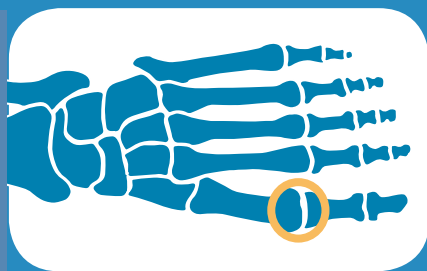


PATIENT GUIDE FOR THE TREATMENT OF TOE ARTHRITIS

A NATIONWIDE SURGEON SURVEY ON OVER 2,000 HEMICAP TOE PROCEDURES



INCLUDES:

- Patient Function and Activity Milestones
- Patient Rehabilitation & Physiotherapy Information
- Treatment Comparisons of Joint Replacement and Fusion
- Surgeon Satisfaction Ratings and Recommendations

Survey results are based on the experience of 35 foot & ankle surgeons, who together performed more than 2200 procedures with the Toe HemiCAP® and ToeMotion® Systems since 2005. Collectively, they have extensive experience with ArthroSurface toe implants and forefoot surgery. Their responses are based on long term observations and treatment of Hallux Rigidus. The purpose of this surgeon survey was to analyze their experience in comparison to fusion procedures and share the results with patients and doctors. Survey participants were compensated for their time to complete the survey and to provide feedback on their experiences.

Nationwide
SURVEY

.....
**35 FOOT
& Ankle
SURGEONS**

.....
**2261
HemiCAP
PROCEDURES**

.....
**8 YEARS
AVERAGE
HemiCAP
Experience**

Introduction to Hallux Rigidus

Arthritis at the base of the first toe is the most common form of arthritis in the foot and many patients have symptoms in both toes. This condition is also called Hallux Rigidus or Hallux Limitus. Early stage management consists of non-operative treatments using shoe modifications, pain medication and other modalities or surgery using a cheilectomy procedure which removes the bony bump on the top of the toe. (See Figure 2). Treatment options for later stages are divided into two categories: joint replacement, to maintain toe motion and treat arthritic pain and joint fusion, to remove any motion in the arthritic joint by making it permanently stiff to treat arthritic pain. When the bones in the joint no longer move against each other the motion that caused pain is gone and so is the pain. Both have been extensively described in the scientific literature. Over the last decade, new implant designs have been introduced providing new motion preserving alternatives to fusion.

Keywords

Arthrodesis: Surgical technique to produce permanent stiffness of the joint
Arthroplasty: Joint Replacement
Fusion (same as Arthrodesis): Surgical technique to produce permanent stiffness of the joint
Hallux Rigidus/Hallux Limitus: Joint arthritis at the base of the first toe
Hemiarthroplasty: Joint replacement on one side of the joint
MTP: Metatarso-Phalangeal Joint at the base of the toe
Total Toe Arthroplasty: Joint replacement on both sides of the joint

Joint Replacement Features

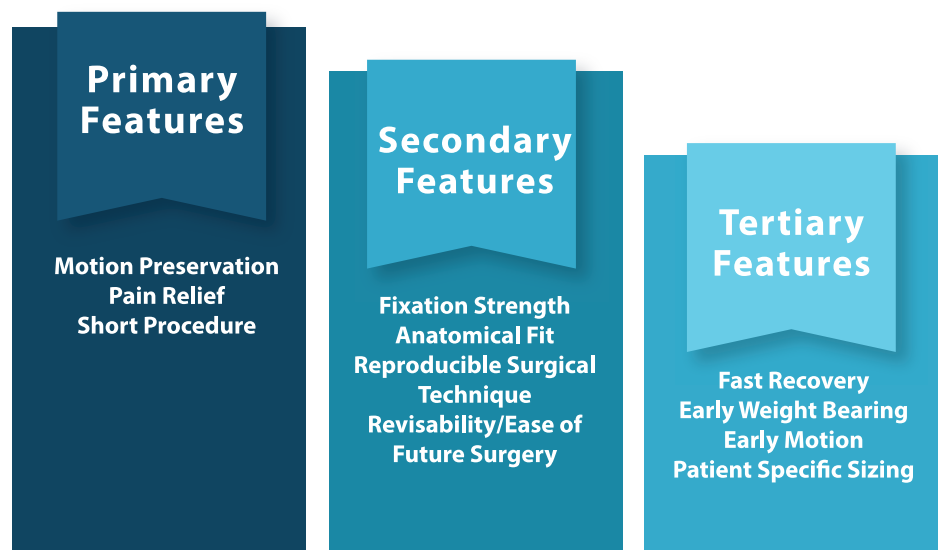
Based on their overall experience, surgeons were asked about the clinical benefits of the Toe HemiCAP® and ToeMotion® Systems. Results according to primary, secondary, and tertiary features are summarized in Figure 1.

