Understanding & Treating

ANKLE ARTHRITIS...

APEX 3D™
TOTAL ANKLE REPLACEMENT

RESEARCH DRIVEN.
SOLUTION FOCUSED.

Exclusively foot & ankle
Paragon 28®

APEX 3D™

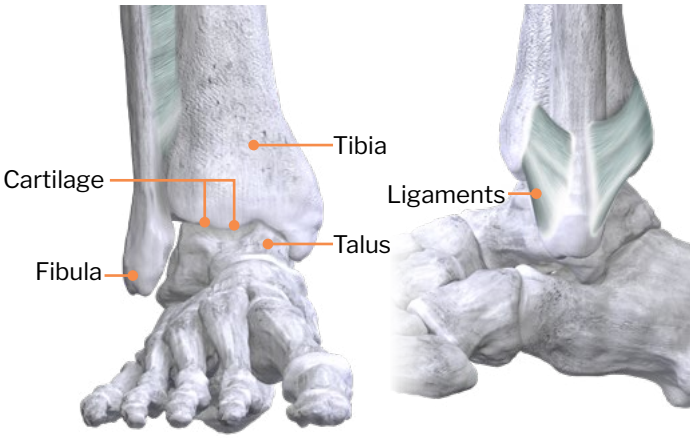
CONTENTS

In general, healthy patients with painful and disabling ankle arthritis that have failed to improve with non-surgical treatment options are considered candidates for ankle replacement. Only your surgeon can determine this. Consult with your doctor regarding your lifestyle and health to find out if surgery with the APEX 3D System is a good option for you. Individual results and activity levels after surgery vary and depend on many factors including age, weight, and prior activity levels. The following information is for reference only and is not meant to provide a diagnosis of your condition.

ANKLE ANATOMY

The ankle joint is a flexible, free-moving joint made up of three bones: the tibia, the fibula, and the talus. The ankle joint allows the foot to point up, point down, and move side-to-side.

Full function of the ankle joint depends on the successful coordination of many interrelated parts including bones, cartilage, muscles, ligaments, tendons, synovial fluids, and nerves.



Cartilage is the specialized smooth-gliding, shock-absorbing joint tissue that covers bones and allows them to move in relation to each other with ease.

Ligaments are strong bands of tissue that connect bones to each other. They are located on each side of the ankle joint to create stability.

Tendons* are strong bands of tissue that connect muscle to bone and allow for motion.

Synovial Fluid* is a clear, smooth, oil-like lubricating liquid that makes it easier for the joints to move.

*Not Pictured

ANKLE ARTHRITIS

Ankle Arthritis is a common and progressive joint disorder caused by aging, trauma, and/or the body's own immune system that can significantly impact joint mobility.

In some cases, the cartilage has worn down, resulting in bone-on-bone contact, causing pain and limiting activity.

Symptoms May Include:

- Reduced comfort
- Problems standing and walking due to pain
- Inflammation, swelling, and stiffness
- Decreased joint mobility

Chronic Ankle Pain

Chronic ankle pain due to arthritis can be debilitating, limiting your daily activities, keeping you from doing the things you love and interfering with your overall quality of life.

COMMON TYPES OF ARTHRITIS

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

When pain and lack of mobility reaches an advanced stage, ankle replacement may be recommended. Speak with your doctor about what treatment options might be best for you.

Primary Osteoarthritis is considered a degenerative joint disease that develops due to aging and general wear and tear on the joint. With osteoarthritis, the cartilage becomes thin and eventually wears down causing bone on bone contact. This results in pain and the loss of movement in the joint.

Post Traumatic Arthritis is the most common type of osteoarthritis impacting the ankle joint. It affects millions of people in the U.S. and develops after a sudden or recurring injury to a foot or ankle joint, such as a fracture, dislocation or any other type of physical injury. Trauma can cause damage to the joint cartilage and start to break it down as a result. Arthritic symptoms may not begin to appear until 2-5 years after an injury to the joint.

