ENG

Integra®

PyroDisk™ Interpositional CMC Implant

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

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Surgical Technique

As manufacturer of this device, Ascension Orthopedics does not practice medicine and does not recommend this or any other surgical technique for use on a specific patient. The surgeon who performs any procedure is responsible for determining and using the appropriate technique in each patient.

Design Rationale

The PyroDisk™ CMC implant is a biarticular convex disc made of PyroCarbon, designed to resurface the thumb carpometacarpal (CMC) joint damaged by arthritis with resultant pain and loss of function. The implant and CMC joint are stabilized by the flexor carpi radialis tendon, transferred and passed through the trapezium, through the implant, and into the first metacarpal. A healing bone-tendon interface within the trapezium and the metacarpal give alignment and stability to the implant, which is additionally supported by the prepared concave surfaces of the joint and the convex surfaces of the implant. Goals are pain relief and restoration of motion.
As this operation preserves trapezial bone stock, normal thumb length and pinch strength are realistic and achievable goals. Finally, saving the trapezium permits greater choices should revision surgery be indicated.

Indications

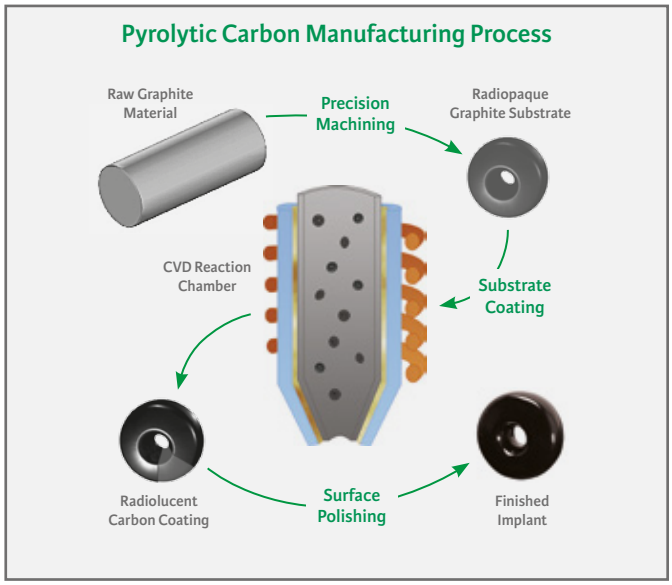
The PyroDisk™ CMC implant is intended to replace the joint between the first metacarpal and the trapezium in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation or bone loss which present as either a painful, unstable thumb,
or a thumb with limited range of motion.

