a talar dome and an insert. Both the tibial tray and talar dome are secured to patient anatomy; the insert is rigidly fixed to the tibial tray intra-operatively. When all three components are implanted, the insert acts as a bearing along the talar dome, enabling flexion and extension movement at the replaced joint.

Each of the three components is available in a variety of sizes and design configurations intended for both primary surgery and revision surgery applications.

Tibial Tray

- Material: Titanium Alloy (Ti-6Al-4V ELI)
- Pegs and posterior tab designed for initial fixation and to prevent post-operative migration
- 9 sizes, left foot and right foot specific

Talar Dome

- Material: Cobalt Chrome Alloy (CoCrMo)
- Pegs designed for initial fixation and to prevent post-operative migration
- 5 sizes, left foot and right foot specific

Insert

- Material: Highly cross-linked Ultra High Molecular Weight Polyethylene (UHMWPE)
- 5 sizes, 7 heights, left foot and right foot specific
- Neutral, anterior-biased, posterior-biased options
System Features and Benefits

The Integra® Cadence® Total Ankle System provides the following features and benefits:

1. **Anatomic Implant Designs**
   - Side specific (L/R) tibial trays, talar domes, and poly inserts.
   - Anatomic shaped tibial trays for tri-cortical endplate coverage; extended length option and cut out for incisura.
   - Anatomical articulating surface designed to recreate conical flexion and extension of the ankle
   - Comprehensive selection; 672 possible implant combinations

2. **Designed to preserve patient anatomy**
   - Protect and reduce risk of injury to malleoli with customized tibial cut guides and perforating pin technique.
   - Multiple bone prep technique steps performed using same pins.
   - Minimal Talar Resection (4.3mm)

3. **Designed to reduce dissymmetry and mal-alignment of prosthesis**
   - Anterior and posterior biased inserts designed to accommodate patients with subluxed talus in the sagittal plane.
   - Talar tensioning technique step to ensure final implant is placed on horizontal plane, reduce risk of mal-alignment to coronal plane.

4. **Designed for Increased Prosthesis Survivorship**
   - HXL Ultra High Molecular Weight (UHMWPE) bearing material for improved wear characteristics1

5. **Designed for streamlined, repeatable technique**
   - Single alignment guide allows for adjustment to patient anatomy.
   - Many multi-purpose instruments, each used for multiple technique steps.
   - All instruments contained in two color-coded trays to facilitate procedure flow.

Integra Cadence Total Ankle System

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1 Data on File
Positioning of the Patient

The patient is placed in the supine position with the foot near the edge of the table. A bump is placed under the ipsilateral hip to achieve neutral rotation of the operative extremity.

The affected ankle is positioned with a bump under the tibia so that the heel is off of the OR table.

The contralateral leg/foot may be frog-legged on a stand to make clearance for lateral view c-arm images intra-operatively.

Surgical Approach

An anterior longitudinal incision is made starting just lateral to the subcutaneous border of the tibia proximally and extending across the midline of the ankle joint to the dorsal medial border of the midfoot.

**TIP:** If the distal incision is placed slightly medial to the midline, it helps to further protect against injury to the Superficial Peroneal Nerve (SPN).

The retinaculum is identified and incised. The ends are tagged to facilitate repair later in the case.

Care is taken to protect the anterior neurovascular bundle as the dissection is carried down beneath the anterior tibia tendon bed, carefully mobilizing the deep neurovascular bundle in a lateral direction along with the Extensor Hallucis Longus (EHL) tendon.

As this dissection is taken inferiorly the ankle joint capsule is exposed, then perform a midline arthrotomy. Medial dissection is taken to the medial gutter so that the medial malleolus and the deltoid ligament can be visualized. Laterally, the dissection is taken so that the anterior inferior tibiofibular syndesmotic ligament and the tubercle of Chaput are visible. The lateral talofibular articulation and the medial aspect of the fibula should be visible by the end of this lateral exposure.

Osteophytes on the tibia are removed, particularly on the antero-lateral aspect. Osteophytes on the talar neck and anterior aspect of the medial malleolus are also removed.

**TIP:** Laminar spreaders are carefully placed into the ankle joint and distracted maximally. The laminar spreaders are left in the joint for approximately one minute to allow for tissue creep (gradual lengthening of the ankle ligaments and joint capsule). If adequate range of motion can not be achieved, a careful release of the medial and/or lateral ankle ligaments can be performed while the laminar spreaders are in place or after their removal.

**TIP:** An osteotome is often useful to take down the anterior most aspect of the distal tibial plafond. This allows visualization of the apex of the distal tibial articular surface upon which the tibial resection is referenced in subsequent steps of the procedure.

**TIP:** It may be necessary to perform soft tissue releases, osteotomies and/or fusions, before or following implantation of the Cadence prosthesis, to achieve desired final range of motion and balance in the ankle joint.
As the manufacturer of this device, Integra does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Step 1 • Tibial Alignment Guide Initial Positioning

Assembly

The Distal Tibial Alignment Block (10203001), the Tibial Rod (10203004), the Proximal Tibial Clamp (10203003), the Rod Connector (10203005), and the Proximal Translation Block (10203006) are assembled on the table before positioning on the patient.

Slide the Proximal Translation Block to the center location of the Proximal Tibial Clamp.

Assemble a hex screwdriver by attaching a Screwdriver Handle (10204145) to an AO Hex Driver (10204146).

Tighten locking screw with the assembled hex screwdriver.

**Note**
The assembled hex screwdriver may be used to tighten and loosen any Locking Screws (10204217) as needed throughout the entire procedure.

Slide the anterior end of the Proximal Translation Block through mating hole in the Rod Connector. Slide the proximal end of the Tibial Rod through mating hole in the Rod Connector.

Press buttons on both ends of the Rod Connector to allow the Tibial Rod and Proximal Translation Block to slide freely into position. Release buttons to lock location.

