

## Summary of Safety and Effectiveness Data

### I. General Information

Device Generic Name: Finger joint semi-constrained uncemented prosthesis

Device Trade Name: Ascension® MCP

Applicant Name and Address: Ascension Orthopedics, Inc.  
8200 Cameron Road, C-140  
Austin, TX 78754

Premarket Approval (PMA) Number: P000057

Date of Panel Recommendation:

Date of Notice of Approval to the Applicant:

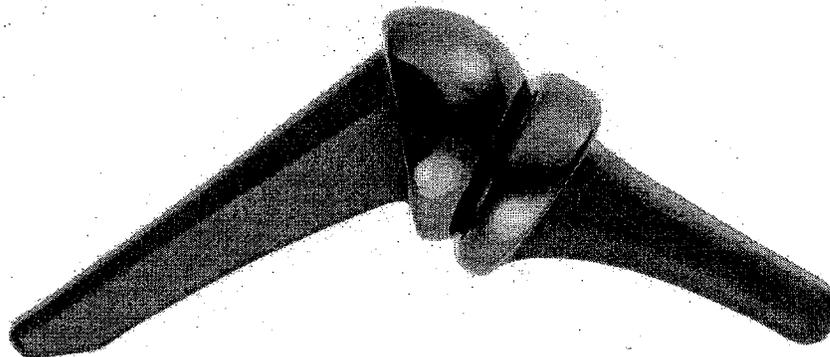
### II. Indications for Use

The Ascension® MCP is intended for use as a total joint replacement of index, long, ring, and small finger metacarpophalangeal (MCP) joints that exhibit symptoms of pain, limited range of motion, or inadequate bony alignment (i.e., subluxation or dislocation) secondary to articular destruction or degenerative disease related to rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis where soft tissue reconstruction can provide stabilization.

### III. Device Description

The Ascension MCP is a two component, semi-constrained prosthesis consisting of a proximal component with a ball shaped articular surface and a distal component with a cup shaped articular surface as shown in Figure 1. It is designed to be a press-fit device achieving fixation by means of direct implant/bone apposition. The Ascension MCP is a semi-constrained device because dorsal-volar and medial-lateral translation of the components relative to each other is limited due to the geometry of the articulating surfaces.

Figure 1. Ascension® MCP.



Each component of the Ascension MCP device is comprised of a thick pyrocarbon layer encasing a high strength graphite substrate. Similar pyrocarbon-graphite components have been used successfully for more than 25 years in prosthetic mechanical heart valves. Over two million pyrocarbon heart valves have been implanted with results demonstrating the superior biocompatibility, strength, fatigue resistance and wear resistance of the pyrocarbon material.<sup>1</sup>

In addition to superior biocompatibility, pyrocarbon has a modulus of elasticity similar to cortical bone making it biomechanically compatible with bone<sup>2,3,4</sup>. Numerous laboratory animal studies<sup>5,6,7,8,9,10,11</sup> and human clinical use<sup>12</sup> have confirmed the biocompatibility of pyrocarbon with bone and demonstrated that pyrocarbon implants support direct bone apposition.

The graphite substrate material in the Ascension MCP is impregnated with a small amount (10 weight percent) of tungsten. Due to the density difference between carbon and tungsten, 10 weight percent tungsten is approximately 1 atomic percent. This small amount of tungsten renders the graphite substrate radiopaque so that Ascension MCP components are clearly visible on radiographs as in Figure 2.

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<sup>1</sup> Haubold AD, "On the durability of pyrolytic carbon in vivo," *Medical Progress through Technology*, Vol. 20, 201-208, 1994.

<sup>2</sup> Medical Carbon Research Institute, Austin, Texas, Technical Bulletin No. 0002, 1996.

<sup>3</sup> Cook SD, Weinstein AM, Klawitter JJ, "Parameters affecting the stress distribution around LTI carbon and aluminum oxide dental implants," *J Biomed Material Res*, Vol. 6, 875-885, 1982.

<sup>4</sup> Cook SD, Klawitter JJ, Weinstein AM, "The influence of implant elastic modulus on the stress distribution around LTI carbon and aluminum oxide dental implants," *J Biomed Material Res*, Vol. 15, 879-887, 1981.

<sup>5</sup> Anderson RA, Cook SD, Weinstein AM, Haddad RJ, "An evaluation of skeletal attachment to LTI pyrolytic carbon, porous titanium and carbon-coated porous titanium implants," *Clin Ortho and Related Res*, No. 182, 242-257, 1984.

<sup>6</sup> Kent JN, Cook SD, Weinstein AM, Klawitter JJ, "A clinical comparison of LTI carbon, alumina, and carbon-coated alumina blade-type implants in baboons," *J Biomed Mater Res*, Vol. 16, 887-899, 1982.

<sup>7</sup> Thomas KA, Cook SD, Renz EA, Anderson RC, Haddad RJ, Haubold AD, Yapp R, "The effect of surface treatments on the interface mechanics of LTI pyrolytic carbon implants," *J Biomed Mater Res*, Vol. 19, 145-159, 1985.

<sup>8</sup> Cook SD, Weinstein AM, Klawitter JJ, "Quantitative histologic evaluation of LTI carbon, carbon-coated aluminum oxide and uncoated aluminum oxide dental implants," *J Biomed Mater Res*, Vol. 17, 519-538, 1983.

<sup>9</sup> Cook SD, Thomas KA, Kester MA, "Wear characteristics of the canine acetabulum against different femoral prostheses," *J Bone and Joint Surg*, Vol. 71-B, 189-197, 1989.

