IMPORTANT INFORMATION regarding:

TOUCH® CMC 1 PROSTHESIS

KERI MEDICAL SA
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CAUTION: U.S. Federal law restricts CMC prosthesis to sale by or on the order of a licensed practitioner

1 – INTRODUCTION

These instructions for use apply to TOUCH® CMC 1 Prosthesis manufactured by KERI MEDICAL SA.

Note: "CMC 1" or "CMC" is the abbreviation for "1st Carpo-Metacarpal". Trapezo-Metacarpal ("TMC") can also be used to define the treated joint.

Device Description

TOUCH® CMC 1 Prosthesis is a cementless, ball-and-socket dual-mobility, total CMC 1 (1st Carpo-metacarpal) joint replacement prosthesis made of:
- a metacarpal implant (stem), available in 6 sizes (XS, 0, 1, 2, 3, 4)
- a trapezial implant (cup), available in 2 variants (spherical and conical) and 2 sizes per variant (Ø9mm and Ø10mm)
- a junction implant (neck) topped with a liner, available in 2 variants (straight and 15°offset) and 3 lengths per variant (S-6mm, M-8mm and L-10mm)

All sizes and variants are compatible in dimensions and can be associated without restrictions.
Refer to external labelling to identify the component size and/or variant.
TOUCH® CMC 1 Prosthesis is non-absorbable and is intended for single use only.

How it's supplied

TOUCH® CMC 1 Prosthesis components are supplied in sterile state, individually packaged in a double sterile barrier (primary packaging) placed in a unit box (secondary packaging).

Target population

Any type of population requiring a surgical procedure covered by the device indications and contraindications.

TOUCH® CMC 1 Prosthesis is intended to treat adults with symptomatic Eaton-Littler Stage II or III thumb carpometacarpal osteoarthritis who have failed non-conservative treatment.

TOUCH® CMC 1 Prosthesis is *not* intended to treat pediatric patients (<22 years of age) or pregnant or nursing women.

Expected Medical benefits

- Decrease of pain
- Reduction of functional disability

2 – INDICATION FOR USE

TOUCH® CMC 1 Prosthesis is intended for 1st carpometacarpal (CMC) primary total joint replacement (arthroplasty) in patients with symptomatic Eaton-Littler Stage II or III osteoarthritis (OA).

3 – CONTRAINDICATIONS

- Acute or chronic infections, local or systemic.
- Muscular, neurological, or vascular severe deficiency affecting the joint.
- Inadequate bone quality or quantity preventing the implant fixation*
- Bones dimensions incompatible with implant sizes.
- Patients who are allergic to the product's materials.
- Any concomitant disorder that may affect the function of the implant.

*Note: in many cases, a plain radiograph is sufficient to evaluate bone quality, however, in certain cases a computerized tomography (CT) scan may be necessary.

4 – WARNINGS AND PRECAUTIONS

Related to CMC 1 joint arthroplasty surgery:

- Implantation of these medical devices should be performed by a surgeon who understands all aspects of the surgical procedure and requires the use of the dedicated instrumentation in an aseptic environment such as an operative room.
- Inspect the sterile packaging for punctures or other damages prior to use. Any damage to the packaging may compromise the sterility of its content. Do not use if USE BY date has expired.
- Remove the implant from its packaging using an aseptic technique to limit infection risk.
- Use extreme care in handling of implants and protect them from being marked, nicked, or notched to ensure its technical performances. Do not use a damaged implant.
- The implantable components are for single use only; never reuse an implant, even though it may appear undamaged. Reuse and/or resterilization of implant is strictly forbidden because of the chemical and biological risks (infection, contamination, toxicity, allergy) and mechanical risks (implant deterioration and wear).
- Cup centering and orientation shall be one of the major concerns to avoid intra-prosthetic conflicts and limit migration or loosening risks. Particular attention must be taken regarding sufficient bone stock and bone quality surrounding the cup. Optimal location, orientation, size, depth, shape of bone preparation must be achieved according to local anatomy and surgeon judgment. Pay attention to respect the cup orientation at the impaction step.
- Do not oversize the implants and favor progressive impaction to limit the risk of per-operative fracture.
- To reduce the risk of fracture, avoid compression of reamed (empty) metacarpal bone prior to device implantation.
- Do not use bone cement for implants fixation.
- Carefully wash implantation site before implantation to remove debris which may compromise implantation or generate soft tissue calcification. Dry taper connection and remove bone debris from prosthetic articular surfaces to limit the risk of decreased mechanical performances.
- Do not use stainless steel cup and neck versions on patients who have chromium and/or nickel allergies (non-exhaustive, refer to "MATERIALS").
- Handle the implanted thumb with care immediately after surgery. Do not lift the hand by the thumb.

Precaution related to patients:

Safety and effectiveness in pregnant or nursing women and pediatric patients (age < 22 years) have not been established.

The following risk factors, individually or together, may result in poor clinical outcomes:
- Strenuous physical activities (e.g., active sports, heavy physical work, strong vibrations)
- Muscle deficiencies
- Multiple joint disabilities such as scaphotrapeziotrapezoidal OA
- Additional or alternative OA diagnosis
- Refusal to follow postoperative care instructions
- Patient history of infections or falls
- Patient using crutches or a walking stick
- Systemic diseases and metabolic disorders (e.g., diabetes)
- Local or disseminated neoplastic diseases
- Drug therapies that adversely affect bone quality, healing, or resistance to infection
- Drug dependency or abuse, including excessive alcohol consumption and smoking
- Severe osteoporosis, osteomalacia or osteopenia
- Bone cyst in trapezium or metacarpal bone
- Severe deformities
- Patient's resistance to disease generally weakened (e.g., HIV, tumor, infections)
- Obesity

5- LIMITATION OF THE DEVICE

- Do not use the product for cases where a nearby joint has undergone arthrodesis or hardware is present that may compromise implantation.
- DO NOT mix implant components from different manufacturers for metallurgical, biomechanical, and functional reasons.
- Only use the dedicated instrumentation.
- DO NOT use for surgical procedures other than those mentioned in "Intended Use". Off-label use increases the risk of functional limitation, reduced lifetime, and mechanical failures. Implants have not been designed nor evaluated for revision surgeries. KERI MEDICAL SA cannot be liable of any responsibility in case of off-label use.

6 – INFORMATION FOR USE

Preoperative phase

The surgeon should discuss all physical and mental limitations particular to the patient, see section 7, and all aspects of the surgery and the prostheses with the patient before surgery. The discussion should include the limitations and possible consequences of joint replacement, and the necessity to follow the surgeon's instructions postoperatively, particularly in regard to patient activity. Pathologies associated with CMC1 joint arthroplasty surgery, such as carpal tunnel syndrome, De Quervain's tenosynovitis or trigger thumb, must be considered in the treatment plan. At the time of operation, the appropriate implants and instruments must be available.
The surgeon must receive the proper information about the product and related surgical procedure to ensure its safe and effective use.
The patient must be informed that a second surgery may be necessary due to complications. In certain perioperative or postoperative cases, conversion to trapeziectomy may be required.

Surgical technique

Main steps of the surgical technique are presented below, for more precision refer to the detailed TOUCH® CMC 1 Prosthesis surgical technique (ST_110-32E005):

- Incise the damaged CMC 1 joint,
- Resect the metacarpal head and osteophytes if any to ensure the release of metacarpal base,
- Open the intramedullary canal of the metacarpal bone and shape it to receive the metacarpal stem using the dedicated instruments (awl, raps) paying attention to the dorsal face identification and the preservation of a cancellous bone layer,
- Place the stem pattern in the metacarpal bone (gap filler),
- Properly identify the cup implantation site and place a K-wire at the desired location. It is recommended to perform X-ray control at this stage to confirm proper centering and orientation,
- Prepare the trapezium bone using first the starter and then the reamer of the chosen shape and size,
- Clean the implantation site and insert the chosen Cup and Stem implant (after pattern removal, paying attention to dorsal side),
- Control joint tension and motion; prevent a cam effect by choosing appropriate neck implants using the provided neck patterns (trials). If necessary, adjust bone resection.
- Check for stem taper cleanliness (e.g., debris) before impaction of the final neck
- Impact the final neck, and reduce the joint
- Closure and dressing.

7 – PATIENT INFORMATION

The patient must receive an individual Implant Card completed with the device traceability information. This implant card is provided in neck component box and patients label included in each individual packaging must be stuck on this card to ensure traceability.

The patient must be informed by the surgeon of the risks and the potential adverse events and complications related to the implantation of TOUCH® CMC 1 Prosthesis.

The patient has to be aware that regular follow-up by a hand surgeon may allow for early detection of prosthesis failure before any functional changes are apparent.

Prior to and after TOUCH CMC 1 Prosthesis implantation, the following information should be shared with the patient:

- The patient should be informed about the importance of following the prescribed postoperative rehabilitation in order to optimize outcomes and to avoid excessive activities that may damage the implant. The patient must be warned that failure to follow postoperative care instructions may cause the prosthesis or treatment to fail.
- The device is not designed to withstand the stress of weight bearing, excessive load bearing, or excessive physical activity. Device loosening, premature mechanical failure, bone or soft tissue injury may occur when the implant is subjected to excessive loading.
- Potential construct failures such as stress fractures of the bones, loosening of the construct and/or fixation, subsidence, soft tissue irritation, or incomplete healing may occur as a result of patient non-compliance to post operative rehabilitation, excessive activities or construct overloading.
- Never intentionally do movements which could lead to the prosthesis dislocation,
- Consult the surgeon in the event of a fall, injury, infection, hand pain, or change in thumb function,
- Never do intramuscular injection near (on the side of) the prosthesis
- During any treatment (e.g., injection) or investigation (e.g., MRI, CT-Scan & X-Rays) affecting the treated hand, the patient must inform the practitioner about having received an artificial joint.

The patient must be cautioned, preferably in writing, about the use, limitations and possible adverse effects of this device including the possibility of device or treatment failure as a result of loose fixation,

loosening, stress, excess activity, or weight bearing or excessive load bearing, and the possibility of nerve or soft tissue damage related to either surgical trauma or the presence of the device.

8 – PROBABLE ADVERSE EFFECTS

Contact KERI MEDICAL SA in case of adverse effect: uscomplaints@kerimedical.com
Patient should be informed about inherent limits and risks due to the prosthesis. Some complications can lead to a re-operation.
In rare cases, the following adverse effects can appear after prosthesis implantation.

Related to any CMC1 joint arthroplasty device:

- Allergic reaction
- Metallosis
- Osteolysis (Osseous resorption)
- Per-operative or post-operative fractures
- Calcification / Ossification
- Prosthetic components migration
- Prosthetic components loosening or unsealing
- Mechanical complications: implant breakage, disassembly or deformation, premature wear, intra-prosthetic conflicts, dislocation
- Functional complications: reduced range of motion, joint stiffness, painful limitations, joint instability

Related to CMC1 joint arthroplasty surgery:

- Early and/or late infection
- Hematoma
- Pain
- De Quervain Tenosynovitis, tendonitis
- Trigger Thumb
- Inflammatory or allergic reaction
- Surrounding soft tissues damages
- Neurological complications, Dysesthesia (decreased sensitivity)
- Acute (<3 months) complex regional pain syndrome (CRPS)

9 – POTENTIAL ADVERSE EFFECTS

Related to CMC1 joint arthroplasty surgery:

- Cutaneous necrosis
- Thrombosis, cardiovascular disorder

10 – PACKAGING AND LABELLING

The TOUCH® CMC 1 Prosthesis components are presented in individual unit packages.
The external box label allows for product identification and traceability during supply, storage and at the point of use.
In the external box, the implants are packaged in a double sterile barrier packaging which bears the internal label for product identification at the point of use.

The external box also contains patients labels and patient card (for neck component only) for end user traceability.

Do not use the devices in case of damaged packaging and/or labelling. Do not use in case of unintentional opening of the packaging before use.
Notify your contact person at KERI MEDICAL SA if this situation arises.

11 – IMPLANTS STERILIZATION

The implants have been sterilized by gamma irradiation.
Re-sterilisation has not been validated and is prohibited. The manufacturer assumes no responsibility for implants being re-sterilized by customers.
Before use, check the expiry date on the external label (as well as packaging integrity) as it ensures the product sterility.

Instruments are provided nonsterile. For cleaning, sterilization, inspection and maintenance, refer to KERI MEDICAL SA instructions for reprocessing 000-21A003.

12 – MATERIALS

- TOUCH® CMC 1 Prosthesis stem is in Titanium alloy TA6V ELI (ISO 5832-3) coated with Titanium T40 (ISO 13179-1) and hydroxyapatite (HAP) (ISO 13779-2).
- TOUCH® CMC 1 Prosthesis cup is in Stainless Steel 1.4472 (ISO 5832-9) and coated with Titanium T40 (ISO 13179-1) and HAP (ISO 13779-2).
- TOUCH® CMC 1 Prosthesis neck is in Stainless Steel 1.4472 (ISO 5832-9)), topped by a liner in cross-linked Polyethylene (UHMWPE (ISO 5834-2)).

13 – HANDLING AND STORAGE

Products should be stored in a dry, clean environment, and protected from direct sunlight.

14 – MAGNETIC RESONANCE (MR) SAFETY INFORMATION

MRI Safety Information

A person with KeriMedical's TOUCH Implant may be safely scanned at 1.5 T or 3 T under the following conditions. Failure to follow these conditions may result in injury.

Parameter	Condition
Device Name	KeriMedical's TOUCH Implant
Static Magnetic Field Strength (B0)	1.5 T and 3 T
MR Scanner Type	Cylindrical
B0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	30 T/m (3,000 G/cm)
Maximum Gradient Slew Rate	200 T/m/s per axis
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	Integrated Whole Body Transmit Coil
Operating Mode	Normal Operating Mode
Whole Body Averaged SAR	Whole Body Averaged SAR ≤ 2 W/kg
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back to back series/scan without breaks).
Image Artifact	The presence of KeriMedical's TOUCH Implant may produce an image artifact of 5.3 cm. Some manipulation of scan parameters may be needed to compensate for the artifact.
Patient Characteristics	The safety of this item during scanning has not been proven if there is another implant within 2 cm.

15 – DISPOSAL

Safely dispose of used products as biological waste, in accordance with local procedures and guidelines. In case of explant investigation, package and label the explants to identify its biological hazard nature before shipping back to KERI MEDICAL SA.

16 – SUMMARY OF CLINICAL EVIDENCE

A. STUDY DESIGN

Keri Medical conducted a prospective, comparative and independent cohort issued from a Swiss study for the investigational device TOUCH® CMC 1 Prosthesis group and a Swiss study for the control group, trapeziectomy with ligament reconstruction and tendon interposition (LRTI), both from the Schulthess Klinik in Switzerland.

The clinical study compared the TOUCH® CMC 1 Prosthesis versus the control treatment of LRTI for the treatment of osteoarthritis of the carpometacarpal (CMC) joint. The study employed a composite clinical success (CCS) primary endpoint evaluated at 24 Months for the treatment group and 12 Months for the control group. The components of the CCS were comprised of three outcomes (pain, function, and safety). The individual components of the primary outcome measures were the Numerical Rating Scale (NRS) for pain during activities, maintenance or improvement in function as measured via key pinch strength, and safety success (freedom from serious device-related or procedure-related adverse events or subsequent surgical interventions (SSI)).