Rheumatoid Arthritis is one of the most serious and disabling types, affecting mostly women in which the person's own immune system attacks the synovial lining of the joints. As a result, the joint lining becomes inflamed.

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If you're suffering from Chronic Pain and have been diagnosed with ankle arthritis, you may be a candidate for an innovative treatment option.

One Solution... for ankle arthritis is an ankle replacement surgery. Ankle replacement is a fast-growing effective surgical procedure used to remove the diseased cartilage and bone, then replace the joint with implants to reduce pain and restore motion.

WHAT DOES IT INVOLVE?

Ankle replacement surgery is done through a series 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 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 or other protective device.

HAVE QUESTIONS?

Your physician will be able to answer questions specific to your situation.

When considering surgery, most patients are concerned with the following:

- How long will I be in pain?
- How long before I return to normal activity?
- Will I have a big scar?
- Will I have limitations?

Meet the

APEX 3D™ TOTAL ANKLE REPLACEMENT SYSTEM

from Paragon 28®

3

Three anatomically contoured implant components designed to

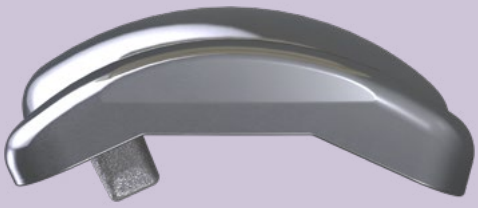
help reduce persistent pain and restore natural motion.

APEX 3D™ Printed Tibial Implant

The 3D printed low-profile implant covers the bottom of the tibia to provide a stable platform. The tibial implant is attached to your tibia with bone cement to ensure a secure fit.

APEX 3D Vitamin E Insert

The Vitamin E highly cross-linked polyethylene insert is connected to the tibial implant. The bottom portion of the insert glides over the top surface of the talar implant.



APEX 3D Anatomic Talar Implant

The talar implant replaces the top surface of the talus. The talar implant is designed to provide a stable footprint and help mimic natural motion. The talar implant is attached to your talus with bone cement to ensure a secure fit.

APEX 3D™ Low-profile Fully 3D Printed Tibial Implant *(Material: Titanium Alloy)*

Vitamin E Polyethylene Insert Allows for Smooth Anatomic Gliding

Anatomically Contoured Talar Implant Designed to Mimic Natural Motion *(Material: Cobalt Chrome Alloy)*

What is the APEX 3D Total Ankle Replacement System?

The APEX 3D System...

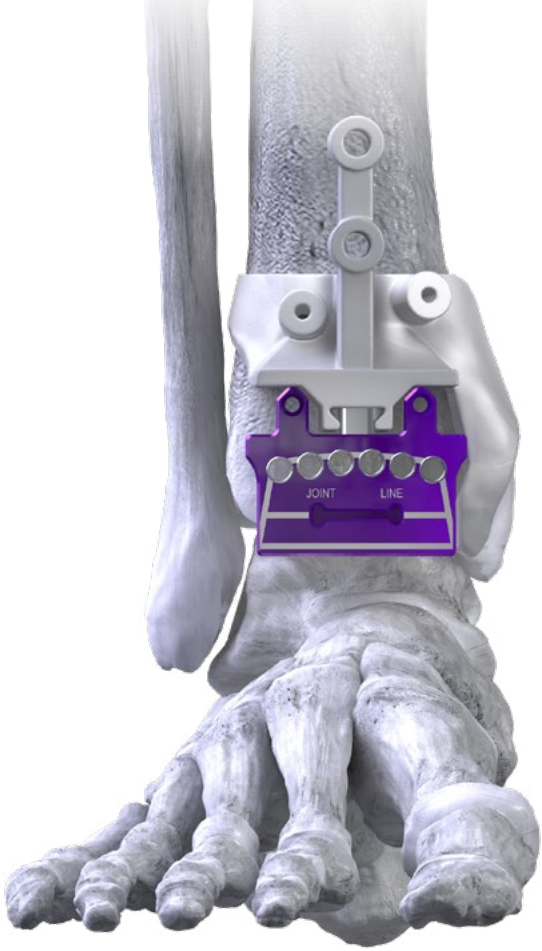
- Is modeled after healthy anatomy
- Is designed to reproduce the natural movement of the ankle
- Marks the next generation in total ankle joint replacement systems
- Features more implant size options to match your anatomy than any other ankle product offering on the market

APEX 3D™ SYSTEM

The APEX 3D System is based on over a century of combined clinical experience, cutting-edge research, and extensive R&D testing.

