

Integra®

PyroCarbon Lunate

SUTURE ANCHOR
SURGICAL TECHNIQUE



INTEGRA®
LIMIT UNCERTAINTY

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Indications

The PyroCarbon Lunate is intended for replacement of the lunate bone in the proximal carpal row of the wrist in the presence of:

- Avascular necrosis (Kienboch's disease)
- Localized osteoarthritic changes
- Long-standing dislocations

Contraindications

- Acute or chronic infection
- Radial scaphoid arthritis
- Gross carpal instability

See package insert for full prescribing information.*

Warnings

- Strenuous loading, excessive mobility, and articular instability all may lead to eventual failure by loosening, fracture, or dislocation of the device. Patients should be made aware of the increased potential for device failure if excessive demands are made upon it.
- Do not modify the PyroCarbon Lunate implant in any manner. Reshaping the implant using cutters, grinders, burs, or other means will damage the structural integrity of the device.

Precautions

- Do not use the PyroCarbon Lunate in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the native lunate, the PyroCarbon Lunate attains stabilization from the surrounding capsuloligamentous structures. If soft tissue reconstruction cannot provide adequate stabilization, the device may dislocate or loss of motion may occur.
- 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. Reuse of this product may result in infection or other systemic complication that may affect the patient's overall health. Additionally, the reuse of this product could adversely affect function of the 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 and should be discarded.
- Do not grasp the PyroCarbon Lunate implant with metal instruments, or instruments with teeth, serrations, or sharp edges. The PyroCarbon Lunate is made of pyrocarbon, which is a ceramic-like material. Mishandling implants could cause surface damage that reduces their strength which could result in implant fracture and/or particulate debris.
- Do not use metal suture/wire for implant fixation as damage to the implant may occur that reduces strength which could result in implant fracture and/or debris generation.
- The PyroCarbon Lunate has not been evaluated for safety and compatibility in the MR environment. The PyroCarbon Lunate has not been tested for heating or migration in the MR environment.

Product Description

The PyroCarbon Lunate is an anatomically designed lunate replacement with essentially the same shape as the native lunate bone. The Lunate implant acts as an articulating spacer to maintain the relationship of adjacent carpal bones after excision and to maintain mobility of the wrist. The articular concavity that captures the capitate is more exaggerated to enhance stability. The PyroCarbon Lunate is constructed of a high strength On-X[®] PyroCarbon layer deposited on a graphite substrate. The graphite is impregnated with tungsten making the Lunate implant radiopaque. The PyroCarbon Lunate is available in 5 sizes for use in left or right applications.

Surgical Technique



As the manufacturer of this device, Integra LifeSciences Corporation 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.

Caution: Federal law restricts this device to sale by or on the order of a physician or practitioner.

Step 1 • Skin Incision

- 1-1** Make a 7-10 cm midline dorsal longitudinal incision across the radiocarpal area.

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It is recommended to support the wrist on a modest bump to induce a small degree of flexion.

- 1-2** The third extensor compartment is incised and then elevated to create an ulnarly based flap of the fourth compartment roof and a radially based flap of the second compartment roof. Care is taken to identify and protect the dorsal radial and ulnar sensory nerves. The extensor pollicis longus is retracted radially while the extensor digitorum communis tendons are retracted ulnarward.



Step 2 • Capsulotomy

- 2-1** Specific landmarks are identified and palpated on the wrist. These mark the placement of the capsular incision. Caution is taken to protect the terminal branch of the posterior interosseous nerve.

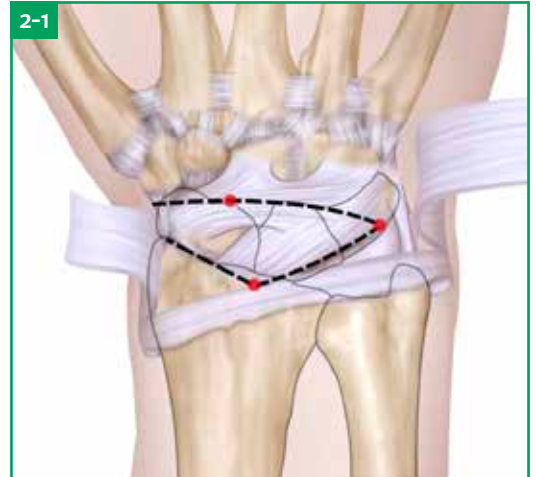
Landmarks:

1. The midpoint of the dorsal radiocarpal ligament attachment to the radius.
2. The dorsal tubercle of the triquetrum.
3. The sulcus between the scaphoid and the trapezoid.

These landmarks are marked, and the surgeon connects the dots with a full thickness incision. This capsular incision reveals the longitudinally split fibers of the DIC and DRC ligaments. Once the ligament-splitting incisions are made, the capsulotomy can be completed by following the dorsal rim of the radius to the level of the styloid process. When the radio-carpal capsulotomy is complete, the radially based flap of capsule is tangentially elevated off the dorsal surfaces of the capitate and lunate.