Other secondary outcomes were studied and included: NRS for pain at rest and during activity, key pinch strength, thumb opposition using the Kapandji index, brief Michigan Hand Outcomes Questionnaire (bMHQ) scores, Quality of Life (EQ-5D-5L) scores, EQ-5D-VAS scores, time to return to work, and radiographic evaluation of the TOUCH® CMC 1 Prosthesis.

Baseline differences in the study groups were evaluated using a propensity score (PS) design for the comparison of the two arms of this study. This PS-weighted design is leveraged for comparing the outcomes of the TOUCH® and control groups. FDA noted statistical concerns that the PS-weighted approach may have failed leading to evaluation of non-comparable groups adding uncertainty to the primary study findings.

Study Inclusion/Exclusion Criteria

To be eligible for the study, subjects had to meet all of the inclusion criteria and none of the exclusion criteria:

Inclusion Criteria
1. Adult patient (> 22 years) 2. Surgically treated with a thumb carpometacarpal joint arthroplasty (TOUCH® CMC 1 Prosthesis) or with trapeziectomy and LRTI after conservative treatment failure (splint, one to three steroid injections) 3. Patients with Eaton-Littler Stage II or III osteoarthritis 4. Patients with a Swiss or international health insurance or are being treated at their own expense
Exclusion Criteria
1. No consent for reuse of the data 2. Pregnant women 3. Patients who received the TOUCH® CMC 1 Prosthesis as a revision procedure 4. Patients with contraindications to surgery in general 5. Poor bone quality preventing the implant fixation 6. Any concomitant disorder that may affect the function of the implant (e.g., osteoarthritis of the wrist)

Follow-Up Schedule

Following a baseline visit, treated patients were assessed post-operatively at follow-up visits (6 weeks, 3, 12, 24, months). The primary safety and effectiveness parameters assessed during the follow-up are shown in the table below.

Table 1: Schedule of Visits

	Baseline	Surgery	6 Weeks[1]	3 Months	1 Year	2 Years[1]
Sociodemographic	X					
Diagnosis	X					
Eaton Stage of OA	X					
Surgery detail		X				
Implant detail[1]		X				
Kapandji	X		X	X	X	X
Brief MHQ	X		X	X	X	X
Pain at rest	X		X	X	X	X
Pain during activities	X		X	X	X	X
EQ-5D-5L	X		X	X	X	X
EQ-5D VAS	X		X	X	X	X
Return to work			X	X	X	X
Key pinch	X		X	X	X	X
Radiography	X		X	X[1]	X[1]	X
Adverse event		X	X	X	X	X

[1] *Data only for the TOUCH® group.*
Note: Control subjects returned only for 3-month, and 1-year follow-up visits.

Primary Endpoint

The primary endpoint for this study was developed to measure the safety and effectiveness of the TOUCH® CMC 1 Prosthesis at 24-Months follow-up when compared to the control treatment (LRTI) at 12-Months follow-up. A subject was considered a study success if he/she met all of the following criteria:

- **Improvement in Pain:** a clinically meaningful improvement in pain is defined as a decrease in the NRS pain score (during activities) of ≥30% on a 10-point scale.
- **Maintenance or Improvement in Function:** defined by key pinch strength which is ≥85% of the subject's pre-operative key pinch strength.
- **Safety:** success is defined as freedom from:
    - SSIs (i.e., reoperation, revision, removal, or modification of any study component, or supplemental fixations) on the study carpometacarpal joint, or
    - Serious, device-related or procedure-related adverse events.

Secondary Endpoints

- Pain (NRS) at rest and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- Pain (NRS) during activities and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- Key pinch (kg) using a pinch gauge and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- Thumb opposition: Kapandji index and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- Hand function: brief Michigan Hand Outcomes Questionnaire (bMHQ) and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- Quality of Life: EQ-5D-5L and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- EQ-5D VAS and changes from baseline to 6 weeks, 3 months, 1 and 2 years
- Return to work (days)
- Individual components of the primary endpoint, including need for revision surgery
- Radiographic evaluation (TOUCH group only at all follow up visits)

B. ACCOUNTABILITY OF PMA COHORT

The primary analysis set included N=149 subjects in the TOUCH® group and N=76 subjects in the control group receiving the LRTI treatment.

C. SUBJECT POPULATION DEMOGRAPHIC AND BASELINE PARAMETERS

Table 2 and **Table 3** display a summary of the demographic continuous and categorical variables for all subjects in the investigational TOUCH® and control LRTI groups. The mean age at time of surgery was highly similar for both groups: 62.7 years for TOUCH® subjects and 63.4 years for the control. Both males and females were treated, with a higher percentage of females (about 70% females) in both groups. Baseline PROMs data were also highly similar between groups.

Table 2: Summary of Demographic and Baseline Continuous Variables PS Selected mITT Analysis Set (N=149 TOUCH®, N=76 Control LRTI)

	TOUCH® CMC 1 (N=149)			LRTI (N=76)			TOUCH® – LRTI[1]		
Demographics - All	**Mean**	**SD**	**Med**	**Mean**	**SD**	**Med**	**Diff**	**LB**	**UB**
Age at surgery (yrs)	62.7	8.1	62.2	63.4	7.9	62.4	-0.71	-2.94	1.53
Baseline PROMs	**Mean**	**SD**	**Med**	**Mean**	**SD**	**Med**	**Diff**	**LB**	**UB**
Kapandji Index	8.73	1.93	10.00	8.33	1.86	9.00	0.40	-0.14	0.93
Brief MHQ	44.29	14.44	43.75	48.23	16.84	47.92	-3.93	-8.22	0.36
Pain at rest	5.21	2.45	5.00	4.72	2.21	5.00	0.49	-0.18	1.15
Pain during activities	7.43	1.75	8.00	6.88	1.74	7.00	0.55	0.06	1.04
EQ-5D-5L	0.73	0.17	0.79	0.67	0.22	0.74	0.06	0.01	0.12
EQ-5D VAS	73.54	19.17	80.00	69.88	19.75	71.00	3.66	-1.79	9.12
Key Pinch (kg)	4.58	2.61	4.00	3.92	2.02	3.40	0.65	-0.02	1.33

Notes:
[1]Group differences and 95% confidence intervals (CI) for group differences
Diff: The estimated difference between the two groups
LB: Lower Bound of the confidence interval
UB: Upper Bound of the confidence interval
SD: Standard Deviation

The majority of patients treated in both groups were Eaton Stage III (about 85%), which is an advanced stage of CMC joint osteoarthritis.

Table 3: Summary of Baseline Categorical Variables – PS Selected mITT Analysis Set (N=149 TOUCH®, N=76 Control LRTI)

	TOUCH® CMC 1 (N=149)		LRTI (N=76)		TOUCH® – LRTI[1]		
Gender	**N**	**%**	**N**	**%**	**Diff (%)**	**LB**	**UB**
Males	42	28.2	20	26.3	1.9	-10.4	14.1
Females	107	71.8	56	73.7	/	/	/
Affected side	**N**	**%**	**N**	**%**	**Diff (%)**	**LB**	**UB**
Right	72	48.3	42	55.3	-6.9	-20.7	6.8
Left	77	51.7	34	44.7	/	/	/
Dominant Side	**N**	**%**	**N**	**%**	**p[2]**		
Right (or not available)	119	79.9	66	86.8	0.195	/	/
Left/both	30	20.1	10	13.2	/	/	/
Dominant side affected	**N**	**%**	**N**	**%**	**Diff (%)**	**LB**	**UB**
Yes	85	59.4	41	53.9	5.5	-8.3	19.3
No	58	40.6	35	46.1	/	/	/
(not available)	6	4.0	0	0.0	/	/	/
Other Hand in dataset	**N**	**%**	**N**	**%**	**Diff (%)**	**LB**	**UB**
Yes	32	21.5	0	0.0	21.5	14.9	28.1

	TOUCH® CMC 1 (N=149)		LRTI (N=76)		TOUCH® – LRTI[1]		
No	117	78.5	76	100.0	/	/	/
Employed	**N**	**%**	**N**	**%**	**Diff (%)**	**LB**	**UB**
Yes	81	56.6	28	36.8	19.8	6.3	33.4
No	62	43.4	48	63.2	/	/	/
Not available	6	4.0	0	0.0	/	/	/
Diagnosis	**N**	**%**	**N**	**%**	**p[2]**		
OA	149	100.0	76	100.0	/		
Post-traumatic	0	0.0	0	0.0			
RA	0	0.0	0	0.0			
Other	0	0.0	0	0.0			
Eaton Stage	**N**	**%**	**N**	**%**	**p[2]**		
II	24	16.1	11	14.5	0.749	/	/
III	125	83.9	65	85.5	/	/	/

[1]Group differences and 95% confidence intervals (CI) for group differences
[2]P-value for Chi-Square test

D. SAFETY AND EFFECTIVENESS RESULTS

Effectiveness Outcomes

Primary Endpoint Analysis

The success measurement was developed to measure the safety and effectiveness of the TOUCH® CMC 1 Prosthesis at 24-months follow-up when compared to the control treatment (LRTI) at 12-months follow-up. The pre-specified analysis of effectiveness defined in the study was based on the primary analysis cohort, including all TOUCH® CMC 1 treated subjects (N=149) and LRTI treated subjects (N=76). The study success and primary CCS endpoint of the clinical study was met in the ITT-PS Selected Completers Analysis Set (**Table 4**).

Table 4: Primary Endpoint Analysis at 24-Months

	TOUCH® CMC 1 Prosthesis			LRTI (Control)			Difference
	N	n	%	N	n	%	
Composite Clinical Success	115	96.3	83.8%	50	36.4	72.8%	**11.0%**

Individual Components of the Primary Endpoint

An evaluation of the components of the primary composite endpoint was also performed.

Table 5 demonstrates the investigational treatment (TOUCH®) had similar or higher responder rates for each component of the composite primary endpoint.

Table 5: Percentages of Subjects Achieving Success in Month 24 CCS and Components of CCS Average Treatment Effect on the Treated (ATT) with ATT Weighted and Employment Status Adjusted Group Differences and 90% Confidence Intervals ITT-PS Selected Completers Analysis Set[1]

	Touch®[2]			LRTI[2]			Touch® - LRTI[3]		
	N	n	%	N	n	%	Diff (%)	LB	UB
Composite Clinical Success	115	96.3	83.8%	50	36.4	72.8%	11.0	-3.4	25.5
(1) No Secondary Surgical Intervention[4]	149	140.6	94.3%	76	75.2	98.9%	-4.6	-8.5	-0.6
(2) Pain (During Activities) Responder[5]	122	119.1	97.6%	75	68.3	91.1%	6.5	0.3	12.8
(3) Key Pinch Strength Responder[6]	117	108.7	92.9%	49	41.4	84.5%	8.4	-2.1	19.0
(4) No Serious Device- or Procedure-Related AEs[7]	149	142	95.3%	76	75	98.7%			

Notes:
[1] The primary ITT (PS Selected) analysis set includes all Touch® subjects (N=149) and 76 controls. 115 of 149 (77.2%) of Touch® and 50 of 76 (65.8%) were evaluable for Month 24 CCS.
[2] LRTI numbers of subjects meeting criterion (n) is computed as the ATT weighted and employment status adjusted success rate multiplied by the actual sample size (N). This results in fractional values for "n". For LRTI, the sum of the ATT weights was 69.6. Touch® numbers of subjects meeting criterion (n) is computed as the ATT weighted (all Touch weights = 1) and employment status adjusted success rate multiplied by the actual sample size (N). The adjustment for employment status results fractional values for "n".
[3] These columns contain the primary ATT estimand and its 90% confidence interval. These were determined as differences in ATT weighted responder rates. The model also controlled for employment status (employed vs not employed) as specified in the PS Design Memo to account for residual bias. The lower bound (LB) of the 90% CI is equivalent to the LB of the 1-sided 95% CI.
[4] Absence of additional surgical intervention, defined as revision, removal, reoperation or supplemental fixation/fusion in a separate surgery subsequent to the index procedure over the initial 24 months.
[5] Pain Responder is defined by a decrease in the Numerical Rating Scale (NRS) pain score of >=30% on a 10-point scale. This is determined at Month 24 for Touch® and Month 12 for LRTI.
[6] Key Pinch Strength Responder is defined by a key pinch strength value of >=85% of pre-op value which reflects maintenance or improvement in function. This is determined at Month 24 for Touch® and Month 12 for LRTI.
[7] At 24 months, absence of a serious device-related or serious procedure-related adverse event for Touch® and absence of a serious procedure-related adverse event for LRTI. Observed data is reported for this row; there were too few events for a meaningful estimation of the weighted group difference and confidence interval.

Secondary Effectiveness Endpoints

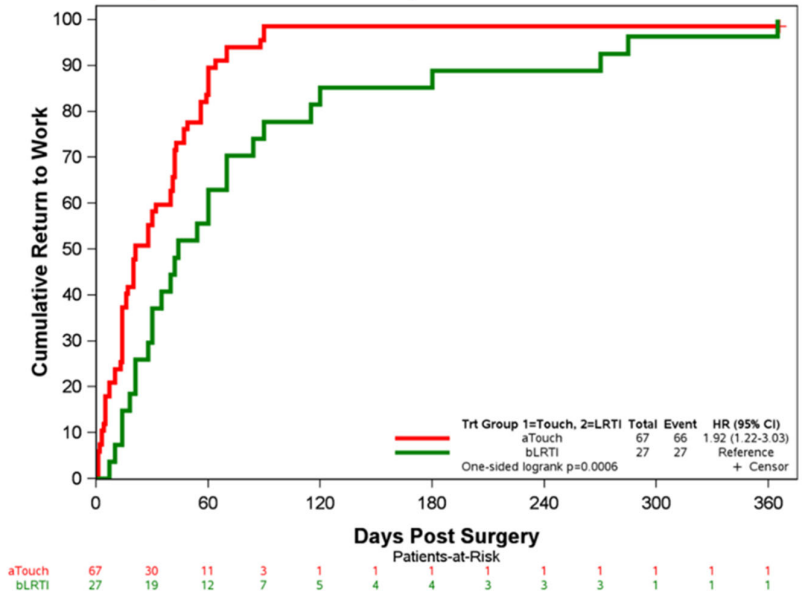
Results for secondary endpoints measuring improvements in function, pain, and quality of life patient-reported outcomes were also measured. Improvements in pain and function of the TOUCH® group were reflected in NRS, Kapandji Thumb Opposition Test (or Kapandji Index score) and bMHQ. The TOUCH® group showed greater reductions in pain and greater improvements in function compared to the control group. Patients reported outcomes including the EQ-5D-5L and EQ-5D VAS results show general improvement in patient quality of life in both groups.

For those subjects who were employed prior to the index surgery, a time to return to work (RTW) was calculated. In general, patients treated with the control LRTI procedure were slower to return to work and gradually returned through Month 13, demonstrating a benefit for the TOUCH® CMC 1 Prosthesis.