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1-3 Place distal end of the Tibial Rod into mating hole of the Distal Tibial Alignment Block. Tighten Locking Screw with hex screwdriver.

1-4 Ensure that the Distal Tibial Alignment Block and the Proximal Translation Block are placed in their neutral starting positions.

1-5 Ensure that the 5 tibial alignment guide Locking Screws are in position and initially locked.

Note
Spare Locking Screws can be found in the Pins and Accessories Module
Initial Patient Positioning

The Proximal Tibial Clamp is adjusted to the tibial tuberosity while its arms are held open and then closed around the proximal calf.

The Distal Tibial Alignment Block is positioned on the center of the distal tibial metaphysis in the M/L direction.

**TIP:** Occasionally, distal anterior osteophytes or bony prominences will need to be debrided and removed to allow the Distal Tibial Alignment Block to sit flush with the distal tibial metaphyseal flare.

Adjust the Tibial Rod until it is parallel to the tibia in the sagittal plane.

Adjustments can be made by depressing the Rod Connector button closest to the Proximal Translation Block.

**TIP:** For the Tibial Rod to be parallel to the tibia, the distance between the tibia and the Tibial Rod is typically 6-7 cm (approximately 3 fingers breadth). Further adjustments and/or confirmation of sagittal plane alignment are made in subsequent steps.
**Set Initial Distal/Proximal Resection Height**

Align the Gap Sizer (10204074) with the anterior lip of the distal tibia.

Adjust the initial distal/proximal location of the Distal Tibial Alignment Block by depressing the button on the Rod Connector closest to the Tibial Rod. Bring the Distal Tibial Alignment Block into contact with the proximal surface of the Gap Sizer.

If necessary, remove bony prominences on the anterior lip of the distal tibia to properly align the Gap Sizer.

**TIP:** For correct orientation, the etched marking “TIBIAL SIDE” on the Gap Sizer should be in contact with the Distal Tibial Alignment Block.

Minimum resection removes 4.3 mm from talus; Gap Sizer should be placed such that the black etched line aligns with the apex of the talar dome.
Attach the Sagittal Rod (10204029) to the Sagittal Connector (10204028).

Secure with Bone Pin

Place a Long Shouldered Bone Pin (10204023) through the proximal portion of the Distal Tibial Alignment Block to hold the position.

**TIP:** Do not place bone pin through the distal portion of the Distal Tibial Alignment Block at this time to allow for fine adjustments in position in subsequent steps.
Snap the Sagittal Connector to the Tibial Rod.

Establish sagittal plane orientation

If needed, adjust the anterior/posterior position of the Rod Connector, to bring the Sagittal Rod in alignment (or parallel) with the posterior border of the tibia in the sagittal plane. Adjustments can be made by depressing Rod Connector button closest to the Proximal Translation Block.

Confirm using flouroscopy.

Remove Sagittal Rod and Sagittal Connector.
Adjust initial Medial-Lateral position

While maintaining the central position of the Distal Tibial Alignment Block on the distal tibia, make adjustments, if needed, to the position of the Proximal Tibial Clamp. Goal is neutral coronal plane alignment for the overall Tibial Alignment Guide.

Confirm using fluoroscopy.

Note
In patients with talar varus/valgus or a distal tibial flare, the Tibial Rod will need to be medial or lateral to the midline of the tibial diaphysis when the overall Tibial Alignment Guide is in neutral coronal plane alignment.

Adjustments can be made after loosening the locking screw on the Proximal Translation Block.

Note
Medial translation moves the tibial alignment guide into valgus, lateral translation moves the tibial alignment guide into varus.

TIP: To tighten the Proximal Translation Block Locking Screw, it may be necessary to move the Rod Connector anteriorly to access the Locking Screw. Return Rod Connector to desired position after securing the Locking Screw.

If needed, re-tighten the Locking Screw on the Proximal Translation Block.

If needed, use a second long shoulder pin through the proximal portion of the Distal Tibial Alignment Block to hold the position.

TIP: If a second pin is placed through the Distal Tibial Alignment Block, no more adjustments can be made in the coronal or sagittal plane for the tibial cut.

TIP: If needed, a long shoulder pin may also be placed through the Proximal Tibial Clamp to further secure the alignment guide.
Step 2 • Adjust Tibial Alignment Guide

Establish Rotational Alignment

2-1 Place the thin end of the Gutter Indicators (10204150) into both the medial gutter and the lateral gutter.

2-2 Place the Angle Bisector (10204148) into the central hole of the distal portion of the Distal Tibial Alignment Block (10203001).

2-3 Loosen the Locking Screw that controls rotation and adjust the rotational position of the Distal Tibial Alignment Block until the Angle Bisector bisects the angle created by the two Gutter Indicators.

**TIP:** The proper rotational alignment can be double checked by assessing the alignment of the Angle Bisector with the second metatarsal.

Lock the rotational Locking Screw after establishing the proper rotational alignment.
Establish Medial/Lateral position for tibial resection

2-4 Depending on the size of the tibia, select either the Size 1/2/3 Tibial Cut Guide (10203023) or the Size 3/4/5 Tibial Cut Guide (10203024).

**TIP:** The correct Tibial Cut Guide should have at least one of the lateral holes in the saw slot extend into the medial portion of the fibula.

2-5 Slide selected Tibial Cut Guide onto the Distal Tibial Alignment Block until the anterior face of the cut guide is flush with the anterior face of the Distal Tibial Alignment Block.

**TIP:** The marking signifying the correct side ("LEFT" or "RIGHT") should be facing forward or on the anterior side of the Tibial Cut Guide when in position (i.e. If a right ankle, the word "RIGHT" should be on the anterior side of the Tibial Cut Guide when placed in position).

