SUMMARY OF SAFETY AND CLINICAL PERFORMANCE INTENDED FOR USERS / HEALTH PROFESSIONALS

Document revision: 18 APR 2023

Date issued: 18 APR 2023

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device.

The SSCP is not intended to replace the Instructions For Use as the main document to ensure the safe use of the device, nor is it intended to provide diagnostic or therapeutic suggestions to intended users or patients.

The following information is intended for users/healthcare professionals. Following this information there is a summary intended for patients.

Contents

A. IDENTIFICATION OF THE MEDICAL DEVICE AND THE MANUFACTURER

A.1 Medical Device

TOUCH® CMC 1 Prosthesis

A.2 Manufacturer's name and address

KERI MEDICAL SA
Route des Acacias 45A
Geneva 1227
SWITZERLAND

A.3 Single Registration Number

CH-MF-000021960

A.4 Basic UDI-DI

764018116010AV

A.5 Medical Device Nomenclature (EMDN,…)

GMDN Code: 40126 - A sterile implantable device designed to replace the proximal end (base) of the first metacarpal of the thumb carpometacarpal (CMC) joint (articulation with the trapezium) typically to treat thumb instability/motion disabilities caused by arthritis or fracture. It is typically a one-piece device, made of one or several materials (e.g., carbon, graphite, metal); implantation may be performed with or without bone cement.
UMDNS code: not applied
EMDN code: P090404 - Hand Prostheses Trapezio-Metacarpal Components

A.6 Class of device

☐ I ☐ IIa ☐ IIb ☒ III

According to Annex VIII, Rule 8, "All implantable devices and invasive surgical-type devices for long-term use are Class IIb unless they are total or partial joint replacement implants, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments."

A.7 Year when the first certificate (CE) was issued covering the device

First certificate by Lapé in 2012 and was resumed by KERI MEDICAL SA in 2018.

A.8 Authorized representative if applicable

KERI MEDICAL FRANCE : FR-AR-000009590

A.9 Notified Body Name

Intertek Medical Notified Body AB

A.10 Notified Body Single Register Number

Identification number 2862

B. INTENDED PURPOSE OF THE DEVICE AND ANY INDICATIONS, CONTRAINDICATIONS, AND TARGET POPULATIONS

B.1 Medical Device intended purpose

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

B.2 Indications(s) & target population(s)

The indication is the Symptomatic Trapeziometacarpal (TMC) joint osteoarthritis (OA), also called rhizarthrosis, thumb base OA or 1st Carpometacarpal (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.

The target population is 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 postmenopausal 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.

B.3 Contraindication(s), restrictions for use and/or limitation(s) of the device

The contraindications are the following:

- 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 the implant sizes,
- Do not use on patients who are allergic to the product's components or who have known allergies (chromium, nickel),
- Any concomitant disorder that may affect the function of the implant,
- Do not use on pediatric population and pregnant or nursing women.

The limitations of the device are the following:

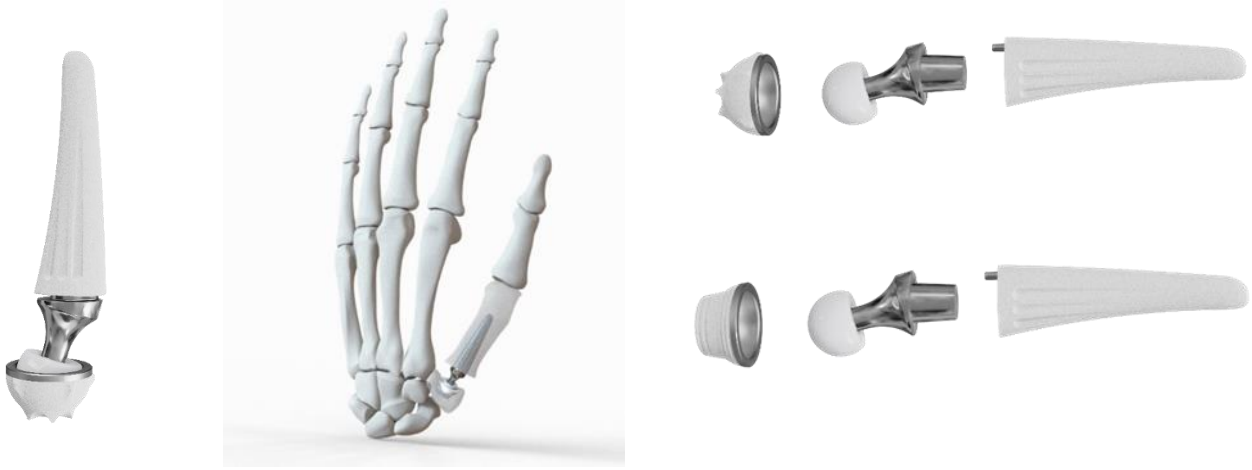
- Do not use the product in case a nearby joint has been treated by arthrodesis or with a hardware which may compromise the implantation.
- The association of TOUCH® components with implants having another origin is not allowed. In this condition, adequacy of materials and sizes is not ensured.
- Only 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.