The results of the secondary endpoints results are summarized in **Table 6** and demonstrate that TOUCH® provides improvements in pain during activities and at rest, function, and overall quality of life.

Table 6: Secondary Endpoint Results Summary – PS mITT Analysis Set

Secondary Endpoint – *Mean Scores at Last Follow-Up:*	**TOUCH® (N=149)** ***T=24-Months***	**Control LRTI (N=76)** ***T=12-Months***
Pain During Activities (NRS 10-point scale)		
Total Score	1.1	1.8
Change from Baseline	-6.3	-5.1
% Success (Improvement >=30%)	97.5%	88%
Pain at Rest (NRS 10-point scale)		
Total Score	0.5	0.8
Change from Baseline	-4.7	-3.9

Secondary Endpoint – ***Mean Scores at Last Follow-Up:***	**TOUCH® (N=149)** ***T=24-Months***	**Control LRTI (N=76)** ***T=12-Months***
Thumb Function: Key Pinch Strength (kg)		
Total Score	7.13	4.25
Change from Baseline	2.49	0.43
% Success (Improvement >=85%)	93.3%	77.6%
Thumb Opposition: Kapandji Index		
Total Score	9.8	8.9
Change from Baseline	0.9	0.6
Hand Function: bMHQ		
Total Score	90.3	84.6
Change from Baseline	44.8	36.2
Quality of Life: EQ-5D-5L		
Total Score	0.90	0.89
Change from Baseline	0.17	0.22
Overall Health: EQ-5D-VAS		
Total Score	84.1	79.7
Change from Baseline	10.5	9.8
Time to Return to Work (RTW)		
Cumulative RTW Rate: Month 1	58.2%	37%
Cumulative RTW Rate: Month 2	75%	41.2%
Cumulative RTW Rate: Month 3	85.71%	40%
Cumulative Return to Work Rate up to Month 12	TOUCH® subjects returned to work quicker  (Red = TOUCH®, Green = LRTI)	

Effectiveness Conclusions

The patients treated with TOUCH® CMC1 Prosthesis in the clinical study at the Schulthess Klinik experienced similar or better improvements in pain, function, return to work, and quality of life as compared to the LRTI control treatment. Improvements from baseline were maintained through the Month 24 time point. Conclusions of the device's effectiveness are supported by the clinical data:

- Pain Improvement: At 24-months, TOUCH® subjects had less pain during activities overall (1.1 compared to 1.8 points) and a higher percentage of TOUCH® subjects experienced clinically significant change in pain (97.5% TOUCH® vs. 88% control shown a pain improvement of ≥30%). On average, the TOUCH® subjects experienced a mean improvement from baseline in pain during activities of -6.3 points and -4.7 points in pain scores at rest (on a 10-point scale).
- Function or Key Pinch Strength Improvement: TOUCH® subjects experienced improvements in KPS (mean change +2.49kg) by Month 24, with a high percentage of subjects (94%) meeting the CCS criteria for clinically significant change in key pinch strength. This increase in strength leads to improvements in overall thumb function.
- Quality of life and overall hand function: Kapandji Index, bMHQ, EQ-5D-5L, EQ-5D VAS, and time to return to work data demonstrate other benefits of TOUCH®.

In conclusion, the effectiveness data demonstrates that patients treated with TOUCH® CMC1 Prosthesis are likely to experience benefits such as improvements in pain, function, and overall quality of life.

Safety Outcomes

All safety tables in this section are censored at the 24-Month follow-up window (up to post-operative day 790). "I" stands for the investigational TOUCH® group and "C" stands for the control LRTI group.

The safety results were based on the cohort of TOUCH® CMC 1 Prosthesis subjects and the LRTI control subjects as presented below (

Table 7). The overall adverse event rate was similar in the TOUCH® CMC 1 Prosthesis group (14.1%) and the control group (17.1%), with the latter reporting a slightly higher percentage of adverse events. A higher percentage of adverse events were considered “serious” in the investigational group (4.3%) compared to the control group (1.3%). There were no significant, life-threatening adverse events and the adverse events that did occur were successfully resolved.

Table 7: Summary of Adverse Event Rates PS Selected mITT Analysis Set

	Touch (N=149)			LRTI (N=76)			Touch vs. LRTI[1]		
	No. of Events	No. of Pts.	% of Pts.	No. of Events	No. of Pts.	% of Pts.	Diff (%)	LB	UB
Any Adverse Event (per patient)	26	21	14.1	15	13	17.1	-3.0	-13.2	7.1
Any Device-Related AE[2]	2	2	1.3	0	0	0.0	1.3	0.5	3.5
Any Procedure-Related AE[2]	25	20	13.4	15	13	17.1	-3.7	-13.8	6.4
Any Serious Adverse Event	10	7	4.7	1	1	1.3	3.4	-0.9	7.6
SAE, Device/Procedure-Related	10	7	4.7	1	1	1.3	3.4	-0.9	7.6
SAE, Device-Related	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
SAE, Procedure-Related	10	7	4.7	1	1	1.3	3.4	-0.9	7.6
Secondary Surgical Intervention[3]	9	9	6.0	1	1	1.3	4.7	0.1	9.3
Deaths	1	1	0.7	0	0	0.0	0.7	-0.6	2.0

Notes:

[1] Unadjusted device group differences and 95% binomial confidence interval.

[2] Device or Procedure relatedness includes possibly, probably, and definitely related. Device related only measured in Touch.

[3] Secondary surgical intervention include reoperations, revisions, removals, modifications to any study component or supplemental fixations on the carpometacarpal joint.

Adverse Events Requiring Secondary Surgical Intervention (SSI)

Some adverse events resulted in a subsequent surgical intervention (SSI). Secondary surgical interventions, classified as revisions, removals, reoperations, modifications to any study component or supplemental fixations, were categorized as study failures per FDA's Guidance Document, *Clinical Data Presentations for Orthopedic Device Applications (2004)*. Overall, there were nine (9) SSI failures in the TOUCH® group and one (1) SSI failure in the control LRTI group. In the TOUCH® group, 5 SSIs were classified as reoperations, 2 as revisions, and 2 as removals. Only one SSI in the TOUCH® group was categorized as probably related to the device. The one SSI in the control group was possibly related to the index procedure which resulted in a reoperation for trigger thumb (i.e., tendovaginitis stenosans thumb).

Serious Device-Related Adverse Events

One subject experienced a serious device-related AE (implant loosening) in the TOUCH® group (0.7%). As shown below, the device related SAE occurred between Month 3 and Month 12.

Table 8: Serious Device Related Adverse Events by Timecourse in TOUCH Group

Specific Adverse Event	Intraop	< Month 3	Month 3 to < Month 12	Month 12 to < Month 24	Totals
	I	I	I	I	I
Implant loosening	0	0	1	0	1
Implant dislocation or migration	0	0	0	0	0
Implant breakage	0	0	0	0	0
Periprosthetic fracture	0	0	0	0	0
Tendovaginitis de Quervain	0	0	0	0	0
Tendovaginitis stenosans thumb	0	0	0	0	0
Tendon rupture	0	0	0	0	0
Pain	0	0	0	0	0
Carpal tunnel syndrome	0	0	0	0	0
Stiffness	0	0	0	0	0
Wound problems	0	0	0	0	0
Infection	0	0	0	0	0
Complex regional pain syndrome	0	0	0	0	0
FCR tendinitis or (partial=) rupture	0	0	0	0	0
Intraoperative trapezium fracture	0	0	0	0	0
Other	0	0	0	0	0
Total	0	0	1	0	1

Serious Procedure-Related Adverse Events

Table 9 includes all serious procedure-related adverse events by category for both the TOUCH® and LRTI groups. There were 10 events in 7 subjects in the TOUCH® group categorized as a serious procedure related adverse events. In the control group, one subject experienced a serious procedure-related adverse event (1.3%). The greatest number of specific procedure-related AEs were recorded from Month 3 through Month 12 visit.

Table 9: Serious Procedure-Related Adverse Events

	Touch (I) (N=149)			LRTI (C) (N=76)			I vs C[1]		
Specific Adverse Event	No. of Events	No. of Pts.	% of Pts.	No. of Events	No. of Pts.	% of Pts.	Diff	LB	UB
Implant loosening	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Implant dislocation or migration	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Implant breakage	0	0	0.0	0	0	0.0	.	.	.
Periprosthetic fracture	0	0	0.0	0	0	0.0	.	.	.
Tendovaginitis de Quervain	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Tendovaginitis stenosans thumb	1	1	0.7	1	1	1.3	-0.6	-3.5	2.2
Tendon rupture	0	0	0.0	0	0	0.0	.	.	.
Pain	2	2	1.3	0	0	0.0	1.3	-0.5	3.2
Carpal tunnel syndrome	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Stiffness	1	1	0.7	0	0	0.0	0.7	-0.6	2.0
Wound problems	0	0	0.0	0	0	0.0	.	.	.
Infection	0	0	0.0	0	0	0.0	.	.	.
Complex regional pain syndrome	0	0	0.0	0	0	0.0	.	.	.
FCR tendinitis or (partial=) rupture	0	0	0.0	0	0	0.0	.	.	.
Intraoperative trapezium fracture	0	0	0.0	0	0	0.0	.	.	.
Other	0	0	0.0	0	0	0.0	.	.	.
Total counts / subjects with at least 1 AE	10	7		1	1				

Notes:
[1] Exact 95% binomial confidence interval.

Safety Conclusions

In this study, the TOUCH® device was found to have a reasonable assurance of safety and to be at least as safe as the control LRTI treatment. The overall adverse event rate for the TOUCH® group was lower than the LRTI group, 14.1% vs. 17.1%, respectively. There were no significant, life-threatening adverse events and the adverse events that did occur were able to be successfully resolved.

There were nine (9) SSI failures in the TOUCH® group and one (1) SSI failure in the control LRTI group. In the TOUCH® group, 5 SSIs were classified as reoperations, 2 as modifications, and 2 as removals. Only one SSI in the TOUCH® group was categorized as probably related to the device. The one SSI in the control group was possibly related to the index procedure, which resulted in a reoperation for trigger thumb (i.e., tendovaginitis stenosans thumb). Although the overall revision rate was slightly higher in the TOUCH® group (6% vs. 1.3% LRTI), the TOUCH® CMC 1 Prosthesis offer advantages over LRTI, such as shorter recovery rate (evidenced by the quicker RTW rate) and better functional improvements (evidenced by the better key pinch strength data).

Importantly, all TOUCH® subjects that had the device removed underwent successful secondary surgeries (either component replacement or conversion to trapeziectomy with LRTI), with no other adverse events recorded. It is important to note that, in the case of implant removal and conversion to trapeziectomy with LRTI, the current standard of care in the US for Eaton-Littler Stage II or III osteoarthritis of the 1st CMC joint is trapeziectomy with LRTI. Therefore, this demonstrates that a failed TOUCH® implant can be safely and effectively revised with a subsequent standard of care procedure, if needed.

In conclusion, the safety data collected in this study demonstrate the positive safety profile of the TOUCH® CMC 1 Prosthesis implanted in the first CMC joint. While improving patients' pain and function, the data herein demonstrate there is a reasonable assurance of safety. TOUCH® is at least as safe as the control in regard to adverse event rates and secondary surgeries.

Radiographic Measurements

Radiographic data were collected as another secondary outcome measure to characterize the TOUCH® CMC 1 Prosthesis' safety. The radiographic analyses conducted on the TOUCH® group included the absence of device migration, osteolysis, radiolucencies or fracture. As the control group (trapeziectomy with LRTI) does not have an implant, there was no radiographic evaluation or success criterion for this arm of the study. The radiographic analysis was conducted by independent reviewers.

Radiographic outcomes for TOUCH® group are presented in

Table 10**.** During the 24-month study duration, there were 1 case of migration >2mm, 21 cases of radiolucent lines proximal to the cup, and 1 fracture of the trapezium. Overall, the rate of radiographic success was high, with 95.8% of subjects experiencing no implant migration at any timepoint. It can also be concluded that although some radiographic findings such as radiolucencies were observed, they were not necessarily indicative of failure.

Table 10: Summary of Radiographic Endpoints PS Selected mITT Analysis Set – TOUCH® (N=149)

Timepoint	Week 6		Month 3		Month 12		Month 24		Timepoint[2]	
	n		n		n		n		n	
Number of subjects	141		73		134		127		142	
Migration of Stem or Cup	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
No	141	100.0	71	97.3	130	97.0	124	97.6	136	95.8
Yes	0	0.0	2	2.7	4	3.0	3	2.4	6	4.2
Migration Grade of Stem or Cup	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Minimal (<=2mm)	0	0.0	2	2.7	2	1.5	2	1.6	3	2.1
Large (>2mm)	0	0.0	0	0.0	2	1.5	1	0.8	3	2.1
Direction of the Migration[1]	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Proximal	0	0.0	2	2.7	3	2.2	2	1.6	5	3.5
Distal	0	0.0	0	0.0	0	0.0	1	0.8	1	0.7
Ulnar	0	0.0	0	0.0	1	0.7	0	0.0	1	0.7
Radial	0	0.0	0	0.0	1	0.7	1	0.8	1	0.7
Radiolucent Line	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
No	115	81.6	58	79.5	109	81.3	106	83.5	112	78.9
Yes	26	18.4	15	20.5	25	18.7	21	16.5	30	21.1
Location of Radiolucent Line	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Proximal at Cup	26	18.4	15	20.5	25	18.7	21	16.5	30	21.1
Distal at stem	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0
Fracture	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
No	140	99.3	72	98.6	132	98.5	126	99.2	139	97.9
Yes	1	0.7	1	1.4	2	1.5	1	0.8	3	2.1
Localization of Fracture	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**
Trapezium (proximal)	1	0.7	1	1.4	2	1.5	1	0.8	3	2.1
Metacarpal bone (distal)	0	0.0	0	0.0	0	0.0	0	0.0	0	0.0

Notes:
[1] More than one direction is possible.
[2] Either Month 12 or Month 24

E. ADDITIONAL CLINICAL EVIDENCE

The safety and effectiveness of the TOUCH® CMC 1 Prosthesis device are further supported by additional, published clinical evidence collected outside the United States under the device's CE Mark. The clinical evidence includes an additional 823 TOUCH® CMC 1 Prosthesis devices implanted in 787 subjects from 16 centers in European Union countries.[1,2,3,4,5,6,7] These published RWD studies include patients with the same inclusion criteria as the above study (e.g. indication, adult patients) and no differences in the exclusion criteria (e.g., allergy to components, not consent to the study).

While the studies use different assessment tools (e.g., VAS, PRWE, Quick DASH etc.) from the clinical study present above, all authors report clinically meaningful improvements in pain and function (key pinch strength, Kapandji), as well as increases in range of motion in the target

[1] [Lussiez et al. 2021]
[2] [Froschauer et al. 2021]
[3] [Gonzales-Espino et al. 2021]
[4] [Van Melkebeke et al. 2022]
[5] [Falkner et al. 2023]
[6] [Guzzini et al. 2023]
[7] [Tchurukdichian et al. 2023]

patient population. Importantly, revision rates were quite low; considered together, the studies result in an overall revision rate of 2.7% (21 revisions and 1 removal in 823 devices total). The adverse event rates were quite low, too, and the studies support the long-term durability of the device through at least 6 years.

