Natural Anatomic Alignment.

Trabecular™ Metal Total Ankle

ZIMMER BIOMET

Your progress. Our promise.®

Table of Contents

Trabecular Metal Total Ankle

Total ankle arthroplasty is intended to provide patients with limited mobility of the ankle, by reducing pain and preserving the flexion/extension (up and down) movement within the ankle joint.

The Trabecular Metal Total Ankle replacement system is an innovative design intended to replace the articulating surfaces of the ankle that have been affected by disease or injury. This system brings contemporary advances realized in knee and hip arthroplasty technology to total ankle arthroplasty while utilizing a lateral (side) surgical approach.

Advantages of a Lateral Approach

The Trabecular Metal Total Ankle replacement system has been developed to give your surgeon an option for restoring natural movement to the ankle joint. Unlike other ankle replacement surgeries which use an incision on the front of the ankle, this procedure uses an incision on the side of the ankle, which is why it is called a lateral (side) approach. In this approach, the lower portion of the fibula is surgically moved to the side to perform the procedure and is later repositioned with a metal plate.

The lateral approach offers a number of benefits, including:

- Less disruption of nerves and soft tissues surrounding the ankle joint, which may speed up recovery and help restore a natural walking gait.
- The "side" view of your ankle joint during surgery allows your surgeon to see the joint better and is intended to help position the ankle replacement implant more precisely.
- If you've already had surgery on your ankle from a previous injury, the surgeon may be able to use the existing incision on the side of your ankle instead of having to create a new one.[1]

Innovative Implant Design

For decades, Zimmer Biomet has led the way with joint replacement innovations. Many of those advancements are reflected in the Trabecular Metal Total Ankle replacement implant.

- The implant has a low-profile design that allows your surgeon to retain more of your natural bone than with many other implants. This is called bone sparing.
- Components of the implant work together to restore the natural movement of the ankle joint. This provides for integrated movement with muscles and tendons to help achieve a normal walking gait.[1]
- The Trabecular Metal Total Ankle replacement system offers a number of sizing options, giving your surgeon the ability to choose the closest fit for your ankle anatomy.

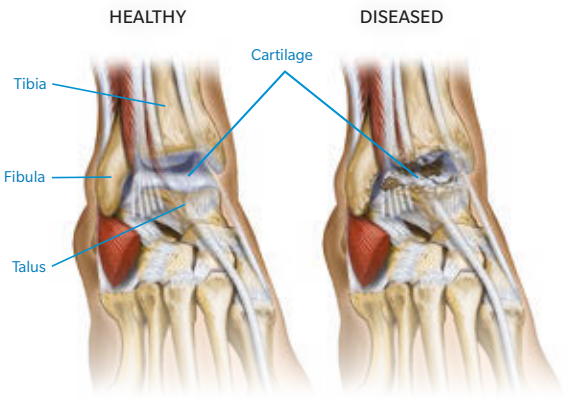
Zimmer Biomet Proven Technologies

Prolong® Highly Crosslinked Polyethylene

In ankle replacement surgery, the "bearing" material is the polyethylene surface that the metal components of the implant move against. Zimmer Biomet has developed a unique material that has shown to be resistant to wear.[1] This material, Prolong Highly Crosslinked Polyethylene, has been used for many years in other joint implants and is intended to provide durability in the replacement ankle joint.[2]

Trabecular Metal Technology

This implant material is not a coating but rather an advanced 3-dimensional structure that closely resembles the porous structure of natural cancellous ("spongy") bone.[3]



Why Does My Ankle Hurt?

In a healthy ankle, a layer of cartilage "cushions" the joint and protects the surface of the bones as the ankle moves. When the cartilage is damaged or worn away, the bones may rub together, causing friction, pain and eventual deterioration of the bone surfaces. The most common cause of cartilage deterioration is wear and tear, called osteoarthritis. This condition may be triggered by other traumatic events, resulting in post-traumatic arthritis.

Since no medication or treatment can make the damaged cartilage grow back, an ankle replacement procedure is the only way to relieve severe pain while maintaining function of the joint.

Other Treatment Options

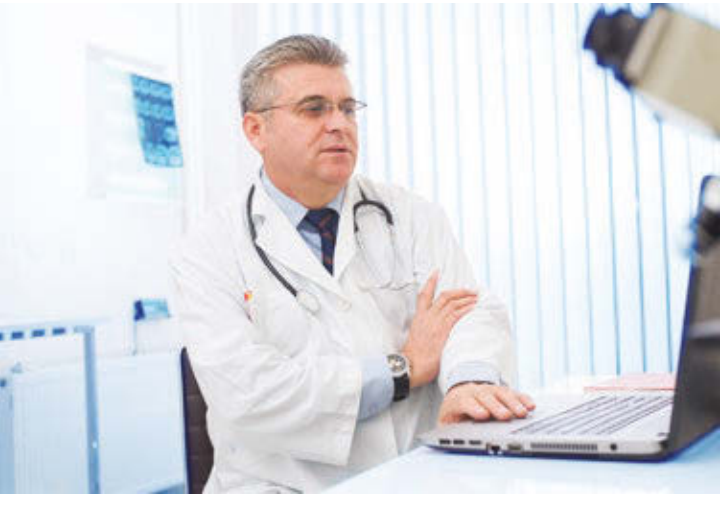
One type of surgery is ankle fusion, also known as arthrodesis. This surgery fuses the bones in your ankle joint together using metal screws. The bones grow together, and the motion in your ankle is lost.

