

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 component, semi-constrained, uncemented, finger joint prosthesis intended to replace the metacarpophalangeal (MCP) joint of the hand. The proximal component has a “ball-shaped” articular surface and stem and the distal component has a “cup-shaped” articular surface and stem. Each component is constructed of a pyrocarbon layer encasing 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 trials, 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 indicated for use as a total joint replacement of index, long, ring, and small finger metacarpophalangeal (MCP) joints that exhibit symptoms of pain, limited motion, or inadequate bony alignment (i.e., subluxation/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 adequate stabilization.

3. CONTRAINDICATIONS

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

4. WARNINGS AND PRECAUTIONS

WARNINGS:

- Do not modify the Ascension MCP implant 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 and/or particulate debris.
- Do not mismatch proximal and distal component sizes. For example, a Size 10 proximal component should be matched with only a Size 10 distal component. The wear behavior of mismatched proximal and distal component size combinations has not been evaluated, and is unknown.
- Do not grasp the Ascension MCP implant with metal instruments, or instruments with teeth, serrations, or sharp edges. Implants should be handled only with instrumentation provided by Ascension Orthopedics. Ascension MCP implants are made of pyrocarbon, which is a ceramic-like material. Mishandling implants could cause surface damage and reduce their strength, and could result in implant fracture and/or particulate debris.
- Do not use Ascension MCP components in combination with proximal and distal components from other products. The wear behavior of Ascension MCP components against proximal and distal component from other products has not been evaluated, and could damage the structural integrity of the device and result in implant fracture and/or particulate debris.

PRECAUTIONS:

- Do not use the Ascension MCP in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the natural joint, the Ascension MCP attains stabilization from the surrounding capsuloligamentous structures. Because soft tissue reconstruction may be unable to maintain joint stability, the Ascension MCP is not recommended for use in joints:
 - where it is not possible to reconstruct the radial-collateral ligament, or
 - in joints that exhibit extension lag greater than 45 degrees,
 - ulnar deviation greater than 30 degrees, or
 - severe subluxation and/or shortening greater than 1 centimeter.
 - Special attention should be given to soft tissue reconstruction and joint stability in the ring and small fingers.
- Corrective wrist surgery may be required prior to use of the Ascension MCP. In patients with severe intercarpal supination and radial deviation of the wrist, ulnar deviation of the digits may not be correctable with soft tissue reconstruction at the MCP alone. In these instances, it is recommended that corrective wrist surgery be performed first at a separate setting.

- Obtain proper training prior to use. Surgeons should obtain training from a qualified instructor prior to implanting the Ascension MCP to ensure thorough understanding of the indications, implantation and removal techniques, instrumentation, and post-operative rehabilitation protocol.
- Inspect the articulating surfaces of the Ascension MCP to insure they are clean and free of all debris prior to use. Foreign debris could result in excessive wear.
- Do not resterilize this device. Resterilization could lead to mishandling and surface damage that could result in implant fracture.
- Do not reuse this device. Any implant that has been damaged, mishandled, or removed from the sterile field may have surface damage that could result in implant fracture and should be discarded.

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

The sponsor used an earlier version of the Ascension MCP device clinically. Therefore, the reported adverse effects identified in this section are those observed while using the earlier device design. For clarity, the earlier device design is designated as the “Pyrocarbon MCP.”

REPORTED ADVERSE EFFECTS

The most commonly reported patient adverse events were:

- recurrent deformity
- subluxation / dislocation
- re-operation for soft tissue reconstruction
- implant removal
- implanted joint pain, and
- synovitis

A detailed discussion and complete list of the frequency and rate of complications and adverse events identified in the case history review is provided below in section 7 Clinical Case Studies.

POTENTIAL ADVERSE EFFECTS

Potential adverse effects associated with total joint prostheses and surgery in general include, but are not limited to:

- pain

- bleeding
- infection
- swelling
- damage to surrounding blood vessels, nerves, or soft tissue
- implant migration within the bones
- implant loosening
- excessive implant wear and particulate
- allergic or foreign body reaction
- implant fracture
- bone fracture
- implant subluxation or dislocation
- finger deformity (radial or ulnar deviation, supination or pronation)
- reduction or loss of joint motion
- loss of finger or hand function
- lengthening or shortening of the finger

These adverse effects may lead to additional surgery and could result in:

- implant removal
- joint fusion
- amputation
- death

7. CLINICAL CASE STUDIES

The Ascension MCP device described in section 1, Device Description, is a modification to an earlier version of the device that was used in the clinical case series (summarized below). For clarity, the earlier device design is designated as the "Pyrocarbon MCP." The results of pre-clinical testing demonstrated that the design and materials of the Pyrocarbon MCP were similar to the Ascension MCP. Therefore, the following clinical data for the Pyrocarbon MCP was provided to support a determination that the Ascension MCP is safe and effective.