These published clinical data sources provide additional RWD to further support the body of clinical evidence on the investigational device in further support of the safety and effectiveness of the TOUCH® CMC 1 Prosthesis.

F. CONCLUSIONS

The clinical study compared the TOUCH® CMC 1 Prosthesis device to the control treatment, LRTI, for treatment of carpometacarpal joint osteoarthritis. The TOUCH® group experienced a high rate of composite clinical success, demonstrating reasonable assurance of safety and effectiveness despite statistical concerns precluding statistical inference. TOUCH® CMC 1 Prosthesis subjects also benefit from improvements in post-operative pain and function, while avoiding safety risks with a low revision rate. The probable benefits of TOUCH® CMC 1 Prosthesis outweigh the probable risks.

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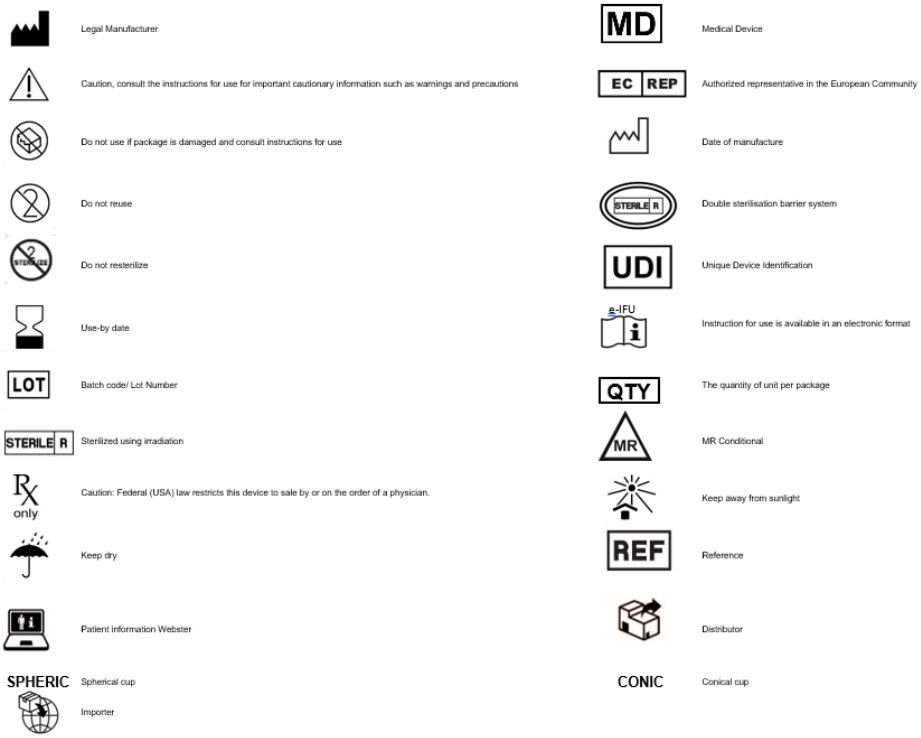

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Surgical technique

TOUCH® INTL USA Surgical technique - 110-32E007.00_En

TABLE OF CONTENT

INDICATIONS FOR USE

TOUCH® CMC 1 Prosthesis is intended for 1st carpometacarpal (CMC) primary total joint replacement (arthroplasty) in patients with symptomatic Eaton-Littler Stage II or III osteoarthritis (OA).

CONTRAINDICATIONS

- Acute or chronic infections, local or systemic.
- Muscular, neurological, or vascular severe deficiency affecting the joint.
- Inadequate bone quality or quantity preventing the implant fixation*
- Bones dimensions incompatible with implant sizes.
- Patients who are allergic to the product's materials.
- Any concomitant disorder that may affect the function of the implant.

*Note: in many cases, a plain radiograph is sufficient to evaluate bone quality, however, in certain cases a computerized tomography (CT) scan may be necessary.

WARNINGS AND PRECAUTIONS

See package insert for warnings, precautions, adverse effects, information for patients and other essential product information.

Before using TOUCH® CMC 1 Prosthesis instrumentation, verify:

- Instruments have maintained design integrity
- Proper size configurations are available

For instructions for cleaning, sterilization, inspection and maintenance of orthopaedic medical devices, refer to 000-21A003 - METAL - KERI MEDICAL SA Instrumentation - Instruction for reprocessing.

DEVICE DESCRIPTION

The TOUCH® CMC 1 Prosthesis is a cementless, ball-and-socket dual-mobility, total CMC 1 (1st Carpo-metacarpal) joint replacement prosthesis made of:

- a metacarpal implant (stem), available in 6 sizes (XS, 0, 1, 2, 3, 4)
- a trapezial implant (cup), available in 2 variants (spherical and conical) and 2 sizes per variant (Ø9mm and Ø10mm)
- a junction implant (neck) topped with a liner, available in 2 variants (straight and 15°offset) and 3 lengths per variant (S-6mm, M-8mm and L-10mm)

All sizes and variants are compatible in dimensions and materials and can be associated without restrictions.

TOUCH® CMC 1 stem and cup are intended for press-fit application. The outer surfaces of the stem and the cup are coated with Hydroxyapatite (HA) over a pure titanium plasma spray substrate.
The TOUCH® CMC 1 Prosthesis is delivered with instrumentation that accommodates all surgical approaches per surgeon's preference. The present Surgical technique illustrates the dorsal approach.

Surgical technique, regardless of the approach selected, must respect the prosthesis biomechanics to minimize adverse events such as implant dysfunction.

CMC1J RADIOLOGICAL ASSESSMENT

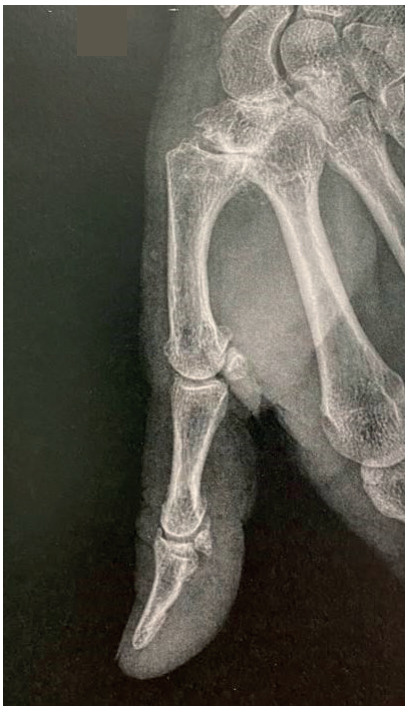
Accurate X-rays are required to assess CMC joint anatomy before and during surgery. The X-ray windows must be large enough to include the wrist, the STT level and the MP sesamoids.

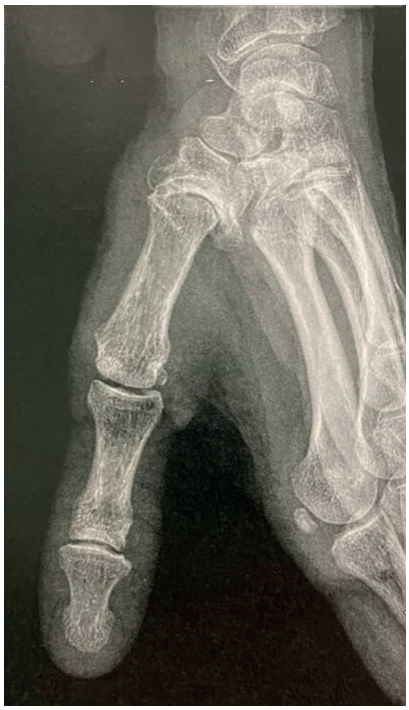
Lateral view (left):

- Sesamoids bones of the MP must be visible and overlapping. All the trapezium surrounding joint spaces must be visible

Frontal view (right):

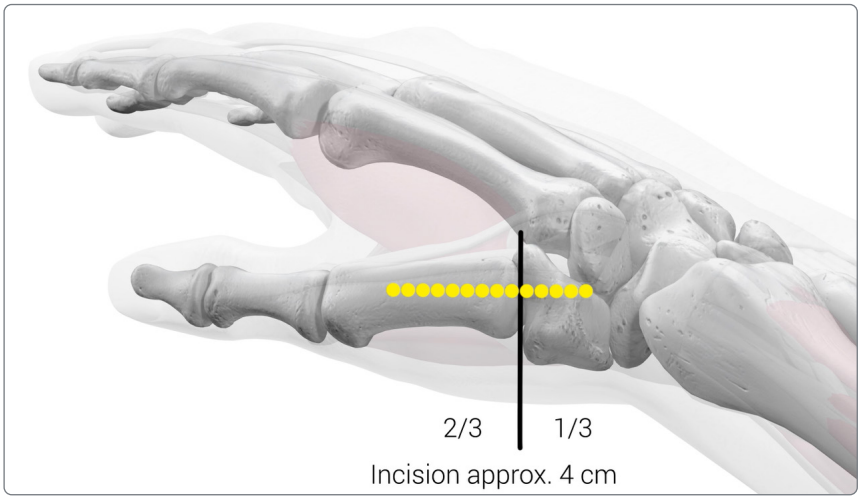
- Sesamoids bones of the MP should not be visible. All the trapezium surrounding joint spaces must be visible





INCISION AND EXPOSURE

Incise the skin over the CMC1 joint (2/3 metacarpal, 1/3 trapezial) to favor a good joint exposure (about 4 cm).

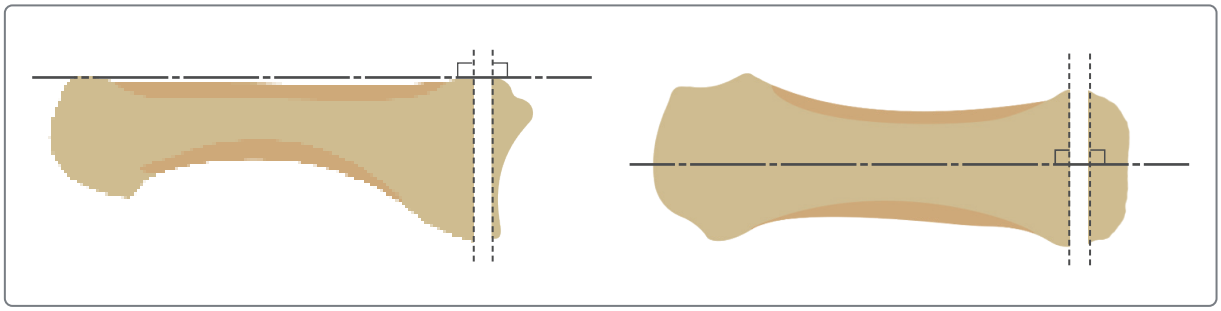


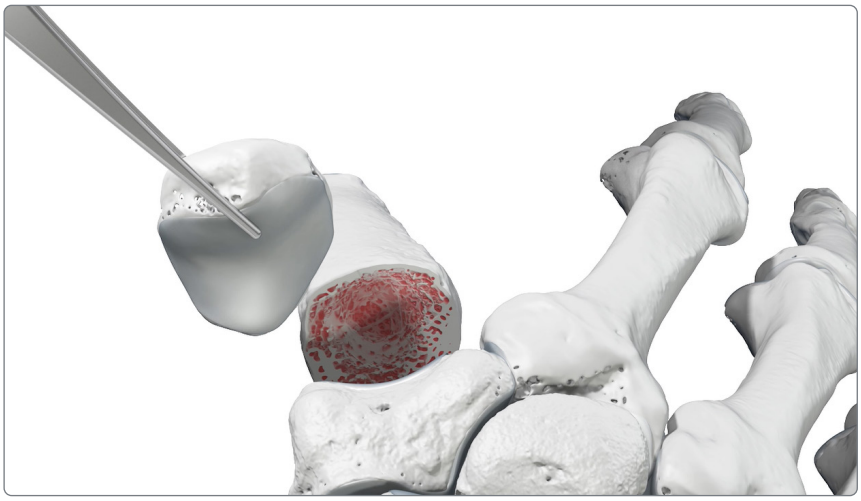
Open the capsule and release all the capsular ligamental attachments.

Mobilization of the metacarpal base is the key for the exposure of the trapezium.

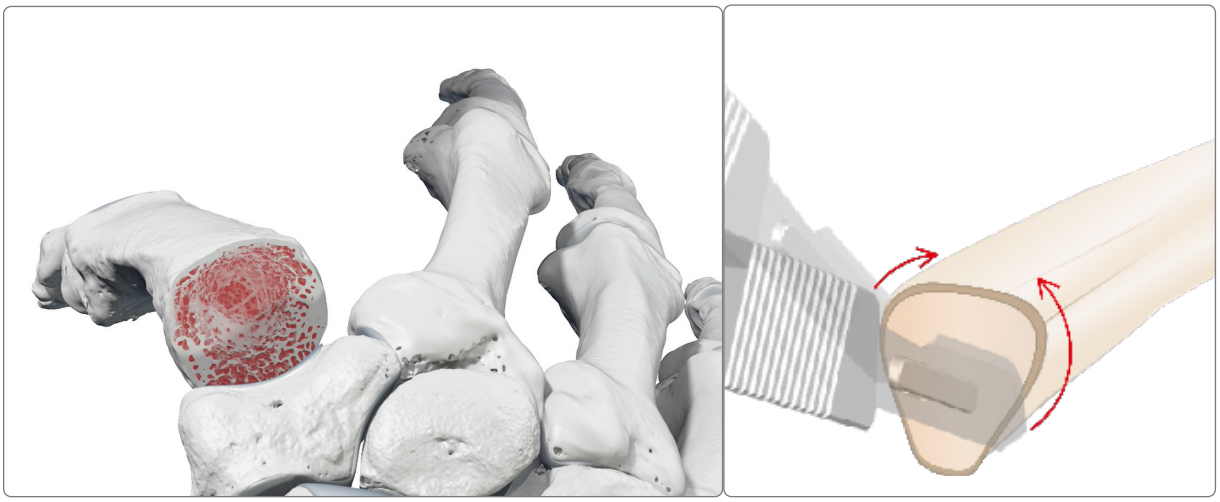
STEP 1 - RESECTION AND RELEASE

Use a saw to perform a free hand resection of the metacarpal base perpendicular to the metacarpal axis (both frontal and sagittal planes) and in regard of the volar beak.



