SUMMARY OF SAFETY AND CLINICAL PERFORMANCE INTENDED FOR PATIENTS

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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 information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

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1. Device Identification and general information

- **Device trade name**

  TOUCH® CMC 1 Prosthesis

- **Manufacturer, name and addresses**

  KERI MEDICAL SA
  Route des Acacias 45A
  Geneva 1227
  SWITZERLAND

- **Basic UDI-DI**

  764018116010AV

- **Year when the device was first CE-marked**

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

2. Intended use of the device

○ Intended purpose

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

○ Indications and intended patient groups

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.

○ Contraindications

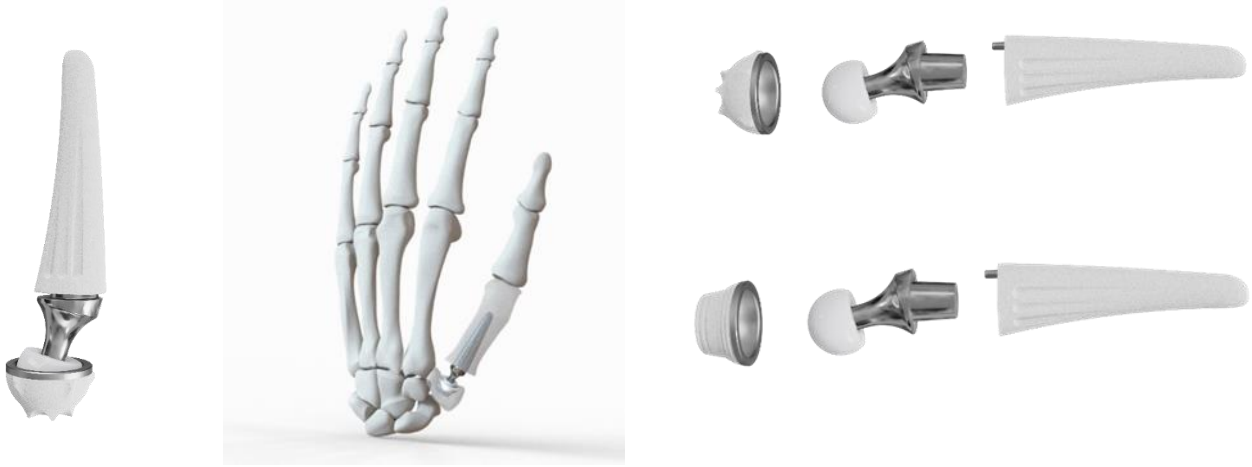
The contraindications are the following:
- Acute or chronic infections, local or systemic,
- Muscular, neurological, or vascular severe deficiency affecting the joint,
- Poor bone quality preventing the implant fixation,
- Bones dimensions incompatible with the implants sizes,
- Do not use on patients 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.

3. Device description

- **Device description and material/substances in contact with patient tissues**

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 “Rhizarthrosis”, “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.

a. 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 range of the stems is composed of 6 different sizes (XS, 0, 1, 2, 3, 4).
The TOUCH® stem is made of Titanium TA6V ELI (ISO 5832-3) and coated with Titanium T40 (ISO 13179-1) and hydroxyapatite (ISO 13779-2).
The stem double coating provides a secondary stability. HAP is osteoconductive and therefore favours bone regrowth whereas the porous titanium interface provides secondary mechanical stability.

b. 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).
The TOUCH® neck is in Stainless Steel 1.4472 (ISO 5832-9) and is topped by a liner in cross-linked Polyethylene (UHMWPE (ISO 5834-2)).

c. 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:
- 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 with a conical shape. By its design the conical cup can be suspended and allows a stable fixation (primary) for patients with thin trapezium.

The size range of the spherical cup comprises 2 sizes (Ø 9 / height 5.2 mm and Ø10 / 5.7 mm height). Similarly, the size range of the conical cup comprises 2 sizes (Ø9 / height 5 mm and Ø10 / height 5.5mm). The TOUCH® cup is in Stainless Steel 1.4472 (ISO 5832-9) and coated with Titanium T40 (ISO 13179-1) and hydroxyapatite (ISO 13779-2).