Objective and Design

Between 1979 and 1987, a total of 151 Pyrocarbon MCP finger joint devices were implanted in 53 patients at the Mayo Clinic, Rochester Minnesota, USA by Drs. Beckenbaugh and Linscheid. Of these, 147 implants were primary ball-and-cup, uncemented, Pyrocarbon MCP implants; 2 were condylar pyrocarbon implants (implants with a conical shaped bump in the center of the articulating surface of the distal component that interfaced with a groove on the proximal component's articulating surface); and 2 were revision ball-and-cup Pyrocarbon MCP implants (one uncemented and one cemented). The 53 patients who received the 147 primary ball-and-cup uncemented Pyrocarbon MCP implants represent the case series upon which the clinical data in this PMA is based.

A retrospective case series analysis of the 53 patients who received the 147 primary, ball-and-cup, uncemented, Pyrocarbon MCP total joint implants was reviewed to evaluate the safety and effectiveness of the Ascension MCP. In this retrospective case history review, 53 patients

received 147 Pyrocarbon MCP prostheses and the last patient evaluation was at an average of 8.5 years (range 1.7 months – 17.2 years) after implantation. Case histories for the study population were reviewed and information used to evaluate device safety and effectiveness was gathered. An independent contract research organization (CRO) audited and validated the accuracy and completeness of the case history records. The CRO entered information into a computerized database, and analyzed the data to determine study population demographics, patient evaluations, and the frequency and severity of all adverse events.

To evaluate safety and effectiveness of the Ascension MCP, patients were stratified and evaluated based on two baseline medical conditions: 1) osteoarthritis/post traumatic (OA/Trauma), and 2) rheumatoid arthritis/systemic lupus erythematosus (RA/SLE). 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 endpoints (including implant and bone fracture, infection, and adverse biological reactions) were established retrospectively.

Separate success/failure criteria were defined for the OA/Trauma and RA/SLE patient groups as summarized below. Each implant was determined to have an outcome of excellent, good, unsatisfactory, or indeterminate. Implants with an excellent or good outcome were considered a success while implants with an unsatisfactory outcome were considered a failure. Patients lacking information required as part of the success/failure definition were considered indeterminate.

Patient Population and Demographics

The study population consisted of 45 females and 8 males with a mean age of 57.5 years (range 21 – 78 years). Patients were diagnosed with 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). For patients diagnosed with RA or SLE, the mean time from diagnosis until implantation of the first Pyrocarbon MCP was more than 16 years (range 3-36 years).

Table 1. Patient Demographics and Baseline Clinical Characteristics.

	All Diagnoses	OA/Trauma	RA/SLE
Age (years)			
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
Gender			
Male	8 (15%)	7 (88%)	1 (2%)
Female	45 (85%)	1 (12%)	44 (98%)
Hand dominance			
Right	49 (92%)	7 (88%)	42 (93%)
Left	2 (4%)	1 (12%)	1 (2%)
Unknown	2 (4%)		2 (4%)
Diagnosis			
OA	3 (6%)	3 (38%)	-
Trauma	5 (9%)	5 (62%)	-
RA	43 (81%)	-	43 (96%)
SLE	2 (4%)	-	2 (4%)
Time from diagnosis to first pyrocarbon implant surgery (years) for RA/SLE patients			
N	-	-	40
Mean (sd)	-	-	16.3 (8.4)
Median	-	-	16.0
Min – Max	-	-	3.0 – 36.0

Patient Evaluations

The mean last evaluation time point for all patients was 8.6 years (range 1.7 months – 17.2 years). Two years after receiving a Pyrocarbon MCP implant, 82% (41/50) of the patients were evaluated. At greater than ten years post implantation, 72.5% (29/40) of the patients were evaluated.

Table 2. Last Patient Evaluation Time Point.

	All Diagnoses	OA/Trauma	RA/SLE
Patients			
N	53	8	45
Mean	8.6 y	9.0	8.5
Min – Max	1.7 m – 17.2 y	1.7 m – 16.0 y	8.1 m – 17.2 y
Implants			
N	147	9	138
Mean	7.8 y	9.4 y	7.7 y
Min – Max	0.9 m – 17.2 y	1.7 m – 16.0 y	0.9 m – 17.2 y

Table 3. Proportion of Patients Evaluated Over Time.