C. DESCRIPTION OF THE MEDICAL DEVICE

C.1 Description of the Medical Device

C.1.1 Design characteristics

The TOUCH® - CMC1 Prosthesis, is a cementless, ball-and-socket dual-mobility, total CMC I joint replacement prosthesis, designed to treat symptomatic 1st Carpo-MetaCarpal (CMC I) joint osteoarthritis, also called “Rizarthrosis”, “Thumb base OA” or “Trapezo-MetaCarpal (TMC) joint OA”.



The TOUCH® CMC 1 prosthesis is composed of three elements:

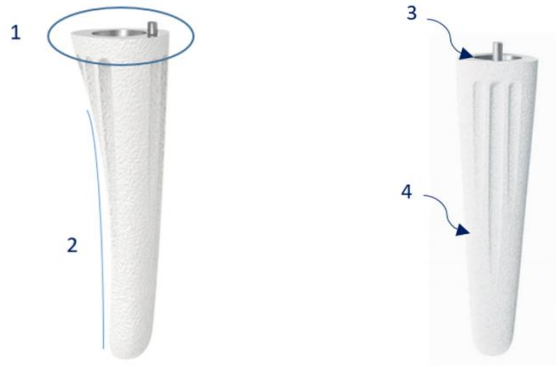
- a metacarpal implant (stem),
- a trapezial implant (cup), and
- a junction implant (neck) topped with a liner.

Device name	Commercial reference
TOUCH® – Stem XS	STOXS
TOUCH® – Stem 0	STO0
TOUCH® – Stem 1	STO1
TOUCH® – Stem 2	STO2
TOUCH® – Stem 3	STO3
TOUCH® – Stem 4	STO4
TOUCH® – Straight neck 6-S	NTO06
TOUCH® – Straight neck 8-M	NTO08
TOUCH® – Straight neck 10-L	NTO010
TOUCH® – Offset neck 6-S	NTO156
TOUCH® – Offset neck 8-M	NTO158
TOUCH® – Offset neck 10-L	NTO1510
TOUCH® – Cup Ø9 spherical	CTO09
TOUCH® – Cup Ø10 spherical	CTO10
TOUCH® – Cup Ø9 conical	CTO109
TOUCH® – Cup Ø10 conical	CTO110

C.1.1.1 TOUCH® Stem

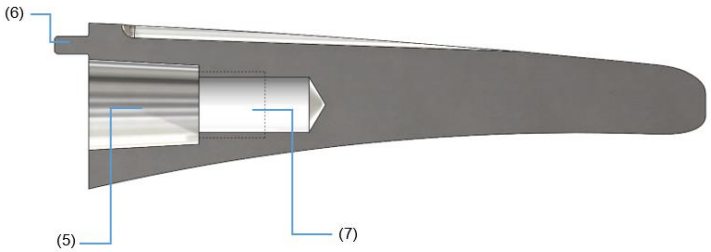
The TOUCH® - CMC1 Prosthesis stem has been designed with a so-called “anatomical shape” providing primary stability (ability to remain at its location after implantation).

The TOUCH® - CMC1 Prosthesis stem is characterized by :
- A flared shape at the level of the metaphysis (1) to limit the migrations of the stem in the metacarpal bone
- A curved profile (2) that allows finding the correct orientation of the stem using the curvatures of the metacarpal bone
- A triangular section (3) to limit the rotation of the stem around the main axis of the metacarpal



This primary stability of the stem is reinforced by its implantation using a "press - fit" technique to obtain a congruence between the implant and the bone preparation.

