Integra®

NuGrip™ CMC Implant

SURGICAL TECHNIQUE

INTEGRA®
LIMIT UNCERTAINTY

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Indications For Use

The NuGrip™ CMC Implant is intended to replace the proximal end of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis, post fracture deformity or bone loss which presents 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

Warnings and Precautions

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 NuGrip implant in any manner. Reshaping the implant using cutters, grinders, burrs, or other means will damage the structural integrity of the device.
- Do not grasp the NuGrip implant with metal instruments, or instruments with teeth, serrations, or sharp edges. Implants should be handled only with instrumentation provided by Integra. NuGrip 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.

Precautions

- Do not use the NuGrip in a joint where soft tissue reconstruction cannot provide adequate stabilization. Similar to the natural joint, the NuGrip 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. 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.
- Implants should be handled with blunt instruments to avoid scratching, cutting or nicking the device so as not to adversely affect the implant performance. Polished bearing and taper surfaces must not come in contact with hard or abrasive surfaces.

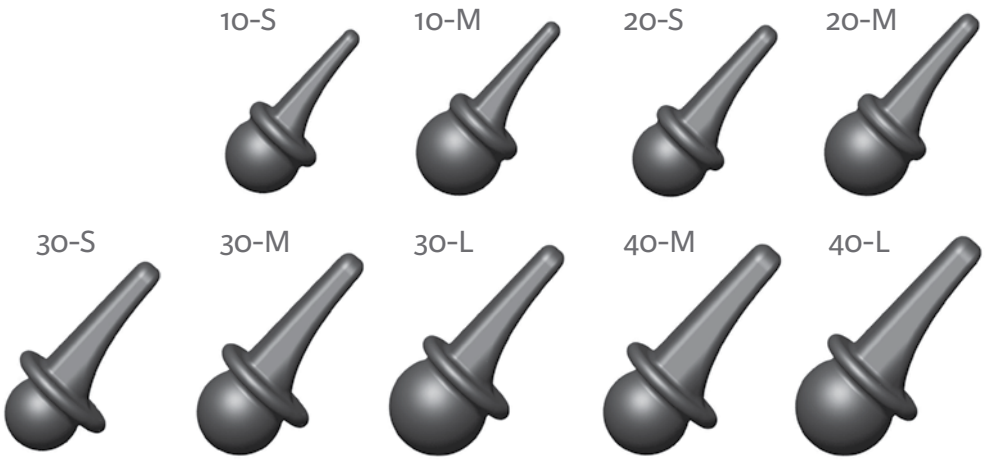
Product Description

The NuGrip CMC Implant is designed to relieve pain and restore range of motion in the first carpometacarpal (CMC) joint of patients with arthritis.

The NuGrip CMC Implant, made of PyroCarbon, is a single component which minimizes bone resections and preserves the trapezium. The stem is anatomically designed to press fit within the intramedullary canal without cement. The stem and collar enhance stability and minimize the possibility of movement or toggling of the stem within the canal. The spherical head provides the maximum opportunity for range of motion. The instrumentation is streamlined and color coded for simplified use. There are nine sizing options.

NuGrip CMC Implant
Sizing Options

STEM SIZE	HEAD SIZE		
	S	M	L
10	●	●	
20	●	●	
30	●	●	●
40		●	●



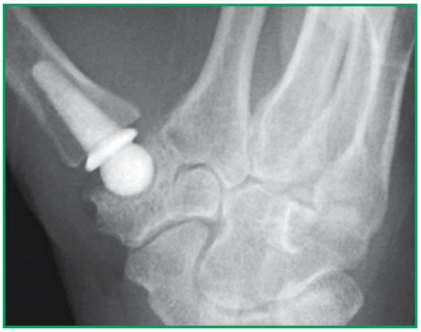
Surgical Technique

This technique has been developed with the help of Steven Moran, M.D. of the Mayo Clinic; and Lorenzo Pacelli, M.D. of the Scripps Hospital.

As the manufacturer of this device, Integra 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 implant procedure is responsible for determining and using the appropriate techniques for implanting the device in each patient.