Evaluation (years)	Cumulative Deaths	Patients Left	Patients Evaluated	Proportion of Patients Evaluated (%)
0	--	53	53	100%
≥ 1	--	53	49	92%
≥ 2	3	50	41	82%
≥ 5	6	47	38	81%
≥ 10	13	40	29	73%

Complications and Adverse Events

The complications and adverse events identified during the case series analysis of the Pyrocarbon MCP are provided below. The most commonly reported patient adverse events were:

- recurrent deformity
- subluxation / dislocation
- re-operation for soft tissue reconstruction
- implant removal
- implanted joint pain, and
- synovitis

Table 4. Complications and Adverse Events.

Complication / Adverse Event	Implants (N = 147)	% Implants	Patients (N = 53)	% Patients
Recurrent Deformity	49	33%	20	38%
Subluxation/Dislocation	31	21%	17	32%
Soft-tissue Re-operation	22	15%	11	21%
Implant Removal	21	14%	11	21%
Implanted joint pain	13	9%	11	21%
Synovitis	24	16%	10	19%
Stiffness / Loss of Motion	12	8%	6	11%
Subsidence	9	6%	6	11%
Loosening	7	5%	5	9%
Black Tissue Stain	7	5%	4	8%
Implant modification	5	3%	3	6%
Radiographic changes:				
lucency	4	3%	3	6%
sclerosis	1	1%	1	2%
heterotopic bone	2	1%	2	4%
cyst	1	1%	1	2%
erosion	2	1%	1	2%
Superficial Wound Infection	--	--	2	4%
Sensory Abnormality	3	2%	2	4%
Excessive erythema	2	1%	2	4%
Implant Fracture:				
in vivo fracture	0	0%	0	0%
intra-op fracture:				
at implantation	4	3%	4	8%
at removal	6	4%	3	6%
Bone Fracture:				
in vivo fracture	0	0%	0	0%
intra-op fracture	3	2%	2	4%

Implant Removals

A total of 21 (14%) Pyrocarbon MCP implants were removed from 11 (21%) patients. No 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 Pyrocarbon MCP implants were reinserted with bone cement, and two new Pyrocarbon MCP implants were used. Of the 21 implants that were removed, 6 implants were removed less than 1 year after implantation; 9 implants were removed between 1 and 5 years after implantation; and 6 implants were removed greater than 5 years after implantation (range 5-11 years).

Table 5. Summary of Implant Removals.

	All Diagnoses (N=53 patients)	OA/Trauma (N=8 patients)	RA/SLE (N=45 patients)
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%)

Soft Tissue Re-Operations

Eleven (11) soft tissue re-operation procedures were performed on a 22 (15%) joints in 11 (21%) Pyrocarbon MCP patients. Procedures were performed to correct recurrent MCP joint deformities such as implant subluxation/dislocation, ulnar/radial deviation, extension lag or loss of motion, or extension contracture. All but one of the soft tissue re-operations was on RA/SLE patients. Three (3) of the 22 implants were eventually removed, all due to recurrent subluxation or dislocation. Sixteen (16) of the 22 joints were operated on less than 1 year post-implantation.

Table 6. Summary of Soft Tissue Re-operations.

	All Diagnoses (N=53 patients)	OA/Trauma (N=8 patients)	RA/SLE (N=45 patients)
Number of Implants	147	9	138
Number of Implants Re-operated	22 (15%)	1 (11%)	21 (15%)
Reason for Re-operation			
Subluxation / Dislocation	7 (5%)	0 (0%)	7 (5%)
Ulnar / Radial Deviation	7 (5%)	1 (11%)	6 (4%)
Extension Lag / Loss of Motion	5 (3%)	0 (0%)	5 (4%)
Extension Contracture	3 (2%)	0 (0%)	3 (2%)

Intraoperative Implant Fractures

There were a total of 10 intraoperative Pyrocarbon MPC implant fractures, i.e., fractures that occurred during either implantation or revision of the device. Four of the 10 intraoperative fractures occurred during the implantation of 295 components for a rate of 1.4% (4/295). In 3 of the 4 cases, the fractured component was easily removed and a new Pyrocarbon MCP component was inserted while in the fourth case, the fragment was left *in situ* and a silicone spacer was inserted. Six of the 10 fractures occurred during implant revision and removal of 42 components (21 devices) for a rate of 14% (6/42). Five of these fractured devices were replaced with a silicone spacer while the 6th fractured device was essentially intact and was reinserted with bone cement. All intraoperative fractures were uneventful and no *sequelae* resulted.

Black Staining of Tissue and Synovitis

Although the sponsor concluded that there was no adverse tissue reaction to the Pyrocarbon MCP joint implant, carbon particles, or “fine particle matter” in samples evaluated by the histopathologist, there were reports of black staining of tissue and synovitis.

