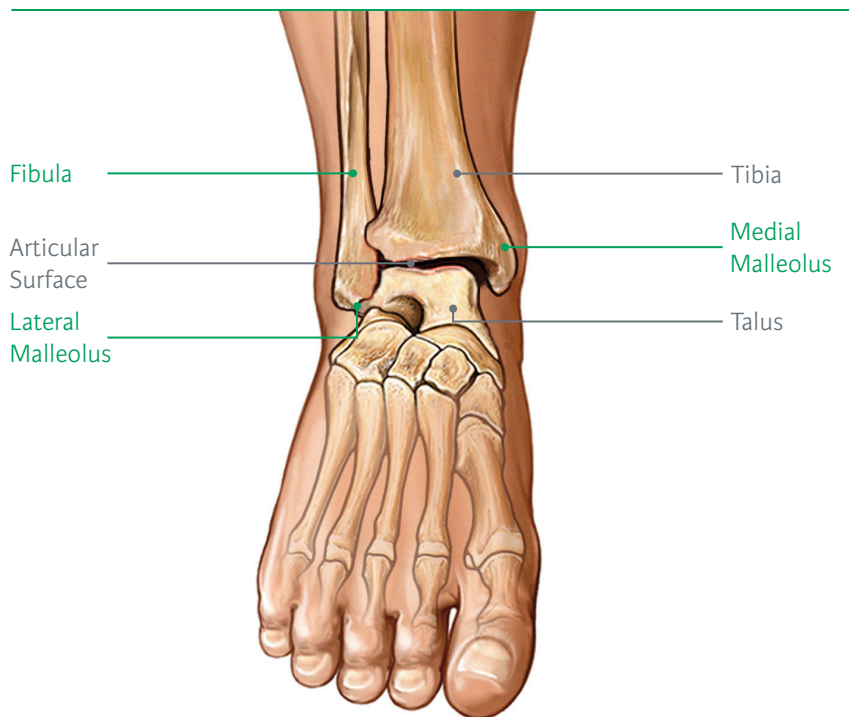


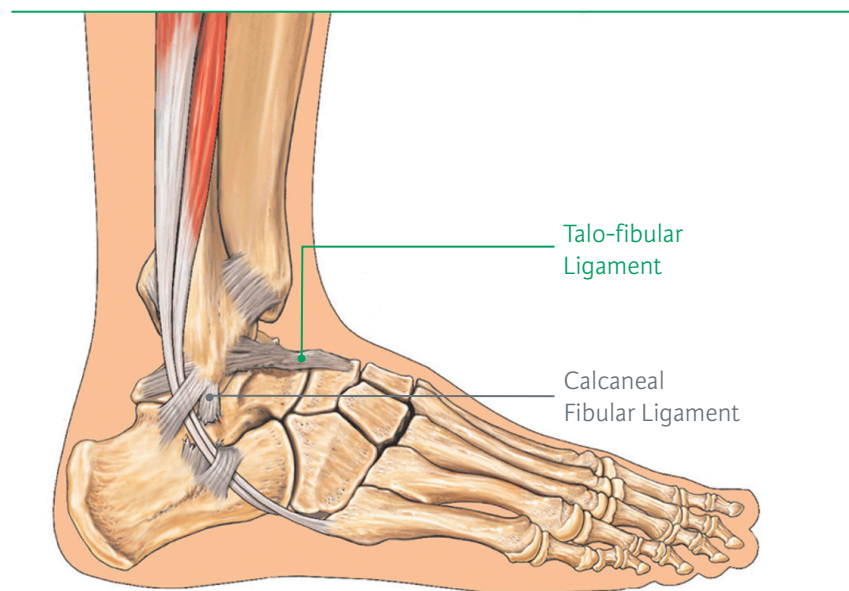
Integra®
Cadence®
Total Ankle System

PATIENT
INFORMATION





Anterior view of the right ankle region



Lateral (side) view of the right lower leg

Ankle Overview

The ankle joint is located at the junction of the leg and the foot. It is made up of three bones: the tibia, the fibula and the talus. The ankle joint allows the foot to dorsiflex (point the foot up) and plantarflex (point the foot down).

Ligaments (strong fibrous bands of tissue that connect two bones) are located on each side of the ankle joint to create stability in the joint. Tendons (strong fibrous structures that connect muscle to bone) are located throughout the foot to allow for motion in the other parts of the foot such as the movement of the toes.

Cartilage is the specialized joint tissue that covers bones and allows the bones to move in relationship to each other with minimal friction. Loss of the cartilage can decrease joint function and produce pain, stiffness, swelling and warmth.

Why Live with Chronic Ankle Arthritis Pain?

Ankle replacement (also called ankle arthroplasty) can offer new hope for patients suffering from chronic ankle pain due to arthritis. Ankle replacement is a fast growing type of joint replacement.

