

TC-PLUS[®] Primary Knee

IMPORTANT MEDICAL INFORMATION

SPECIAL NOTE

This Package Insert is for product distributed in the US only.

The component material is provided on the outside carton label. Components from different manufacturers should not be mixed, except when advised by the manufacturer. All implantable components are designed for single use only. Some of the instruments are also designed for single use only as noted on the package label.

INDICATIONS

The TC-PLUS Primary Knee is intended as a cemented surface replacement in treating patients who are candidates for primary total knee arthroplasty or revision knee arthroplasty. It is indicated for degenerative, post traumatic or rheumatoid arthritis, avascular necrosis of the femoral condyle, post-traumatic loss of joint configuration, in particular in the event of patello-femoral erosion, functional disability or an earlier patellectomy; moderate varus, valgus or flexure deformity and to correct earlier unsuccessful attempts at surgery.

CONTRAINDICATIONS

1. Acute or chronic infections (local or systemic) or a history of infection
2. Severe muscular, neurological, or vascular deficiencies which compromise the affected extremity
3. Bone defects or insufficient bone quality which may affect the stability of the implant
4. Any concomitant illness which may compromise the function of the implant
5. Severe obesity
6. Allergy to the implant materials
7. Subluxation of the femur against the eminentia
8. Ligament instability
9. Severe varus or valgus misalignment
10. Retropatellar degenerative arthritis
11. Extensive contractures over 10°

WARNINGS/PRECAUTIONS

PREOPERATIVE PLANNING

1. Smith & Nephew medical devices should only be used by physicians experienced with joint replacement surgery. Additionally Smith & Nephew recommends participation in training sessions and/or demo surgeries performed by our primary reference surgeons.
2. The operating surgeon should read this package insert, the implant labels, and the corresponding product and surgical technique information prior to using the products. Additional documentation as to the use of these products can be obtained by contacting the appropriate company representative or from the company's web site.
3. Smith & Nephew, as the manufacturer of medical devices, does not practice medicine, and does not recommend these or any other devices or surgical techniques for use on a particular patient. The surgeon performing any implant procedure is responsible for determining and utilizing the most appropriate device and surgical technique for each individual patient based on the patient's individual circumstances.

4. The physician has the responsibility to inform the patient about the details of the surgical procedure as well as the risks, precautions and potential adverse events associated with the surgical procedure including those described in this package insert. The patient should also be made aware of how his/her own behavior can affect the safety and life span of the implant. The physician should document all information given to the patient.
5. NO REUSE: Surgical implants are intended for single use only. Surgical implants are NEVER TO BE REUSED following implantation. Stresses and fracture, even though not noticeable by visual inspection, may have been created during implantation.
6. NO IMPLANT ALTERATIONS: Unless an implant is designed to be physically altered, it should not be altered in any way. If the implant is designed to be altered, it should only be altered in accordance with manufacturer's instructions. In no case should an implant be sharply bent, twisted, notched, gouged, reamed, scratched or cut.
7. PATIENT SENSITIVITY TO IMPLANT MATERIALS: Patients may exhibit sensitivities or allergies to the materials of the implants, particularly metal and metal alloys. The materials of construction for each implant are provided on the box label and on the product specification sheets. The implanting surgeon should evaluate these possible risks during preoperative planning and when reviewing the details and risks of surgery with the patient.
8. COMPONENT COMPATIBILITY: Components are available in many styles and sizes and are manufactured from various types of metals. Use only components made from the same material together unless specifically approved by the manufacturer in the appropriate surgical technique. Do not mix dissimilar metals or components from different manufacturers unless specifically approved by the manufacturer of the components.
9. SURGICAL INSTRUMENTS: Only Smith & Nephew surgical instruments or instruments distributed by Smith & Nephew should be used to implant Smith & Nephew implants unless these instruments are commonly available in the operating room and/or described in the corresponding surgical technique.
10. STERILE PRODUCT STORAGE: Implants supplied sterile should always be stored unopened in their original packaging protected from direct sunlight. Implants should be stored at typical indoor temperatures and humidity, and exposure to extremes of temperature and humidity minimized.
11. EXPIRATION DATING: Implants supplied sterile should not be used in any surgical procedure after the expiration date printed on each device label. Expired implants should be returned to the manufacturer in their original packaging.
12. PREOPERATIVE PLANNING: Preoperative planning allows the surgeon to assess the suitability of components and combinations of components for a particular operation. Surgery should be planned in great detail based upon analytic findings (e.g. x-rays, MRI). Additional implants should be available in the event that other sizes are required or should the planned implant be deemed unsuitable. Failure to conduct proper planning may result in an inappropriate choice of implant type and/or size, and may further lead to incorrect implant positioning. For further information regarding preoperative planning and the use of x-ray templates, refer to the corresponding surgical technique and/or contact a company representative.
13. COMPUTER ASSISTED SURGERY: If a computer assisted surgery system is used, consult the applicable software and hardware reference manuals provided by the manufacturer to ensure proper operation of this equipment.
14. For computer assisted surgery systems, it is extremely important to correctly select input parameters (e.g. bony landmarks). Operators of this equipment should be familiar with the anatomy relevant to the procedure. Failure to provide proper input could cause problems such as violation of critical anatomical structures and improperly positioned implants.
15. INSTRUMENTS: Check instruments for damage and proper functionality prior to use. The use of damaged instruments may lead to suboptimal implant performance.
16. DECONTAMINATION & STERILIZATION: Follow decontamination and sterilization instructions below for preparation of instruments provided non-sterile.