2-6 Lock the Locking Screw on the Tibial Cut Guide.
2-7 Loosen the medial/lateral Locking Screw on the Distal Tibial Alignment Block.

2-8 Using the medial/lateral adjustment screw on the Distal Tibial Alignment Block, align centers of the medial holes of the Tibial Cut Guide with the proximal medial border of the talus.

**TIP:** If the ankle joint is subluxed medially, instead align the centers of the medial holes of the Tibial Cut Guide with medial gutter.

2-9 Lock the medial/lateral Locking Screw on the Distal Tibial Alignment Block

**Establish Tibial Resection Level**

2-10 Place the Tibial Resection Template (10203012) into the slot of the selected Tibial Cut Guide. Advance Tibial Resection Template until the etched black line contacts the Distal Tibial Alignment Block.

**TIP:** The post on the Tibial Resection Template should slide into either the slot in the Distal Tibial Alignment Block or the slot in the Tibial Cut Guide to ensure that the Tibial Resection Template is securely seated.
Loosen the distal/proximal Locking Screw on the Distal Tibial Alignment Block.

Using fluoroscopy, adjust the distal/proximal location of the Tibial Cut Guide until the inferior tips of the posts on the Tibial Resection Template are aligned with the most superior aspect of the distal tibial plafond.

**TIP:** A direct lateral view during this step is critical to ensure the proper amount of tibial resection. The fluoroscopy targets on both the Tibial Cut Guide and the Tibial Resection Template will be perfect circles under a direct lateral view.

**TIP:** When using the Tibial Resection Template, confirm the posts are at a 4 degree angle relative to the long axis of the tibia. If needed, adjust the slope on the tibial alignment guide.

Once the proper distal/proximal location is achieved, lock the distal/proximal Locking Screw on the Distal Tibial Alignment Block and remove the Tibial Resection Template.

Loosen the Locking Screw on the Tibial Cut Guide, then advance the cut guide until it contacts the tibia. Tighten the Locking Screw to re-secure the cut guide.
Step 3 • Tibial Bone Resection

**3-1**

Using fluoroscopy, confirm the medial holes of the Tibial Cut Guide are aligned with proximal medial border of the talus. If necessary, make adjustments by loosening the medial/lateral adjustment screw on the Distal Tibial Alignment Block (10203001).

Determine the medial extent of the fibula and place a Straight Bone Pin with Trocar Tip (10204026) into the most lateral bone pin position possible in the Tibial Cut Guide without hitting or damaging the fibula.

**TIP:** The fibula is posterior and medial to the tubercle of Chaput. Cutting straight posterior from this point would transect the fibula. The lateral pin should be inserted into the more medial hole to assure that the fibula is not transected.

**TIP:** The numbers marking the lateral bone pin positions on the Tibial Cut Guide correspond to the medial/lateral widths of the tibial implants. The bone pin position selected during this step can be used to provide an initial assessment of the correct tibial implant size to be used.

**WARNING:**

Do not use Bone Pins with Drill Tip on any holes in line with the saw slot of Tibial Cut Guide; use of Bone Pins with Drill Tip may result in damage to pins and instrumentation.

**TIP:** A Long Shouldered Bone Pin may be inserted through the distal portion of the Distal Tibial Alignment Block for added stability during the tibial cut.

**3-2**

Marking the Resection and Protecting the Malleoli

Using a Straight Bone – Drill Tip (10204025), mark the medial resection line of the distal tibia by drilling bicortically through each of the three medial distal holes on the Tibial Cut Guide (10203023 or 10203024).

**TIP:** Drill distal holes first, proximal hole last

**3-3**

Place a Straight Bone Pin with Trocar Tip, in the hole adjacent to the saw slot to protect the medial malleoli during resection.
Cutting Bone

3-4 Perform the tibial resection, extending carefully to the back, through the posterior cortex. A 1.27mm thick saw blade is recommended for this step (SAW6944T-SAW6949T).

3-5 After completing the saw cut, remove the Tibial Cut Guide and the Straight Bone Pins with Trocar Tip to gain access to the resected tibial bone.

3-6 Complete the medial resection of the tibia by cutting the bone remaining between the previously drilled holes with the Corner Osteotome (10204079).

TIP: A reciprocating saw (SAW6950T) may also be used to complete the medial resection of the tibia.

WARNING: Do not lever medial-lateral with the corner osteotome; levering medial-lateral increases risk of fracturing medial malleolus.

TIP: Check etchings on the Corner Osteotome, which correspond to AP depth of implants, to ensure sufficient bone is resected and avoid over-insertion.

The Slap Hammer (10203194) may be used to assist in extracting the Corner Osteotome from bone.
Remove Resected Bone

3-7

Using osteotomes, rongeurs, or other surgical instruments remove the resected tibial bone.

TIP: After the anterior portion of the tibial resection has been removed, inserting a Lamina Spreader (10203035) helps with access to the posterior portion of the remaining bone. Release of the posterolateral ligaments helps to mobilize the fragment and aids in removal.

3-7a

Alternatively, the 5.0mm Diameter Bone Pin (10204191) can be used in conjunction with the Screwdriver Handle (10204145) to obtain leverage on the resected tibial bone and aid in removal.

WARNING:
Be careful to apply only anteriorly directed force to remove the resected bone. Internal and external rotation levering can put the malleoli at risk for fracture.

WARNING:
The 5.0mm Diameter Bone Pin should be inserted parallel to the tibial resection to avoid gouging the distal tibia by protruding through the proximal surface of the tibial resection during placement.

TIP: It is often easier to remove the posterior aspect of the tibial resection after the flat cut has been made on the talus (See step 5). Therefore, only remove enough of the anterior aspect of the tibial resection to allow full placement of the Talar Cut Guide (Step 5). As a check, the flat section of the Talar Cut Guide (10203031 or 10203032) should sit on top of the talus.
Step 4 • Talar Tensioning

4-1 Depending on the size of the talus, select either the Small Talar Cut Guide (10203031) or the Large Talar Cut Guide (10203032)

TIP: Trial the Small Talar Cut Guide first; if the lateral most hole of the cut guide does not overlap the lateral gutter, use the larger cut guide.