Patient Selection

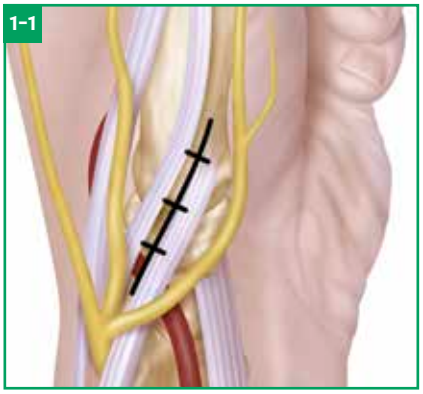
The NuGrip is intended for use in patients who have arthritis affecting the first carpal metacarpal (CMC) joint. It is not designed for use in patients who, in addition to first CMC arthritis, have significant scaphotrapezial trapezoidal arthritis.



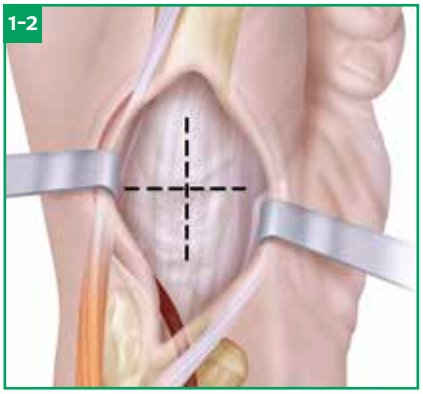
Step 1 • Skin Incision and Capsular Exposure

1-1 Make a 4-5 cm longitudinal incision over the CMC joint in line with the first dorsal compartment tendons.

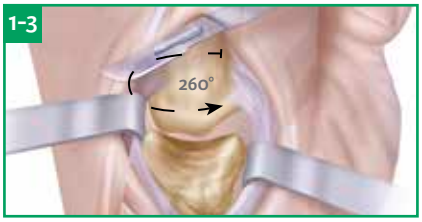
Elevate the subcutaneous tissues, identifying and protecting the superficial radial nerve branches. Spread the soft tissues to expose the deep branch of the radial artery, which is angled dorsally just proximal to the STT joint. Free the radial artery and protect with a vessel loop. Open the interval between the adbuctor pollicis longus (APL) and the extensor pollicis brevis (EPB). Retract the EPB ulnarly while the multiple slips of the APL are retracted radially. This allows for good visualization of the CMC joint capsule. If further visualization is needed, the slip of the APL attaching to the first metacarpal can be released and tagged for later repair.



1-2 Open the STT joint through a longitudinal capsular incision and inspect to ensure the presence of satisfactory articular cartilage. Repair capsular incision at STT joint. Extend the longitudinal incision along the metacarpal base 3 cm and the CMC joint to the trapezium. Make transverse cuts over the CMC joint directly over the trapezium "T-ing" the CMC capsule Figure 1-2. Elevate the capsular periosteal flaps anteriorly and posteriorly to allow complete exposure of the CMC joint.



1-3 Additional dissection is carried distally up the radial and ulnar sides of the metacarpal shaft to release a portion of the adductor and opponens muscles. Create a subperiostial sleeve of tissue approximately 260° around the circumference of the base of the thumb metacarpal. Dissect off volar attachments, leaving only the adductor tissues intact. This allows thumb metacarpal to subflux dorsally. Dissecting from the dorsal metacarpal head 180° ulnarly, then all the way to the insertion of the adductor equaling 260° is needed to expose trapezium and prepare metacarpal base resection.

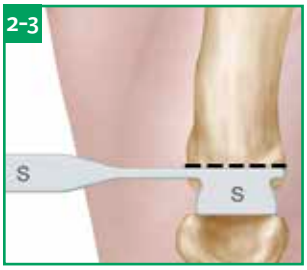


Step 2 • Sizing

2-1 Place Hohmann retractor(s) on the volar aspect of the trapezium to help retract the metacarpal and visualize the trapezium.

2-2 Place the NuGrip Sizing Template against the distal surface of the trapezium.

2-3 The appropriate Sizing Template should closely match the surface area of the central distal surface of the trapezium. A solid rim of cortical bone should surround the Sizing Template for proper stabilization of the implant in the trapezium. Use the sizing template on the metacarpal base to determine ideal site of osteotomy by inserting the "keel" portion of the template into the CMC joint until the cutting edge is flat on the dorsal metacarpal. Depending on the amount of subluxation/bony erosion more or less bone may need to be removed (3-5 mm).



