5. Potential Undesirable Side Effects

Potential complications may occur with this procedure. Information about the side effects of your operation are available from your doctor. The risk of a serious complication is low. There is a risk that you may require additional operations or treatments for a variety of reasons. Please talk to your doctor if you have concerns.

Possible side effects may include:

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)

6. Expected Lifetime and Follow Up

The manufacturer recommends that patients follow and comply with all physician recommendations, precautions, and post-surgical medical appointments.
The durability of the devices can be affected by patient activity among other factors (e.g. localized trauma, patient anatomy, etc.). The expected prosthesis lifetime is 10 years. Patients should discuss appropriate activity and precautions in order to preserve the long-term performance and durability of the devices.

7. Reporting Adverse Effects

If you wish to report any serious incident that occurs in relation to the device, please speak to your medical team or report the information to the Keri Medical Quality Department: complaints@kerimedical.com

You may also wish to contact the Therapeutic Goods Administration online at https://www.tga.gov.au/safety/reporting-problems

Australian Sponsor
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https://www.kerimedical.com

Patient Information Leaflet - 110-21C001.02_En

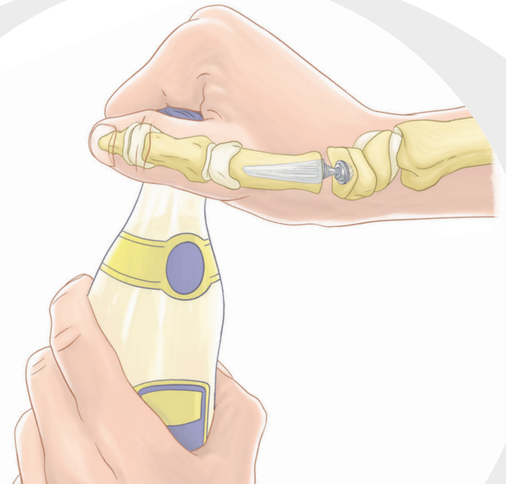
Patient Information Leaflet (PIL)

TOUCH®
CMC1 prosthesis

TOUCH®
CMC1 prosthesis

This leaflet contains important information about your implant.
You should speak to your doctor if you have any concerns or questions. All implantable medical devices have risks and benefits. Follow the advice from your healthcare team, even if it differs from the information contained in this leaflet. Please read this information carefully and keep it for future reference.

The name and reference number of your prosthesis can be found on your implant card that has been provided by your doctor.



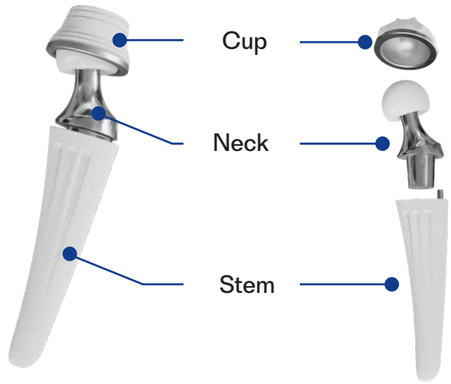
1. Device description

TOUCH® CMC 1 prosthesis is a cementless, ball-and-socket dual-mobility, total CMC 1 (1st Carpo-Metacarpal) joint replacement prosthesis, designed to treat osteoarthritis of the base of the thumb.

The TOUCH® CMC 1 Prosthesis is a thumb joint implant which is made up of three modular components:

1. TOUCH® Cup: a stainless steel trapezial implant (cup) with a dual coating of plasma sprayed titanium and hydroxyapatite; TOUCH® Cup is available in two options: spherical and conical
2. TOUCH® Liner and Neck: a junction implant (neck) topped with a liner pre-assembled to stainless steel neck available in two designs (straight and offset 15°) and three heights (6,8 and 10 mm)
3. TOUCH® Stem: a titanium alloy metacarpal implant (stem) with a dual coating of plasma sprayed titanium and hydroxyapatite available in six sizes (XS, 0,1,2,3 and 4)

Your doctor will choose the implants to meet your medical needs.



2. Product Material

TOUCH® CMC 1 stem is in Titanium alloy TA6V ELI coated with Titanium T40 and hydroxyapatite (HAP).

TOUCH® CMC 1 cup is in Stainless Steel 1.4472 and coated with Titanium T40 and HAP.

TOUCH® CMC 1 neck is in Stainless Steel 1.4472 topped by a liner in crosslinked Polyethylene (UHMWPE).

3. Intended Purpose

TOUCH® CMC 1 prosthesis is intended to surgically treat 1st Carpo-Metacarpal (CMC) joint osteoarthritis (OA) by total joint replacement (arthroplasty). Treatment selection for the patient is the surgeon's responsibility.
TOUCH® implants are indicated for:
Symptomatic Trapezo-Metacarpal (TMC) joint osteoarthritis (OA), also called rhizarthrosis, thumb base OA or 1st Carpo-Metacarpal (CMC) joint OA.

4. Information for safe use

After TOUCH® prosthesis implantation, it is advisable to respect 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