<sup>10</sup> Hetherington VJ, Kavros SJ, Conway F, Mandracchia VJ, Martin W, Haubold AD, "Pyrolytic carbon as a joint replacement in the foot: a preliminary report," *J Foot Surg*, Vol. 21, No. 3, 160-165, 1982.

<sup>11</sup> Hetherington VJ, Park JB, Drews M, Neville R, "Pyrolytic carbon, porous implants, and the fibrin adhesive system," *J Foot Surg*, Vol. 25, No. 5, 341-347, 1986.

<sup>12</sup> Cook SD, Beckenbaugh RD, Redondo J, Popich LS, Klawitter JJ, Linscheid RL, "Long term follow-up of pyrolytic carbon metacarpophalangeal implants," *J Bone and Joint Surg*, Vol. 81-A, No. 5, 635-648, 1999.

**Figure 2. Radiographic appearance of the Ascension MCP.**



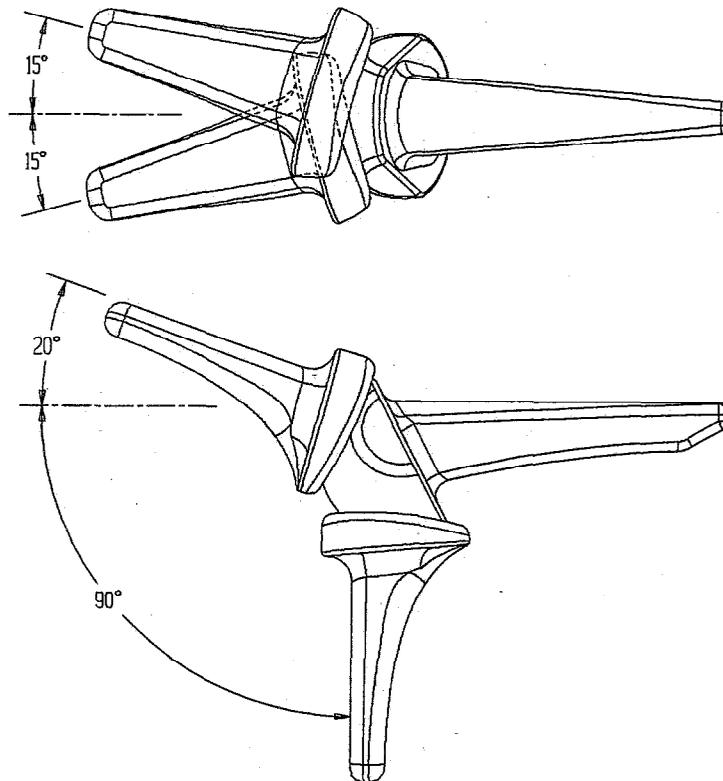
Planar sub-articular collars on both components of the Ascension MCP provide for simple, one-cut, planar bone resections. Furthermore, collars are inclined so that minimal bone stock removal is required allowing for preservation of the anatomic insertion sites of the surrounding ligamentous structures. Relief planes on the radial and ulnar aspects of the proximal component allow clearance for collateral ligament motion during joint flexion/extension. Anatomic shaped component stems are designed to fill the medullary canal and promote component fixation.

The Ascension MCP implant is available in a range of five sizes. An alpha-numeric coding system in parallel with a two level color coding system is used to distinguish both implant sizes, and proximal and distal components. A full set of

surgical instrumentation including x-ray overlay sizing templates, alignment guides, cutting guides, broaches, and trial devices is available.

Accurate placement of the proximal and distal components of the Ascension MCP results in a total joint arthroplasty that serves to reestablish functional joint mechanics. The range of motion allowed by all sizes of the prosthesis is 20 degrees of hyperextension to 90 degrees of flexion, and  $\pm 15$  degrees of abduction-adduction motion as illustrated in Figure 3.

**Figure 3. Ascension<sup>®</sup> MCP range of motion.**



## IV. Contraindications, Warnings, and Precautions

### CONTRAINDICATIONS

- inadequate bone stock
- indications of active sepsis or infection in the MCP joint
- nonfunctioning and irreparable MCP musculotendinous system
- interference with or by other prostheses
- procedures requiring modification of the prosthesis
- skin, bone, circulatory and/or neurological deficiency

### WARNINGS

- Ascension® MCP implants must not be modified in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device and could result in implant fracture.
- Mismatching of proximal and distal component sizes has not been evaluated and should not be done.

### PRECAUTIONS

- Ascension® MCP implants are made of pyrocarbon, which is a brittle material. Surface damage on the pyrocarbon implants may reduce their strength and could result in implant fracture. The pyrocarbon implants should be handled only with instrumentation provided by Ascension Orthopedics. They should never be grasped with metal instruments, especially instruments with teeth, serrations, or sharp edges. Ascension® MCP implant components should never be interchanged with other products.
- Do not resterilize this device.
- Do not reuse this device. Any implant that has been damaged, mishandled, or removed from the sterile field should be discarded.
- It is crucial that the articulating surfaces of the Ascension® MCP implant are clean and free of all debris prior to use.

## **V. Alternative Practices and Procedures**

Conservative early stage treatment includes joint injections, anti-inflammatory drug therapy (e.g. aspirin, NSAID) and avoidance of heavy stress through the joints (however, regular, gentle, active exercises are needed to maintain joint range of motion). Resting splints worn at night may slow the disease progression rate.

Surgical intervention may restore some range of motion and is typically used when conservative measures no longer give relief. Surgical treatment may include fusion of the bones, interposition arthroplasty with tendon or joint replacement surgery with a silicone rubber spacer. Individuals who are very active and use their hands heavily may not be good candidates for silicone rubber implants.