Arthritis is a joint condition of damaged cartilage and/or bone which causes the bones to grind on each other with movement, thus causing pain and inflammation. Ankle arthritis is the progressive loss of the smooth gliding surface that lines the ends of the bones that form the ankle. This produces pain, stiffness, swelling and warmth at the joint. These detrimental effects lead to reduced comfort and endurance for standing and walking activities.

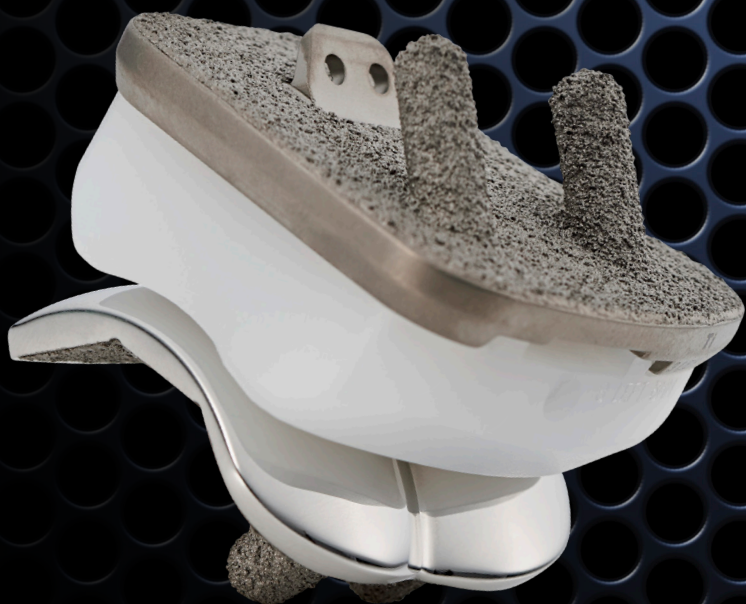
Common Types of Arthritis

Common types of arthritis affecting the ankle joint are: osteoarthritis (degenerative), rheumatoid arthritis (inflammatory), and post traumatic arthritis.

The most common is osteoarthritis, which is a degenerative joint disease. With osteoarthritis, the cartilage that covers the ends of the bones in the joint deteriorates. Cartilage becomes thin and eventually wears out, causing bones in the ankle joint to rub together. This results in pain and the loss of movement in the joint. When pain and lack of mobility reaches an advanced stage, ankle replacement may be recommended.

Rheumatoid arthritis, an autoimmune disease in which the joint lining becomes inflamed as part of the body's immune system activity. Rheumatoid arthritis is one of the most serious and disabling types, affecting mostly women.

Another type of arthritis is post traumatic arthritis, often related to sport, car accident or recurring injuries.



Treatment Options

One solution for ankle arthritis is an Ankle Replacement. The Cadence® Total Ankle System is modeled after the human anatomy and is designed to reproduce the natural movement of the ankle.

Compared to Cylindrical ankle replacement implants available in the US, the Cadence Total Ankle System more closely respects the natural anatomy of the ankle and will theoretically avoid overstressing of the ankle ligaments.*

What Does It Involve?

Ankle replacement surgery is done through a succession of carefully coordinated steps:

- The surgeon makes an incision through the skin on the front of the ankle and top of the foot.
- Next, the surgeon will make resurfacing bone cuts on the tibia and talus to remove the remaining worn off cartilage and make room for the implant.
- Once the tibia and talus are prepared, the final implants are placed in the joint and the ankle replacement is complete.
- Additional procedures may be performed at the same time as necessary. The surgeon then closes the incision and places the foot in a splint.

Have Questions?

Your physician will be able to answer questions specific to your situation. The following information is for reference only and is not meant to provide a diagnosis of your condition.

What is Ankle Arthritis?

Ankle arthritis is the progressive loss of the smooth gliding cartilage that lines the ends of the bones that form the ankle. This produces pain, stiffness, swelling and warmth at the joint. These detrimental effects lead to reduced comfort and endurance for standing and walking activities. Ankle arthritis can be as a debilitating disease as end-stage hip / knee arthritis.

What is Ankle Replacement?

