Axiom PSR System

restor3d, inc

Durham, NC 27709 U.S.A.
www.restor3d.com

℞ ONLY

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

DEFINITIONS

Symbol	Definition
	Batch code
	Catalog number
	Do not re-use
	Caution, consult accompanying documents
	Use by
	Temperature limitation
	Keep dry
	Keep away from sunlight
	Date of manufacture
	Manufacturer
	Sterilized using ethylene oxide
	Sterilized using radiation
	Do not resterilize
℞ ONLY	For prescription use only

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

GENERAL PRODUCT INFORMATION

The instruments herein are designed for single patient use. They are additively manufactured with features and geometry that will function as intended only when used with the patient for which they have been designed. The instruments are provided non-sterile and must be sterilized before use. The instruments are not reusable and must be properly disposed of after use. The steps for processing the single use, patient specific surgical instruments are provided herein. Please refer to the Kinos Axiom Total Ankle System surgical technique guide for further information regarding the use of Kinos Axiom instruments.

INTENDED USE

The Axiom PSR System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding bone cutting. Axiom PSR System is intended to be used with the Kinos Axiom Total Ankle System and its cleared indications for use, provided that anatomic landmarks necessary for alignment and positioning of the implant are identifiable on patient imaging scans.

While the Axiom PSR provide initial positioning of the instruments used in the total ankle replacement surgery, it is the responsibility of the operative surgeon to confirm the final position of an implant construct for each individual patient and surgery. Axiom PSR are intended for single patient and one-time use only.

The Kinos 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 Axiom PSR System is intended to be used as patient specific surgical instrumentation to assist in the positioning of total ankle replacement components intraoperatively and in guiding bone cutting. The Axiom PSR System is intended to be used

with the Kinos Axiom Total Ankle System and its cleared indications for use.

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

The Kinos Axiom Total Ankle System is additionally indicated for patients with a failed previous ankle surgery.
CAUTION: In the United States, the Kinos 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
- Poor skin coverage around the ankle joint which would make the procedure unjustifiable
- Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.
- Suspected or documented metal allergy or intolerance.

WARNINGS

- The Axiom PSR System components are defined according to a surgeon approved plan from a patient's imaging data. The presence of prior hardware may impact the accuracy of the patient's imaging data.
- To avoid serious injury, patient identification on guides and models must be verified and confirmed against patient identification prior to use.
- Guides and models are designed for a specific patient. To avoid the potential for serious injury, guides and models should not be modified in any way.
- To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides and models prior to use.
- Device(s) are single use only and designed for use with a specific patient only. Guides and models may be re-sterilized a single time, but may not be re- used for additional surgical procedures.
- Prior to use of any Axiom PSR guides and models, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
- The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 60 minutes, then the cycle is not considered sterile.
- Revert to standard Kinos Axiom Total Ankle Arthroplasty instrumentation if the device is dropped in the surgical suite.
- Pre-existing metal should be removed where interference may affect the fit of the device to patient anatomy.
- Revert to standard Kinos Axiom Total Ankle Arthroplasty instrumentation if the device does not fit patient anatomy.

PRECAUTIONS

- Axiom PSR guides and models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
- To ensure that damage has not occurred during shipping and handling, inspect all guides and models for damage prior to use. Do not use if the guides or models are broken, cracked or otherwise damaged.
- To ensure successful surgery in the event of device malfunction, have a tray of standard Kinos Axiom Total Ankle Arthroplasty instrumentation available at the time of surgery.
- To avoid material toxicity reactions, contact time for each material in the Axiom PSR System should be limited to the time shown below:

Material	Device	Contact Duration	Body Contact Area
Ti-6Al-4V	Resection Guides	≤24h	Total Ankle Surgical Site
Methacrylic acid esters	Bone Models	No direct contact	No direct contact

RESTRICTIONS ON REPROCESSING

- The Axiom PSR instruments are designed with patient specific criteria and therefore only for a single patient.
- The medical provider must match the case number provided on the Pre-Operative Plan with the case number on the device labeling.

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- A patient's anatomy or condition may be subject to change over time. The medical provider is responsible for determining if the patient condition and/or anatomy has changed in such a way that requires a redesign of the patient specific device.
- The Axiom PSR instruments are to be destroyed at the conclusion of the surgery for which they were designed.

MATERIALS.

The resection guides are implant-grade titanium alloy (Ti-6Al-4V). The bone models are biocompatible polymer (Methacrylic acid esters). The general instruments are stainless steel and radel.

PACKAGING

Guides and models are provided in Non-Sterile condition. Cleaning and sterilization are required prior to use.

The health care facility and its personnel bear the ultimate responsibility for ensuring that any material or container used during the sterile processing at the facility is validated for the sterilization.

CLEANING

Manual Cleaning Method:

1. Prepare neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device in to the prepared detergent and allow the device to soak for 5 minutes.
3. While immersed, use a soft bristle brush to brush this device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas.
5. Rinse the device under running reverse osmosis – deionized water (RO/DI) at ambient temperature.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Wipe dry with sterilized lint free cloth or wipes.

Automated Cleaning Method

Manual Pre-Cleaning:

1. Prepare a neutral pH enzymatic detergent solution following the manufacturer's recommendation.
2. Fully immerse the device in to the prepared detergent and allow the device to soak for 5 minutes.
3. While immersed, use a soft bristle brush to brush the device, paying particular attention to crevices and other hard to reach areas.
4. Use a syringe to flush the holes or lumens and any difficult to reach areas.
5. Rinse the device under running reverse osmosis – deionized water (RO/DI) at ambient temperature.
6. While rinsing, use a syringe to flush the holes and difficult to reach areas.
7. Transfer the test articles onto rack system contained inside the washer for processing.
8. Automatic Cleaning Parameters:

Phase	Recirculation Time (min)	Temperature	Detergent Type & Concentration
Pre Wash 1	2:00	Cold tap water	N/A
Enzyme Wash	2:00	Hot tap water	Enzymatic cleaner 1oz/gallon
Wash 1	2:00	65.0^{o}C Set Point	Enzymatic cleaner 1oz/gallon
Rinse 1	2:00	Hot tap water	N/A
RO/DI Rinse	0:10	43^{o}C	N/A
Dry Time	7:00	115.0^{o}C	N/A

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STERILIZATION

The minimum recommended steam sterilization conditions for Axiom PSR components 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
Prevacuum 270°F (132°C)	Exposure Temperature	270°F (132°C)
	Exposure Time	4 minutes
	Dry Time	30 minutes
	Cool Down Time	30 minutes

3. After Sterilization, remove the component from its wrapping using accepted sterile technique with powder-free gloves. Ensure that instruments are at room temperature prior to use. Avoid contact with hard objects that may cause damage.
4. 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.

STORAGE

Axiom PSR components that will not be used within a short time should be stored clean and completely dry. The packaging used for steam sterilization is an FDA-cleared CSR wrap or similar type non-woven medical grade wrapping material. This may offer a level of contamination protection. The Axiom PSR instruments must be stored in a clean, dry environment, out of direct sunlight and not subjected to extreme temperatures.