Prosthetic Screw, TSV

Manufacturer:

Smart Denture Conversions, LLC
56 Hunter St
Suite 320
Apex NC, 27502
855-550-0707
www.SmartDentureConversions.com

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, TSV	PS-007	SF-003/SF-004	0.05" Hex	Titanium alloy – Ti-6AI-4V ELI (90% Ti, 6% Al, 4% V)	15 Ncm	Single

Indications for Use:

Prosthetic screws are used for prosthetic restorations of dental implants or for assisting procedures in the dental laboratory.

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:

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).

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.

Application and Directions for Use:

The screw is for fixing prosthetic restorations and auxiliary abutments over the implant or analogue. Make sure to secure the parts with their corresponding screws and observe the specified torque value for the device (specified in the table).

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

- Use the suitable model key and size for tightening and unscrewing. If in doubt, check that the next size key does not fit into the seat. The screwdriver should be placed on the longitudinal axis of the prosthesis/ implant assembly. A new screw should be used when assembling a prosthesis for the first time and for every check thereafter.
- For immediate load, screw manually, avoiding excessive torque, and prevent the implant from turning while screwing.
- 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.
- Position the patient to avoid aspiration should the screw fall during screwing/unscrewing.
- Check compatibility of the screw with the implant model to which it will be connected.
- 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 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.

Warning:

- 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:

SDC products should only be used by dental specialists with experience in maxillary 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. SDC products designed for “single use only” 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 such as patient tissue infection. 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. U.S. Federal law restricts those devices to sale by or on the order of a licensed dentist / physician.

The following precautions are required before or during treatment:

- 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.

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. Their shelf life is not limited. Therefore, a date is not labelled.

Sterilization Instructions:

All products are supplied non-sterile. Devices must be sterilized before use on the patient.

For sterilization, autoclave treatment at 121 ° C for 30 minutes, drying 30 minutes (according to UNE-EN ISO 17665-1 and UNE-EN ISO 17665-2) is recommended.

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.

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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, TSV	ZVTS-PSK	PS-007	+D990ZVTS-PSK0
Recharge Kit w/ Tall Spare Parts, TSV	ZVTS-RK	PS-007	+D990ZVTS-RK0
Recharge Kit w/ POC, TSV	ZVTS-RKPOC	PS-007	+D990ZVTS-RKPOC0
Separable Fastener Assembly 10PK - Drill Kit Included, TSV	ZVTS-SFA10PKDK	PS-007	+D990ZVTS-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.

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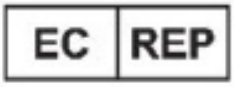
Symbols Glossary:

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		