# Orientation Posts

**Manufacturer:**

Smart Denture Conversions, LLC
1800 N. Salem St.
Suite 104
Apex NC, 27523
855-550-0707
www.SmartOnX.com




**Training:**

It is strongly recommended that clinicians, new as well as experienced implant and abutment users, always go through special training before undertaking a new treatment method. Smart Denture Conversions offers a wide range of courses for various levels of knowledge and experience. For more information, please visit www.SmartOnX.com.

**Product Description:**

Orientation Posts are tools designed to thread into the prosthetic side of an Omnibut multi-unit abutment. These posts enable the user to precisely adjust the orientation of the high retention swivel. They also provide a visual indication of the screw channel direction. The table below summarizes the items:

| Name | Compatible Parts | Material | Use Type |
|---|---|---|---|
| Orientation Post | Omnibut Multi-Unit Abutments | 300 Series Stainless Steel and Unfilled PEEK (Poly-Ether Ether Ketone) | Multi-use |

**Intended Use/Indications for Use:**

Orientation Posts are intended to be used with Omnibut multi-unit abutments to adjust the orientation of the high retention swivel attachment and provide a visual indication of the screw channel direction. Orientation Posts are intended to be reprocessed until they do not work as intended. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartOnX.com.

**Note:** The Orientation Post must be properly aligned with the axis of Omnibut screw channel prior to screwing in the Post.

**Contraindications:**

It is contraindicated to using Smart Denture Conversions' Orientation Posts:

- Patients who are medically unfit for an oral surgical procedure.
- Patients in whom adequate sizes, numbers or desirable positions of implants are not reachable to achieve safe support of functional or eventually parafunctional loads.
- Patients who show signs of allergy or hypersensitivity to the chemical components of the materials listed in the chart above.

**Warning:**

- Orientation Posts are not intended to tighten the Omnibut Orientation Screw.
- Components are to be used by dental health care professionals and are to be used in patients subject to dental implant treatment.
- If the indication or the nature of use is not clear, do not use until all points have been clarified.
- Do not use if package is damaged.
- Always inspect components before use. Do not use damaged, deformed, corroded, or discolored components.
- Ensure products are secured against aspiration when handled intraorally. Aspiration of products may lead to infection or unplanned physical injury.

- Failure to follow the procedures outlined in these instructions may lead to any or all of the following complications: Aspiration or swallowing of a component, follow-up treatment, incorrect impression resulting in incompatible restorations.
- As the clinical outcome of dental treatment is influenced by multiple variables, even if the product is used according to the instructions for use the residual risks described below can. anaphylaxis (severe allergic reaction); aspiration or swallowing of components; pain; local infection; inflammation; local irritation; loss of product function; follow-up treatment.
- Smart Denture Conversions is not liable for damage resulting from use outside the intended use of the product.

**Cautions/Precautions:**

The following precautions are required before or during treatment:

- Do not use Smart Denture Conversion components after the expiration date indicated on the packaging.
- All products intended for single use must not be reused. Re-use of single use devices creates a potential risk of patient or user infection and misfitting components.
- Before every procedure make sure that all required components, instruments, and auxiliary equipment are complete, in operating order and available in the required quantity.
- If, due to unfavorable anatomical conditions, instruments do not fit or cannot be used for other reasons, the course of treatment planned with them must not be continued and alternatives must be sought.
- Always wear suitable personal protective equipment for your own safety.
- Position the patient such that the danger of aspiration of components is minimized.
- All components used in the patient's mouth must be secured to prevent aspiration and swallowing.

**Magnetic Resonance Imaging (MRI) Safety Information:**

Smart Denture Conversion LLC Orientation Posts are tools that are used in the operatory with transient patient contact, and do not remain in the body. These products have not been evaluated for safety and compatibility in the MR environment. They have not been tested for heating, migration, or image artifact in the MR environment. The safety of the Smart Denture Conversion LLC Orientation Posts in the MR environment is unknown.

**Cleaning Instructions:**

Components are delivered non-sterile by Smart Denture Conversions and are intended for reuse. Prior to first and subsequent uses, the devices must be cleaned and sterilized by the user.

