

SURGICAL TECHNIQUE GUIDE
STABLYX[®]
cmc arthroplasty system



 **skeletal dynamics[®]**
UNDERSTANDING THE UPPER EXTREMITY

As described by:
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STABLYX[®]

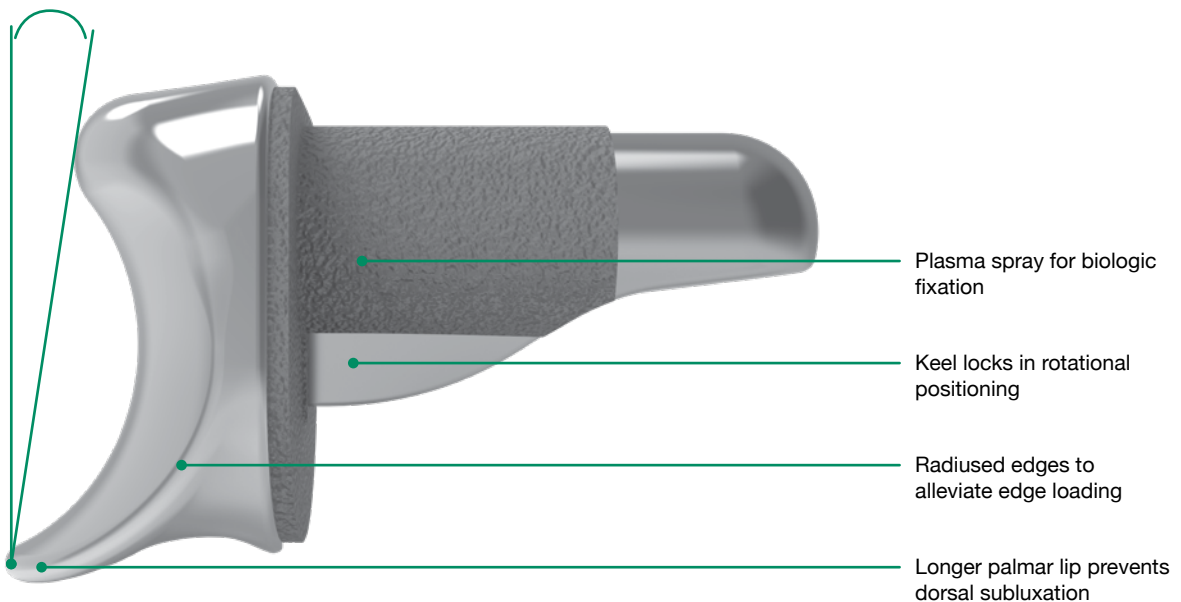
cmc arthroplasty system

Indications for Use

The STABLYX[®] CMC Arthroplasty System is intended to replace the base of the first metacarpal in cases of rheumatoid arthritis, traumatic arthritis, osteoarthritis or post fracture deformation of bone loss that present as either a painful, unstable thumb, or a thumb with limited range of motion. This implant is intended for noncemented, press fit use.

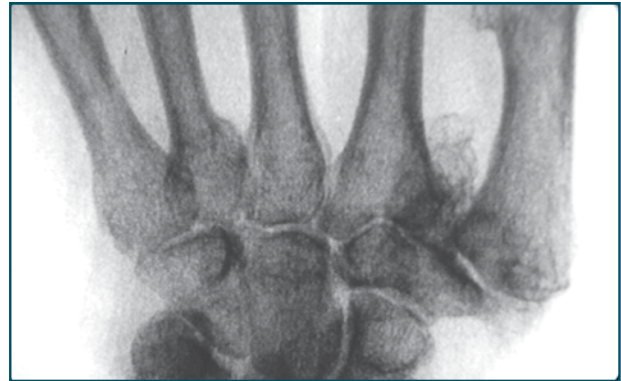
Please refer to the STABLYX[®] Instructions for Use to review the warnings, precautions and contraindications for this system.

30° redirected surface
to support joint reaction force



1

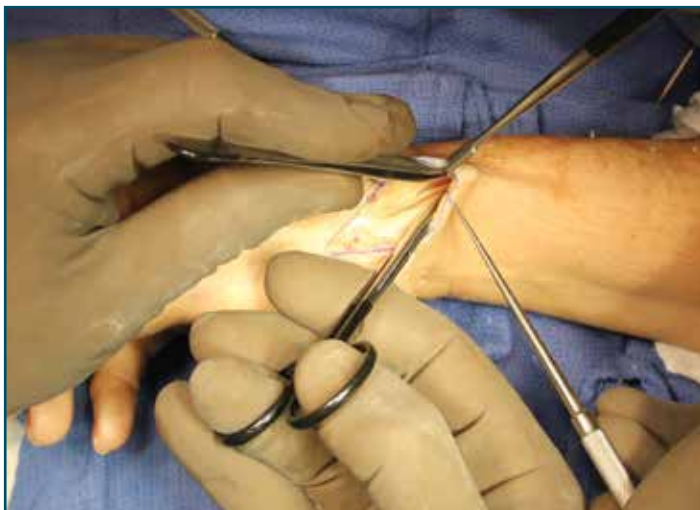
EXPOSURE



Make a 4cm incision centered over the carpometacarpal (CMC) joint along the course of the extensor pollicis brevis (EPB) tendon.