Figure 1:

Primary Features—selected by more than 80% of the surgeons.

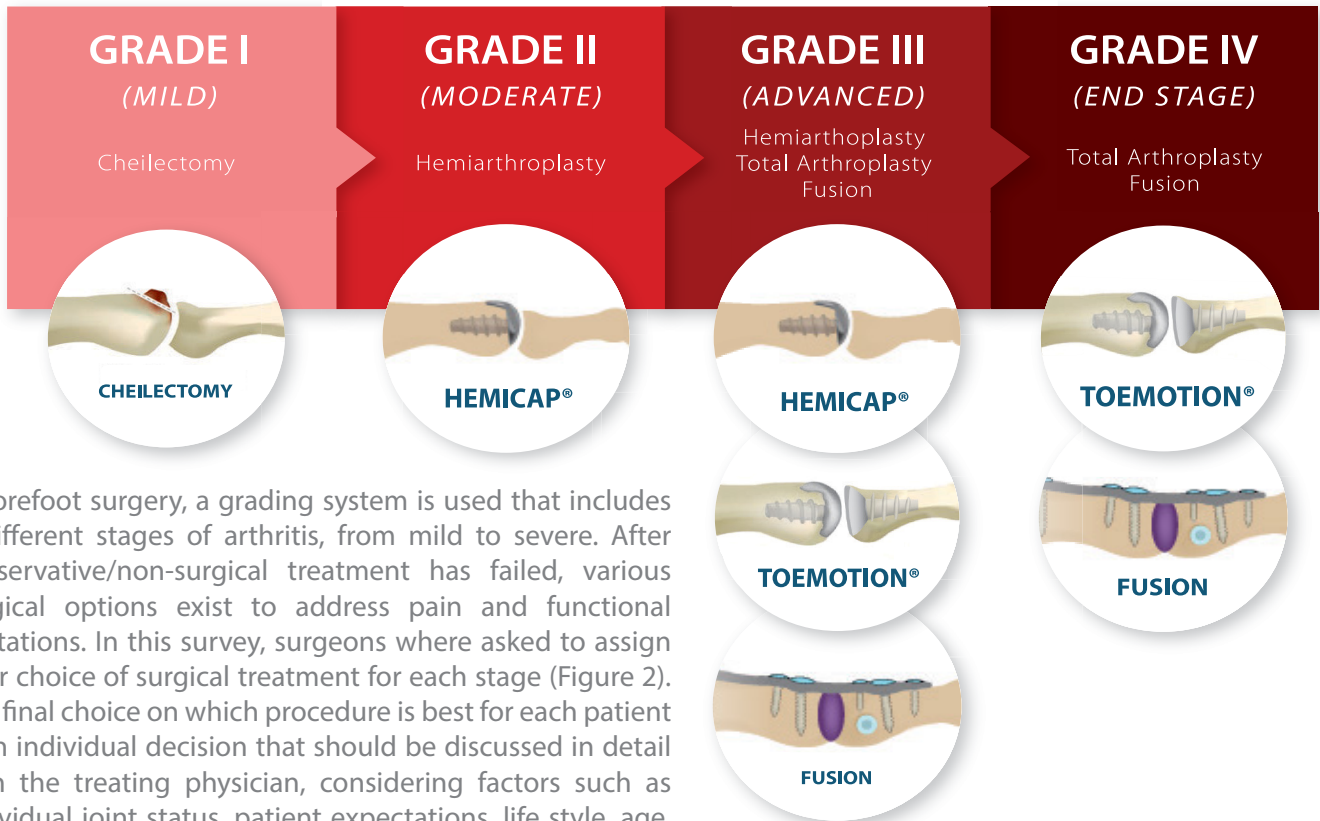
Secondary Features - selected by more than 50% of surgeons.

