



Learn more about
Anika's toe solutions

A Patient's Introduction to
Toe Solutions



Our Patients Stay Active

The Anika Toe Systems preserve the native anatomy of your joint and can allow you to resume full activity levels.

Has your doctor diagnosed you with arthritis (deterioration and/or loss of cartilage) or pain in your big toe that is limiting your range of motion? **The Anika HemiCAP®** implant systems may be a great option for the younger, active patient with specific amounts of deterioration. These implant systems consist of a cap and screw that allow the surgeon to restore only the damaged areas of the joint. Your natural anatomy, including the shape of the bone and surrounding muscles, tendons and ligaments are preserved, allowing you to Stay Active® without pain.



*Actual ToeMotion patient

Find out if the Anika Toe products are right for you!

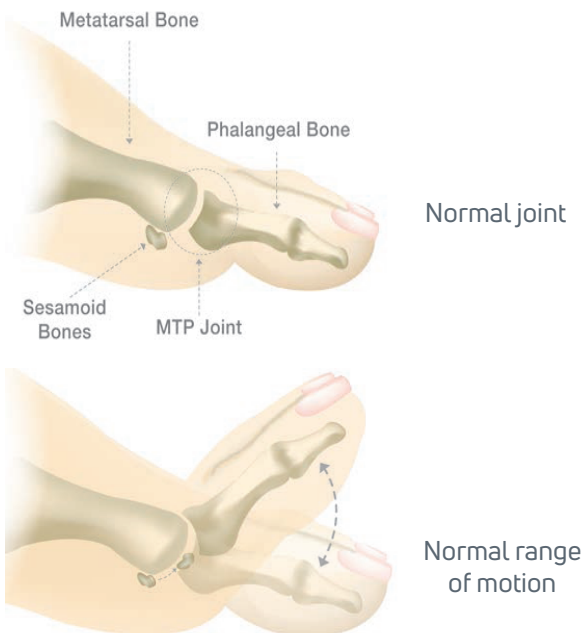
HemiCAP® DF ToeMotion® Total Toe System





Anatomy of the big toe

The great or “big” toe is an important part of how we walk. It bends with every step while giving us the ability to push off and move into our next stride. There is a major joint at its base called the metatarsal-phalangeal joint or MTP joint. The MTP joint is located where the metatarsal and phalangeal bones meet and glide against each other. The ends of these bones are covered with a smooth articular cartilage that helps the bones move together freely.



How does cartilage get damaged?

A variety of events can damage cartilage, including trauma (injury), infection, inflammation or a joint that is not properly aligned. A traumatic injury can cause an isolated defect, while malalignment tends to cause widespread damage to both sides of the joint, similar to the way a car tire loses its tread when the wheels are not properly aligned.

ARTHRITIS =
deterioration and/or loss of cartilage

Can arthritis get worse?

Any event, continued malalignment or disease process (i.e. inflammation) that injures the cartilage may cause joint damage or arthritis. A small cartilage injury may become larger and lead to widespread cartilage loss or degenerative joint disease over time. Typically, as the "wear and tear" on the MTP joint progresses, there are bone spurs or osteophytes that form on top of the bones. These bone spurs can limit the motion of the joint because they are painful when the toe moves over them. With time, the spurs get larger, the cartilage starts to wear away and the toe becomes stiff. In the big toe, this condition is called Hallux Limitus or Hallux Rigidus.





What are the treatment options for Hallux Rigidus and damaged cartilage?

Depending on the degree of cartilage injury, the age of the patient and the level of activity desired, patients may be candidates for: a cheilectomy, an Anika HemiCAP®, a total joint replacement or even a joint fusion (arthrodesis). 10 years ago, Anika introduced joint preserving technologies that would allow the damaged part of the joint to be restored without limiting motion or removing significant amounts of bone and tissue.

What about a Cheilectomy?

This technique involves making a diagonal cut off the top (dorsal) portion of the metatarsal head to remove bone spurs. By taking away the painful spurs and making the end of the joint smaller, it allows the toe to move more freely. This procedure is quick and easy but may remove up to 40% of the metatarsal joint surface. A cheilectomy leaves bone exposed, so while it may provide pain relief, it usually doesn't eliminate the pain altogether. A cheilectomy may be ideal when the primary problem is spurring on the top of the metatarsal head and the space between the joints is sufficient. However, because x-rays do not show

cartilage, doctors often underestimate the extent of the disease. Therefore, what may have been planned as a cheilectomy could have been a HemiCAP® procedure.