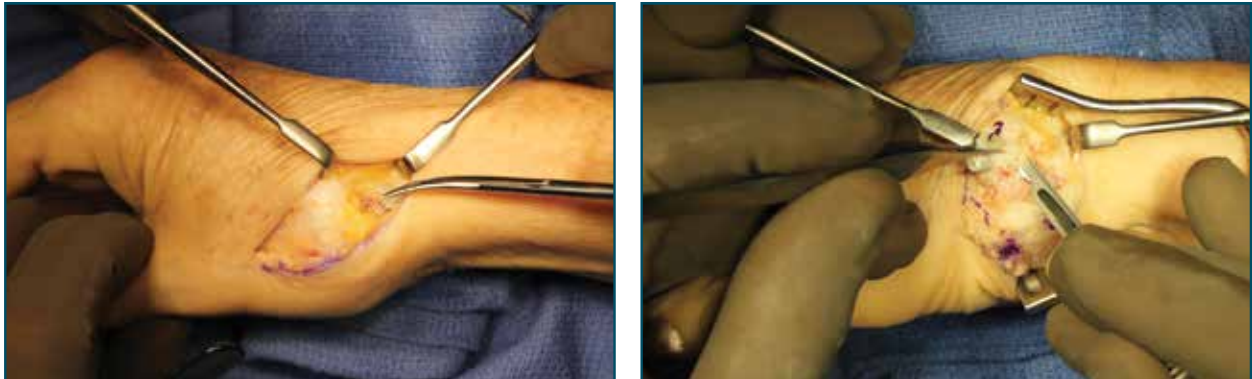
2

EPB TENDON RELEASE



Dissect to expose and release the EPB tendon proximal up to the 1st compartment and distal, then retract it ulnarly.

Be sure to protect the radial artery, as well as the lateral and dorsal branches of the radial nerve.



The blood supply to the trapezium originates from a small branch of the radial artery that courses over the proximal aspect of the trapezium. To avoid devascularization of the trapezium, limit the proximal release of the capsular flap just to expose the dorsal osteophytes.

Now mark the flap and elevate it as a proximally based flap and releasing the dorsal ligaments.

Caution:

Avoid a longitudinal capsulotomy, as it is more likely to devascularize the trapezium.

Partially release the proximal insertion of the abductor pollicis longus (APL) tendon to allow full access to the base of the metacarpal.

Note:

The STABLYX® Bone Holding Forceps secured to the metacarpal provide added leverage.



FRCP-BHS-RTC: Bone Holding Forceps

5

METACARPAL RESECTION



Using a sterile pen, mark a longitudinal line on the dorsal aspect of the metacarpal to aid in referencing a perpendicular base cut.

Select any Trapezial Sizer and position its shaft proximal and perpendicular to the previously marked longitudinal line. Now mark the distal edge of the sizer to establish the resection level.

Resect the base of the metacarpal confirming that the cut is perpendicular to the metacarpal axis.



STX-SZX: Trapezial Sizer, Sz. X

6

ACCESSING THE VOLAR CAPSULE



Expose the joint to remove excessive synovium.

Resect osteophytes from the metacarpal and the dorsal aspect of the trapezium.

LOCATING PALMAR OSTEOPHYTE

7



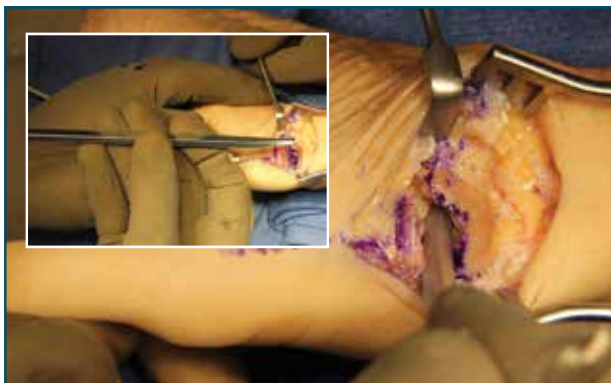
A palmar osteophyte on the trapezium prevents joint reduction in osteoarthritic patients. Using a sterile pen, mark the offending palmar and surrounding osteophytes. Use the tip of the Capsular Elevator to locate the FCR tunnel. Now release the volar capsule from the trapezium to isolate the palmar osteophyte.



STX-VCE: Capsular Elevator

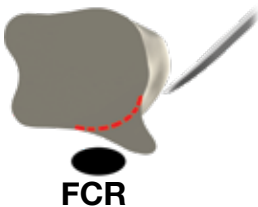
REMOVAL OF PALMAR OSTEOPHYTE

8



The FCR tendon is found beneath the palmar osteophyte.