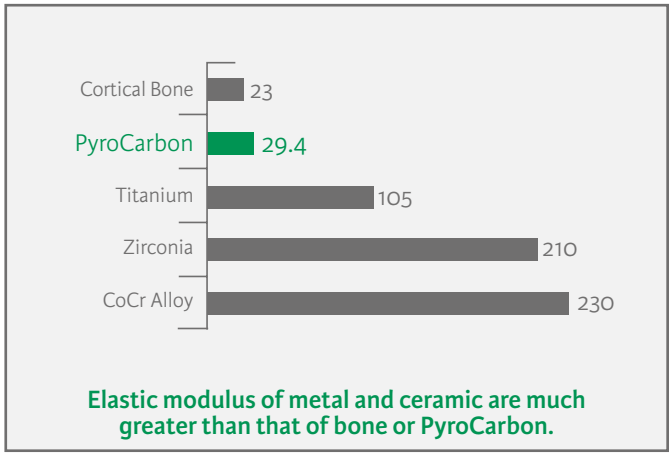
Contraindications

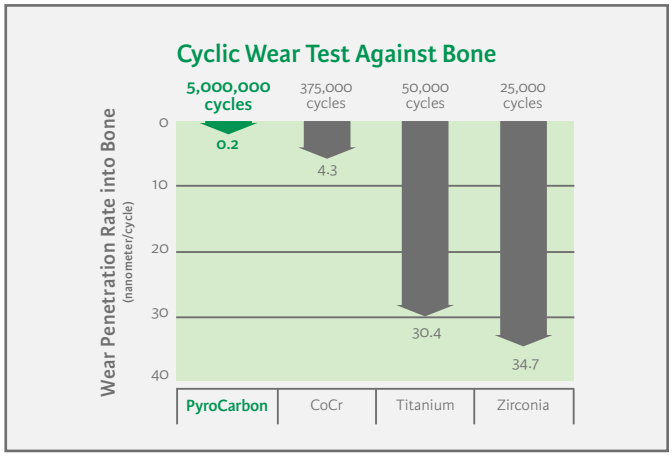
- Inadequate bone stock or soft tissue coverage
- Previous open fracture or infection in the joint
- Skeletal immaturity
- Physical interference with or by other prostheses during implantation or use
- Procedures requiring modification of the prosthesis
- Skin, bone, circulatory and/or neurological deficiency at the implantation site

See package insert for full prescribing information*.

* ESSENTIAL PRODUCT USE INFORMATION: For additional important information pertaining to the use of this product, please see product package insert. This information was current at the time of printing, but may have been revised after that date.







Pyrocarbon Advanced Material

PyroCarbon is a specific form of carbon that has been tailored for durability and compatibility. PyroCarbon has portions of 2-D and 3-D crystalline structures, resulting in excellent strength and wear properties between those of graphite and diamond. PyroCarbon should not be confused with carbon fibers, which are minute particles used to strengthen other materials.

The elastic modulus of PyroCarbon is very similar to cortical bone resulting in biomechanical compatibility with bone. Unlike surgical grade metals, PyroCarbon transfers load from implant to bone more effectively, thus reducing stress shielding and potential bone resorption.*

PyroCarbon exhibits exceptional wear performance against bone compared to ceramic and metals. After cyclic testing to 5,000,000 cycles, PyroCarbon demonstrated minimal wear into cortical bone. It was not possible to test the other materials past 375,000 cycles with Cobalt Chrome, 50,000 cycles with Titanium and 25,000 cycles with Zirconia because the bone specimens had worn away.**

* **Stanley J, Klawitter JJ, More R,**
Replacing joints with pyrolytic carbon. In Joint replacement technology
Ed. Peter A Revell. Woodhead Publishing, 2008, 651
** **Strzepa P, Klawitter JJ,**
Ascension PyroCarbon Hemisphere Wear Testing Against Bone.
Poster No. 0897, 51st Annual Meeting of the Orthopedic Research Society.

Preoperative Assessment

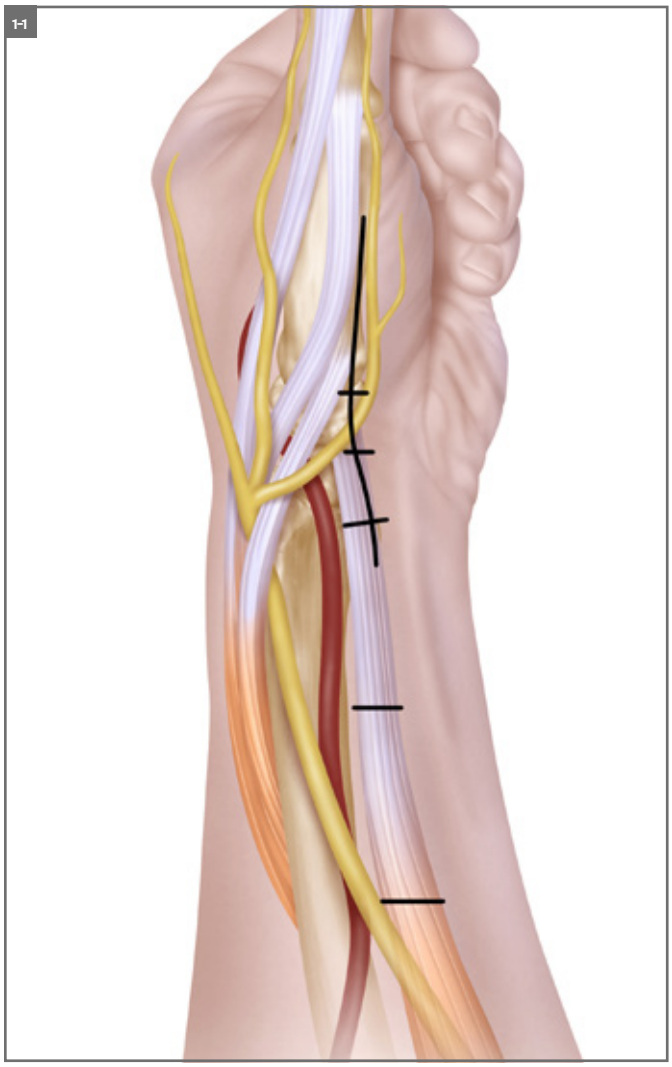
A prerequisite of surgery, and essential to its success, is adequate trapezial bone stock, assessed preoperatively by X-ray evaluation and confirmed by inspection during surgery.

