iTotal® CR Total Knee Replacement System (Model Number)

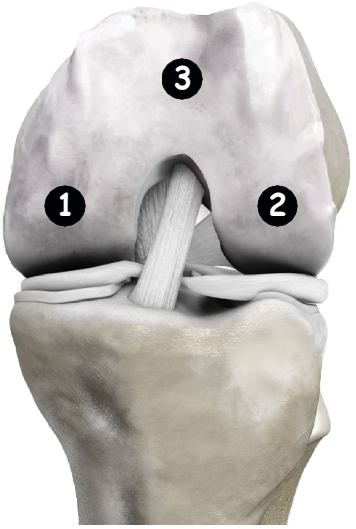
CONFORMIS

FORM · FIT · FUNCTION

UNDERSTANDING YOUR KNEE

To understand the benefits of the Conformis personalized approach, it's important to understand the anatomy of your knee.

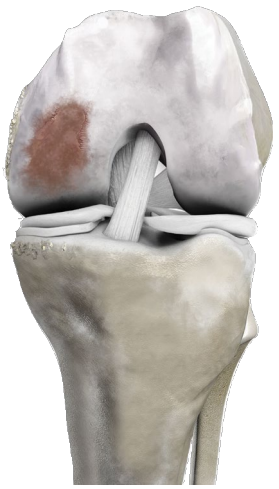
Your knee joint is formed by the intersection of the femur (thigh bone), the tibia (shin bone) and patella (knee cap). These bones form three "compartments" or sections.



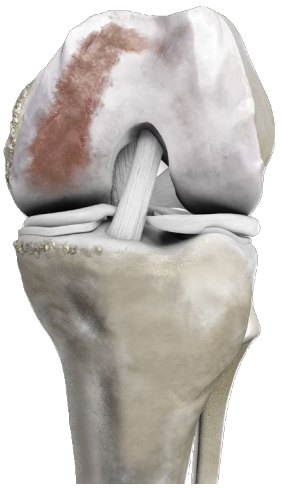
1. *Medial compartment* (inner half of your knee)
2. *Lateral compartment* (outer half of your knee)
3. *Patellofemoral compartment* (behind the knee cap)

Osteoarthritis (OA) is a degenerative joint disease characterized by the breakdown and wearing away of cartilage causing the bones to rub together and result in pain. It can affect all of the knee or just parts, depending on the severity.

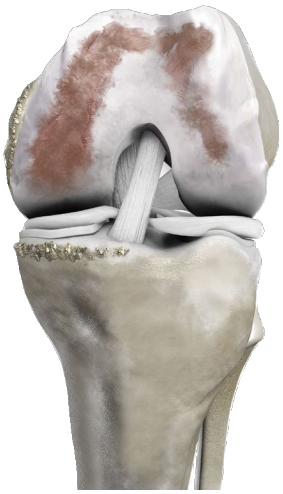
A partial knee replacement (PKR) is an option for people who have OA in one or two compartments. A total knee replacement (TKR) is an option for people with OA in all three compartments.



Unicompartmental OA

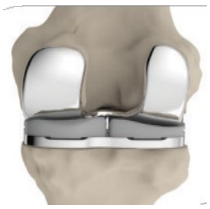


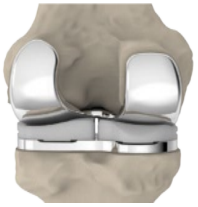
Bicompartmental OA

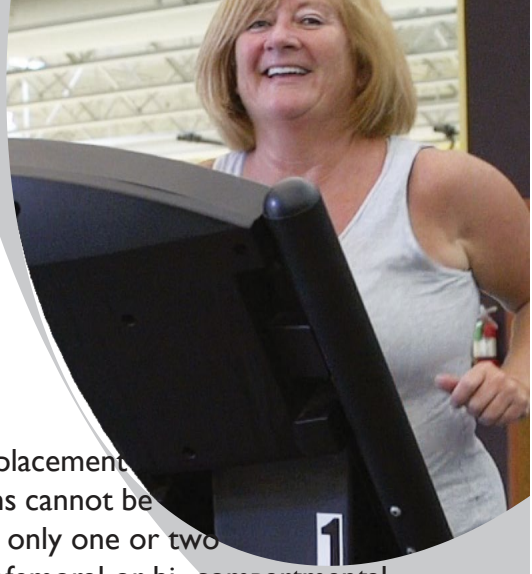


Tricompartmental OA

INTENDED PURPOSE







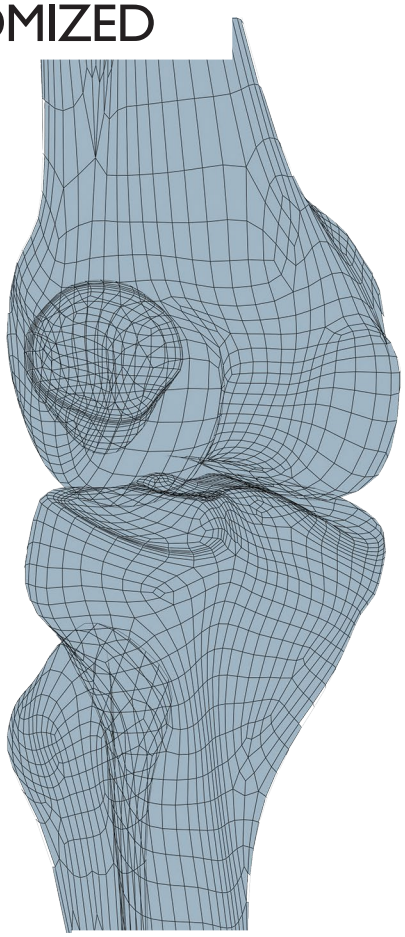
The iTotal® CR System is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three knee compartments, such as unicondylar, patellofemoral or bi- compartmental.