Black Staining of Tissue

A total of 7 implants caused black stained tissue in 4 of 53 patients for a rate of 7.5% (4/53). Four (4) events occurred during removal of implants from each finger on one patient's hand. All four fractured implants were removed by drilling them out of the bone. After the drilling process, black stained tissue was observed in each finger. No tissue samples were taken from this patient.

In addition, there were 3 events observed during operations to remove implants that were potentially loose in 3 patients. Tissue samples from these three patients were excised during removal for histopathologic examination. The histopathologist concluded that the tissue did not reveal any negative tissue reaction. All implants were revised. Two (2) implants were revised to silicone spacers and 1 Pyrocarbon MCP implant was reinserted with cement.

Synovitis

A total of 24 synovitis events were reported for 10 patients for a rate of 19% (10/53). Tissue samples were available for examination from 5/24 joints including samples from 2 RA patients and one Trauma patient. The histopathologist's review concluded that there was no adverse tissue reaction to the implant, carbon particles, or "fine particle matter" in these samples.

Success/Failure Analyses

To evaluate safety and effectiveness of the Ascension MCP, patients were stratified and evaluated based on two baseline medical conditions: 1) osteoarthritis/post traumatic (OA/Trauma), and 2) rheumatoid arthritis/systemic lupus erythematosus (RA/SLE). 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 endpoints (including implant and bone fracture, infection, and adverse biological reactions) were established retrospectively.

Separate success/failure criteria were defined for the OA/Trauma and RA/SLE patient groups as summarized below. Each implant was determined to have an outcome of excellent, good, unsatisfactory, or indeterminate. Implants with an excellent or good outcome were considered a success while implants with an unsatisfactory outcome were considered a failure. Patients lacking information required as part of the success/failure criteria were considered indeterminate.

The OA/Trauma patients and the RA/SLE patients presented with distinct treatment objectives and associated physician expectations. Treatment objectives and physician expectations were derived retrospectively from the pre-operative notes and physical exam records. Safety and effectiveness criteria were defined retrospectively with the treatment objectives and physician expectations in mind.

RA/SLE Patients

Treatment Objectives (RA/SLE)

The following 4 potential primary objectives for finger joint replacement in the RA/SLE group were defined:

- A. In cases with limited extension (that is 30 degrees or more of extension lag), the primary expectation was to increase extension.

- B. In cases with pain, the primary expectation was to relieve pain.
- C. In cases with a destroyed or eroded articular surface, the primary expectation was to replace the eroded surfaces and provide a reduced joint.
- D. In cases with a pre-operative dislocation, the primary expectation was to provide a reduced or subluxed joint.
- E. And, in cases presenting with a combination of these conditions, that is A, B, C, and/or D, the primary objective was to address each of the individual conditions.

Each patient's treatment objectives were derived retrospectively from pre-operative surgeon's notes and physical exam records.

Success/Failure Analysis (RA/SLE)

For the RA/SLE group, effectiveness criteria were defined for a 1-5 year treatment outcome analysis, and for a longer-term treatment outcome analysis. Both sets of criteria acknowledge and accommodate the potential confounding influence on treatment outcomes of soft tissue attenuation related to progression of the RA/SLE baseline medical condition.

Effectiveness Analysis (RA/SLE 1-5 Year Evaluation)

For the RA/SLE cohort, the following effectiveness criteria were applied on an implant basis to determine the treatment outcome category for each implant. An implant with an Excellent or Good outcome was considered a Success while an implant with an Unsatisfactory outcome was considered a Failure.

Excellent

1. Physical exam, ROM data, and radiographic data > 1 year¹ indicating:
 - a. Improvement of all treatment objectives;
 - b. Pain free joint; and
 - c. Reduced implant position.
2. Subjective or objective information indicating a reduction in the improvement of treatment objectives after 5 years is acceptable.

Good

1. Physical exam, ROM data, and radiographic data < 1 year¹ indicating:
 - a. Improvement of all treatment objectives;
 - b. Pain free joint; and
 - c. Reduced implant position; and
2. Subjective or objective information (a physical exam at another clinic (orthopedic, rheumatology, etc.), radiographic data, a questionnaire or telephone conversation with a physician) at > 1 year indicating:
 - a. maintenance of the improvements; or
 - b. implant survival.
3. Subjective or objective information indicating a reduction in the improvement of treatment objectives after 5 years is acceptable

¹ Note: Although a 1 year criteria was established for an implant to be considered a success (i.e., excellent or good outcome), as discussed in the following results section, 72% of the successful implants had an evaluation at > 2 years post implantation.