INTRA-OPERATIVELY

1. Always follow aseptic practices when handling sterile implants and instruments.
2. The protective packaging for implant should only be removed immediately prior to implantation.

3. Always check that the implant matches the description on the package (e.g. product number, size). For traceability purposes, the lot number and other identifying information of the inserted implant should be documented in the appropriate patient files. Stickers are included in the product box to assist this documentation process.
4. Use extreme care in handling implant components. Cutting, bending or scratching the surface of metal components can cause internal stresses which significantly reduce the strength and fatigue resistance. It is important that the implant be carefully examined for signs of damage prior to implantation and prior to surgery closure.
5. If the implant is found to be damaged, scratched, and/or if the original packaging and labeling is not intact, the implant must not be used. Return the affected devices to the appropriate company representative.
6. For implants intended for cemented implantation, the surgeon should follow the cement manufacturers' instructions concerning the preparation of the cement, cementing technique, and other information and recommendations for the use of cement.
7. Proper implant fixation is an essential factor for a firm and long term implant seating. The following may cause the implant to loosen and can lead to complications:
 - a. Excessive weakness of the bone structure caused by preparation of the bone bed
 - b. Unsuitable choice of implant size
 - c. Inadequate cleaning of the bone bed before implantation
 - d. Application of excessive pressure when placing or fixing the implant leading to fractures or bone damage.
 - e. The presence of foreign particles, bone cement, bone chips, and other debris on the articulating surface.
8. Prior to closure, the surgical site must be thoroughly cleaned of foreign particles, bone cement, bone chips, and other debris.

POSTOPERATIVELY

1. Each patient must be monitored post-operatively by the attending surgeon and qualified staff.
2. Postoperative instructions to patients and appropriate nursing care are critical. The patient should be instructed on the limitations of the device and should be cautioned regarding load bearing, range of motion, and allowed activity levels.
3. Upon discharge, the patient should be instructed to identify and report any unusual changes regarding the operated site or the device's functionality to their physician.