Using the Curved Osteotome, first score the border of the palmar osteophyte, and then impact it from side to side in an attempt to remove the osteophyte in one piece.



OST-CRV: Curved Osteotome

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FCR TENDON RELEASE



Mobilize the FCR tendon away from the trapezium.

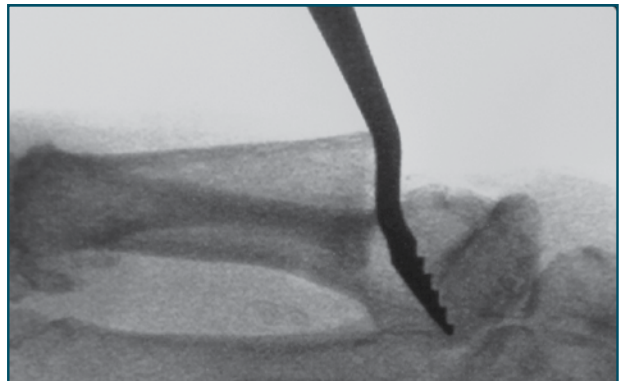
Fully release the FCR tendon as close to the base of the second metacarpal as possible. This minimizes post operative irritation.

Note:

The proximal attachment point at the ridge of the trapezium decreases the chance for the FCR tendon to retract.

10

TRAPEZIOPLASTY (Initial Shaping)



Insert the Trapezial Rasp between the FCR tendon and the trapezium.

Rasp the central palmar aspect of the trapezium into a saddle shape while taking care not to damage the articular surface.

The Capsular Elevator can be used as a probe to confirm that the palmar osteophyte has been removed.



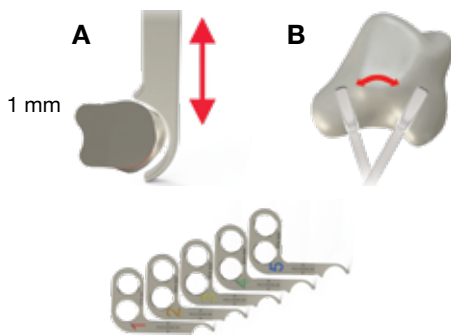
STX-VOR: Osteophyte Rasp

TRAPEZIAL SIZING 11

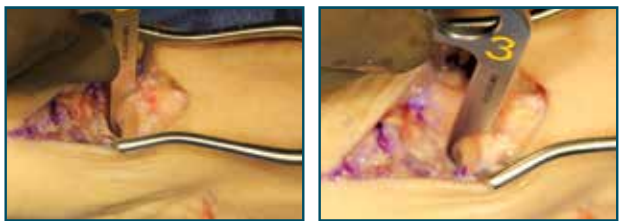
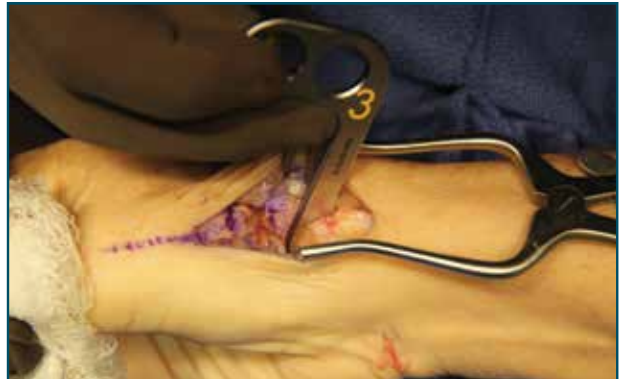
Determine the size of the trapezium by positioning the Trapezial Sizing Tool over the midpoint of the trapezium.

The correct sizing is achieved when the Trapezial Sizing Tool:

- A. Loosely fits to allow 1mm of translation in the AP direction
- B. Can fit across the width of the trapezium



STX-SZX: Trapezial Sizer, Sz. X



TRAPEZIOPLASTY (Trapezial Finishing) 12

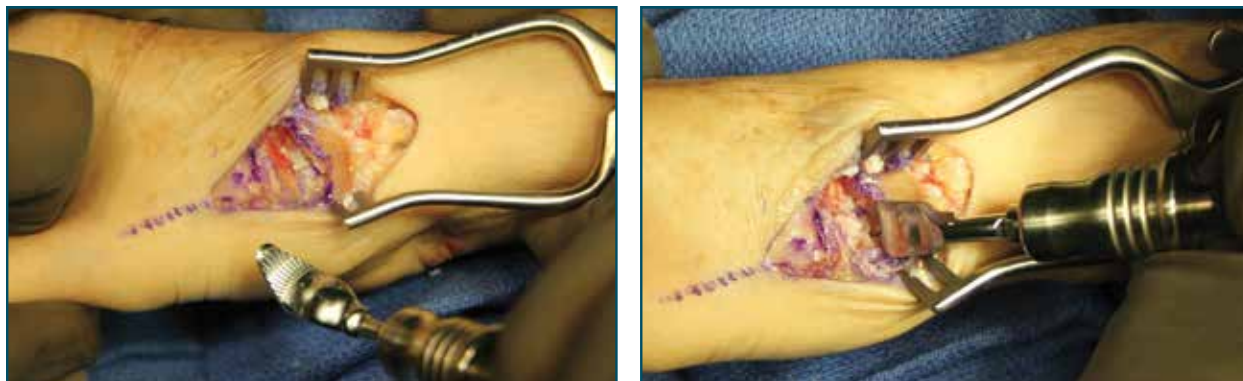


Insert the appropriately sized trapezial finishing tool between the FCR tendon and trapezium. Move the instrument repeatedly, both up-and-down and side-to-side, in order to identify and remove any remaining bone impeding a smooth saddle shape.