## **VI. Marketing History**

Ascension Orthopedics, Inc. has received approval to market the Ascension MCP in the following countries and regions:

1. European Community (CE Mark)
2. Canada
3. Australia
4. New Zealand
5. South Africa
6. Hong Kong
7. Malaysia
8. Pakistan
9. India
10. Singapore
11. China
12. Estonia

The Ascension MCP has not been withdrawn from any market for any reason related to safety or effectiveness of the device.

## VII. Potential Adverse Effects of the Device on Health

Potential adverse effects associated with total joint prostheses include loosening, fracture, dislocation, and infection. Strenuous implant loading, excessive mobility, the presence of articular instability, improper implant size selection and patient overactivity or misuse increase the potential for complications. The adjacent bone and soft tissue may be inadequate to support the implant or may deteriorate in time, resulting in instability, deformity or both. Injury to surrounding tendons, soft tissues, nerves, or blood vessels may occur. Providing each patient with counseling of potential complications is recommended.

## VIII. Summary of Pre-Clinical Studies

Extensive pre-clinical studies were performed to support the safety and effectiveness of the Ascension MCP. Pre-clinical studies included animal testing, *in vitro* mechanical testing, finite element analysis (FEA) stress and strain examinations, and material biocompatibility evaluations. Components from both the Ascension MCP and the pyrocarbon MCP implant used clinically were subjected to testing. Recognized standards were used in the design and conduct of these non-clinical studies where appropriate. Prior to commencing mechanical testing and FEA analysis, the biomechanics literature was reviewed to establish proper test loads and support conditions for the testing program. All pre-clinical studies revealed that the Ascension MCP is a robust and durable device capable of supporting functional joint motion and grip and pinch strength expected in the normal hand, and of maintaining a high level of performance for the long term. Pre-Clinical study results are summarized below.

### Animal Studies

Animal studies utilizing pyrocarbon MCP implants were conducted in order to further demonstrate the potential for biological fixation of pyrocarbon implant components in bone, and to evaluate the clinical suitability of the uncemented, semi-constrained pyrocarbon MCP implant design concept. Five pyrocarbon MCP prostheses and one Steffee (metal and polyethylene) MCP prosthesis were implanted into the long finger metacarpophalangeal joints of four baboons. Four of the pyrocarbon implants were inserted without bone cement; the fifth pyrocarbon implant and the Steffee implant were inserted using bone cement. Nine months after insertion, the implants and surrounding tissues were removed *en bloc* and evaluated radiographically and histologically. Histologic evidence of direct appositional bone fixation along the medullary stem was observed in one of the uncemented pyrocarbon specimens, and a combination of bone fixation with an interposing fibrous tissue membrane was observed in the others. There was no evidence of bone resorption around the stems of the uncemented pyrocarbon implants, and functional fixation was obtained with all of the uncemented pyrocarbon implants. No foreign body reaction was observed in the soft tissues, and no evidence of intracellular particles was present with the uncemented pyrocarbon implants. The cemented pyrocarbon implant showed evidence of bone resorption at the cement-bone interface around one component, and

intermittent lucent lines along the cement-bone interface on the other component. Evidence of bone resorption and gross implant loosening was observed in the cemented metal and polyethylene implant.

The results of this animal study demonstrated the potential for biological fixation of pyrocarbon implants in bone, and confirm the clinical suitability of the uncemented, semi-constrained Ascension MCP implant design.

#### Laboratory Studies

*In Vitro* mechanical tests were designed and carried out to evaluate five distinct performance characteristics of the Ascension MCP:

1. strength
2. cyclic endurance (fatigue resistance)
3. wear resistance
4. coronal load strength
5. contact test

All mechanical tests were conducted on final sterilized Ascension MCP components. Test specimens were mounted and loaded to simulate rigorous and demanding physiologic support and loading conditions determined based on a review of the biomechanics literature. Strength tests and contact tests were conducted on size 10, 30, and 50 proximal and distal components whereas cyclic endurance tests were conducted on size 10 proximal and distal components. The coronal load strength test was conducted on size 10 distal components. Size 10 components only were used for cyclic endurance test and the coronal load strength test because this size exhibited the lowest fracture strength compared to the larger sizes. For the strength test, cyclic endurance test, coronal load strength test, and contact test, components were held with 1/3 of the stem proximal to the collar unsupported; the distal 2/3 portion of the stem was rigidly supported. Cyclic endurance tests were carried out with a maximum load of 80 lb. for 10 million cycles at a rate of 30 Hz. Wear testing was conducted in a joint simulator wear test apparatus with a load of 14 pounds for 10 million cycles at a rate of 4 Hz in sterilized blood serum at room temperature. Wear test specimens were size 10 and size 50 Ascension MCP devices; wear test control specimens included Avanta SR MCP small and extra-large implants (a CoCr-on-UHMWPE MCP implant commercially available in Europe), and axi-symmetric CoCr ball-on-UHMWPE cup specimens. For the articulating surface contact test, the maximum load was 80 lb.; all specimens were inspected visually with a microscope and with dye penetrant before and after the test to identify potential damage on the articulating surfaces due to the contact load. A summary of the mechanical test results is shown in Table 1.

