Hintermann Series H3™
Total Ankle Replacement System

PATIENT EDUCATION

DRAFT

Caution: Federal (USA) law restricts the sale of this device to or on the order of a licensed physician.

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Glossary

Ankle joint: the joint between the lower leg and foot. Three bones come together to create the ankle joint: the tibia, the fibula, and the talus.

Arthritis: an inflammation of the joints. Arthritis causes joint pain and stiffness. The most common types of arthritis are osteoarthritis and rheumatoid arthritis.

Arthrodesis: a surgery that fuses the three ankle bones together. After surgery you can move your ankle up and down but not side to side.

Arthroplasty: a surgical procedure to treat painful conditions of the ankle, the most common being arthritis. The surgery removes the ankle joint and replaces it with an artificial implant.

Cartilage: the tissue that covers the ends of your bones. Healthy cartilage allows your bones to glide smoothly at your joints. Injured, inflamed, or damaged cartilage can cause pain at your joints.

Cortisone: a chemical that your physician injects into your ankle joint to reduce swelling and pain.

Fibula: the smaller bone of the lower leg. It is from the knee to the ankle and forms the outside anklebone.

Ligament: a tough band of tissue that holds one bone to another. Ligaments help to provide support to a joint.

Non-surgical treatment: any treatment option that does not involve surgery. Typically, it includes methods to reduce pain for the patient such as pain medications, physical therapy, orthotics, braces, walkers, and compression stockings.

Osteoarthritis: occurs when the cartilage becomes thin and eventually wears out, causing bones in the ankle joint to rub together. This causes pain and the loss of movement in the joint.

Post-traumatic arthritis: arthritis that develops after a sports injury, car accident, or from a recurring injury.

Rheumatoid arthritis: occurs when the cartilage around the ankle joint becomes inflamed because of an immune system activity. This is one of the most serious type of arthritis. It occurs more often in women than men.

Talus: the anklebone. The talus is located between the heel bone (calcaneus) and the fibula and tibia. The bone connects the leg and foot so the body's weight can be transferred which allows a person to walk.

Tendon: a tough piece of tissue that connects muscle to bone.

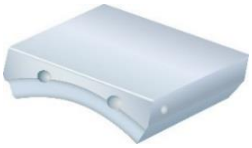
Tibia: the large bone of the lower leg. It is from the knee to the ankle and forms the inside anklebone. It is more commonly referred to as the shin bone.

What is the Hintermann Series H3™ Total Ankle Replacement System?

The Hintermann Series H3™ TAR, also referred to as H3™, is a three-part total ankle replacement (TAR) prosthesis (artificial body part):

- **Metal Tibial Part** – the upper part of the TAR that covers the upper part of your ankle joint, which is the bottom of the tibia (shin bone).

- **Polyethylene Sliding Insert (PE Inlay)** – the middle part of the TAR is made of polyethylene (plastic). It sits between the upper and lower metal parts to allow the ankle to move.

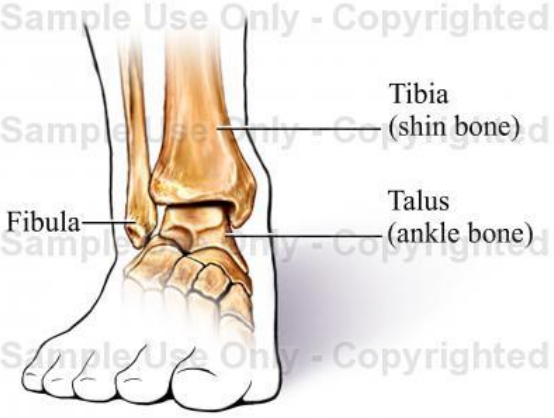


- **Metal Talar Part** – the lower part of the TAR that covers the lower bone of the ankle joint, the talus.

The Hintermann Series H3™ TAR tibial and talar components are made from a metal called Cobalt Chromium alloy. They have two coats of porous Titanium and Hydroxyapatite (a ceramic like material) on the sides that have contact with (touch) the bones. This coating promotes bone growth into the tibial and talar metal parts.