STX-TPX: Trapezial Finishing Tool, Sz. X

13 TRAPEZIOPLASTY (Undersurface Contouring)



Insert the Trapezial Contouring Tool between the FCR tendon and the trapezium. Confirm that only the smooth surface of the tool contacts the articular surface of the trapezium.

Complete the final contouring of the trapezium into a smooth saddle shape using an oscillating rotary motion.



STX-TC1: Trapezial Contouring Tool

14 SURROUNDING OSTEOPHYTE REMOVAL



If the final Trapezial Sizer does not translate smoothly across the width of the trapezium, remove any remaining offending dorsal, medial or lateral osteophytes.

IDENTIFYING THE METACARPAL CANAL

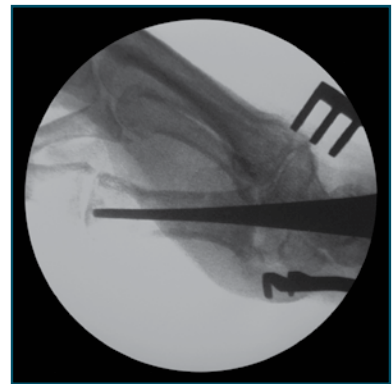
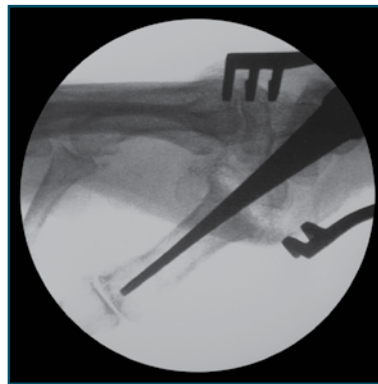
15

Using the Straight Awl, locate and mark the entry point for the metacarpal canal.

Confirm the proper entry point and trajectory of the canal in both the AP and ML planes using fluoroscopy.



AWL-STR-020: Awl, Straight, 2mm



METACARPAL CANAL PREPARATION

16

The system includes five Metacarpal Rasps that correspond to each of the Trapezial Sizing Tools.

Insert the rasps sequentially to the etched depth mark as you attempt to rasp up to the corresponding Trapezial Sizing Tool used in Step 11.

If unable to rasp to the corresponding Trapezial Sizer, additional trapezioplasty may be required.

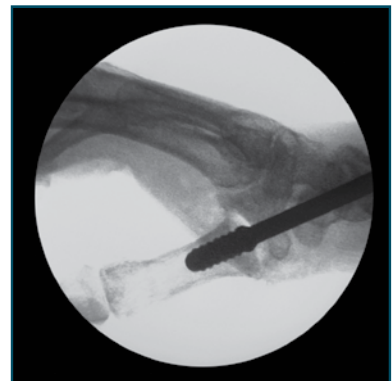
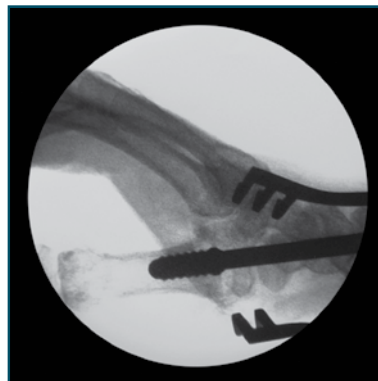
If necessary, prepare the resected end of the metacarpal using the Metacarpal Planar.



STX-MRX: Metacarpal Rasp, Sz. X



STX-MP1: Metacarpal Planar



17 TRIAL VALIDATION



Insert the Trial prosthesis that corresponds to the final Metacarpal Rasp into the canal.

When reducing the CMC joint, be sure to avoid injury to the articular surface of the trapezium by using the shoehorn function on the back of the Capsular Elevator.

Confirm that the proper clearance for the volar lip has been achieved by placing the thumb in full opposition and observing that hinging of the CMC joint does not occur.

