Instructions for Use

Read carefully before use!

5C® Knee System

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CE 0482

PRODUCT IDENTIFICATION AND MATERIALS

This information concerns:

- 5C® PS femoral component cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® PS femoral component slim cementless (*Material:* CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® PS femoral component cemented (*Material:* CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® PS femoral component slim cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)

- 5C® CR femoral component cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® CR femoral component slim cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® CR femoral component cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® CR femoral component slim cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)

- 5C® LATic femoral component cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® LATic femoral component slim cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® LATic femoral component cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® LATic femoral component slim cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)

- 5C® MEDic femoral component cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® MEDic femoral component slim cementless (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® MEDic femoral component cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® MEDic femoral component slim cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)

- 5C® tibial component cemented (*Material*: CoCrMo acc. to ISO 5832-4, with and without TiN-coating)
- 5C® tibial component cementless (*Material*: $TiAl_6V_4$)
- 5C® tibial component cementless (*Material*: CoCrMo acc. to ISO 5832-4, with TiN-coating)

- 5C® CR PE-insert (*Material*: UHMW-PE acc. to ISO 5834-2)
- 5C® CR PE-insert implacross® E (*Material* crosslinked UHMW-PE with vitamin E)
- 5C® UC PE-insert (*Material*: UHMW-PE acc. to ISO 5834-2)
- 5C® UC PE-insert implacross® E (*Material:* crosslinked UHMW-PE with vitamin E)
- 5C® PS PE-insert (*Material*: UHMW-PE acc. to ISO 5834-2)
- 5C® PS PE-insert implacross® E (*Material*: crosslinked UHMW-PE with vitamin E)
- 5C® LATic PE-insert (*Material*: UHMW-PE acc. to ISO 5834-2)
- 5C® LATic PE-insert implacross® E (*Material*: crosslinked UHMW-PE with vitamin E)
- 5C® MEDic PE-insert (*Material*: UHMW-PE acc. to ISO 5834-2)
- 5C® MEDic PE-insert implacross® E (*Material*: crosslinked UHMW-PE with vitamin E)

- 5C® patella (*Material*: UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3 (X-ray marker))
- 5C® pivot patella (*Material*: UHMW-PE acc. to ISO 5834-2; $TiAl_6V_4$ acc. to ISO 5832-3 (X-ray marker))

- 5C® tibial spacer (*Material*: $TiAl_6V_4$ acc. to ISO 5832-3)
- 5C® tibial spacer screw (*Material*: $TiAl_6V_4$ acc. to ISO 5832-3)
- 5C® tibial spacer spacer hull (*Material*: $TiAl_6V_4$ acc. to ISO 5832-3)

The chemical compositions of the individual materials used are available on our homepage under the following link.

https://www.implantcast.de/en/company/technology/

The CE mark is applicable only if it is also show on the product label.

INTENDED USE AND PRODUCT DESCRIPTION

The 5C® Knee System is a total knee replacement system that consists of numerous components intended to resurface the articulating surface of the femur, tibia and patella.

The 5C® CR Knee System is intended only for use in patients, in which the posterior cruciate ligament is intact. In combination with 5C® UC PE-Insert, the 5C® CR Knee System can also be used if both cruciate ligaments are lost or damaged.

The 5C® PS Knee System is intended for the functional replacement of the posterior cruciate ligament in cases of concurrent loss/damage of both cruciate ligaments.

The 5C® MEDic and 5C® LATic Knee Systems are intended to allow the preservation of the posterior cruciate ligament.

The 5C® Tibial Component is a tibial component intended for cemented or cementless fixation to resurface the tibial condyles.

The 5C® CR/PS/MEDic/LATic Femoral Component is a femoral component intended for cemented or cementless fixation to resurface the femoral condyles and trochlear groove.

The 5C® CR/UC/PS/MEDic/LATic PE-Insert is a tibial fixed-bearing insert intended to articulate with a femoral component.

The 5C® Patella and 5C® Pivot Patella (5C® MEDic Patella) are all-poly patella implants intended for cemented fixation to resurface the natural patella.

The 5C® Tibial Spacer is a tibial spacer intended for cemented fixation to fill and replace bone defects within the proximal tibia.

CLINICAL INFORMATION

Benefit

If all conservative or otherwise available therapeutic measures for the treatment of the present disease do not achieve the desired success or are exhausted, the 5C® Knee System can be used.

The use of the 5C® Knee System allows to treat the underlying disease, to achieve freedom from pain, to restore the functionality of the affected extremity or mobility and thus the independence in work and everyday life as far as possible. The improvement of the quality of life is the highest priority.

