

ATTENTION: OPERATING SURGEON PLEASE READ THE FOLLOWING INFORMATION PRIOR TO USE OF VANTAGE PSI SYSTEM PLAN, GUIDES, AND MODELS.

3D Systems, Inc.

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VANTAGE PSI SYSTEM GUIDES AND MODELS



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

DESCRIPTIONS:

3D System's Vantage PSI System is patient-specific guides created to fit the contours of the patient's distal tibial and proximal talar anatomy. The guides and models are designed and manufactured from patient imaging data (CT) and are made from biocompatible nylon. The surgical guides in combination with Advita Ortho Vantage Total Ankle reusable instruments, facilitate the positioning of Vantage Total Ankle Implants. 3D System's Vantage PSI System produces a variety of patient specific outputs including surgical guides, anatomic models, and case reports.

INDICATIONS FOR USE:

The Vantage PSI System is intended to be used as patient specific surgical planning and instrumentation to assist in the positioning of total ankle replacement components intraoperatively, and in guiding bone cutting. The Vantage PSI System is intended for use with Advita Ortho's Vantage Total Ankle System and its cleared indications for use.

CONTRAINDICATIONS:

The guides and models from the Vantage PSI System and the associated case report should not be used if any of the following occur:

1. Patient has an active infection.
2. Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.
3. Patient has an existing total ankle arthroplasty in the ankle of interest.

MATERIALS:

Patient contact materials used in the guides and models have been tested and shown to be biocompatible in accordance with ISO 10993-1. The materials used to manufacture guides and models are nylon blends.

SHELF LIFE:

Refer to the expiration date listed on the part package label for product shelf life. Guides and models are to be used within 3 months of the manufacture date.

WARNINGS:

1. To avoid serious injury, patient identification on guides and models must be verified and confirmed against patient identification prior to use.
2. 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.
3. 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.
4. 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.
5. Prior to use of any Vantage PSI guides and models, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
6. 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.
7. Switch to standard Advita Ortho Vantage Total Ankle Arthroplasty instrumentation if the device is dropped in the surgical suite.
8. Switch to standard Advita Ortho Vantage Total Ankle Arthroplasty instrumentation if the device does not fit patient anatomy or pre-existing metal interferes with device use.
9. When an extra-articular deformity of greater than 5° in the operative lower extremity is present, the Vantage PSI System may not be appropriate and standard instrumentation should be considered.

PRECAUTIONS:

1. Vantage PSI guides and models are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
2. 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.
3. To ensure successful surgery in the event of device malfunction, have a tray of standard Advita Ortho Vantage Total Ankle Arthroplasty instrumentation available at the time of surgery.
4. To avoid material toxicity reactions contact time for each material should be limited to the time shown below:

MATERIAL APPLICABILITY TABLE:

The following table defines the basic methods that must be used for cleaning and sterilization of the Vantage PSI guides and models:

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CLEANING & STERILIZATION:

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

Material	Cleaning	Sterilization
Duraform ProX PA®	Automatic or Manual	Steam

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 And Concentration (If Available)
Pre-wash 1	02:00	Cold tap water	N/A
Enzyme Wash	02:00	Hot tap water	Enzymatic cleaner 1 oz / gallon
Wash 1	02:00	65.0°C Set Point	Enzymatic cleaner 1 oz / gallon
Rinse 1	02:00	Hot tap water	N/A
Pure Water Rinse	00:10	43°C	N/A
Dry Time	07:00	115°C	N/A

Material	Device	Contact Duration	Body Contact
DuraForm ProX PA®	Guides & Models	Limited (≤ 24 hours)	Tissue/Bone/ Mucosal Membrane

Sterilization Method / Instructions:

1. **Packaging:** Wrap parts using an FDA cleared sterilization wrap (e.g. Kimguard® Sterilization Wrap, P/N KC600)
2. **Cycle Type:** Dynamic-Air-Removal Sterilization (Pre-Vacuum / Steam)
3. **Preconditioning Pulses:** 4
4. **Cycle Temperature:** 132°C.
5. **Cycle Time:** 4 minutes
6. **Dry Time/Cool Time:** DuraForm ProX PA guides: 30 minute dry time, 30 minute cool down.
7. **Storage in Sterile State:** Product is intended for use immediately after sterilization only. Do Not Unwrap until ready for use.

Comments or questions regarding the use of this device can be directed to Attn:

Customer Service
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Symbol Legend:



Warning

Symbol indicates a potentially hazardous situation, which if not avoided could result in death or serious injury to the user.



Caution

Symbol indicates a situation that the user must take into consideration to ensure the safe and effective operation of the equipment and associated accessories.



Manufacturer



Date of Manufacture



Non-Sterile



Do Not Re-Use



Catalog Number



Prescription Only



Batch Code



Consult Instructions for Use