

Summary of Safety and Probable Benefit

I. General Information

Device Generic Name: Prosthesis, finger, semi-constrained, pyrolytic carbon, uncemented

Device Trade Name: Ascension® PIP

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

Date of Humanitarian Use Device Designation: December 12, 2001

Humanitarian Device Exemption (HDE) Number: H010005

Date of Panel Recommendation: None

Date of Good Manufacturing Practice Inspection: April 16 – 18, 2001

Date of Notice of Approval to the Applicant: MAR 22 2002

II. Indications for Use

The Ascension PIP is indicated for use in arthroplasty of the proximal interphalangeal (PIP) joint when the patient:

- Has soft tissue and bone that can provide adequate stabilization and fixation under high-demand loading conditions after reconstruction; and
- Needs a revision of a failed PIP prosthesis, or has pain, limited motion, or joint subluxation/dislocation secondary to damage or destruction of the articular cartilage.

III. Contraindications

- Inadequate bone stock at the implantation site;
- Active infection in the PIP joint;
- Nonfunctioning and irreparable PIP musculotendinous system;
- Physical interference with or by other prostheses during implantation or use;
- Procedures requiring modification of the prosthesis; or
- Skin, bone, circulatory and/or neurological deficiency at the implantation site.

IV. Warnings and Precautions

WARNINGS

- Do not modify the Ascension PIP 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 match proximal and distal component sizes except as indicated in the following table. The wear behavior of component size combinations designated “Do Not Match” has not been evaluated, and is unknown.

Allowable Ascension PIP Component Size Combinations

		Proximal Component			
		Size 10	Size 20	Size 30	Size 40
Distal Component	Size 10	✓	✓	Do Not Match	Do Not Match
	Size 20	✓	✓	✓	Do Not Match
	Size 30	Do Not Match	✓	✓	✓
	Size 40	Do Not Match	Do Not Match	✓	✓

- Do not grasp the Ascension PIP implant with metal instruments, or instruments with teeth, serrations, or sharp edges. Implants should be handled only with instrumentation provided by Ascension Orthopedics. Ascension PIP 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 PIP components in combination with proximal and distal components from other products. The wear behavior of Ascension PIP 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 PIP in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the natural joint, the Ascension PIP attains stabilization from the surrounding capsuloligamentous structures. If soft tissue reconstruction cannot provide adequate stabilization, the device may subluxate or dislocate, lateral or longitudinal deformities may occur, or minimal motion or loss of motion may occur.

- Obtain proper training prior to use. Surgeons should obtain training from a qualified instructor prior to implanting the Ascension PIP to ensure thorough understanding of the indications, implantation and removal techniques, instrumentation, and post-operative rehabilitation protocol.
- Inspect the articulating surfaces of the Ascension PIP 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 and/or particulate debris.
- 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/or particulate debris and should be discarded.
- Do not use excessive impact force on the broach. Excessive impact force may cause bone fracture. Remove and reinsert broach frequently to obtain maximum cutting efficiency.
- Do not use excessive impact force to seat the proximal sizing trial. Excessive impact force could cause sizing trial fracture. The sizing trial collar should abut the osteotomy after 2 impacts. If not, re-broach to increase cavity size and/or remove additional bone to provide clearance for the saddle area.
- Do not use excessive impact force to remove the proximal sizing trial. Excessive impact force could cause sizing trial fracture. If possible, the sizing trial should be removed without the use of a hammer. If a sizing trial does fracture, and it is not possible to easily remove the remaining stem fragment, a k-wire driven into the fragment may provide sufficient purchase for removal. Then, re-broach to increase cavity size and/or remove additional bone to provide clearance for the saddle area.
- Do not use excessive impact force to seat the implant components, especially if there has been a prior sizing trial fracture. Excessive impact force could cause component fracture. The component collar should abut the osteotomy after 2 impacts. If not, re-broach to increase cavity size or remove additional bone to provide clearance for the saddle area on the proximal component.

