


ATTENTION: OPERATING SURGEON PLEASE READ THE FOLLOWING INFORMATION PRIOR TO USE OF VSP® ORTHOPEDICS PLAN AND MODELS.

3D Systems, Inc.
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VSP® ORTHOPEDICS MODELS

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

DESCRIPTION:

The VSP® Orthopedics System is intended to assist a surgeon with pre-operative planning and transfer of the pre-operative plan to the surgery in orthopedic procedures. The system contains several physical and digital outputs including patient-specific anatomical models, templates, and guides (physical outputs); and patient-specific surgical plans and digital files (digital or documentation outputs).

INDICATIONS FOR USE:

The VSP® Orthopedics System is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies for adult patients in the distal femur, tibia, and non-sacrum pelvis.

CONTRAINDICATIONS:

The templates and guides from the VSP® Orthopedics System and the associated case report are not recommended for:

1. Patients with a metallic implant at the proposed osteotomy site.
2. Patients under 21 years of age.
3. Patients with an active infection.
4. Patients with significant changes to anatomy occurring after the medical scan used for product definition was obtained.

MATERIALS:

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

Selective coloration within ClearView® models may fade significantly during sterilization.

SHELF LIFE:

Refer to the expiration date listed on the part package label for product shelf life.

 **WARNINGS:**

1. To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the models prior to use.
2. To avoid serious injury, patient identification on models must be verified and confirmed against patient identification prior to use.
3. Device(s) are single use only and designed for use with a specific patient only. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilize or in any way re-use the models
4. Prior to use of any VSP® Orthopedics models, 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 60 minutes, then the cycle is not considered sterile.

 **PRECAUTIONS:**

1. VSP® Orthopedics 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 models for damage prior to use. Do not use if the models are broken, cracked or otherwise damaged.
3. Handle models delicately and with caution to avoid damage.
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 VSP® Orthopedics models:

| Material | Device | Contact Duration | Body Contact |
|-------------|--------|----------------------|--------------|
| ClearView® | Models | Limited (≤ 24 hours) | Tissue/Bone |
| ArthroView® | | | |

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CLEANING & STERILIZATION:

Models are provided in Non-Sterile condition. Cleaning and Sterilization are required prior to use.

| Material | Cleaning | Sterilization |
|-------------|----------|---------------|
| ArthroView® | Manual | Steam |
| ClearView® | 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 or soft bristle brush 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 enzymatic solution.
6. Soak each part in purified 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. **Cycle Temperature:** 132°C.
4. **Cycle Time:** 4 minutes
Dry Time/Cool Time: 60 minute dry time for ClearView and ArthroView models (NOTE: Open sterilization chamber and let models cool prior to removal from chamber.)
5. **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