The aim of a revision surgery is the restoration of the stability, infection treatment, treating damage to nerves or blood vessels, pain reduction or eradication or the restoration of mobility. The main priority are issues of social medicine such as maintaining independence or reintegration into working life.

The 5C® Knee System should only be revised if it is medically necessary, i.e., is indicated. If a revision diagnosis remains untreated patients face the possibility of severely detrimental consequences for their health.

Patient Target Group

Patients, that meet the indications given in this instruction for use and the implantation of 5C® Knee System is a suitable therapy. The treating surgeon decides whether and which version of the implant is suitable for each patient. This decision depends on several factors, such as the patient's age and weight, bone quality, shape of the bone and deformation of the joint.

Indications

The decision for replacement of the joint should be based on careful evaluation. The indication for this type of surgery should only be made when all other conservative or surgical alternatives are less promising.

Danger of post-operative complications can be limited by careful evaluation of the individual anatomical and load conditions, the condition of the soft tissues and the condition of the bone bed for the implants.

The provision of 5C® Knee System is generally indicated only in patients whose skeleton is fully grown

Before intervention, preoperative examinations should be performed. The examinations depend on the patient's medical history.

Under consideration of these conditions the 5C® Knee System applies to the following indications:

- Non- inflammatory degenerative joint disease including osteoarthritis and avascular necrosis,
- Post-traumatic osteoarthritis,
- Treatment of fractures that are unmanageable using other surgical techniques
- Rheumatoid arthritis.
- Revision arthroplasty (revision prosthesis)

The use of a retropatellar replacement is particularly recommended for the following indications:

- large and thick patella,
- deformed non-conforming patella,
- severe pre-operative patella pain.

ATTENTION: The 5C® femoral components may only be used in patients with sufficient stability of the knee joint provided by the collateral ligaments!

The cruciate retaining (CR) 5C® femoral components may only be used in patients, in which the posterior cruciate ligament (PCL) is intact. An exception is the combination with the 5C® UC PE-insert, which can also be used in the loss or defect of the cruciate ligaments.

The posterior stabilizing (PS) 5C® femoral components are indicated in patients with loss or defect of both cruciate ligaments.

Contraindications

The longevity of an orthopaedic implant can be reduced by biological aspects, material characteristics and biomechanical factors. Therefore, a careful examination of the indications is recommended in overweight patients, in patients with very high joint loads due to high physical activity as well as in patients younger than 60 years.

Knee joint replacement is contraindicated in cases of:

- Allergy to one of the implant materials. (The label on the secondary packaging of the respective component indicates the materials used. It is strongly recommended to perform an allergy test.)
- Ongoing infections
- Physiological or anatomic conditions, which preclude or are not expected to maintain an adequate bony support of the implant or do not allow the implantation of a sufficiently large prosthesis
- Bone tumors in the implant fixation area
- Untreated vascular diseases which limit blood supply to the affected limb
- Metabolic disorders that may impair bone formation

  In case of insufficient quantity and quality of bone stock, an alternative prosthetic treatment allowing for sufficient bony fixation should be considered.
- Severe axis deviation
- Ligament instability

Risk Factors

The following risk factors may affect the success of the 5C® Knee System:

- Excessive loading of the operated joint by strong physical work and/or inappropriate sports
- Severe deformities which lead to an impairment of bone fixation or the exact positioning or the function of the implant
- Therapies that may affect bone quality
- Muscle insufficiency
- Neuromuscular disease of the affected limb
- Conditions that restrict the patient's ability or willingness to comply with medical instructions, especially during the healing process
- Obesity
- Nicotine and/or drug abuse
- Alcoholism
- Previous surgeries on the affected limb
- Diabetes
- Psoriasis

Operation Specific Complications

(Negative Effects / Side-Effects)

The following procedure-related complications (side-effects) can be associated with orthopaedic surgeries:

- Wound hematoma and delayed or impaired wound healing
- Cardiovascular disturbances, venous thrombosis, pulmonary embolism, stroke
- Renal (kidney), urinary, hepatic (liver) or gastrointestinal complications
- Respiratory disorders
- Blood loss requiring transfusions

Implant Specific Complications

(Negative Effects / Side-Effects)

As with all surgical interventions side effects (negative effects) and complications can occur with the implantation of the 5C® Knee System. In the following the most frequent side effects and complications are listed, which can occur in connection with the implantation of 5C® Knee System.

