

For Symbols Glossary, please refer to <https://restor3d.com/resources/instructions>

Rx ONLY

Caution: U.S. law restricts this device to sale by or on the order of a physician.

DEFINITIONS

Abbreviation	Material
Ti	Titanium
Ti6Al4V	Titanium Alloy
CoCr	Cobalt Chrome Alloy
SS	Stainless Steel
UHMWPE	Ultra High Molecular Weight Polyethylene

GENERAL PRODUCT INFORMATION

Ankle replacement has evolved to allow surgeons to restore mobility, correct deformity and reduce pain for many patients. While the prostheses used are largely successful in attaining these goals, it must be recognized that they are manufactured from a variety of materials and that any ankle replacement system, therefore cannot be expected to withstand activity levels and loads as would normal healthy bone. In addition, the system, including the bone/implant interface, will not be as strong, reliable or durable as the natural human joint.

Fixed bearing ankle replacements comprise a tibial implant, bearing implant and talar implant. The UHMWPE bearing implant is rigidly affixed to the tibial implant to create a two-piece articulating prosthesis. Implant components are available in a variety of sizes and configurations to match patient anatomy and pathology.

INTENDED USE

The Kinoss Axiom Total Ankle System is intended to give a patient limited mobility by reducing pain, restoring alignment, and replacing the flexion extension movement of the ankle talocrural joint.

INDICATIONS FOR USE

The Kinoss Axiom Total Ankle System is indicated for patients with ankle joints damaged by severe rheumatoid, post-traumatic or degenerative arthritis.

The Kinoss Axiom Total Ankle System is additionally indicated for patients with a failed previous ankle surgery.

CAUTION: In the United States, the Kinoss Axiom Total Ankle System is intended for cement use only.

CONTRAINDICATIONS

- Insufficient bone quality to ensure close apposition of the cut bone surfaces to the prosthesis
- Sepsis, Infection, or osteomyelitis
- Vascular deficiency in the ankle joint
- Skeletally immaturity
- Neuropathic joints
- Excessive loads caused by activity or patient weight
- Pregnancy

- Severely compromised or inadequate musculature or neuromuscular function
- Patient incapable of following instructions

WARNINGS

- Component loosening is most likely to occur in patients who are young, physically active and/or heavy.
- The Axiom Ankle System has 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 the Axiom Ankle System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

PRECAUTIONS

- Implants are for single patient use only
- Do not resterilize
- Avoid scratching, gouging, or notching the prosthesis. Do not use any component that is damaged during implantation.
- Improper component size selection or placement or fixation may result in unusual loading conditions, reducing implant service life.
- The interference fit of the bearing implant may only be engaged one time. Do not attempt to reinsert a bearing implant that has already been inserted into a tibial implant.

ADVERSE EFFECTS

The following adverse effects have been reported for joint replacement:

- Deep wound infection
- Component loosening
- Dislocation or subluxation
- Malalignment
- Inflammatory reaction or osteolysis
- Metal sensitivity
- Tissue reactions to implant materials
- Bone damage or fracture
- Hematoma and/or delayed wound healing
- Temporary or permanent nerve damage resulting in numbness or pain

POTENTIAL COMPLICATIONS

Improper implant placement, selection, and fixation of the implant components may result in excessive loading conditions and subsequent reduction in service life of the implant. The surgeon must be meticulously aware of the surgical technique, implant and instruments. Periodic long-term follow-up is recommended to monitor the patient and implant performance.

Proper surgical procedure and technique is the responsibility of the medical professional. Each surgeon must evaluate the appropriateness of the procedure based on individual medical training and experience. Kinoss provides a technique for reference. The surgeon must select the appropriate technique for each individual patient.

Materials. The Axiom Total Ankle System components are manufactured from cobalt chromium molybdenum alloy, titanium alloy, commercially pure titanium and ultra-high molecular weight polyethylene (UHMWPE), all of which conform to ASTM or ISO standards.

Handling and Sterilization

Sterile Packaged Implants and Instruments

Components labeled as sterile on their packaging have been sterilized and should always be stored unopened. Resterilization of the implants is not recommended. This product should be stored in a clean, dry location at room temperature and out of direct sunlight.

Instrument Cleaning:

- Disassemble all components as per manufacturer instructions (if appropriate).
- Rinse with cold tap water to remove gross contamination
- Soak in an enzymatic detergent solution per manufacturer directions for 5 minutes.
- Scrub thoroughly with a soft brush and/or pipe cleaner
- Rinse with cold tap water for 4 minutes. While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Soak in a detergent solution per manufacturer directions for 5 minutes
- Scrub thoroughly with a soft brush and/or pipe cleaner
- Rinse thoroughly/flush with reverse osmosis/deionized (RO/DI) water for 4 minutes.
- While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Sonicate for a minimum of 10 minutes in an enzymatic detergent solution per manufacturer directions
- Rinse thoroughly/flush with reverse osmosis/deionized (RO/DI) water
- While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Sonicate for a minimum of 10 minutes in reverse osmosis/deionized (RO/DI) water
- Rinse thoroughly/flush with reverse osmosis/deionized (RO/DI) water.
- While rinsing, actuate any moveable parts and scrub exposed internal components with a soft brush/pipe cleaner.
- Use a 20 mL syringe to flush lumens and internal features.
- Dry with a clean, soft, disposable cloth and allow to air dry for 20 minutes.
- Visually inspect for debris and cleanliness. Reclean if necessary.

Steam Sterilization of Instruments:

The minimum recommended steam sterilization conditions for reusable instruments are as follows:

1. Double wrap the component in an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material.
2. Autoclave according to the following parameters:

Steam Sterilization		
Cycle Time	Parameter	Minimum Set Point
Pre-vacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	30 minutes

3. After Sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that implants are at room temperature prior to implantation. Avoid contact with hard objects that may cause damage. These recommendations are consistent with ANSI/AAMI ST 79 guidelines and have been developed and validated using specific equipment. Due to variations in environment and equipment, it must be demonstrated that these recommendations produce sterility in your environment. If processing conditions, wrapping materials, or equipment changes occur, the effectiveness of the sterilization process must be demonstrated.

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