EN

Instructions for Use

TOUCH® CMC 1 PROSTHESIS

CAUTION:
U.S. Federal law restricts this device to sale by or on the order of a licensed practitioner

Instructions for Use 110-21B001.01_En

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1 | Introduction

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

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

3.1.1. p.d. atitikimas: mechaninis tvirtinimas

Device Description

TOUCH® 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.
Refer to external labelling to identify the component size and/or variant.
TOUCH® prosthesis is non-absorbable and is intended for single use only.

How it’s supplied

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

Intended Use

TOUCH® CMC 1 prosthesis is intended to surgically treat 1st carpometacarpal (CMC) joint osteoarthritis (OA) by total joint replacement (arthroplasty).

Intended Users

Hand surgeons

Target population

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

No specific group is targeted because of evolving indications related to the idiopathic character of the target pathological condition: though literature data emphasizes the prevalence of rhizarthrosis in post-menopausal women, there are large population groups presenting same problem because of occupational activities continuously evolving (recently including overuse of smartphones) or different etiologic factors.
TOUCH® prosthesis is not intended to treat children or pregnant or nursing women.

Expected Medical benefits

- Decrease of pain
- Reduction of functional disability

Expected Lifetime

10 years

2 | Indication

Symptomatic Trapezo-Metacarpal (TMC) joint osteoarthritis (OA), also called rhizarthrosis, thumb base OA or 1st Carpo-Metacarpal (CMC) joint OA.

Staging and severity: though scientific studies attest use of similar devices in CMC1 OA stages II, III and IV, they also show these radiological degeneration stages to be uncorrelated with symptoms, therefore the indication will be based by the specialized medical practitioner on the whole clinical picture, including severity stages but also symptoms such as pain and disability and their intensity, as well as patients'occupational needs and demands.

3 | Contraindication

- Acute or chronic infections, local or systemic
- Muscular, neurological, or vascular severe deficiency affecting the joint
- Poor bone quality preventing the implant fixation
- Bones dimensions incompatible with implant sizes
- Do not use on patients who are allergic to the product's components or who have known allergies (chromium, nickel). Refer to "MATERIALS" for information on substances
- Any concomitant disorder that may affect the function of the implant
- Do not use on pediatric population and pregnant or nursing women

4 | Adverse events and complications

KERI MEDICAL SA must be informed of any adverse effect reported to the Competent Authority in medical device surveillance.
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 the 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 (dislocation) or deformation, premature wear, intra-prosthetic conflicts, luxation
- Functional complications: reduced range of motion, joint stiffness, painful limitations, joint instability

Related to the surgery:

- Early and/or late infection
- Hematoma
- Cutaneous necrosis
- Thrombosis, cardiovascular disorder
- Pain
- De Quervain Tenosynovitis, tendonitis
- Trigger Thumb
- Inflammatory or allergic reaction
- Neurological complications, Dysesthesia (decreased sensitivity)
- Temporary complex regional Pain syndrome (CRPS)

5 | Limitation of the device

- Do not use the product in case a nearby joint has been treated by arthrodesis or with a hardware which may compromise the implantation
- The association of TOUCH® components with implants having another origin is not allowed. In this condition, adequacy of materials and sizes is not ensured
- 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. Do not use bone cement for implants fixation. KERI MEDICAL SA cannot be liable of any responsibility in case of off-label use.

6 | Warnings and precautions

- Implantation of these medical devices should be performed by a hand 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
- 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
- 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 intraprosthetic conflicts and limit migration or loosening risks. A 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 impaction step
- Do not oversize the implants and favor progressive impaction to limit the risk of peroperative fracture
- Do not apply pressure on empty metacarpal bone to avoid per-operative fracture
- 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

7 | Packaging and labelling

The TOUCH® prosthesis components are presented in individual unit packages.
The external box bears external label which allows to ensure 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.

8 | 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.

9 | Materials

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

The information below lists the substances in the implant. Additional trace substances may be present due to the manufacturing process. Please contact KERI MEDICAL SA for additional information.