4-2 Place selected talar cut guide into position on the Distal Tibial Alignment Block (10203001). Advance the cut guide until it contacts the talus.

TIP: Prior to inserting the Talar Cut Guide, inspect the talar neck for osteophytes or excess bone on the medial aspect (as often seen in talar varus deformities). Remove any osteophytes and fashion the talus at the neck-body junction as needed to ensure the Talar Cut Guide can be properly seated. The Talar Cut Guide should sit flush with the talar neck just anterior to the talar body.

4-3 Secure the Locking Screw on the Talar Cut Guide.
4-4 Loosen the distal/proximal Locking Screw on the Distal Tibial Alignment Block.

4-5 Using the two Lamina Spreaders (10203035), extend the Talar Cut Guide as far distally as possible until the collateral ligaments are tightened and the Talar Cut Guide is compressed against the underlying talus.

4-6 Lock the distal/proximal Locking Screw on the Distal Tibial Alignment Block. Remove Lamina Spreaders.
Step 5 • Initial Talar Bone Resection

5-1 Marking the Resection and Protecting the Malleoli

While the foot is held in neutral plantigrade position, insert a Long Shouldered Bone Pin (10204023) through the Talar Cut Guide (10203031 or 10203032) and into the talus.

TIP: A second Long Shouldered Pin may be inserted for additional fixation.

Note
Alignment of the hindfoot in the sagittal plane is checked visually. Neutral dorsiflexion of the hindfoot is the desired position. Once the Talar Cutting Guide is secured to the talus a lateral fluoroscopy view should be obtained to confirm talar position in the sagittal plane. If proper foot position is not achieved, the bone pins should be removed and this step should be repeated.

5-2 Insert a Straight Bone Pin - Trocar Tip (10204026) on both the medial side and the lateral side of the saw slot of the Talar Cut Guide. This is to protect the malleoli while performing the initial talar resection; Bone Pins should be placed in positions that allow the entire proximal surface of the talus to be resected while still preventing damage to the malleoli.

WARNING:
Do not use Bone Pins with Drill Tip on any holes in line with the saw slot of talar cut guide; use of Bone Pins with Drill Tip may result in damage to pins and instrumentation.

Cutting Bone

5-3 Perform the talar resection, extending carefully to the back, through the posterior cortex. A narrow width, 1.27mm thick saw blade is recommended for this step (SAW6944T, SAW6946T, SAW6948T).

5-4 Remove entire tibial alignment guide assembly (see step 1), the Talar Cut Guide, and all of the bone pins from patient.
Step 6 • Verify Required Implant Gap

6-1 Marking the Resection and Protecting the Malleoli

Use the Gap Sizer (10204074) to ensure that sufficient tibial and talar bone has been resected.

Note
15mm is the minimum amount of space required for positioning of the tibial and talar implant components with a 6mm thick polyethylene insert implant component.

6-2 If not enough bone has been resected, resulting in the Gap Sizer being tight or not fitting, the 2mm Tibial Cut Guide (10204202) can be inserted to resect 2mm of additional bone from the distal tibia.

Using a Lamina Spreader (10203035) in the posterior aspect of the ankle joint, ensure that the 2mm Tibial Cut Guide is opposed to the overlying tibia throughout the length of the cut tibial surface.

Pin the 2mm Tibial Cut Guide (10204202) to the distal tibia using two Short Shouldered Bone Pins (10204022). Perform the additional tibial resection, extending carefully to the back, through the posterior cortex. A 1.27mm thick saw blade (SAW6944T-SAW6949T) is recommended for this step. Repeat this process as needed until the minimum amount of bone has been resected.

Remove 2mm Tibial Cut Guide and Bone Pins after desired bone is resected. Recheck resulting gap with Gap Sizer.

Remove Resected Bone

Using osteotomes, rongeurs, or other surgical instruments, remove all resected talar bone and any remaining resected tibial bone. Take care to protect both the medial and lateral malleoli from inadvertent fracture during this process.

Check resulting gap with Gap Sizer

Use 2mm Tibial Cut Guide, as needed, to resect additional tibial bone

Pin to Distal Tibia
Using 2 Short, Shouldered Bone Pins
Step 7 • Select Talar Dome Size

7-1 Select a Talar Sizer (10204085-10204089) and insert into the Talar Sizer Holder (10203008). Slide tip of Talar Sizer Holder into the selected Talar Sizer until it “clicks.”

7-2 Place the selected Talar Sizer onto the cut surface of the talus. The outline of the Talar Sizer corresponds to the outline of the talar implant component.

TIP: For optimal sizing, the outer surfaces of the Talar Sizer should match the outer edge of the talar bone in both the medial/lateral and anterior/posterior directions.

TIP: If patient anatomy is in between two sizes, select the smaller size.
**Step 8 • Final Talar Bone Preparation**

**8-1 Align sizers**

After choosing the proper size, establish the proper rotational alignment of the selected Talar Sizer (10204085-10204089) by aligning the handle of the Talar Sizer Holder (10203008) with the second metatarsal.

**8-2 Expand the Talar Sizer Holder against the distal tibia to maintain the proper medial/lateral, anterior/posterior, and rotational alignment of the Talar Sizer.**

**8-3 Using fluoroscopy, check the anterior/posterior alignment of the Talar Sizer. Ideally, the radius of curvature of the simulated articular surface of the Talar Sizer should blend smoothly with both the anterior and posterior radius of curvature of the natural talus.**

**TIP:** The point at the top of the triangle containing the saw slot on the Talar Sizer represents the anterior/posterior center. This point can be used as a visual reference for aligning the Talar Sizer with the anterior/posterior center of the distal tibia.