V. Device Description

The Ascension PIP is a two-component, bi-condylar, semi-constrained total joint prosthesis designed to replace the articulating surfaces of the proximal interphalangeal joint. Each component has an articulating surface, a sub-articular collar, and an intramedullary stem. Two convex articulating surfaces on the proximal component engage with and glide on two mating concave articulating surfaces on the distal component. This bi-condylar articulation allows joint flexion-extension motion while restricting abduction-adduction motion. Component stems have an anatomic shape, and are designed to be press-fit into the intramedullary canal. Components achieve fixation by means of direct implant/bone apposition. Bone cement is not required.

Each component of the Ascension PIP is fabricated from a thick pyrocarbon layer encasing a graphite substrate. The graphite substrate material in the Ascension PIP is impregnated with a small amount (1 atomic percent) of tungsten. This small amount of tungsten renders the graphite substrate radiopaque so that Ascension PIP components are clearly visible on radiographs.

Ascension PIP components are provided in four sizes. To ensure proper fitting to the patient, the proximal and distal component sizes are interchangeable. Each component can be matched with an opposite component of the same size, one size smaller, or one size larger.

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 sizing trial devices is available.

On the proximal component, the articular surface terminates at a bi-planar sub-articular collar that includes a vertical plane on the dorsal aspect, and an oblique plane on the volar aspect. This bi-planar design is intended to preserve collateral ligament insertion sites and other soft tissue structures surrounding the joint when articular cartilage is removed during the osteotomy. Both the vertical and oblique collar planes are offset from the center of rotation of the prosthesis. This offset is intended to minimize bone removal and preserve soft tissue structures such as the volar plate attachment site.

On the distal component, the sub-articular collar is a single vertical plane. The uni-planar feature of this collar is intended to simplify the surgical technique necessary to properly prepare the bone so that it mates congruently with the implant.

The Ascension PIP has an “intercondylar groove” between the condyles of the proximal component and an “intercondylar notch” on the dorsal aspect of the distal component. These design features are intended to allow the Ascension PIP to accommodate the extensor expansion “central slip” during joint flexion and extension. During joint flexion, the Intercondylar Centering Pad (ICP), a distinct region on the volar surface of the central slip, mates with the intercondylar groove thus centering the central slip between the condyles of the proximal component. As flexion increases, the central slip follows the ICP and wraps onto the intercondylar notch, thus enhancing lateral stability of the central slip. In addition, the intercondylar notch in the distal component maintains the anatomic attachment site of the central slip median band as it inserts into the base of the middle phalanx.

Accurate placement of the Ascension PIP is intended to result in a total joint arthroplasty that reestablishes functional joint mechanics. Design features are intended to preserve the insertion sites for the collateral ligaments and provide for a free, unobstructed pathway for the collateral and retinacular ligaments in order to contribute to joint stability and function. Anatomic shaped component stems are designed to fill the medullary canal and promote component fixation. The prosthesis is designed to accommodate maximum anatomic range of motion. Motion allowed by all sizes of the prosthesis is 20° of hyperextension and 100° of flexion in the sagittal plane, and $\pm 0^\circ$ of radial and ulnar motion.

VI. Alternative Practices and Procedures

Non-surgical early stage treatments include joint injections, anti-inflammatory drug therapy (e.g. aspirin, non-steroidal anti-inflammatory drugs), avoiding heavy stress through the joints or heavy use of the fingers and hand, and physical therapy exercises to maintain joint range of motion and splints to correct finger deformity. Resting splints worn at night may slow the rate of disease progression.

Surgical intervention may restore some range of motion and is typically used when non-surgical measures no longer give relief. Surgical treatment may include fusion of the bones, interposition arthroplasty with tendon, or resection arthroplasty with a silicone rubber spacer. Individuals who are very active and use their hands for heavy labor may not be good candidates for resection arthroplasty with a silicone rubber spacer.

VII. Marketing History

Ascension Orthopedics, Inc., is distributing the Ascension PIP in the following countries and regions: European Community (CE Mark), Canada, Australia, and South Africa.