Your ankle joint is located where your leg and foot meet and is made of three bones:
the **fibula (leg bone)**, the **tibia (shin bone)**, and the **talus (ankle bone)**.

A layer of **cartilage** (padding) pads the joint and allows the bones to move easily. If the cartilage is damaged, it can cause pain, and may cause the bone to wear down.



Why Doctors Use It

Doctors use the Hintermann Series H3™ TAR to replace your ankle joint when you have had ankle pain from arthritis (a condition that causes pain, stiffness, swelling, and even warmth at the ankle) for a long time. There is no cure for arthritis.

The Hintermann Series H3™ TAR is indicated for use as a non-cemented implant to replace a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis or arthritis secondary to inflammatory disease.

- Primary osteoarthritis: arthritis that occurs when the protective padding on the ends of your ankle bones wears down over time
- Post-traumatic arthritis: arthritis that is caused by an injury to the ankle.
- Arthritis secondary to an inflammatory disease: arthritis that is caused by an inflammatory disease (disease that causes the body's defense system to attack the ankle)

Who Cannot Have This Done (Contraindications)

The Hintermann Series H3™ TAR should not be used if you have any of the conditions listed below. Your surgeon will help you understand if any of these conditions apply to you.

- Skeletal immaturity (bones that are not fully grown)
- Poor quality bone that keeps the bone from supporting the implant
    - Some conditions that cause poor bone quality are osteopenia and osteoporosis (conditions where bones become brittle and may break)
    - Avascular necrosis (death of bone due to lack of blood) of the talus
- Infection now or in the past in the ankle joint or the bones next to the ankle

- Poor ankle alignment (ankle bones not lined up correctly) or severe deformity of the ankle or nearby bones and joints.
    - These problems can keep your foot from being flat to the ground
    - Poor knee alignment (knee bones not lined up correctly)
    - Poor support from ankle ligaments (tissue that holds the ankle joint together) that cannot be repaired during surgery

- Charcot joint (disease that destroys bones and soft tissues) or peripheral neuropathy (numbness, weakness or pain in your ankle and foot) that can cause Charcot joint of the affected ankle such as diabetes
- Poor muscle function around the ankle
- Not enough blood flowing to the bones of your foot
- Poor skin and soft tissue quality around the surgical area
- Immunosuppressive therapy (medications that decrease your ability to fight infection)
- Prior ankle fusion or revision (replacement) of total ankle replacement
- High demanding sport activities (e.g. contact sports, jumping)
- Suspected or documented metal allergy or intolerance

Things You Must Do to Avoid Serious Harm (Warnings)

Serious complications after surgery with the Hintermann Series H3™ TAR may occur if you:

- Are not in good general physical condition
- Have severe osteoporosis (a condition that causes poor bone quality)
- Have body or bodily structure abnormalities
- Have allergies or other reactions to foreign (not normally found in the body) materials
- Have disorders that affect the whole body or disorders caused by abnormal chemical reactions in your body
- Have a severe deformity (part of the body that is not normal)

Things You Must Do to Avoid Other Harm (Precautions)

- The Hintermann Series H3™ TAR requires special training to be implanted correctly. Please ask your surgeon whether he or she has been trained to implant the Hintermann Series H3™ TAR .
- It is important to follow your surgeon’s advice regarding which activities you should not do after undergoing a Hintermann Series H3™ TAR . This advice will likely include no running, jumping, or heavy work (work that requires manual labor or lifting heavy items). Not

following this advice may cause the TAR to wear out early, loosen or break or cause a broken bone. Any of these problems might require additional surgery to replace all or part of the TAR or to remove the TAR and fuse your ankle (join your ankle bones together).