Step 1 • Skin Incision, Capsular Opening & Exposure

1-1 After proper general or regional anesthesia, the hand and arm are prepped and draped in the usual manner with high arm tourniquet control.

A longitudinal incision is made along the radial base of the first metacarpal, passing ulnarly at the wrist flexion crease. Subcutaneous sensory branches of the radial nerve are identified and protected. The capsule is entered in line with the incision from the mid-portion of the metacarpal to the base of the trapezium. Further retraction should be exerted on the capsule alone to prevent any neuropraxic injury to radial nerve branches. At this juncture, the CMC joint is opened transversely and inspected. The scapho-trapezial (ST) joint is also entered, with care taken to protect the branch of the radial artery passing dorsally in this area.

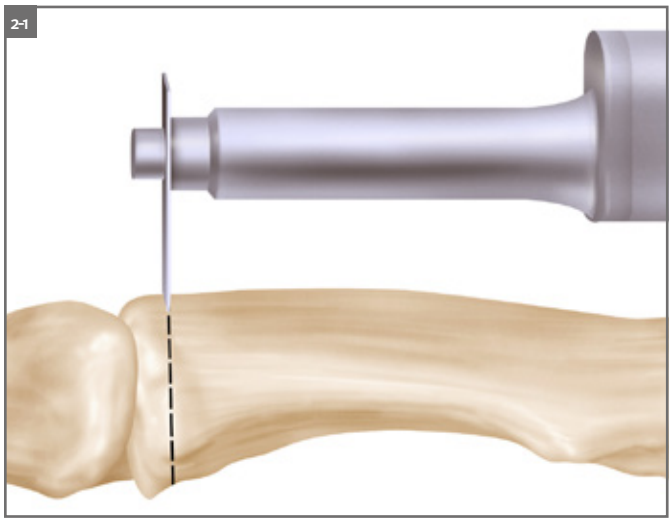
1-1



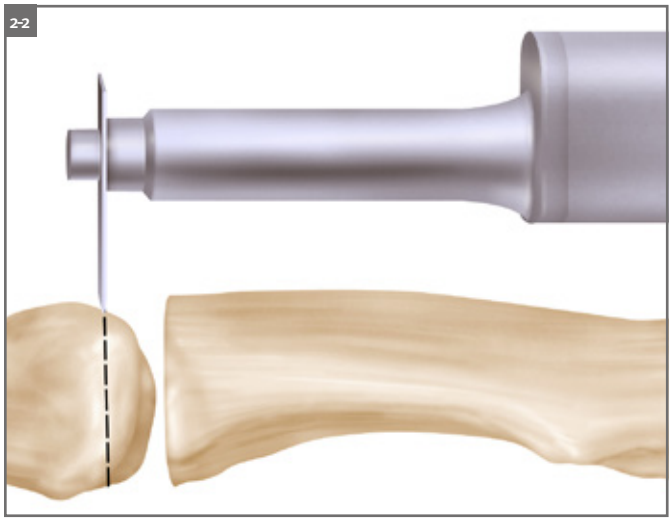
Step 2 • Metacarpal & Trapezial Preparation

2-1 Architectural definition of the CMC joint and the trapezium will have been established with preoperative X-rays. Intraoperative assessment of trapezial integrity must support this, as advanced cases of degeneration with significant joint subluxation often results in erosion of the ulnar side of the metacarpal and the radial side of the trapezium. The trapezium must have adequate size to permit decortications of the distal surface, with residual height to support the implant.

An oscillating saw is used to remove 2-3 mm from the metacarpal base. The cut should be made parallel to the transverse axis of the metacarpal phalangeal (MP) joint.