Cheilectomy

What about the Anika HemiCAP Toe DF (Hemiarthroplasty) implant?

The HemiCAP Toe DF implant is a technologically advanced system designed to match the shape and contour of the individual patient's cartilage surface. It is a contoured cap that goes over the area of damaged cartilage on the metatarsal side of the joint and is designed to protect the remaining (healthy) cartilage. Instead of a one-piece implant with a stem built in, the HemiCAP has two components. It consists of a cap and screw that mate together via taper lock. Stemmed implants have been shown to loosen, whereas the HemiCAP screw system has been a stable construct over the last 10 years. The philosophy behind the system is to prevent further damage to the joint while maintaining the patient's native anatomy and motion. The HemiCAP Toe DF not only matches the diameter of the damaged area but also the precise radius of both curvatures on the patient's joint surface. The physician uses a unique 3-D mapping system to optimize the implant to each patients' anatomy. Once the mapping



points are defined, the appropriate implant is chosen and then implanted into the patient. Different diameters & curvatures are available to provide a proper fit for each patient. The HemiCAP® Toe DF system is indicated for the treatment of patients with the following clinical conditions: hallux rigidus, hallux limitus, hallux valgus and an unstable or painful MTP joint.

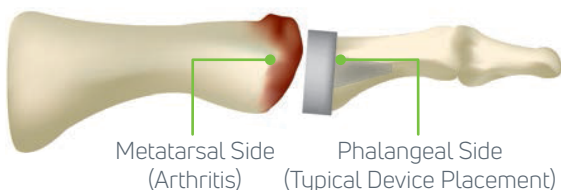


HemiCAP DF

Why is the HemiCAP Toe DF placed on the metatarsal side?

The HemiCAP implant was the first implant designed for the metatarsal side of the joint, which is where the arthritic changes begin. This side also tends to have more wear and tear as well as spurring. Other hemiarthroplasty devices replace the phalangeal side, which may still have remaining cartilage and fails to address the primary disease site, which is the metatarsal.

Other Devices (Phalangeal Metal Hemi Toe)



Does it “burn” any bridges?

There is minimal bone removed with the HemiCAP[®] implant, while existing joint replacements surgically remove the entire bone surface (on both sides of the joint). This means there is far less of the natural bone to work with if future surgery is required. The HemiCAP system leaves more bone intact, therefore providing more options should future surgery be required.

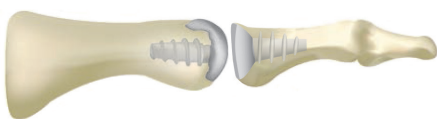
Is there clinical data to support this product?

Yes. Positive results have been published in peer reviewed medical journals. Please contact Anika directly for the specific information at: customerservice@anika.com.



Does Anika provide a Total Toe replacement option?

For patients with extensive damage on both sides of the joint, Anika provides a total toe replacement; The ToeMotion® Implant System. This consists of the metatarsal based HemiCAP® implant and a metal baseplate with plastic insert for the phalangeal side of the joint. The difference between the Anika total toe and other existing replacements is that it is implanted into the bone rather than on top, leaving natural bone to support the implant around its edges. This type of implant placement does not disturb any of the surrounding tissue attachments which are needed to maintain stability and lift-off for walking. The Anika ToeMotion is also the only total toe replacement that is implanted with screws on both sides of the joint to provide solid fixation. For patients looking to maintain an active lifestyle, receiving a fusion may not be a viable or appealing option. With the Anika ToeMotion, there is now a system that is minimally invasive, completely stable and motion preserving.



ToeMotion

A Solution for Failed Synthetic Cartilage Implants

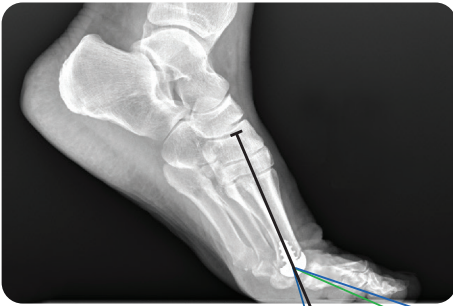
Anika now offers the BOSS™ Toe Fixation Post that is used in conjunction with both the HemiCAP® DF and ToeMotion® Implant Systems. The BOSS Toe Fixation System was specifically designed to fill the distal bone void left behind by synthetic cartilage implants (amongst others). It is a great solution for patients who want to maintain their motion and avoid a toe fusion.



How are the Anika HemiCAP Toe DF & ToeMotion Systems different from other (existing) devices?