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

VIII. Potential Adverse Effects of the Device on Health

The Ascension PIP has been used clinically in Europe, Canada, Australia and South Africa. Through December 31, 2001, 164 devices have been implanted. No serious adverse events or complications have been reported for these devices. There have been reports of intra-operative complications as summarized in the following table. All of these complications were uneventful and were resolved immediately. The fractured proximal sizing trials and components were removed and new components were successfully inserted, while the bone fractures were grossly stable and the medullary canals ultimately were properly prepared and implant components were successfully inserted. No sequelae have been reported for any of these complications.

Summary of Ascension PIP Adverse Events and Complications

	Implants (%) n = 164
Bone fracture (intra-operative)	3 (1.8%)
Proximal sizing trial fracture (intra-operative)	6 (3.7%)
Proximal component fracture (intra-operative)	3 (1.8%)

Information on these intra-operative complications was acquired and evaluated in accordance with the sponsor's ISO 9001 compliant Customer Feedback System. The severity and affect on the patient's health due to the adverse event was determined by follow-up communication with the source of the information. For complications summarized in the table above, no reports of sequelae were received over the course of

this follow-up communication. The mean time and range of this follow-up communication was 28 days post-operative (range 13 – 54 days).

In addition, although not intended for use in the PIP joint, clinical results and adverse effects for the Pyrocarbon metacarpophalangeal (MCP) implant have been reported in the premarket approval application (PMA) for the Ascension MCP.¹ Please note that the “Pyrocarbon MCP” is an earlier version of the Ascension MCP that was used clinically to support the safety and effectiveness of the Ascension MCP. Adverse effects for the Ascension PIP may be similar to those reported for the Pyrocarbon MCP because both devices share numerous identical attributes including design concept, construction, materials, and insertion and fixation methods. In addition, the primary objectives of PIP total joint arthroplasty are identical to those of MCP total joint arthroplasty, namely, relief of pain due to articular damage or destruction, and improvement in joint range of motion. Similarities between the Ascension PIP and Pyrocarbon MCP are further elaborated below in section X (Summary of Clinical Experience). Reported adverse effects identified below are those observed while using the Pyrocarbon MCP device.

PYROCARBON MCP REPORTED ADVERSE EFFECTS

In a retrospective case history review, 53 patients received 147 Pyrocarbon MCP prostheses and had last evaluations at an average of 8.5 years (range 1.7 months – 17.2 years) after implantation. The most commonly reported 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 for the Pyrocarbon MCP implant is provided below in section X (Summary of Clinical Experience).

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 debris;
- 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; or
- Lengthening or shortening of the finger.

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

- Implant removal;
- Joint fusion;
- Amputation; or
- Death

IX. Summary of Pre-Clinical Studies

The sponsor performed the following pre-clinical studies to demonstrate the safety of the Ascension PIP:

- Mechanical testing of Ascension PIP components;
- Finite element analyses of Ascension PIP contact stress;
- Biocompatibility testing of the pyrocarbon material and the sizing trial polymer material; and
- Animal testing of Pyrocarbon MCP implants.

Recognized standards were used in the design and conduct of these pre-clinical studies where appropriate. Prior to commencing FEA and mechanical testing of the implant, 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 PIP is capable of supporting functional joint motion and grip and pinch strength for the long term. Pre-clinical study results are summarized below.

Mechanical Testing

The objectives of the mechanical testing were to characterize the mechanical properties of the Ascension PIP. Mechanical testing evaluated the following Ascension PIP characteristics:

- Wear resistance;
- Fracture strength;
- Cyclic endurance (fatigue resistance);
- Axial load fracture strength; and
- The affect of articulating surface contact.

All testing was performed on final sterilized proximal and distal components. Test specimens were mounted and loaded to simulate biologically demanding physiologic support and loading conditions. Specimen mounting and loading conditions were determined based on a review of the biomechanics literature.^{2,3,4,5,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22} Biomechanically demanding loads were determined to be 83 lb. for strength, endurance, and contact testing, and 14 lb. for cyclic wear testing.

Results from all *in vitro* testing demonstrate that the Ascension PIP has adequate wear resistance, strength, and endurance (i.e., resistance to cyclic fatigue). Further, results show that the device is capable of supporting demanding biomechanical loads. Brief descriptions of the tests conducted and the corresponding results are summarized below.