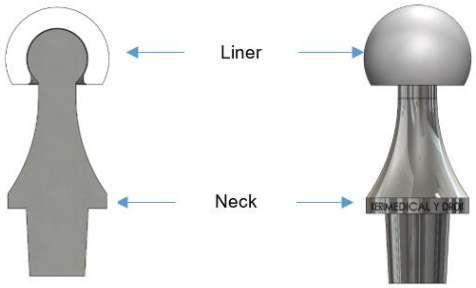
The stem has a double coating (4) of porous titanium and hydroxyapatite (HAP) providing a secondary stability. HAP is osteoconductive and therefore will favour bone regrowth whereas the porous titanium interface will provide secondary mechanical stability.
The connection of the stem with the neck is provided by a self-locking taper (5) ; the mechanical principle of the Morse taper is to enable “automatic” centering and symmetric grip, ensuring adherence between the two components.
Orientation of the neck (especially for the offset neck) is provided by assembly of the pin (6) of the stem in the groove of the neck. The interface with the instruments (“holder” and/or impactor) is ensured by a thread (7).



The dimensions are identical for the male taper (neck) and female taper (stem) and for the groove (neck) and pins (stem) in order to allow the modularity between different sizes of stems and necks.
The range of the stems is composed of 6 different sizes (XS, 0, 1, 2, 3, 4).

C.1.1.2 TOUCH® Neck & liner

There is a ball joint between the head of the neck and the concave internal surface of the liner and a second articulation between the convex surface of the liner and the concave inner surface of the cup.



The retentivity of the liner is done by the geometric coverage made by the liner on the head of the neck. This retentiveness is intended to avoid intra-prosthetic dislocation.

The size range of the neck comprises 6 different sizes distributed in 3 lengths (6mm, 8mm and 10mm) and 2 variants (straight and 15° offset).

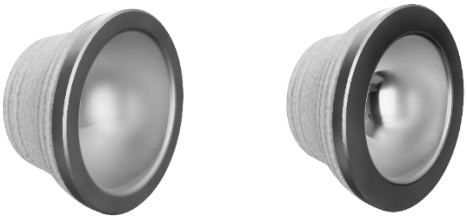
C.1.1.3 TOUCH® Cup

The cup is intended to be implanted in the trapezium bone.
The stability of the cup is reinforced by its implantation using a "press-fit" technique to obtain a congruence between the implant and the bone preparation.
The internal surface of the cup permits a connection with the liner (ball and socket principle).

There are 2 external shapes of cup:
a) The cup with a spherical shape. This form aims a minimal footprint in order to preserve the bone stock of the patient and allow the surgeon to refine its orientation per-operatively.
The cup is topped at its pole with 6 fins and displays 5 additional anti-rotatories fins at its equator to allow immediate post-operative primary stability.
The size range of the spherical cup comprises 2 sizes (Ø 9 / height 5.2 mm and Ø10 / 5.7 mm height).

b) The cup with a conical shape. By its design the conical cup can be suspended and allows a stable fixation (primary) for patients with thin trapezium. This conical design limits the rotation of the implant during the bone preparation regardless of the depth. The specific features of this cup design are 2 series of external grooves (triangle section angled at 60°), meant to enhance post-operative primary stability.

The size range of the conical cup comprises 2 sizes (Ø9 / height 5 mm and Ø10 / height 5.5mm).



C.1.2 Information on single use

The TOUCH® CMC 1 prostheses are intended for single-use only.

C.1.3 Sterilization method

The implants are 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.

C.1.4 Materials

- TOUCH® stem is in Titanium 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 cross-linked 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.

C.1.5 Operating principles & mode of action

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

Main steps of the surgical technique are presented below, for more precision refer to the detailed TOUCH® surgical technique:

- 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,
- 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. In 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 technique 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.

C.2 A reference to previous generation(s) or variants if such exist, and a description of the differences

In 2012, the evaluated device was initially developed by LAPE Medical.

In 2013, in order to improve its stability, LAPE changed the cup's shape/geometry.

In 2014, following the production of the 1st series of the TOUCH® - CMC1 Prosthesis, for reasons of ease of machining, LAPE decided to make two changes on the TOUCH® - CMC1 Prosthesis' cup: change in the tolerance of the diameter of internal sphere and change the shape of picks.