Tertiary Features – mentioned as additional benefits.



Treatment Options for First Toe Arthritis

Figure 2: Stages and Treatment Options for First Toe Arthritis. Early stage, mild arthritis includes non-surgical management or surgical cheilectomy with removal of the bony bump on the top of the toe. More advanced stages are typically treated with joint replacement or fusion procedures. Based on survey results, the most popular (>50%) treatment choices per grade are shown below.

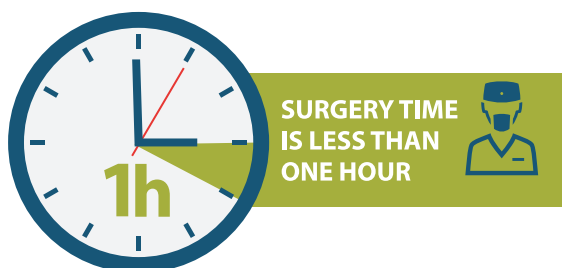


In forefoot surgery, a grading system is used that includes 4 different stages of arthritis, from mild to severe. After conservative/non-surgical treatment has failed, various surgical options exist to address pain and functional limitations. In this survey, surgeons were asked to assign their choice of surgical treatment for each stage (Figure 2). The final choice on which procedure is best for each patient is an individual decision that should be discussed in detail with the treating physician, considering factors such as individual joint status, patient expectations, life style, age, surgical history, physical examination, the ability to heal an arthrodesis, or the willingness to undergo a procedure where future surgery might be required.

Procedure and Hospital Stay Timelines

Based on surgeon experience, the typical duration of the Toe HemiCAP® and ToeMotion® joint replacement procedure was less than 60 min by 97% and of those, 34% indicated a procedure length of less than 30 minutes. All surgeons indicated that the procedure is performed on an outpatient basis with a hospital stay of less than 24 hours.

Figure 3: Procedure and Hospital Stay Timelines after Toe HemiCAP® and ToeMotion® joint replacement procedures



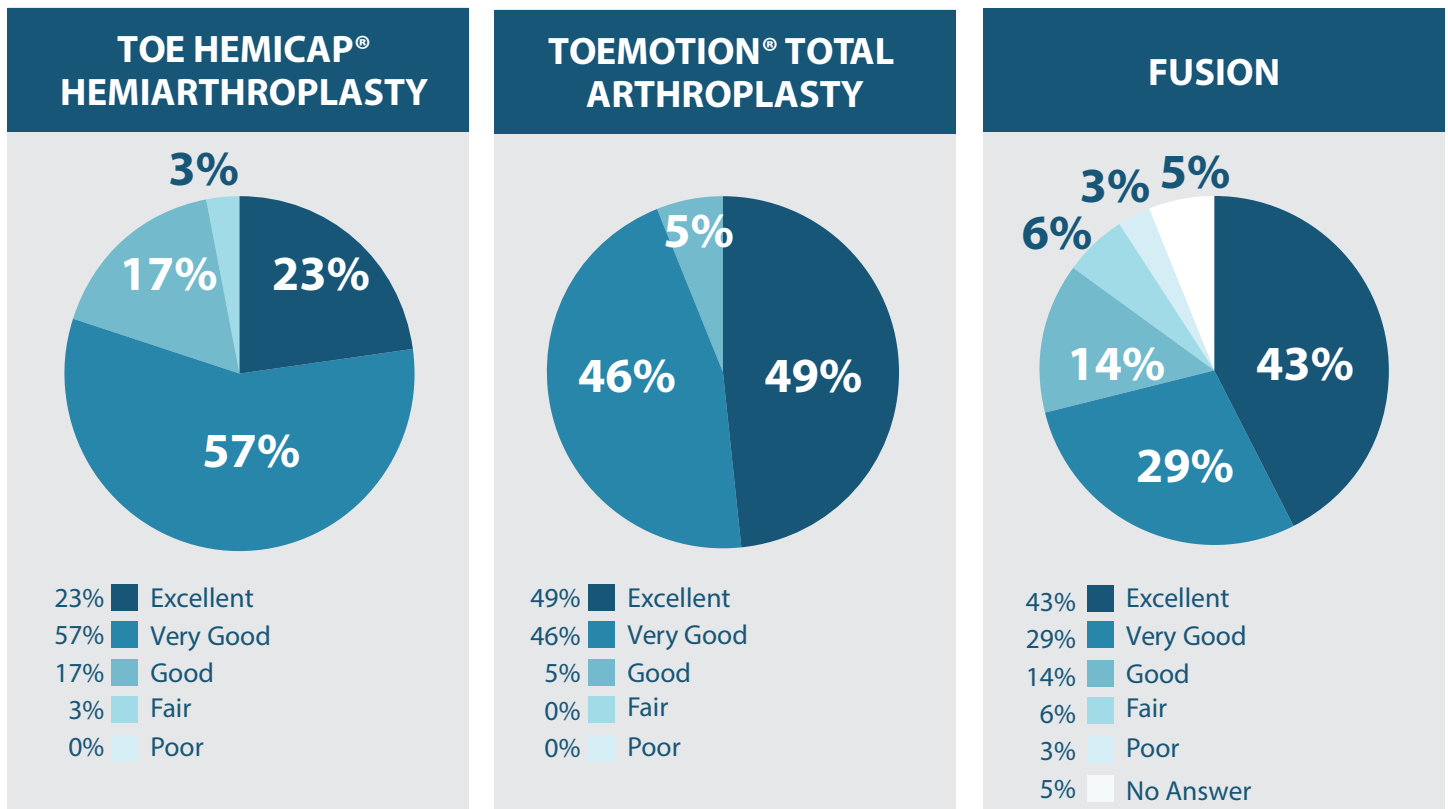
Pain Relief Comparison of Hemiarthroplasty, Total Toe Replacement, and Joint Fusion