Risks of Using the Hintermann Series H3™ TAR

The complications that may occur when using the Hintermann Series H3™ TAR are:

- Fractures of bones next to the ankle implant area during and after surgery
- Soft tissue injuries at or next to the surgical area during surgery with injury to blood vessels or nerves
- Malalignment (not lined up correctly) of the ankle during surgery
- Infection in area of the incision (cut in skin during surgery) or an infection involving the TAR
- Loosening of the TAR parts
- Bone loss of the tibia, talus or fibula
- Sinking of the TAR parts
- Problems with the polyethylene (plastic) TAR inlay part such as fracture (breaking), wear (wearing out) and making the ankle unstable
- Arthritis in nearby areas
- Lack of ankle motion due to scar tissue, friction, or muscle or ligament tightness
- Avascular necrosis of the talus (death of ankle bone due to lack of blood)
- Long lasting pain, extreme sensitivity and pain
- Swelling
- Bone growth in unusual areas like soft tissues
- Numbness, weakness or pain in your ankle and foot
- Blood clot that stops blood from flowing in a blood vessel
- Wound healing problems

Any of these complications could require treatment such as medicine or another operation that could involve replacing or removing part or all of your TAR.

A study of 298 patients who had the Hintermann Series H3™ TAR was conducted. The adverse events (complications) related to the Hintermann Series H3™ TAR that were reported in the study are listed below in Table 1. Five of the adverse events were ongoing and had not been treated when the study ended.

Table 1: Adverse Events Related to the Use of Hintermann Series H3™ TAR

Description of Adverse Event related to the use of the H3 TAR	Total number of patients for whom this adverse event was reported out of the total number of hips in the study	Percent (%) of patients who had this adverse event	Treatment or testing needed due to this adverse event	Number of patients needing this treatment
Long Lasting Pain	1/273	0.4%	Tibia post replaced	1

Description of Adverse Event related to the use of the H3 TAR	Total number of patients for whom this adverse event was reported out of the total number of hips in the study	Percent (%) of patients who had this adverse event	Treatment or testing needed due to this adverse event	Number of patients needing this treatment
Aseptic Loosening	2/273	0.7%	Ankle fused	1
			Inlay replaced	1
Aseptic Loosening- Tibia	1/273	0.4%	Tibia part replaced	1
Bone Loss	1/273	0.4%	Ongoing, no treatment	1
Bone Loss - Talus	1/273	0.4%	Talas part replaced	1
Bone Loss – Tibia	2/273	0.7%	Ongoing, no treatment	1
Fracture - Inlay Part	2/273	0.7%	Tibia part replaced	1
			Inlay replaced; hindfoot/midfoot fusion	1
Wear – Inlay Part	2/273	0.7%	Inlay replaced	1
			1 or both metal parts replaced; cheilectomy	1
Sinking – Talus Part	4/273	1.5%	Talus part replaced & ligaments repaired	1
			Talus part replaced	1
			Ongoing, no treatment	2
Sinking – Talus & Tibia Parts	1/273	0.4%	Ongoing, no treatment	1
Sinking – Tibia Part	1/273	0.4%	Ankle fused	1

Benefits Observed Using the Hintermann Series H3™ Total Ankle Replacement System

Good results after TAR surgery are not guaranteed, but TAR surgery may help you return to a more active life and may reduce pain and improve the motion in your ankle joint.

The results of a study of the Hintermann Series H3™ TAR in patients who had TAR surgery are included in the section called "*What Are the Results of Studies of the Hintermann Series H3™ TAR System?"* These results describe the benefits these patients experienced.

How to Decide About This Treatment

Discuss the possible risks and benefits associated with this surgery with your surgeon and with your family or caregiver to decide if the Hintermann Series H3™ TAR is the right treatment for you.

What Happens Before the Surgery?

Before surgery, your surgeon wants you to be as healthy as you can be. In the weeks before your surgery, you need to:

- Schedule your pre-operative (before surgery) visit with your surgeon;
- Have a general physical examination by your primary care physician;
- Find out if you need to stop taking any medicine before your surgery;
- If you smoke, think about quitting;
- Lose some weight if your surgeon tells you to;
- Get any lab tests that may be needed;
- Speak to a physical therapist;
- Plan for any care and therapy you may need after your surgery; and
- Fast (do not eat or drink) the night before your surgery.

What Happens During the Surgery?