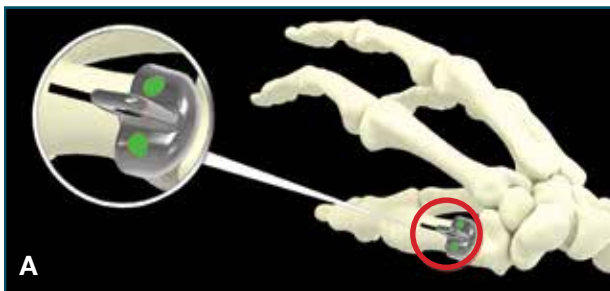


STX-VCE: Capsular Elevator



STX-TSX: CMC Trial, Sz. X

18 ESTABLISHING METACARPAL ROTATION

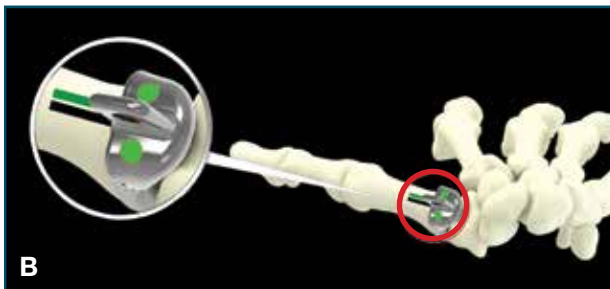


A

To establish the correct rotational alignment of the metacarpal:

A. Oppose the thumb to the small finger while applying some axial loading, and then mark the location of the tab on the metacarpal.

B. Now place the thumb in full radial abduction while applying axial loading and mark the location of the tab on the metacarpal.



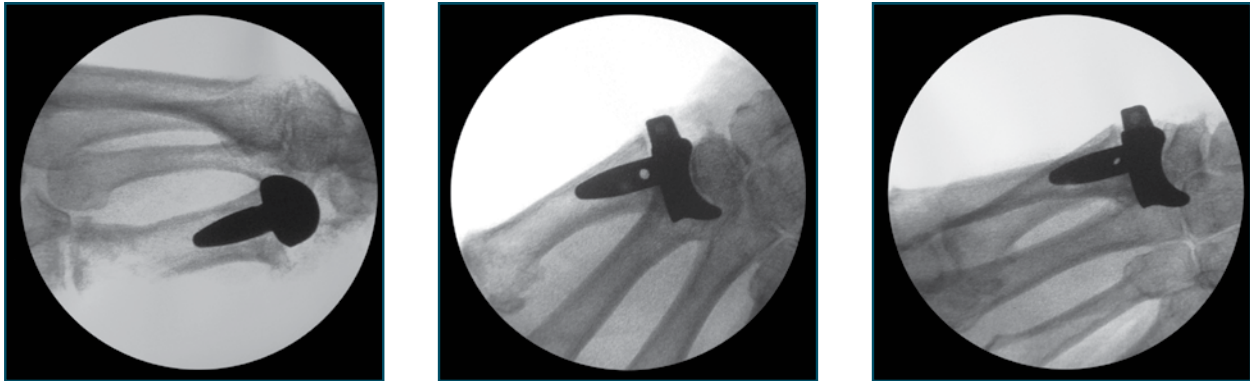
B

These steps help to identify the rotational midpoint of the metacarpal.

Note:

If there is a substantial gap between the two marks due to a shift in rotation of the Trial prosthesis, reassess the trapezium for dorsal osteophytes.

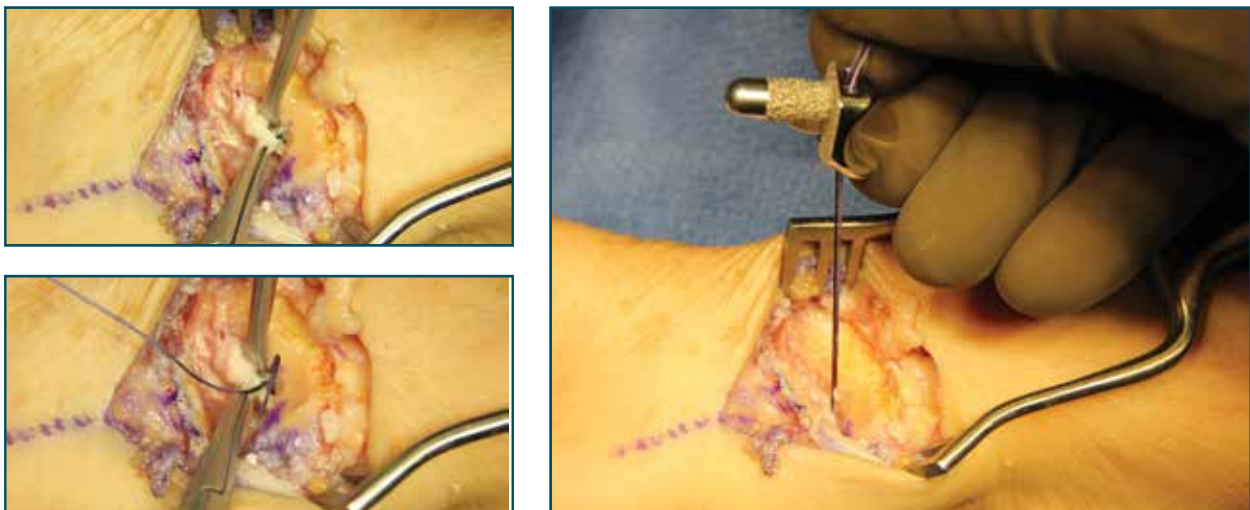
TRIAL CONFIRMATION 19



Using fluoroscopy, articulate the joint through its full range of motion to confirm proper alignment and kinematics.

