

ATTENTION: OPERATING SURGEON PLEASE READ THE FOLLOWING INFORMATION PRIOR TO USE OF VANTAGE PSI SYSTEM FLUOROSCOPIC INSERT.

3D Systems, Inc.
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VANTAGE PSI SYSTEM FLUROSCOPIC INSERTS



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.

MATERIALS:

All inserts for Vantage PSI System are made from surgical instrument grade stainless steel that complies with ASTM F899-11.

 **WARNINGS:**

1. 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.
2. After use, this product may be a potential biohazard and should be rinsed and processed immediately using the cleaning and sterilization procedures contained below.
3. To avoid the potential for serious injury, Vantage PSI Fluoroscopic Inserts should not be modified in any way.
4. Prior to use of any Vantage PSI Fluoroscopic Inserts, the user must thoroughly review this instruction for use and all other labeling provided with the devices.
5. The presence of any moisture on the wrap should be visually monitored. If any moisture is observed after 20 minutes, then the cycle is not considered sterile.
6. Device(s) are single use only.

 **PRECAUTIONS:**

1. Vantage PSI Fluoroscopic Inserts are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.
2. The surgeon should confirm the Fluoroscopic Inserts fit correctly with the guides prior to use.
3. Thoroughly inspect the inner edges / surfaces of the drill guides for enlargement of the hole, irregularities in the surfaces that contact the drill, cracking, debris, or other signs of damage. If any of these signs are present, replace the instrument prior to use.
4. Fluoroscopic Inserts should be cleaned immediately after surgery to prevent drying of materials on the inserts. If stored in a non-sterile state, inserts must be re-cleaned prior to sterilization.

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CLEANING & STERILIZATION:

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

Material	Cleaning	Sterilization
17-4 Stainless Steel	Manual	Steam

Manual Cleaning Method:

1. Prepare neutral pH enzymatic cleaner per manufacturer's instructions using water less than 25°C.
2. Immerse parts in the solution and agitate until all surface bubbles have been removed and slots and holes are in contact with the solution. Use a small syringe to flush solution into small areas when necessary.
3. Soak one (1) minute.
4. While immersed, use a soft wipe (such as a cleanroom wiper or 4X4 lap sponge), a soft bristle brush or pipe cleaner (as appropriate) to gently wipe or brush all surfaces, including the small openings for a minimum of one (1) minute. Use a brush or probe that is small enough to access any small openings.
5. Rinse each part under running tap water which is less than 25°C for a minimum of one (1) minute. After the rinse, use a 60 cc syringe filled with tap water which is less than 25°C to aspirate water through all channels, slots, small openings or crevices to remove the neutral pH enzymatic cleaner solution.
6. Soak each part in RO/DI water for a minimum of one (1) minute, and then agitate sample for 30 seconds in the rinse water to ensure complete rinsing, repeat two (2) more times.
7. Visually inspect surfaces prior to drying, re-rinse if residues and soils are found.
8. Wipe dry with sterilized cloth or wipes.

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:**
20 minute dry time (NOTE: open sterilization chamber and let cool prior to removal from chamber).
7. **Storage in Sterile State:** Inserts may be stored in a sterile, wrapped state in accordance with hospital standard practices. If inserts are stored in a non-sterile state, they must be cleaned immediately prior to sterilization. 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