- Custom matched and fit to the patient's joint shape and size
- Screw fixation provides a stable implant and has shown superior strength when compared to simple push-in and press-fit implants
- It is placed into the surface rather than on top, leaving the joint less surgically altered
- Motion and natural anatomy of the toe is preserved
- May be performed on an outpatient basis
- Positive results published in peer reviewed medical journals

Literature range of motion measurements



52° HemiCAP¹⁻¹⁰
42° Normal Gait

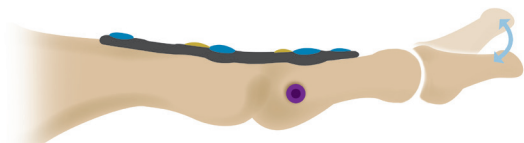
1. Aslan H, Citak M, Bas EG, Duman E, Aydin E, Ates Y. Early results of HemiCAP® resurfacing implant. *Acta Orthop Traumatol Turc.* 2012;46(1):17-21. **2.** Kline AJ, Hasselman CT. Metatarsal head resurfacing for advanced hallux rigidus. *Foot Ankle Int.* 2013 May;34(5):716-25. **3.** Erdil M, Elmadağ NM, Polat G, Tunçer N, Bilsel K, Uçan V, Erkoçak OF, Sen C. Comparison of arthrodesis, resurfacing hemiarthroplasty, and total joint replacement in the treatment of advanced hallux rigidus. *J Foot Ankle Surg.* 2013 Sep-Oct;52(5):588-93. **4.** Meriç G, Erduran M, Atik A, Köse O, Ulusal AE, Akseki D. Short-Term Clinical Outcomes After First Metatarsal Head Resurfacing Hemiarthroplasty for Late Stage Hallux Rigidus. *J Foot Ankle Surg.* 2015 Mar-Apr;54(2):173-8. **5.** Göçer H, Çıraklı A, Köken M, Yazıcı AK, Çağatay Zengin E. Midterm Results of HemiCAP Operation in the Surgical Treatment of hallux Rigidus. *J Clin Anal Med* 2015;6(suppl 4): 431-3. **6.** Cerci E, Tuzuner T, Sukur E, Baris A, Kanay E. Metatarsal head resurfacing arthroplasty in the treatment of hallux rigidus: is it reliable treatment option? *Musculoskelet Surg.* 2016 Aug;100(2):139-44. **7.** Mermerkaya MU, Adli H. A comparison between metatarsal head-resurfacing hemiarthroplasty and total metatarsophalangeal joint arthroplasty as surgical treatments for hallux rigidus: a retrospective study with short- to mid-term follow-up. *Clin Interv Aging.* 2016 Dec 13;11:1805-1813. **8.** Mermerkaya MU, Adli H. A comparison between metatarsal head-resurfacing hemiarthroplasty and total metatarsophalangeal joint arthroplasty as surgical treatments for hallux rigidus: a retrospective study with short- to mid-term follow-up. *Clin Interv Aging.* 2016 Dec 13;11:1805-1813. **9.** Range of Motion literature summary measurements: <https://www.arthrosurface.com/wp-content/uploads/2017/07/ROM-Comparison-Lat-x-ray-V2.jpg>. **10.** Average includes both dorsiflexion and plantarflexion as provided in reference 13

What happens if the HemiCAP® Toe DF or ToeMotion® Implant fails?

In case additional surgery may become necessary in the future, Toe HemiCAP DF Hemiarthroplasty can be converted to a total toe replacement or a fusion according to patient and surgeon preferences. The ToeMotion Total Toe Replacement can be converted to a fusion as well if a future revision may be required.

What is a Toe fusion (Arthrodesis)?

A fusion is a procedure where the phalangeal bone and the metatarsal bones are cut and shaped to fit together. The two bones are then aligned, set at a predetermined angle and permanently fixed with either screws or a plate, with the goal being to have the 2 bones “fuse” together overtime. Once fusion is achieved, the toe can no longer bend, altering the way you walk. Although it provides excellent pain control, a fusion is considered a procedure of last resort because it eliminates the majority of movement, making it especially difficult for women who want to wear high heels. It may limit activities such as running, golf and tennis as well as jobs or activities where kneeling or reaching up are required. It is considered an appropriate treatment for the older, sedentary and less active patient.



Arthrodesis (Fusion)



A patient's story

"For the last two years, the pain in my foot got progressively worse, so much, that I started to change the way I walked just so I could avoid walking on my toe. When I started walking on the outside of my foot, I ended up getting neck and back pain as well, which just made matters worse.