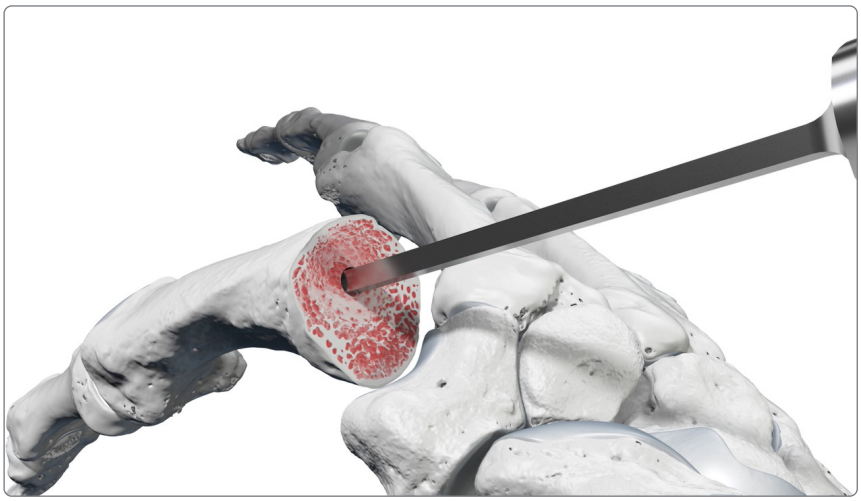


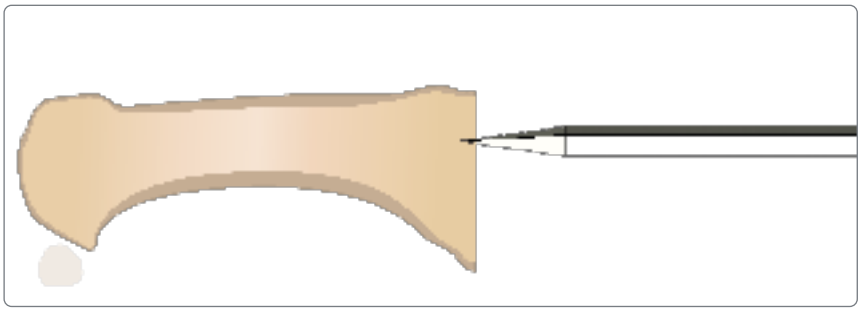
Complete the metacarpal base release around the metacarpal base.



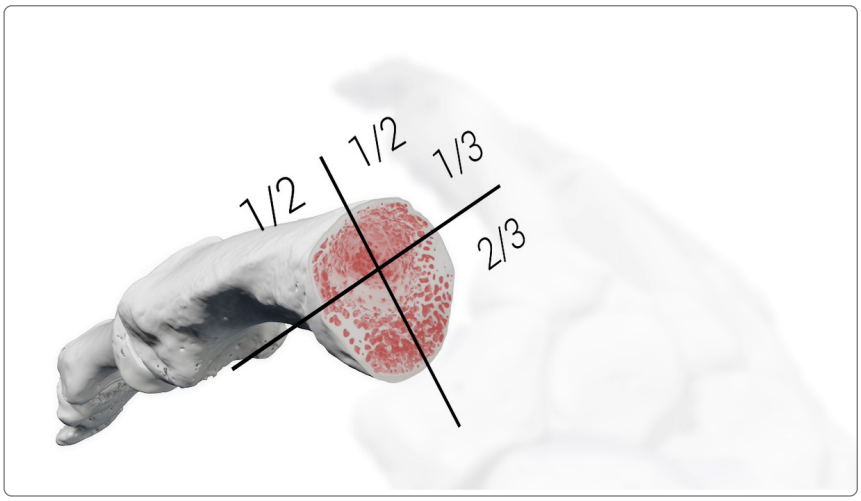
STEP 2 - METACARPAL PREPARATION

Insert the awl to open the medullary canal paying attention to keep the alignment with the metacarpal dorsal side.

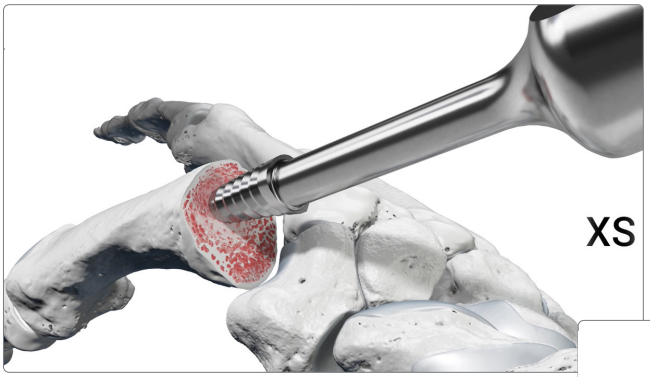


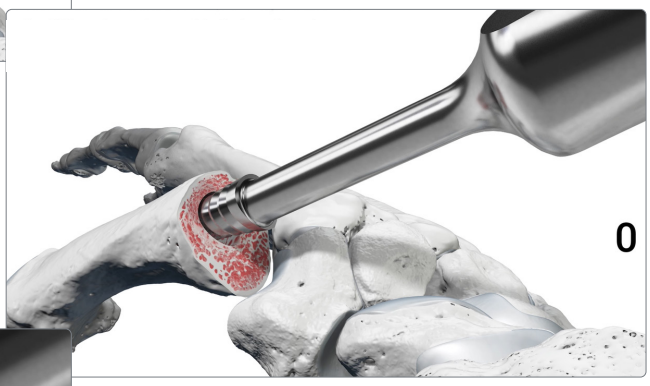


Insertion point is rather 1/3 dorsal.

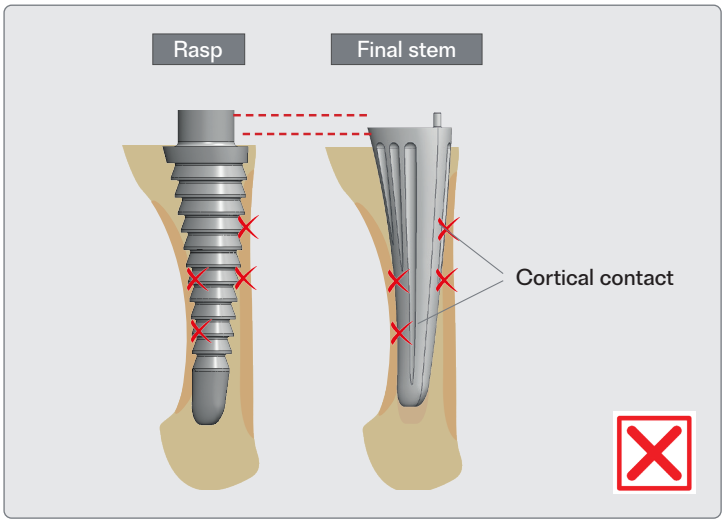


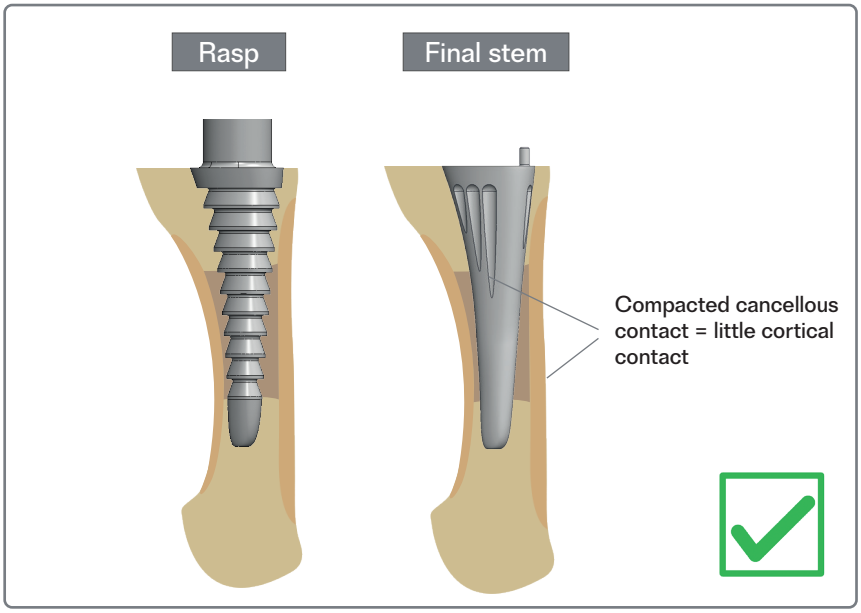
Broaching is then performed beginning with the size XS broach. The dorsal side of the broach (identified with an arrow on the broach) should be oriented to the dorsal side of the metacarpal bone and in both sagittal and lateral planes. Sequentially broach upward in size until the proper size is achieved, defined as when a small layer of cancellous bone is preserved and broach stability is achieved in rotation.





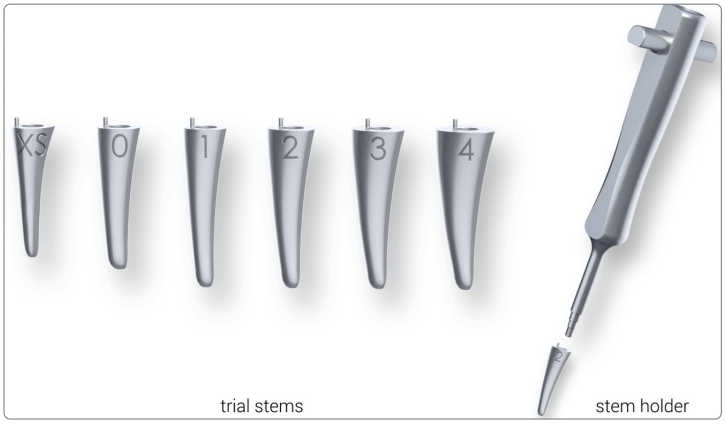
Avoid oversizing the broach. Reaching the cortical contact is unnecessary to prevent stem subsidence.





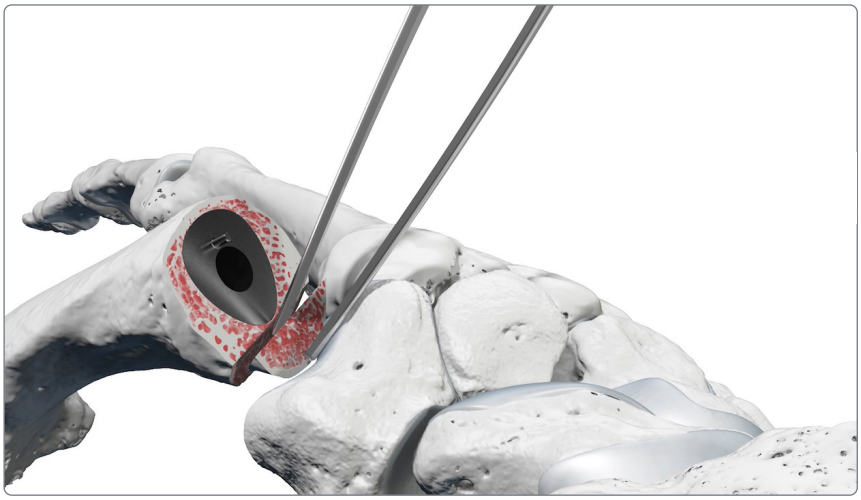
STEP 3 - STEM TRIAL INSERTION AND VOLAR BEAK RESECTION

Screw the stem trial corresponding to the proper broach size on the stem holder and gently insert it in the prepared metacarpal bone.



At this stage, the final stem implant can be inserted instead of the stem trial at surgeon's discretion.

Unscrew the stem holder and perform a free-hand oblique cut to resect the volar beak.



This step aims to avoid intraosseous impingements which may lead to implant dislocation.

Complete the release of the metacarpal base on the volar side, if necessary.

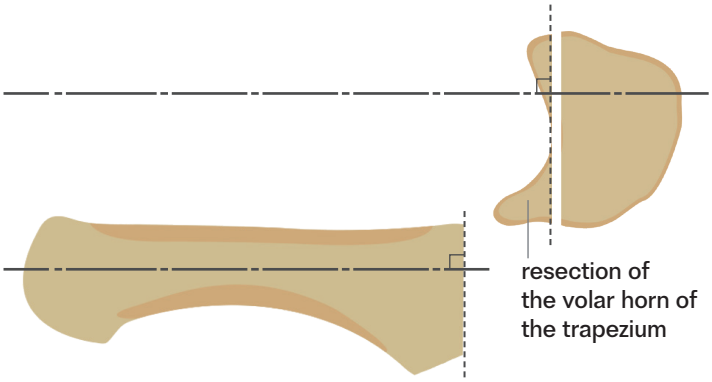
After complete release, the metacarpal bone must be pushed down on the volar side to allow trapezium articular surface free access.

Either the stem trial or the stem implant must stay in place during trapezium preparation to prevent fracture.

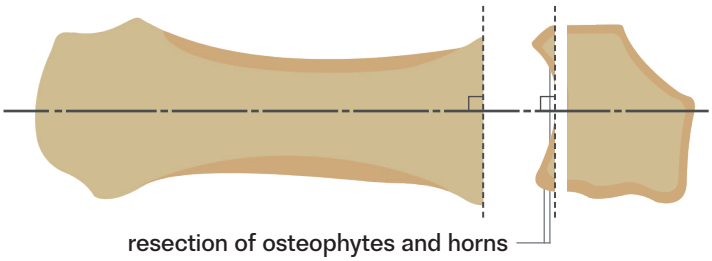
STEP 4 - TRAPEZIUM SURFACE PREPARATION

Only remove osteophytes and horns; keep as much as possible the hard central subchondral bone for cup primary stability.

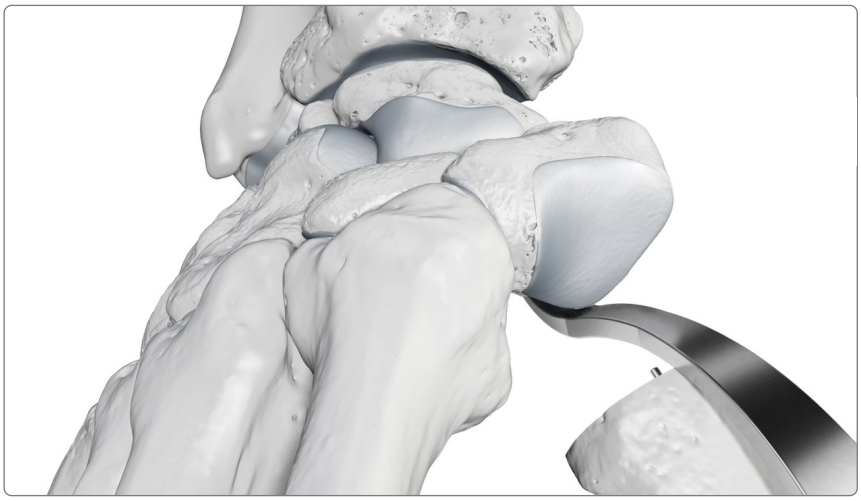
Lateral view



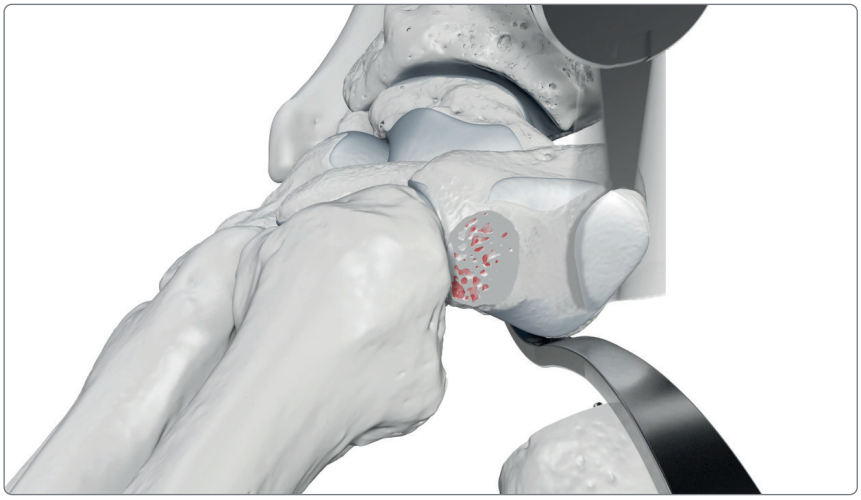
Posteroanterior view



Expose the trapezium articular surface using dedicated forked retractor to lower down the metacarpal.