The typical pain relief following First Toe joint replacement procedures and fusion are summarized in Figure 4. The highest agreement for an excellent to very good rating was achieved by Total Toe Arthroplasty (94%), followed by HemiCAP DF (80%), and fusion (72%).

Figure 4: Post Operative Pain Relief Ratings

Surgeons were asked to rate postoperative pain relief for three different procedures including hemiarthroplasty, total toe replacement and joint fusion. Answers for joint replacement procedures were specific to the Toe HemiCAP® System, whereas fusion ratings were non-specific and based on various fusion techniques.

Post Operative Pain Relief Ratings



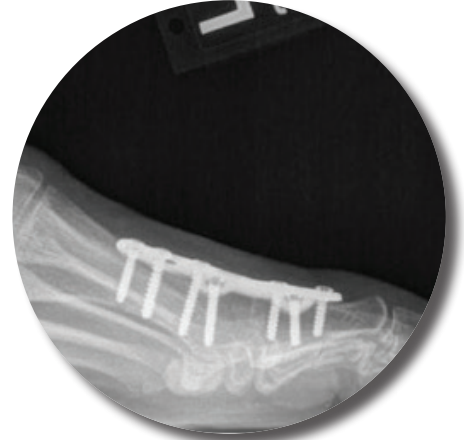
Toe HemiCAP[®]
Hemiarthroplasty
Implant System