Smart Denture Conversions recommends the following procedure for cleaning and sterilization of the devices prior to each use.

<u>Initial Treatment at Point of Use Prior to Reprocessing:</u>

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe for soil and debris in cavities.
3. Rinse the devices with cold running tap water.

<u>Containment and Transportation/Shipping to Reprocessing Area:</u>

4. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
5. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

   **Note:** Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.

6. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 mL lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP or Neodisher Medizym; maximum 45°C (113°F)) using an irrigation needle connected to a 20 mL syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solutions.
6. Immerse the device in an ultrasonic bath containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP or Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45° (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 mL lukewarm tap water using an irrigation needle connected to a 20 mL syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting or cracked seals, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

**Reuse Instructions:**

Components are delivered non-sterile by Smart Denture Conversions and are intended for reuse. Prior to use, clean and sterilize the product following the instructions in the Cleaning and Sterilization Instructions section.

Orientation Posts shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Orientation Posts shall be discarded if any of the following criteria are met:

- If any wear, abrasion of the anodization, deformations or corrosion is visible on the component.
- If the Orientation Post does not engage properly with compatible surgical or prosthetic components.

**Sterilization Instructions:**

Components are delivered non-sterile by Smart Denture Conversions. Prior to use, the devices must be sterilized by the user. Smart Denture Conversions recommends the following procedure for sterilization prior to use. Sterilization is recommended to be performed corresponding to the following scheme:

1. **Preparation for sterilization:** Place components (up to 6 devices) in a sterilization pouch which is FDA-cleared for the intended cycle.
2. **Sterilization:**

| Method | Cycle | Temperature | Exposure Time* | Dry Time |
|---|---|---|---|---|
| Steam | Dynamic Air Removal (Prevacuum) | 132°C (270°F) | 4min | 20min |
| Steam | Gravity Displacement | 121°C (250°F) | 30min | 30min |

*Minimum exposure times, the operating times are longer and may vary depending on the device.

# Orientation Posts

**Storage, Handling and Transportation:**

The devices must be stored in a dry place in their original packaging at room temperature and protected from direct sunlight. Improper storage may compromise essential material and design characteristics, leading to device failure.

**Disposal:**

Safely discard potentially contaminated or no longer usable medical devices as healthcare (clinical) waste in accordance with local healthcare guidelines, country and government legislation or policy. Separation, recycling or disposal of packaging material shall follow local country and government legislation on packaging and packaging waste, where applicable. If there is no current legislation, pack them in a perforating waste/sharps disposal container and dispose of them in hospital waste.

**Basic UDI-DI Information:**

The following table lists the Basic UDI-DI information for the devices described in this IFU.

| Product | Catalog Number | Basic UDI-DI Number |
|---|---|---|
| Orientation Post 1PK | OP1PK | +D990OP1PK0 |
| Orientation Post 10PK | OP10PK | +D990OP10PK0 |

**Validity:**

Upon publication of these instructions for use, all previous versions are superseded.

**Availability:**

Some items of Smart Denture Conversions are not available in all countries.

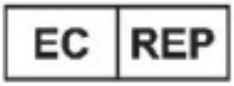
**Warranty:**

Please visit www.SmartOnX.com for the most up to date warranty information.

# Orientation Posts

**Symbols Glossary:**

The following Symbols may be present on the device labeling or in information accompanying the device. Refer to the device labeling or accompanying information for the applicable symbols.

| | | | |
|---|---|---|---|
|  | Manufacturer |  | Date of Manufacture |
|  | Use By Date |  | Serial Number |
|  | Batch Code |  | Catalog Number |
|  | Unique Device Identifier |  | Medical Device |
|  | CE Mark |  | UK Representative |
|  | United Kingdom Conformity Assessment Mark |  | United Kingdom Conformity Assessment Mark with Approved Body Number |
|  | European Representative |  | Non-Sterile |
|  | Keep Dry |  | Consult Instructions for Use |
| RX Only | For Prescription Use Only |  | Keep Away from Sunlight |
|  | Do Not Use if Packaging is Damaged |  | Caution, Consult Accompanying Documents |