Also confirm that all offending osteophytes have been removed and that proper clearance for the palmar lip of the Trial prosthesis has been achieved.

OPTIONAL SUTURE ATTACHMENT 20

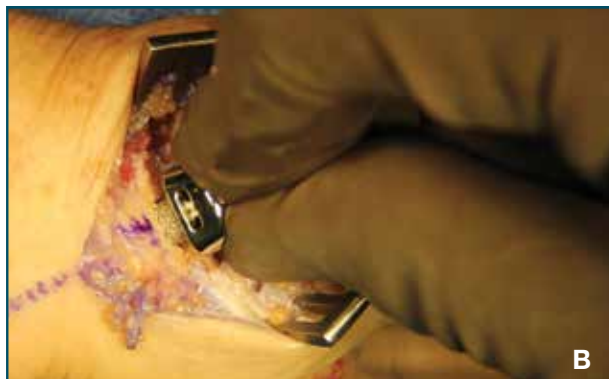


For cases where the FCR tendon interposes during abduction, or when severe laxity of the CMC joint is evident, the STABLYX® prosthesis includes suture holes for attachment to the FCR tendon. Using the Suture Passer, pierce the FCR tendon at the midpoint of the trapezial width. Load an absorbable suture into the jaw of the Suture Passer leaving even lengths of suture at both ends. Pass each lead of the suture through the corresponding hole of the final prosthesis.



STX-CMA-STP: Suture Passer

21 ROTATIONAL ALIGNMENT



The rotational alignment of the prosthesis should correspond to the previously marked rotational midpoint on the metacarpal.

A. Align the etched mark located on the dorsal side of the prosthesis to the marked rotational midpoint on the metacarpal.

B. Now insert the prosthesis until the keel firmly engages cancellous bone.

22 PROSTHETIC SEATING



Use the Impactor to fully seat the prosthesis.

Confirm that the prosthesis is fully seated before reducing the CMC joint.

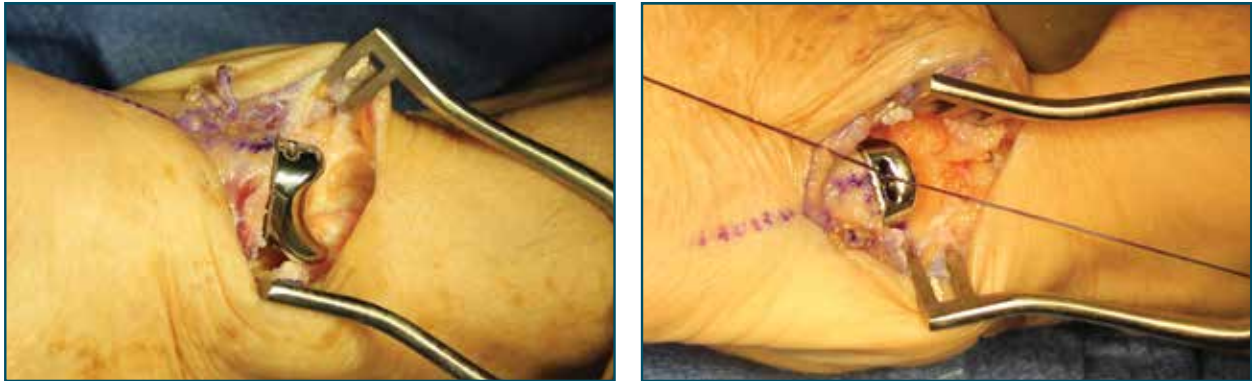
Note:

If using the optional suture attachment points of the prosthesis, be sure to keep the suture lines taut prior to seating the prosthesis and after reducing the CMC joint.



STX-CMA-IMP: CMC Impactor

JOINT REDUCTION 23



Reduce the CMC joint while protecting the trapezium using the shoehorn function of the Capsular Elevator. Confirm that the FCR tendon is not interposed within the CMC joint.

