

# PRODUCT LAUNCH

## ToeMotion Modular Restoration System



The Arthrosurface® ToeMotion™ System restores mobility and maintains native biomechanics using a dual curved HemiCAP DF® and a new modular tray-style phalangeal implant with a threaded baseplate. Fourth generation fixation components provide stable constructs on both sides of the joint.

[www.arthrosurface.com](http://www.arthrosurface.com)

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# Market Summary

## Hallux Rigidus

Arthritis of the first metatarsophalangeal (MTP) joint, also known as hallux rigidus, is a progressive disorder causing pain, stiffness and enlargement of the joint. Several surgical procedures have been used to address the pain and stiffness associated with this disease at various stages. Although cheilectomy and a number of osteotomies may be suitable for stage I & II hallux rigidus, these procedures are not effective for the treatment of more advanced stages.

Resection arthroplasty, interpositional arthroplasty, hemiarthroplasty, total joint arthroplasty and arthrodesis have all been used for more advanced stages of the disease. Each of these procedures has their own benefits and deficits. Hemiarthroplasties, which resurface the proximal phalangeal base, have shown promise. However, stiffness, continued joint pain and prosthetic loosening are still limitations to these techniques. Arthrodesis has been advocated by many authors for treating advanced hallux rigidus, and a recent study showed outcomes of arthrodesis after 30 months follow-up to be superior to metallic hemiarthroplasties that resurface the phalangeal base with 79.4 months follow-up. However, limitations in shoe wear, transfer metatarsalgia, permanent activity modifications, and complications from malrotation, malpositioning, malunion, or nonunion have made this procedure less attractive to the younger, active patient.



- 2.5% of all people over 50 are affected by Hallux Rigidus
- 95% have bilateral disease
- Cheilectomy is used for early stage disease and Arthrodesis for late stage disease
- Ideal HemiCAP patients are those with Stage II & III

Existing implants are implanted using sawcuts and rasps as the implants are press-fit. Loosening and poly wear debris remain the major concerns along with the fact that the large bony resection, especially on the phalangeal side, compromises the soft tissue attachments. The loss of the soft tissue compromises toe push-off and function.

The market is looking for a system that provides solid fixation, minimal bone resection, modularity and a reproducible technique. In addition, inlay arthroplasty is more anatomic and stable than an onlay so that is a desirable feature, especially on the phalangeal side.

# Design Rationale

The HemiCAP® platform technology was designed to resurface the damaged articular surface of the metatarsal head and now with the addition of the phalangeal components both sides of the joint can be restored. The concept is based on intraoperative joint mapping and implantation of matching, congruent resurfacing prostheses, allowing for joint preservation and restoration of the normal geometry.

The system consists of a HemiCAP DF implant with tapered screw on the metatarsal side and a threaded baseplate with modular poly inserts for the phalangeal side. There are two curvatures of poly to match the HemiCAP DF and each poly has two thicknesses to allow for proper joint articulation.

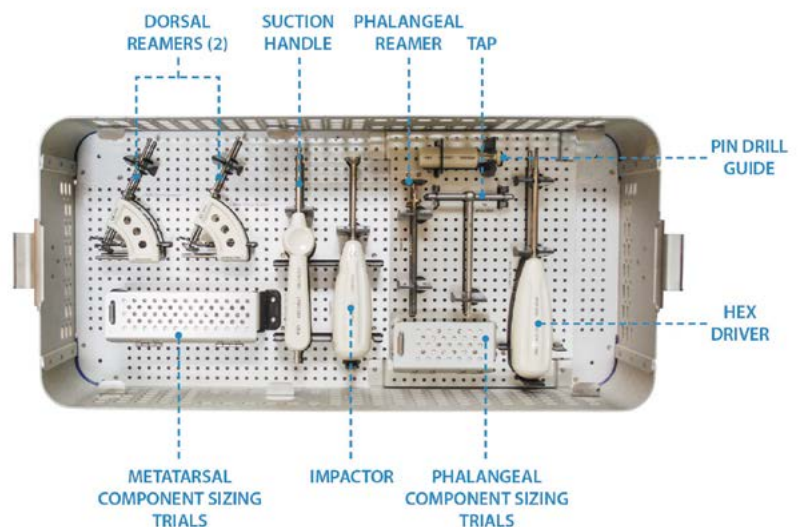
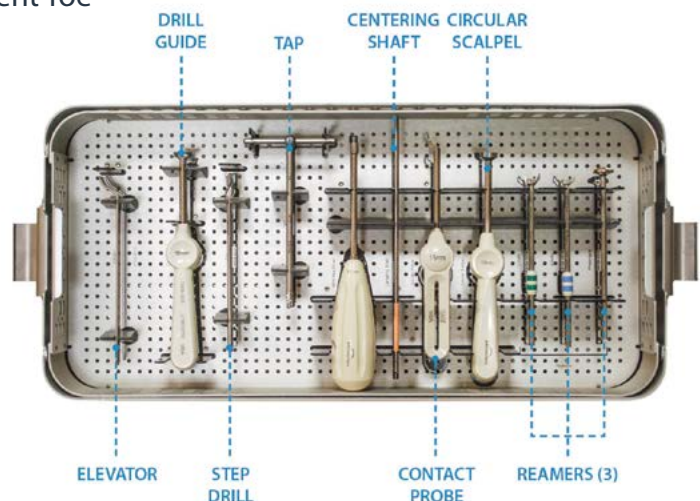
## The Current Market Competitors with Total Toe Devices are:

- Integra (previously Ascension)- The Movement Toe
- Osteomed- Reflexion Total Toe
- Merete Medical- ToeMobile

## Instrumentation & Packaging

The new instrument tray now contains all the instruments to perform the HemiCAP DF and the ToeMotion phalangeal implant. Three trays have been combined into one making this a versatile, user friendly system.

\* ALL IMPLANT COMPONENTS and THE DELIVERY TOOL ARE PROVIDED STERILE.

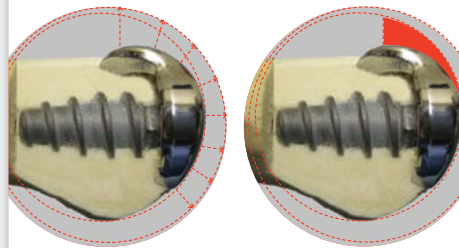


# Features & Benefits

Inlay arthroplasty provides stability and preserves bone



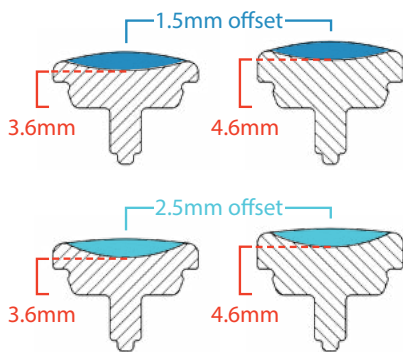
Dual curves allow for dorsal roll off and dorsal flange prevents osteophytes



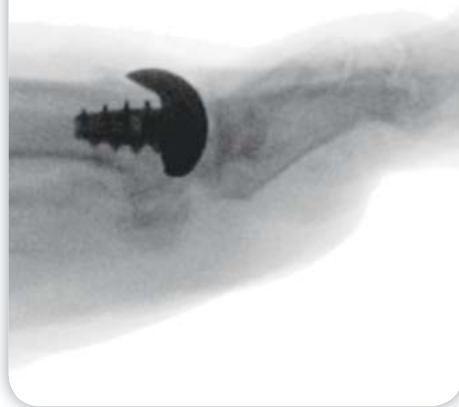
Double rock solid fixation with morse taper interlock