Wear Resistance

Wear testing in a cyclic articulation joint motion simulator was conducted to evaluate wear resistance of the Ascension PIP. Specimens were tested at 4 Hz in bovine serum at room temperature with an axial load of 14 lb. for 10 million cycles. Size 10 proximal components were articulated against size 20 distal components in order to maximize radial clearance and, therefore, contact pressure. This was the only Ascension PIP size combination tested because previous testing of Ascension MCP components has demonstrated that: 1) wear behavior is independent of device size; and 2) the smallest size device and largest radial clearance results in the smallest contact area and highest contact stress. A total of six Ascension PIP wear couples were tested; a seventh couple was not subjected to wear testing and served as a non-wear pyrocarbon control.

The control device was a commercially available, two-component PIP implant that has a CoCr proximal component and an UHMWPE (polyethylene) distal component. Two control devices were used; one device was subjected to wear testing while the other was used as a non-wear control. The control devices were finished sterilized devices purchased from a commercial distributor.

The Ascension PIP device exhibited adequate wear resistance under the test conditions outlined above. Proximal and distal components did not show measurable material removal (resolution ≈ 0.0002 inch) at 10 million cycles. Wear was characterized by an absence of macroscopic material removal from the articulating surface, and by the occasional shallow scratch 0.3 – 1.0 micrometers deep on the articulating surface.

In contrast, the control device exhibited 0.0025 inches of wear on the distal polyethylene component at 10 million cycles. The CoCr proximal component did not show measurable material removal (resolution ≈ 0.0002 inch), but did exhibit scratches on the articulating surface 0.3 – 0.5 micrometers deep.

These results demonstrate the Ascension PIP exhibits adequate wear resistance under the test conditions outlined above.

Fracture Strength

Strength tests were conducted to evaluate the fracture strength and failure mode of the Ascension PIP. Size 10 and 40 proximal and distal components were tested because these sizes represent the smallest and largest size components, respectively, and because previous fracture strength testing of Ascension MCP components demonstrated that the smallest size components exhibited the lowest fracture strength. Specimens were held with 1/3 of the stem proximal to the collar unsupported and the distal 2/3 of the stem rigidly supported. Specimens were oriented so that loading produced bending in the sagittal plane. The load angle was 38 degrees for proximal components and 13 degrees for distal components. Testing was conducted at room temperature in air.

The failure mode for all specimens was catastrophic crack propagation. For proximal specimens, the primary fracture location was on the stem where it extended above the fixture, although some components exhibited secondary fracture locations on the head. Distal specimens exhibited primary fracture locations on both the stem where it extended above the fixture, and on the head.

Size 10 components exhibited lower average fracture strength than larger size 40 components. Overall, size 10 distal components exhibited the lowest average fracture strength of 149 lb. with a range from 134 to 182 lb. This fracture strength is greater than a biomechanically demanding load for the PIP joint of 83 lb.

These results demonstrate that Ascension PIP components are capable of supporting loads exceeding a biomechanically demanding load.

Cyclic Endurance (Fatigue Resistance)

Cyclic endurance tests were conducted to evaluate the fatigue endurance behavior of the Ascension PIP. Size 10 proximal and distal components only were tested because they exhibited the lowest average fracture strength compared to larger sizes and therefore represent a rigorous and demanding test condition. As with the strength test, specimens were held with 1/3 of the stem proximal to the collar unsupported and the distal 2/3 of the stem rigidly supported. Specimens were oriented so that loading produced bending in the sagittal plane. The load angle was 38 degrees for proximal components and 13 degrees

for distal components. Specimens were subjected to an 8.3 to 83 lb. sinusoidal load at 30 Hz for 10 million cycles at room temperature in air.

All test specimens survived the 8.3 to 83 lb. cyclic load for 10 millions cycles. Visual and dye penetration inspection revealed that the applied cyclic load did not damage the test specimens. Furthermore, endurance testing did not reduce the average fracture strength of test specimens as compared to non-endurance tested components.

These results demonstrate that Ascension PIP components exhibit adequate fatigue resistance, and are capable of supporting a biomechanically demanding load in the long term.