Material description	Material nominally contains the following substances (mass %)
Stainless steel 1.4472 (ISO 5832-9)	Chromium – 19.5 to 22 Nickel – 9 to 11 Manganese – 2 to 4.25 Molybdenum – 2 to 3 Silicon - 0.75 max Niobium – 0.25 to 0.8 Nitrogen – 0.25 to 0.5 Copper – 0.25 max Carbon – 0.08 max Phosphorus – 0.025 max Sulfur – 0.01 max Iron – balance
Highly cross-linked UHMWPE (ISO 5834-1)	Ethylene homopolymer (C2H4)n Titanium – 0.004 max Calcium – 0.0005 max Chlorine – 0.003 max Aluminium – 0.002 max Ash – 0.0125 max
Titanium alloy TA6V ELI (ISO 5832-3)	Aluminium – 5.5 to 6.5 Vanadium – 3.5 to 4.5 Iron – 0.25 max Oxygen – 0.13 max Carbon – 0.08 max Nitrogen – 0.05 max Hydrogen – 0.012 max Titanium – balance
Hydroxyapatite (ISO 13779-2)	Phosphocalcic ceramic (Ca, P) : 1.61 to 1.76 Ca:P atomic ratio Arsenic – 0.0003 max Cadmium – 0.0005 max Mercury – 0.0005 max Lead – 0.003 max Heavy Metals – 0.005 max
Titanium T40 (ISO 13179-1)	Oxygen – 10 max Nitrogen – 5 max Iron – 0.6 max Hydrogen – 0.3 max Carbon – 0.1 max Titanium – balance

Note: There are no restricted substances or material of animal or human origin in the TOUCH® prosthesis, nor medicinal substances.

10 | Handling and storage

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

11 | 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 sticked 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® prosthesis. Any serious incident that has occurred in relation with the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

The patient has to be aware that regular follow-up by a hand surgeon may allow to detect the signs of prosthesis failure before any functional alterations.
After TOUCH® prosthesis implantation, it is advisable to inform the patient of the following precautions:

- Respect the prescribed surgeon post-operative protocol
- Never intentionally do movements which could lead to the prosthesis luxation
- Limit «at risk» activities (carry heavy objects, practice hand contact sports) or wear protective means during these activities according to surgeon recommendations.
- Consult the surgeon in the event of a fall, injury, infection, or unusual implants behavior
- 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 Summary of Safety and Clinical Performance (SSCP) is available on KERI MEDICAL SA patient page accessible via https://www.kerimedical.com. Once possible, this SSCP will be made available on the European database on medical devices (Eudamed).

12 | Magnetic resonance (MR) safety information

Non-clinical testing has demonstrated that the TOUCH® prosthesis range is MR Conditional at 1.5T and 3T in accordance with the ASTM F2503-20 standard definitions. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static Magnetic Field Strength: 1.5 or 3 T
- Cylindrical-bore
- Horizontal magnetic field (B_0)
- Maximum spatial field gradient:
  - 1.5 T: 34.67 T/m (3467 G/cm)
  - 3 T: 17.34 T/m (1734 G/cm)
- Radiofrequency (RF) field exposure:
  - RF excitation: Circularly Polarized (CP)
  - RF transmit/receive coil: whole-body transmit/receive coil
  - Maximum permitted whole-body averaged specific absorption rate (SAR): Normal Operating Mode, 2 W/kg
- Scan duration and wait time: maximum 1h of continuous scanning
- MR image quality may be compromised if the imaging area of interest is in the exact same area of the implant. Some manipulation of scan parameters may be required to compensate for the artifact. In non-clinical testing, the image artifact caused by the device extends approximately 36 mm from the TOUCH® prosthesis when imaged with a spin echo pulse sequence and 56 mm with a gradient echo, both at 1.5T.

13 | Information for use

Main steps of the surgical technique are presented below, for more precision refer to the detailed TOUCH® surgical technique (ST_110-32E001) available on request:

- 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-rays 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, and the absence of CAM effect with neck patterns. If necessary, adjust bone resection
- Clean and dry the taper connection. Impact the final neck
- Closure and dressing

Caution: The user must receive the proper information about the product and related surgical procedure to ensure its safe and effective use.

It is recommended to follow-up patient on regular basis. Follow-up frequency or reported outcomes has to be defined by the surgeon.

The Summary of Safety and Clinical Performance (SSCP) is available on KERI MEDICAL SA HCP page accessible via https://www.kerimedical.com. Once possible, this SSCP will be made available on the European database on medical devices (Eudamed).

14 | 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.

15 | CE Marking

CE 1250

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https://www.kerimedical.com

European Union Authorized Representative (EC REP):

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Explanation of symbols and abbreviations used on product labels

Symbol	Description
	Legal Manufacturer
	Distributor
	Caution, consult the instructions for use for important cautionary information such as warnings and precautions
	Medical Device
	Authorized representative in the European Community
	Unique Device Identification
	Date of manufacture
	Use-by date
	Reference
	Batch code/ Lot Number
	The quantity of unit per package
	Do not use if package is damaged and consult instructions for use

Symbol	Description
	Sterilized using irradiation
	Double sterilization barrier system
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	MR Conditional
	Do not reuse
	Do not resterilize
	Keep dry
	Keep away from sunlight
	Instruction for use is available in an electronic format
	Patient information website
SPHERIC	Spherical cup
CONIC	Conical cup

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