CITIUS®

HIGH FLEX TOTAL KNEE REPLACEMENT SYSTEM- CEMENTED

INTENDED USE

CITIUS® High Flex Total Knee Replacement System- Cemented is intended to provide primary or revision options to the surgeons to reduce or eliminate pain, restore motion, and/or correct deformity.

CITIUS® High Flex Total Knee Replacement System- Cemented, consists of the following components: PS Femoral component and **Tibial base plate** made of Cobalt-Chromium (Co-Cr) alloy, **PS Tibial Insert** and P**atella component** made of UHMWPE. Bone cement is used to fix the components to the bone.

CITIUS® **PS Femoral Component (Right / Left)/** CITIUS® **PS Femoral Component with Modular Peg (Right / Left)/** CITIUS® **PS Femoral Component without Peg (Right / Left):**

CITIUS® PS Femoral Component is made of Co-Cr Alloy. This alloy complies with the material standards of ISO 5832-4 & ASTM F75.

CITIUS® PS Femoral Component has an integrated peg on the distal side.

CITIUS® PS Femoral Component with Modular Peg variant has a modular peg on the distal side which will be provided separately, and can be fixed by the surgeon, as desired.

CITIUS® PS Femoral Component is also available without peg.

These Femoral Components are available in 9 sizes (1 to 9) in both Right and left versions and can be paired with CITIUS® PS tibial inserts of any sizes

CITIUS® **PS Tibial Insert**

CITIUS® PS Tibial Insert is made of UHMWPE. This UHMWPE Complies with the material standards of ISO 5834-2 & ASTM F648, Fabricated form.

CITIUS® PS Tibial Insert is Available in 4 options depending on the Tibial Size (For Size-1, Size 2/3, Size 4/5 and Size 6/7) and each size having 8 thicknesses (6,8,10,12,14,16,18 & 20mm). Compatibility between CITIUS® Tibial base plate and CITIUS® PS Tibial insert is given in Table-1

CITIUS® **Tibial Base plate**

CITIUS® Tibial Base plate is made of Co-Cr Alloy. This alloy complies with the material standards of ISO 5832-4 & ASTM F75.

The Tibial Base plate is available in 7 Sizes (1 to 7).

Compatibility between Tibial base plate and PS Tibial insert is given in Table-1

CITIUS® **Patella Component**

CITIUS® Patella Component is made of UHMWPE. This UHMWPE Complies with the material standards of ISO 5834-2 and ASTM F648, Fabricated form.

It is available in 5 Sizes. Citius® Patellar component of any size can be paired with Citius® PS Femoral components / PS Femoral components with modular peg / PS Femoral components without peg of any sizes

INDICATIONS

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis, traumatic arthritis where one or more compartments are involved.
2. Correction of varus, valgus, or posttraumatic deformity.
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous joint replacement procedure(s).

Additionally, the following general conditions are considered by surgeons

- Skeletally mature
- Stable and intact ligaments for medial and lateral collateral
- Intact quadriceps and hamstring mechanisms
- Primary or Revision surgery where there is suitable bone stock (complete cortical contact with the tibial and femoral component edges) to provide sufficient seating of the components.

CONTRAINDICATIONS

- Active or recent infection
- Neuromuscular compromise(s)
- Poor bone quality, such as Osteopenia, osteoporosis or osteomalacia, where in the surgeon's opinion, there is inadequate bone to support the implants.
- Active malignancy in the knee joint
- Documented metal allergy or intolerance
- Mentally Incompetent
- Pregnancy or women planning to become pregnant
- Patient BMI > 40 kg/m^2
- Metabolic disorders which may impair bone formation

PRECAUTIONS

CITIUS® High Flex Total Knee Replacement System- Cemented is intended to be used by surgeons **qualified** in orthopaedic surgery who have a thorough knowledge of knee arthoplasty, joint morphology and the biomechanical principles of the knee.

Before clinical use, the surgeon should be familiar with all the aspects of the surgical procedure. Patients should be instructed about the limitations of the prosthesis and should be taught to govern their activities accordingly.

Patients receiving knee joint replacement(s) should be advised that the longevity of the implant may depend on their BMI and level of activity.