Just for you...

PATIENT-SPECIFIC SURGICAL PLANNING



MAVEN™

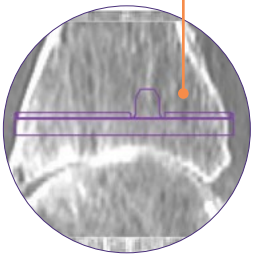
PATIENT SPECIFIC SURGERY

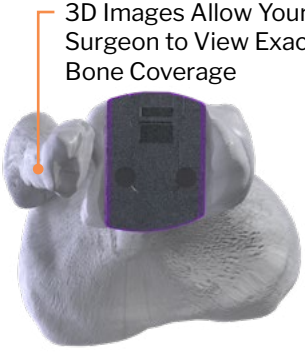
Enhanced Decision Making.

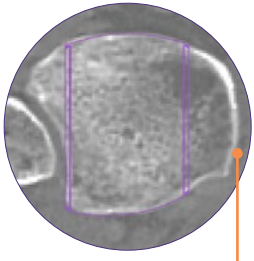
How it Works: MAVEN™ Patient-Specific Technology

- Your surgeon schedules a CT scan of your leg before surgery
- The CT scan is used to create 3D printed instruments and bone models, specific to your ankle anatomy
- The instruments are designed to help your surgeon establish accurate implant size selection and placement
- The bone model allows your surgeon to view your anatomy before surgery

Visit www.apexankle.com for more information







AM I A CANDIDATE FOR ANKLE REPLACEMENT?

Not everyone is a good candidate for the APEX 3D™ Total Ankle Replacement System. Talk to your doctor to discuss your lifestyle and health to find out if surgery with the APEX 3D System is a good option for you. Individual results and activity levels after surgery vary and depend on many factors including age, weight, and prior activity levels.

Only your surgeon can determine this. In general, patients with painful and disabling ankle arthritis that have failed to improve with non-surgical treatment are considered candidates for ankle replacement.

Patients must have adequate skin coverage over the ankle, be infection-free both at the ankle and elsewhere, as well as normal sensation and muscle control of the foot and ankle.

A surgeon specialized in foot and ankle surgery can best evaluate your condition and determine if an ankle replacement is right for you.

Prior to use of this system, your surgeon should refer to the product instructions for use package insert for warnings, precautions, indications, contraindications, and adverse effects.

For more information, please review product "Indications for Use" at **www.paragon28/ifus/**.

WHAT ARE THE ALTERNATIVES?

There are both **surgical** and **non-surgical** alternatives to ankle replacement surgery. First line treatments for arthritis of the ankle are non-surgical methods.

Several of the non-surgical methods provide relief by decreasing the irritation of the arthritic joint.

One such method is the use of **shoe inserts (orthotics)**, such as pads and arch supports.

The use of an **ankle brace or a cane** can also help to take pressure and stress off the arthritic joint.

An ankle-foot orthrosis (AFO), or a **custom-made shoe** with a stiff sole and a rocker bottom, can also work by decreasing motion through the ankle joint.

Direct injection of medication into the arthritic joint can give up to several months of pain relief.

It is important to note that weight control is also an important method of decreasing the stress on the ankle. Although none of these treatments can reverse or cure the damaged cartilage, they can provide improved function with decreased pain.

If the non-surgical treatments don't adequately reduce your pain, surgical options can be pursued. The specific surgery, decided by your doctor, that is right for you depends on the extent and pattern of cartilage damage and level of pain associated with the ankle.