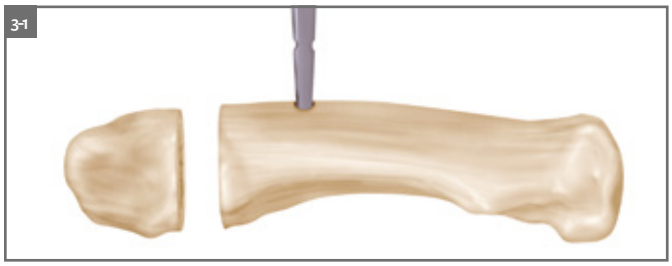


2-2 The trapezial saddle is then flattened, using the transverse axis of the MP joint and the metacarpal cut for alignment. Minimal resection of the medial and lateral flare, or "horns," of the trapezium and its distal cortical surface is ideal. A complete joint synovectomy is then carried out, along with removal of all small bone fragments. Be sure to remove all degenerative bone which often builds up behind the metacarpal. The terminal insertion of the flexor carpi radialis (FCR) tendon can be seen at the base of the resected joint.



Step 3 • Tendon Passage Preparation

3-1 The Awl is now inserted into the flat dorsal aspect of the metacarpal, 1 cm distal to the proximal end of the bone, to make a passage through the metacarpal. The hand Gouge is used secondarily to enlarge and smooth the passage. Gentle brisk turning of the Awl and Gouge without undue pressure minimizes the risk of splitting the metacarpal or fracturing the trapezium.



3-2 The medullary canal of the metacarpal is also entered with the Awl and Gouge to make a connection with the dorsal circular window.

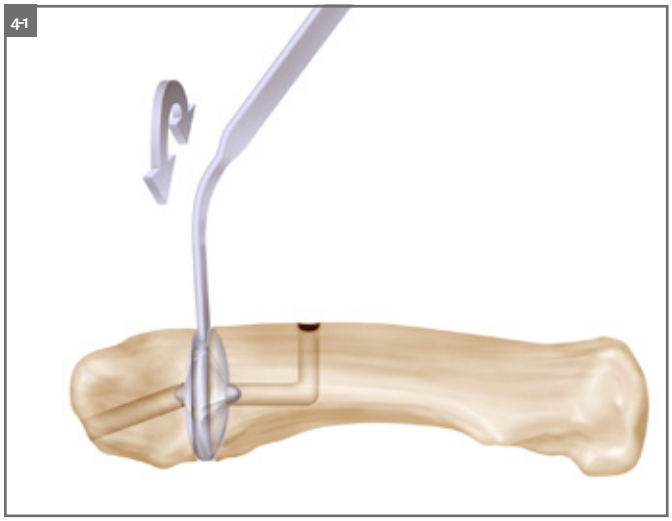
3-3 A passage is now made through the trapezium. The Awl is placed beneath the trapezium and directed to the center of the distal resected surface. The Gouge enlarges this hole.

Step 4 • Preparing Joint Surfaces & Trial Reduction

4-1 Proper implant diameter is determined by selecting the Trial that best fits diameter of the metacarpal base. The trapezial surface is not circular so the metacarpal base is the proper reference for sizing. There should be no overhang of the Trial. The thickness of the Trial is related to the amount of bone resected, and a thinner PyroDisk may translate into greater motion.

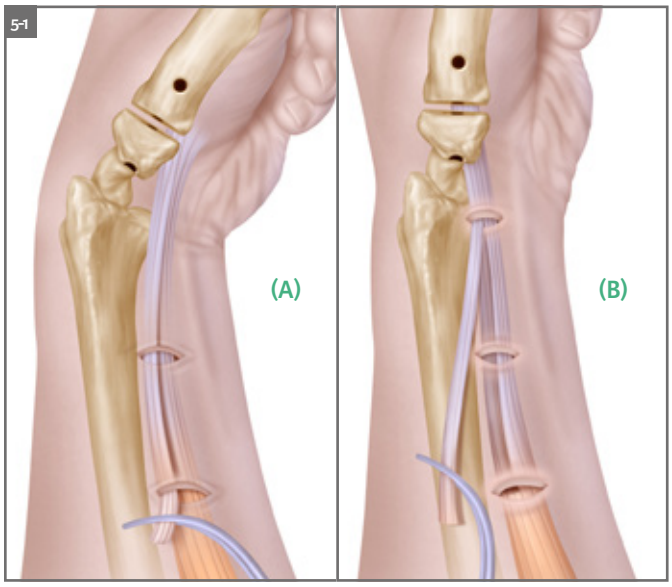
After choosing the appropriate diameter, the corresponding Finishing Shaper is used to create a modest concavity between the base of the metacarpal and the distal surface of the trapezium. The center protrusions on the Finishing Shaper are placed in the holes, and a gentle twisting back and forth motion creates a surface that mirrors the convexity of the implant.

