

Agility™

TOTAL ANKLE SYSTEM

about ankle replacement



an alternative
to fusion



Agility™

TOTAL ANKLE SYSTEM

Contact your local DePuy sales representative for additional information about an entire range of implants for both upper and lower extremity joint replacement, trauma and a complete line of bone cement products.

REFERENCE

1. The Arthritis Foundation, Lawrence, R.C., et al. "Estimates of the prevalence of arthritis and selected musculoskeletal disorders in the United States." *Arthritis & Rheumatism* 41, May 1998: 778-799.

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

US Patent 5,326,365.

The Agility Ankle prosthesis is indicated for use with bone cement.

Developed in conjunction with Frank Alvine, MD, of Alvine Orthopaedics in Sioux Falls, South Dakota.

For more information, consult your surgeon or visit www.allaboutarthritis.com or www.agilityankle.com.



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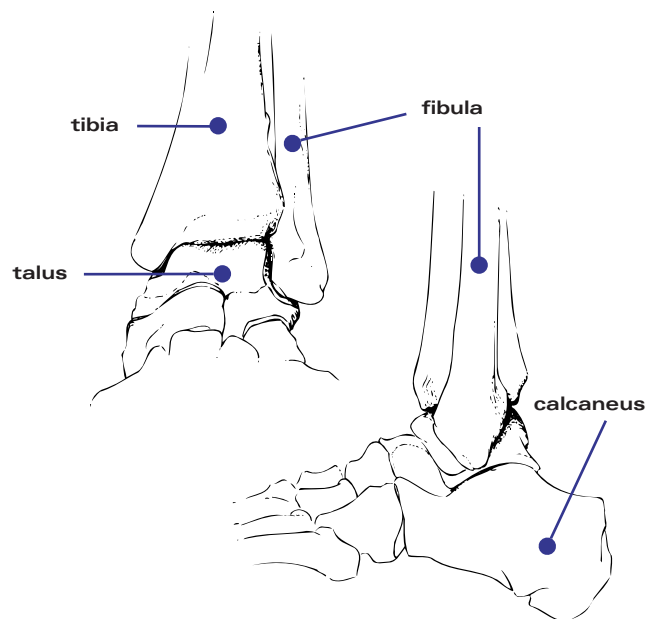
introduction

This pamphlet has been designed to give you an overview of ankle replacement surgery and illustrate the anatomy of the ankle joint. It also outlines the need for surgery, what to expect both before and after surgery, and how to return to a normal lifestyle once you are back at home.

Note: Please understand that the following information is provided for reference purposes only. Your surgeon may change any or all aspects of your treatment as discussed in this pamphlet based on his/her experience, preferences and your particular situation.

the ankle joint

A joint is a junction where two or more bones meet. The ankle is a complex joint involving three bones — the tibia, the fibula and the talus. The ankle joint allows for an up-and-down motion, as well as a slight side-to-side rotation. Ligaments (which connect bone to bone) on the inside and outside of the ankle act to stabilize the joint.



healthy ankle joint

when joint problems arise

The most frequent source of debilitating pain and joint destruction is arthritis. It is estimated that 43 million people in the United States have some form of arthritis.¹ That is one in seven people.

Of the more than 100 types of arthritis, the following three are the most common sources of joint damage:

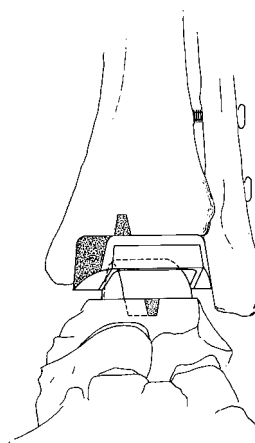
Osteoarthritis, sometimes called degenerative arthritis, is a disease that involves the breakdown of the tissue (cartilage) that normally allows the joint to move smoothly. When the gliding surface of the cartilage is gone, the bones grind against each other, creating popping sounds, pain and loss of normal movement. This condition occurs primarily in people over 50.

Traumatic arthritis or trauma-related arthritis results when the joint is injured either by fracture, dislocation or damage to the ligaments surrounding the joint. This resulting damage predisposes the joint to traumatic arthritis, which may occur later in life.