ALTERNATIVES CONT.

Alternative surgical options to ankle replacement include:

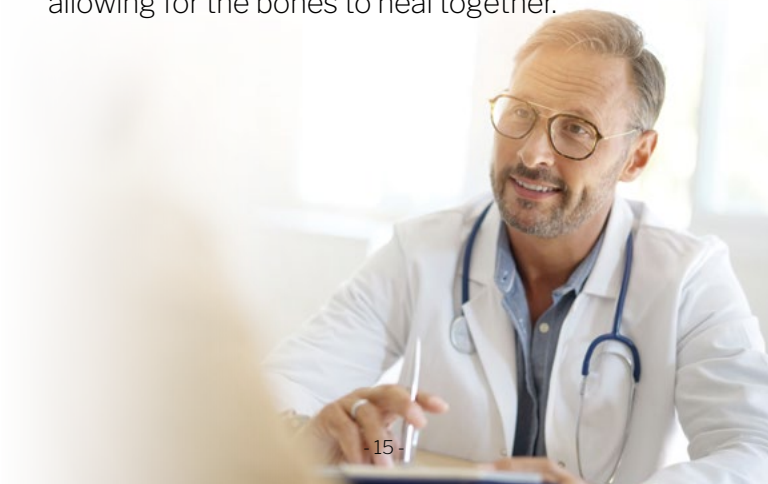
- Debridement
- Allograft arthroplasty
- Distraction arthroplasty
- Arthrodesis (fusion)

Debridement is essentially "cleaning up the ankle joint" that can provide pain relief for several months to years. This procedure involves the removal of inflamed tissues, loose cartilage, and small pieces of arthritic bone.

An **allograft** is tissue that is transplanted from one person to another and used to repair anatomy, relieve pain, and/or improve function.

Distraction arthroplasty is a surgery that relies on the use of an external fixation "frame" to create space between the joint surfaces with tension. An external "frame" remains outside the body during treatment.

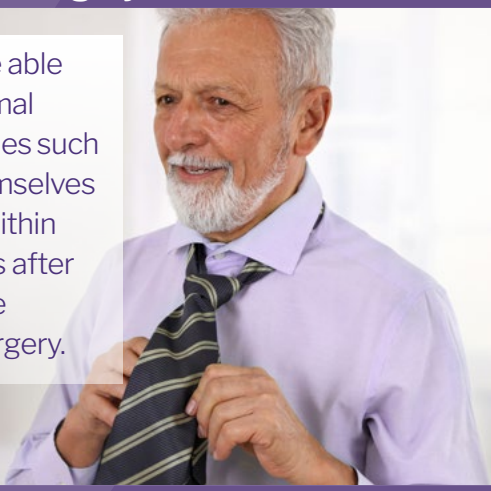
Arthrodesis (fusion) is a procedure where your orthopaedic surgeon uses screws and/or other "hardware" to stabilize and eliminate joint motion, allowing for the bones to heal together.



FREQUENTLY ASKED QUESTIONS

How Soon Can I Return to Normal Activities After Surgery?

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.



Will I Have Any Restrictions?

Standing and walking 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. 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.

FREQUENTLY ASKED QUESTIONS

How Long Until I Can Drive?

It will be dependent on which leg was operated on and 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, generally **at least 3-4 months** after surgery.