**Table 1. Summary of Mechanical Test Results for the Ascension® MCP.**

Test	Device Type and Size	Results
Wear Test	Ascension MCP size 10 Ascension MCP size 50  Avanta SR MCP size "SM" Avanta SR MCP size "XL"  Axi-symmetric CoCr-UHMWPE size 10 Axi-symmetric CoCr-UHMWPE size 50	Size 10 and Size 50 Ascension MCP implants exhibited identical wear behavior.  Measurable wear did not occur on Ascension MCP components, Avanta SR MCP CoCr proximal components, or axi-symmetric CoCr proximal components (sensitivity = 0.0002 inch).  Wear on Avanta SR MCP UHMWPE distal components and axi-symmetric UHMWPE distal components ranged from 0.0020 to 0.0040 inches.
Strength Test	Ascension MCP size 10 Proximal Ascension MCP size 30 Proximal Ascension MCP size 50 Proximal  Ascension MCP size 10 Distal Ascension MCP size 30 Distal Ascension MCP size 50 Distal	Size 10P: 279 ± 46 lb. (205 – 324) Size 30P: 351 ± 56 lb. (268 – 446) Size 50P: 454 ± 64 lb. (327 – 544)  Size 10D: 186 ± 22 lb. (150 – 219) Size 30D: 234 ± 31 lb. (190 – 275) Size 50D: 353 ± 64 lb. (307 – 423)
Endurance Test	Ascension MCP size 10: Proximal & Distal	No failures occurred. All specimens survived 10 million cycles with 80 lb. maximum load.
Coronal Load Strength Test	Ascension MCP size 10 Distal	Stem fractures: 171 ± 31 lb. (121 – 213) Head fractures: 174 ± 28 lb. (148 – 204)
Articulating Surface Contact Test	Ascension MCP size 10, 30, 50: Proximal & Distal	No damage occurred on articulating surfaces subjected to 80 lb. load.

Extensive strain gage testing and finite element analysis (FEA) studies were conducted in order to demonstrate that the strength of the Ascension MCP is greater than or equal to that of the pyrocarbon MCP implants used clinically. For the pyrocarbon MCP implants used clinically, standard size components were evaluated because it was the middle size of three sizes implanted, whereas for the Ascension MCP, the smallest size 10 and middle size 30 components were evaluated. Stress was determined by the FEA method and strain was measured on components equipped with strain gages and tested under the same constraint and loading conditions used in the strength and cyclic endurance studies. A fracture stress failure criterion was established using the FEA stress results in conjunction with component strength test results. The strength of the pyrocarbon MCP implants used clinically was then estimated and compared to the strength of the Ascension MCP. FEA results are summarized in Table 2. As shown in the table, even the smallest size 10 Ascension MCP components have greater fracture strength than estimated for the middle, standard size pyrocarbon MCP implants used clinically.

**Table 2. Summary of FEA Results.**

Device	Size	Component	Fracture Strength (lb.)
Pyrocarbon MCP	Standard	Proximal	122*
Ascension MCP	10	Proximal	279 <sup>+</sup>
Ascension MCP	30	Proximal	351 <sup>+</sup>
Pyrocarbon MCP	Standard	Distal	132*
Ascension MCP	10	Distal	186 <sup>+</sup>
Ascension MCP	30	Distal	234 <sup>+</sup>

\*Estimated fracture strength based on FEA.

+Fracture strength measured in component strength test.

### Biocompatibility Evaluations

Biocompatibility studies on the pyrocarbon material used in the Ascension MCP were conducted in accordance with ISO 10993 and U.S. Pharmacopeia 23, 1995. All biocompatibility studies revealed that the pyrocarbon is non-mutagenic, non-cytotoxic, not an irritant, non-pyrogenic, and having physiochemical properties exceeding the minimum U.S.P. levels set for plastics.

## **IX. Summary of Clinical Case Studies**

From December 1979 to February 1987, 53 patients at the Mayo Clinic received 147 primary pyrocarbon MCP total joint implants having a ball-and-cup design. Results from a Case History Review of those patients demonstrate that the Ascension MCP prosthesis is a safe and effective device for use in MCP joint arthroplasty treatment in cases of osteoarthritis (OA), post-traumatic arthritis (TA), rheumatoid arthritis (OA), and systemic lupus erythematosus (SLE).

### Case Study Design

A two-phase approach was used in the Case History Review. In Phase 1, an independent Contract Research Organization, Boston Biostatistics, Inc. (BBI) examined the Case History source documents, audited the source documents for validity and completeness against the patient medical records at Mayo Clinic, established consistency rules for data extraction and database creation, and built a patient database. All information, clinical findings, and observations recorded in the source documents related to the patients' wrists, hands, fingers, and MCP joints at baseline and at all follow-up visits were extracted from the source documents and entered into the patient database. The patient database included demographic information (age, gender), diagnosis, hand dominance, general medical history, prior treatments of the elbow, wrist, hand, thumb, and fingers, baseline and all available follow-up data on objective clinical variables (MCP joint range of motion (flexion and extension), grip and pinch strength, and ulnar deviation) and subjective clinical attributes (pain, activity level, satisfaction, and cosmesis), radiographic information, surgical information (including all concurrent and post-operative implant revision and soft-tissue reconstruction procedures), and all potential adverse events and complications. The demographic data, subjective attributes and objective variables at baseline and follow-up were analyzed and displayed in various tabular and graphical formats.

Kaplan-Meyer survival curves for the pyrocarbon MCP implants were provided and discussed. Potential adverse events and complications related to device safety were identified and analyzed by diagnosis, operated and non-operated joint, finger, and hand.

In Phase 2 of the Case History Review process, the patient population was stratified and grouped by baseline medical condition and the treatment expectations for each patient. Success/failure criteria with respect to device effectiveness endpoints (including criteria for implanted joint pain, joint function, and radiographic data), and success/failure criteria with respect to device safety were established. Each implanted joint was then evaluated against these effectiveness and safety criteria, and the number of successes and failures were determined. In addition, in order to conduct a comprehensive assessment of the potential benefit of the Ascension MCP implant, multiple longitudinal outcomes analysis were conducted using both “clinically relevant” and potentially “worst case” success/failure criteria for the RA/SLE patients. Under the “clinically relevant” criteria, reductions in treatment improvements due to disease progression in RA/SLE patients at follow-up times greater than five (5) years were not considered a device failure, whereas under the “worst case” criteria these reductions were considered failures.

