

The **STAR**[™] Total Ankle Replacement



Patient Information



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SMALL BONE INNOVATIONS, INC.

Patient Information

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Patient results may vary. Please consult your physician to determine if this product is right for you.

For more information about SBI's products or prescribing information, including warnings and contraindications, please read the product labeling or visit www.totalsmallbone.com.

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Caution: United States federal law restricts this device to sale by or on the order of a physician.

Glossary of Terms

• **Conservative treatment** is a term used to describe any treatment option that does not involve surgery. Conservative treatment options vary depending upon the seriousness of the issue, from pain medications to simple therapies to help lower pain, to physical therapy, ankle foot orthotics, molded ankle braces, and compression stockings.

• **Cortisone** is an artificially produced chemical that reduces swelling of the ankle joint. It is typically injected to help ease pain. It is not injected into the blood stream, but rather into the area of swelling. Cortisone has many different trade names (e.g., Celestone, Kenalog, etc.).

• **Degenerative arthritis ('OA')**, also known as osteoarthritis, is a medical condition in which swelling of the ankle joint results in pain.

It is caused by:

1) An abnormal wearing of the cartilage that covers these joints and acts as a cushion inside joints; and
2) A decrease of the fluid that normally 'lubricates' those joints. As the bone becomes less protected by cartilage, patients are likely to have more pain when walking. As a result of this kind of arthritis, the involved joint(s) appear larger, and are stiff and painful. The joints usually feel worse the more they are used throughout the day.

• **Rheumatoid arthritis ('RA')**, unlike OA, is a longer-term disorder that causes the immune system to attack the ankle joint(s). This disease results in stiffness, swelling and damage to the joints. The condition can be disabling and painful, and can lead to loss of mobility. It could even lead to a total breakdown of the joint.

• **Ankle structures** are the supporting ligaments, cartilage and bone surrounding the ankle, which provide support for the ankle's motion.

• **Fuse/fusion/fusing** of the ankle joint refers to a surgery done for the treatment of ankle arthritis, where worn-out joint surfaces are removed. The ankle bones are then held together with metal implants. The bone surfaces then heal in this position. The joint remains stiff after ankle fusion, but the result is usually a pain-free joint.

What Should I Know about Ankle Replacement?

Replacement of the ankle joint with an artificial implant is designed to treat painful conditions of the ankle, such as arthritis. Arthritis is a condition that can take many forms. Your surgeon may have used a different name to describe it. At this time, your ankle does not work properly and is causing you pain. Sometimes, arthritis can be treated without surgery. For example, patients can take pain medicine, or other medicine(s) to treat arthritis and/or using a brace. However, if these types of treatments do not relieve your pain, surgery may be an option.

Your surgeon has asked you to consider the replacement of your ankle joint with an artificial implant called the “STAR™ Ankle.” STAR™ stands for “Scandinavian Total Ankle Replacement.” A well known surgeon in Scandinavia designed this device. “Total” means that your entire ankle joint will be replaced.

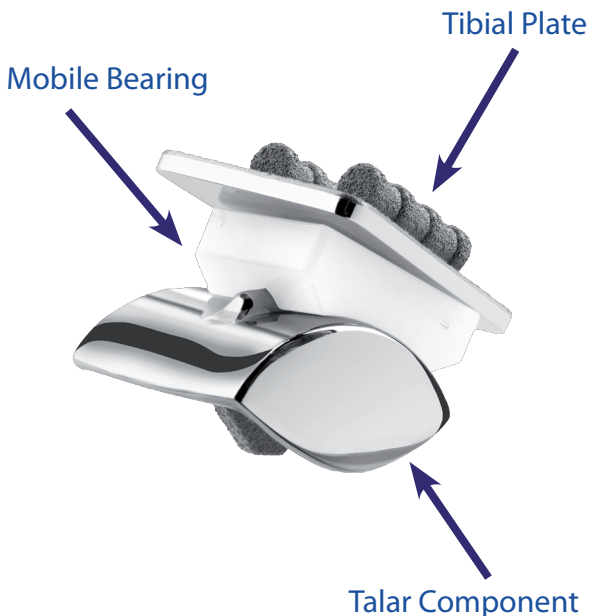


The purpose of total ankle replacement surgery is to help relieve the pain in your ankle, while still allowing you to move your ankle.