Total ankle replacement surgery removes the damaged parts of the ankle joint and installs new parts in their place. The surgeon cuts through the skin on the front of the ankle and then cuts the tibia (shin bone) and talus (ankle bone) to remove the damaged cartilage (padding) and make room for the ankle implant. After surgery, the foot is placed in a splint (bandage that will not bend that keeps the ankle from moving).

What Happens After the Surgery?

Usually, two to four days after TAR surgery, your foot is placed in a cast for about six weeks to keep your foot from moving. Most patients will have some pain for the first two weeks after surgery. This pain should decrease over time and with prescribed, or over-the-counter, pain medication. In addition, limit the weight you place on your ankle for the first week or two after surgery. When you move around, use a wheelchair, scooter, or crutches. Also, keep your foot raised as much as possible after surgery to help with healing.

Your surgeon will watch how you heal and usually six weeks after surgery, you may return to your normal daily activities. Once your surgeon allows you to, you can walk, swim, and even take part in non-impact sports, such as golf or hiking. Do not run, jump, or lift anything heavy unless your surgeon says you can. These types of activities could cause the device to wear out too quickly, loosen, or break, which may require additional surgery. Speak with your surgeon if you have any questions about activities not listed.

Even when your surgeon allows you to return to your normal daily activities, you may have some pain for up to three months after your surgery. Also, you may see some slight swelling of your ankle for up to

a year after surgery. Your surgeon may suggest wearing a compression stocking (a long sock that gently squeezes your leg to move blood up your leg) to avoid swelling for four to six months following your surgery.

How your TAR implant wears over time is based on a variety of conditions. Recent studies show that there is a 94% chance your TAR will still work well after five years of use, and an 80% chance that your TAR will still work well after ten years without any changes to the implants.[1]

When to Call Your Doctor

Call your surgeon if you experience any of the following:

- Signs of infection (if you have a fever, chills, redness around your incision, increased pain, the feeling of pressure in the ankle, or trouble walking). Infection can cause an implant to fail and require you to have a second surgery to remove or replace the ankle implants.
- Bleeding or excessive drainage (continued oozing of liquid) from your incision(s) that is more than what your surgeon told you to expect. Too much bleeding or drainage may be a sign that your wound is not healing correctly and you need to have your surgeon examine it. You may need to take medicine, or you may need to have the incision re-opened to make sure it will heal correctly.
- Severe pain that comes on quickly or an increase in your pain level that limits your ability to function. This kind of pain may indicate that there is a problem with your ankle implant and you should call your surgeon to see if you should be examined.
- Loss of sensation (feeling), or significantly decreased sensation (your feeling is dull or numb) in your leg/foot. This may indicate that there is a problem with your hip replacement and you should call your surgeon to see if you should be examined.
- Ongoing changes in your medical condition. You and your surgeon will need to decide if your medical condition or surgery could make it more likely that the Hintermann Series H3 Ankle may break, loosen or fail, or that your bones may be damaged. This could lead to the need for additional treatment, including surgery.

[1] Barg et al. "HINTEGRA Total Ankle Replacement: Survivorship Analysis in 684 Patients."(July 2013). *Journal of Bone and Joint Surgery America.* http://jbjs.org/content/95/13/1175

Where You Can Find Out More

This document is provided to give you information about your treatment choices. It is not intended to replace advice from a doctor. If you have any further questions or need additional information about the Hintermann Series H3™ TAR, speak with your surgeon.

The company that makes the Hintermann Series H3™ TAR is:

DT MedTech, LLC
110 West Road, Suite 227
Baltimore, MD 21204
Telephone: (410) 427-0003

Travel

Due to the metal in your ankle replacement, 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. When passing through an electronic detection system you may use this card to notify security of your implant.

How Clinical Studies Were Done

One clinical study compared the safety and effectiveness of the 298 patients with the Hintermann Series H3™ TAR to a Performance Goal (PG) based on the published literature and registry data of another legally marketed TAR system (control device).

All of the H3™ TAR study patients had ankle arthritis that was not relieved by non-surgical treatments. Each patient's pain and ankle function were recorded before and after the TAR surgery.