### Case Study Results

#### *Phase 1*

Phase 1 of the Case History Review revealed that the study population consisted of 53 patients who underwent 147 primary MCP total joint arthroplasties using a pyrocarbon ball-and-cup prosthesis. As shown in Table 3, the 53 patients who received the pyrocarbon implants had arthrosis due to one of four conditions: 43 (81%) patients had rheumatoid arthritis (RA), 2 (4%) had systemic lupus erythematosus (SLE), 5 (9%) had arthritis due to trauma (TA), and 3 (6%) had osteoarthritis (OA). Females accounted for 85% of the patients who received the pyrocarbon implants. For patients diagnosed with RA or SLE, the mean time from diagnosis until the first pyrocarbon implant was 195.8 months, more than 16 years.

**Table 3. Patient Demographics and Baseline Clinical Characteristics.**

	All Diagnoses (N=53)	OA/Trauma (N=8)	RA/SLE (N=45)
<b>Age (years)</b>			
N	53	8	45
Mean (sd)	57.5 (12.6)	54.9 (18.4)	58.0 (11.5)
Median	60	60	58
Min-max	21, 78	21, 77	35, 78
<b>Gender</b>			
Male	8 (15%)	7 (88%)	1 (2%)
Female	45 (85%)	1 (12%)	44 (98%)
<b>Hand dominance</b>			
Right	49 (92%)	7 (88%)	42 (93%)
Left	2 (4%)	1 (12%)	1 (2%)
Unknown	2 (4%)		2 (4%)
<b>Diagnosis</b>			
OA	3 (6%)	3 (38%)	-
Trauma	5 (9%)	5 (62%)	-
RA	43 (81%)	-	43 (96%)
SLE	2 (4%)	-	2 (4%)
<b>Time from diagnosis to first pyrocarbon implant surgery (months)</b>			
N	40	-	40
Mean (sd)	195.8 (100.4)	-	195.8 (100.4)
Median	192.0	-	192.0
Min-max	36.0, 432.0	-	36.0, 432.0

This phase of the Case History Review sought and realized both short term and long term patient follow-up with mean follow-up time for all patients of 8.6 years (range 1.7 months – 17.2 years). Two years after receiving a pyrocarbon implant, 41 (82.0%) patients with no indication of death were still being followed. At greater than ten years post implantation, 72.5% of the patients with no prior indication of death were still being followed. Thus, a significant portion of the patient population provided clinically relevant data regarding device safety and effectiveness at very long-term follow-up. Furthermore, subjects underwent longitudinal clinical assessments as part of their post-operative follow-up care regimen. On average, there were over 12 post-surgery clinical follow-up visits per patient.

Kaplan-Meyer life tables, using an endpoint of implant fracture or implant removal for any reason, revealed 94% implant survival at 2 years, 88% implant survival at 5 years, and 84% implant survival at 10 years. These survival rates correspond to an annualized failure rate of approximately 3% per year during the first five years with a decrease to approximately 1% per year thereafter.

Patient satisfaction with the general condition, treatment outcome or function of their hand(s) was high with 38 out of 48 (79%) satisfied at last follow-up

observation. Cosmesis was judged acceptable by 88% of the study population at last observation.

Pain relief in the RA patients was difficult to localize to the implanted joint due to disease presence throughout the hand, wrist and upper extremity. Pre-operatively, only 11% were pain free in the operated hand. At last observation, 49% of patients reported complete absence of pain in the operated hand. When accounting for pain that was attributed to the implanted joint, there were 14 reports of implanted joint pain affecting 13 (9%) of the study implants in 11 (21%) patients at any time during follow-up. Of the 14 reports of implanted joint pain, 6 of the implants in 5 patients were reported to exhibit a condition of chronic long-term pain that was usually in association with long standing rheumatoid arthritis.

A significant improvement in extension deficit to a more functional position was achieved post-operatively for the study population. A baseline extension deficit mean of -47 degrees was corrected to a mean of -20 degrees for all fingers at last observation (Table 4). A significant improvement in arc of motion from a baseline mean of 35 degrees to 41 degrees at last observation for all fingers was found for the study population (Table 5).

**Table 4. Mean Extension Deficit (degrees).**

	Baseline (Pre-Op)	Last Follow-Up
Time (months)	Mean = -5.14 (-93.36 to -0.07)	Mean = 30.90 (0.56 to 201.02)
N	141	140
Mean (sd)	-47.06 (26.44)	-20.47 (22.21)
Mean change from baseline		
N		134
Mean (sd)		26.46 (35.04)
Paired t-test p-value		<0.001

**Table 5. Mean Arc of Motion (degrees).**

	Baseline (Pre-Op)	Last Follow-Up
Time (months)	Mean = -5.14 (-93.36 to -0.07)	Mean = 30.90 (0.56 to 201.02)
N	141	134
Mean (sd)	34.70 (24.00)	41.24 (18.71)
Mean change from baseline		
N		134
Mean (sd)		6.05 (31.47)
Paired t-test p-value		0.028

Radiographic and clinical assessments revealed an average pre-operative ulnar deviation of approximately 20 degrees. A significant correction in ulnar deviation was accomplished following surgery. At long term, radiographic evaluation revealed an average ulnar deviation of 20 degrees. Although initial post-operative

improvements were not maintained, the pyrocarbon implants appeared to halt the inevitable progression of ulnar deviation, with no difference between the pre-operative and long-term post-operative ulnar deviation.