In 2015, following feedback from surgeon users of the TOUCH® - CMC1 Prosthesis, LAPE decided to:

- change the geometry of the stem in order to be closer to the anatomy of the bony canal of the first metacarpus to improve the bone / stem contact
- add a size 0 to the range of stems

In 2016, for reasons of ease of machining of the TOUCH® - CMC1 Prosthesis, LAPE decided to change the tolerances for the groove of the straight and offset necks and to change the tolerances for the offset neck. **In December 2016, the TOUCH® - CMC1 Prosthesis was bought by KERI MEDICAL SA.**

In 2017, at the request of KERI MEDICAL SA, the inner groove of the TOUCH® - CMC1 Prosthesis' cup is removed and the radius on the edges inside and outside of the cup are increased from R0.1 to R0.3 ; these changes facilitate the use of the cup holder and the release of the cup at the implantation site.

In 2018, KERI MEDICAL SA took the CE of the TOUCH® - CMC1 Prosthesis over and therefore changed the engraving of implants by replacing the LAPE logo by the KERI MEDICAL SA logo. The TOUCH® - CMC1 Prosthesis range of devices taken over by KeriMedical were identical in terms of geometry, surface states, materials and manufacturing methods (still performed by LAPE) to the TOUCH® - CMC1 Prosthesis by LAPE.
At the same time, KERI MEDICAL SA expanded the range of cups by offering a conical version. This new cup version was designed to better adapt to trapezium specificities.
KERI MEDICAL SA also introduced a second manufacturing source without changing the product specifications (same geometry, same surface state, same materials, same manufacturing technologies but different suppliers).

In July 2019, KERI MEDICAL SA added a new XS size (Size 05) for the stem for small metacarpal.
In December 2019, KERI MEDICAL SA changed the liner raw material from a standard polyethylene (UHMWPE) to a cross-link UHMWPE version to enhance the liner resistance to wear and offer a larger margin of safety for active patients.

In 2020 & 2021 substantial manufacturing changes have been implemented.

In 2022, KERI MEDICAL SA launches the MDR transition of the TOUCH prosthesis. E-IFU was implemented on the labels.

C.3 Description of any accessories which are intended to be used in combination with the device

Not applicable

C.4 Description of any other devices and products which are intended to be used in combination with the device

The TOUCH® CMC 1 Prosthesis is supplied with a dedicated set of surgical instruments available as either cannulated or non-cannulated (details can be found in TOUCH® surgical technique available on request).

The surgical instrumentation is either purchased CE marked by their respective manufacturer or legally manufactured by KERI MEDICAL SA.

Several instruments are manufactured by KERI MEDICAL SA. These instruments are either MDD class I medical devices per rule n°6, or MDR class I medical devices per rule n°1.
All other instruments (purchased CE marked) are MDD class I medical devices, MDR class I medical devices except for the self-retaining retractors (MDD class IIa) and Kirschner wires (MDD class IIb).
GMDN code: 44054 - Orthopaedic surgical procedure kit, non-medicated, reusable

D. RISKS AND WARNINGS

D.1 Residual risks and undesirable effects

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).

Quantification of risks
For TOUCH® prostheses, the following trend report methodology has been put in place based on complaints follow-up data bases regarding Expected side effects/risks. The following complaints rates are observed: between 0.12 and 0.34% by year over the last 4 years.

The number of incidents over the 4 years (2017-2021) were collected and used to have the average value per year. The rate is obtained by the division of each occurrence of an event by the number of implants (1 implant = neck + cup + stem) over the 4 years (26518).

Related to the device

Adverse events / Complication	Indicator	Observation period	Non-Conforming Event (2017-2021)
Allergic reaction	Number of cases	Annually	0%
Metallosis			0,015 % (2 cases/10000)
Osteolysis (Bone resorption)			0%

Adverse events / Complication	Indicator	Observation period	Non-Conforming Event (2017-2021)
Per- or post-op fractures			0,011% (2 cases/10000)
Calcification			0,004% (1 case/10000)
Ossification			0%
Migration			0%
Loosening or unsealing			0,041% (5 cases /10000)
Breakage (dislocation) / damage			0%
Intra-prosthetic conflicts			0,023% (3 case/10000)
Wear**			0,026% (3 cases /10000)
Luxation			0,034% (4 cases /10000)
Functional complication: reduced range of motion, joint stiffness, painful limitations, joint instability			0,004% (1 case/10000)

Related to the surgery

Adverse events / Complication	Indicator	Observation period	Non-Conforming Event (2017-2021)
Early and/or late infection	Number of cases	Annually	0%
Hematoma			0%
Cutaneous necrosis			0%
Thrombosis, cardiovascular disturb			0%
Pain (>score 3 VAS)***			0,045% (5 cases /10000)
De Quervain Tenosynovitis, Tendonitis			0%
Trigger Thumb			0%
Neurological complications, Dysesthesia			0%
Temporary complex regional Pain syndrome (CRPS),			0%

****** the wear appreciation will take in account the patient activity.

*** Concerning pain: the trend analysis will take in account the pain period of time. A differentiation between abnormal and normal pain period of time will be considered.