What Is the STAR™ Ankle System and How Is It Implanted?

The STAR™ Ankle is made up of three parts. The first part covers the lower bone of the ankle joint, a bone called the talus bone. The second part covers the very bottom of your “shin bone.” This is the long bone that runs from the bottom of your knee to the top of your ankle. This bone is also called the tibia. Both of these parts that cover your bone are made of a combination of metals called cobalt chromium alloy. These parts are coated with another metal, pure titanium, in the places where they actually touch your bone. The third part of the STAR™ Ankle is called a Mobile Bearing and is placed in between the two metal parts. This part is made out of medical grade plastic called polyethylene. The plastic piece is designed to move in between the metal parts as you move your ankle.

The materials that the STAR™ Ankle is made of have been used in artificial hips and knees for many years. They have shown to be extremely well accepted by the body.



The STAR™ Ankle procedure requires the surgeon to make a cut along the front of the ankle to open the ankle joint. Approximately 3/8" of bone is then removed from the ankle joint to make space for the metal and medical grade plastic parts described previously. Unlike other ankle replacement systems, the STAR™ Ankle does not require the use of bone cement. The surgeon then shapes the bones of your ankle so the STAR™ Ankle replacement will fit in place.

For What Conditions is STAR™ Approved (Indications for Use)?

The Scandinavian Total Ankle Replacement (STAR™ Ankle) is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to osteoarthritis, post-traumatic arthritis or rheumatoid arthritis.

Who Should Not Have the STAR™ Ankle (Contraindications)?

- Regarding deep infection in your ankle joint or connected bones: Failing to tell this to your surgeon could lead to serious infection.
- Regarding previously fused ankle(s), it is not possible to implant the STAR™ Ankle.
- The STAR™ Ankle may not work correctly if your surgeon does not think that he can get your foot flat to the ground. This could fail, break, loosen or cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.
- Regarding ankle deforming, the STAR™ Ankle may not work correctly and could fail, break, loosen or cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.
- Implanting a STAR™ Ankle may cause additional damage to your bones if there is not enough blood getting to the bones of your foot, or the ankle replacement may fail to attach to your bones. This may lead to the need for additional treatment, including surgery to remove the ankle replacement.
- Regarding nerve problems around the ankle and you cannot feel the position of your ankle or pain in your ankle or foot, this may lead to stress on the ankle that could damage the STAR™ Ankle. This damage may cause the implant to fail, loosen or break, or may cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.
- Regarding poor bone quality that may not let the STAR™ Ankle attach to your bones, placing a STAR™ Ankle could cause more damage to your bones which may cause the implant to break, loosen or fail.

This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- Regarding poor support from your ankle ligaments that your surgeon cannot fix: This could lead to stress on the STAR™ Ankle that could cause the implant to fail, loosen or cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- Regarding bones that are not fully grown, putting in the STAR™ Ankle could damage your bones so that they do not fully grow.

- The clinical investigation of the STAR™ Ankle was limited to patients weighing no more than 250 pounds. Therefore, if you weigh over 250 pounds, the clinical study does not show results for patients whose weight is similar to your weight.

- Regarding poor skin and soft tissue quality around the surgical site: The operation to place the STAR™ Ankle could further damage your skin and soft tissues. This may require additional treatment, including surgery to try and repair or heal the soft tissues around your ankle, or possibly remove the ankle replacement.

- Regarding prior surgery and/or injury that has caused excessive damage to the bones in your ankle: Placing a STAR™ Ankle could cause further damage to your bones that may cause the implant to break, loosen or fail. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- Regarding medical condition resulting in the lack of normal muscle function around your problem ankle: If you do not have normal ankle muscle function, this may lead to stress on the ankle joint. This stress may damage the STAR™ Ankle. This could cause the implant to fail, loosen or break, or may cause damage to your bones. This could lead to the need for additional treatment, including surgery to reposition or remove the ankle replacement.