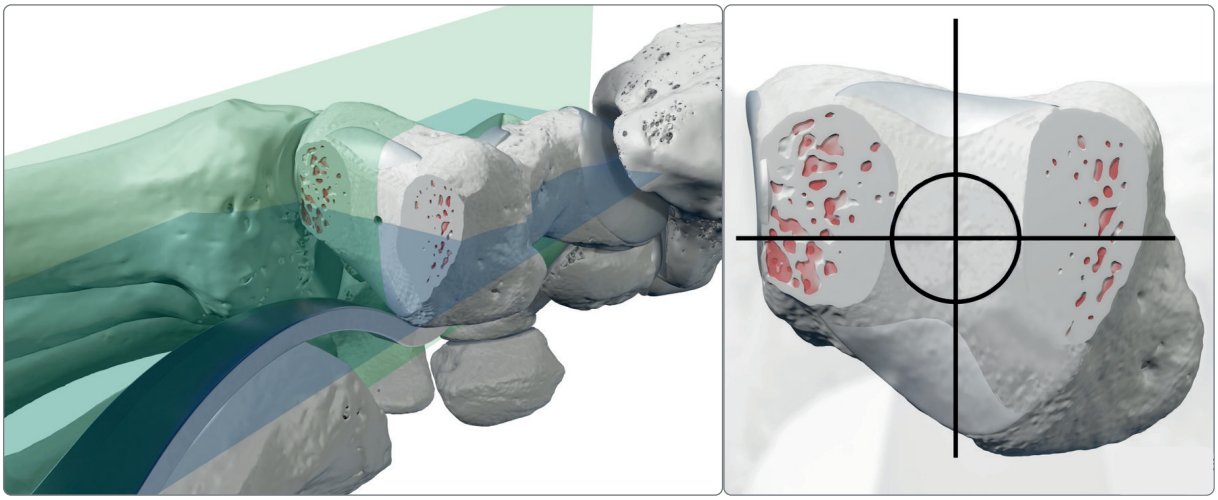
Prepare the trapezium surface using a saw to have a flat surface perpendicular to the metacarpal axis in neutral position (metacarpal axis align with the axis of the anatomical snuffbox). The resection level must be at maximum flush to the worn area of the trapezium surface.



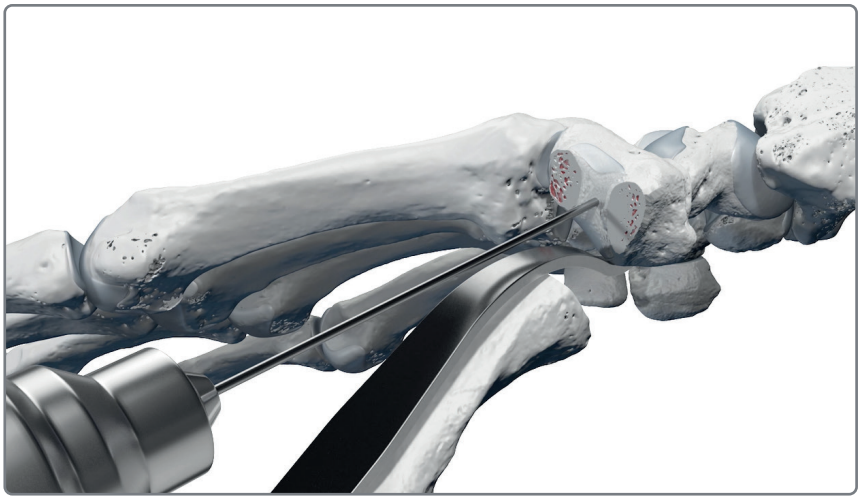
Remove osteophytes and trapezium horns before cup centering to prevent cup mispositioning; the presence of the osteophytes gives wrong information on the trapezium bulk.

STEP 5 - CENTERING

Identify the trapezium surface center.

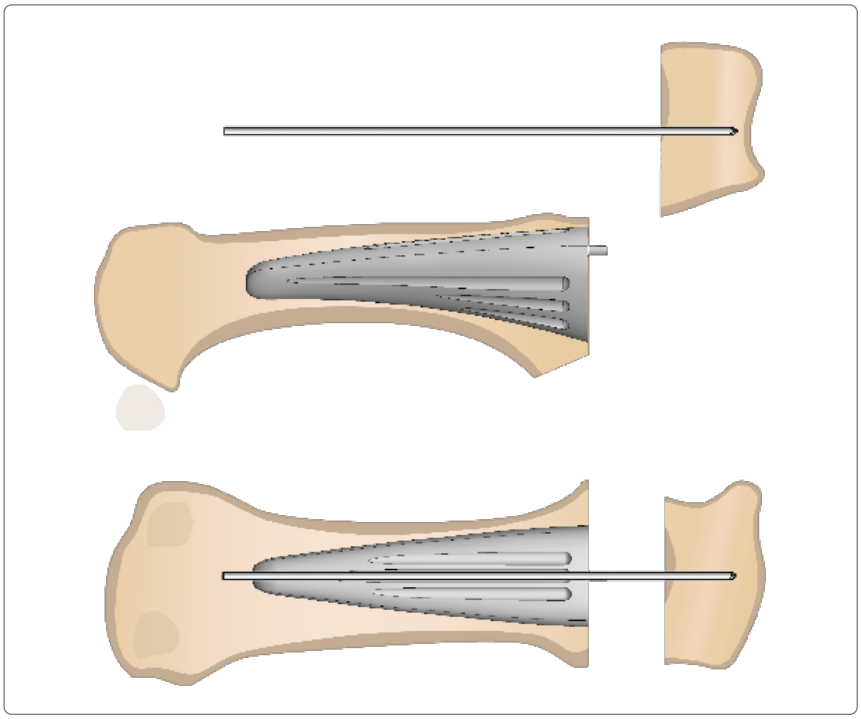


Insert the K-wire perpendicular to the trapezium surface in both frontal and lateral plane using the centering guide.



Do not bend the K-wire during its insertion; lower down the motor as much as possible. The goal is to have a centered and straight K-wire.

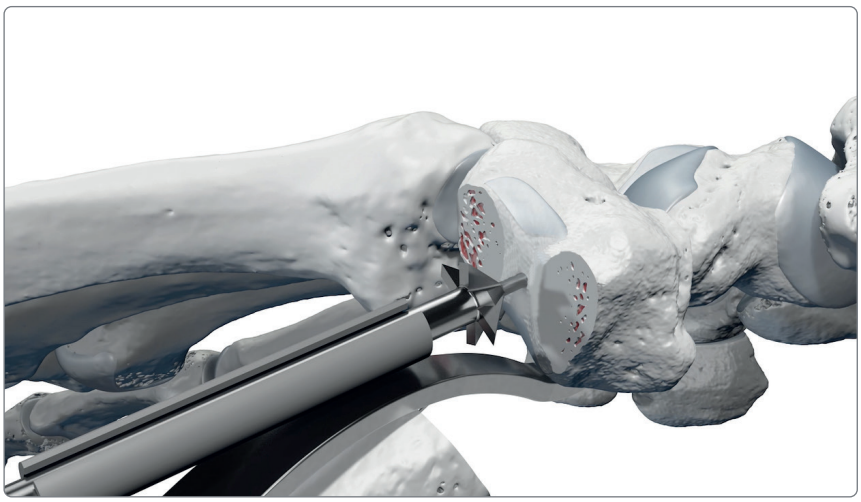
X-ray the joint in both frontal and lateral views to check the K-wire centering and orientation.



Proper positioning of the K-wire is the critical step of the trapezium preparation as it will guide the reaming step. Reiterate K-wire positioning and X-Ray control until achieving suitable positioning (location and orientation).

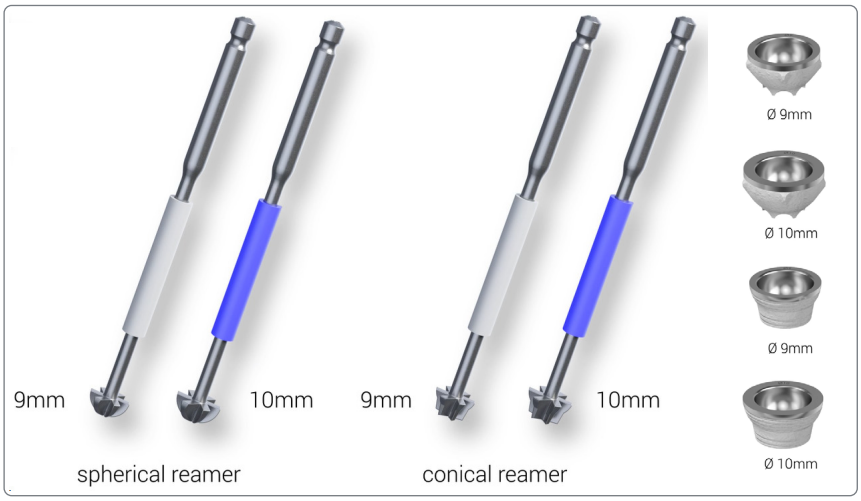
STEP 6 - REAMING AND TESTING

Initiate the trapezium reaming with the cannulated starter until complete seating of the starter tip in the trapezium.



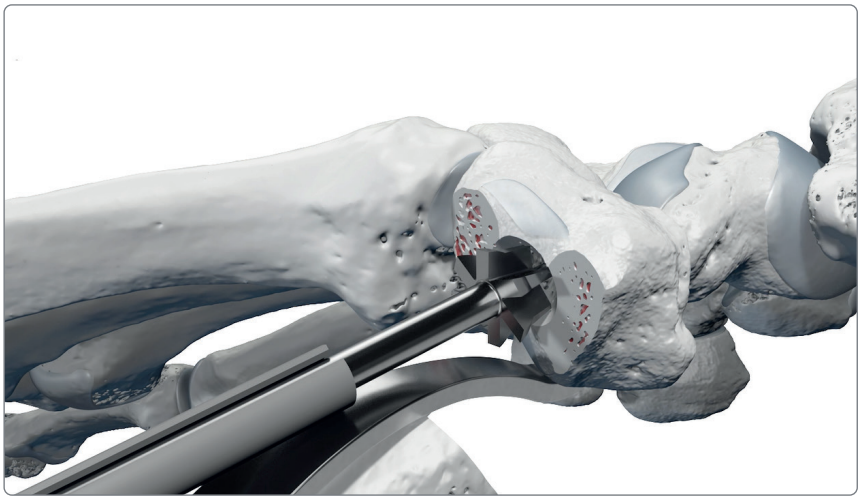
Do not bend the K-wire during reaming; lower down the reamer handle as much as possible.

Select the cannulated reamer corresponding to the chosen cup shape (conical or spherical), always start with the Ø9mm (grey sleeve).



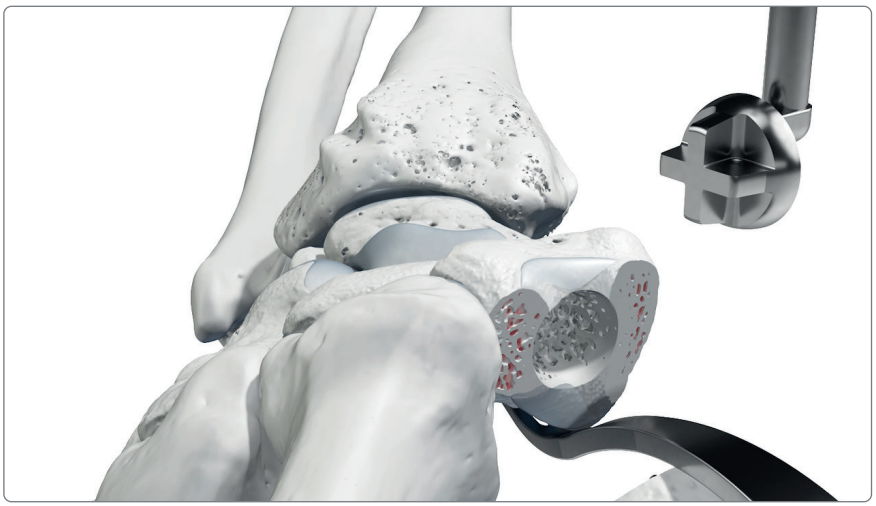
Trapezium reaming is crucial to favor cup primary stability. Reaming must be done carefully over the K-wire to have a round preparation, deep enough to seat the cup. Do not ream the bone without the K-wire in place.

Ream carefully with the selected cannulated reamer until flush with the bone surface.

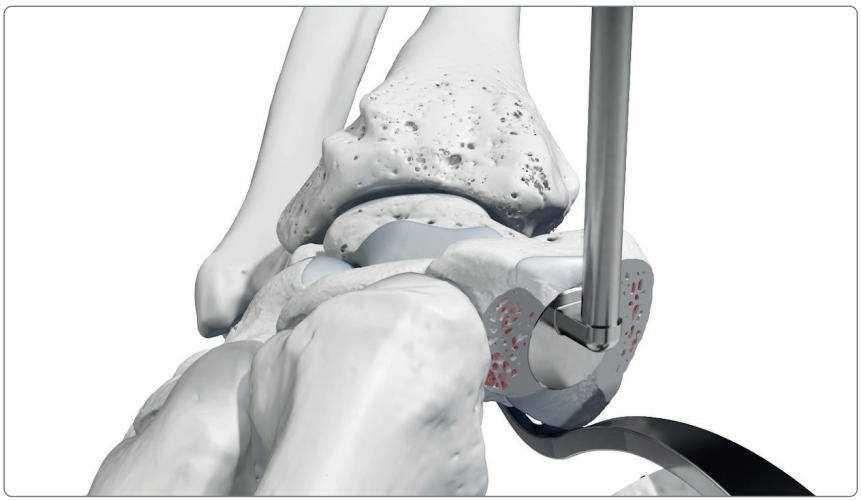


Do not bend the K-wire during reaming; lower down the reamer handle as much as possible.

Remove the K-wire, clean and dry the trapezium and select the corresponding cup trial (conical or spherical, Ø9 or Ø10 mm) to test the trapezium bone preparation.