Trial fitting of the implant is now achieved by selecting from the six sizes provided. The goal is a gentle rocking and modest gliding of the disc on the trapezium. Intraoperative fluoroscopy confirms proper sizing.



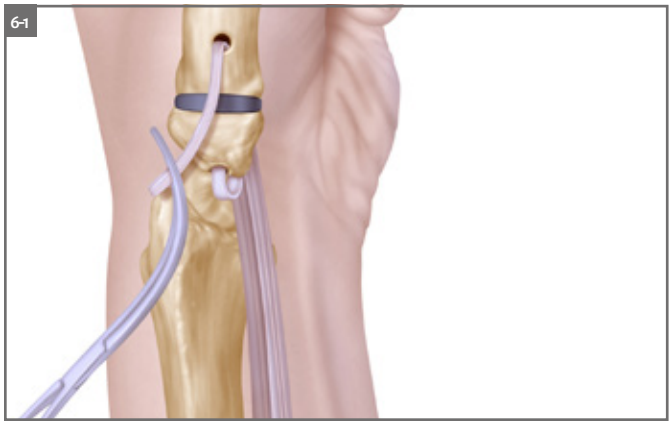
Step 5 • Harvesting the Tendon

5-1 Attention is directed to the distal radial flexor surface of the forearm. Two small transverse incisions permit access to harvest 1/3 to 1/2 of the FCR tendon from its musculotendinous junction to the tuberosity of the scaphoid (A). By wrist positioning in various degrees of flexion, the tendon can be visualized throughout tendon mobilization (B). The remaining FCR muscle/ tendon unit retains function as an important wrist flexor. Individual preferences for FCR tendon mobilization are respected. The tendon is then passed beneath the tendons of the first dorsal compartment to the rim of trapezium where the entry hole has been made. The goal is to have adequate tendon length and strength to achieve passage through the trapezium and the implant, into the metacarpal, and out the dorsal window, with enough tendon length left to reinforce and create a strong capsular closure.

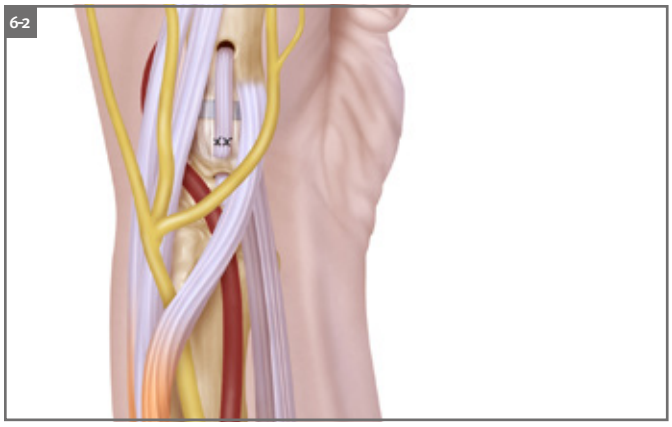


Step 6 • Implantation

6-1 After joint irrigation and injection of local anesthesia,the tendon is passed sequentially through the trapezium into the resected joint, through the selected PyroDisk implant, and into the first metacarpal to exit dorsally from the prepared passage. The longitudinal tendon and the prepared surfaces of the CMC joint help to restore alignment and give stability to the thumb.



6-2 Gentle traction on the tendon prior to closure enhances this stability. The goal is free rotatory motion of the CMC joint, not a tight or compressed joint. The residual tendon is then folded back to be incorporated into a secure capsular closure using absorbable sutures.