- Regarding emotional problems that may not allow you to cooperate before and after surgery: You are unable to follow the pre and post-operative instructions and to keep the follow up appointments necessary for successful healing and for prevention of additional treatment or surgery.
- If your knee is too crooked to place the ankle replacement in the proper position, the STAR™ Ankle may not work correctly. It could fail, loosen or break, or cause damage to your bones. This could lead to the need for additional treatment. This may include surgery to reposition or remove the ankle replacement.

What Warnings Should I Know about When This Device Is Used?

The following conditions may lead to severe issues when undergoing a STAR™ Ankle replacement. Each must be discussed with your surgeon.

- Any known allergies to metals. Such allergies may cause an allergic reaction to the materials used in this device.
- Premature or excessive weight bearing on the STAR™ Ankle before the supporting bones are healed. This may result in failure of the ankle replacement. Please also see the section titled "What Short-Term Lifestyle Changes Will I Have to Make?" for additional information about weight bearing after surgery.
- Ongoing changes in your medical condition, including recent surgery. You and your surgeon will need to decide if your medical condition or surgery could make it more likely that the STAR™ Ankle may break, loosen or fail, or that your bones may be damaged. This could lead to the need for additional treatment, including surgery.





What Are Some Precautions and Risks for This Device?

The STAR™ Ankle requires special training for successful implantation. Please ask your surgeon whether he or she has been trained to implant the STAR™ Ankle.

It is important to follow your surgeon's advice regarding which activities you should not do after undergoing a STAR™ Ankle replacement. This advice will likely include no running, jumping, or heavy work. Not following this advice may result in early failure or loosening of the ankle replacement. It may also result in breakage of a bone which might require additional surgery.

What Are Some Alternatives to STAR™ Ankle Replacement Surgery?

You should discuss other methods for treating your ankle pain with your surgeon. Treatments for ankle arthritis range from a variety of conservative treatment methods to surgery. Initial treatment includes arthritis medicine(s), avoiding painful activities and using a specialized ankle brace. Physical therapy may be beneficial in some cases. A cortisone injection into the ankle joint may also help to relieve the pain, although usually this treatment is a temporary measure. When conservative therapy fails to relieve patient symptoms, surgical intervention may be recommended. One surgical procedure to relieve your ankle pain is to stop the movement of your ankle by fusing (joining) the ankle bones together. This surgery is referred to as "ankle fusion" or "arthrodesis".

There are different methods that can be used for ankle fusion. These methods involve using screws or other metal “hardware” to hold the ankle bones in place until the bones around the joint grow together. Once an ankle is successfully fused, it never moves again. Another option for treating your ankle pain is a total ankle replacement, either with the STAR™ Ankle or with a different device. With all ankle replacements, the ankle joint is replaced by a prosthetic device, which attempts to mimic the movement of the ankle. Currently, there are several ankle replacements other than the STAR™ Ankle available in the United States (U.S.). **The STAR™ Ankle differs from other ankle replacements in that it uses a mobile bearing versus a fixed bearing and does not require the use of bone cement during implantation.**



How Do I Make My Choice for Ankle Therapy?

You should discuss total ankle replacement using the STAR™ Ankle with your surgeon. You should also discuss other methods, such as fusion surgery, for treating your ankle pain. Please ask your surgeon any questions you have so that you will make the best decision. It is important to fully understand the risks and benefits of each type of treatment before you make your decision.

What Short-Term Lifestyle Changes Will I Have to Make?

To prepare yourself for surgery, you may be asked to lose weight if you are overweight. Smokers will need to stop smoking 2 weeks before surgery.

For the first two weeks after surgery, you will likely not be able to bear any weight on your ankle. You need to keep your ankle elevated as much as possible and limit your activities. Once you are in your removable cast, you can do more activities, including walking. Over the next month you will be gradually allowed to go back to your normal daily activities. For all of these steps, however, you need to follow the specific advice of your surgeon.



What Long-Term Lifestyle Changes Will I Have to Make?