D.2 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.
- 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 intra-prosthetic 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 per-operative 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.

D.3 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 or infection,
- Never do intramuscular injection near (on the side of) the prosthesis
- During any treatment (e.g. injection) or investigation (e.g. MRI) affecting the treated hand, the patient must inform the practitioner about having received an artificial joint.

D.4 Other relevant aspects of safety, including a summary of any field safety corrective action (FSCA including FSN), if applicable

Not applicable

E. SUMMARY OF CLINICAL EVALUATION AND POST-MARKET CLINICAL FOLLOW-UP (PMCF)

E.1 Summary of clinical data related to equivalent device, if applicable

Not applicable

E.2 Summary of clinical data from conducted investigations of the device before the CE-marking, if applicable

Not applicable

E.3 Summary of clinical data from other sources, if applicable

Scientific literature on TOUCH® CMC1 Prosthesis analysis gives the following results:
Return to work was reported to average 2.6 months in 88.2% of cases.
Before surgery, pain was rated at 9 (range, 8–9.75) on 0–10 VAS and postoperatively at 0 (range, 0–2.75).
Functional improvement was moderate and rapid.
Satisfaction rates averaged 95%.
Complications rates averaged 15% (4.6-25%), with main occurrence being asymptomatic periprosthetic ossification (25%), tendinopathy (15%), aseptic loosening 7.6% (1.8-13%) with moderate cup migration in 12%, 1.7% of dislocation and 1.8% of wear, with a revision rate of 3.3% (2-4.6%).
Implant survival rate averaged 97.7% but follow-up (range 1.33 to 3 years) is inferior to 10 years for the moment (95.4-100%)[1, 2, 3, 4, 5].

1. Froschauer, S.M., et al., Autologous Fat Transplantation for Thumb Carpometacarpal Joint Osteoarthritis (Liparthroplasty): A Case Series with Two Years of Follow-UP. J Clin Med, 2020. 10(1).
2. Gonzalez-Espino, P., et al., Touch® double mobility arthroplasty for trapeziometacarpal osteoarthritis: outcomes for 92 prostheses. Hand Surgery and Rehabilitation, 2021. 40(6): p. 760-764.
3. Lussiez, B., C. Falaise, and P. Ledoux, Dual mobility trapeziometacarpal prosthesis: a prospective study of 107 cases with a follow-up of more than 3 years. J Hand Surg Eur Vol, 2021. 46(9): p. 961-967.
4. Moreels, R., et al., Early dislocation of a dual mobility ball-and-socket prosthesis: importance of early sequential postoperative radiography. Hand Surgery and Rehabilitation, 2022.
5. Van Royen, K., J. Goubau, and C.K. Goorens, Traumatic intraprosthetic dislocation of a dual mobility trapeziometacarpal joint prosthesis: a case report. J Hand Surg Eur Vol, 2021. 46(2): p. 193-195.

E.4 An overall summary of the clinical performance and safety

The expected medical benefits of the TOUCH® CMC1 Prosthesis are decrease of pain and reduction of functional disability. Documented clinical benefits from literature review (§E.3) and ongoing post-market clinical follow-up (§E.5) give the following findings.

- Decrease of pain

The pain relief, measured with a visual analog scale, was statistically significant in all studies. At baseline, the mean pain was 7.83 ; it decreases to 1.5 the first months and stabilizes at 0.94 after one year.

- Reduction of functional disability

The mean global functional improvement, measured with the DASH questionnaire, shows an improvement of functionality of more than 30% at 1 year follow-up.
The mean thumb mobility evolution through Kapandji's opposition scores changes from 8.1 at baseline to 9.6 at one year.
The mean grip and key pinch strength respectively increase from 12kg to 15kg and from 3.5kg to 5.6kg at one year follow-up.