Poly inserts available with multiple offsets & thicknesses



Long-term clinical history with over 20,000 MTP implants







Easy & accurate instrumentation





# Competitive Matrix

MANUFACTURER	Arthrosurface	Integra	OsteoMed	Merete Medical
Device Trade Name	Arthrosurface® ToeMotion – Modular Toe Restoration System	Movement™ Great Toe System	ReFlexion™ 1 <sup>st</sup> MPJ Implant System	ToeMobile Anatomical Great Toe Resurfacing System
Image				
510(k) Number	K132496	K102549	K922211	K072251
Classification Product Code	LZJ	LZJ	LZJ	LZJ
Regulation Number	Unclassified (Reason: Pre-Amendment)	Unclassified (Reason: Pre-Amendment)	Unclassified (Reason: Pre-Amendment)	Unclassified (Reason: Pre-Amendment)
Regulation Description	Prosthesis, Toe (Metatarsophalangeal), Joint, Metal/Polymer, Semi-Constrained	Prosthesis, Toe (Metatarsophalangeal), Joint, Metal/Polymer, Semi-Constrained	Prosthesis, Toe (Metatarsophalangeal), Joint, Metal/Polymer, Semi-Constrained	Merete ToeMobile Anatomical Great Toe Resurfacing System
Indications For Use	<p>The Arthrosurface Modular Toe Restoration System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only.</p> <p>Indications for use include:</p> <ul style="list-style-type: none"> <li>Painful degenerative metatarso-phalangeal joint change</li> <li>Hallux rigidus stage 3 and 4</li> <li>Hallux valgus and hallux rigidus</li> <li>Hallux limitus with painful arthrofibrosis</li> <li>Revisions after moderate proximal phalanx resection</li> </ul>	<p>The Ascension MOVEMENT Great Toe System, Total Arthroplasty is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only.</p> <p>Indications for use include:</p> <ul style="list-style-type: none"> <li>Painful degenerative metatarso-phalangeal joint change</li> <li>Hallux rigidus stage 3 and 4</li> <li>Hallux valgus and hallux rigidus</li> <li>Hallux limitus with painful arthrofibrosis</li> <li>Revisions after moderate proximal phalanx resection</li> </ul>	<p>The OSTEOMED ReFlexion Toe System (RTS) is indicated for reconstruction of the severely disabled and/or painful metatarsophalangeal joints resulting from osteoarthritis, rheumatoid arthritis, arthritis secondary to trauma or failure of prior arthroplasty. Device is intended for bone cemented use only.</p>	<p>The Merete ToeMobile Anatomical Great Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint. The device is intended for cemented use only.</p> <p>Indications for use include:</p> <ul style="list-style-type: none"> <li>Painful degenerative metatarso-phalangeal joint change</li> <li>Hallux rigidus stage 3 and 4</li> <li>Hallux valgus and hallux rigidus</li> <li>Hallux limitus with painful arthrofibrosis</li> <li>Revisions- after moderate proximal phalanx resection</li> </ul>
Metatarsal Implant Material	Cobalt Chromium alloy (CoCrMo) CP Titanium Plasma Spray	Cobalt Chromium alloy (CoCrMo) CP Titanium Plasma Spray	Cobalt Chromium alloy (CoCrMo) Titanium Stem	Cobalt Chromium alloy (CoCrMo) CP Titanium Plasma Spray
Phalangeal Implant Material	Titanium alloy (Ti-6Al-4V) UHMWPE	Titanium alloy (Ti-6Al-4V) UHMWPE	Titanium alloy (Ti-6Al-4V) UHMWPE	Titanium alloy (Ti-6Al-4V) UHMWPE
Articular Surface Anatomically Curved	Yes	No	No	No
Multiple size offerings	Yes	Yes	Yes	Yes
Configuration	2 piece UHMWPE assembled to Ti base during procedure	2 piece UHMWPE assembled to Ti base prior to packaging	2 piece UHMWPE assembled to Ti base prior to packaging	2 piece UHMWPE assembled to Ti base prior to packaging
Mechanical Fixation	Threaded Fixation Post	Stemmed Fixation Post	Stemmed Fixation Post	Threaded Fixation Post

# Indications, Regulatory, Inventory

## FDA Approved Indications for Use

The Arthrosurface Total Toe Resurfacing System is a two-piece implant that is intended to be used as prosthesis for the metatarso-phalangeal joint (MTP). The device is intended for cemented use only.

Indications for use include:

- Painful degenerative metatarso-phalangeal joint change
- Hallux rigidus stage 3 and 4
- Hallux valgus and hallux rigidus
- Hallux limitus with painful arthrofibrosis
- Revisions after moderate proximal phalanx resection

## Regulatory & Product Support Information

510(k) Number: K132496

FDA Summary Document: [http://www.accessdata.fda.gov/cdrh\\_docs/pdf13/K132496.pdf](http://www.accessdata.fda.gov/cdrh_docs/pdf13/K132496.pdf)

## Inventory & Demo

There will be approximately 20 instrument sets and 90 implant sets available for launch in June. Another 50 instrument sets and 250 implants will be coming into stock in August just in time for the Toe Summit. At this point approximately 60% of the Toe DF cases are the 2.5 \* 4.5 so if that holds true with ToeMotion then the poly implants should reflect that trend. Demo product will be provided as loose samples and then a new fauxbone model will be designed and ordered for 2015.

### Instrumentation System

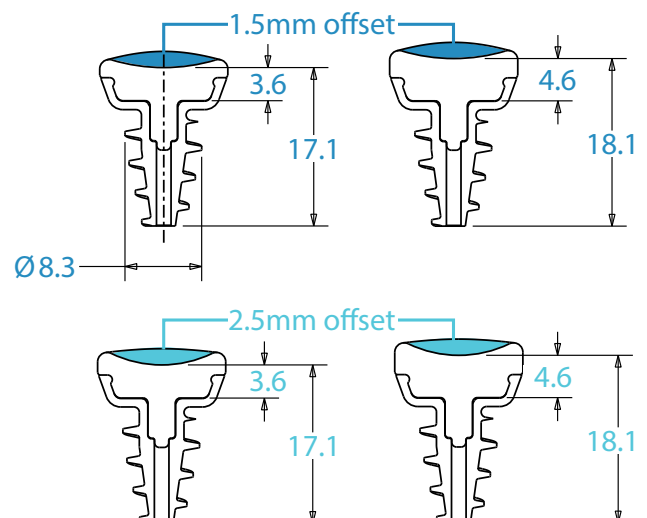
9000-3002	Instrument Kit, ToeMotion
6007-1200	2.0mm Guide Pin for Metatarsal Implants