After an ankle replacement you can do as much walking and swimming as you are comfortable with. You can also participate in sports that do not put too much force on your ankle (called “non-impact athletics”), such as golf and hiking. You should not run, jump, perform heavy lifting or manual labor unless specifically allowed by your surgeon. These types of activities may cause the STAR™ Ankle replacement parts to wear out prematurely, loosen or even break. Ask your surgeon about specific activities that you are interested in. Things that you can do to increase the life of the STAR™ Ankle replacement include keeping your weight down and not smoking.

How Do I Know if the STAR™ Ankle is Working Properly?

For the first two weeks after surgery it is normal to have a moderate amount of pain. You may need to use pain medicine(s). This pain will slowly decrease over time, but it is not unusual to experience some discomfort for up to three months and swelling may continue for up to a year after surgery.

Contact your surgeon right away if at any time you notice:

- Fluid leaking from your wound
- Redness around your wound
- Pain or swelling that starts suddenly (especially after an ankle twist or fall) or
- Severe pain after the initial two weeks following your surgery.



What Have Clinical Studies Shown About This Device?

The clinical studies show the STAR™ Ankle is reasonably safe and effective for the treatment of ankle arthritis. One multicenter pivotal two-year clinical study was conducted to compare the safety and effectiveness of the STAR™ Ankle to ankle fusion. A total of 224 patients (158 STAR™, 66 fusion) were enrolled in the study. Data from an additional series of 448 STAR™ Ankle patients (continued access cohort) were enrolled to add to the results of the pivotal study. All patients enrolled in these studies had ankle arthritis and failed six months of conservative therapy. In all studies, each patient's pain was recorded as well as how well their ankle functioned before and after the surgery.

In the pivotal study, the STAR™ Ankle showed favorable results when compared to ankle fusion. STAR™ patients had superior effectiveness compared to ankle fusion and had comparable safety results were comparable to ankle fusion. Outcomes for ankle range of motion and improvement in pain were shown to be better in STAR™ Ankle patients. Patient satisfaction at 2 years with the STAR™ Ankle was good to excellent in 86% of patients, compared to 85% of fusion patients. The continued access cohort also had favorable results further supporting the safety and effectiveness of the STAR™ Ankle. In the continued access cohort, fewer patients needed a second operation compared to the pivotal study, which is most likely attributed to experience and improvements in the STAR™ Ankle surgery technique. The clinical outcomes between the STAR™ Ankle and ankle fusion differ because the STAR™ Ankle is intended to preserve range of motion while ankle fusion is intended to prevent ankle motion.

Ask your surgeon for more details about the clinical study and its results and see the following section which describes the types of problems you may encounter.

What Problems May I Expect?

Like other joint implants, the STAR™ Ankle will wear with time and may need a replacement part, may need to be replaced or your ankle joint may need to be fused. The life span of the STAR™ Ankle is not easy to estimate, and depends on many things. This may include your body type, and any defect of your ankle joint and the activities in which you take part. If you are overweight, smoke, or take part in activities that put stress on your ankle, the life span of the STAR™ Ankle may be shorter.



The most common problems observed in the company's clinical studies were pain, nerve injury, wound healing problems, and bone fracture. Many of these problems occurred during the surgery to implant the device and did not affect the good to excellent clinical results seen with the STAR™ Ankle.

Following ankle replacement surgery, pain is often experienced while your ankle is healing. In the Pivotal Trial, 22% of STAR™ Ankle patients experienced pain during the period from just after surgery to three months after surgery. By 24 months after surgery, 12% of the patients reported pain. Of the patients reporting pain at 24 months, nearly all had less pain than before their ankle replacement surgery.

During ankle replacement surgery, nerve injuries including numbness around the surgical scar sometimes occur. In the STAR™ Ankle Pivotal Trial, 12% of patients reported a nerve injury during the period from just after surgery to three months after surgery. After that early post-operative period, the number of patients reporting a nerve injury was lower. By 24 months after surgery, only 2% of the patients reported a nerve injury or numbness. Nerve injury is not a common event during or after fusion surgery.

At any point during the 2 year Pivotal Trial, 18% of patients reported a bone fracture related to the STAR™ Ankle; half of these fractures occurred during surgery and were taken care of by the surgeon at the time of surgery. Other fractures occurred during the weeks following surgery. By 24 months after surgery, all but 1% of fractures were healed.