**TIP:** The small slot toward the posterior aspect of the Talar Sizer that can be seen in the lateral view represents the trajectory of the saw slot. This slot can be used to perform a visual assessment of how much of the posterior talus will be removed with the current positioning of the Talar Sizer.
Cut Posterior Chamfer

8-4 Place a Short Shouldered Bone Pin (10204022) and a Straight Bone Pin – Drill Tip (10204025) into the bone pin holes to hold the location.

8-5 Remove the Talar Sizer Holder from the Talar Sizer.

8-6 Place a narrow width saw blade in the saw slot of the Talar Sizer and perform the posterior chamfer resection. A 1.27mm thick saw blade is recommended for this step (SAW6944T, SAW6946T, SAW6948T).
After completing the posterior chamfer resection, re-engage the Talar Sizer Holder with the Talar Sizer and expand again against the distal tibia to maintain the current location of the Talar Sizer.

Remove the Short Shouldered Bone Pin and replace with another Straight Bone Pin – Drill Tip.

Slide the Talar Sizer off over the two Straight Bone Pins – Drill Tip, leaving the bone pins in their current location in the talus.
Align the holes of the Talar Chamfer Cut Guide (10203030) with the two Straight Bone Pins - Drill Tip. Slide into position until the Talar Chamfer Cut Guide comes to rest on the initial flat cut surface of the proximal talus.

**TIP:** If a Size 1 or Size 2 Talar Sizer was chosen the two Straight Bone Pins will align with the two inside holes of the Talar Chamfer Cut Guide. If a Size 3, Size 4, or Size 5 Talar Sizer was chosen the two Straight Bone Pins will align with the two outside holes of the Talar Chamfer Cut Guide.

**Ream anterior chamfer**

Place a Medium Shoulder Bone Pin (10204027) through each of the top holes of the Talar Chamfer Cut Guide. Confirm Talar Chamfer Cut Guide is secured to bone. If additional fixation is needed, Long Shouldered Bone Pins (10204023) may be used.

**TIP:** If it is desired to avoid breaching the subtalar joint, advance each pin into the talus under fluoroscopy until desired depth is obtained.

**WARNING:**

When a Long Shouldered Bone Pin is fully seated through a top Talar Chamfer Cut Guide hole, the pin will breach the posterior facet of the subtalar joint. Breaching the subtalar joint may cause degradation of the joint.

**WARNING:**

If pins are placed through the subtalar joint, do not forcefully manipulate the joint, forcefully manipulating the subtalar joint while pins are in place may cause injury of the subtalar joint articular cartilage.

Remove the two Straight Bone Pins – Drill Tip from the Talar Chamfer Cut Guide.
Place the Talar Chamfer Reamer Guide (10204031) into the Talar Chamfer Cut Guide. Initially, ensure that the “# 1” markings are in the top left and top right hand corners of the Talar Chamfer Reamer Guide.

Place the Talar Reamer (10204057) down through one of the holes in the Talar Chamfer Reamer Guide and ream the anterior surface of the talus. Ensure that the shoulder of the Talar Reamer comes into contact with the face of the Talar Chamfer Reamer Guide to ensure that the anterior surface of the talus is cut to the correct depth. Repeat for all 9 holes in the Talar Chamfer Reamer Guide.

**TIP:** When reaming, secure the Talar Chamfer Reamer Guide by pressing the Talar Chamfer Reamer Guide against the Talar Chamfer Cut Guide.

Alternatively, the Talar Chamfer Reamer Guide may be manually held in place using the Tibial Impactor Adaptor (10204106). With the Tibial Impactor Adaptor attached to the Talar Impactor Handle (10203137), gently apply pressure to one of the reamer guide holes while reaming.

**WARNING:**
When reaming, the trajectory of the Talar Reamer should be perpendicular to the Talar Chamfer Reamer Guide. Reaming off-axis may result in damage to instrumentation and/or incorrect bone resection.

**WARNING:**
Use care when reaming the top medial hole and top lateral hole of the Talar Reamer Guide; do not ream through a hole if the medial malleolus and/or fibula is in the path of the Talar Reamer.

Remove the Talar Chamfer Reamer Guide and rotate 180 degrees, then replace into the Talar Chamfer Cut Guide. The “# 2” markings should be in the top left and top right hand corners of the Talar Chamfer Reamer Guide (10204031).

Repeat step 8-14 for all 9 holes in the Talar Chamfer Reamer Guide.

Remove the Talar Chamfer Reamer Guide from the Talar Chamfer Cut Guide.
Drill Talar Post Holes

8-18 Place the Talar Chamfer Drill Guide (10204033) into the Talar Chamfer Cut Guide (10203030). Ensure that the “TOP/PROXIMAL” and “BOTTOM/DISTAL” markings are oriented properly.

8-19 Place the Post Drill (10204058) down through one of the holes in the Talar Chamfer Drill Guide and drill a talar implant post hole into the talus.

To ensure correct depth, advance the Post Drill until the shoulder of the drill contacts the bottom of the hole in the Talar Chamfer Drill Guide.

Repeat this step for the second hole in the Talar Chamfer Drill Guide.

8-20 Remove the Talar Chamfer Cut Guide, the Talar Chamfer Drill Guide and both bone pins from the talus.

Using osteotomes, rongeurs, or other surgical instruments, remove all resected bone.
**Step 9 • Place Talar Trial**

**9-1** Select the Talar Trial (10205101-10205105 or 10205201-10205205) corresponding to the Talar Sizer (10204085-10204089) chosen in Step 7.

Place the posts of the Talar Trial into the prepared post holes in the talus.

**9-2** Use the Talar Impactor (10203098) to fully seat the Talar Trial.

**Note**
If a Talar Trial is desired to be selected that is different than the Talar Sizer used in Step 7, please refer to the chart below to confirm compatibility.