### Metatarsal Articular Components

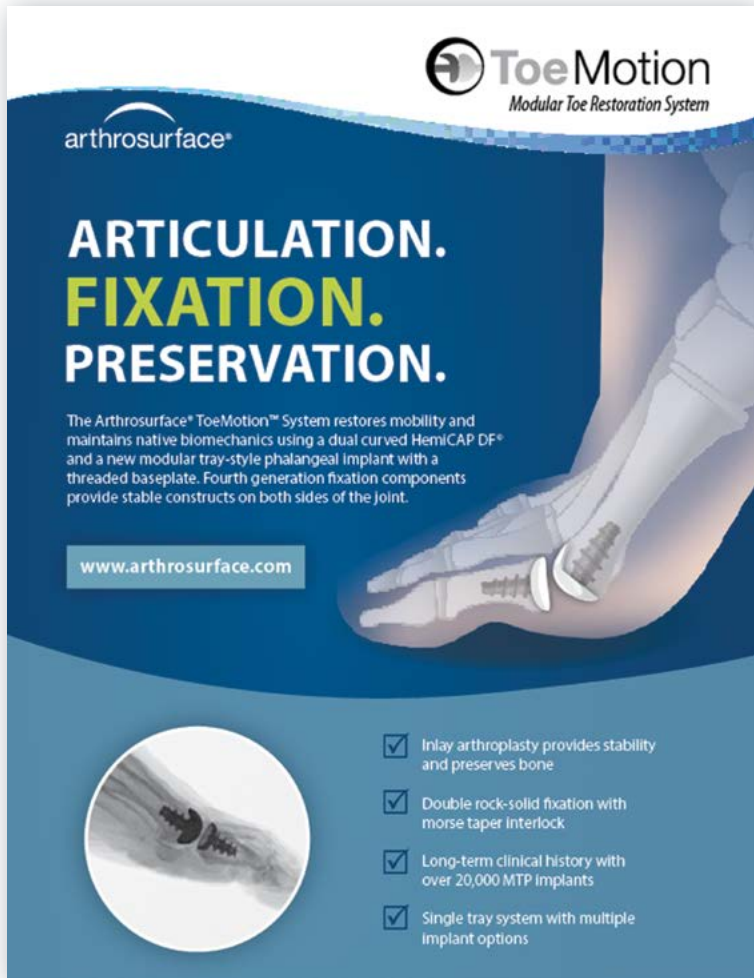
9M52-1535	1.5mm x 3.5mm Offset
9M52-1545	1.5mm x 4.5mm Offset
9M52-2535	2.5mm x 3.5mm Offset
9M52-2545	2.5mm x 4.5mm Offset
9095-0018	Taper Post, 9.5mm x 18mm (for Metatarsal only)

### Proximal Phalanx Articular Components

9P15-0100	Insert Delivery Tool
9P15-PA01	Modular Insert, 1.5 mm Offset - 01 (3.6 mm Thick)
9P15-PA02	Modular Insert, 1.5 mm Offset - 02 (4.6 mm Thick)
9P15-PB01	Modular Insert, 2.5 mm Offset - 01 (3.6 mm Thick)
9P15-PB02	Modular Insert, 2.5 mm Offset - 02 (4.6 mm Thick)
9P15-S180	Fixation Component, DF-P



# Product Collateral




The ArthroSurface® ToeMotion™ System restores mobility and maintains native biomechanics using a dual curved HemiCAP DF® and a new modular tray-style phalangeal implant with a threaded baseplate. Fourth generation fixation components provide stable constructs on both sides of the joint.

[www.arthrosurface.com](http://www.arthrosurface.com)

- ✓ Inlay arthroplasty provides stability and preserves bone
- ✓ Double rock-solid fixation with morse taper interlock
- ✓ Long-term clinical history with over 20,000 MTP implants
- ✓ Single tray system with multiple implant options

ToeMotion One Pager



The ToeMotion™ Modular Restoration System re-approximates native anatomy and preserves bone and soft tissue by using the proven Metatarsal based HemiCAP DF® and an inlay, screw-based Phalangeal component.

- ✓ Inlay arthroplasty for metatarsal & phalangeal joint restoration
- ✓ Tapered screw & morse taper interlock for proven rock solid fixation
- ✓ Dual implant curvatures & super smooth surfaces for improved dorsal roll-off

ToeMotion Tech Guide



# Product Collateral



arthrosurface

## Are you living with toe pain?

Unlike a toe fusion, the Arthrosurface® Joint Restoration Systems can allow you to resume full activity and preserves the natural anatomy of your joint. Find out if the Arthrosurface Toe HemiCAP® is right for you!