Note:

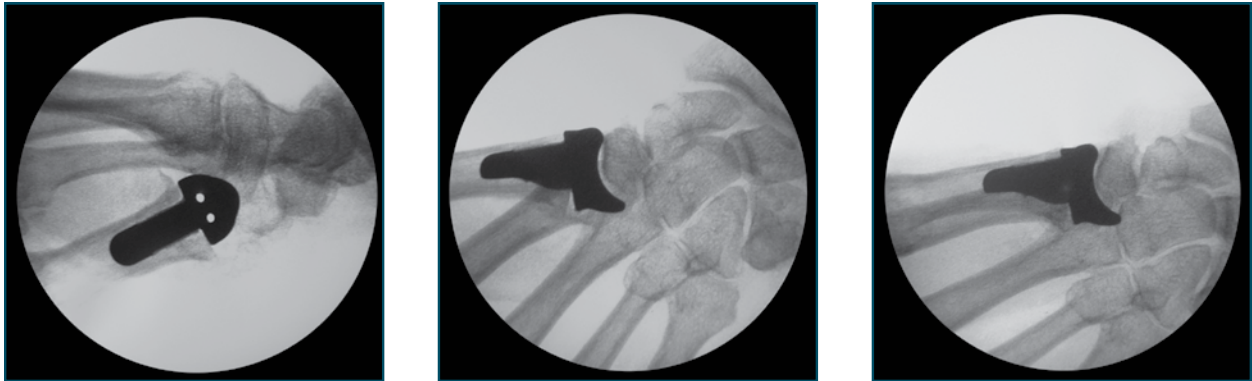
If using the optional suture attachment points, tie the suture over the prosthesis creating a suspensionplasty.

IMPLANT VALIDATION 24

Manipulate the joint through its full range of motion to confirm implant stability and proper kinematics.



25 FINAL CONFIRMATION



Confirm proper implant placement through the full range of motion using fluoroscopic imaging.

26 WOUND CLOSURE

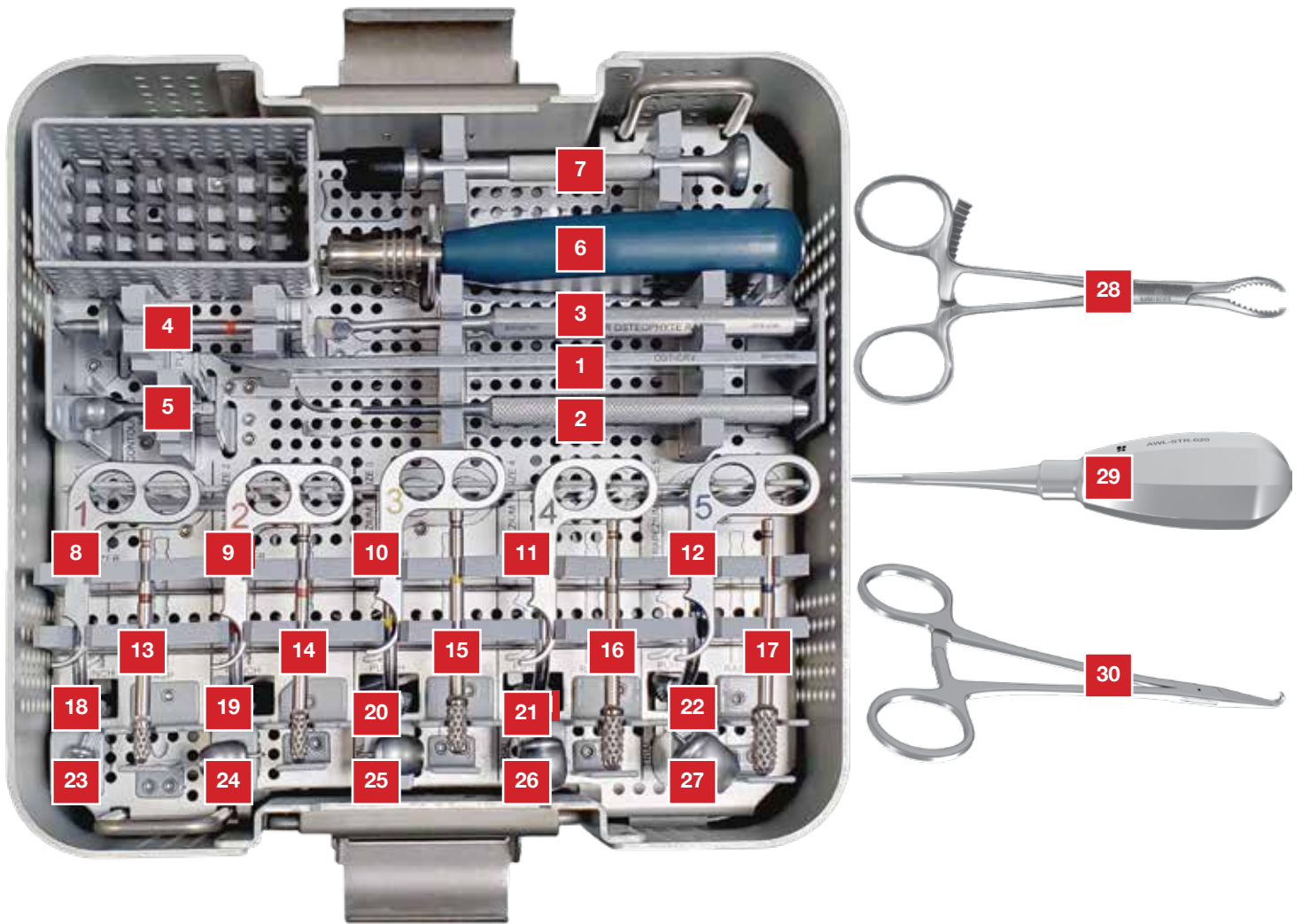


Suture back the proximal based capsular flap to the APL tendon, and then close the incision in your usual fashion.