- Other outcomes

An average of 96% of the patients return to work after the surgery with a mean timelapse of nearly 2.5 months.
The mean timelapse to resume daily activities is 0.5 months.
Patient satisfaction rate following this surgery is 93.6%.
In this light, all above relevant outcome parameters (pain relief, functional improvement, resuming daily living activities or work and satisfaction) represent different forms of patient benefit, with the mention that benefit cannot be related solely to the evaluated device but the whole device and associated treatment (including instruments making possible this treatment), situation which is identical for the safety. The above forms of benefit were cumulated by most patients.

- Safety

The implant survival rate at middle term is 97.7%. As the implant expected lifetime is 10 years, long-term data are needed. Currently, 2 ongoing studies will provide data at 10 years in the coming years.
The main risks identified are:

- Complex Regional Pain Syndrome (CRPS, 1%), infection (0.4%) and De Quervain tenosynovitis (5.6%) as surgery related complications.

- Dislocation, luxation, loosening, migration, subsidence wear, metallosis and calcification as prosthesis related complications. The latter presenting rates 1%, except for mild migration accruing in 2.38% in a study also showing stabilization 3 months after. Revision surgery was under 3%.

In order to obtain further comprehensive data on the performance and safety of the device, long-term clinical data will be collected within ongoing PMCF studies (see §E.5).

E.5 Ongoing or planned post-market clinical follow-up

Four post-market clinical follow-up investigations are currently conducted in order to obtain further comprehensive data on the performance and safety of the TOUCH® CMC1 Prosthesis.

E.5.1 PMCF Touch (sponsor Keri Medical SA)

In November 2019, KERI MEDICAL SA launched its own prospective, multicenter, observational, non-comparative PMCF study on TOUCH® CMC1 Prosthesis: “Efficacy and safety of the Touch® prosthesis used with its instruments in the treatment of rhizarthrosis: an observational post-market clinical study”.

6 centers in France are participating. The primary objective is to evaluate the effectiveness of the TOUCH® CMC1 Prosthesis in reducing pain in the trapeziometacarpal joint and in restoring functional mobility at three months post-op. This study will allow to monitor performance (mainly through pain reduction (VAS), Kapandji index, Key Pinch value, functional outcomes (PWRE score)) and safety over 10 years. Data will be collected before surgery (inclusion visit), at the surgery, at the first follow-up visit at 3 months post-surgery and at regular follow-up visits according to usual management.

To date, all the 221 patients are included, and 196 surgeries were performed. The results of the study are not yet available.
The study was stopped prematurely for 14 patients: 12 due to loss of follow-up and 2 due to the following adverse events:

- Trapezoidal fissure during acetabular impaction. Bone grafting per-operative. At the 3-month follow-up visit: trapezium fracture and migration of the acetabulum: removal of the prosthesis and trapeziectomy (0.51%);
- Mobilization of the acetabulum through the trapezium due to effort to get out of the bathtub by leaning on the sink at day + 2 months. The patient did not consult and a revision of surgery by trapeziectomy is done at 3 months (0.51%).

E.5.2 TOUCH Dual mobility trapeziometacarpal prosthesis (Investigator Initiated Study)

This prospective observational study will follow 310 patients for 15 years. The primary objective is the implant survival at middle and long term. The 3 years results were published in 2021 [3].

In 2019, a continuous series of 310 patients were included. Among these 310 patients, the results of the first 118 cases are reported with a follow-up of more than 3 years and a mean follow-up of 40 months (range: 36-52 months). Eleven patients of this series were lost to follow-up, and 107 prostheses were analyzed. The patients in this series had a mean age of 64.6 years (range: 44 to 84 years) and 80.5% were women.
34% of patients were working, with a preoperative level of work or leisure activities scored as light work in 48%, heavy work in 12% and housework in 40% of cases. According to Dell's classification, 56% of patients presented stage 3 osteoarthritis and 31% presented stage 2 osteoarthritis.

No cases of extraprosthetic or intraprosthetic dislocations were observed. However, 5 complications (4.6%) required surgical revision:

- 1 Early cup dislocation, requiring a change of cup
- 2 cases of cup loosening, requiring a change of cup in both cases (same size)
- 2 cases of wear of the polyethylene insert after 4 years of follow-up in a man who had returned to heavy work. Total trapeziectomy was performed with ligamentoplasty using a strip of abductor pollicis longus with a good result.