Surgical Pearl

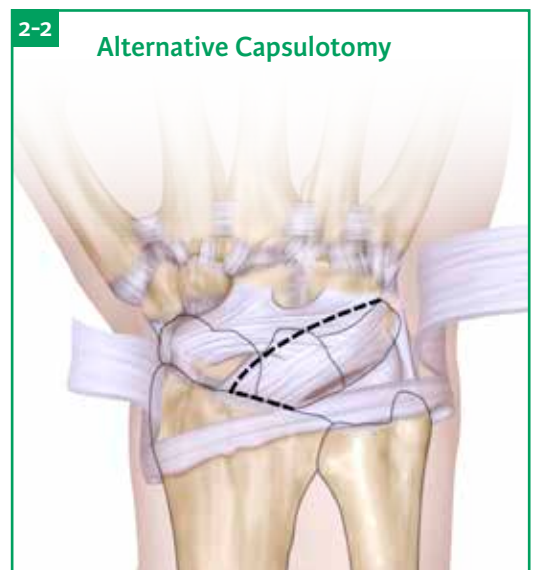
After the capsulotomy has been created, the surgeon should closely examine the scaphoid fossa within the radius. If there is evidence of significant arthritis, the procedure should be abandoned for an alternative wrist salvage procedure, as ongoing pain will continue at the radioscapoid fossa despite replacement of the lunate.



Alternative Capsulotomy:

- 2-2** The wrist is palpated and marked prior to elevation of the dorsal capsular flap, which will then provide access to the radiocarpal and midcarpal joints. The distal margin of Lister's tubercle is identified, and a J shape line is drawn toward the dorsal tubercle of the triquetrum. An incision is then made to follow this line, extending from the distal margin of Lister's tubercle obliquely toward the dorsal tubercle of the triquetrum.

This incision is designed to split the fibers of the radiocarpal ligament and preserve the branches of the posterior interosseous nerve within the flap. The capsular flap is then raised tangentially off the dorsal surface of the scaphoid, lunate, triquetrum, and the proximal portion of the capitate. If additional exposure is required, an additional cut may be made in line with the fibers of the dorsal intercarpal ligament extending from the triquetrum towards the trapezium. This will further expose the neck of the capitate and the waist of the scaphoid bone, if necessary for completion of the surgical procedure.



Step 3 • Resection of the Lunate

3-1 The lunate is resected with great care to remove the lunate in-total if possible, to allow for easy assessment of implant size. If the lunate has experienced significant collapse or fragmentation, templating against the normal wrist is recommended.



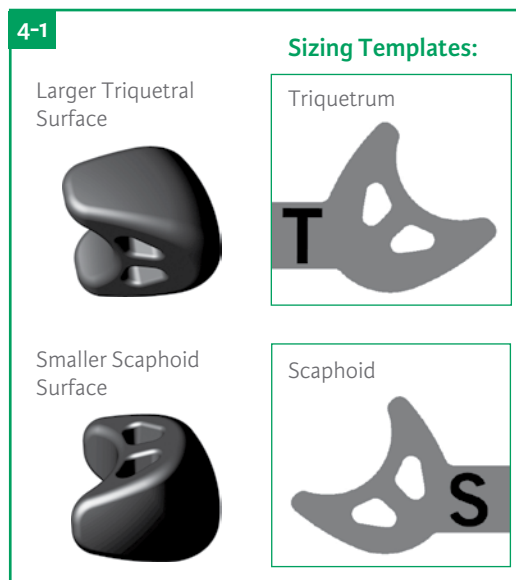
Step 4 • Sizing

4-1 The PyroCarbon Lunate comes in 5 sizes for the right and left hand. The deep concavity of the lunate straddles the head of the capitate distally. The shorter flat surface articulates with the scaphoid and the longer surface with the triquetrum.

The Sizing Template provided can be used to help estimate the implant fit on the surfaces of the triquetrum, scaphoid, and capitate. Radiopaque Lunate Trials are also used to help with determining the correct size implant. Implant sizing should always start with the smallest trial incrementing up in size until a comfortable fit in the lunatectomy space is obtained.

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Reference Gilula's lines and take care to avoid overstuffing the joint, as this can potentially distract the first carpal row and could result in excessive implant force loading and displacement.