For the study population of 147 primary implants, a total of 21 (14%) implants were removed from 11 (21%) patients (Table 6). No primary implants were removed for implant fracture or clinical complications such as bone fracture, infection, sensory abnormality, allergic or foreign body reaction, iatrogenic complications or wound complications. Three (2%) implants were removed for loosening while 18 implants (12%) were removed for deformity associated with disease progression related to RA/SLE (extensor lag, flexion contracture, ulnar deviation, subluxation or dislocation). All removed implants were successfully revised; fifteen were replaced with silicone spacers, four primary pyrocarbon implants were reinserted with bone cement, and two new pyrocarbon implants were used.

**Table 6. Summary of Implant Removals.**

	All Diagnoses (N=53)	OA/Trauma (N=8)	RA/SLE (N=45)
Number of Implants	147	9	138
Number of Removals	21 (14%)	1 (11%)	20 (14%)
Reason for Removal			
Fracture	0 (0%)	0 (0%)	0 (0%)
Loosening, Subsidence, Migration	3 (2%)	1 (11%)	2 (1%)
Clinical Complication	0 (0%)	0 (0%)	0 (0%)
Disease Progression	18 (12%)	0 (0%)	18 (13%)

Tissue sections from a total of 9 joints with study implants were examined. Features observed on all sections were consistent with diagnoses of RA and OA. One tissue section exhibited fine particulate matter, but no indications of negative tissue reaction due to the presence particulate matter or the pyrocarbon implant were seen. Similarly, for the 8 remaining sections, no indications of negative tissue reaction due to the presence of the pyrocarbon implants were seen, e.g., no foreign body granuloma or other negative foreign body reactions were observed in any of the sections.

For the study population of 147 implants, there were no reports of implant site infections, and there were no reports of *in vivo* implant fracture events. The only potential safety issue reported was for intraoperative implant fractures, i.e., fractures that occurred during either implantation or revision of the device. A total of 4 (1.4%) intraoperative fractures occurred during the implantation of 295 components; in 3 of the 4 cases, the fractured component was easily removed and a new pyrocarbon component was inserted successfully while in the fourth case, the fragment was left *in situ* and a silicone spacer was successfully inserted. During implant revision, 6 (14%) fractures were reported during removal of 42 components (21 devices); 5 of these fractured devices were successfully replaced with a silicone spacer while the sixth fractured device was essentially intact and was reinserted with bone cement. All intraoperative fractures were uneventful

and no *sequelae* resulted. No other significant safety issues were identified for this device. These results demonstrate the following with respect to device safety:

- There were no post-operative bone or non-intraoperative implant fractures, biological reactions to the implant, or implant related infections.
- All intraoperative implant fractures were uneventfully removed and replaced with another pyrocarbon implant or a silicone spacer.
- In cases where advancing disease and soft tissue degradation caused joint instability leading to revision, or in cases of implant loosening, the pyrocarbon implant was uneventfully replaced with a silicone spacer.

### *Phase 2*

In Phase 2 of the Case History Review, the study population was stratified and evaluated based on two baseline medical conditions: 1) osteoarthritis/post traumatic (OA/TA), and 2) rheumatoid arthritis/systemic lupus erythematosus (RA/SLE). This stratification provided for a clear evaluation of device performance and a demonstration of the potential benefit of the Ascension MCP both with and without the confounding influence of the RA/SLE disease and its concomitant soft tissue degradation. With this stratification, the OA/TA patients served as the perfect model in which to examine the implant's sole purpose of functioning as a normal joint, since in these patients the articular surface is damaged or destroyed and needs to be replaced while the soft tissue structures that provide joint stability and mobilization are normal or near normal. On the other hand, the RA/SLE patients allowed for an assessment of implant performance in the presence of remittent, progressive soft tissue degradation.

For the OA/TA patient cohort, the Case History Review revealed the following:

- 7 of the 9 (78%) implants in the OA/TA cohort had a "Successful" outcome (6 Excellent and 1 Good), 1 implant had an "Unsatisfactory" outcome, and 1 implant had an "Indeterminate" outcome.
- 6 of the 8 (75%) OA/TA patients had all implants with a "Successful" outcome.
- OA/TA patients with "Successful" implant outcomes had last follow-ups ranging from 3.5 to 17.0 years.

These results clearly demonstrate the potential of the Ascension MCP to provide a long term, stable, functional, and pain free total joint replacement for the OA/TA patient.

For the RA/SLE patient cohort, the Case History Review revealed the following when "clinically relevant" success/failure criteria (i.e., criteria that did not consider a reduction in treatment improvements due to disease progression at

follow-up greater than 5 years as a device failure) were used:

- 82 of the 138 (59%) implants in the RA/SLE cohort had a “Successful” outcome (46 Excellent and 36 Good), 37 implants had an “Unsatisfactory” outcome, and 19 “Indeterminate”.
- 27 of the 45 (60%) RA/SLE patients had all implants with a “Successful” outcome.
- RA/SLE patients with “Successful” implant outcomes had last follow-up ranging from 1.0 to 16.8 years, with 72% (59 / 82) of the implants having a last follow-up > 2 years.

Similar to the OA/TA cohort, these results demonstrate the potential of the Ascension MCP to provide a long term, stable, functional, and pain free total joint replacement for the RA/SLE patient.

Combining the outcome results for the OA/TA and RA/SLE patient cohorts yields the overall summaries shown in Table 7 and Table 8. For the study population that is heavily weighted (85%) by patients affected with a remittent progressive disease that significantly limits the treatment expectations, 61% (89 / 147) of the implants were considered successful on an “intent to treat basis”. When only implants with a known outcome are considered, a full 70% (89 / 127) of the implants had an Excellent or Good outcome in which all primary treatment objectives were obtained and thus were considered a success.