- Movement restrictions in the affected knee joint, such as arthrofibrosis, joint stiffness, flexion contracture
- Subluxation, dislocation or instability
- Implant subsidence or early loosening
- Periprosthetic fractures. Bone fractures can occur intraoperatively or due to implant loosening, overload as well as one-sided joint load.
- Heterotopic ossification
- Injury of surrounding blood vessels, soft tissue (such as quadriceps arthropathy, tibial tendon dysfunction, PCL rupture) or nerves with temporary or continuing nerve malfunctions
- Infection (such as acute postoperative wound infections, deep infections with possibility of sepsis, cellulitis (bacterial infection of the skin and tissues underneath the skin))

- Inflammation, such as synovitis, bursitis, adhesive capsulitis (adhesion)
- Adverse local tissue reaction (ALTR) to foreign body or abrasion particles
- Allergic reactions to the implant materials
- Separation of modular components
- Excessive wear of articulating components
- Deformities or breakage of an implant
- MRP (metal-related pathology) due to corrosion and/or fretting
- Fretting and/or corrosion of modular connections
- Patella erosion or progressive patellar arthrosis (in case of no patella replacement)
- Lengthening or shortening of the affected extremity
- Pain

Expected Lifetime and necessary follow-up

The materials used for implants are not as resilient as the natural bone structures and joints. They have a limited lifetime. The expected lifetime of the implant generally depends on several factors that can shorten or lengthen it. Some of these factors are the patient's health, activity level and exact implantation of the product.

Under normal conditions the following survival rates (lifetime) are expected for knee arthroplasties. The following values are given in various national endoprostheses registers.

YEARS	SURVIVAL RATE IN % (CONFIDENCE INTERVAL 95%)
5	96.8 (96.6 – 96.9)
10	95.2 (94.9 – 95.4)

Subsequently, minor surgically invasive procedures, such as the replacement of individual components, may be necessary or the implantation of a completely new implant may be necessary. This depends on the reason for the revision.

PRECAUTIONS

Implantcard

The product description, size, product code and lot / batch number and the UDI can be found on the outside product label and patient labels provided within the packaging.

For traceability, the lot / batch and item numbers and the UDI of the products used must be documented. The included labels need to be attached to the implant card that is to be provided to the patient. We also recommend to attach the labels to the applicable surgery documents.

User and Training

The use of this implant is restricted to persons who, based on their education, knowledge and practical experience, are capable of proper handling and use of the device.

It is important to carefully read the instructions for use and the respective surgical technique before using this product. The implantation according to the established surgical technique and complying with the information described in this instructions for use are mandatory to achieve the best possible outcome. A list of the associated surgical techniques is provided at the end of this instruction for use.

The implantcast GmbH offers special user trainings to ensure an optimal preparation.

Packaging

The implants are individually packed in sealed triple peel pouches or double Blister packaging and then packed in a sealed carton. The outer peel pouch serves as protective packaging. Only implants provided in their original intact packaging with the original label should be used.

Sterilisation

The implants are provided packaged sterile.

The components of the 5C® Knee System that are manufactured from metal alloys are sterilised by gamma radiation with a minimal dose of 25 kGy. All polyethylene components are sterilised by ethylene oxide. A corresponding icon of the sterilisation method can be found on the product label.

Before surgery the implant packaging should be visually inspected for any damage. The product is sterile unless the packaging is damaged or opened or the "Use before" date is exceeded. Non-sterile products must not be used and should be returned to implantcast GmbH.

The implantcast GmbH instruments are supplied non-sterile and must be disinfected, cleaned, and sterilized before use. For the correct procedure, please refer to document RA_000_ROW_Instruction for reprocessing of surgical instruments. If the equipment is not treated before use, there is a risk of infection.

Resterilisation

Re-sterilisation of any implant of the implantcast GmbH is not permitted!

The manufacturer is only liable for implants that have been implanted immediately after removal from the original packaging; re-sterilisation is not permitted and is beyond implantcast's responsibility and liability.

Storage

The implant should always be kept in the unopened original packaging in a storage repository suitable for sterile goods and be protected from excessive temperatures, humidity and direct sunlight.

Single-Use

An implant may under no circumstances be re-used. Each component is manufactured for single use only!

The mechanical and biological safety of the implant can no longer be guaranteed if it is re-used inadmissibly.Although not visibly apparent, damage may be present which can affect the functioning or life of the implant.

The hygienic safety of the implant can no longer be guaranteed if it is re-used inadmissibly. There is a risk of infection.

For safe disposal of the product, the hospital guidelines and other applicable legal provisions must be followed accordingly. During disposal, microbiological and physical hazards, such as infections, potentially contaminated explants and/or sharp edges of the product must be taken into account.