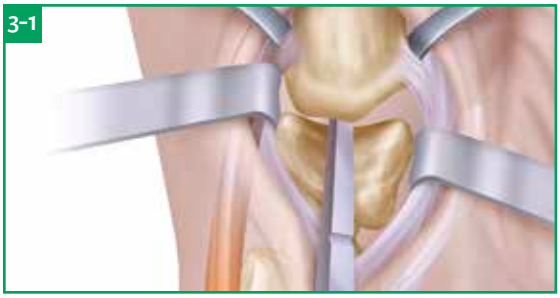
Step 3 • Metacarpal Resection

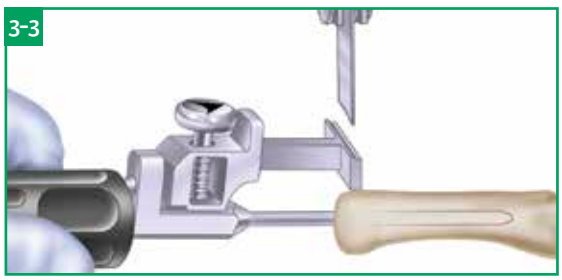
3-1 Place Hohmann retractors under the metacarpal to elevate the base of the metacarpal into the operative field. The Starter Awl or K-wire is inserted into the central dorsal third of the metacarpal. X-rays are taken to confirm the proper starting point.

3-2 Mount the external Alignment Guide on the Alignment Awl, insert the Alignment Awl into the shaft of the metacarpal. The external Alignment Guide should be parallel to the dorsal surface of the metacarpal and centered within the metacarpal.

3-3 The Alignment Guide should lay over the mid-point of the nail. X-rays are taken to ensure proper position.

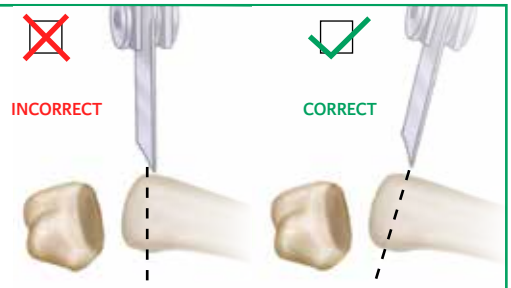
Remove the external Alignment Guide and place the Vertical Cutting Guide on the Alignment Awl. The osteotomy is made at the junction of the metacarpal base and the articular base of the metacarpal, 3-5 mm of bone are resected depending on amount of subluxation or bony erosion present. Using a sagittal saw, place the blade in the slot of the Vertical Cutting Guide to make a vertical cut in the metacarpal. Remove the Alignment Awl and complete the osteotomy by following the plane established by the external guided cut. Additional bone removal may be required in order to increase the joint spacing.





Surgical Pearl: Ensure a perpendicular osteotomy by cutting along the dorsal, radial, and ulnar sides of the metacarpal base with cut guide in place. Avoid an angled osteotomy which may lead to gaps under collar of implant, and possible shifting of stem. Figure 3-1.

3-1



Surgical Pearl: Use the sizing template to estimate osteotomy location. Once the resection is complete, the NuGrip Sizing Template can be placed between the trapezium and the metacarpal to estimate joint spacing. Figure 3-2.

3-2

Lateral view of sizing template in joint space

Step 4 • Trapezial Preparation

4-1 A 1.57 mm (0.062 inch) K-wire is inserted into the center of the trapezium. X-rays are taken to confirm center positioning. Confirm position both radiographically and clinically, and then proceed to preparing the trapezial surface.

Prepare a trapezial cup, with A) Axial Cannulated Cutters or B) by manually sculpting with small round burrs. Leave a solid cortical rim of bone around the cup to support the head of the implant. The trapezial cup may be safely deepened to a level equal with the distal third of the trapezium, maintaining as much of the cortical bone as possible. Use continuous irrigation when preparing the trapezium.

A. Axial Cannulated Cutters

Note: Cannulated Cutters are single use instruments.

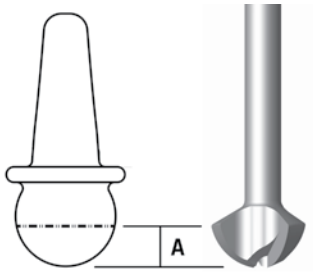
Circumferentially dissect around the base of the metacarpal and elevate remaining volar capsule subperiosteally to gain axial view of the trapezium position.