As shown in Table 8, 39 (74%) patients had 1 or more successful implants, and 33 (62%) patients had all their implants considered successful. For patients with known implant outcomes (i.e., excluding patients with all implants having “Indeterminate” outcome), 80% had 1 or more successful implant, and 67% had all their implants considered successful.

**Table 7. Overall Implant Treatment Outcomes.**

Implants	All Implants (Intent to Treat)		Implants w/ Known Outcome	
	N	%	N	%
<b>Total</b>	147		127	
<b>OA/PT</b>	9	6%	8	6%
<b>RA/SLE</b>	138	94%	119	94%
<b>Successful</b>	89	61%	89	70%
<b>Failure</b>	38	26%	38	30%
<b>Indeterminate</b>	20	14%	--	--

**Table 8. Overall Patient Treatment Outcomes.**

Patients	All Patients		Patients w/ 1 or more Known Implant Outcome	
	N	%	N	%
<b>Total</b>	53		49	
<b>w/ 1 or more Successful implants</b>	39	74%	39	80%
<b>w/ All implants Successful</b>	33	62%	33	67%

**X. Conclusions Drawn from the Studies**

The following conclusions can be drawn from the Pre-Clinical and Clinical Case Study results summarized above:

- The Ascension MCP is a robust and durable device that is capable of supporting functional joint motion and grip and pinch strength expected in the normal hand, and of maintaining a high level of performance for the long term.
- Case Study source documents were substantial and provided necessary and sufficient information to allow a determination of the safety and effectiveness of the Ascension MCP.
- There are no significant safety issues related to the use of the Ascension MCP; thus, the device will not expose patients to an unreasonable or significant risk of illness or injury.
- The Ascension MCP can potentially provide a long-term stable, functional, and pain free total joint replacement.
- The Ascension MCP prosthesis is a safe and effective device for use in MCP joint arthroplasty treatment in cases of osteoarthritis, post-traumatic arthritis, rheumatoid arthritis, and systemic lupus erythematosus.

**XI. Panel Recommendations**

**XII. CDRH Decision**

**XIII. Approval Specifications**

## Proposed Instructions For Use

**Caution: Sterile** 

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

### ***Ascension*® MCP** Metacarpophalangeal Joint Implant



#### **1. DEVICE DESCRIPTION**

The *Ascension*® MCP is a two-piece total joint prosthesis composed of a proximal and a distal component in a ball-and-cup design. Each component is constructed of a pyrocarbon layer deposited on a high-strength graphite substrate. The *Ascension*® MCP is available in five sizes to accommodate various operative requirements. Instrumentation, including x-ray templates and color-coded sizing sets, are available for proper size determination. Intramedullary stem broaches for each size implant are available to properly prepare the intramedullary canal. This will help to achieve a “press fit” between the stem of the device and the intramedullary canal of the bone. No bone cement is required.

#### **2. INDICATIONS FOR USE**

The *Ascension*® MCP is intended for use as a total joint replacement of index, long, ring, and small finger metacarpophalangeal (MCP) joints that exhibit symptoms of pain, limited range of motion, or inadequate bony alignment (i.e., subluxation or dislocation) secondary to articular destruction or degenerative disease related to rheumatoid arthritis, systemic lupus erythematosus, osteoarthritis, or post-traumatic arthritis where soft tissue reconstruction can provide stabilization.

#### **3. CONTRAINDICATIONS**

General contraindications for this implant include:

- inadequate bone stock
- indications of active sepsis or infection in the MCP joint
- nonfunctioning and irreparable MCP musculotendinous system
- interference with or by other prostheses
- procedures requiring modification of the prosthesis
- skin, bone, circulatory and/or neurological deficiency

#### 4. WARNINGS AND PRECAUTIONS

**Warning:** *Ascension*® MCP implants must not be modified in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device and could result in implant fracture.

**Warning:** Mismatching of proximal and distal component sizes has not been evaluated and should not be done.

**Caution:** *Ascension*® MCP implants are made of pyrocarbon, which is a brittle material. Surface damage on the pyrocarbon implants may reduce their strength and could result in implant fracture. The pyrocarbon implants should be handled only with instrumentation provided by Ascension Orthopedics. They should never be grasped with metal instruments, especially instruments with teeth, serrations, or sharp edges. *Ascension*® MCP implant components should never be interchanged with other products.

**Caution:** Do not resterilize this device.

**Caution:** Do not reuse this device. Any implant that has been damaged, mishandled, or removed from the sterile field should be discarded.

**Caution:** It is crucial that the articulating surfaces of the *Ascension*® MCP implant are clean and free of all debris prior to use.

#### 5. STERILITY

This implant has been sterilized by moist heat. If either the implant or the package appears damaged, or if sterility is questioned for any reason, the implant should not be used. Resterilization of this product is not recommended.

#### 6. ADVERSE EVENTS

Potential adverse events associated with total joint prostheses include loosening, fracture, dislocation, and infection. Strenuous implant loading, excessive mobility, the presence of articular instability, improper implant size selection and patient overactivity or misuse increase the potential for complications. The adjacent bone and soft tissue may be inadequate to support the implant or may deteriorate in time, resulting in instability, deformity or both. Injury to surrounding tendons, soft tissues, nerves, or blood vessels may occur. Providing each patient with counseling of potential complications is recommended.