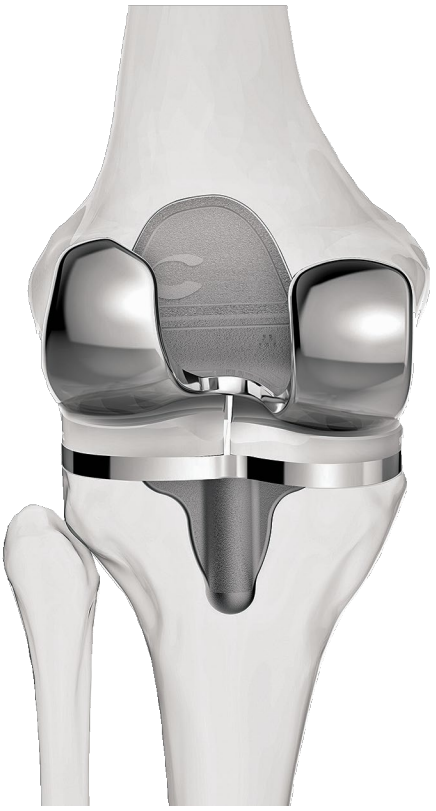
Indications for use include:

- Painful joint disease due to osteoarthritis, traumatic arthritis, rheumatoid arthritis or osteonecrosis of the knee
- Post-traumatic loss of joint function
- Moderate varus, valgus or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Failed osteotomies, hemiarthroplasties, and unicondylar, patellofemoral or bicompartmental implants
- Revision procedures provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans

The iTotal® CR System is intended for cemented use only.

CUSTOMIZED DESIGN





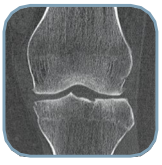
Customized *just for you*

Conformis iFit® image-to-implant® technology converts a CT scan of your knee into a 3D model and then designs an implant that's unique to you. This fully automated process ensures that your implant is made for your knee, and only your knee.

SCHEDULING A CT SCAN

Your doctor will give you a prescription for a diagnostic CT scan of your hip, knee, and ankle

GETTING YOUR KNEE SCANNED



The CT scan will be sent to Conformis

RECREATING YOUR KNEE

Using your CT scan, a 3-D model of your knee is developed and will be used to individualize your implant

PERSONALIZING YOUR IMPLANT

Your implant and surgical instrumentation are designed and manufactured specifically for you

PREPARING FOR SURGERY

Your implant will be delivered to the hospital a few days before surgery

FOLLOWING YOUR SURGERY

Your surgeon will provide you with written instructions regarding post-op therapies and activities

POTENTIAL RISKS

Known risks of knee replacement surgery

As with any major surgery, knee replacement involves potential complications and risks both during and after the procedure. Only a licensed physician can help you determine the appropriate medical treatment. If a surgeon determines that total knee replacement is the best medical option and decides to use this device in a patient with any of the above conditions, the surgeon must inform the patient about the strength limitations of the implant materials and the need to reduce or eliminate any of the above conditions when possible.

The pre and post-operative care and management of the patient must be carried out with all existing conditions considered, including any mental attitudes or disorders. A patient's failure to adhere to the surgeon's postoperative instructions may delay recovery and/or increase the risk of adverse effects, including fixation failure or implant failure. Your care team takes many precautions to prevent and manage the following possible risks:

- Infection, tissue reaction to implant materials or wear debris.
- Cardiovascular disorders and thromboembolic disease.
- Pain, dislocation or subluxation.
- Flexion Contracture, Range of Motion.
- Change in position of the components.
- Loosening.
- Bending.
- Cracking, fracture, deformation or wear of one or more of the components.
- Lengthening or shortening of leg caused by improper positioning.
- Fracture of the patella, femur or tibia.

If you experience any pain, swelling, instability or other symptoms in the vicinity of your implant, or if you have any questions, please contact your surgeon. Excessive physical activity or trauma to the joint during recovery may contribute to premature failure of the replacement by causing a shift in position, fracture or increased wear of the implants.

The functional life expectancy of this knee implant is not known at this time. Factors such as weight and activity level may significantly affect wear and subsequent device life.

Risk of magnetic field interference from MRI devices

The iTotal® CR system is manufactured of non-ferromagenetic materials such as cobalt-chromium-molybdenum alloy and polyethylene. Non-clinical testing demonstrated that this system is "MR Conditional". A patient can be scanned safely, immediately after surgery, under certain conditions which your surgeon can describe. Magnetically induced displacement force and torque testing indicated that the implants posed no known risks with regard to displacement force and torque in the MRI environment.

www.conformis.com

Caution:
The iTotal® CR Knee Replacement System (KRS) is intended for use as a total knee replacement in patients with knee joint pain and disability whose conditions cannot be solely addressed by the use of a prosthetic device that treats only one or two of the three compartments. These implants are intended for cemented use only. Only a licensed physician can help you determine the appropriate medical treatment. There are potential risks to knee replacement surgery, and individual results may vary

Before making any decisions concerning medical treatment, consult your physician regarding your options and the risks of those options. The longevity, performance and feel of any knee implant will depend on various factors, including your physical condition, your activity level, adherence to your physician's instructions, and other factors.

Please notify your surgeon if you have any questions or concerns. Any serious incidents that occur in relation to the device should be reported to the manufacturer at +1781.345.9001 and to the Therapeutic Goods Administration (TGA) at www.tga.gov.au

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