<table>
<thead>
<tr>
<th>Talar Sizer used for talar bone resection</th>
<th>Talar Trial selected</th>
<th>Interchangability after Talar Bone Resection</th>
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<tr>
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**TIP:** Fluoroscopy may be used to confirm talar chamfers are properly prepared and talar trial is fully seated.
Step 10 • Select Tibial Tray Size

10-1 Select the Tibial Trial (10204270-10204288) corresponding to the lateral pin placed through the Tibial Cut Guide (10203023 or 10203024) during the tibial resection (Step 3-1).
Place the selected Tibial Trial into the joint space and confirm appropriate medial-lateral coverage.

WARNING:
Avoid oversizing; if the Tibial Trial fits snug into the joint space with little to no space to move, consider downsizing one size.

10-2 Use the Tibial Implant Sizer (10204076) to measure the anterior/posterior length of the distal tibia.
With the Tibial Implant Sizer hooked onto the posterior cortex of the distal tibia, determine the line on the Tibial Implant Sizer that most closely approximates the anterior cortex of the distal tibia and read the corresponding tibial implant size.

TIP: The reading from this step can be combined with the medial/lateral width determined from the Tibial Trial range in this tip: Tibial Trial (10204270-10204288) and selected Talar Trial (10205101-10205105 or 10205201-10205205) to choose the best tibial implant size. (Step 9)

TIP: Confirm sizing at multiple sections along the resected tibia. The smallest size of the readings should be chosen to avoid extending the baseplate into the soft tissue.

Use the chart below to aid in choosing the proper tibial implant size.

<table>
<thead>
<tr>
<th>Selected Talar implant size</th>
<th>M/L Width Determined by Tibial Tray Trial</th>
<th>A/P Length Determined from Tibial Implant Sizer</th>
<th>Recommended Tibial Tray Implant size</th>
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Note
“X” sizes have the same ML width as the corresponding standard size but have the same AP length as the next standard size up. Example, Size 1X has the same ML width as Size 1 but the AP length of Size 2.
**Step 11 • Place Tibial Tray Trial w/ Insert Trials**

Select the Tibial Trial (10204270-10204288) corresponding to chosen tibial implant size (Step 10).

Select the Insert Trial (102061XX-102065XX) corresponding in size to the Talar Trial (10205101-10205105 or 10205201-10205205) placed on the talus (Step 9). For example, if a Size 4 Talar Trial was placed on the talus, choose a Size 4 Insert Trial. Initially, choose the 6mm thickness of the Insert Trial for evaluation of joint spacing and kinematics.

Slide the Insert Trial into the dovetail of the Tibial Trial.

**TIP:** The Insert Trials are reversible and can be used as either a right-hand or left-hand Insert Trial. When selecting a right-hand Insert Trial, the “RIGHT” and “R” markings should be facing in the anterior direction. When selecting a left-hand Insert Trial, the “LEFT” and “L” markings should be facing in the anterior direction.

**TIP:** Use of the Joint Distractor (119.653ND) may be necessary to place Insert Trials.

Place one tip of the Joint Distractor on the tibia and one on the talus. Place one Long, Shouldered Bone Pin (10204023) through each of the tips and into the bone. Then, expand the Joint Distractor to open the joint space.

**Biased Inserts**

**TIP:** The Integra Cadence® Total Ankle System also features Anterior Biased Insert and Posterior Biased Insert implants to provide additional joint constraint/support on patients with either an anterior or posterior subluxed talus.

If it is determined through a lateral, fluoroscopic evaluation of the implant trials that the patient may benefit from the use of an Anterior or Posterior Biased Insert implant, the Biased Insert Trial Extensions (10205001-10205005) can be used to evaluate their benefit and make a final determination if biased insert implants should be used.

Choose the Biased Insert Trial Extension corresponding in size to the chosen Insert Trial.

**TIP:** The Biased Insert Trial Extension will be the same color as the insert trial.

Push the post of the Biased Insert Trial Extension into the threaded hole in the center of the Insert Trial until the mating surfaces of the two components are flush.

The Biased Insert Trial Extension should be placed on the anterior surface of the Insert Trial for simulation of an Anterior Biased Insert implant. Conversely, the Biased Insert Trial Extension should be placed on the posterior surface of the Insert Trial (102061XX-102065XX) for simulation of a Posterior Biased Insert implant.
Place the Tibial Trial and Insert Trial assembly into position on the distal tibia. Mate the articular surface of the Insert Trial with the articular surface of the Talar Trial (10205101-10205105 or 10205201-10205205).

A mallet may be necessary to seat the Tibial Trial and Insert Trial assembly.

Perform a dynamic flexion/extension test on the foot to check the joint’s kinematics and to evaluate joint tension. The Tibial Trial will find its optimal position in the frontal, sagittal, and rotational planes.

**TIP:** If the joint is found to be too loose during this evaluation, remove the Tibial Trial and Insert Trial assembly and replace the Insert Trial with incrementally thicker trials until optimal joint kinematics and tension are achieved.

**Note**

Insert Trials are offered in 6-12mm thicknesses in 1mm increments.

Verify that the Tibial Trial is placed properly on the resected tibia and that the Talar Trial is placed properly on the resected talus.

Verify the following visually or under fluoroscopy:

(A) The anterior aspect of the Tibial Trial is flush against the anterior cortex of the distal tibia.

(B) Posterior aspect of the Tibial Trial extends to but not past the posterior cortex of the distal tibia.

(C) Proximal surface of the Tibial Trial is sitting flush across the entire distal surface of the tibia.

(D) Chamfered surfaces of the Talar Trial are sitting flush with the resected chamfered surfaces of the proximal talus.
Step 12 • Final Tibial Bone Preparation

12-1 After confirming proper placement of the Tibial Trial (10204270-10204288), place two Short Shouldered Bone Pins (10204022) through the two bone pin holes in the anterior face of the Tibial Trial to maintain its position.