Combinability

The 5C® CR femoral components can be used only with 5C® CR and UC PE-inserts.

The 5C® PS femoral components can be used only with 5C® PS PE-inserts.

The 5C® MEDic femoral components can be used only with 5C® MEDic PE-inserts.

The 5C® LATic femoral components can be used only with 5C® LATic PE-inserts.

The 5C® femoral components can be used in combination with the 5C® PE-inserts of the identical size.

The 5C® CR, UC, PS, MEDic and LATic PE-inserts can be used with the 5C® tibial components of the identical size, one size smaller and three bigger sizes.

The 5C® patella can be used with 5C® PS and CR femoral components according to the following pattern: 5C® patella size A ↔ 5C® PS and CR femoral component sizes 1-4; 5C® patella size B ↔ 5C® PS and CR femoral component sizes 5-8; 5C® patella size C ↔ 5C® PS and CR femoral component sizes 9-12.

The 5C® pivot patella can be used only with 5C® MEDic and LATic femoral components according to the following pattern: 5C® pivot patella size A ↔ 5C® MEDic and LATic femoral component sizes 1-4; 5C® pivot patella size B ↔ 5C® MEDic and LATic femoral component sizes 5-8; 5C® pivot patella size C ↔ 5C® MEDic and LATic femoral component sizes 9-12.

The 5C® tibial spacer can be used only with the cemented 5C® tibial component of the identical size. The 5C® tibial spacer and the 5C® tibial component are connected via 5C® tibial spacer screw and 5C® tibial spacer spacer hull. The height of the 5C® tibial spacer screw must correspond to the height of the 5C® tibial spacer.

The 5C® tibial component can be used with ACS® double taper for MK stems and ACS® double taper regardless of the size.

All sizes of the 5C® tibial components can be used with ACS® extension stem male taper of the size 14.

All sizes of the 5C® tibial components can be used with cone plug for FB tibial component.

The components of the 5C® Knee System are fully compatible and may only be used or combined with each other. Combinations with components from other manufacturers is not permitted.

The user should follow the instructions of combinations provided in the implantcast GmbH surgical technique for the product. Additional information regarding the combinations can also be obtained directly from implantcast GmbH.

It should be noted that the cutting blocks and saw guides are precisely aligned to the saw blades offered by the implantcast GmbH so that only these combinations are approved.

Influence of imaging techniques and active invasive surgical procedures

The 5C® Knee System has not been evaluated for safety and compatibility in the MR environment. The 5C® Knee System has not been tested for heating, migration, or image artefact in the MR environment. The safety of the 5C® Knee System in the MR environment is unknown. Scanning a patient who has this device implanted may result in patient injury.

Any contact between the electrosurgical high-frequency instruments (e.g. high-frequency electrocautery) and the metallic implants should be avoided to prevent damage to the implant due to flashover. An increased hazard exists in case of revision surgery.

When using water-jet surgery, any contact with the implant should be avoided.

The safety and the performance of the implant-components made of polyethylene are unknown after the radiation associated with diagnostic or therapeutic procedures.

Pre-operative Instructions

A pre-operative planning is mandatory for optimal results. Before surgery a surgical planning with regard to the dimensions of the prosthetic model and the positioning of the implant components in the bone has to be carried out by the surgeon.

For this purpose, x-ray templates are available:

Digital templates: Digital templates are included in the data base of the common planning systems. For missing templates, please contact the provider of the planning software and request for these templates.

Radiographic templates: Alternatively, radiographic templates are available in various scale factors, which can be obtained from your local representative.

The surgeon must ensure that:

- all needed components are available during surgery. An adequate number of all necessary implant components will be available during surgery. It should be determined whether the implantation should be done cemented or cementless.
- all instruments necessary will be present for surgery and that they match the implants being used. Only instruments designed for use with the implant system by implantcast GmbH should be used. An exception are exclusively the standardized instruments used during surgery.
- The correct sized instruments are used during surgery to prevent damage to the implants.

Operative Instructions

Before using, the implant should be checked to ensure that the product reference number, lot number and size correspond with the data on the labelling (REF, LOT and size).

Use appropriate aseptic technique when removing the implant from the packaging. The user is taking full responsibility for this. Implants should be implanted immediately after removal from the original packaging.

The surfaces of the implants are extremely sensitive. Implants should not be allowed to come into contact with objects that could damage the surfaces.

Before implantation, the implant should be visually inspected by the user for possible damage. Damaged implants must not be used.