Unsatisfactory

1. Primary treatment objective(s) same or not improved by the surgery;
2. Implant related pain at last evaluation;
3. Implant loosening;
4. Implant removal < 5 years;
5. Implant dislocation < 5 years; or
6. Post-operative implant fracture

Indeterminate

1. No information > 1 year, or insufficient information > 1 year to indicate maintenance of the improvements at < 5 years

Effectiveness Results (RA/SLE 1-5 Year Evaluation)

In the RA/SLE cohort, the 1-5 year effectiveness analysis revealed the following:

Table 7. RA/SLE 1-5 Year Effectiveness Results.

	Implants (N = 138)	Patients (N = 45)
“Success”	82 (59%) (46 Excellent, 36 Good)	--
“Failure”	37 (27%)	--
“Indeterminate”	19 (14%)	--
Patients w/ All Implants “Success”	--	27 (60%)
Patients w/ All Implants “Failure”	--	8 (18%)
Patients w/ All Implants “Indeterminate”	--	3 (7%)
Patients w/ multiple Implant Outcomes (“Success” and/or “Failure”, and/or “Indeterminate”)	--	7 (15%)

Forty-six (46) implant outcomes were considered excellent with a final evaluation occurring at an average of 8.3 years (range 1.0-16.8 years) after implantation, and 37 of the 46 implants having a final evaluation > 2 years after implantation. Thirty-six (36) implant outcomes were considered good with a final evaluation occurring at an average of 5.9 years (range 1.2-13.6 years) after implantation, and 22 of the 36 implants having a final evaluation > 2 years after implantation. Thus, 59 of the 82 successful implants had a final evaluation at greater than 2 years after implantation, a rate of 72% (59/82).

Successful implants were in 33 of the 45 RA/SLE patients, a rate of 73% (33/45). Of the 33 patients who had at least one successful implant, 27 had all their implants considered successful, a rate of 82% (27/33). Therefore, 60% (27/45) of the patients in the RA/SLE cohort had all their implants considered successful.

For the group of implants demonstrating excellent and good outcomes, there were no reports of implanted joint pain at a final evaluation occurring at an average of 6.4 years (range 0.4 to 16.8 years) after implantation, with 1 patient reporting hand pain at 10.0 years. The average extension increase was 34.0 degrees (range -20 to 125 degrees) with a final evaluation occurring at an average of 2.0 years (range 0.1 to 11.7 years) after implantation. All patients with a primary treatment expectation of increasing extension showed an extension increase except for 2 implants

(1 each in 2 patients) that showed no increase, but had ROM > 40 degrees. Accordingly, these 2 implants had an outcome of Good. Five implants in 4 patients with a treatment expectation of joint reduction and/or surface replacement and/or pain relief showed an extension decrease, but had good to excellent post-operative ROM averaging 29.0 degrees (range 20 to 50 degrees). Of the 82 implants considered successful, 77 had a final radiographic evaluation that showed 61 implants reduced at an average of 3.9 years (range 0.1 to 12.9 years) after implantation, a rate of 79% (61/77). Eleven implants were subluxed (average final evaluation of 7.0 years, range 1.4 - 13.0 years), and 5 were dislocated. Of the 5 dislocated implants, 4 were in one patient with 2 dislocations noted at 10.0 years and 2 more noted at 11.5 years, and the 5th was in another patient and noted at 11.0 years after implantation. There were 6 implants removed from 2 patients in this group; 4 implants were removed from 1 patient at 5.5 years due to disease related flexion contracture and ulnar deviation deformity, and 2 implants were removed from the other patient at 11.0 years due to subluxation/dislocation related to soft tissue attenuation. All removed implants were successfully converted to a silicone spacer.

For the group of implants with an unsatisfactory outcome, 14 implants in 8 patients were removed. Two implants were removed due to loosening (1 at 1.5 years and 1 at 4.9 years). The 12 other implants removed were revised due to disease related soft tissue degradation that resulted in flexion contracture (4 implants: 2 each in 2 patients), ulnar deviation deformity and dislocation (3 implants in 1 patient), or subluxation/dislocation (5 implants: 1 in 1 patient, and 2 each in 2 other patients). All removed implants were successfully revised (9 were replaced with silicone spacers, 4 Pyrocarbon MCP implants were reinserted with bone cement, and 1 new Pyrocarbon MCP implant was inserted).

The other 23 implants with an unsatisfactory outcome were in 8 patients, and were unsuccessful due to extension contractures (4 implants: 3 in 1 patient and 1 in another patient), lack of extension improvement or extension deficit (12 implants: 4 each in 2 patients, and 2 each in 2 other patients), recurrent severe ulnar deformity (4 in 1 patient) and dislocation (3 implants: 2 in 1 patient and 1 in another patient). Thus, of the 37 implants with unsatisfactory outcome in 15 patients, only 2 were directly related to implant loosening. All other unsatisfactory outcomes were due to disease related soft tissue degradation leading to loss of extension or joint location, or recurrent ulnar deformity.