Axial Load Fracture Strength

An axial load strength test was conducted to evaluate the fracture load and failure mode of Ascension PIP components subjected to applied load acting parallel to the axis of the stem. Size 10 proximal and distal components only were tested because they exhibited the lowest average fracture strength as compared to larger size devices and, therefore, represent a rigorous and demanding test condition. Specimens were held with 1/3 of the stem proximal to the collar unsupported and the distal 2/3 of the stem rigidly supported, and oriented so that the longitudinal axis of the specimen was vertical.

For all specimens, the failure mode was catastrophic crack propagation, and the primary fracture location was on the component head. Proximal components exhibited lower average fracture strength than distal components. Size 10 proximal components exhibited the average fracture strength of 159 lb. with a range from 147 to 175 lb. This fracture strength is greater than a biomechanically demanding load for the PIP joint of 83 lb.

These results demonstrate that Ascension PIP components are capable of supporting loads exceeding a biomechanically demanding load.

Articulating Surface Contact Test

The articulating surface contact testing was conducted to determine the extent of damage on the articulating surface due to a biomechanically demanding load. Size 10 and size 40 proximal and distal components were tested because these sizes represent the smallest and largest size components, respectively, and because fracture strength testing demonstrated that the smallest size components exhibited the lowest fracture strength. Specimens were subjected to a biomechanically demanding load of 83 lb. with a mating component. Mating component sizes were chosen to maximize radial clearance and contact stress. The proximal test specimens were loaded with a size 40 distal component, and distal test specimens were loaded with a size 10 proximal component. As with the strength and endurance testing, specimens were held with 1/3 of the stem proximal to the collar unsupported and the distal 2/3 of the stem rigidly supported. Testing was conducted at room temperature in air.

The articulating surface was inspected before and after the applied load. Visual inspection with a stereo microscope and with dye penetration revealed that the applied load did not damage the articulating surface of the specimens.

These results demonstrate that the Ascension PIP is capable of supporting a biomechanically demanding load without sustaining damage to the articulating surface.

Mechanical Testing Summary

A brief summary of the mechanical test results discussed above is provided in the following table.

Summary of Mechanical Test Results for the Ascension PIP

Test	Device Type and Size	Results
Wear Test	Size 10 Proximal articulating against a Size 20 Distal	Measurable wear did not occur on Ascension PIP components (sensitivity = 0.0002 inch).
	For comparison, wear testing of a commercially available CoCr-on-UHMWPE PIP implant was performed.	Measurable wear did not occur on the CoCr proximal components (sensitivity = 0.0002 inch). Wear on the UHMWPE distal component was approximately 0.0025 inches.
Strength Test	Size 10 Proximal Size 40 Proximal	155 ± 5 lb. (147 – 163) 217 ± 30 lb. (182 – 254)
	Size 10 Distal Size 40 Distal	149 ± 14 lb. (134 – 182) 254 ± 42 lb. (198 – 325)
Endurance Test	Size 10 Proximal Size 10 Distal	No failures occurred. All specimens survived 10 million cycles with 83 lb. maximum load.
Axial Load Strength Test	Size 10 Proximal Size 10 Distal	159 ± 10 lb. (147 – 175) 201 ± 33 lb. (154 – 247)
Articulating Surface Contact Test	Size 10 and 40 Proximal Size 10 and 40 Distal	No damage occurred on articulating surfaces subjected to 83 lb. load.

FEA Contact Stress Analysis

Finite element stress analysis (FEA) was conducted to determine the contact stresses in the Ascension PIP device. The effect of variations in radial clearance was also examined. A size 10 proximal component in contact with a size 20 distal component was analyzed because it is the size combination that results in the smallest contact area, largest radial clearance, and, therefore, the highest contact stress. FEA models assumed that a

biomechanically demanding load of 83 lb. was applied to a single condyle, a very rigorous loading condition that is realized only when the entire joint reaction force is supported by a single condyle. Under clinical conditions, the joint reaction force normally is supported by both condyles with each supporting approximately ½ of the entire load. Thus, FEA models evaluated a “worst-case” loading condition.