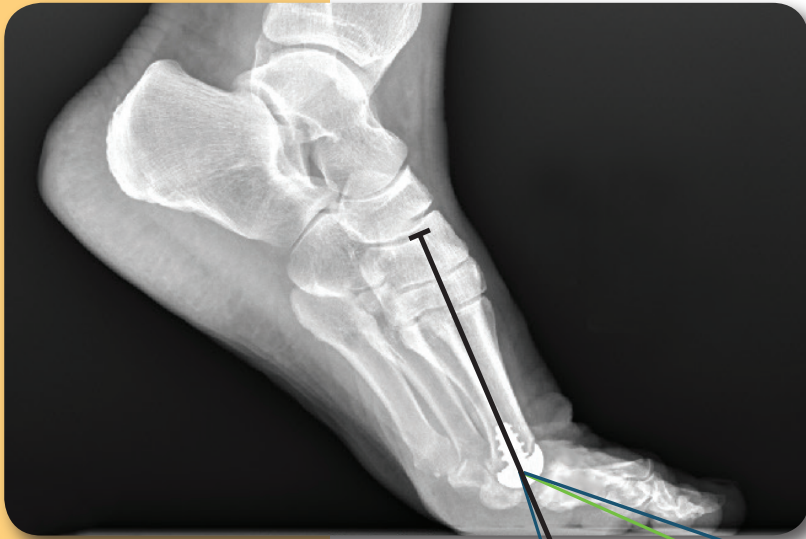
ToeMotion[®]
Total Toe
Implant System



CheckMATE[®]
Fusion Plate
System



Range of Motion Results from Scientific Literature



52° HemiCAP¹⁻¹⁰
42° Normal Gait

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8. PMA P150017. Summary of Safety and Effectiveness Data. Page 55. https://www.accessdata.fda.gov/cdrh_docs/pdf15/P150017B.pdf Accessed 6/1/2017
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

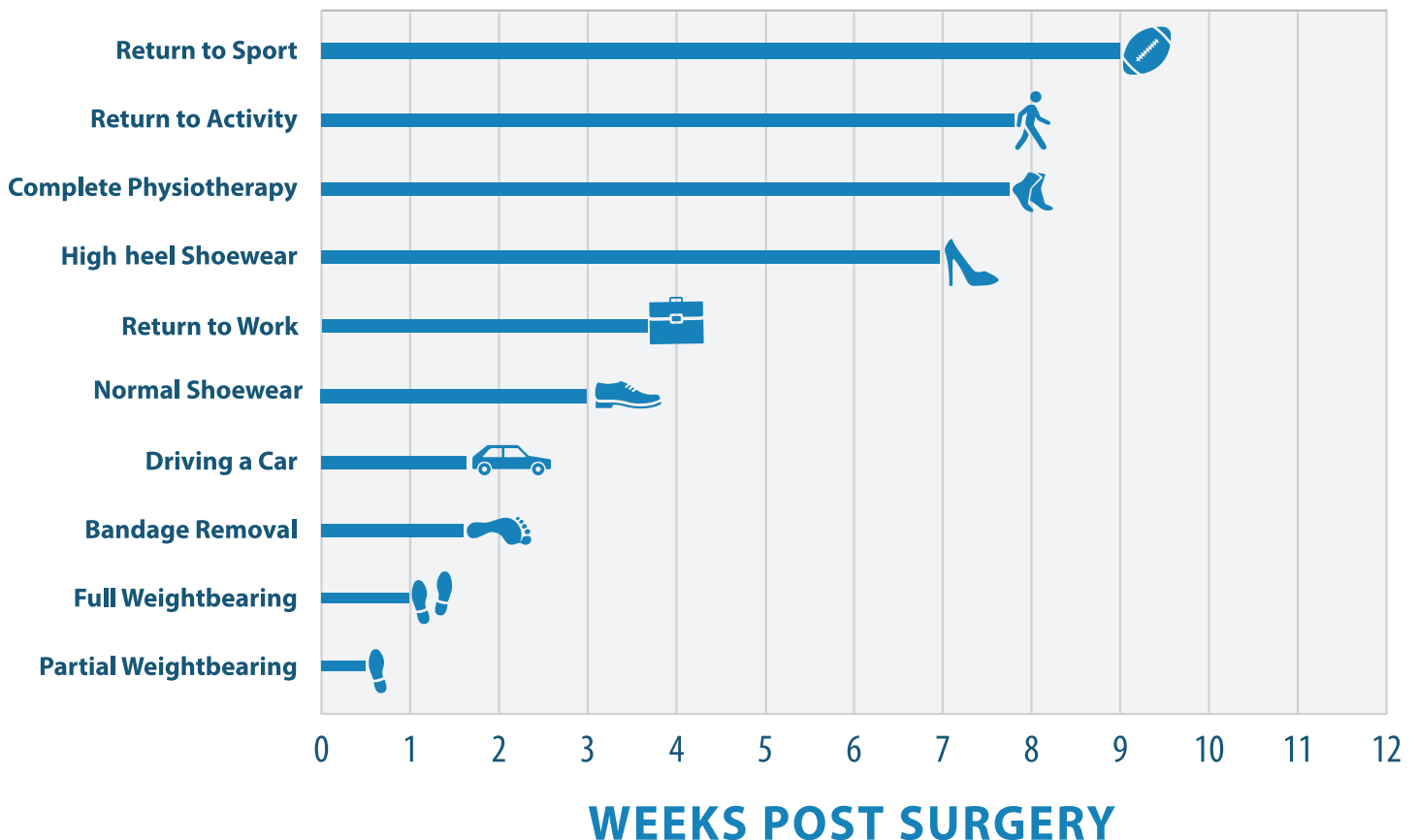
Typical Patient Function & Activity Milestones after Hemiarthroplasty or Total Toe Replacement