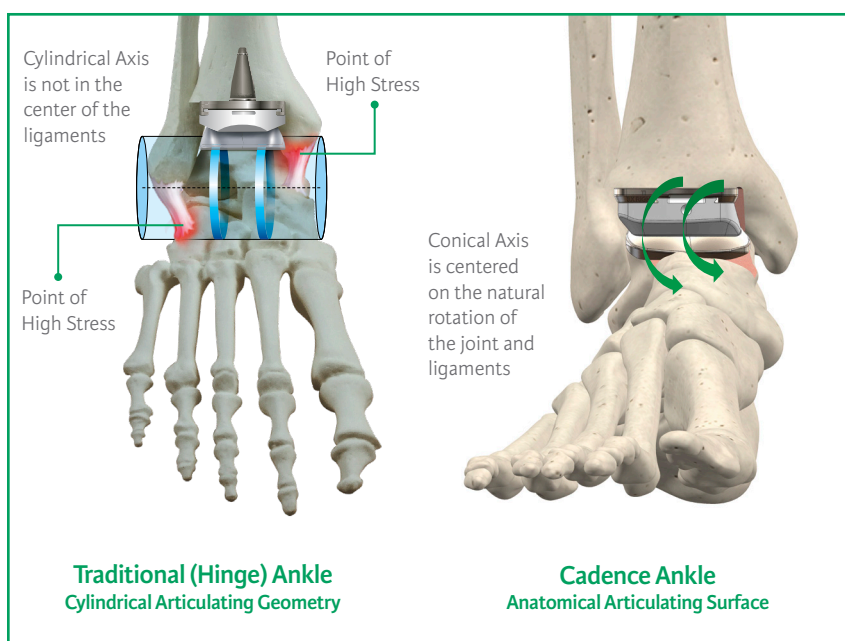
Ankle replacement is the surgical procedure used to expose the ankle joint, remove the diseased cartilage and bone and insert a metal and plastic prosthesis that reduces pain while maintaining ankle motion.

Am I a Candidate for Ankle Replacement?

Only your surgeon can determine this. In general, healthy patients with painful and disabling ankle arthritis that has failed to improve with non-surgical treatment are candidates for ankle replacement. Patients must have adequate skin coverage over the ankle, be infection-free both at the ankle and elsewhere, have normal sensation and muscle control of the foot and ankle. The ideal candidates are also older, have same side foot arthritis or opposite side ankle arthritis. A surgeon specialized in foot and ankle surgery can best evaluate your condition and determine if an ankle replacement is right for you.

*Data on file with Integra

The Cadence ankle replacement has an anatomic shaped articulating surface, and allows for natural motions of the deltoid and lateral ligaments.



The Cadence Total Ankle System is designed to restore the natural ankle motion of the ankle by recreating the conical axis of motion. This is not available with every ankle prosthesis. There are differences in ankle implants. The Cadence ankle system anatomically matches the bone resection to cover the resected tibial surface.

The Cadence Ankle Replacement System also offers a Highly Cross Linked Polyethylene which has been proven to offer better wear characteristics over time when compared to conventional PE¹. Also, Cadence offers anterior and posterior inserts allowing for a customizable PE insert giving the surgeon the ability to manage intraoperative sagittal alignment.

¹ World J Orthop. 2011 Oct 18;2(10):93-101. doi: 10.5312/wjo.v2.i10.93.
Role of polyethylene particles in peri-prosthetic osteolysis: A review.
Atkins GJ1, Haynes DR, Howie DW, Findlay DM.

What is the Cadence Ankle Replacement Implant?

The Cadence Ankle Replacement Device is an advancement over current implants. It is designed to minimize talar resection and maximize bone to implant coverage to match each patients anatomic needs.



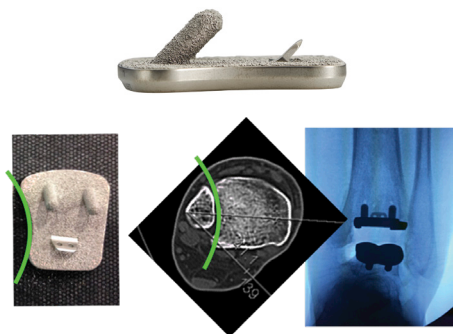
Talar Component

- Minimal Talar Bone resection
- Anatomic shaped implants; replicates natural ankle kinematics
- Material: Cobalt Chrome Alloy (CoCrMo)



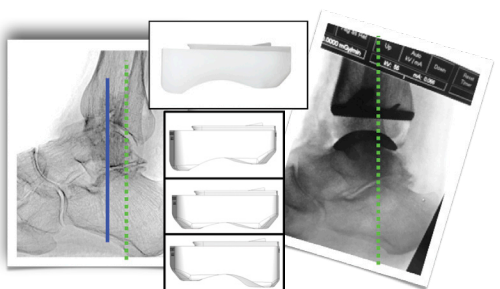
Tibial Component

- Anatomic Tibia Coverage for the entire resected are of the tibia
- Maximize Tibial Fixation
- Material: Titanium Alloy (Ti-6Al-4V ELI)



Polyethylene Inserts

- Made from Highly Crosslinked HMWPE
- Three types of PE Inserts to match patient needs
- Material: Highly cross-linked Ultra High Molecular Weight Polyethylene (UHMWPE)



Will Insurance Cover It?