[www.arthrosurface.com](http://www.arthrosurface.com)

## Toe Patient Brochure

in these implants may  
y with the silicone  
to balance the tissues  
j the implants in, which  
ones (subluxation).  
cant movement and  
ir ability to push off  
tendons and muscles  
ant.



placement

For patients looking to maintain an active lifestyle, receiving a fusion and never being able to move their toe again is not a viable or appealing option. With the Arthrosurface ToeMotion™, there is now a system that is minimally invasive, completely stable and motion preserving.



### What about the Arthrosurface Toe HemiCAP® implant?

The HemiCAP® 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® is 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 with no reported loosening over the last 10 years. The idea behind the system is to prevent further damage to the joint while maintaining the patient's native anatomy and motion.

The HemiCAP® matches not only the diameter of the damaged area but also the precise radius of both curvatures on the patient's joint surface. 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 individual patient.

### If I have widespread arthritis, does Arthrosurface® provide a total toe replacement? If so, how is it different from other existing replacements?

For patients with extensive damage on both sides of the joint, Arthrosurface provides a total toe replacement called the ToeMotion™ 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 Arthrosurface® 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 Arthrosurface ToeMotion™ is also the only total toe replacement that is implanted with screws on both sides of the joint to provide rock solid fixation.

# Soft Tissue Dissection

The toe joint is like an upside down knee. The sesamoid bones, which are under your metatarsal head, are like your patella or kneecap. If your knee worked like your toe, you would walk on your kneecap! This is why when performing a total toe restoration arthroplasty care must be taken to address proper sesamoid function.

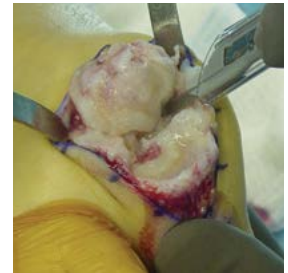
## The three keys to success are:

1. Proper joint alignment
2. Immediate rigid fixation of the components
3. Appropriate soft tissue releases

The soft tissue releases and proper component placement are performed by the surgeon and the rigid fixation is provided by the HemiCAP implants.

The soft tissue contractures determine which releases need to be performed. In hallux rigidus the majority of the contractures are on the plantar surface. For this reason alone few patients if any, have an unstable first MTP joint after hemiarthroplasty. In fact the opposite is usually true. Patients are more often stiff and contracted after receiving a hemi. One of the theories to explain hallux rigidus is that it begins with plantar contractures. The shortening of the soft tissues under the toe decreases the joint space and this leads to dorsal impaction of the joint, osteophyte development, loss of cartilage and finally arthritis. This is why in hallux rigidus the cartilage loss starts on the metatarsal head and proceeds from superior to anterior. If the primary plantar contracture is not addressed then future outcomes may be compromised.

The soft tissue releases of the first met include the sesamoidal ligaments, collateral ligaments and plantar plate (fig 1). Essentially, all soft tissues are released to include the distal 3 cm of the metatarsal head (fig 2). The dissection is similar to the release of the medial structures when doing a total knee replacement for a varus knee. A curved osteotome or similar device is placed just proximal to the sesamoid articulation and the plantar plate is released from its insertion into the metatarsal (fig 3). Since the blood supply within the bone is not disrupted with an osteotomy, the risk of avascular necrosis should not been an issue with this technique. Based on almost 500 cases, Hasselman reports that instability after the procedure has not been an issue as long as subperosteal stripping is performed.



**(Fig. 1)** Soft tissue release of the metatarsal head to include the sesamoidal ligaments and collateral ligaments.



**(Fig. 2)** Complete release of all soft tissues off the metatarsal head from the joint to 3 cm proximal to the joint line.



**(Fig. 3)** Use of a curved osteotome to release the plantar plate proximal to the sesamoid articulation with the metatarsal head.

# Soft Tissue Dissection

The soft tissues of the proximal phalangeal base are released similar to the sesamoid dissection, with the collateral ligaments being freed directly off the periosteum. The plantar plate and flexor hallucis brevis are released by sharp periosteal dissection. This can be done with a knife or curved osteotome (fig 4). The key is that the release should NOT cut the flexor hallucis brevis but rather dissect it sharply off the bone. In the knee this would be the very much like the release of the hamstrings for a flexion contracture of the knee during TKR (fig 5). By dissecting the flexor brevis off the bone rather than transecting the tendon, flexion strength can be maintained and range of motion improved.

In cases of severe phalangeal arthrosis the ToeMotion phalangeal base can be implanted to prevent impaction into the arthritic phalangeal base thereby restoring a smooth gliding joint. After placing the metatarsal HemiCAP and before implanting the phalangeal implant, all remaining osteophytes and any remaining medial or lateral articular surfaces are removed off the metatarsal head. This way, just the implant articulates with the phalangeal HemiCAP.