Based on their experience, surgeons rated the time it took for patients to achieve certain milestones after surgery such as driving a car, walking in shoes and returning to work, activity or sport. The majority of surgeons reported that their patients' return to activities of daily living, including return to work within 1 month after surgery.

Following Toe HemiCAP[®] hemiarthroplasty, or ToeMotion[®] Total Toe replacement, all surgeons stated that patients are expected to return to work with maintenance of their job levels. No job, sports or activity restrictions were recommended. Following these procedures, most patients are expected to return to work within 4 weeks after surgery (77%) or within a 15-30 day range (33.3%). The time to return to work was classified as equal or faster than cheilectomy and other implants and faster than fusion. Sports participation was started at a mean of 63 days and the satisfaction regarding the return to sport and an active lifestyle was rated as Excellent to Very Good in 86% and good in 14%.

Figure 5: Time Points for Returning to Various Activity levels After Surgery.

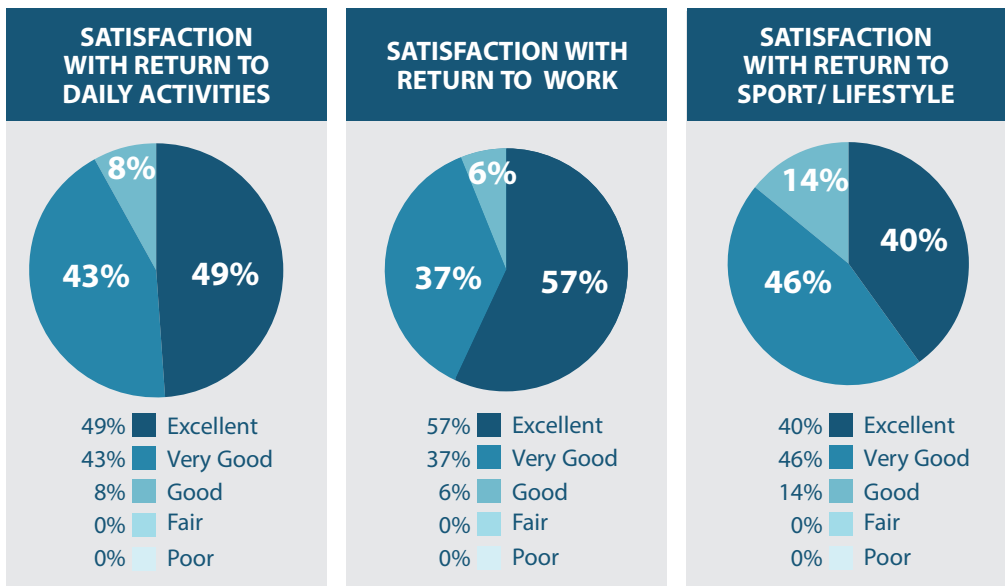
Typical Timepoints for the Return to Activity After Toe HemiCAP[®] or ToeMotion[®] Total Toe Surgery (Weeks)



Satisfaction Rating For Hemiarthroplasty and Total Toe Anthroplasty

Surgeons' overall satisfaction after Toe HemiCAP® or ToeMotion® Total Toe Replacement was rated Excellent to Very Good for Return to Activities of Daily Living (92%), Return to Work (94%), Return to Sports and Active Lifestyle (86%).

Figure 6: Satisfaction Rating after Toe HemiCAP® or ToeMotion® Total Toe Replacement for Return to Activities of Daily Living, Return to Work, and Return to Sport and Active Lifestyle.



Overall Satisfaction

98% of surgeons surveyed reported Very Good to Excellent Satisfaction ratings with the Toe HemiCAP® & ToeMotion® Implant systems.

Surgeons' Choice

97% of surgeons indicated that they would undergo a Toe HemiCAP® Arthroplasty themselves and would recommend the procedure to their friends and family.





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