Furthermore, 10 minor complications were observed: 4 cases of De Quervain's tenosynovitis and 6 cases of trigger thumb between 3 and 12 months after arthroplasty. No cases of infection or complex regional pain syndrome were observed.

102 patients (95%) were very satisfied or satisfied with the functional outcomes. The mean pain intensity in visual analog scale decreased from 4.7 to 0.8 ($p<0.001$). Thumb opposition (Kapandji score) index increased from an average of 8.0 to 9.4, while the mean QuickDASH score improved from 38 preoperatively to 20 at follow-up ($p<0.01$). Key-pinch strength improved from 3.5kg (range 0.5 - 9.5) to 5.5kg (range 3.0 – 11.5).

E.5.3 Cost-effectiveness analysis (Investigator Initiated Study)

A cost-effectiveness study of TOUCH® CMC1 Prosthesis versus resection-suspension-interposition (RSI) arthroplasty was initiated by the Schulthess Klinic (Switzerland) in March 2021. The study will be a prospective mono-center clinical cohort study.
Patients with primary osteoarthritis (OA) at the thumb carpometacarpal (CMC I) joint who will be operated with a TOUCH® CMC1 Prosthesis and who are working will be included (n=80). Patients with a revision surgery, rheumatoid arthritis or non-working patients will be excluded.
As comparison group, the data of a previous cohort of patients who had a RSI arthroplasty and were working (n=42) will be used.
The primary research outcome is the direct medical and indirect costs, and the effectiveness derived from the EQ-5D-5L questionnaire.
The data collection period from first patient first visit (FPFV) to last patient last visit (LPLV) will be 3.5 years. Including study preparation and writing of the final report, the study will last 5 years. A first interim analysis regarding loss of productivity of the 6 months follow-up with half the sample will be available 2.5 years after signing of the contract.

In March 2022, 38 patients have been included for the TOUCH® group.

E.5.4 Comparative study (Investigator Initiated Study)

The BG Klinik of Ludwigshafen initiated a study in 2019 to compare the TOUCH® CMC1 Prosthesis with trapeziectomy: “Comparison of dual mobility Touch® prosthesis with trapeziectomy with ligament

reconstruction for surgical treatment of painful trapeziometacarpal joint osteoarthritis: a matched-pair analysis"
This study is prospective, non-randomised, bicentric, matched-pair (Ethics Committee 2019-14184).
The patients are free to decide their preferred surgical treatment. However, if the criteria for the inclusion were fulfilled, an advice was given to consider insertion of a TOUCH® CMC1 Prosthesis. The matching criteria are the age, the gender and the dominant-hand.
The patients will be followed for 2 years after the implantation.

In June 2021, 15 matching pairs were identified and all patients for the TOUCH® group were included (52 patients for 55 prostheses) and preliminary results were disclosed at the 2021 FESSH congress. [F. Falkner et al, Comparison of dual mobility Touch® prosthesis with trapeziectomy with ligament reconstruction for surgical treatment of painful trapeziometacarpal joint osteoarthritis: a matched-pair analysis, FESSH 2021]
The authors announced that functional results within the early postoperative follow-up after implanting a dual mobility prosthesis were comparable to those of trapeziectomy.
Mobility was more preserved in the arthroplasty group, though evolution of Kapandji index was not significantly different. Moreover, graphs from the presentation attest that pain relief is more rapid in the arthroplasty group (1.5 months instead of 3 months for trapeziectomy) and remains stable from 3 to 12 months follow-up, except for trapeziectomy where pain continues to decrease a bit from 6 to 12 months.
The values for pinch-strength and grip-strength in the dual mobility cohort were significantly superior to those for trapeziectomy and thumb shortening could be avoided.
No adverse events have been declared at this follow-up.

F. POSSIBLE DIAGNOSTIC OR THERAPEUTIC ALTERNATIVES

- Conservative Treatment

The National Institute for Health and Clinical Excellence (NICE) [6, 7], the American College of Rheumatology (ADR)[8] and the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT)[9, 10] published guidelines (and a quality standard of care) for osteoarthritis (including rhizarthrosis) management.

