

Prosthetic Screw, Low Profile

Manufacturer:



Smart Denture Conversions, LLC
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Training:

The following descriptions are insufficient to allow immediate use of the Smart Denture Conversions’ system. Knowledge of implant-prosthetic treatment and instruction in the handling of the Smart Denture Conversions’ system provided by an operator with the relevant experience are necessary. It is strongly recommended that new and experienced users of Smart Denture Conversions’ products complete special training before using a new product for the first time. Smart Denture Conversions offers a variety of training options. Please go the www.SmartDentureConversions.com for more information.

Product Description:

Prosthetic screws are pre-manufactured dental screws designed for fixing prosthetic restorations onto the implant abutment. The table below summarizes the characteristics of the prosthetic screw covered in this IFU:

| Name | Part Number | Compatible TiBase | Driver | Material | Torque | # of Uses |
|-------------------------------|-------------|--------------------|------------|--|--------|-----------|
| Prosthetic Screw, Low Profile | PS-008 | SF-012/ SF-012L | 0.048” Hex | Titanium alloy – Ti-6Al-4V ELI (90% Ti, 6% Al, 4% V) | 15 Ncm | Single |

Indications for Use:

The supplied Prosthetic Screws are indicated for use with Smart Denture Conversions’ TiBases and screw-retained multiple-unit abutments in the maxilla and mandible. The prosthetic screws can be used with either the Standard TiBases or Tall TiBases within their respective family. The supplied Prosthetic Screws are intended for single use and a single patient. Re-use of single use devices creates a potential risk of patient or user infection and misfitting components. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartDentureConversions.com.

Contraindications:

It is contraindicated to using Smart Denture Conversions’ Prosthetic Screws in:

- 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.

Application and Directions for Use:

The screw is for fixing prosthetic restorations and auxiliary abutments over the Multi-Unit Abutment or analog. Make sure to torque to 15 Ncm.

For best results, the following conditions must be adhered to meticulously:

- Use the suitable model screwdriver and size for tightening and unscrewing. If in doubt, check that the next size screwdriver does not fit into the seat. The screwdriver should be placed on the longitudinal axis of the prosthesis/implant assembly.

Prosthetic Screw, Low Profile

- A new screw should be used when assembling a prosthesis for the first time and for every check thereafter.
- When transferring to the patient, use a new screw.
- Position the patient to avoid aspiration should the screw fall during screwing/unscrewing.

Warning:

- Products distributed by Smart Denture Conversions, LLC should only be used by dental specialists with experience in maxillofacial implantology and other specialties, such as dental diagnosis, planning, dental surgery, or prosthetic techniques. If in doubt regarding the product's use, please contact the manufacturer.
- All materials used are biocompatible; however, some patients may be allergic or hypersensitive to any of the materials and their components (specified in the table).
- Products marked for single use exhibit a “Do not re-use” symbol on the product label. Products bearing this symbol on the label must never be re-used. If reused, there is a risk that product damage and deterioration of its characteristics could lead to prosthetic solution failure and/or other deterioration of the patient's health like patient tissue infection.
- For immediate load prostheses, screw manually, avoiding excessive torque, and prevent the implant from turning while tightening.
- When transferring to the patient, do not use the same screw that was used in the laboratory.
- Make sure the correct model of screw is used for each case.
- 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.
- Overtightening may cause the Prosthetic Screw or other components to become deformed, broken, stuck or dislodged in the implant analog or abutment, resulting in damage to 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:

Products covered in this document must be dry fitted before use to check that the fit is correct. The clinician is responsible for the correct application of restorative products as planning and procedures are under his/her control. This is the reason why only dental specialists with the appropriate experience and training should work with these products. In case of doubt, please contact the manufacturer or your local distributor.

During any intraoral use and manipulation all products must be secured to prevent aspiration due to its shape and size.

Caution: U.S. Federal law restricts this device to be sold to, or on the order of, a licensed dentist or physician.

We recommend an annual inspection of the prosthetic restoration by the dentist and the laboratory. This yearly inspection must consist of a screw check. If the screws are subject to unusual wear, the complete integrity of the

Prosthetic Screw, Low Profile

implant abutment should be checked. New screws must be used for any adjustment, correction, or replacement. Failure to follow this instruction puts the patient at risk and will void the warranty.

The following precautions are required before or during treatment:

- Do not use Smart Denture Conversion components after the expiration date on packaging (if applicable).
- 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.

Magnetic Resonance Imaging (MRI) Safety Information:

All Smart Denture Conversion LLC products which remain in the patient's body 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 products in the MR environment is unknown. Scanning a patient who has such a product may result in patient injury.

Cleaning and Sterilization Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for single use. Prior to use, the devices must be autoclaved by the user.

The recommended sterilization cycle is standard gravity autoclave, exposure at 121 °C / 250 °F for 30 minutes with a drying time of 30 minutes (in accordance with the UNE-EN ISO 17665-1 and 2), using a sterilization wrap that is FDA cleared for the indicated cycle.

Re-use:

Discard single-use devices immediately after use. Furthermore, any attempt to reuse such products seriously increases the risk of mechanical failure caused by material fatigue. No warranty claim resulting from the reuse of a single-use device will be accepted.

Shelf Life:

Clinical screws are intended to be handled by professionals for implant-prosthesis fixation, and once assembled, they are not susceptible to variations in environmental conditions. Clinical screws and products supplied non-sterile do not have a shelf life. Therefore, neither the shelf life of the device nor the shelf life of the package is limited and no "use by" date is provided on the label.

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.

Prosthetic Screw, Low Profile

Basic UDI-DI Information:

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

| Product | Catalog Number | Included Parts | Basic UDI-DI Number |
|--|----------------|----------------|----------------------|
| Premium Starter Kit, Low Profile | ZVLP-PSK | PS-008 | +D990ZVLP-PSK0 |
| Recharge Kit w/ Tall Spare Parts, Low Profile | ZVLP-RK | PS-008 | +D990ZVLP-RK0 |
| Recharge Kit w/ POC, Low Profile | ZVLP-RKPOC | PS-008 | +D990ZVLP-RKPOC0 |
| Separable Fastener Assembly 10PK - Drill Kit Included, Low Profile | ZVLP-SFA10PKDK | PS-008 | +D990ZVLP-SFA10PKDK0 |

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:













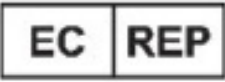













Please visit www.SmartDentureConversions.com for the most up to date warranty information.

OBSOLETE

Prosthetic Screw, Low Profile

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 |
|  | Comes Sterilized |  | Comes Sterilized using Aseptic Processing |
|  | Comes Sterilized using Ethylene Oxide Processing |  | Comes Sterilized using Irradiation Processing |
|  | Comes Sterilized using Dry Heat Processing |  | Do Not Resterilize |
|  | Do Not Reuse |  | Consult Instructions for Use |
|  | Keep Dry |  | Keep Away from Sunlight |
| RX Only | For Prescription Use Only |  | Caution, Consult Accompanying Documents |
|  | Do Not Use if Packaging is Damaged | | |