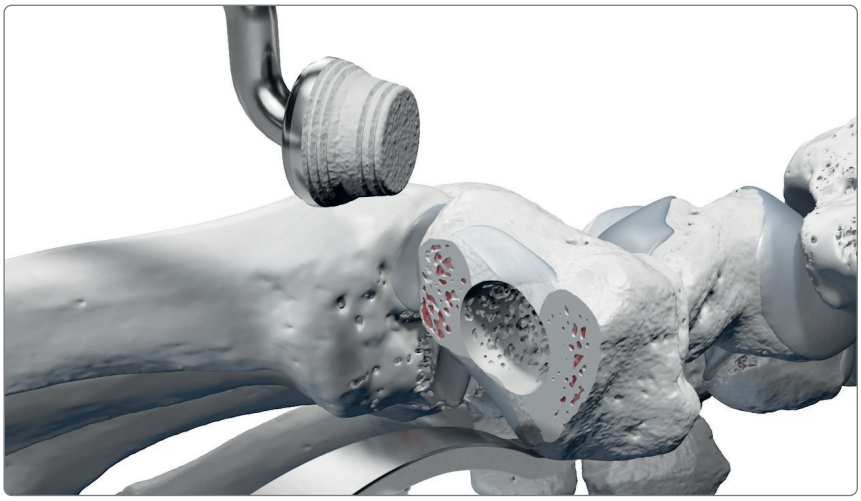
Insert the trial in the bone preparation and verify the complete seating of the tip as well as the stability (the trial must self-hold in the trapezium).

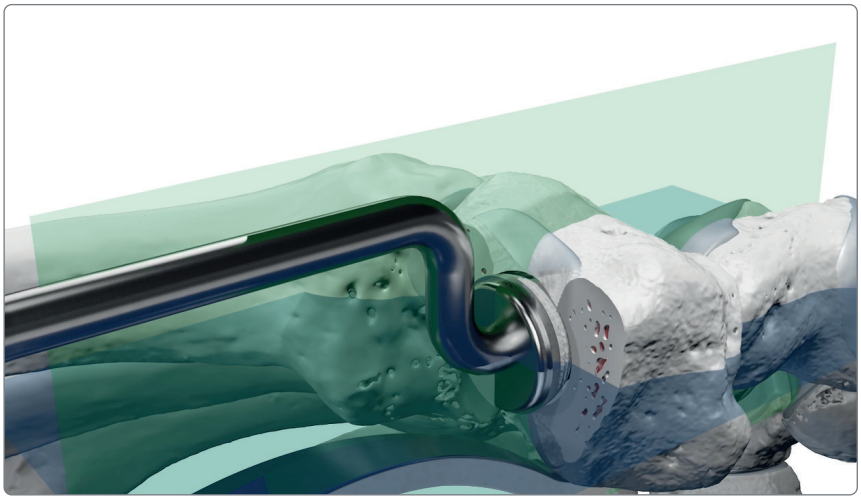


In case stability is not achieve, reiterate reaming and testing steps.

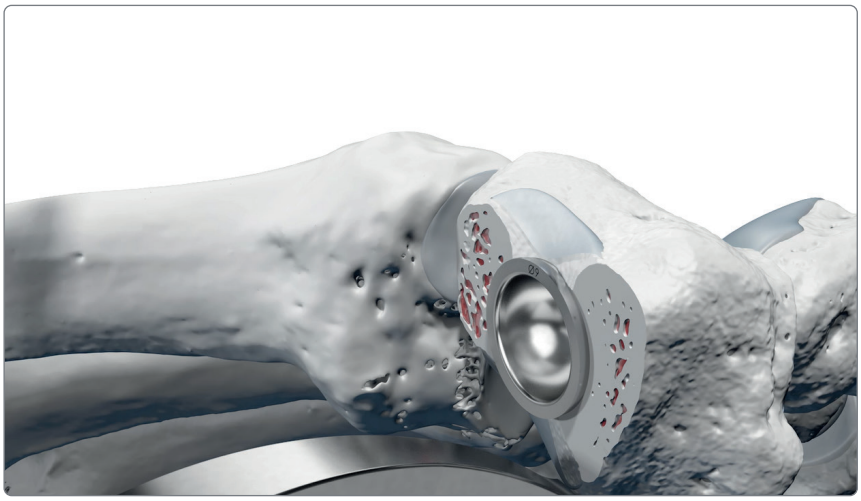
STEP 7 - IMPLANTING THE CUP

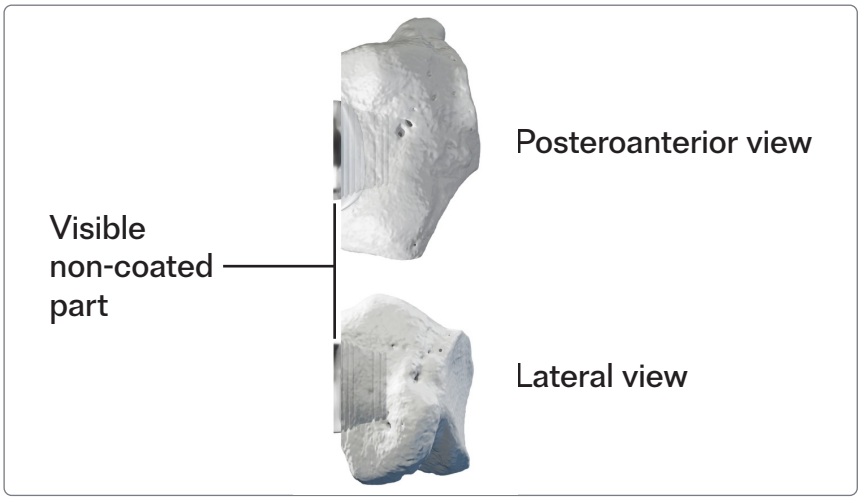
Select the final cup implant corresponding to the desired shape (conical or spherical) and size (Ø9 or Ø10 mm).
Wash and dry carefully the implantation site.
Hold the implant with the dedicated cup holder and press the cup in the prepared trapezium bone.





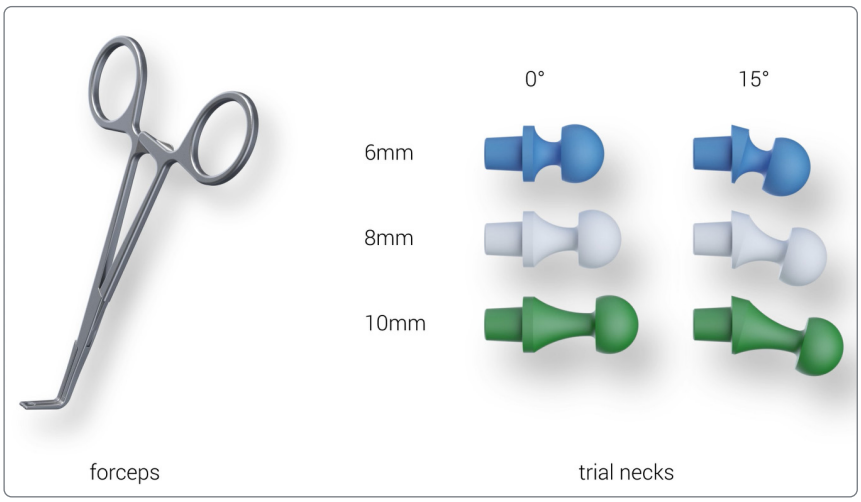
Gently impact with a hammer until the coated part of the cup implant is seated in the bone.

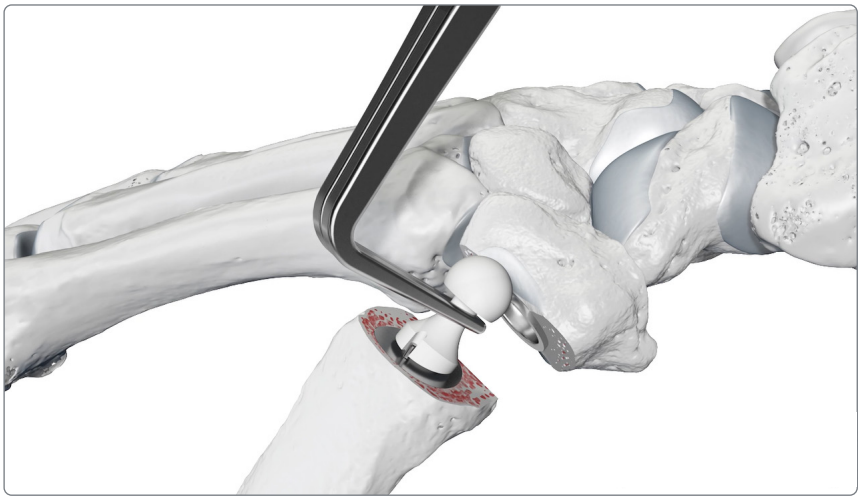




STEP 8 - NECK SIZE AND VARIANT EVALUATION

Use the neck holding forceps to place the neck trial on the stem. Reduce the joint and check for appropriate neck size and type.





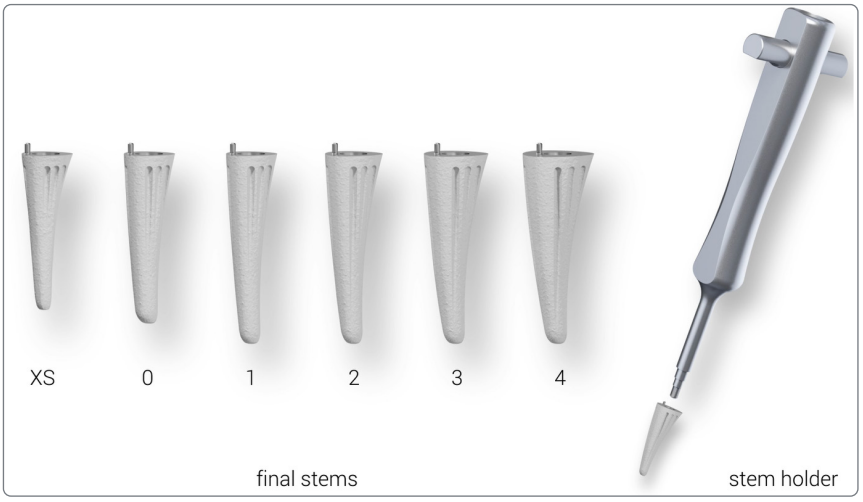
Over-tensioning and mechanical impingement must be avoided at any time.

After selecting the proper neck implant, remove the trial.

STEP 9 - IMPLANTING THE STEM

If the stem trial is still in place, remove the stem trial using the stem holder.

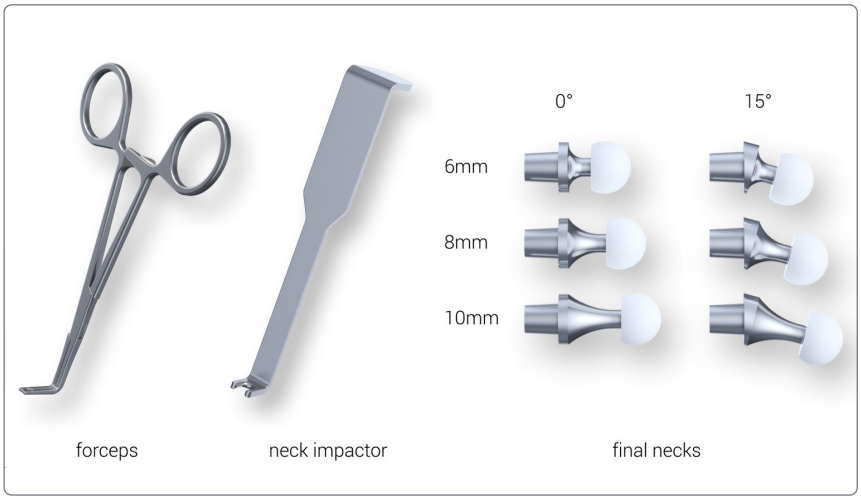
Select the implant corresponding to the desired size (XS, 0, 1, 2, 3 or 4). Wash and dry carefully the implantation site.



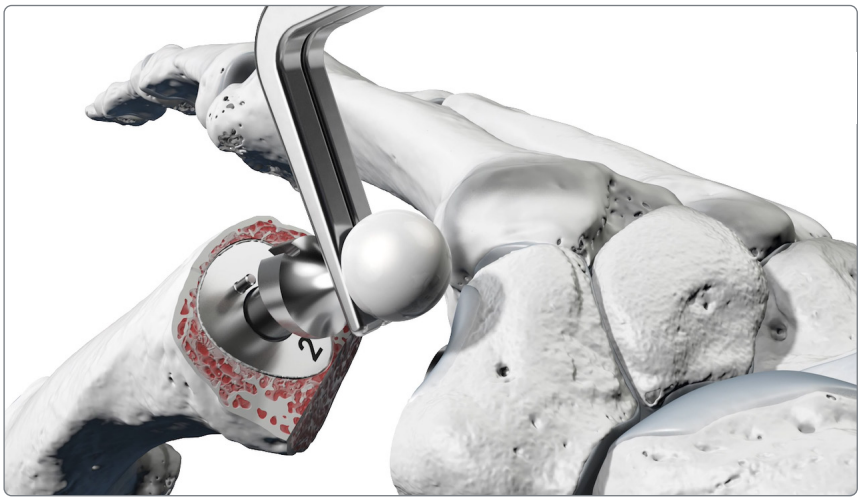
Screw the final stem on the stem holder.
Implant the final stem in the metacarpal bone. Impact gently on the stem holder with a hammer until the coated part of the stem implant is seated in the bone.

STEP 10 - IMPLANTING THE NECK

Select the final neck implant corresponding to the desired shape (straight or offset) and length (6mm, 8mm or 10mm) based on the selected trial.

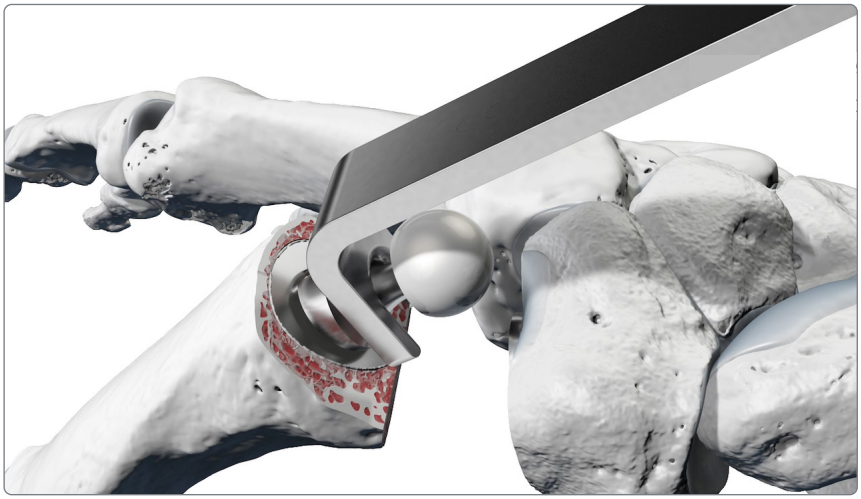


A check is performed to ensure no debris is present in the final stem taper before placing the final neck implant using the neck holding forceps.