Rheumatoid arthritis is considered a systemic disease because it can attack any or all joints of the body. It affects women more often than men and can strike both young and old. Rheumatoid arthritis causes the body's immune system to produce a chemical that attacks and destroys the protective cartilage that covers the joint surface, causing deterioration and pain.

When conservative measures of treatment fail to provide adequate relief, either an ankle fusion or ankle arthroplasty may be considered. Ankle fusion has been the traditional

method of treating arthritis of the ankle. However, due to the detrimental long-term effects that ankle fusion may have on the other joints in the foot, ankle replacement surgery may be a better alternative.



reconstructed ankle joint

The ankle joint, in the process of wearing

out, can either settle with the foot turned in or turned out. Most of these deformities can be corrected at the time of surgery, but the primary purpose of ankle replacement surgery is to relieve pain. Motion can be gained following replacement surgery, but this is somewhat dependent on the amount of stiffness before surgery and the length of time the joint was stiff. Generally, ankle motion after surgery will be similar to that before surgery. Postoperatively, therapy is important and may be started soon after surgery, based on the advice of your surgeon.

your ankle evaluation

Your orthopaedic surgeon will evaluate your ankle to determine the type of arthritis you have and other important factors in deciding whether or not an ankle replacement is advisable. In the process of the examination, not only will the motion of your ankle be measured, but fluid may be taken from the joint to determine if infection is present. X-rays will also be taken to assess the size and condition of your ankle.

It is extremely important to notify your surgeon if you have diabetes. Diabetic patients will require additional testing. The long-term effects of diabetes could prevent the possibility of a total ankle replacement.



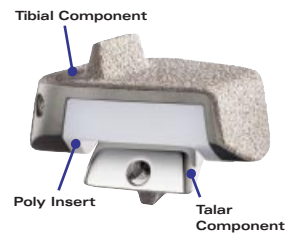
before surgery



after surgery,
with components
in place

components of ankle replacement

Total ankle replacement removes and then replaces both sides of the ankle joint with specially designed artificial parts called prostheses. The tibial or mortise prosthesis consists of a titanium alloy shell that contains a polyethylene (medical grade plastic) insert. These prostheses are inserted into the tibia and fibula, giving the implant a wider base of support. The talus, the bone of the foot that glides against the tibia, is replaced with



the Agility™ Total Ankle System from DePuy Orthopaedics, Inc.

a talar component made of cobalt chromium alloy, another metal commonly used in joint replacement prostheses.

Your surgeon has chosen a prosthesis made by DePuy Orthopaedics, Inc., a Johnson & Johnson company, of Warsaw, Indiana, called the Agility™ Total Ankle System. The design is based on numerous research studies of the structure and mechanics of the ankle joint.

before your operation general medical health

All patients need to see their family physician or an internist for a thorough physical and past medical history evaluation at least one week prior to hospital admission. This will ensure that any medical condition such as

urinary tract infection, cardiac disease or high blood pressure can be detected, treated and controlled prior to surgery — minimizing the possibility of your surgery being rescheduled. Your orthopaedic surgeon will need to obtain a report from your physician regarding your general medical health and copies of test results. Some common tests that may be required include a complete blood count, blood clotting times, blood chemistries and urinalysis.

For some patients, typically those over 40, a chest x-ray and an electrocardiogram (EKG) may need to be performed. If any test result is abnormal or outdated, it may need to be repeated upon arrival at the hospital to help ensure the safest possible operation.

In some cases, you may be asked to lose weight. If you smoke, it is important to stop two weeks before surgery and to consider quitting all together.

admission

Check with your surgeon's office to determine when you should plan to arrive at the hospital. Most patients are admitted the day of surgery. **Note:** You cannot eat or drink anything after midnight the night before surgery.

medications

If you are taking any anti-inflammatory medications, your surgeon may advise you to stop taking them one week prior to surgery to help minimize bleeding during your operation. Anti-inflammatory medications include any form of aspirin, including coated or buffered aspirin, or other brand name products containing aspirin. Do not change or stop taking any medication unless instructed to do so by your internist, family physician or surgeon.

minor surgical procedures and dental care

Do not schedule minor surgical procedures such as urological manipulators or exams, or dental procedures such as teeth cleaning, cavity repairs or oral surgery within two weeks of your scheduled surgery.