I'm a carpenter, which means I spend a lot of time going up ladders, bending, kneeling and reaching into difficult places. The pain got so bad I could no longer do my job. That's when I decided to go see a specialist. When I first saw my surgeon, he told me that my only option to get rid of the pain was a fusion. Even though it sounded pretty drastic, I decided to schedule the surgery.

Being a carpenter, I am very familiar with the concept of fusing things together, so I knew that I would end up losing most of the movement in my toe. Not a great option, but at that point there was nothing else that would take care of my pain.

As fate would have it, just days before my surgery, my surgeon advised me that there might be another option. He told me about a product called the HemiCAP® which was an implant that would replace the arthritic part of my joint and give me a

new surface. I could avoid getting a fusion, keep the movement of my toe, and if it worked as planned, I would have relief from my pain.

Even though it was new for the toe, the HemiCAP® implant had already been used successfully in several hundred patients in the hip, shoulder, and knee. Deciding to try it wasn't a difficult decision, especially given my other choice, a fusion.

Two weeks after surgery, my swelling was down, my pain was virtually gone and I had the movement back in my toe. The strangest thing was that I had to learn how to walk on my toe again. I can bend, jump, walk up ladders, and after 6 weeks I was walking 3 miles a day, 5 days a week!

Seven weeks after surgery, I was working and doing things that I hadn't been able to for years. The best part was that I didn't have any more pain in my neck or back either. When I decided to have surgery I never expected that it would turn out this good. The fact that I have no more pain and still have my movement is just fantastic."

**"It's now been over ten years and
I COULDN'T BE HAPPIER!"**

– J.R., Pennsylvania



Will I feel my implant?

No. Your surgeon will map your joint during surgery so the implant will articulate with the sesamoids and phalangeal bones as they did originally. The bone and the implant become a smooth surface you will not feel.

What type of physical therapy will I need to do?

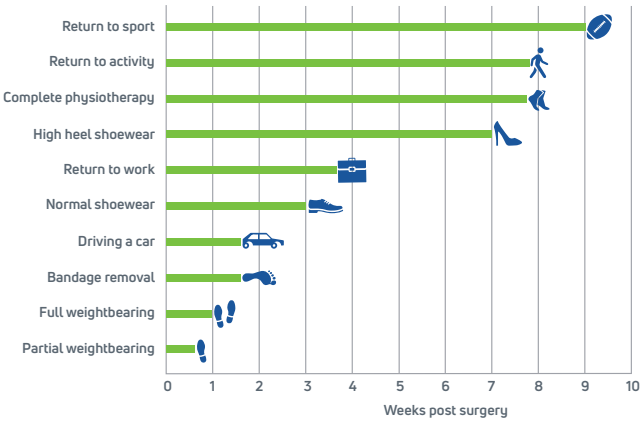
Your doctor and physical therapist will design a rehabilitation protocol to return range of motion and strength to your foot so that you can resume your original lifestyle as quickly as possible. Your rehab is crucial to your post operative motion. Therefore, it is very important that you make a strong effort after surgery to follow a protocol that enables you to maintain motion. The more you work on post-operative motion, the better your outcome will be.

Patients are typically encouraged to begin walking the day after surgery without a post-operative shoe. Pain medication should be sufficient so it does not limit your ability to move or your ability to complete your physiotherapy tasks. Formal therapy usually starts within two weeks after surgery to ensure motion is maintained.



ToeMotion® patient wearing high heels after surgery

Average timepoints for the resumption of activity after HemiCAP® Toe DF or ToeMotion® Total Toe surgery



When can I return to work?

This will depend on your overall health, range of motion and the type of work you do. Patients are encouraged to walk and move their toes immediately to prevent the buildup of scar tissue and rehab is usually measured in weeks rather than months. Many patients have experienced a rapid return to daily activities. However, as with all medical treatments, individual results may vary.

Are you a candidate?

- Aged 35 to 75 years old
- You want to fix your toe problem now versus waiting for your toe to undergo further damage
- Want to regain your active lifestyle
- Your surgeon has told you that you will need a total toe replacement or fusion in the future
- Want to be able to bend your toe, reach up and kneel again
- Want to wear normal shoes such as high heels or boots

To find a doctor near you, visit
www.anika.com/find-a-doctor

Due to its general applicability, do not rely on information in this brochure to assess any particular patient condition. Individual results may vary. Seek professional medical advice for specific personal care. Do not delay seeking professional medical advice or disregard professional medical advice because of something you have read in this brochure.

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