Step 7 • Secondary Deformities

7-1 During capsular closure, the insertional integrity of the abductor pollicis longus tendons should be restored. With the completed arthroplasty, assess the stability of the MP joint volar plate. Painful MP joint hyperextension is often a secondary deformity of the damaged CMC joint, wherein subluxation and proximal migration of the first metacarpal leads to an adduction contracture of the thumb and attritional stretching and laxity of ligaments at the MP joint. PyroDisk arthroplasty helps to restore CMC joint alignment and thumb length which can minimize the MP joint symptoms. In the face of significant instability, MP volar plate ligament reconstruction or MP joint arthrodesis may be indicated.

Postoperative Care

After skin closure, the incisions are dressed and a modest thumb spica cast is applied, with the thumb in the mean or “fist” position. The thumb interphalangeal joint may remain free. At one week, the cast may be changed and the skin sutures removed.

A new cast is applied for an additional 2-3 weeks. At 3-4 weeks postoperatively, a soft neoprene splint is provided for graduated use. The thumb may be unprotected at 6-8 weeks, depending on patient comfort and confidence. Ongoing improvement in comfort and strength may be expected for 3-6 months.

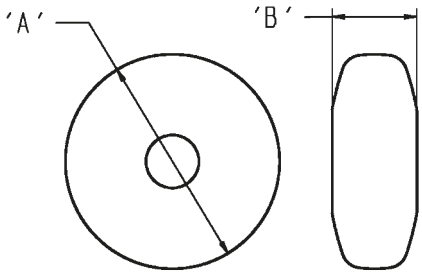
Implants

Implant List

Reference	Description
PYD-420-145	PyroDisk Implant, Size 145
PYD-420-165	PyroDisk Implant, Size 165
PYD-420-167	PyroDisk Implant, Size 167
PYD-420-168	PyroDisk Implant, Size 168
PYD-420-187	PyroDisk Implant, Size 187
PYD-420-189	PyroDisk Implant, Size 189

Implant Dimensions (mm)

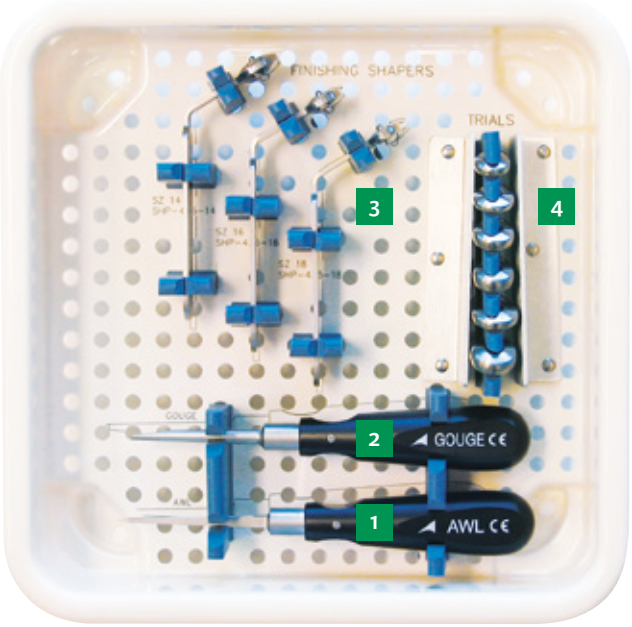
Size	A. Disk Diameter	B. Disk Height
145	14	5.5
165	16	5.5
167	16	7.0
168	16	8.0
187	18	7.0
189	18	9.0



Instrumentation

Instruments List

Reference	Description
CSA-000-05	General Instrument Case Lid
CSA-420-02	PyroDisk Instrument Case Base
AWL-420-00	Awl
GOU-420-00	Gouge
SHP-425-14	Finishing Shaper, Size 14
SHP-425-16	Finishing Shaper, Size 16
SHP-425-18	Finishing Shaper, Size 18
TRL-420-145	PyroDisk Trial, Size 145
TRL-420-165	PyroDisk Trial, Size 165
TRL-420-167	PyroDisk Trial, Size 167
TRL-420-168	PyroDisk Trial, Size 168
TRL-420-187	PyroDisk Trial, Size 187
TRL-420-189	PyroDisk Trial, Size 189



1. Awl
2. Gouge
3. Finishing Shapers
4. Trials

Integra

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