Following ankle replacement surgery, wound problems sometimes occur. In the STAR™ Ankle Pivotal Trial, 20% of patients experienced a wound problem during the period from just after surgery to three months after surgery. By 24 months after surgery, less than 1% of these problems persisted.

Based on two year results, problems with the STAR™ Ankle that required additional surgery occurred in about 17% of patients in the Pivotal Trial; about 8% involved the replacement or removal of all or part of the STAR™ Ankle. Of the ankle fusion patients, 11% required an additional surgery. In the continued access cohort, 8% of patients required an additional surgery; about 3% involved the replacement or removal of all or part of the STAR™ Ankle.

Will My Implant Set off a Metal Detector?

Due to the metal in your ankle replacement, MRI and metal detectors may be affected. A patient ID card will be provided to you by the manufacturer through your surgeon. The card will identify you as having a total ankle replacement that may activate these devices. You need to show this card when getting x-rays and MRIs. When passing through an electronic detection system you may use this card to notify security of your implant.

Frequently Asked Questions and Answers about the STAR™ Ankle

Q: How long will I be in the hospital after surgery?

A: Most patients are in the hospital for two or three days. Some patients have shorter stays in the hospital. However, a small number of patients may stay in the hospital for longer than five days.



Q: Will my activity be restricted after surgery?

A: Typically, prior to putting any weight on your ankle, you will use crutches or a walker for a minimum of two weeks after surgery. Your doctor will let you know when you can begin putting some of your weight on your ankle. If your surgeon allows, you can put full weight on your ankle about four weeks after the operation. In most cases, your cast will be removed six weeks after the operation.

Q: Have the materials in the STAR™ Ankle been used in the human body before?

A: Yes, the STAR™ Ankle device uses the same materials (i.e., cobalt chromium alloy, titanium, and polyethylene) that have been used for the last 30 years in artificial hip and knee replacements.



Q: What are the similarities and differences between the STAR™ Ankle and fusion?

A: The STAR™ Ankle replacement is designed to maintain as much of your ankle's normal range of motion as possible while relieving your pain. Fusing the ankle hopes to relieve your pain by restricting the ankle's range of motion. Pain is common and occurred at similar rates in STAR™ and ankle fusion patients in a two-year study following surgery. There is also a slightly greater chance for reoperation with the STAR™ Ankle based on the results of this two year study. However, providing ankle motion allows you to perform your daily activities with more normal body motion. It is generally believed that providing ankle motion places less stress on your body as a whole.

Q: What will I be permitted to do after I have recovered from the ankle surgery?

A: After an ankle replacement, you can do as much walking and swimming as you like. You can also do as much non-impact athletics as you like, such as golf. You should not run, jump, perform heavy lifting or manual labor unless your surgeon allows it. These types of activities may cause the STAR™ Ankle to wear out prematurely, loosen or break. This may require further therapy, including surgery, to correct. Ask your surgeon about specific activities that you are interested in.

Q: What are the similarities and differences between the STAR™ Ankle and other ankle replacements?

A: During all total ankle replacement surgeries, metal components replace the bone surfaces in your ankle. In the STAR™ Ankle, the two metal parts are separated by a piece of polyethylene (a medical grade plastic) which moves between both metal parts. This polyethylene piece is called a Mobile Bearing, and helps to maintain the normal motion of the ankle as you do daily activities like walking and going up and down stairs. All other ankle implants in the U.S. have the plastic attached to one of the metal parts. **The STAR™ Ankle is the only ankle replacement used in the United States that attaches directly to your bone without the need for bone cement. Ankle implants, other than the STAR™ Ankle, require the use of bone cement, a type of grout, to attach the implants to the bone.**

LIMITED WARRANTY

Implants

SBi warrants that this product meets the manufacturer's specifications and is free from manufacturing defects at the time of delivery. This warranty specifically excludes defects resulting from misuse, abuse or improper handling of the product subsequent to receipt by the purchaser. SBi does not warrant the outcome of the surgical procedure.



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