## 7. CLINICAL CASE STUDIES

Fifty-three patients (45 female, 8 male) receiving a total of 147 pyrocarbon implants were studied retrospectively over a mean follow-up time of 8.5 years. Forty-five of them were rheumatoid arthritis/systemic lupus erythematosus (RA/SLE) patients; eight were osteoarthritis/trauma (OA/Trauma) patients.

### Patient Demographics and Baseline Clinical Characteristics

	All Diagnoses (N=53)	OA/Trauma (N=8)	RA/SLE (N=45)
<b>Age (years)</b>			
N	53	8	45
Mean (sd)	57.5 (12.6)	54.9 (18.4)	58.0 (11.5)
Median	60	60	58
Min-max	21, 78	21, 77	35, 78
<b>Gender</b>			
Male	8 (15%)	7 (88%)	1 (2%)
Female	45 (85%)	1 (12%)	44 (98%)
<b>Hand dominance</b>			
Right	49 (92%)	7 (88%)	42 (93%)
Left	2 (4%)	1 (12%)	1 (2%)
Unknown	2 (4%)		2 (4%)
<b>Diagnosis</b>			
OA	3 (6%)	3 (38%)	-
Trauma	5 (9%)	5 (62%)	-
RA	43 (81%)	-	43 (96%)
SLE	2 (4%)	-	2 (4%)
<b>Time from diagnosis to first pyrocarbon implant surgery (months)</b>			
N	40	-	40
Mean (sd)	195.8 (100.4)	-	195.8 (100.4)
Median	192.0	-	192.0
Min-max	36.0, 432.0		36.0, 432.0

A significant improvement in extension deficit to a more functional position was achieved post-operatively for the study population. A baseline extension deficit mean of -47 degrees was corrected to a mean of -20 degrees for all fingers at last observation. A significant improvement in arc of motion from a baseline mean of 35 degrees to 41 degrees at last observation for all fingers was found for the study population.

Mean Extension Deficit (degrees)

	Baseline (Pre-Op)	Last Follow-Up
Time (months)	Mean = -5.14 (-93.36 to -0.07)	Mean = 30.90 (0.56 to 201.02)
N	141	140
Mean (sd)	-47.06 (26.44)	-20.47 (22.21)
Mean change from baseline		
N		134
Mean (sd)		26.46 (35.04)
Paired t-test p-value		<0.001

Mean Arc of Motion (degrees)

	Baseline (Pre-Op)	Last Follow-Up
Time (months)	Mean = -5.14 (-93.36 to -0.07)	Mean = 30.90 (0.56 to 201.02)
N	141	134
Mean (sd)	34.70 (24.00)	41.24 (18.71)
Mean change from baseline		
N		134
Mean (sd)		6.05 (31.47)
Paired t-test p-value		0.028

Of the 147 implants, 21 were revised; 18 of these were due to RA/SLE disease progression and 3 were due to loosening. No implants were removed for clinical complications such as bone fracture, infection, sensory abnormality, allergic or foreign body reaction, iatrogenic complications or wound complications. All removed implants were successfully revised; fifteen were replaced with silicone spacers, four pyrocarbon implants were reinserted with bone cement, and two new pyrocarbon implants were used.

Implant Removals

	All Diagnoses (N=53)	OA/Trauma (N=8)	RA/SLE (N=45)
Number of Implants	147	9	138
Number of Removals	21 (14%)	1 (11%)	20 (14%)
Reason for Removal			
Fracture	0 (0%)	0 (0%)	0 (0%)
Loosening, Subsidence, Migration	3 (2%)	1 (11%)	2 (1%)
Clinical Complications	0 (0%)	0 (0%)	0 (0%)
Disease Progression	18 (12%)	0 (0%)	18 (13%)

No cases of *in-vivo* implant fracture, surface wear, or infection were reported. A total of 10 intraoperative implant fractures were reported: 4 (1.4%) intraoperative fractures occurred during the implantation of 295 components while during implant revision, 6 (14%) fractures were reported during removal of 42 components. All fractured devices were successfully replaced with a new pyrocarbon implant or a silicone spacer.

For the OA/Trauma patients, 78% (7 / 9) of the implants were "Successful", and 75% (6 / 8) of the patients had all implants with a "Successful" outcome.

For the RA/SLE patients, 59% (82 / 138) of the implants were "Successful", and 60% (27 / 45) of the patients had all implants with a "Successful" outcome under success/failure criteria that did not consider a reduction in treatment improvements due to disease progression at follow-up greater than 5 years as a device failure.

Overall results for the study population that was heavily weighted (85%) by RA/SLE patients showed that 61% (89 / 147) of the implants were considered "Successful", 74% (39 / 53) of the patients had 1 or more "Successful" implants, and 62% (33 / 53) of the patients had all their implants considered "Successful".

## 8. SURGICAL PROCEDURE

It is the responsibility of the surgeon to become familiar with the surgical technique for implantation of these devices. A *Surgical Technique* manual is available which outlines the basic procedure for implantation, as well as implant removal options. Prior to use of this device, the surgeon should review the *Surgical Technique* manual. In addition, a set of surgical instrumentation is provided which, when used properly, will provide the optimum implantation and reconstruction results. The use of these instruments is also described in the *Surgical Technique* manual.

Meticulous preparation of the implant site and selection of the proper size implant increase the potential for successful reconstruction. A complete set of instruments for each type of implant is available to aid bone preparation and reduce the operative time. It is suggested that the proper size implant be removed from its sterile package only after the implant site has been prepared and properly sized.

Anatomical dimensions limit the physical size of the device that can be implanted. In most cases, the largest possible implant should be selected which, in the opinion of the surgeon, does not require excessive bone resection or in any way limits function or healing.

**Disclaimer of Warranties**

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