4-1

A. Single Use Cannulated Cutter

B. CMC Disposable Pack Burrs

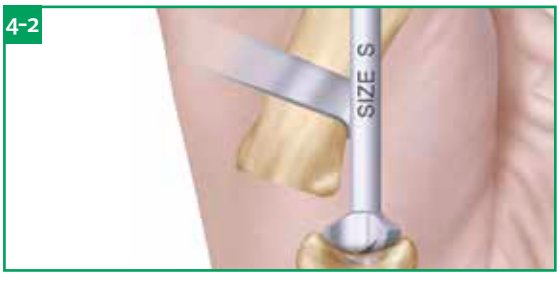
Axial Cannulated Cutter depth = 40% of Implant Head



Head Size	40% Head Depth (A)
S	4.1 mm
M	4.6 mm
L	5.3 mm

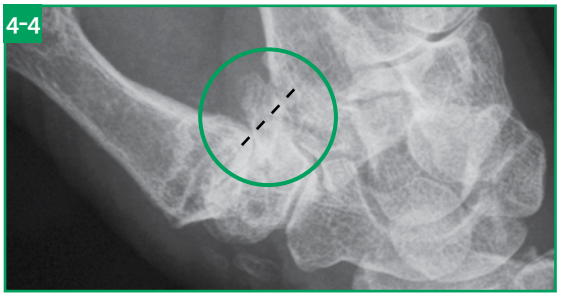
4-2 Ream the trapezium with the size Small Cannulated Cutter ensuring to initiate the cutter before contacting bone.

4-2



4-3 The trapezial cup may be safely deepened to a level equal with the distal third of the trapezium, maintaining as much cortical bone as possible. Confirm the cup depth with the implant trial and X-rays. Increase the Cannulated Cutter size progressively to the implant head size previously determined with the Sizing Template. Smooth the cup in the trapezium with the corresponding size NuGrip Finishing Shaper (S, M, L), by moving it back and forth across the surface.

Surgical Pearl: If medial osteophytes on the volar proximal lip of the metacarpal or the trapezium are present, Figure 4-4, impingement on the index finger metacarpal or the implant during extremes of motion may occur. It is suggested to remove any osteophytes present with a ronguer or saw blade prior to implant placement.



X-ray courtesy of Dr. Mark Ross

B. Manual Sculpting and Finishing Shapers

4-5 Place and remove a K-wire to create a pilot hole in the center of the trapezium. Using a small round burr, remove the surface cortical bone and create a small cup.

4-6 Using a large round burr, enlarge the cup in the trapezium to the previously determined head size (S, M, L). The trapezial cup may be safely deepened to a level equal with the distal third of the trapezium. During the burring process, confirm the cup depth with the implant Trial and X-rays. Smooth the cup in the trapezium with the corresponding size NuGrip Finishing Shaper (S, M, L), by moving it back and forth across the surface.

Step 5 • Metacarpal Broaching

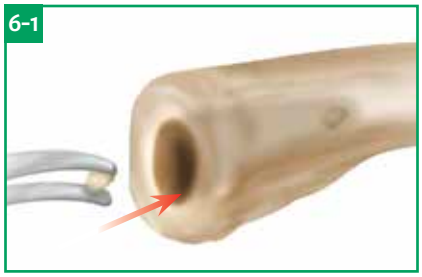
5-1 Mount the external Alignment Guide on the size 10 CMC Broach. Insert the broach keeping the Alignment Guide parallel to the dorsal surface of the metacarpal bone. X-ray to ensure proper alignment in the medullary canal. Broach progressively larger until the medullary canal is filled in both dorsal and lateral views, keeping the sizing options in mind.

STEM SIZE	HEAD SIZE		
	S	M	L
10	●	●	
20	●	●	
30	●	●	●
40		●	●

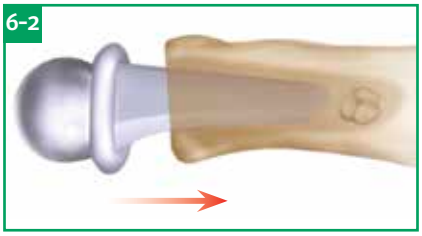
5-1

Surgical Pearl: Use impaction grafting from resected metacarpal before final implant is seated. This ensures a snug fit and allows time for bone to remodel around stem. Figures 6-1 and 6-2.