Safety Information

The primary safety assessment for this study compared the H3™ TAR Serious Adverse Device-Related Events (SADEs) reported in the study and combined SADEs reported for the H3 TAR in the literature and a national joint registry to the combined SADEs reported for the control device in publications and a national joint registry.

Among the three groups compared, the H3™ study group had the lowest rate of SADEs (16 out of 273 patients or 5.9%), although the H3™ literature rate was very similar (146 out of 243.7 or 6.0%). The SADE rate for the control group (316 out of 3020 patients or 10.5%), was significantly higher than those for the H3™ TAR.

The rate of replacement or removal of the H3™ TAR in the study (27 out of 273 patients or 9.9%) and in the literature (134 out of 2437 patients or 5.5%) was lower than that for the control group (391 out of 3020 patients or 12.9%).

Additional safety results of this study are shown in the section titled, "*Risks of Using the Hintermann Series H3™ TAR*."

Effectiveness Information

The study had 3 co-primary effectiveness endpoints:

1. American Orthopaedic Foot and Ankle Society (AOFAS) Hindfoot Score at least 2 years after surgery The AOFAS Hindfoot Score is a score that covers three categories: pain, function and range of motion, and ranges from 0 (worst) to 100 (best).
2. Survivorship (no TAR parts replaced or removed) within 5 years of surgery, and
3. Rate of patients with a serious complication related to the TAR (SADE) other than a replacement or removal of 1 or more TAR parts within 2 years after surgery.

The PG for the AOFAS score at least 2 years after surgery was 71 and the average for the Hintermann Series H3™ TAR was 78 with a lower 95% confidence limit of 76.12. The PG for Survivorship was 0.83 and for the Hintermann Series H3™ TAR was 0.912 with a lower 95% confidence limit of 0.878. The PG for the rate of subjects with an SADE was 0.937 and for the Hintermann Series H3™ TAR was 0.963 with a lower 95% confidence limit of 0.939. For all 3 co-primary effectiveness endpoints, the Hintermann Series H3™ TAR results were higher than the PGs. Thus, the H3™ TAR is an effective treatment for a painful arthritic ankle joint due to primary osteoarthritis, post-traumatic osteoarthritis or arthritis secondary to inflammatory disease.

The rate of replacement or removal of the H3™ TAR in the study (9.9%) and in the literature (5.5%) was lower than the rate of 12.9% for the control device.

Additional safety results of this study are shown in the section titled, "*Risks of Using the Hintermann Series H3™ TAR*."

More Information About Your Condition

Although your surgeon is planning to use the Hintermann Series H3™ TAR for your ankle replacement, you should be aware that there are alternative (other) treatments. Patients, with their surgeon's help, are likely to choose from one or more of the following options.

- No treatment. With this option, your surgeon will continue to watch your ankle but will advise you to delay having ankle surgery.
- Your surgeon may prescribe over-the-counter or prescription pain medication for your ankle pain. Your doctor may suggest wearing a brace, orthotics (shoe inserts), or using a cane to put less pressure on your ankle joint and tell you to avoid any activities that may cause you pain. Or,

your doctor may inject cortisone into your ankle joint to help relieve pain. These treatments can relieve some of the pain caused by arthritis but will not cure the disease.

- When non-surgical treatments no longer work, your doctor may recommend surgery.
    - One surgical procedure, arthrodesis (ankle fusion), is fusing your ankle joint (joining the bones together) to decrease the movement of the ankle. While ankle fusion limits motion, it can permit the resumption of heavy lifting or more vigorous activities, unlike total ankle replacement. Many studies also suggest that the need for further surgical procedures is less with ankle fusion than TAR.
    - Another surgery is total ankle replacement (TAR) where implants are placed on the tibia (shin bone) and talus (ankle bone) to create a new ankle joint. Some TAR implants have 2 parts and some have 3 parts. The Hintermann Series H3™ TAR has 3 parts.

Questions & Answers: Hintermann Series H3™ TAR

Q: What is the typical length of hospital stay after TAR surgery?

A: Usually, TAR patients stay in the hospital for two or three days after surgery. During this time your surgeon will watch your progress to see if you require additional recovery time.

Q: Are my activities restricted after TAR surgery?