Ankle replacement surgery is generally covered by Medicare and Medicaid as well as most private insurance companies. Your surgeon's office will contact your insurance provider to determine coverage under your specific plan.

What is the Ankle Device Made Of?

There are several components that make up the ankle replacement device. All of the parts are made from highly biocompatible materials, including titanium and cobalt chrome metals on the tibial and talus sides of the joint. Between those two components, a third component made of a biocompatible plastic called polyethylene is attached to the tibial component to help the components glide against each other. These are identical materials to those used in hip and knee replacements. All of the materials have a long and successful track record for use in human joint replacements.

How Soon Can I Return to Normal Activities After Surgery and Will I Have Any Restrictions?

Most people are able to return to normal everyday activities such as dressing themselves and grooming within the first 2 weeks after successful ankle replacement surgery. Your ambulation will be restricted for approximately 6-8 weeks (or until cleared by your surgeon) until you start your rehabilitation therapy. Your doctor will advise you on specific limitations, including the amount of walking you can do on the ankle that was operated on. Many surgeons restrict their patient's ambulation for a period of time. Your doctor will also let you know when you can begin ambulating more freely, and when you can return to other activities. Contact sports may be restricted in the long term.

How Long Until I Can Drive?

You must be off all pain medication before you consider returning to driving. Consult with your surgeon on their individual recommendation.

When Can I Return to Work?

The decision to return to work is individualized and is influenced by your job, your employer and your post-operative course. In most circumstances, patients can return to office work in about 2-3 weeks if accommodations are made for transportation, parking, office access, rest and foot elevation. Patients that perform physical work may return to work once they recover endurance for standing and walking, this is at least three to four months after surgery.

How Long Until I Regain Full Use of My Ankle?

The recovery of full ankle function may take as much as 12 months, provided you followed the recommended physical therapy regimen. Most improvements are maximized by six months after surgery and residual swelling generally persists for 6 to 12 months.

Before and After Surgery

Ankle replacement can help reduce chronic ankle pain and can allow you to regain range of motion. It may help you return to normal daily activities.

What To Expect

Ankle replacement surgery is performed in the hospital by an experienced, specialized surgical team. The procedure generally takes about 2-3 hours, and a hospital stay of approximately 1-3 days can be expected.

Most people are able to return to normal everyday activities such as dressing themselves and grooming within the first two weeks after successful ankle replacement surgery. Your physician will let you know when it is safe to drive and perform other tasks.

Recovery may take as much as 12 months with the majority of motion improvements generally occurring in the first 6 months, even though benefits may continue to occur for as much as 12 months.

As with any surgery, success will depend on your age, activity level and other factors. Your doctor will determine if you are a good candidate for ankle replacement surgery, and can help you understand what to expect from the procedure and your recovery.





What You Need To Know

Before Surgery:

If you are considering ankle replacement surgery, you probably have many questions about preparing for surgery, the surgical procedure, the recovery, and your long-term outcome. You should consult with your foot and ankle specialist about what to expect before and after surgery based on your specific condition.

After Surgery:

The hospital stay is generally 0-3 days and you will go home with the leg in a splint or cast. A physical therapist will guide you through the exercises you can do at home.

Activity At Home

Everyone's progress is different after this surgery. Follow all specific instructions from your surgeon, nurse and physical therapist. The following guidelines may be of benefit.

- Use crutches, wheel chair, scooter, etc. as directed. It will avoid bearing any weight on your implant and allow the soft tissues to heal and regain normal strength.
- No standing on your leg until given permission by the surgeon. This is important to maximize the healing process of your ankle.
- Increase your activity only as your surgeon has directed.

Follow-up Appointments

- Your surgeon will have you return for a follow-up examination to be sure your ankle is healing properly. This is usually within two weeks of your surgery. An appointment can be set for you at the time of your preoperative visit.
- At the time of the appointment, x-rays may be obtained.
- Following the initial appointment, you may need to be seen approximately 6 weeks postoperatively, then again at 12 weeks postoperatively. If everything is going well at that point, then you may be asked to follow-up at 6 months and then on a yearly basis to obtain an x-ray and make sure all of the components are working properly.

Alert Future Physicians and Dentists

- You must always protect this new part of your body from infection. Expect to take an antibiotic before and after any invasive procedure to help protect the new joint from the possibility of infection.
- Always notify your physicians and dentists that you have an ankle replacement. You may need to take antibiotics before dental work, surgery or other medical procedures.

For more information or to place an order, please contact:
Integra ▪ 311 Enterprise Drive, Plainsboro, NJ 08536
877-444-1122 USA ▪ 609-936-5400 outside USA ▪ 866-800-7742 fax
integralife.com

Manufacturer:



Ascension Orthopedics, Inc.
11101 Metric Blvd
Austin, TX 78758 ▪ USA