Only your doctor can tell for sure if you are a candidate for ankle replacement surgery. If the above treatment has failed, or you aren't a candidate for it, your doctor can help you determine if it's time to consider ankle replacement surgery.

Is it Time for Ankle Replacement?

That's a question you and your orthopedic surgeon will have to answer together. But when ankle pain is so bad it actually interferes with the things you want or need to do, the time may be right. Here are some signs to consider:

- Medication and using a cane are not delivering enough relief.
- Pain is keeping you up at night.
- You have given up activities you used to enjoy.
- You are no longer as mobile as you'd like to be.



What Happens During Ankle Replacement Surgery?

It's the same idea as having most things fixed – worn parts are taken out and new parts are installed in their place. In surgery, the damaged portions of the lower end of your shin bone (tibia) and the top of your foot bone (talus) are removed. Through a lateral approach, the metal parts of the Trabecular Metal Total Ankle implant are attached by placing them tightly against the bones and utilizing special cement to fix portions of the components to the bone. To finish, the fibula will be repositioned with a metal plate and the incision is closed.

What Happens Afterward?

Considering the complexity of your surgery, your doctor will give you specific instructions on wound care, pain control and when you can resume other activities like walking with both feet.

Generally after surgery, you will be in a well-padded splint for the first 2-3 weeks. You can use a wheel chair or crutches during this time. After that, you will transition to a boot, but you will still need to use crutches or a roll-about until your doctor gives you permission to put full weight on your ankle.

What Risks are Involved?

As with any surgery, the general risks of total ankle replacement surgery include bleeding, blood clot and infection. More specific risks for ankle replacement surgery are:

- Ankle weakness, stiffness or instability
- Loosening of the artificial joint over time
- Skin not healing after surgery
- Nerve damage
- Blood vessel damage
- Bone break during surgery
- Dislocation of the artificial joint
- Allergic reaction to the artificial joint
- Poor range of motion
- Pain and inflammation
- Fibula not healing
- Tendon or ligament damage

Frequently Asked Questions

Q: Can I get an ankle replacement if I have a fused ankle?

A: Your orthopedic surgeon will determine if you are a suitable candidate, but it is possible to get an ankle replacement even if you have already had an ankle fusion. The surgeon would remove the metal screws and perform a total ankle replacement surgery.

Q: Will I set off metal detectors?

A: Metal detectors may be set off due to the metal in your implant. A Patient ID card may be requested through the surgeon, which is provided by the manufacturer. This ID card will identify that you have an ankle replacement so you may notify security prior to going through a metal detector; however, additional screening may be required to pass through security. You may also want to show this card when getting X-rays and MRIs.

Q: What is the implant made of?

A: The components are made of special metal and polyethylene that have been used in artificial hips and knees for many years.

Specifically, the tibia component is made of Tivanium® alloy and the talus component is made of cobalt chrome. The plastic bearing is made of a unique wear resistant material (polyethylene), which has been used in other joints successfully for many years.

Q: How long will it last?

A: Every patient is different. Many factors can influence the longevity of a joint replacement implant like activity levels, weight and your compliance with the instructions given by your orthopedic surgeon.

Q: Will insurance cover it?

A: Yes. This procedure is covered by most major insurance carriers along with Medicare and Medicaid.

Alert Physicians and Dentists

In order to avoid infection and protect this new part of your body, always notify your physicians and dentists that you have an ankle replacement.

References:

1. Data on file at Zimmer Biomet
2. Gsell R, Yao JQ, Laurent MP, Crowninshield RD: Improved oxidation resistance of highly crosslinked UHMWPE for total knee arthroplasty. Society for Biomaterials 27th Annual Meeting Transactions, 84, 2001.
3. Bobyn JD, Hacking SA, Chan SP, Toh KK, Krygier JJ, Tanzer M. Characterization of a new porous tantalum biomaterial for reconstructive orthopaedics. Annual Meeting of the American Academy of Orthopaedic Surgeons edition. Anaheim, CA; 1999.

There's help for ankles in need.

To learn more about Zimmer Biomet joint replacements, obtain helpful information for patients and caregivers, or for assistance in finding a surgeon familiar with our products and surgical techniques, call toll free: 800-447-5633 or visit zimmerbiomet.com

Important Note: This brochure is intended to provide an overview of ankle replacement surgery and should be reviewed with your doctor. It does not include all of the information needed to determine eligibility for ankle replacement or for the proper use and care of artificial ankle replacements. Please consult your surgeon for more information. Information may also be obtained by calling the toll free number or visiting the web site. The toll free number also can be used to obtain complete product contraindications, warnings, precautions, and possible adverse effects. Individual results may vary. Your results will depend on your personal circumstances. How long an ankle replacement will last varies from patient to patient. It depends on many factors, such as the patient's physical condition, activity level, and body weight and the surgical technique. Replacement joints are not as strong or durable as a natural, healthy joint, and there is no guarantee that an artificial joint will last the rest of a patient's life. All ankle replacements may need to be replaced at some point.

This device is available only on the order of a physician.

ZIMMER BIOMET

Your progress. Our promise.®