A: Yes. usually two to four days after TAR surgery, your foot is placed in a cast or you will be given walker to use. Do not place any weight on your ankle for at least two weeks after surgery. Use crutches, a walker, or a wheelchair for this period or until your surgeon tells you to begin putting weight on your ankle again. Typically, you can put full weight on your ankle four weeks after surgery. Your cast will be removed, or you can quit using your walker about six weeks after surgery. Until then, there will be restrictions on your activities.

Q: When can I return to my normal daily activities?

A: Your surgeon will tell you when you can walk, swim, and participate in non-impact activities such as golf or hiking. Do not run, jump, or lift heavy items without discussing this with your surgeon first. These types of activities place a stronger force on the ankle implant and may cause it to wear out early, loosen, or break. It could also cause pain and require additional surgery to fix the issue. Discuss with your surgeon any activities not listed to see if they may be continued, or if some modification is needed.

Q: When can I return to work?

A: Before returning to work, think about your rate of recovery and pain tolerance. Also look at your job description and what your employer will do to minimize chances of injury to your ankle. This includes getting to work, parking, getting to your work area, being able to rest, and to elevate (raise) your foot. If you perform physical work, you may return to work once you are able to stand and walk for as long a time as your work requires, which may not be until three to four months after surgery. Your doctor may also recommend that you change to lighter work to protect your new ankle.

Q: How long until I can drive?

A: Before returning to driving, you need to quit taking all prescription pain medications. Patients who have minimal pain and a car with automatic transmission may be able to drive about two months after surgery.

Q: Will my insurance cover my TAR surgery?

A: Yes, this procedure is usually covered by most major insurance carriers along with Medicare and Medicaid. However, you should speak with your insurance provider to determine coverage under your specific plan.

Q: What happens should I ever need an X-ray or MRI, or need to pass through a metal detector?

A: Since certain parts of your Hintermann Series H3™ TAR prosthetic are made of metal, your surgeon will issue you a card from the manufacturer stating you had a device implanted in your ankle that may be dangerous to you if you have an MRI and may activate metal detectors. Be sure to carry this card with you at all times, especially when getting x-rays or MRIs, and ask your physician if it is safe for you to have an MRI. Also have this card available when passing through metal detectors.

Q: Are the materials in the Hintermann Series H3™TAR prosthesis safe for implantation?

A: Yes. The materials used in the Hintermann Series H3™ TAR prosthesis (i.e., Cobalt Chromium alloy, Titanium, Hydroxyapatite, and Polyethylene) are the same materials that have been used in other prosthetic devices, such as hip and knee replacements, for the last 40 years.

Q: What is the difference between the Hintermann Series H3 ™TAR implant surgery and ankle fusion (ankle arthrodesis) surgery?

A: The Hintermann Series H3™ TAR system was designed to maintain your ankle's normal range of motion (movement) after removing the painful arthritis. Arthrodesis fuses the ankle bones together to relieve your arthritic pain but limits your ankle's range of motion. However, it is important to remember that some pain may remain due to pre-existing damage to the surrounding soft-tissues.

There is no guarantee that additional surgeries will not be needed after both surgical techniques. While ankle fusion limits motion more significantly, it can permit the resumption of heavy lifting or more vigorous activities, unlike total ankle replacement. Many studies also suggest that the need for further surgical procedures is less with ankle fusion than TAR. However, with the Hintermann Series H3™ TAR you will maintain some of the movement of your ankle, which may allow you to continue with most of your daily, normal activities after recovery. It is generally believed that by maintaining ankle motion, less stress is placed on the body as a whole and may limit development of arthritis in the joints next to your TAR.

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This patient education brochure is presented by DT MedTech, LLC to provide an overview of ankle replacement surgery, and does not include all information needed to determine eligibility for this ankle replacement device or for the proper use and care of this implanted device. Patient results may vary, as results depend on personal circumstances. How long an ankle replacement lasts, also varies from person to person. There is no guarantee it will last for the rest of a patient's life and it may need to be replaced at some point-in-time. We ask that you please consult your physician to determine if this product is right for you.

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