6-1



6-2

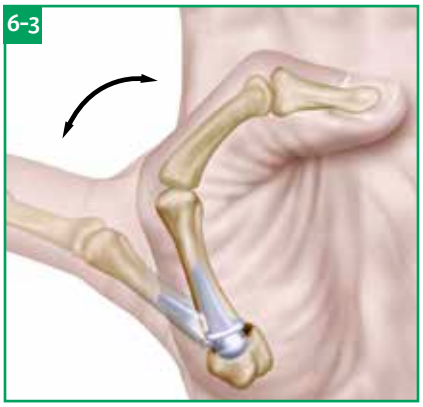


Step 6 • Trial Reduction

6-3 Insert Trial. The vent groove corresponds to the dorsal surface of the metacarpal. Lightly impact the Trial with the impactor provided and reduce the joint. The implant has been designed to provide a space between the trapezium and metacarpal base with no impingement of the metacarpal on the trapezium during the extremes of thumb circumduction. Check thumb adduction with simultaneous thumb MP and IP joint flexion.

X-ray to ensure that there are no osteophytes on the trapezium or the metacarpal, which may impede full range of motion, and in extreme cases, could cause the implant to sublux. Remove osteophytes using an osteotome or rongeur.

6-3

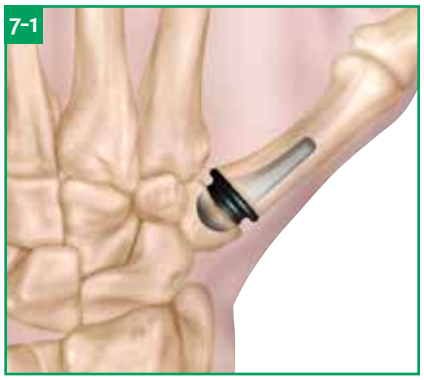


Step 7 • Implantation

7-1 Open the appropriately sized sterile NuGrip Implant and insert the device using finger pressure. Ensure the correct axial rotation of the implant is maintained during insertion. Confirm the dorsal surface of the implant stem is parallel to the dorsal surface of the metacarpal. Lightly impact the implant with the impactor provided and reduce the joint.

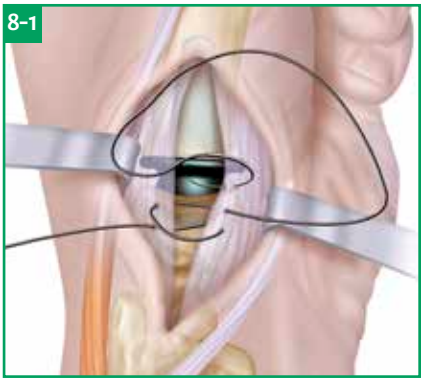
Check passive thumb adduction combined with MP and IP flexion. The resting stance of the thumb should be that of slight abduction.

Check for MP hyperextension. If greater than 30°, fusion may be indicated. If between 10-30°, pinning or capsulodesis may decrease subluxation potential and increase thumb pinch function.

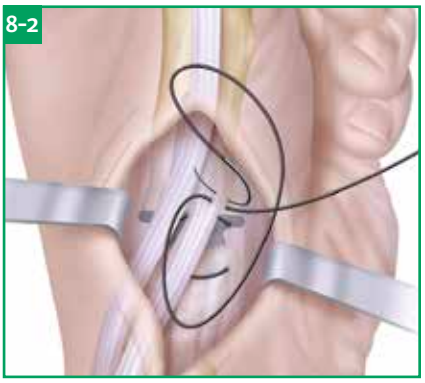


Step 8 • Closure

8-1 Repair the capsule with side-to-side, 2-0 or 3-0, non-absorbable horizontal mattress sutures.



8-2 The repair is performed with the thumb widely abducted and the MP joint flexed. The extensor pollicis brevis tendon can be tenodesed to the base of the metacarpal to prevent MP hyperextension and potentially increase CMC abduction.



Step 9 • Dressing

Place the hand in a bulky dressing with plaster splints to hold the thumb metacarpal widely in abduction with the MP flexed. Use X-rays to confirm the implant position.

