



It's your knee

Help keep it that way

PERSONALIZED
TOTAL KNEE IMPLANTS

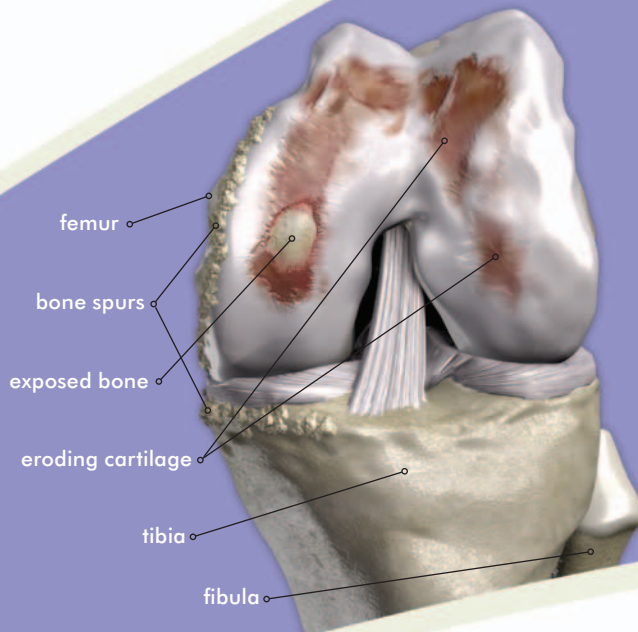

CONFORMIS

Osteoarthritis

the disease

Osteoarthritis (OA) is the most common form of arthritis, affecting tens of millions of people worldwide. It is a degenerative joint disease characterized by the breakdown and eventual loss of joint cartilage. The breakdown and wearing away of cartilage causes the bones to rub together resulting in extreme pain. OA resulting from “wear and tear” is the most common reason individuals need to undergo knee replacement surgery.

How osteoarthritis affects the knee



Symptoms of osteoarthritis in the knee:

- Knee pain associated with:
 - Standing or walking short distances
 - Climbing up or down stairs
 - Sitting in or standing up out of chairs
- Initial pain and/or stiffness with activities initiated from a sitting position
- Stiffness in the knee after getting out of bed
- A crunching sensation when the knee is used

Personalization process

STEP 1: Scheduling a CT scan

Developing your personalized implant begins with images of your knee. Your doctor will give you a prescription to have a diagnostic scan at a nearby imaging center.

STEP 2: Getting your knee scanned

The imaging center will take a CT scan of your leg and send a diagnostic report to your surgeon for evaluation.

STEP 3: Recreating your knee

Using your CT scan, a computer generated 3-D virtual model of your knee is developed and will be used to individualize your implant for a personalized fit and correct alignment.

STEP 4: Personalizing the implant

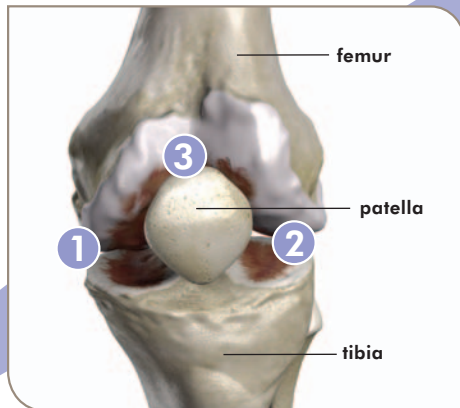
Using a proprietary process, your implants are designed and manufactured for delivery in 7 weeks.

STEP 5: Preparing for surgery

Your implant will be delivered to your surgeon for the day of surgery. Speak to your surgeon about scheduling your surgery and what to expect.

STEP 6: Getting back on your feet

While every person's experience is different, many people return to their daily activities within 6 weeks. More physical activities such as sports may take up to 3 months. Consult your doctor or physical therapist about your individual goals and limitations.



Left Knee: Osteoarthritis can affect one, two or all three compartments of the knee.

Understanding your knee.

Your knee joint is formed by the intersection of the femur (thigh bone), the tibia (shin bone), and the patella (the 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 Patella femoral compartment (behind the knee cap)

In a normal functioning knee, each bone glides smoothly against the other on a layer of cartilage that covers the ends of the bone. In a knee joint affected by osteoarthritis, the smooth cartilage lining on the inside of the joint has worn away. Your surgeon can determine the extent and severity of your OA.