In cases where the sesamoids are painful and arthritic it is best to fuse. However, if they are very damaged but functional, a piece of collagen allograft or xenograft can be placed between the sesamoids and the metatarsal head to prevent impaction of the joint. Future studies are needed to support use of this technique.

The other key is rigid fixation of the device into bone so that early range of motion can begin. There are several metatarsal head resurfacing implants on the market but most are pressfit and rely on bony ingrowth to support fixation. This requires approximately six to 10 weeks and if excessive forces are transmitted across the implant during this time a fibrous fixation, rather than a bony incorporation of the implant will occur. This may lead to early component failure and migration which is why the threaded fixation is so important. The secondary benefit is that the immediate fixation allows for aggressive early range of motion, a key advantage in any arthroplasty procedure, no matter which joint.

Although implant arthroplasty of the first MTP is still in its infancy there was a time not that long ago where hip, knee and ankle arthroplasty was considered experimental. Fusion is not without its complications so there is a need to find options that allow pain relief without sacrificing joint motion. A step-wise approach, with proper soft tissue releases, immediate implant fixation, surface restoration and early rehabilitation are all key to long term implant survival and patient satisfaction.



**(Fig. 4)** Subperosteal dissection of the flexor digitorum brevis and plantar plate from the proximal phalangeal base using a knife.



**(Fig. 5)** Further dissection of the flexor digitorum brevis and plantar plate from the proximal phalangeal base using a curved osteotome.

# Launch Plan

## Target Territories

The product will be launched in the US market first on June 2nd. All territories are expected to launch simultaneously however, because of limited launch inventories early cases will have to be carefully managed through head office.

## Target Customers

There are four target customers:

1. Existing HemiCAP DF users
2. Previous HemiCAP users
3. Fusion surgeons
4. Competitive total toe users

The target customers are ranked by priority. Existing users will be the easiest to convert, whereas competitive total toe users will be the hardest. While it seems counter-intuitive, fusion surgeons will be fairly easy to convert as the reasons they don't use implants are: significant bone loss, loosening, hemi's only address one side of the joint, difficult revision and non-anatomic implants. All of these concerns are addressed with the ToeMotion system.

## Market Strategy

There is pent up demand for a total toe as the market dynamics over the last decade have changed from fusion to implant and, from pain relief only to pain relief with motion. When the HemiCAP toe was launched almost 10 years ago ArthroSurface had the only met head implant on the market. Today there are at least 5 met head implants on the market so implant use is becoming more common. The main criticisms against a total were that the implants loosen, take away too much bone and they overstuff the joint. The AS strategy is simple: leverage the positive fixation history of the met head screw for the phalangeal side and the joint preservation features of inlay arthroplasty. The message will be to promote that AS has the strongest fixation in toe implants and that the inlay technology is also the most stable and anatomic.

The tagline will be: articulation, fixation, preservation.

The roll out to the surgeon and distribution community will happen through the Toe Summit, the Ferkel Foot Club meeting in August and the Master Cadaver course in September. In addition, a full media blitz will begin on June 2nd with the blog, Facebook, Twitter, Website and then Journal Advertising in the summer and Regional Podiatric Meetings such as the Western Podiatric Meeting in June.

A direct mail campaign will also be initiated to all the existing and previous toe users as well as a purchased list of operative podiatrists.



# Launch Plan

## Sales Strategy

The first targets will be existing users where we have surgeon advocacy to get it into the institution quickly and approved by the pricing committee. Next the focus will be on previous users or those lost to the competition, and then finally competitive accounts. The CPT code used is 28293 (see [Ingenix Code & Description on page 15](#)), which is correction of an arthritic bunion with implant. The code does not distinguish between the phalangeal side, metatarsal side or both sides. The reason it may be hard to get a separate code in the future is because silastic implants, which resurface both sides with one implant, have been on the market for a long time and continue to be used as the default total toe. The AAOS has taken a position regarding silastic implants that they should not be used in the foot.

For this reason, the main focus should be hospitals as they can bill for all the implants used. Care should be taken to avoid ASC's, especially those with no carve-outs in their insurance contracts because they tend to receive a global fee for the procedure which is usually insufficient to cover the cost of the implant. Because of reimbursement and the higher price for a total, academic centers and institutions that already perform total toes are ideal as their reimbursement tends to be higher.

