







Individual results and activity levels after surgery vary and depend on many factors including age, weight and prior activity level. There are risks and recovery times associated with surgery and there are certain individuals who should not undergo surgery. Only a physician can tell you if this product and associated procedure are right for you and your unique circumstances. Please consult with a physician for complete information regarding benefits, risks and possible outcomes.

The views, opinions and product experiences discussed in this presentation, whether implicit or explicit, are those of the presenting surgeon and do not necessarily reflect the views and opinions of Wright.

This speaker is a consultant for Wright Medical.



Anatomy of the Ankle



As one of the most flexible, free-moving joints in the body, the ankle joint is formed by the union of three bones. The top of the **talus** fits inside a socket that is formed by the lower end of the **tibia**, often called the shINFINITY, and the **fibula**, the small bone of the lower leg. The bottom of the talus sits on the heel bone, called the **calcaneus**. The normal ankle can move forwards, from side-to-side, and twist.



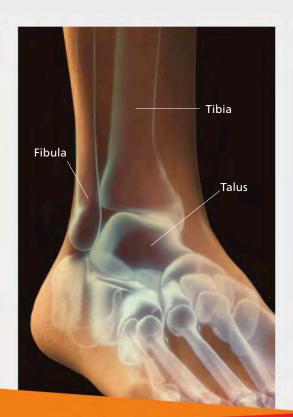
Anatomy of the Ankle



Like other free-moving joints, the ankle contains **cartilage** which absorbs shock. It is held together with **ligaments** – straps of tough tissue, which help prevent the joint from dislocating. Arthritis is one of the most common reasons for ankle replacement surgery, where the cartilage in the joint has worn down. This results in bone-on-bone contact, causing pain and limited activity.



Diseases of the Ankle



Osteoarthritis, also known as degenerative arthritis, is the most common joint disorder. This is due to aging and wear and tear on a joint.

Rheumatoid arthritis occurs when the body's own immune system attacks the synovial lining of the joints, just as it would a foreign bacteria. Synovial fluid is a clear, smooth, oil-like lubricating liquid that makes it easier for the joints to move.



Diseases of the Ankle



Tarsal Tunnel Syndrome is the result of nerve compression in the ankle as the sensory nerve passes under the tarsal tunnel and the tunnel is irritated by pressure. The result is numbness and tingling in the foot and ankle.

Ankle injury occurs when there is trauma to the joint. Symptoms include swelling, pain, weakness and difficulty walking. These injuries can significantly affect your mobility.



Non-Surgical Treatment



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 because they limit motion, thus 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.



Non-Surgical Treatment



An ankle-foot orthrosis (AFO), or a custom-made shoe with a stiff sole and a rocker bottom, can also work by decreasing motion thru 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 deteriorated 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 that is right for you depends on the extent and pattern of cartilage damage and level of pain associated with the ankle. Alternatives to ankle replacement include: debridement, allograft (cadaver) arthroplasty, distraction arthroplasty, and arthrodesis (fusion).





A debridement is essentially "cleaning up the ankle joint" and can be done arthroscopically or through open techniques. This procedure involves the removal of inflamed synovial tissue (joint lining), loose cartilage fragments and osteophytes (bone spurs). In ankles that still have a reasonable amount of normal cartilage remaining, this method can give relief from pain for several months to years.





Another surgical procedure is an allograft, where cadaver donated cartilage and bone can be transplanted into your ankle in order to replace focal areas of damaged cartilage. Distraction arthroplasty typically involves a debridement of the ankle, followed by application of a wire frame thru the bones above and below the ankle. This apparatus holds the ankle stiff and slightly separated, in order to allow some cartilage healing to occur.





For ankles that have diffuse cartilage loss, arthrodesis (fusion) is a procedure where your orthopaedic surgeon takes out the remaining cartilage and uses screws and other metal "hardware" to stabilize the joint to allow the bone to heal together and eliminate motion and pain.



More About Ankle Fusions



Traditional
Ankle Fusion

An orthopedic surgeon or doctor of podiatric medicine will determine whether internal or external fixation is most appropriate for each patient. In external fixation, surgical pins are fixed inside the leg and ankle bones to keep the bones in place, and an outer metal rod and pins hold the bones in place until they heal. More commonly, in an internal fixation approach, the cartilage at the ankle joint is removed, and the ankle and leg bones are compressed with internal plates and screws so that the bones fuse.





The INFINITY™ Total Ankle System consists of a highly polished metal talar dome, a titanium alloy tibial tray, and an ultra-high molecular weight polyethylene insert (UHMWPE). All components are available in varying sizes to best match your anatomy.





INFINITY™ Tibial Tray

The tray component covers the bottom (distal end) of the shinbone (tibia) to provide a large footprint for fixation and minimize implant subsidence. The tray component is attached to your shinbone (tibia) with bone cement.