Conservative options are the first intention care to be proposed to patients with rhizarthrosis:

- Aids and devices – orthoses: people with trapeziometacarpal osteoarthritis who experience biomechanical joint pain or instability should wear orthoses (splints) as an adjunct to their core treatments.
- Pharmacological treatments: oral analgesics, topical treatments, NSAIDS, intra-articular injections, all for pain relief.
- Thermotherapy (heat or cold) allowing short term pain relief.
- Exercise and manual therapy focus on stabilizing the TMC joint, increasing pain-free thumb joint range of movement and general body conditioning.
- Electrotherapy as an adjunct to core treatments for pain relief.
- Interventional ultrasound therapy has therapeutically beneficial effects on pain and functional outcomes in the management of osteoarthritis.
- Radiotherapy is an effective treatment option for pain reduction in case of inoperability.
- Nutraceuticals for improving pain.

Optimal management of hand OA requires a combination of non-pharmacological and pharmacological treatment. Conservative treatments will be efficient, especially for incipient stages of TMC arthritis, for a limited time by reducing symptoms. Although this will not eliminate the problem or alter the underlying disease process, it allows the patient the opportunity to plan for surgical treatment at the most opportune time.

- Surgical Treatment

International guidelines and a large number of published studies recommend joint surgery for people with osteoarthritis who experience joint symptoms (pain, stiffness and reduced function) with a substantial impact on their quality of life and are refractory to non-surgical treatment.

The goal of surgical intervention is to eliminate pain and restore hand function while maintaining stability and mobility. A range of surgical options are available to achieve this goal under an open surgery or arthroscopic frame.

The open surgery options include ligament reconstruction, denervation, metacarpal osteotomy, arthrodesis (joint fusion), trapeziectomy with or without ligament reconstruction and/or tendon interposition and/or interposition arthroplasty and partial (hemi) or total joint replacement. Some surgical options are implant-related procedures which means that implants (different materials such as cobalt chrome, titanium, pyrocarbon, silicon etc) are used to replace or recreate the joint articulation, similarly to knee or hip joint replacements.

The choice among all these options is based on accurate diagnosis and classification of TMC arthritis severity, the extent of arthritic involvement, the impact of symptoms on patient quality of life and the activity related specific patient needs.

6. R.C.o.P., Osteoarthritis: National Clinical Guideline for Care and Management in Adults., N.C.C.f.C. Conditions, Editor. 2008, NICE Clinical Guidelines, No. 59.: (UK). London.

7. National Clinical Guideline, C., National Institute for Health and Clinical Excellence: Guidance, in Osteoarthritis: Care and Management in Adults Clinical guideline CG177 2014, National Institute for Health and Care Excellence (UK), Copyright © National Clinical Guideline Centre, 2014.: London.
8. Hochberg, M.C., et al., American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res (Hoboken), 2012. ***64****(4): p. 465-74.*
9. Kloppenburg, M., et al., 2018 update of the EULAR recommendations for the management of hand osteoarthritis. Ann Rheum Dis, 2019. ***78****(1): p. 16-24.*
10. Zhang, W., et al., EULAR evidence based recommendations for the management of hand osteoarthritis: report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Annals of the rheumatic diseases, 2007. ***66****(3): p. 377-388*

G. SUGGESTED PROFILE AND TRAINING FOR USERS

The users of these devices are hand surgeons.

H. REFERENCE TO ANY HARMONIZED STANDARDS AND COMMON SPECIFICATIONS APPLIED

Applied international standards harmonized under the Medical Device Regulation 2017/745

REFERENCE	Year	EU MDR Harmonized version	TITLE	Applied
NF EN ISO 13485 +A11/2021	*2016*	*2016*	Medical devices — Quality management systems — Requirements for regulatory purposes	In full
NF EN ISO 14971 + A11/2021	*2019*	*2019*	Medical Devices - Application of risk management to medical devices	In full
NF EN ISO 15223-1	*2021*	*2021*	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1:General requirements	In part
NF EN ISO 10993-12	*2021*	*2021*	Biological evaluation of MD - Part 12: Sample preparation and reference materials	In full
NF EN ISO 11137-1 +A2/2019	2016	2019	Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a strerilization process for MD	In full
NF EN ISO 11737-1 + ISO 11737-1 A1/2021	*2018*	*2021*	Sterilization of MD - Microbiological methods - Part 1: Determination of a population of microorganisms on products - amendment 1	In full
NF EN ISO 11737-2	*2020*	*2020*	Sterilization of MD - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	In full