Effectiveness Analysis (RA/SLE Longer-Term Outcome Evaluation)

To conduct the Longer-Term Outcome Evaluation, the Effectiveness Criteria for all outcome categories (Excellent, Good, Unsatisfactory, and Indeterminate) that were established for the 1-5 year evaluation were modified so that reductions in treatment improvements at evaluation times greater than five (5) years were considered during implant outcome evaluation. Thus, the following effectiveness criteria were applied on an implant basis to determine the treatment outcome category for each implant.

Excellent

1. Physical exam, ROM data, and radiographic data > 1 year² indicating:

² Note: Although a 1 year criteria was established for an implant to be considered a success (i.e., excellent or good outcome), as discussed in the following results section, 72% of the successful implants had an evaluation at > 2 years post implantation.

- a. Improvement of all treatment objectives;
- b. Pain free joint; and
- c. Reduced implant position.

Good

- 1. Physical exam, ROM data, and radiographic data < 1 year² indicating:
 - a. Improvement of all treatment objectives;
 - b. Pain free joint; and
 - c. Reduced implant position; and
- 2. Subjective or objective information (a physical exam at another clinic (orthopedic, rheumatology, etc.), radiographic data, a questionnaire or telephone conversation with a physician) at > 1 year indicating:
 - a. maintenance of the improvements; and
 - b. implant survival.

Unsatisfactory

- 1. Primary treatment objective(s) same or not improved by the surgery;
- 2. Implant related pain at last evaluation;
- 3. Implant loosening;
- 4. Implant removal;
- 5. Implant dislocation; or
- 6. Post-operative implant fracture

Indeterminate

- 1. No information > 1 year, or insufficient information > 1 year to indicate maintenance of the improvements

Effectiveness Results (RA/SLE Longer-Term Evaluation)

In the RA/SLE cohort, the longer-term evaluation revealed the following:

Table 8. RA/SLE Longer-Term Effectiveness Results.

	Implants (N = 138)	Patients (N = 45)
“Success”	51 (37%) (30 Excellent, 21 Good)	--
“Failure”	73 (53%)	--
“Indeterminate”	14 (10%)	--
Patients w/ All Implants “Success”	--	17 (38%)
Patients w/ All Implants “Failure”	--	18(40%)
Patients w/ All Implants “Indeterminate”	--	3 (7%)
Patients w/ multiple Implant Outcomes (“Success” and/or “Failure”, and/or “Indeterminate”)	--	7 (15%)

Thirty (30) implant outcomes were considered excellent with a final evaluation occurring at an average of 7.6 years (range 1.0-15.9 years) after implantation; 23 of those 30 implants had a final evaluation > 2 years after implantation. Twenty-one (21) implant outcomes were considered good with a final evaluation occurring at an average of 6.8 years (range 1.3-16.8) after

implantation; 11 of those 21 implants had a final evaluation > 2 years after implantation. Thus, 34 of the 51 successful implants had a final evaluation greater than 2 years after implantation, a rate of 67% (34/51).

Under the modified longer-term criteria, successful implants were in 23 of the 45 RA/SLE patients, a rate of 51% (23/45). Of the 23 patients with at least one successful implant, 17 had all their implants considered successful, a rate of 74% (17/23). Therefore, 38% (17/45) of the patients in the RA/SLE cohort had all their implants considered successful when applying longitudinal effectiveness criteria.

For implants demonstrating excellent and good outcomes, the primary treatment objectives for all implants were obtained. There were no reports of implanted joint pain at a final evaluation occurring at an average of 7.0 years (range 1.0-16.8 years) after implantation, and no reports of hand or finger pain. The average extension increase was 33.7 degrees (range of -50 to 125 degrees) with a final evaluation occurring an average of 3.3 years (range 0.1-16.8 years) after implantation. All patients with a primary treatment expectation of increasing extension showed an extension increase. Five implants in 4 patients with a treatment expectation of joint reduction and/or surface replacement and/or pain relief showed an extension decrease, but had good to excellent post-operative range of motion (ROM) averaging 28.0 degrees (range 20 to 40 degrees). Of the 51 implants considered successful, radiographic data showed 43 implants reduced, a rate of 84% (43/51); and 8 implants were subluxed at a final evaluation occurring an average of 4.2 years (range 0.1-13.1 years) after implantation. No successful implants were dislocated in the long-term.