Postoperative Care

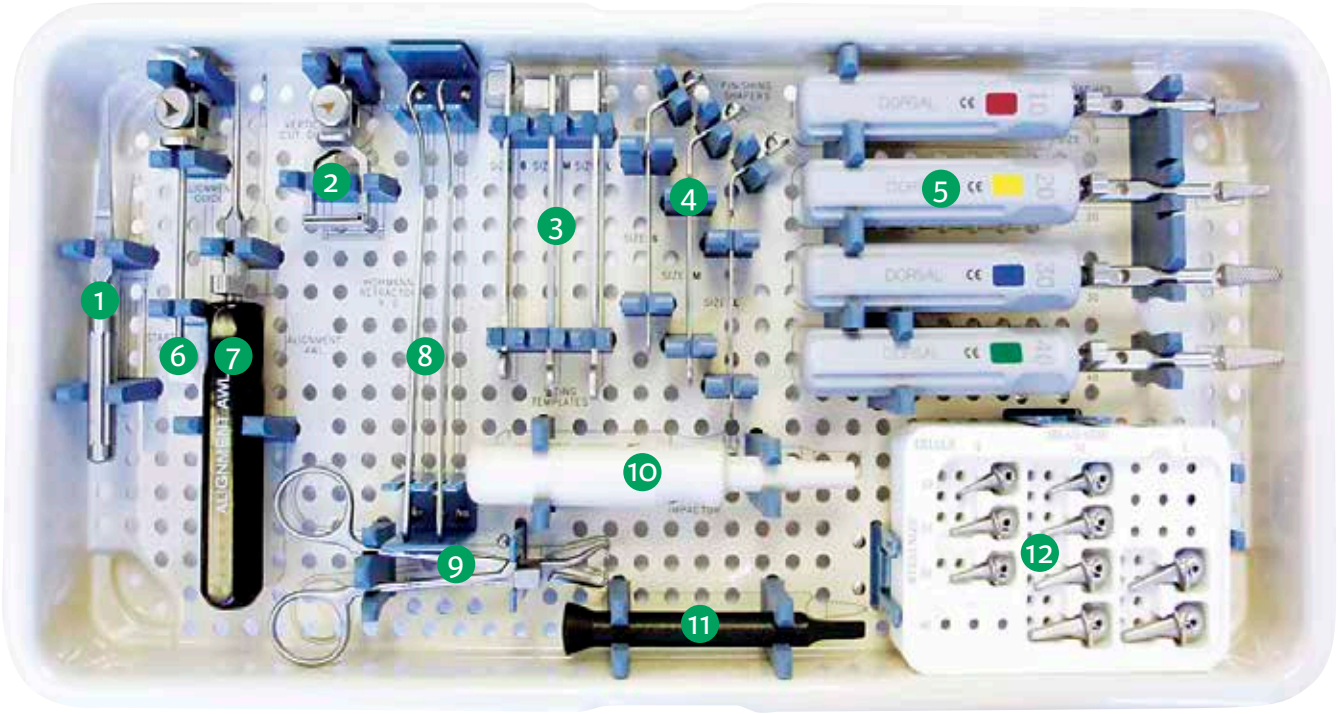
2 Days Postoperatively
Place the patient in a cast with the IP of the thumb free, the proximal phalanx flexed, and the metacarpal fully abducted – palmarly and radially.

2 Weeks Postoperatively
Change the cast after X-ray confirms proper positioning of implant, sutures are removed, and a new cast is applied at 2 weeks postoperatively.

4-6 Weeks Postoperatively
Place the patient in a removable splint in the same position (full CMC abduction and slight MP flexion).
Instruct the patient in active-only radial and palmar abduction and adduction exercises. These exercises are performed 4-5 times daily for 10 repetitions out of the splint. The splint is otherwise worn fulltime, except for showers. There should be no gripping with the thumb while out of splint.

8-10 Weeks Postoperatively
Remove the splint and instruct the patient to gradually increase to normal activities over the next 6 weeks, after which full activities may be performed. No further formal exercises are performed and full normal use of the thumb is encouraged.

