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

3D Systems, Inc.
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VSP® ORTHOPEDICS TEMPLATES AND GUIDES

℞ Only 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 guides and templates have been tested and shown to be biocompatible in accordance with ISO 10993-1. The materials used to manufacture guides and templates are nylon blends.

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 guides and templates prior to use.
2. To avoid 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. Guides and templates may be re-sterilized a single time, but may not be re-used for additional surgical procedures.
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® Orthopedics guides and templates, 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® Orthopedics 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. 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 guides and templates:

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

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CLEANING & STERILIZATION:

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

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

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 min
5. **Dry Time/Cool Time:** 30 minute dry time, 30 minute cool down for DuraForm ProX PA guides and templates.
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:

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Phone: (720) 643-1001
Fax: (720) 643-1009

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