For the group of 73 implants with an unsatisfactory outcome in 25 patients, 20 implants in 10 patients were removed. Two implants were removed due to loosening (1 at 1.5 years and 1 at 4.9 years). The 18 other removed implants were revised due to disease related soft tissue degradation that resulted in flexion contracture (8 implants: 2 each in 2 patients and 4 in another), ulnar deviation deformity and dislocation (3 implants in 1 patient), or subluxation/dislocation (7 implants: 1 in 1 patient, and 2 each in 3 other patients). All removed implants were successfully revised; 15 were replaced with silicone spacers, 4 Pyrocarbon MCP implants were reinserted with bone cement, and 1 new Pyrocarbon MCP implant was inserted.

The other 53 implants with an unsatisfactory outcome in 18 patients were unsuccessful due to extension contracture or flexion lag (13 implants: 1 each in 4 patients, 2 in 1 patient, 3 in 1 patient, and 4 in 1 patient), lack of extension improvement or extension deficit (27 implants: 4 each in 4 patients, 3 in 1 patient, 2 each in 3 patients, and 1 each in 2 patients), recurrent severe ulnar deformity (4 in 1 patient), dislocation (7 implants: 4 in 1 patient, 2 in 1 patient, and 1 in 1 patient), and loss of motion (2 implants in 1). Thus, of the 73 implants with unsatisfactory outcome in 25 patients, only 2 were directly related to implant loosening. All other unsatisfactory outcomes were due to disease related soft tissue degradation leading to reduction or loss of motion, joint dislocation, or recurrent ulnar deformity.

Comparison of RA/SLE Effectiveness Results

The impact of applying the modified longer-term effectiveness criteria to determine effectiveness results for the RA/SLE patient cohort is shown below.

Table 9. RA/SLE 1-5 Year and Longer Term Effectiveness Results Comparison.

	1 – 5 Year Criteria		Longer-Term Criteria	
	N	%	N	%
Total	138		138	
Excellent & Good	82 (46 Ex & 36 Gd)	59%	51 (30 Ex & 21 Gd)	37%
Unsatisfactory	37	27%	73	53%
Indeterminate	19	14%	14	10%

When reductions in treatment improvements at evaluation times of greater than five (5) years are considered, the number of successful implants (excellent and good outcomes) decreases from 82/138 (59%) to 51/138 (37%), while the number of implants with unsatisfactory outcome increases from 37/138 (27%) to 73/138 (53%). For the 36 additional implants with unsatisfactory outcome, 6 implants were removed from 2 patients (4 from 1 patient at 5.4 years due to flexion contracture and ulnar deviation deformity, and 2 from another patient at 11.0 years due to subluxation/dislocation); all 6 removed implants were successfully replaced with a silicone spacer. The other 30 additional implants with unsatisfactory outcome were considered failures due to extension lag (15 implants in 6 patients), flexion lag/stiffness (9 implants in 5 patients), dislocation (4 implants in 1 patient), and loss of motion (2 implants in 1 patient). Thus, all 36 additional implants with unsatisfactory outcome under the modified effectiveness criteria were unsuccessful due to disease related soft tissue degradation and attenuation leading to reduction or loss of motion, joint dislocation, or recurrent ulnar deformity.

Safety Analysis (RA/SLE)

The frequency and severity of the following events were evaluated for purposes of determining device safety:

1. Intraoperative implant fracture
2. Non-intraoperative implant fracture
3. Unstable intraoperative bone fracture
4. Post operative bone fractures
5. Implant related infection
6. Adverse biological reaction to implant

Safety Results (RA/SLE)

Intraoperative implant fractures occurred in two patients during implantation of the device. In one patient the fractured component was removed and a new Pyrocarbon MCP component was inserted successfully while in the other patient the fractured fragment was left *in situ* and a silicone spacer was successfully inserted. In addition, 6 components fractured in 3 patients during revision. As noted above, all implants that fractured during removal were successfully revised; silicone spacers were inserted in 2 patients, and the fractured Pyrocarbon MCP implant removed from the third patient was reinserted with bone cement. Similar to the OA/Trauma cohort, there were no other reported occurrences of the implant safety criteria listed above. A complete list of adverse events for the entire study population was provided in Table 4.

OA/Trauma Patients

Treatment objectives (OA/Trauma)

The OA/Traumatic Arthritis patients presented with damaged or destroyed articular surfaces and almost always had pain and limited motion. Most of these patients needed treatment in only one MCP joint; only one patient required treatment in multiple MCP joints.

For the OA/TRAUMA cases, the physician had the expectation that total joint arthroplasty would relieve pain, maintain reasonable joint range of motion (ROM), and maintain joint reduction.

Success/Failure Analysis (OA/Trauma)

For the OA/TRAUMA group, effectiveness criteria were defined for a greater than 2 year treatment outcome analysis. Two (2) years was set as the minimum amount of time that the surgical improvement must be maintained to be deemed successful.