## Sales Force Education

Webinars will be held in June where Steve and Dr. Hasselman will review the pearls and pitfalls of the system based on the first clinical cases. In addition, a sawbone instructional video has been created and placed on the iPad app so reps can review it prior to surgery. Technically, the phalangeal HemiCAP technique is not significantly different from a standard HemiCAP however, the choice of poly inserts along with their placement will require some additional technical knowledge. To assist the reps in the step by step procedure for the phalanx a powerpoint picture gallery will be created which will be placed on the iPad app and the website so that reps can access the technique prior to a case.

## Surgeon Education / Events

1. Toe Summit: August 2014 in Dallas, Texas
2. Toe Masters Course: September 2014, Miami, Florida
3. Ferkel Foot Club: August 2014, LA, California
4. Preceptorships and Workshops

For those existing users of the HemiCAP the training can be conducted on a sawbone as the only significant difference in the technique is the placement of the poly component. The Toe Summit will assemble the top Podi's and Ortho Foot & Ankle docs so they can be updated and educated on the entire Arthrosurface Foot and Ankle product portfolio. These docs will then become regional and national instructors/preceptors for the entire toe product line. In September there will be a Toe Masters Course, which will be a podiatry only event, for 20-30 docs where they will learn the full portfolio with additional focus on the ToeMotion system. Local and regional training will be conducted with the network of instructors created through the Summit and Masters course.

# Launch Plan

## Advertising & PR

Journal ads and web based information will be uploaded and live starting in June. The Press Release was already issued when the product was FDA cleared and another was sent out on June 3rd highlighting the first cases.

The advertisement features the ArthroSurface logo at the top right. The main headline reads "ARTICULATION. FIXATION. PRESERVATION." in large, bold letters. Below this is the "ToeMotion" logo, which includes a stylized foot icon. The text describes the system: "The ArthroSurface® ToeMotion™ System restores mobility and maintains native biomechanics using a dual curved HemiCAP DF® and a new modular tray-style phalangeal implant with a threaded baseplate. Fourth generation fixation components provide stable constructs on both sides of the joint." The website "www.arthrosurface.com" is listed. On the right side, there is a 3D anatomical illustration of a foot with the implant. At the bottom left, there is a circular inset showing a close-up of the implant. To the right of this inset is a list of four bullet points with checkmarks:

- ✓ Inlay arthroplasty provides stability and preserves bone
- ✓ Double rock-solid fixation with Morse taper interlock
- ✓ Dual implant curvatures for improved dorsal roll-off
- ✓ Long-term clinical history with over 20,000 MTP implants

At the bottom, a small line of text reads: "For additional product information, including indications, contraindications, warnings, precautions and potential adverse effects, please visit www.arthrosurface.com"

Podiatry Today Advertisement

This is a screenshot of a PR Newswire press release dated March 7, 2014. The headline is "ArthroSurface's Extremity Portfolio Expands with the ToeMotion Total Toe". The text of the release discusses the FDA clearance of the new ToeMotion™ Total Toe Replacement System, which is a combination of a Metatarsal based HemiCAP® implant and a new inlay metal baseplate with a poly insert for the phalangeal side of the joint. It mentions that the system provides proven fixation, avoids the inlay impingement issue, and is implanted by using saw cuts. A quote from Dr. Thomas Earl Giovanni, a surgeon from the University of Miami, is included, stating that the system avoids resecting the intrinsic ligaments that provide stability to the toe. The release also notes that the surgeon has been using the metatarsal based HemiCAP® with great success.

Press Release, March 2014

This is a screenshot of a PR Newswire press release dated June 3, 2014. The headline is "ArthroSurface® Implants the first ToeMotion Total Toe in the US". The main image shows the ArthroSurface logo. The text of the release describes the first implantation of the ToeMotion Total Toe Replacement System in the United States. It mentions that the procedure was performed by Dr. Thomas Earl Giovanni at the University of Miami. The release also notes that the system provides proven fixation, avoids the inlay impingement issue, and is implanted by using saw cuts. A quote from Dr. Giovanni is included, stating that the system avoids resecting the intrinsic ligaments that provide stability to the toe. The release also notes that the surgeon has been using the metatarsal based HemiCAP® with great success.

Press Release, June 2014

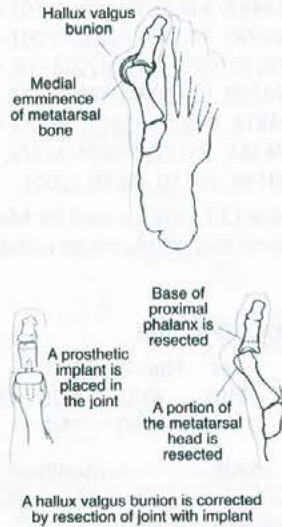
## Key Opinion Leaders

The principle developers involved with the ToeMotion are Dr. San Giovanni from Doctors Hospital Center for Orthopedics and Sports Medicine in Miami, Florida and Dr. Carl Hasselman from UPMC in Pittsburgh, PA. In addition, there will be another 30-40 surgeons from the Toe Summit and Masters Course and that listing will be completed by the end of August.