Total Knee Replacement

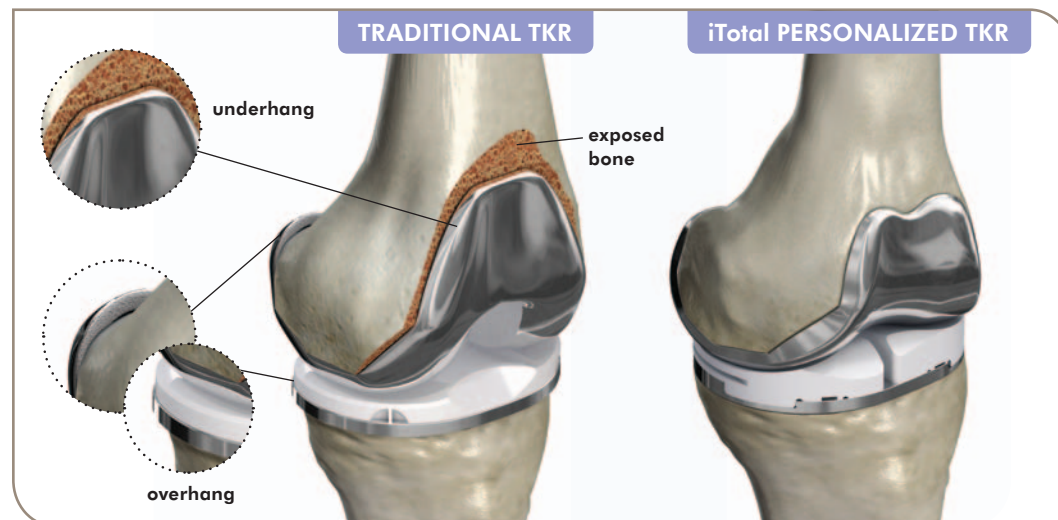
Total knee replacement (TKR), also referred to as total knee arthroplasty (TKA), is a surgical procedure where worn, diseased, or damaged surfaces of a knee are removed and replaced with artificial surfaces. Materials used for resurfacing of the joint are not only strong and durable but also optimal for joint function as they produce little friction.

The goal of total knee replacement surgery is to provide you with a durable solution that can resolve pain, allowing you to stand, sit, walk, and perform other normal activities of daily living.

Who is a candidate for Total Knee Replacement?

Total knee replacements are usually performed on people suffering from painful arthritic conditions of the knee severe enough to limit one’s normal day-to-day activities. Only your physician can determine if you are a good candidate for total knee replacement.

Generally, a person would be considered for a total knee replacement if the individual experiences daily pain, restricting not only work and recreation but also the ordinary activities of daily living. There must also be evidence of significant disease in the knee, which can be determined by your doctor based on clinical examination and imaging tests such as X-rays, MRIs, or CT scans.



The ConforMIS approach makes sure that your implant is made to fit you precisely, avoiding sizing and fit issues common to standard total knee implants.

The ConforMIS personal advantage

The iTotal is designed to fit your anatomy and only your anatomy.

Combining proven total knee replacement (TKR) principles with the unique advantages of a ConforMIS patient-specific knee system, ConforMIS has developed the only personalized total knee system designed to conform precisely to your unique anatomy.

- The iTotal personalized knee implant is specifically designed to fit your knee, avoiding the sizing and positioning compromises common with traditional “off the shelf” total knee replacements that can lead to long-term painful outcomes.¹
- The iTotal is designed to mimic the natural shape of your femur, one of the key determinants of the way your knee moves when you bend and flex. By restoring your shape rather than replacing the femur with a standardized geometry, your knee may feel more like your natural knee.
- The iTotal follows an innovative design approach, allowing for a personalized femoral component that is thinner than traditional total knee replacements. A thinner implant can preserve more of your bone, which may be beneficial for future treatment options.

¹ Mahoney OM, Kinsey T. Overhang of the femoral component in total knee arthroplasty: risk factors and clinical consequences. J Bone Joint Surg [Am] May 2010, Vol. 92-A, No. 5, pp. 1115-1121.



Personalized knee implants

- Designed for each individual based on your anatomy
- Customized fit avoids sizing compromises common with traditional standard implants
- Designed to mimic the natural shape of your knee
- More bone preservation than a standard total knee replacement, allowing for potential treatment options in the future



For more information visit
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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. 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.

USA Federal law restricts the use of these devices to sale by or on the order of a physician.

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Personalized total knee implants

**What you need to
know before, during
and after surgery.**



Once you and your doctor determine that you are an appropriate candidate for a personalized total knee implant, you will be sent for a CT scan, your surgery will be scheduled, and your very own customized implant will be designed.



This guide answers common questions and provides more information about what to expect before, during and after surgery.

Prior to the surgery

Once you and your surgeon have decided to move forward with your personalized knee implant, your surgeon will give you a prescription for a CT scan. The surgery date will be set, and you can begin preparations for surgery and beyond.

Why do I have to get a CT scan?

The CT scan is a diagnostic tool for your surgeon to assess the course of treatment for your knee. Additionally, it is an integral part of creating a personalized knee implant system. The CT scan image provides a detailed three-dimensional image of your knee. From this digital model, your customized implant is designed to fit the unique contours of your knee.

How soon do I need to get my CT scan?