Effectiveness Analysis (OA/Trauma)

For the OA/Trauma cohort, the following effectiveness criteria were applied on an implant basis to determine the treatment outcome category for each implant. An implant with an Excellent or Good outcome was considered a Success while an implant with an Unsatisfactory outcome was considered a Failure.

Excellent

1. Physical exam, ROM and radiographic data > 2 years indicating:
 - a. Pain free implant at last follow-up;
 - b. Increase in range of motion (ROM) from baseline, or ROM > 50 degrees³; and
 - c. Reduced implant position.

Good

1. Physical exam, ROM and radiographic data < 2 years indicating:
 - a. Increase in ROM from baseline, or ROM > 50 degrees; and
 - b. Reduced implant position; and
2. Physical exam or telephone conversation with a physician > 2 years indicating:
 - a. pain free implant; and
 - b. implant survival

Unsatisfactory

1. Implant related pain at last evaluation;
2. Implant loosening or removal;
3. Post-operative implant fracture;
4. Decrease in ROM from baseline with ROM < 50 degrees; or
5. Implant subluxation or dislocation.

Indeterminate

1. No information > 2 years or insufficient information > 2 years to indicate maintenance of the improvements.

³ Mannerfelt L, Andersson K, "Silastic arthroplasty of the metacarpophalangeal joints in rheumatoid arthritis," *J Bone Joint Surg*, Vol. 57-A, No. 4, 484-489, 1975.

Effectiveness Results (OA/Trauma)

In the OA/Trauma cohort, the effectiveness analysis revealed the following:

Table 10. OA/Trauma Effectiveness Results.

	Implants (N = 9)	Patients (N = 8)
“Success”	7 (78%) (6 Excellent, 1 Good)	--
“Failure”	1 (11%)	--
“Indeterminate”	1 (11%)	--
Patients w/ All Implants “Success”	--	6 (75%)
Patients w/ All Implants “Failure”	--	1 (12.5%)
Patients w/ All Implants “Indeterminate”	--	1 (12.5%)

Seven of the nine (78%) implants in this cohort were determined to be a “Success” while only 1 implant (11%) was a “Failure”. Six implants had an excellent outcome, 1 implant had a good outcome, 1 implant was unsatisfactory, and 1 implant was indeterminate.

The implant with an unsatisfactory result was removed due to loosening at 1.1 years and revised with a new Pyrocarbon MCP implant with cement. No other implants in this cohort loosened or were removed.

The 6 implants that had an excellent outcome had their last evaluation ranging from 3.5 to 16.0 years, and all but 1 implant demonstrated an increase in ROM. For the 1 implant that did not show increased ROM, the post-operative ROM was very good at 65 degrees. The implant with a good outcome had a last evaluation indicating implant survival at 17 years, while the implant with indeterminate outcome had a 0.5-year evaluation demonstrating good improvement. All implants demonstrated no joint pain at final evaluation except for the unsatisfactory implant that had pain secondary to loosening.

Safety Analysis (OA/Trauma)

The frequency and severity of the following events were evaluated for purposes of determining device safety in the OA/Trauma group:

1. Intraoperative implant fracture
2. Non-intraoperative implant fracture
3. Unstable intraoperative bone fracture
4. Post operative bone fractures
5. Implant related infection
6. Adverse biological reaction to implant

Safety Results (OA/Trauma)

There were 2 intraoperative implant fractures that occurred in 2 patients in this cohort. Both fractures occurred during implantation, and both fractured implants were removed and a new Pyrocarbon MCP implant was inserted without sequelae. There were no other reported occurrences of the implant safety criteria listed above. A complete summary of adverse events for the entire study population was provided in Table 4.

8. SURGICAL PROCEDURE

A Surgical Technique manual is available which outlines the basic procedure for device implantation and removal and the use of specialized surgical instrumentation, which will provide optimum implantation and reconstruction results.

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.

9. POST-OPERATIVE THERAPY

Post-operative therapy for the Ascension MCP differs for rheumatoid arthritis and osteoarthritis/post-traumatic arthritis patients. A Post-Operative Therapy Protocol is available which summarizes post-operative care. For further information, please contact Ascension Orthopedics' Customer Service at 512-836-5001.

10. TRAINING

Surgeons should obtain training from a qualified instructor prior to implanting the Ascension MCP to ensure thorough understanding of the indications, implantation and removal techniques, instrumentation, and post-operative rehabilitation protocol. Please contact Ascension Orthopedics' Customer Service at 512-836-5001 to arrange training with a qualified instructor.

Disclaimer of Warranties

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