WARNINGS

- Ensure surface area of bearing is clean and free of any particles before assembly.
- The compatibility of the implants vary by what implant is being used. Correct implant choice is crucial in a successful joint replacement. Table-1 is the compatibility chart between CITIUS® Tibial base plate and CITIUS® PS Tibial insert
- Improper selection, placement, positioning, and fixation of the implant components may result in unusual stress conditions and subsequent reduction in the service of the prosthetic implants.
- Heavy labor, active sports, or other disorders of the joints could increase loading and decrease the function and performance of the implant.

Perioperative care :

As in any surgical procedure, there are risks involved in Total Joint Replacement. In general, complications that may develop include: early or late infection that may require that the device be removed and the joint fused, blood vessels and nerves may be damaged, bones may be fractured during the procedure, the device may break, allergic reactions to the metallic components may occur, phlebitis may develop prolonged illness, need for blood transfusions persistent pain, and inconvenience may occur

Very rarely some complications may be fatal. Several additional risks are also present due to anesthesia and general surgery itself. These include, heart damage, brain damage, paralysis either from anesthesia (i.e. Epidural) or neurological damage, tissue necrosis from tourniquet, chance of HIV or other diseases from blood transfusions, and permanent disability.

These complications are not unique to this Total Knee Replacement System but may occur with any total joint replacement operation. Additionally, as with any joint prosthesis.

Postoperative care:
There are postoperative activity limitations that the subject must accept. These activity limitations are often individual in nature, depending on the subject's age, general health, preoperative condition of the knee, condition of other joints, and preoperative activity level. Accepted practices should be followed meticulously during postoperative care and the patient should be made aware of the limitations of total joint reconstruction(s).

MRI Safety Information :

This Knee System has not been evaluated for safety and compatibility in the MR environment. The Knee System has not been tested for heating or migration in the MR environment.

Strict adherence to the precautions and warnings for this product is essential for maximizing implant life.

DISPOSAL:
Follow the local regulation for the disposal of medical product and packaging material.

POSSIBLE ADVERSE EFFECTS:

1. Restrictive Joint motion and/or patient mobility
2. Bone fractures
3. Infections and swelling
4. Possibility for metal sensitivity/allergy
5. Severe joint inflammation
6. Loosening and Dislocation of implant
7. Possible need for revision surgery, such as an alternative prosthesis or arthrodesis
8. Persistent/Increased pain and/or deformity
9. Risks or Complications such as pulmonary or cardiac embolism (PE) and Deep Vein Thrombosis (DVT).
10. Osteolysis/Wear, Subsidence, Instability and stiffness

PACKAGING & STERILIZATION

The components made of UHMWPE material such as the PS Tibial insert and Patella component are terminally sterilized by exposure to Ethylene Oxide (EO), while the metal components made of Co-Cr alloy such as PS Femoral component (Right/Left), PS Femoral component with Modular peg (Right/Left), PS Femoral component without Modular peg (Right/Left), Tibial Base Plate are sterilized by Gamma rays at 25kGy to achieve a Sterility Assurance Level (SAL) of 10^{-6}.

The sterility is validated for a period of 5 years, from the date of manufacturing mentioned in the label. **Contents of the package are for single use only. Contents of a package that is opened or damaged should not be used**. TTK Healthcare Limited (Ortho Division), should be contacted in such cases.

STORAGE CONDITIONS

1. Care must be taken during transporting to avoid damage.
2. Keep away from sunlight.

3. Do not use if package is damaged. The implants should be kept in their non-damaged packages until needed for use.

4. The packages must be stored in a dry place.

5. The packages must be stored in hygiene conditions and in areas which provide protection from dust, insects, chemical vapors.
6. The packages must be stored in as specified in the following temperature limitation.

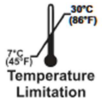

Table 1- Size and component compatibility chart

Size compatibility chart between CITIUS® Tibial Base plate and CITIUS® PS Tibial Insert

CITIUS® Tibial Base Plate (Co-Cr alloy)	CITIUS® PS Tibial Insert (UHMWPE)			
Size →	1	2/3	4/5	6/7
1	✓			
2		✓		
3		✓		
4			✓	
5			✓	
6				✓
7				✓

For Further Details, Kindly contact

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HEALTHCARE

CITIUS®

HIGH FLEX TOTAL KNEE REPLACEMENT SYSTEM-CEMENTED

INSTRUCTIONS FOR USE

Sterilized using ethylene oxide

Sterilized using irradiation

For Single Use only

Do Not Resterilize

Package Sterile Unless Opened or Damage

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