FEA contact area solutions agreed within 6% of values measured experimentally. Larger radial clearance resulted in smaller contact area and higher contact stress. The highest maximum contact stress was determined to be approximately 17.4 ksi; maximum contact stress for nominal radial clearance conditions was determined to be approximately 11.9 ksi. These values are higher than that reported for the Ascension MCP (5.8 ksi in the smallest size 10 device), and roughly 33% - 54% of the 32.5 – 36.2 ksi fracture stress estimated for pyrocarbon components. However, this contact stress is associated with a “worst-case” loading condition in which a single condyle supports the entire joint reaction force (83 lb.); actual contact stress should be less. In addition, contact stress during endurance testing of Ascension PIP size 10 proximal components (loaded with a flat, steel platen) was determined to be a minimum of 21.7 ksi. This is approximately 25% higher than the highest maximum contact stress for the maximum radial clearance condition, and 82% higher than the maximum contact stress in components with nominal radial clearance. As discussed in the Cyclic Endurance section above, visual and dye penetration inspection of endurance test specimens revealed that the cyclic load did not damage the test specimens even through 10 million cycles of applied load.

These contact stress analysis results together with endurance test results demonstrate that the Ascension PIP is capable of supporting a biomechanically demanding load in the long term without sustaining damage to the articulating surface.

Biocompatibility Testing

Biocompatibility testing was conducted to demonstrate the biocompatibility of the pyrocarbon material used in Ascension PIP components and the polymer material used in Ascension PIP sizing trials. Test specimens were manufactured under the exact same conditions as used in processing PIP components and sizing trials. Biocompatibility studies were conducted in accordance with ISO 10993 and U.S. Pharmacopeia 23, 1995.

Studies revealed that the pyrocarbon used in the PIP devices is non-cytotoxic, has a weak allergenic potential, is a negligible irritant, non-pyrogenic, non-mutagenic, and has physiochemical properties exceeding the minimum U.S.P. levels set for plastics. In addition, studies revealed that the polymer material used in the PIP sizing trials is non-cytotoxic, a negligible irritant, and has weak allergenic potential.

Animal Testing

Although not intended for use in the PIP joint, results of animal testing for the Pyrocarbon MCP implant have been reported in the PMA for the Ascension MCP.¹ Please note that the “Pyrocarbon MCP” is an earlier version of the Ascension MCP that was used clinically to support the safety and effectiveness of the Ascension MCP. The objectives of the animal testing were to demonstrate the potential for biological fixation

of pyrocarbon components in bone and/or soft tissue, and to evaluate the clinical suitability of the uncemented, semi-constrained, two-component design concept. The Pyrocarbon MCP has a number of features that are identical to the Ascension PIP. Identical characteristics include anatomic design concept, construction, materials, and insertion and fixation methods. Similarities between the Ascension PIP and Pyrocarbon MCP are further elaborated below in section X (Summary of Clinical Experience). Because the devices are identical in a number of critical aspects, the results from the animal testing with the Pyrocarbon MCP are applicable to the Ascension PIP.

Five Pyrocarbon MCP prostheses and one Steffee (metal and polyethylene) MCP prosthesis were implanted into the long finger metacarpophalangeal joints of baboons. Four of the Pyrocarbon MCP implants were inserted without bone cement; the fifth Pyrocarbon MCP 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 MCP 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 MCP implants, and functional fixation was obtained with all of the uncemented Pyrocarbon MCP implants. No foreign body reaction was observed in the soft tissues, and no evidence of intracellular particles was present with the uncemented Pyrocarbon MCP implants.

The cemented Pyrocarbon MCP 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.

In conclusion, the results of this animal study demonstrate the potential for biological fixation of Pyrocarbon MCP implants in bone and/or soft tissue, and confirm the clinical suitability of the uncemented, semi-constrained, two-component Ascension PIP implant design concept.