It is recommended to book your CT scan appointment as soon as you can. Your personalized knee implant cannot be designed until your CT scan images are received.

Can I go to any Imaging Center?

Your surgeon will recommend an imaging center that has been qualified to perform CT scans that capture the required images to design your individualized implant.

How long will the CT scan take?

The CT scan appointment typically takes 45-60 minutes. It is always a good idea to give yourself more time, and to arrive early to ensure your scan can start on time.

How long does it take to design my implants?

Engineers will begin developing your personalized knee implant immediately upon receiving your CT scan. It takes the engineers approximately 7 weeks to develop your implant. Once the implant is complete, it is sent to the hospital in advance of your surgery date.

How can I prepare for my surgery?

It can be helpful to designate someone as your primary “caregiver.” This person will be there with you on your day of surgery, help carry your belongings and stay in touch with other family or friends during and immediately following your surgery. The primary caregiver may also be helpful following surgery (i.e., driving home, assisting in follow-up doctor visits, physical therapy and completing light chores around the house).

It may also be helpful to complete as many chores and/or errands as possible prior to surgery. Preparing your home by removing tripping hazards such as rugs and moving your living quarters to the ground floor will ensure an easier rehabilitation.

Prior to your day of surgery, be sure to pack a small suitcase with loose fitting comfortable clothing and necessary toiletries. In some cases you may be in the hospital from 1-3 days. Please check with your surgeon on how long you are expected to stay so you can pack accordingly.



The day of the surgery

Plan to arrive early, as you may need time to fill out some paperwork and prepare for surgery.

How long is my surgery going to take?

Knee surgery has become a very common procedure. A total knee replacement can take 60–90 minutes to complete. Be sure to consult with your surgeon about his/her expectations for the surgery.

What happens during surgery?

After you have been admitted and prior to the actual surgery you will receive an IV (intravenous) line that is used to administer antibiotics and anesthesia.

The actual surgery involves a thin incision on the knee that helps the surgeon gain access to the affected compartment(s). Your surgeon will place your personalized surgical instrumentation on your femur (thigh bone) and tibia (shin bone) in order to make the required bone cuts. Your customized implants are then cemented to your bones and the incision is closed.

What is my personalized total knee implant made of?

Your implant will be made of cobalt chromium molybdenum, a standard metal used in orthopedic implants, with an ultra high molecular weight polyethylene insert. *You should notify your surgeon if you are allergic to metals such as nickel.*



following surgery

As your anesthesia wears off a nurse will be there to assist you and provide pain medications. Once you are fully awake you will be taken to your hospital room. Your knee will remain swollen and tender for a few days. After you have returned to your hospital room the primary goal is to get you mobile. A nurse will assist you with moving your knee, standing, and eventually walking.

How long will I have knee pain following surgery?

While every case is different, you should expect to feel significant pain relief within weeks. Be sure to follow your surgeon's recommendations for pain medication and physical therapy.

How soon will I be able to walk?

You should be able to walk, as tolerated, a few hours after surgery. You may be provided with a knee brace and/or aids such as crutches or a walker to assist you.

Will I have to wear a leg brace?

Your surgeon will determine whether or not you will need to wear a brace. If you do, you will likely wear your brace for two weeks or less depending upon your surgeon's recommended weight-bearing protocol.

Will I be able to drive after surgery?

Following surgery you may not have the full leg control required to work the gas and brake pedals. As a safety precaution, your surgeon may recommend that you not drive for a few days.

When can I go back to work?

Your return to work will be dependent on your job requirements and endurance. Typically, patients return to office work in two to three weeks; jobs that require longer periods of standing may require longer periods of time.

Will I have to take any medication after surgery?

Your surgeon may prescribe medication to control pain after surgery and/or coated aspirin to prevent blood clots. It is important that you consult with your physician before taking any non-prescribed medications.

What care will the incision require?

Following surgery, it is important to keep your incision covered with a clean dressing. Your surgeon will recommend that you use caution while bathing to keep your incision dry. Waterproof bandages are recommended. Be sure to contact your surgeon if you notice any changes in the incision such as swelling or drainage during the recovery period.

Is it normal to have a fever following surgery?

Immediately after your procedure, you may have a low grade fever (up to 101 degrees). It is important to contact your doctor if your temperature elevates above 101 degrees or lasts longer than one week.

Will I have to go to physical therapy?

For some patients, physical therapy is not required. Your surgeon can best determine whether or not this is appropriate for you. In all cases, an immediate postoperative recovery will focus on protecting the knee, minimizing discomfort, and ensuring early return to motion. After that, your surgeon will prescribe a set of simple exercises to aid in recovery and strengthen your knee.



Consult your surgeon to discuss the risks and potential outcomes from the surgery. You should contact your surgeon immediately if you develop a fever, notice increased drainage from your incision or experience prolonged pain, swelling or redness.



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