- **Information about medicinal substances in the device, if any**

Not applicable

- **Description of how the device is achieving its intended mode of action**

The TOUCH® CMC 1 prosthesis is intended to surgically treat 1st carpometacarpal (CMC) joint osteoarthritis (OA) by total joint replacement (arthroplasty). See above to have a description of the different parts of the prosthesis.

- **Description of accessories, if any**

Not applicable

4. Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

- **How potential risks have been controlled or managed**

Risk management starts in early development and is performed through the whole product lifecycle. Where possible, identified risks have been reduced to acceptable levels directly by means of the design. In the cases in which this possibility was not given, warnings have been added to the packaging and the instructions for use. A benefit-risk analysis was conducted comprising all identified potential risks ; this analysis is regularly updated.

The manufacturer has implemented a post-market surveillance system and a complaint management system. All information collected from the market is regularly assessed. Complaints on TOUCH® are collected and assessed carefully and undergo regular analysis to identify new unknown side effects or contraindications. In this case, immediate countermeasures will be initiated.

- **Remaining 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 the risks

Side effects of TOUCH® are collected and reported to the manufacturer. Between 2017 and 2021, the following complaints rates were observed: between 0.12% and 0.34% by year. The following side effects related to the device were reported : per or post-op fracture, ossification, migration, loosening or unsealing, wear, luxation and functional complication. Also, some cases of pain related to the surgery were reported. None of these side effects exceed 5 cases/10000 (<0.05%) implantation.

- **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.

- **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.

- **Summary of any field safety corrective action, (FSCA including FSN) if applicable**

Not applicable

5. Summary of clinical evaluation and post-market clinical follow-up

○ Clinical background of the device

KERI MEDICAL SA bought the TOUCH® from Lapé Medical in 2016. The TOUCH® CMC1 Prosthesis has been put on the market since beginning of 2012. This product could be considered with level of novelty low as similar devices are already on the market.
Clinical data show a positive benefit/risk of TOUCH® CMC1 Prosthesis used in accordance with the instruction for use. Market surveillance data reveal a small number of device-related complaints and a low event rate.

○ The clinical evidence for the CE-marking

The expected medical benefits of the TOUCH® CMC1 Prosthesis are decrease of pain and reduction of functional disability. Documented clinical benefits from literature review [1, 2, 3, 4, 5] and ongoing post-market clinical follow-up 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 tenosinovytis (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.

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.

- **Safety**

The current data are in favor of a positive benefit/risk ratio when the use is in accordance with the instructions for use, the indication given by the manufacturer, and respecting the contraindications, the precautions for use and warnings described above. The risks incurred by the implantation of the TOUCH® CMC1 Prosthesis are listed in paragraph 4.
The manufacturer continuously collects information on safety and performance of TOUCH® prosthesis. This is performed by continuous collection and assessment of market feedback and complaint trending, regular screening of literature databases and competent authority website, and careful assessment of any information available on the device and similar devices on the market.
In addition, 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® prosthesis.

PMCF investigation 1:
In 2019, a multicenter (6 in France), prospective, observational and non-comparative investigation was launched. The primary objective is to collect data on effectiveness and safety for 223 patients on long term implantation (10 years).

PMCF investigation 2:
Another multicenter (3 in France), prospective, observational and non-comparative investigation is currently running. It will follow 310 patients for 15 years. The primary objective is the implant survival at middle and long term. Results at 3 years for 107 patients were published [*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.]*

PMCF investigation 3:
In 2021, a cost-effectiveness to compare TOUCH® to trapeziectomy was launched in a Swiss clinic. 80 working patients are expected to be include in the TOUCH® group while 42 working patients have already been included in a previous study for the trapeziectomy group.

PMCF investigation 4:
In 2019, a bicentric (2 in Germany), prospective investigation was launched. 52 patients were included for 55 prostheses. A matched-pair sub-group analysis will also be performed to compare 20 patients having received a Touch® to patients who had a trapeziectomy.

6. Possible diagnostic or therapeutic alternatives

When considering alternative treatments, it is recommended to contact your healthcare professional who can take into account your individual situation.

- **General description of 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.*