RISK FACTORS

The following preoperative factors can influence the success of the operation. The attending physician should consider these possible risk factors in a patient's medical history when considering total joint replacement:

1. Osteoporosis
2. Osteomalacia
3. Severe deformations or congenital luxation
4. Generally weakened patient resistance (e.g. HIV, tumors, infections)
5. Systemic diseases and metabolic disorders which may impact the healing process
6. History of repeated infections
7. History of falling
8. Epilepsy, due to potential risk of falling
9. Drug, nicotine, alcohol, or medication abuse
10. Obesity (body mass index >30)
11. Excessive physical activity during which the implant is subjected to strong vibrations, blows, and/or excessive stresses (e.g. heavy manual labor, extreme sports and hobbies, marathons runs, etc.)
12. History of thrombosis or pulmonary embolism

POTENTIAL COMPLICATONS & ADVERSE EFFECTS

1. Infections, both deep and superficial, have been reported.
2. Venous thrombosis and pulmonary embolism during the operation or immediately post operatively.
3. Cardiovascular events during the operation or immediately post operatively.
4. Fat embolism
5. Neuronal dysfunction
6. Post operative pain
7. Temporary peroneal paralysis as a consequence of the surgical intervention
8. Hematoma, wound hematoma, and delayed wound healing
9. Dislocation
10. Subluxation
11. Insufficient range of movement
12. Undesirable shortening or lengthening of the limb
13. Bone fractures resulting from unilateral strain or weakened bone substance
14. Abnormal bending, loosening and repositioning of the implant
15. Abrasion of the implant surfaces and development of osteolysis as a reaction to foreign bodies
16. Fracture of the implant, bone or cement
17. Although rare, metal sensitivity reactions and/or allergic reactions to foreign materials have been reported.
18. Post-operative morphological changes in the patient with the weakening of the load bearing structures (e.g. tumors, hypertrophy, etc) and/or changes in the materials used (e.g. attrition or fracture of the cement bed and/or tissue reactions to the implant can lead to implant failures.
19. Wearing of the implant components can make it necessary to reoperate on the artificial joint.

PACKAGING AND LABELING

Components should only be accepted if received by the hospital or surgeon with the factory packaging and labeling intact. If the sterile barrier has been broken, return the component to Smith & Nephew, Inc.

STERILIZATION

Implants are supplied sterile to a Sterility Assurance Level (SAL) of 10^{-6} . The method of sterilization is noted on the package label. All radiation sterilized components have been exposed to a minimum of 25 kiloGrays of gamma radiation.

DO NOT REUSE OR RESTERILIZE implant components or disposable instruments. Contact your local Smith & Nephew Sales Representative regarding procedures to return components. If not specifically labeled sterile, reusable instruments are supplied non-sterile and must be cleaned and sterilized prior to surgery using one of the following validated, recommended methods.

Cycle Parameters (Reusable instruments)

- Dynamic Air Removal (Prevacuum) Steam Cycle: 4 pulses at 132°C (270°F) or 3 pulses at 135°C (275°F) with a minimum exposure time of 3 minutes and a minimum drying time of 30 minutes.
- Gravity Displacement Steam Cycle: 132°C to 135°C (270°F to 275°F) with a minimum exposure time of 30 minutes and a minimum vacuum drying time of 30 minutes.
- Flash Steam Cycle: Exposure temperature: 132°C to 135°C (270°F to 275°F). Exposure time for a Gravity Displacement Cycle of 10 minutes or Dynamic Air Removal (Prevacuum) Cycle of 3 to 4 minutes.

Please see also the document, "Recommendations for decontamination and sterilization of Smith & Nephew orthopaedic devices", which is provided with Smith & Nephew instrument sets, for further information on cleaning instructions and validated sterilization procedures.

INFORMATION

For further information or to receive a copy of this package insert in hard copy, please contact Customer Service at (800) 238-7538 for calls within the continental USA and (901) 396-2121 for all international calls.

Manufacturing Facilities:

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Note that the former entities Plus Orthopedics AG, Plus Endoprothetik AG, Precision Implants AG and Intraplant are all part of Smith & Nephew.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

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