X. Summary of Clinical Experience

The clinical use of the Ascension PIP has been summarized in Section VIII (Potential Adverse Effects of the Device on Health). In addition, although not intended for use in the PIP joint, clinical results and adverse effects for the Pyrocarbon metacarpophalangeal (MCP) implant have been reported in the PMA for the Ascension MCP.¹ Please note that the “Pyrocarbon MCP” is an earlier version of the Ascension MCP that was used clinically to support the safety and effectiveness of the Ascension MCP. As shown in the following table, the Ascension PIP has a number of features that are identical to the Pyrocarbon MCP. Identical characteristics include anatomic design concept, construction, materials, and insertion and fixation methods. In addition, the primary objectives of PIP total joint arthroplasty are identical to those of MCP total joint arthroplasty, namely, relief of pain due to articular damage or destruction, and improvement in joint range of motion.

Comparison of Ascension PIP and Pyrocarbon MCP Design Attributes

Attribute	Ascension PIP	Pyrocarbon MCP
two-component, total joint implant	yes	yes
semi-constrained articulation	yes	yes
articulation type	ball-and-cup	bi-condylar
proximal component bi-planar collar	yes	yes
distal component uni-planar collar	yes	yes
intramedullary stem	yes	yes
press-fit insertion	yes	yes
direct bone apposition fixation	yes	yes
pyrocarbon construction	yes	yes
graphite substrate	yes	yes

Therefore, because of these similarities, the clinical safety outcomes for the Pyrocarbon MCP are summarized below.

Pyrocarbon MCP Reported Adverse Effects

Complications and Adverse Events

In a retrospective case history review, 53 patients received 147 Pyrocarbon MCP prostheses and had last evaluations at an average of 8.5 years (range 1.7 months – 17.2 years) after implantation. The patient 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).

The most commonly reported adverse events were:

- Recurrent deformity;
- Subluxation / dislocation;
- Re-operation for soft tissue reconstruction;
- Implant removal;
- Implanted joint pain; and
- Synovitis

A complete list of the frequency and rate of complications and adverse events identified for the Pyrocarbon MCP implant is shown in the table below.

Pyrocarbon MCP 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).

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.

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 MCP 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

There were reports of black staining of tissue and synovitis. However, in the tissue samples evaluated by the histopathologist, there were no reports of an adverse tissue reaction to the Pyrocarbon MCP joint implant, carbon particles, or “fine particulate matter.”

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.

XI. Conclusions Drawn from Studies and Clinical Experience

Pre-clinical testing of the Ascension PIP device demonstrated that the wear resistance, fracture strength, fatigue resistance, and resistance to articulating surface contact damage of the Ascension PIP is acceptable for its intended use. In addition, biocompatibility testing indicates the device is non-cytotoxic, has weak allergenic potential, is a negligible irritant, non-pyrogenic, non-mutagenic, and has physiochemical properties exceeding the minimum U.S.P. levels set for plastics.

Compared to current treatment alternatives, such as arthrodesis or resection arthroplasty with a silicone spacer, the Ascension PIP may provide the potential benefits of increased motion and function, and may be used on patients whose strength and motion demands would exceed the capabilities of the currently available one-piece silicone spacers.

Therefore, based on Ascension PIP pre-clinical testing, and the animal and clinical data for the Pyrocarbon MCP, it is reasonable to conclude that the probable benefit to health from using the Ascension PIP for the target population outweighs the risk of illness or injury, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment, when used as indicated in accordance with the directions for use.

XII. Panel Recommendations

This HDE was not taken to a meeting of the Orthopedics and Rehabilitation Devices Panel because this panel has previously reviewed marketing applications for other finger prostheses. Therefore, it was determined the Panel had already provided input into acceptable kinds of data needed to assess safety and probable benefit.

XIII. CDRH Decision

CDRH has determined that based on the data submitted in the HDE, the Ascension PIP joint implant will not expose patients to an unreasonable or significant risk of illness or injury, and the probable benefit to health from using the device outweighs the risks of illness or injury, and issued an approval letter on MAR 22 2002.

XIV. Approval Specifications

Instructions for use: See Labeling.

Indications for Use: See section II above.

Hazards to Health from Use of the Device: See Contraindications, Warnings, and Precautions in sections III and IV above.

XV. References

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