Pay attention to the proper alignment of the stem pin with the neck groove.

Impact gently on the neck impactor with a hammer.

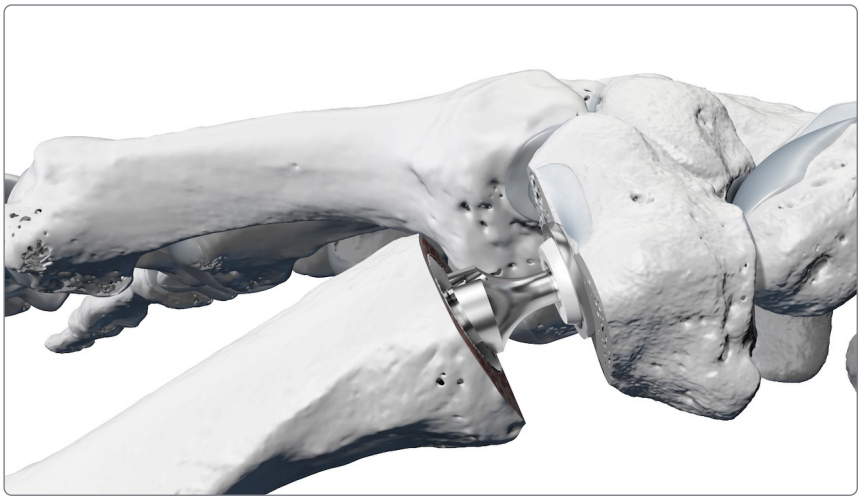


After impaction, a small gap between the neck and the stem is normal.

Pay attention to the neck impactor proper alignment to avoid pull-off effect on the liner. The impactor long axis must be parallel to the neck axis.

STEP 11 - FINAL REDUCTION

Reduce the joint carefully to prevent liner damages.



Proceed to final joint evaluation.

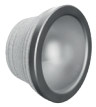
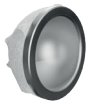
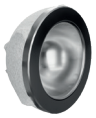
While performing this final evaluation, the surgeon must ensure that:

- Laxity test and piston effect are appropriate.
- Complete thumb mobility can be achieved without bone impingement, intra-prosthetic conflicts and dislocation.

STEP 12 - DRESSING

Apply a soft dressing to keep the opening of the 1st web for about 2 weeks.

CUPS

Conical cup ø 9 mm	CTO109	
Conical cup ø 10 mm	CTO110	
Spherical cup ø 9 mm	CTO09	
Spherical cup ø 10 mm	CTO10	

STRAIGHT NECKS

Straight neck + Liner Size 6	NTO06	
Straight neck + Liner Size 8	NTO08	
Straight neck + Liner Size 10	NTO010	

OFFSET NECKS

Offset neck 15° + Liner Size 6	NTO156	
Offset neck 15° + Liner Size 8	NTO158	
Offset neck 15° + Liner Size 10	NTO1510	

STEMS

Metacarpal stem Size XS	STOXS	
Metacarpal stem Size 0	STO0	
Metacarpal stem Size 1	STO1	
Metacarpal stem Size 2	STO2	
Metacarpal stem Size 3	STO3	
Metacarpal stem Size 4	STO4	

Kit list

Kit designation	Reference document for Kit composition
TOUCH® Kit USA	ITDS_110-007

Disclaimer

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative. KERI MEDICAL SA does not practice medicine. This technique was developed in conjunction with a health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Postoperative management is patient-specific and dependent on the treating professional's assessment. Results will vary based on health, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the order of a surgeon. Rx only.

TOUCH® INTL USA Surgical technique - 110-32E007.00_En - Issue date 2025-03

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KeriMedical

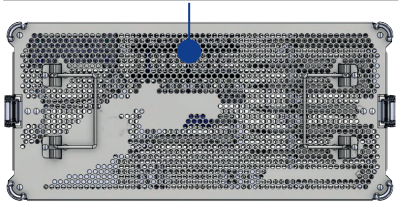
INSTRUMENT TECHNICAL DATA SHEET TOUCH® INTL USA

Instrumentation | Instrumentation dedicated to prosthesis

KeriMedical

TOUCH® INTL lid

SPD12AF02SY1AP



Cannulated spherical reamer	
ø 9 mm	112-A22000
ø 10 mm	112-A22010

Spherical cup pattern (trial)	
ø 9 mm	112-A20000
ø 10 mm	112-A20010

Conical cup pattern (trial)	
ø 9 mm	112-A20100
ø 10 mm	112-A20110

Cannulated conical reamer	
ø 9 mm	112-A22100
ø 10 mm	112-A22110

Cannulated trapezium starter

112-A24000

Centering guide

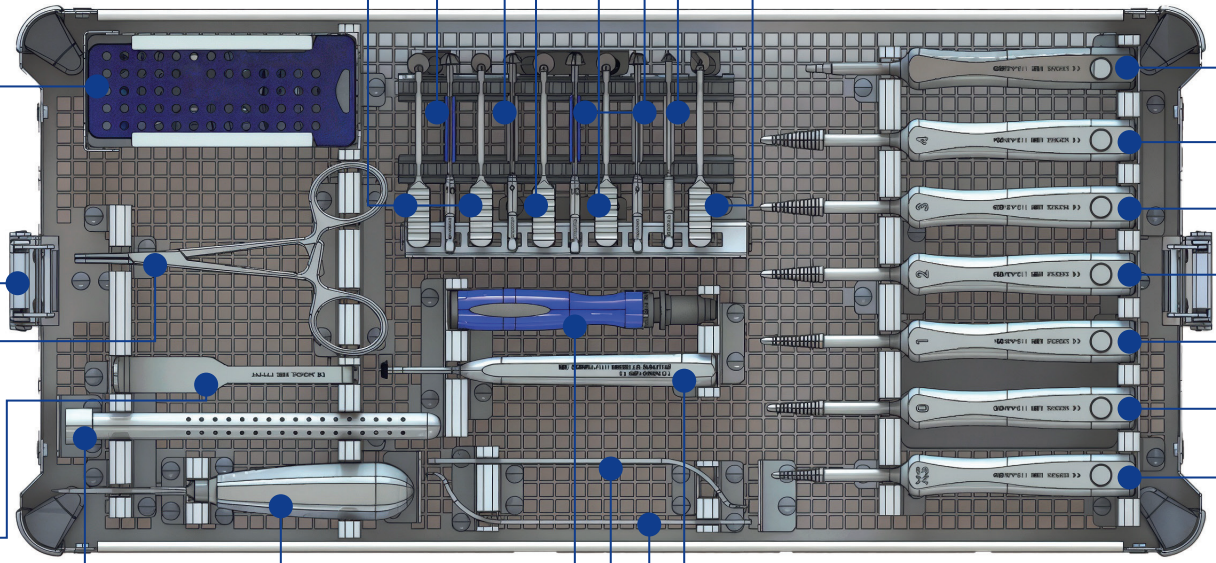
112-A28000

TOUCH® INTL rack

SPD12AF03RK1AP

TOUCH® INTL rack lid

SPD12RK1ACOUV01



TOUCH® INTL tray

SPD12AF01PN1AP

Neck holding forceps

112-A12000

Neck impactor

112-A14000

Kirschner wire tube 16 cm ø12 mm

000-A00500

Stem holder

112-A32000

Metacarpal rasp	
Size 4	112-A31004
Size 3	112-A31003
Size 2	112-A31002
Size 1	112-A31001
Size 0	112-A31000
Size XS	112-A31005

Straight AO handle

112-A91000

Offset cup Holder Positioner Impactor

112-A29400

Bone awl

000-A00900

Snake retractor

000-A00100

Forked retractor

112-A00200

Kirschner wire (provided separately)

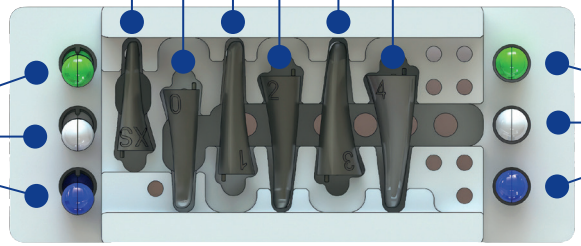
112-A00100

INSTRUMENT TECHNICAL DATA SHEET TOUCH® INTL USA

Instrumentation | Rack

Stem pattern (trial)	
Size XS	112-A30105
Size 0	112-A30100
Size 1	112-A30101
Size 2	112-A30102
Size 3	112-A30103
Size 4	112-A30104

Offset neck pattern (trial)	
Size 10 | L	112-A51510
Size 8 | M	112-A51508
Size 6 | S	112-A51506



Straight neck pattern (trial)	
Size 10 | L	112-A50010
Size 8 | M	112-A50008
Size 6 | S	112-A50006

Rx only

Instrument technical data sheet TOUCH® INTL USA
ITDS_110-007.00
Issue date 2025-03

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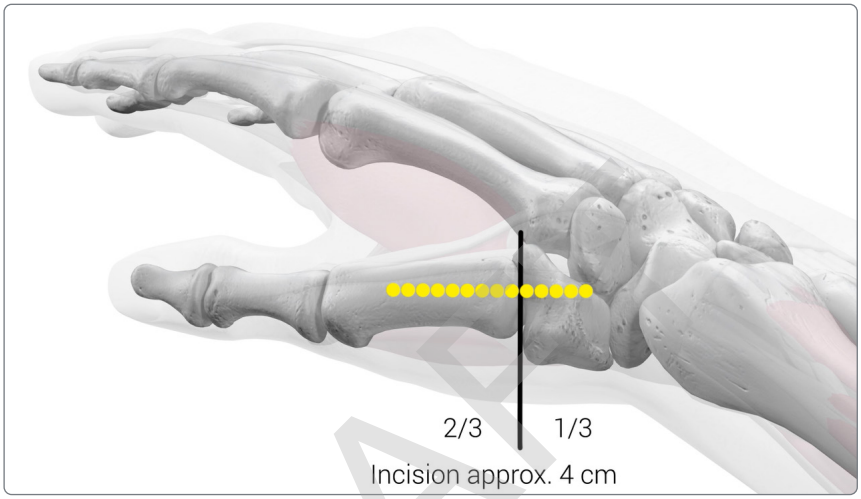
TABLE OF CONTENT

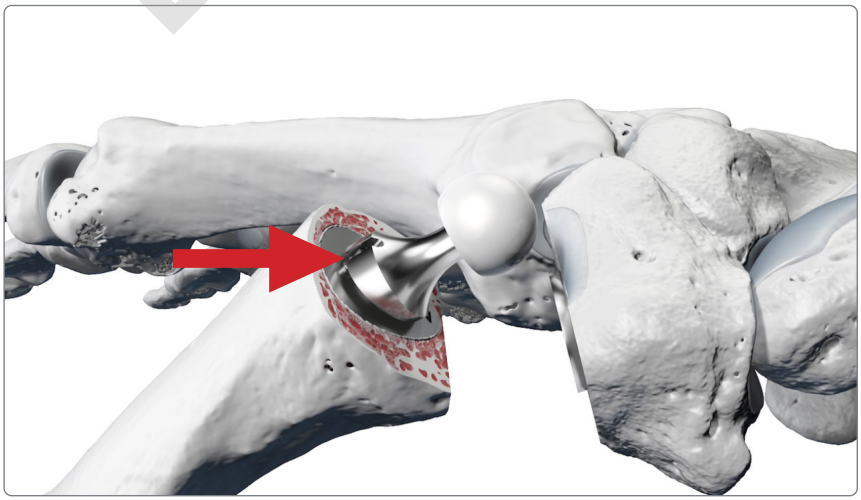
REMOVAL SURGICAL TECHNIQUE

STEP 1 - APPROACH AND NECK REMOVAL

Incise the skin over the CMC1 joint (2/3 metacarpal, 1/3 trapezial) to favor a good joint exposure (about 4 cm).
Open the capsule and dislocate the joint.



Insert a standard osteotome in the gap between the neck collar and the stem. Knock on the osteotome with a hammer to dislocate the taper connection between neck and stem.



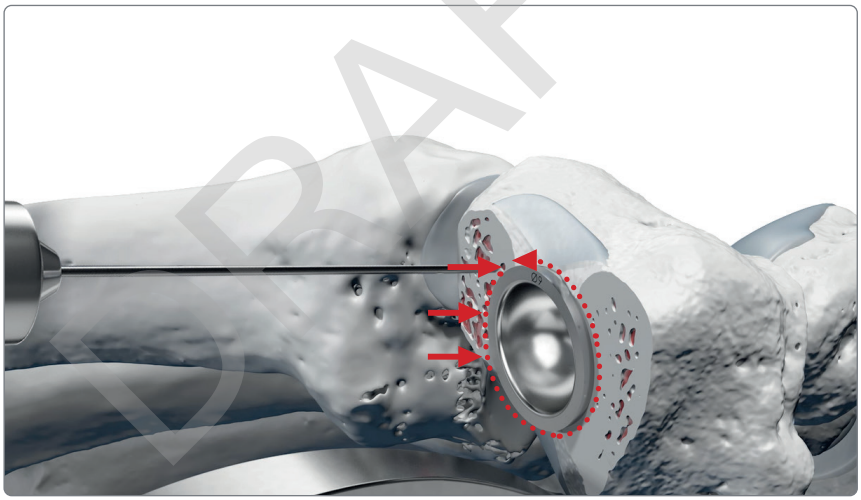
STEP 2 - CUP REMOVAL

CASE 1: The cup is loose

In case the cup is loose, pull on the cup edge using a standard forceps (Adson forceps or needle holder).

CASE 2: The cup is osteointegrated

Use a K-wire to perform small holes all around the cup circumference.
If the cup is spherical, then use a standard osteotome to make the cup flip.
If the cup is conical, then use a standard forceps (Adson forceps or needle holder) to pull on the cup edge.



STEP 3 - STEM REMOVAL

In case of total joint arthropalsty conversion to Trapeziectomy, it is at surgeon's discretion to leave the stem in place or remove it, according to the selected revision surgical procedure and the benefit/risk for the patient.

CASE 1: The stem is loose

In case the stem is loose, screw the stem holder on the stem and remove the stem from the metacarpal bone using a hammer.

CASE 2: The stem is osteointegrated

Use a K-wire to perform small holes all around the stem circumference.
Once the stem become loose, screw the stem holder on the stem and proceed as for case 1.

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Disclamer

For indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert or contact your local representative. KERI MEDICAL SA does not practice medicine. This technique was developed in conjunction with a health care professional. This document is intended for surgeons and is not intended for laypersons. Each surgeon should exercise his or her own independent judgment in the diagnosis and treatment of an individual patient, and this information does not purport to replace the comprehensive training surgeons have received. As with all surgical procedures, the technique used in each case will depend on the surgeon's medical judgment as the best treatment for each patient. Postoperative management is patient-specific and dependent on the treating professional's assessment. Results will vary based on health, activity and other variables. Not all patients are candidates for this product and/or procedure. Caution: Federal (USA) law restricts this device to sale by or on the or on the order of a surgeon. Rx only.

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