The implant should not be modified in any way – modifications to the implant may lead to impairment of its function or early failure. The manufacturer assumes no liability for modified products. In case of changes or manipulation the regulatory responsibility is transferred to the person changing or manipulating the components. The manufacturer no longer guarantees the product.

When acrylic bone cement is used the instruction for use from the cement manufacturer should be followed.

Bone cement should not be allowed to come or remain in contact with the articulating surfaces of the implant during or after the surgery. Bone cement residues that could dislodge over time and get between the articulation surfaces must be removed. Bone cement fragments and residues may lead to increased wear and damage of the implant components.

In cementless applications, a firm fixation of the implant at the time of surgery is essential for the success of the implantation. The cementless components are seated in the bone by pressfit which requires to perform precise surgery and the use of the instruments provided for this purpose.

A reliable fit of taper connections is only possible with completely intact surfaces of the tapers. The taper of the stem must be cleaned and dried before being connected to the taper of the head. Both tapers must be of matching size.

Prior to wound closure, the surgical area including the articulation surfaces of the implant must be thoroughly cleaned to remove any foreign bodies such as bone splinters, bone cement residues and any remaining fragments of a previously revised component or instrument.

It is also recommended to take an intraoperative X-ray image and examine it for remaining particles and remove them before wound closure.

Post-operative Instructions

Post-operative patient care, patient instructions and warnings are of the utmost importance. The use of an external support of the operated extremity for a limited period is recommended.

Active and passive movements of the operated extremity should be monitored.

The post-operative regime should be aimed at the prevention of overloading of the operated extremity and stimulation of the healing process.

Regular monitoring of the position and condition of the prosthetic components and the surrounding bone is recommended.

Patient Information

The treating surgeon must inform the patient before surgery about any alternative surgical treatments and about all aspects of the surgery and the implant, including known complications and side effects and their consequences.

Additionally, the treating surgeon must inform about the post-operative limitations. Patients should be informed by their surgeon that the results and durability of their implant are related to patient compliance, patient weight and the physical activities.

The patient should be made aware of post-operative limitations including the consequences of overloading of the joint by excessive weight, strong mechanical load on the affected extremity, high levels of physical activities and that the patient should adapt his / her lifestyle to these limitations. The patient should be instructed how to adapt the activities accordingly.

The patient should be told that any kind of high-loading sports should be avoided with the operated joint and that implants can break after such excessive loads or otherwise fail.

Depending on the situation (e.g. fall), the use of a device with electric drive, such as an e-scooter, can cause the strong mechanical load / overloading of the affected extremity described above.

The patient should be informed that the instructions of the treating physician for the time after the operation must be strictly followed.

The patient should be noted to immediately inform his doctor if he notices unusual changes in the surgical area.

All information provided to the patient should be documented in writing by the operating physician.

Information to be supplied to the patient with an implanted device is available on our homepage under the following link:

https://www.implantcast.de/en/for-patients/

NOTIFIABLE INCIDENTS

The manufacturer or its representative should be notified of any complication or adverse event that may have been caused by or contributed to by the implant or the instrumentation.

Complications or other negative effects that may result from an incorrect diagnosis, surgical technique or planning as well as improper patient or implant selection, existing concomitant medical conditions or non-compliance with hygiene regulations are the responsibility of the surgeon and cannot be attributed to either the manufacturer or the distributor.

The serious incident can be reported by both the user and the patient.

Any serious incident that has occurred in relation to the product should be reported to the implantcast GmbH (e-mail address: MDVS@implantcast.de) and the national competent authority of the Member State in which the user and/or patient is established.

OVERVIEW OF THE RESPECTIVE SURGICAL TECHNIQUE/-S

REF - NUMBER	ITEM DESCRIPTION
5CCP4OPE	5C® Knee System CR – PS 4in1 surgical technique
5CLA4OPE	5C® Knee System LATic 4in1 surgical technique
5CME4OPE	5C® Knee System MEDic 4in1 surgical technique

Mat.	“Material”

Issued: 18/02/2021
Item Number: 09300229GB

TITLE OF SYMBOLS	
	„Date of manufacture“
	„Use-by date“
	„Batch code“
	„Catalogue number“
	„Serial number“
	„Distributor“
	„Sterilized using ethylene oxide"
	„Sterilized using irradiation"
	„Do not resterilize“
	„Do not use if package is damaged and consult instructions for use”
	„Double sterile barrier system“
	“Do not re-use”
	“Consult instructions for use or consult electronic instructions for use”
	„Caution"
	„Contains a medical substance“
	„Medical device“
	„Unique Device Identifier“
	“Quantity of products within the package”