12-2 Place either the Post Drill (10204058) or the Flex Shaft Drill (10203020) up through one of the holes in the tibial trial. Drill a tibial implant post hole into the tibia. Ensure that the shoulder of the implant Post Drill or Flex Shaft Drill comes into contact with the face of the Tibial Trial to ensure that the post hole is drilled to the correct depth. Repeat for the second hole in the Tibial Trial.

12-3 Remove the two Short Shouldered Bone Pins, the Tibial Trial and the Insert Trial (102061XX-102065XX).

Step 13 • Secure Tibial Tray

13-1 Remove the Talar Trial (10205101-10205105 or 10205201-10205205) from the talus.

**TIP:** The Tibial Impactor Handle (10203137) can be used for this step. Simply screw the threaded end of the Tibial Impactor Handle into the threaded hole on the anterior aspect of the talar trial until the talar trial is lifted off of the talus.

13-2 Select and open the Tibial Tray implant (10207XXX) corresponding in size to the Tibial Trial (Step 11).

Apply bone cement to the flat, titanium plasma sprayed surface of the Tibial Tray. Do not apply bone cement to the posts or the posterior wedge.
Thread the Tibial Impactor Handle into the black-tipped 45° Tibial Impactor Tip (10203102). Slide the dovetail feature of the black-tipped 45° Tibial Impactor Tip into the dovetail of the Tibial Tray until it “clicks” to fully engage the Tibial Tray.

The Tibial Impactor Stop (10203108) may be attached to the black-tipped 45° Tibial Impactor Tip to facilitate implant placement and prevent over-insertion.
1. Gently engage the anterior peg tips of the Tibial Tray into the prepared peg holes.

2. Ensure implant is parallel to the tibial cut, confirm with fluoroscopy. Gently tap the Tibial Impactor Handle, while keeping the Tibial Tray parallel to tibial cut, until the posterior wedge of the Tibial Tray engages into the bone.

3. Continue impacting, under observation of fluoroscopy, until the implant is fully seated.

**TIP:** If needed, the Gap Sizer may be used to complete insertion. Insert the Gap Sizer at an angle and press or gently impact on the posterior end of the Tibial Tray until fully seated. Confirm with fluoroscopy.

**WARNING:**
Do not impact the Tibial Impactor Handle unless the Tibial Tray is parallel to the resected tibia.

Impaction of Tibial Tray while in angular alignment relative to the resected tibia may result in posterior tibial fractures and/or reduced fixation.

**WARNING:**
Avoid excessive impaction of the Tibial Tray to minimize risk of over insertion.

Impact only until the anterior portion of the tibial tray is aligned with the anterior tibia. If the Tibial Impactor Stop is used, impact only until the stop tabs contact the anterior tibia. Ensure that the Tibial Impactor Stop is not contacting any other tissue and remains aligned to the anterior of the Tibial Tray.
TIP: Plantar flex the foot as necessary to achieve proper positioning of the Tibial Tray, prior to impaction. If proper positioning cannot be achieved with the black-tipped 45° Tibial Impactor Tip (10203102), the green-tipped Tibial Impactor Tip (10203101) can also be used; perform steps 13-3 and 13-4 using the green-tipped Tibial Impactor Tip in place of the black-tipped 45° Tibial Impactor Tip.

13-4a TIP: If the foot cannot be plantar flexed to the extent necessary to achieve the proper vector while using the black-tipped 45° Tibial Impactor Tip or the green-tipped Tibial Impactor Tip, the system has an option that will allow for impaction on both the medial and lateral sides of the foot.

i. Unscrew the Tibial Impactor Handle from the green-tipped Tibial Impactor Tip.

ii. Screw the Tibial Impactor Handle into the Tibial Impactor Adaptor.

iii. Place the tip of the Tibial Impactor Adaptor into the socket on the anterior aspect of the green-tipped Tibial Impactor Tip.

iv. Swivel the Tibial Impactor Handle and Tibial Impactor Adaptor assembly back and forth from the medial to the lateral side of the foot while tapping the Tibial Impactor Handle 2 to 3 times lightly with a mallet on each side.

Repeat alternating impactions between the medial and lateral side of the foot until the Tibial Tray seats fully on the distal tibia.
Step 14 • Secure Talar Dome

14-1 Insert the dovetail feature of the Implant Protector (10204305 or 10204306) fully into the dovetail of the Tibial Tray (10207XXX) such that the Implant Protector covers the entire distal face of the Tibial Tray implant. This will serve to protect both the Tibial Tray and Talar Dome (10208XXX) implants from damage while placing the Talar Dome.

14-2 Select and open the Talar Dome implant corresponding in size to the Talar Trial (10205XXX) from step 9.

Apply bone cement to the flat, titanium plasma sprayed surfaces of the Talar Dome. Do not apply bone cement to the posts.

14-3 Place the posts of the Talar Dome implant into the post holes prepared in the anterior chamfer of the talus.

14-4 Use the Talar Impactor (10203098) to fully seat the Talar Dome implant.

**TIP:** Rotate the Talar Impactor to selectively apply posterior impaction and anterior impaction to ensure full seating of the Talar Dome implant.
Step 15 • Secure Insert

15-1 Remove the Implant Protector (10204305 or 10204306) from the Tibial Tray implant (10207XXX).

15-2 Prepare the Insert Inserter (10203007) by sliding the top portion of the instrument forward until it is flush with the etched line corresponding to the selected Insert Trial (102061XX-102065XX) size.

15-3 Select and open the Insert implant (10209XXX) corresponding in size and thickness to the Insert Trial (102061XX-102065XX) chosen in previous steps.