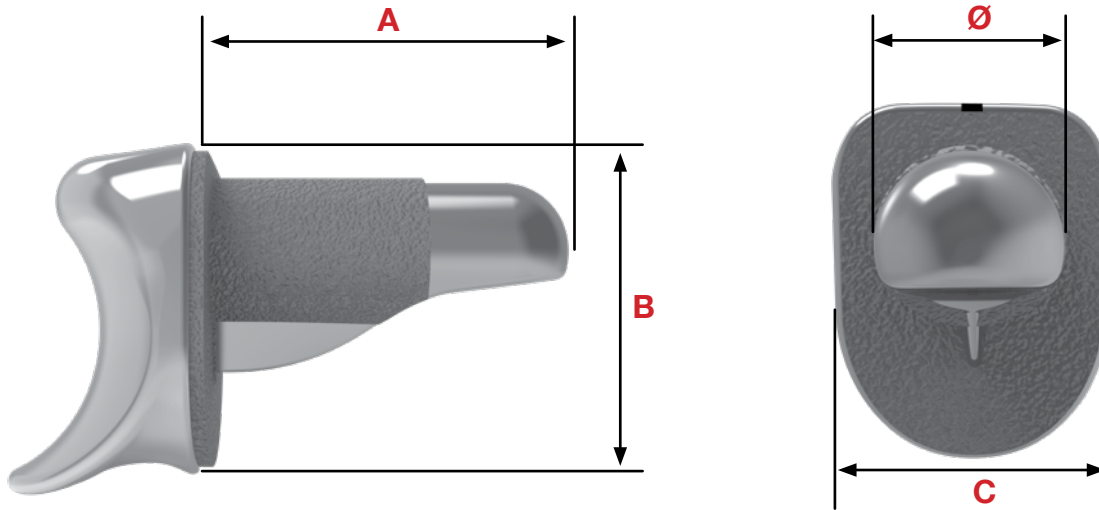
Support the thumb in a splint for three to six weeks, and then allow functional use.



STABLYX® CMC Tray - Standard Set Configuration



Loc #	Catalog #	Description	Loc #	Catalog #	Description
1	OST-CRV	Curved Osteotome	18	STX-TP1	Trapezial Finishing Tool, Sz. 1
2	STX-VCE	Capsular Elevator	19	STX-TP2	Trapezial Finishing Tool, Sz. 2
3	STX-VOR	Osteophyte Rasp	20	STX-TP3	Trapezial Finishing Tool, Sz. 3
4	STX-MP1	Metacarpal Planar	21	STX-TP4	Trapezial Finishing Tool, Sz. 4
5	STX-TC1	Trapezial Contouring Tool	22	STX-TP5	Trapezial Finishing Tool, Sz. 5
6	HNDL-UQC-FXD	Quick Connect Handle	23	STX-TS1	CMC Trial, Sz. 1
7	STX-CMA-IMP	CMC Impactor	24	STX-TS2	CMC Trial, Sz. 2
8	STX-SZ1	Trapezial Sizer, Sz. 1	25	STX-TS3	CMC Trial, Sz. 3
9	STX-SZ2	Trapezial Sizer, Sz. 2	26	STX-TS4	CMC Trial, Sz. 4
10	STX-SZ3	Trapezial Sizer, Sz. 3	27	STX-TS5	CMC Trial, Sz. 5
11	STX-SZ4	Trapezial Sizer, Sz. 4	28	FRCP-BHS-RTC	Bone Holding Forceps
12	STX-SZ5	Trapezial Sizer, Sz. 5	29	AWL-STR-020	Awl, Straight, 2mm
13	STX-MR1	Metacarpal Rasp, Sz. 1	30	STX-CMA-STP	Suture Passer
14	STX-MR2	Metacarpal Rasp, Sz. 2			
15	STX-MR3	Metacarpal Rasp, Sz. 3			
16	STX-MR4	Metacarpal Rasp, Sz. 4			
17	STX-MR5	Metacarpal Rasp, Sz. 5			



Catalog #	Description	Dimensions (mm)			
		A	B	C	Ø
STX-IS1	STABLYX, CMC Arthroplasty Implant, Sz. 1	11.68	13.23	10.01	5.38
STX-IS2	STABLYX, CMC Arthroplasty Implant, Sz. 2	13.44	13.84	11.33	5.99
STX-IS3	STABLYX, CMC Arthroplasty Implant, Sz. 3	15.19	14.88	12.70	6.58
STX-IS4	STABLYX, CMC Arthroplasty Implant, Sz. 4	16.92	15.98	13.94	7.21
STX-IS5	STABLYX, CMC Arthroplasty Implant, Sz. 5	18.67	17.02	15.24	7.85



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