Prosthetic Screw, TSV

Manufacturer:

Smart Denture Conversions, LLC
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Apex NC, 27523
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Important Information for the Clinician:

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.

Product Description:

The TSV Prosthetic Screw is for fixing prosthetic restorations and auxiliary abutments over the Multi-Unit Abutment or analog. The table below summarizes the characteristics of the prosthetic screw covered in this IFU:

Component	ZimVie P/N	Description	Material	Sterilization	Torque	Re-Use
Prosthetic Screw, TSV	UMUA-S	Universal Multi-Unit Abutment Screw, 0.050 Hex	Titanium Alloy – Ti-6AI-4V ELI	Autoclave before intraoral use	15 Ncm	Single

Indications – Please Read Carefully:

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

Prosthetic Screws are designed for multiple-unit screw-retained restorations with up to 30° of implant divergence where the following conditions apply:

- Adequate bone quality
- Adequate inter-arch space for a final hybrid framework
- Appropriate anterior/posterior spread no greater than 1.5mm for cantilever length
- Retained in whole or in part by endosseous implants in the mandible or maxilla.

Contraindications – Please Read Carefully:

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 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 torque the screw to 15Ncm. 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.

Warning:

- Products distributed by Smart Denture Conversions 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.
- 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. Do not re-sterilize product supplied sterile.

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. 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.
- 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.

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.

Magnetic Resonance Imaging (MRI) Safety Information:

MR Conditional

Warning: The RF safety of the device has not been tested. The patient may only be imaged by landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the RF coil.

A patient with this device can be scanned safely in an MR system under the following conditions:

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Static Magnetic Field Strength (B0)	1.5 T and 3.0 T
Maximum Spatial Field Gradient	30 T/m (3,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	For body transmit coil, landmarking at least 30 cm from the implant, or ensuring the implant is located outside of the coil. Extremity T/R coils permitted. Excludes Head T/R coil.
Operating Mode	Normal Operating Mode in the allowed imaging zone
Maximum Whole-Body specific absorption rate (SAR)	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Note: Removable restorations should be taken out prior to scanning.

Sterilization Instructions:

Products covered in this document are supplied NON-STERILE. 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 EU and FDA cleared for the indicated cycle. The non-sterile components are intended for single-use and should not be re-used. They are subjected to a thorough manufacturing, control and cleaning process before being packaged.

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 Product Information:

The following table lists the Product information for the devices described in this IFU.

Component	ZimVie P/N	Description
Prosthetic Screw, TSV	UMUA-S	Universal Multi-Unit Abutment Screw, 0.050 Hex

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.

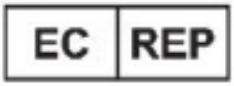
Warranty:

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	 MR Conditional	MR Conditional