sore throat, cold and flu

If you develop a cold, sore throat or the flu within one week of your scheduled procedure, please call your surgeon. These conditions may increase the operative and anesthetic risks, and your procedure may need to be rescheduled.

urinary tract infection

If you develop a urinary tract infection within two weeks of your scheduled procedure, contact your family physician or urologist for treatment and notify your surgeon. This

condition may increase the risk of a postoperative infection, and your procedure may need to be rescheduled.

pregnancy

Elective ankle surgery is rarely indicated during pregnancy. If you become pregnant prior to your scheduled surgery, contact your surgeon so that your surgery can be rescheduled.

dentures and contact lenses

Contact lenses, dentures and plates cannot be worn in the operating room. Be sure to bring your container and solutions to keep these devices protected while you are in surgery.

clothing

Remember to bring comfortable, loose-fitting bed clothing. A robe and slippers are recommended.

daily showers and skin cleaning

It is recommended that you wash your ankle, foot and toes with an antibacterial soap for three or four days prior to admission. Be very careful that you do not nick your skin in the region of your ankle and if you have any breaks in the skin, contact your surgeon's office before going to the hospital.

length of stay

The normal length of stay for ankle replacement surgery is two days, although it may vary depending upon your condition.

what to bring to the hospital

- A robe, slippers and toiletries.
- Your own nightgown or pajamas to wear after surgery. Otherwise, a hospital gown will be provided for you.
- Books, magazines, stationery, hand crafts and hobbies.
- A small amount of money for stamps, etc.
- Any medications that you take on a regular basis. Give these to the nursing staff upon admission.
- Containers and solutions for contact lenses, dentures and plates. These items cannot be worn in the operating room.

what to expect prior to surgery

1. Depending on when you are admitted to the hospital, you may speak to and be examined by a member of the department of anesthesia. This person will ask you questions, explain the anesthetic procedure, and in some cases, allow you to choose the type of anesthesia used.
2. The nursing staff will take your temperature and check your pulse, respiration and blood pressure.
3. You will be visited by a member of the surgical team who will again perform a complete history and physical examination and be available to answer any of your questions.

4. Your family may come with you to the Admissions Department of the hospital. They should keep the staff at the nurses' desk informed of their location during surgery.
5. Before going to the operating room:
 - a. Your ankle area will be scrubbed and prepped.
 - b. You may brush your teeth and rinse your mouth, but do not swallow water.
 - c. An elastic support hose will be applied to your opposite leg to aid with circulation while you are lying on the operating room table.
 - d. You will be asked to empty your bladder.
 - e. To receive medications, an intravenous (IV) line will be started by the nurse or a member of the anesthesiology staff.
 - f. Medications may be given about one hour before surgery to help you relax and dry your mouth and sinuses.
 - g. You will be transferred to the holding area and from there to a stretcher prior to going to the operating room.
6. In the operating room, you will be transferred from the stretcher to a special operating room table. The room is equipped with special overhead surgical lights and anesthetic equipment.

the recovery room

When the procedure is completed, your surgeon will contact your family and friends to update them on your surgery. You will awaken after surgery in the post-anesthesia recovery room, probably feeling as though you were away from your hospital room for only a few minutes. You will remain there for an hour or so, or until you have recovered from the anesthesia, are breathing well and your blood pressure and pulse are stable. If you have pain, the nurses will administer medication. Your ankle will be in a splint so you will not be able to move it.

what to expect after surgery

1. Your foot and lower leg will be elevated and immobilized in a removable ankle boot or splint, so you will not be able to move your ankle. Frequently, blood will be visible on the dressing and should not be cause for alarm. This is common and usually stops after a few hours. The first day after surgery, you will probably be allowed to get out of bed, sit in a chair and, on occasion, start physical therapy. However, **no body weight** should be applied on your ankle until instructed to do so by your surgeon. The dressing is normally removed two days after surgery and movement of your ankle is started in physical therapy.