INFINITY™ UHMWPE Insert

The polyethylene insert acts as the articulating surface of the distal shinbone (tibia). The insert glides along the contours of the ankle (talar) component. The INFINITY™ prosthesis offers a variety of poly thicknesses.





INFINITY™ Talar Dome

The talar dome replaces the proximal (top) of the talus (ankle) bone. The talar dome acts as the surface upon which the insert glides. The talar component is attached to your ankle (talus) with bone cement.



What Are the Benefits?



If your surgeon has decided that you will benefit from ankle replacement surgery, the benefits may include the relief of pain and return of function to the ankle.

- Improve Mobility
- Experience Stability
- Reduce Pain

When thinking about these benefits, you should compare the possible risks and benefits of the INFINITY™ Total Ankle System to the risks and benefits of ankle fusion.



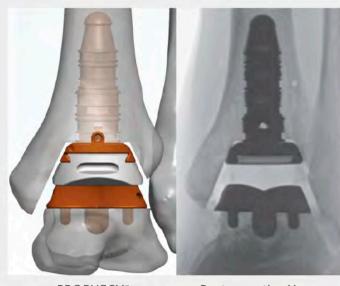
What is PROPHECY™ Navigation?



PROPHECY™ Preoperative Navigation Guides have ushered in a new era of total ankle replacement. Through the combination of computer imaging and the patient's own CT scan, a customized plan can be developed for their own unique anatomy, prior to the ankle replacement surgery.



What is PROPHECY™ Navigation?



PROPHECY® Preoperative Plan

Postoperative X-ray

What are the benefits of preoperative navigation?
PROPHECY™ guides provide the alignment accuracy of the traditional INFINITY™ Total Ankle System, while reducing surgical steps. Patients may benefit from the following:

- Patient-specific instrumentation
- Crucial anatomic landmarks identified before your surgery
- Less radiation exposure from x-rays during surgery



Things You Should Know

The INFINITY™ 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.

The INFINITY™ Total Ankle is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic, or degenerative arthritis.

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



Things You Should Know

You should not receive the INFINITY™ Total Ankle if you have:

- An infection of the body or bone
- Excessive bone loss at the ankle joint
- Steroid use
- Infection at the ankle site or infections at distant sites that could migrate to the ankle
- Sepsis
- Muscular atrophy
- Dementia
- Poor blood supply in the ankle joint
- Skeletally immature patients (patient is less than 21 years of age at the time of surgery)



Things You Should Know

You should not receive the INFINITY™ Total Ankle if you have:

- Inadequate neuromuscular status, poor bone stock, poor skin coverage around the joint, which would make the procedure unjustifiable
- Neuropathic joints
- Hepatitis or HIV infection
- Excessive loads as caused by activity or patient weight
- Female of childbearing age, for whom a negative pregnancy test is not obtained
- Neurological or musculoskeletal disease that may adversely affect gait or weight bearing



What Are the Risks?



As with any surgery, there are risks to consider. The risks and complications associated with the INFINITY™ Total Ankle System include:

- Excessive bleeding
- Damage of blood vessels may occur due to surgery
- Delayed wound healing
- Sudden drop in blood pressure during surgery due to the use of bone cement or anesthesia
- Temporary or permanent nerve damage
- Allergic reaction due to anesthesia, medication, or device material



What Are the Risks?



- Allergic reaction to the implant's materials. As the parts
 rub against each other, metal ions are released into the
 body, which may cause an allergy. There are no known
 medical consequences of these ions at this time, however,
 studies are ongoing
- Infection, which can lead to removal of the device
- Device loosening from surrounding bone
- Increased ankle pain and/or reduced function
- Hardening of the tissue (calcifications) or bony points around the devices
- Device related noise such as, clicking popping, squeaking or grinding
- Overuse of the device from too much weight or activity may cause the device to fail prematurely



What Are the Risks?



- Premature wear or breakage of the implant
- Bone breakage due to osteoporosis or accidents (trauma)
- Damage to the bones and tissue (tissue necrosis, pseudotumor) near the ankle joint, including loss of the surrounding bone (osteolysis) or staining of the ankle joint due to wearing of the metal parts overtime
- Pseudotumor
- Chronic inflammation response due to metal sensitivity (Aseptic Lymphocyte Dominant Vasculitis Associated Lesion – AVAL)



Patients Speak Out



"A couple of months after my surgery, I was visiting my grandchildren and went up and down the stairs with ease."

- Debbie, Total Ankle recipient



Patients Speak Out



"My new ankle allowed me to reclaim my life. I can walk the golf course – up and down hills, and in and out of bunkers."

Jack, Total Ankle recipient



Patients Speak Out



"I never thought I would be able to really live again. It is incredible to do things that haven't been possible for me for thirty years!"

- Roxanne, Total Ankle recipient