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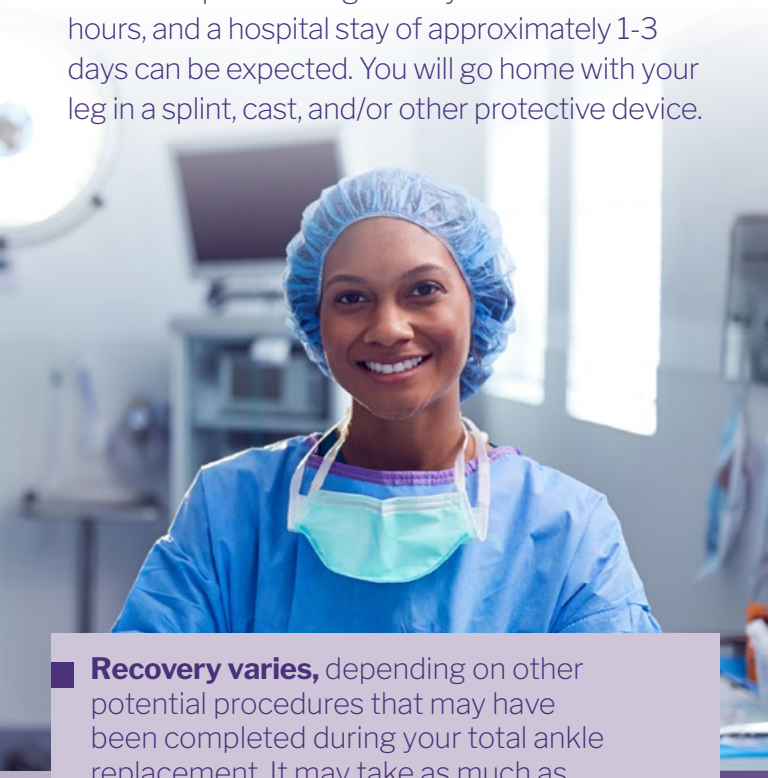
FREQUENTLY ASKED QUESTIONS

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. You will go home with your leg in a splint, cast, and/or other protective device.



Recovery varies, depending on other potential procedures that may have been completed during your total ankle replacement. It 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. A physical therapist will guide you through the exercises you can do at home.

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.

NEED TO KNOW

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. Follow all specific instructions from your surgeon, nurse and physical therapist.

The prosthesis does not replace normal bone, has a finite service life, and future revision surgeries may be necessary.

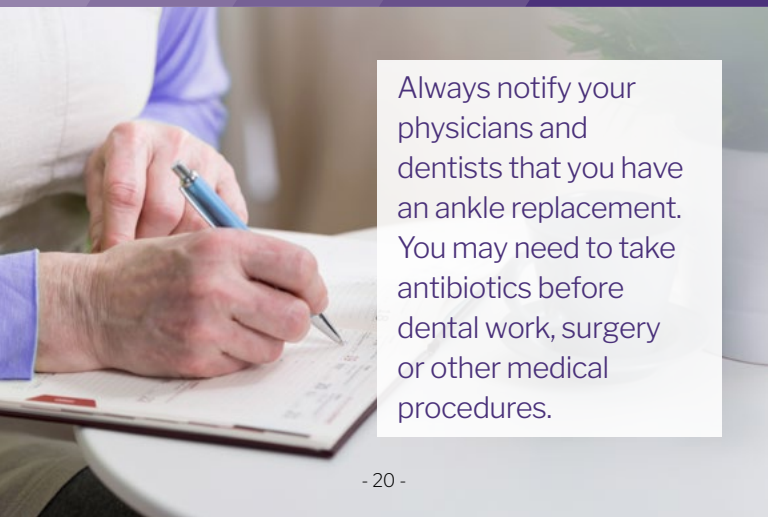
The Following Guidelines May Be of Benefit

- Use of crutches, a wheelchair, or scooter will likely be required following your surgery. These items will help prevent you from putting weight on your implant and allow the soft tissues to heal while you regain normal strength.
- You may be instructed not to stand 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.

NEED TO KNOW

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 2 weeks of your surgery. This appointment may be set for you at the time of your preoperative visit.
- During the initial 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.
- You may be asked 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 implant components are working properly.



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.

- **WARNING:** Always follow your surgeon's directions for activity limitations. Failure to do so may result in damage to your joint and may lead to device failure.
- **WARNING:** Device failure may require additional surgery to remove the device (revision surgery).
- You can ask your doctor about the APEX 3D™ Total Ankle Replacement System or visit: **www.apexankle.com** for more information.

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CAUTION: Federal Law (USA) restricts this device to sale and use by, or on the order of, a physician.