# 28293

**28293** Correction, hallux valgus (bunion), with or without sesamoidectomy; resection of joint with implant



## Explanation

The physician treats a bunion of the foot by removing the joint of the big toe and replacing it with an artificial implant. The physician makes an incision over the big toe where it joins the foot. The incision is carried deep to the joint (first metatarsal phalanges joint). An incision is made in the joint capsule and it is exposed. The physician removes (resects) the surfaces of the bones in the joint. The sesamoid bones of the foot are examined and removed as necessary. The bones are placed in proper alignment and debrided further as needed. An artificial implant is placed in the joint and fixed to the bones. The incision is irrigated thoroughly and closed in layers.

## Coding Tips

To correct severe hallux valgus deformities, this procedure may be used in combination with other techniques. When used in combination with other methods (e.g., double osteotomy), see 28299. According to CPT guidelines, cast application or strapping (including removal) is only reported as a replacement procedure or when the cast application or strapping is an initial service performed without a restorative treatment or procedure. See "Application of Casts and Strapping" in the CPT book in the Surgery section, under Musculoskeletal System. For radiology services, see 73620–73660.

## ICD-9-CM Procedural

77.59 Other bunionectomy

## Anesthesia

**28293** 01480

## ICD-9-CM Diagnostic

- 357.1 Polyneuropathy in collagen vascular disease — (Code first underlying disease: 446.0, 710.0, 714.0)
- 359.6 Symptomatic inflammatory myopathy in diseases classified elsewhere — (Code first underlying disease: 135, 140.0-208.9, 277.30-277.39, 446.0, 710.0, 710.1, 710.2, 714.0)
- 446.0 Polyarteritis nodosa
- 710.0 Systemic lupus erythematosus — (Use additional code to identify manifestation: 424.91, 581.81, 582.81, 583.81)
- 710.1 Systemic sclerosis — (Use additional code to identify manifestation: 359.6, 517.2)
- 710.2 Sicca syndrome
- 714.0 Rheumatoid arthritis — (Use additional code to identify manifestation: 357.1, 359.6)
- 714.89 Other specified inflammatory polyarthropathies
- 715.09 Generalized osteoarthritis, involving multiple sites
- 715.17 Primary localized osteoarthritis, ankle and foot
- 715.37 Localized osteoarthritis not specified whether primary or secondary, ankle and foot
- 715.97 Osteoarthritis, unspecified whether generalized or localized, ankle and foot
- 718.47 Contracture of ankle and foot joint
- 719.57 Stiffness of joint, not elsewhere classified, ankle and foot
- 726.73 Calcaneal spur
- 726.91 Exostosis of unspecified site
- 727.1 Bunion
- 735.0 Hallux valgus (acquired)
- 735.1 Hallux varus (acquired)
- 735.2 Hallux rigidus
- 735.3 Hallux malleus
- 735.8 Other acquired deformity of toe
- 755.66 Other congenital anomaly of toes

## Terms To Know

**osteoarthritis.** Most common form of a noninflammatory degenerative joint disease with degenerating articular cartilage, bone enlargement, and synovial membrane changes.

**polyneuropathy.** Disease process of severe inflammation of multiple nerves.

## CCI Version 17.3

01470, 0213T, 0216T, 0228T, 0230T, 11420-11424, 11730, 11750, 14040-14041, 20550-20553, 20600-20605, 20610, 20650, 20690, 28010-28011, 28022-28024, 28052-28054, 28072-28080, 28090-28092, 28104, 28108, 28111, 28122, 28124-28126, 28150, 28160, 28190-28200, 28208, 28234, 28240, 28270, 28285, 28288, 28306-28308, 28310, 28315, 28476, 28485, 28645, 29130-29131, 29540-29550, 36000, 36400-36410, 36420-36430, 36440, 36600, 36640, 37202, 43752, 51701-51703, 62310-62319, 64400-64435, 64445-64455, 64479, 64483, 64490, 64493, 64505-64530, 69990, 93000-93010, 93040-93042, 93318, 94002, 94200, 94250, 94680-94690, 94770, 95812-95816, 95819, 95822, 95829, 95955, 96360, 96365, 96372, 96374-96376, 99148-99149, 99150, J0670, J2001

Note: These CCI edits are used for Medicare. Other payers may reimburse on codes listed above.

## Medicare Edits

	Fac RVU	Non-Fac RVU	FUD	Status
<b>28293</b>	20.82	30.37	90	A

	MUE	Modifiers		
<b>28293</b>	2	51	50	62* 80

\* with documentation

**Medicare References:** None