Freedom® Total Knee System

⚠ Carefully read all instructions and be familiar with the surgical techniques prior to use.

Description

The Maxx Orthopedics' Freedom® Total Knee System is a system of components intended to replace the femoral, tibial and patella articular surfaces of the knee joint. Components are available in many styles and sizes and are manufactured from various types of metals and non-metallic materials. The different product categories include:

1. The Freedom Total Knee System
    a. Metal Backed Tibial Components
    b. All-Poly Tibial Components (CR and PS)
    c. Femoral (CR and PS)
    d. Cementless Femoral (CR and PS)
2. Freedom Stemmed Tibial Components
3. Freedom PCK Components

The component style, size, compatibility, and specific component material is provided on the outside carton label. The component may be intended for application with or without bone cement. All implantable components are designed for single use only. Note: PCK and Cementless components are not licensed for sale in Canada.

Product Selection Information

- Appropriate matching of the components will occur when the articular component is matched to the femoral component (by letter size designation and constraint style) and to the tibial base (by numerical size designation). For example a size **B1-2 PS (Posterior Stabilized)** articular component is appropriately matched to a size **B PS** femoral component and either a size **1** or size **2** tibial base plate. Mismatching may result in poor surface contact and produce pain, decrease wear resistance, produce instability of the implant, or otherwise reduce implant life.
- Use only instruments and trials specifically designed for use with these devices to help ensure accurate surgical implementation, soft tissue balancing, and evaluation of knee function.
- The Freedom Total Knee System, Freedom Stemmed Tibial Components and Freedom PCK Components are indicated for cemented fixation. Only Cementless Femoral (CR and PS) components with porous coating are additionally indicated for cementless biological fixation application.
- Selections between the various sizes and fixation options are matters of physician discretion.
- Do not use products past their expiration date.

Indications

- Severe knee joint pain, loss of mobility, and disability due to: rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis.
- Correction of functional deformities.
- Post-traumatic loss of knee joint contour, particularly when there is patellofemoral erosion, dysfunction, or prior patellectomy.
- Moderate valgus, varus, or flexion trauma.
- Knee fractures untreatable by other methods.
- Revision surgery where sufficient bone stock and soft tissue integrity are present.

Contraindications

- History of infection in the affected joint that may affect the function of the implanted prosthetic.
- Less than optimal bone stock on femoral or tibial surfaces resulting from a history of disease, infection, or prior surgical procedures which cannot provide adequate support for the implantation.
- Compromised skeletal bone quality.
- Neuropathic disease that adversely affects the prosthetic joint.
- Osteoporosis or deficiency of musculature that compromises the affected limb.
- Pain-free and stable arthrodesis in an adequate functional position.
- Instable knee joint secondary to negative collateral ligament integrity.
- Patients whose weight, age, or activity level might cause extreme loads and early failure of the system.

If at the time of surgery, one or more of the following contradictions become apparent, cementless use is contradicted, and the components should be fixed with cement:

- Patients with vascular deficiency at the bone site.
- Patients with inadequate bone stock to assure a firm press fit and close apposition of the cut bone surfaces to the prosthesis.
- Patients with inadequate bone quality (e.g. severe osteoporosis).
- Lack of stability of the implanted components throughout a full range of motion.

Precautions

- Before clinical use, the surgeon should thoroughly understand all aspects of the surgical procedure and the limitations of the product. Patients should also be instructed on the limitations of the product, including but not limited to, the impact of patient weight and activity, and be taught to govern their activity accordingly.
- The prosthesis will not restore functions to the level expected with normal healthy bone, and the patient should temper their expectations to a realistic level.
- As with all prosthetic implants, the durability of the components is affected by numerous biologic, biomechanical, and other external factors which can limit their service life. Adherence to the indications, contraindications, precautions, and warnings for this product is essential for maximizing service life.
- The Freedom branded devices have not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of Freedom branded devices in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