Step 5 • Suture Anchor Placement

5-1

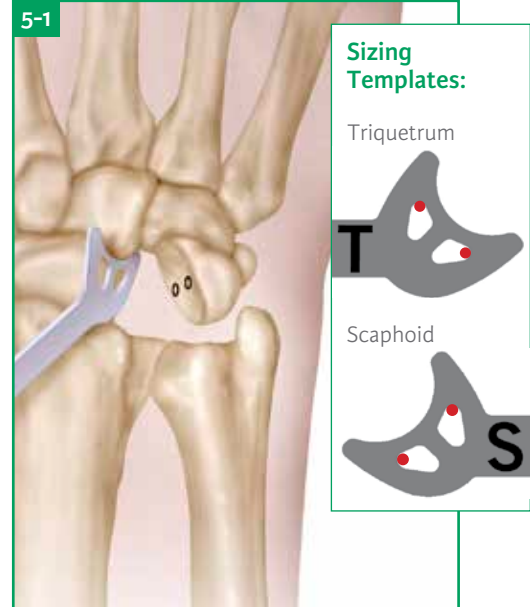
Surgical Pearl

It is recommended to position the suture anchors in the outer most corner of the sizing template to increase stabilization of the implant (see inset).

Utilizing the Sizing Template and a felt tip pen, mark drill points on the scaphoid which will allow insertion of two Mitek mini anchors with several strands of Number 2 Orthocord or similar permanent suture. (DePuy-Mitek, Johnson & Johnson). Two pilot holes are then drilled into the scaphoid, but the anchors are not placed until the triquetrum has been prepared.

Attention is turned to the triquetrum surface. Using the Sizing Template, two marks are made using a felt tip pen. It is recommended the marks be placed on the outer most corner of the template to improve implant stability. A 2 mm drill is then utilized to prepare holes through the triquetrum to allow passage of two channels through the body of the triquetrum.

5-1



Step 6 • Implant Placement & Capsular Repair

6-1

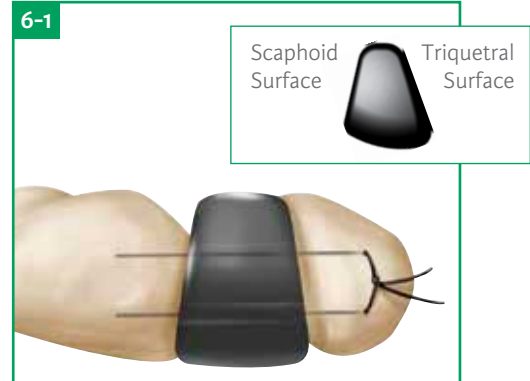
Surgical Pearl

Utilizing a 18 gauge spinal needle and tendon passer (Chia Passer, DePuy), or simple wire loop, may help facilitate the passage of the suture through the triquetrum.

Before inserting the implant, the wound is thoroughly irrigated with saline solution to remove all debris. The PyroCarbon implant should not be handled with metal instruments. Two Mitek anchors are placed in the scaphoid; the suture material is passed through the PyroCarbon Lunate prosthesis and then passed through the previously created channels in the triquetrum. Note that the short flat surface articulates with the scaphoid and the long surface articulates with the triquetrum.

The sutures that are passing through the implant and triquetrum are brought ulnarly and held snugly around the triquetrum. Confirmation X-rays are taken to ensure position of the lunate implant is satisfactory. Following satisfactory confirmation, the two arms of the suture are tied snugly to each other to produce a stabilization of the lunate prosthesis.

6-1



Step 7 • Closure

The capsular flap is repaired with 2-0 Vicryl suture, and the extensor retinaculum is repaired with 3-0 Vicryl suture. Skin incisions are closed with 4-0 nylon suture. Wrist may be placed through range of motion, and Lunate position verified by X-ray.

Postoperative Care

The extremity is elevated for 1-2 days, and patient is instructed to move the shoulder and fingers. A sugar tong splint is applied for the first 3-5 days. This is then changed to a short arm cast. Wrist immobilization is maintained for 6-8 weeks. Skin suture can be removed at 2 weeks. Postoperative therapy should include isometric gripping and movements of the shoulder. Full usage of the wrist is resumed at 12 weeks, unless an intercarpal fusion was performed, which requires a longer casting period.

Instrumentation

1. Sizing Templates
2. Radiopaque Trials



Implants

Catalog Number	Description
LUN-710-01	Lunate Implant, Size 01
LUN-710-02	Lunate Implant, Size 02
LUN-710-03	Lunate Implant, Size 03
LUN-710-04	Lunate Implant, Size 04
LUN-710-05	Lunate Implant, Size 05



Instruments

Catalog Number	Description
TRL-715-01T	Lunate Trial, Size 01
TRL-715-02T	Lunate Trial, Size 02
TRL-715-03T	Lunate Trial, Size 03
TRL-715-04T	Lunate Trial, Size 04
TRL-715-05T	Lunate Trial, Size 05
SZT-715-01S	Lunate Sizing Template, Size 01
SZT-715-02S	Lunate Sizing Template, Size 02
SZT-715-03S	Lunate Sizing Template, Size 03
SZT-715-04S	Lunate Sizing Template, Size 04
SZT-715-05S	Lunate Sizing Template, Size 05

For more information or to place an order, please contact:
Integra ■ 311 Enterprise Drive, Plainsboro, NJ 08536
877-444-1122 USA ■ 609-936-5400 outside USA ■ 866-800-7742 fax
integralife.com