

**ATTENTION: OPERATING SURGEON PLEASE READ THE FOLLOWING INFORMATION PRIOR TO USE OF THE VSP® SYSTEM PLAN, MODELS, TEMPLATES AND GUIDES.**

**Manufactured by:**  
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**VSP® SYSTEM MODELS, TEMPLATES AND GUIDES**



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

**DESCRIPTIONS:**

The VSP® System utilizes a combination of Commercial Off-The-Shelf (COTS) and custom software to manipulate 3D medical images (CT based systems) to create virtual and physical anatomical models, templates, surgical guides, and surgical plans for reconstructive surgical procedures.

**INDICATIONS FOR USE:**

The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

**CONTRAINDICATIONS:**

The models, templates and guides from the VSP® 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:**

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

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

**⚠️ WARNINGS:**

1. To avoid potentially serious allergic reactions, ensure that the patient is not allergic to the materials used in the guides and templates prior to use.
2. To avoid mix-ups and associated serious injury, patient identification on templates and guides 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, guides and templates.
4. Templates and guides are designed for a specific patient. To avoid the potential for serious injury, guide and templates should not be modified in any way.
5. Prior to use of any VSP® guides, templates, models or accessories, 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

**⚠️ PRECAUTIONS:**

1. VSP® models, templates and guides 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 templates for damage prior to use. Do Not Use if the templates or guides are broken, cracked or otherwise damaged.
3. Handle models with delicate anatomy, (i.e. nasal bones, orbital floor) cautiously to avoid damage.
4. Plate bending templates are not intended for patient contact and cannot be sterilized or used within a sterile field.
5. To avoid material toxicity reactions contact time for each material should be limited to the time shown below:

Material	Device	Contact Duration	Body Contact
ClearView®	Models	Limited (≤ 24 hours)	Tissue/Bone
ArthroView®	Models, Guides, Templates, Occlusal Splints		Tissue/Bone/ Mucosal Membrane
AccuView®	Occlusal Splints	Prolonged (≤ 30 days)	Mucosal Membrane

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**MATERIAL APPLICABILITY TABLE:**

The following table defines the basic methods that must be used for cleaning and sterilization of the VSP guides, templates and models:

Material	Cleaning	Sterilization
ArthroView®	Manual	Steam
AccuView®	Manual	Steam
ClearView®	Manual	Steam

**CLEANING & STERILIZATION:**

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

⚠ Plate bending templates are not intended for patient contact and not recommended for sterilization or use within a sterile field.

**Manual Cleaning Method:**

1. Prepare ENZOL® 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 ENZOL® 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.

**Automated Cleaning Method:**

Not Recommended.

**Sterilization Method / Instructions:**

1. **Packaging:** Wrap parts using an FDA cleared sterilization wrap (i.e. 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
5. **Dry Time:** 60 minutes (NOTE: open sterilization chamber and let cool prior to removal from chamber)

6. **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  
3D Systems, Inc.  
5381 South Alkire Circle  
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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