2. To prevent nausea immediately after surgery, you will be given only ice chips or sips of water and soft drinks. The day after surgery, you will be allowed to have regular meals.
3. An IV will normally remain in your arm for one or two days to administer antibiotics and fluids. This helps prevent infection and gives you proper nourishment until you are eating and drinking normally. It is normal to feel pain and discomfort after surgery. Be sure to inform your nurse of pain and medication will be ordered. When the IV is discontinued, you will begin taking oral pain medication, but pain medication is frequently not necessary after the first day, since the ankle is immobilized with a splint.
4. Two days after surgery, the ankle boot or splint will be removed to begin gentle range of motion exercises and then reapplied. The physical therapist will instruct you on the safest method of getting in and out of a chair and will also determine which is the safest way for you to get around, either with a walker or crutches.

progress

You will not be able to put weight on your ankle for the first six weeks, during which time you will be using crutches or a walker. The ankle boot or splint must be worn 24 hours a day and removed only for range of motion exercises. Instructions on how to remove the boot or splint twice a day to perform range of motion exercises will be given prior to your discharge. The sutures will be removed about two weeks after surgery.

at home

Until you see your surgeon for your first follow-up visit, make certain that your wound stays dry and is not draining. If you do notice any drainage or foul odor from your incision, please contact your surgeon. Also, if your temperature goes over 100.4 degrees or you notice any increased swelling or tenderness, call your surgeon. Take time to adjust to your home environment — it's okay to take it easy. You may need help with your daily activities, so it is a good idea to have family and friends prepare to help you. It is normal to feel frustrated about needing assistance, but as you recover, this should improve.

resuming activities

1. You can walk as much as you like using crutches or a walker, as long as you remain non-weightbearing on the operated side for six weeks. Your surgeon will provide specific instructions.

When you rest, be sure to elevate your ankle, preferably above the level of your heart.

2. Do the exercises prescribed by your doctor/physical therapist at least two to three times a day.
3. At night, rest with your leg elevated on one or two pillows.
4. For bathing, sit in the bathtub and wash. Be certain that you keep your ankle dry until the sutures have been removed, then resume normal bathing. On occasion, you may use plastic to cover your ankle so you can shower while the sutures are still in place.
5. You may return to work when authorized by your surgeon.

contact your family doctor if

You develop a cold, fever, sore throat, pulmonary (breathing) problems, cardiovascular (heart or circulation) problems or other general physical difficulties that cause you concern.

contact your surgeon if

You develop an increase in ankle pain, swelling, drainage, temperature or have any problems controlling motion of your ankle.

medication/pain control

It is normal for you to have some discomfort after surgery. You will receive a prescription for pain medication before you leave the hospital. If a refill is needed, please call your surgeon's office at least two to three days prior to when you will need more pills.

special instructions

Normally, you will be seen six weeks and three months after surgery. A six-month exam is also usually scheduled for new x-rays and an assessment of your progress.

Note for the future:

You should always tell your dentist or physician that you have an artificial joint. If you are having dental work performed, notify your dentist or physician so he/she can prescribe antibiotics for the day before and the day of your dental care. Antibiotics must be used before and after **any** medical or dental procedure. This precaution must be taken for the rest of your life.

Any infection must be promptly treated with proper antibiotics because infection can spread from one area to others through the bloodstream. Every effort must be made to prevent infection in your artificial joint. Your surgeon can give you instructions on the use of special antibiotics.

your questions answered

Q How long will I be in the hospital?

A Ankle replacement surgery usually requires hospitalization the day of surgery and two days after. Occasionally, patients can go home one day after surgery. However, additional time may be necessary if you live alone or experience problems.

Q When will I be able to move my ankle?

A The ankle boot or splint is usually removed on the second day and movement of your ankle, up and down, is begun at that time. You will continue to use crutches or a walker with no weightbearing allowed on the operated side for six weeks following surgery.

If additional procedures are performed at the time of your ankle surgery, a plaster splint will be applied, requiring a longer period of immobilization. This will not be removed for two to three weeks. (There will be no range of motion exercises or dressing changes during this period of time).

In addition to this brochure, DynoMed™, Inc., in collaboration with DePuy Orthopaedics, created a video specifically for the patient, titled "Ankle Arthritis and Replacement."

This brief video provides a patient testimonial, procedural background and what to expect before, during and after surgery. In addition to this information, other highlights include ankle anatomy animations, arthritis development and the surgical procedure.

For ordering information please contact DynoMed, Inc. at (877) 396-6633, via fax at (317) 275-6851 or www.dynomed.com.