Instrumentation

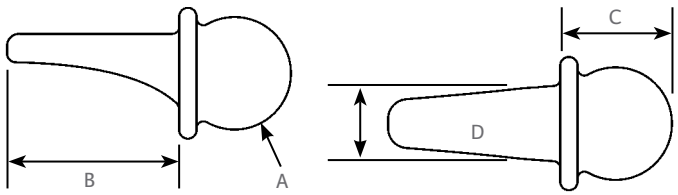


1. Starter Awl
2. Vertical Cut Guide
3. Sizing Templates
4. Finishing Shapers
5. Cutting Broaches
6. Alignment Guide
7. Alignment Awl
8. Hohmann Retractors
9. Trial Extractor
10. Implant Impactor
11. Implant Extractor
12. Metal Trials

Integra®
NuGrip™ CMC Implant

NuGrip CMC Implants

Catalog Number	Description
NUG-443-10S	NuGrip CMC Implant, Size 10-S
NUG-443-10M	NuGrip CMC Implant, Size 10-M
NUG-443-20S	NuGrip CMC Implant, Size 20-S
NUG-443-20M	NuGrip CMC Implant, Size 20-M
NUG-443-30S	NuGrip CMC Implant, Size 30-S
NUG-443-30M	NuGrip CMC Implant, Size 30-M
NUG-443-30L	NuGrip CMC Implant, Size 30-L
NUG-443-40M	NuGrip CMC Implant, Size 40-M
NUG-443-40L	NuGrip CMC Implant, Size 40-L



NuGrip Dimensions (in mm)

SIZE	A	B	C	D
10-S	10.2	15.7	10.1	7.3
10-M	11.6	15.7	11.8	7.3
20-S	10.2	17.3	10.1	8.0
20-M	11.6	17.3	11.8	8.0
30-S	10.2	20.2	10.1	8.9
30-M	11.6	20.2	11.8	8.9
30-L	13.2	20.2	13.1	8.9
40-M	11.6	21.8	11.8	9.9
40-L	13.2	21.8	13.1	9.9

A = Head diameter
B = Length of stem
C = Length from collar to tip of head
D = Width of stem in dorsal view

NuGrip CMC Instrumentation

Catalog Number	Description
INS-443-00	NuGrip Instrument Set
AWL-100-01	Starter Awl
AWL-200-00	Alignment Awl
ALG-100-00	Alignment Guide
OSG-442-00	Vertical Cut Guide
TMP-443-S	Sizing Template, Size S
TMP-443-M	Sizing Template, Size M
TMP-443-L	Sizing Template, Size L
BRH-442-10	Broach, Size 10
BRH-442-20	Broach, Size 20
BRH-442-30	Broach, Size 30
BRH-442-40	Broach, Size 40
TRL-443-10S	Trial, Size 10-S
TRL-443-10M	Trial, Size 10-M
TRL-443-20S	Trial, Size 20-S
TRL-443-20M	Trial, Size 20-M
TRL-443-30S	Trial, Size 30-S
TRL-443-30M	Trial, Size 30-M
TRL-443-30L	Trial, Size 30-L
TRL-443-40M	Trial, Size 40-M
TRL-443-40L	Trial, Size 40-L
IMP-442-00	Impactor
EXT-200-00	Trial Extractor
EXT-100-01	Implant Extractor
SHP-443-S	Finishing Shaper, Size S
SHP-443-M	Finishing Shaper, Size M
SHP-443-L	Finishing Shaper, Size L
RET-443-00	Hohmann Retractor

CMC Disposable Packs

Catalog Number	Description
CMC-DIS-STR	CMC Disposable Pack, Stryker
CMC-DIS-HAL	CMC Disposable Pack, Linvatec/Hall

Single Use Axial Cannulated Cutters:

Catalog Number	Description
CNS-NCUT-INSTR	Cannulated Cutter Set
CUT-443-S	Axial Cannulated Cutter, Size S
CUT-443-M	Axial Cannulated Cutter, Size M
CUT-443-L	Axial Cannulated Cutter, Size L

References

1. Cook SD, Klawitter JJ, Weinstein AM. The influence of implant elastic modulus on the stress distribution around LTI carbon and aluminum oxide dental implants. J Biomed Mater Res 1981;15:879-887.
2. Strzepa P, Klawitter JJ, Ascension PyroCarbon Hemisphere Wear Testing Against Bone, Poster No. 0897, 51st Annual Meeting of the Orthopedic Research Society.

For more information or to place an order, please contact:
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