Slide the anterior portion of the dovetail feature of the Insert implant into the dovetail of the Insert Inserter.

**TIP**: The locking tab feature of the Insert implant faces anterior; the locking tab feature of the Insert implant is loaded into the Insert Inserter.

After the Insert implant is placed on the Insert Inserter, recheck etching corresponds to selected size.

15-4 Place the exposed posterior portion of the dovetail feature of the Insert implant into the dovetail of the Tibial Tray implant. The tip of the Insert Inserter should contact the anterior face of the Tibial Tray implant.

Push the Insert implant into the Tibial Tray implant as far as possible manually.

**TIP**: Use of the Joint Distractor (119.653ND) may be necessary to place a posterior biased insert implant.

Place one tip of the Joint Distractor on the tibia and one on the talus. Place one Long, Shouldered Bone Pin (10204023) through each of the tips and into the bone. Then, expand the Joint Distractor to open the joint spacing.
Using a mallet, gently impact the handle of the Insert Inserter until the Insert implant is seated fully in the Tibial Tray implant. An audible click can be heard when the Insert implant is fully seated.

**WARNING:**
Prior to impaction, ensure that the exposed posterior portion of the dovetail feature of the Insert implant is engaged into the Tibial Tray implant. If the posterior portion of the dovetail feature is not engaged, impaction may prevent proper securing of the insert.

**Step 16 • Verify Final Implant**

16-1 Under a lateral fluoroscopic view, verify the following:

(A) Proximal surface of the tibial implant is sitting flush across the entire distal surface of the tibia.

(B) Posterior aspect of the tibial implant extends to but not past the posterior cortex of the tibia.

(C) Chamfered surfaces of the talar implant are sitting flush with the resected chamfered surfaces of the talus.

16-2 Visually verify the tibial, talar, and insert implants are seated properly:

(D) Anterior aspect of the tibial implant is flush against the anterior cortex of the tibial.

(E) Insert implant is seated fully in the tibial implant and there is no gap between the anterior surfaces of the two implants.

16-3 Perform a dynamic flexion/extension test on the foot to check the joint’s kinematics and to evaluate joint tension.
Implant Removal

The following techniques may be used to remove specific implant components (Insert, Talar Dome, or Tibial Tray) of the Integra Cadence Total Ankle System.

Use any power (i.e. sagittal saw, reciprocating saw) and general instruments (i.e. osteotomes, rongeurs) necessary around implanted components to loosen bone-cement interface and/or facilitate removal.

Insert Removal

The insert may be removed through one of two ways:

1. Place an osteotome into the anterior slot on the Insert and twist to separate the insert from the tray.

2. Thread the 5.0mm DIA Bone Pin (10204191) into the anterior hole of the Insert. Attach the Screwdriver Handle (10204145) to the 5.0mm DIA Bone Pin, then pull straight back to remove the Insert.

WARNING:
When the 5.0mm DIA Bone Pin is threaded into the Insert, do not lever the Bone Pin in a cranial-caudal direction during Insert removal. Levering the Bone Pin during this step may cause damage or breakage to the instrument.

Tibial Tray Removal

Thread the Tibial Impactor Handle (10203137) into the green-tipped Tibial Impactor Tip (10203101). Slide the dovetail feature of the green-tipped Tibial Impactor Tip into the dovetail of the Tibial Tray implant until it “clicks” and engages the Tibial Tray.

Pull the Tibial Impactor Handle to remove the implant.

TIP: A U-joint (10203196) may be attached to the Tibial Impactor Handle for improved access during extraction.

WARNING:
Do not use the Slap Hammer for extraction of the tibial tray; using the Slap Hammer may result in damaged instrumentation and delayed removal of components.
Talar Dome Removal

Using the Talar Implant Extractor (10203028), grasp the Talar Dome Implant along the medial-lateral edges. Once the Talar Dome implant is engaged on to the Talar Implant Extractor, pull on the Talar Implant Extractor away from the implant site.

TIP: The Slap Hammer (10203194) may also be used during removal of the Talar Dome.

Thread the rod end of the Slap Hammer into the Talar Implant Extractor. Impact the Slap Hammer until the Talar implant becomes dislodged.
### Instruments

<table>
<thead>
<tr>
<th>Reference</th>
<th>Description</th>
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<td>Proximal Tibial Clamp</td>
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**Reference** | **Description**
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CSA-1020-0011 | Case for Resection Instruments
CSA-1020-0012 | Case for Trials, Insertion and Removal Instruments
CSA-1020-0015 | Module for Pins, Drivers and Accessories
CSA-000-14 | Instrument Tray Lid
# Tibial Tray, Talar Dome and Neutral (N) Insert Implants

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46
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Cadence Total Ankle System – Implant Compatibility Chart

Tibial Tray

Insert

Talar Dome

Talar Dome Dimensions

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### Instrument Case, Bone Resection Instruments

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### Pins and Accessories Module

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## Instrument Case – Trials, Insertion, and Removal Instruments

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### Saw Blades

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![Saw Blades Diagram](attachment://saw_blades_diagram.png)
Availability of these products might vary from a given country or region to another, as a result of specific local regulatory approval or clearance requirements for sale in such country or region.

- Always refer to the appropriate instructions for use for complete clinical instructions.
- Non contractual document. The manufacturer reserves the right, without prior notice, to modify the products in order to improve their quality.
- Warning: Applicable laws restrict these products to sale by or on the order of a physician.

For more information or to place an order, please contact:

**United States, Canada, Asia, Pacific, Latin America**

USA 800-654-2873 • 888-980-7742 fax
International +1 609-936-5400 • +1 609-750-4259 fax
[integralife.com/contact](mailto:integralife.com/contact)

**Manufacturer:**

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Austin, TX 78758 • USA

Integra LifeSciences Services (France) SAS
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Parc technologique de la Porte des Alpes
69800 Saint Priest • France