Adverse Effects

- Long term swelling or infection.
- No improvement in range of motion.
- Neuropathic disorders.
- Dislocations, bone fractures, and/or joint instability.
- Per literature, there is a chance that wear of polyethylene components may result in bone resorption, loosening, and related infection.
- Possibility for metal sensitivity reactions.
- Venous thrombosis.
- Prolonged and excessive joint pain and/or inflammation.
- Aseptic loosening of implant.
- Possible detachment of the coating(s) on components with porous coating, potentially leading to increased debris particles

Warnings

- This device is for single patient use only. Never reuse the implant, even though it may appear undamaged.
- Discard all damaged implants.
- Polished bearing areas must not come in contact with hard or abrasive surfaces.
- Bearing areas must be free of debris and clean prior to assembly.
- Contouring or bending of the implant may reduce its fatigue strength and cause premature failure under load.
- All-polyethylene tibial base plates should be limited to use in low demand (i.e. modest weight, activity level) patients with good bone quality.
- Return all packages with flaws in the sterile barrier to the supplier. Do not re-sterilize.
- The optional Freedom Stemmed Tibial Augments are intended for screw attachment to the Stemmed Tibial Base Plate.
- The optional Freedom PCK Femoral Augments are intended for screw attachment to the PCK Femoral Component.

Materials

All of the materials used in the Maxx Orthopedics' Freedom® Total Knee System meet ASTM standards for implants. The metal components comply with the F75 Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075), and F136 Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401). The polyethylene components comply with the F648 Standard Specification for Ultra-High-Molecular-Weight Polyethylene Powder and Fabricated Form for Surgical Implants.

Sterilization

- All Implants are supplied sterile in protective packaging to a Sterility Assurance Level (SAL) of 10^{-6} using either gamma radiation or Ethylene Oxide.
- The method of sterilization is provided on the outside carton label. Components sterilized through radiation have been exposed to a minimum dose of 25 kGy of gamma radiation.
- The packaging of all sterile products should be inspected for flaws in the sterile barrier before opening. In the event of such a flaw, the product must be returned non-sterile. Trial components should be used to avoid having to open any aspect of the sterile package prior to the component use.
- Care should be taken to prevent contamination of the component. In the event of contamination, this product should be discarded.
- If the package is opened, but the product is not used, the component should not be re-sterilized and should be discarded or returned to the supplier.

Component Type	Sterilization Method
Femoral Components (CR, PS and PCK)	Ethylene Oxide
Tibial Articular Surfaces (CR, PS, and PCK)	Ethylene Oxide
Tibial Base Plates (Standard and Stemmed)	Ethylene Oxide
All Poly Patellas	Ethylene Oxide
Offset Junctions	Gamma Irradiation
Stem Extensions	Gamma Irradiation
Augments (Tibial and Femoral)	Gamma Irradiation

Patient Guidance

The probability of resulting complications and/or failure of total knee prostheses is increased in cases where the patient's physical and medical presentation (e.g. weight, or other diseases) is a detriment, the patient's functional outcome goals are above what is reasonably attainable, the patient's expectations for knee joint function are unrealistic, and/or the patient's engages in a less than optimal level of rehabilitation post-surgery. Excessive physical activity and injury can result in loosening, wear, and/or fracture of the knee implant. The patient must be instructed about all postoperative restrictions, particularly those related to occupational and sports activities and about the possibility that the implant or its components may wear out, fail, or need to be replaced. The implant may not, and is not guaranteed to last the rest of the patient's life. Because prosthetic joints are not as strong, reliable, or durable as natural, healthy joints, all prosthetic knees may need to be replaced at some point.

CAUTION: **FEDERAL LAW (U.S.A) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A LICENSED PHYSICIAN.**
WARNING: **THIS DEVICE IS INTENDED FOR CEMENTED USE ONLY.**

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Carefully read all instructions and be familiar with the surgical techniques prior to use.

SYMBOL KEY LEGEND	
	MANUFACTURER
REF	CATALOG NUMBER
LOT	BATCH CODE
	DATE OF MANUFACTURE
	USE BY DATE
	CAUTION
	DO NOT RE-USE
STERILE EO	STERILIZED WITH ETYLENE OXIDE
STERILE R	STERILIZED WITH GAMMA IRRADIATION
EC REP	EUROPEAN AUTHORISED REPRESENTATIVE