Instructions for Use (IFU)

Prosthetic Screw, Low Profile

Manufacturer:

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

Important Information for the Clinician:

Before using a product placed on the market by SDC, the clinician should carefully study the following recommendations, warnings and instructions, as well as the available product-specific information (e.g. product literature, surgical/restorative technique) from SDC. SDC is not liable for complications that may arise from the use of the device in circumstances outside of SDC's control including, but not limited to, product selection and deviations from the indicated use or applicable surgical/restorative techniques that are utilized by Clinicians.

Product Description:

Prosthetic screws are used to connect the prosthesis to the abutment or attach the abutment to the dental implant to provide a means for fixing a restorative prosthetic appliance and to permit functioning of that device under normal masticatory forces. The Prosthetic Screw is part of the prosthetic appliance itself, for direct sub-gingival attachment to the implant or supra gingival attachment. The table below summarizes the characteristics of the Prosthetic Screw covered in this IFU:

SDC SKU	Component	ZimVie SKU	ZimVie Description	Material	Sterilization	Torque	Re-Use
ZVLP-PS1PK	Prosthetic Screw, Low Profile	LPCGSH	Gold-Tite® Retaining Screw, 0.048 Hex	Ti-6Al-4V ELI (ASTM F136)	Autoclave before intraoral use	15 Ncm	Single

*SDC Prosthetic Screw ZVLP-PS1PK is manufactured by ZimVie and the original SKU is LPCGSH. For compatibility information, please refer to SDC Compatibility Chart LBL-015, ZimVie Brochure ZV1655 or ZimVie Guidelines Brochure ZVINTST0173.

Intended Use:

Prosthetic Screws are intended to mechanically affix a prosthesis to an abutment or an abutment to a dental implant. In addition, the Prosthetic Screws can be used for securing a prosthesis or abutment to an analog during laboratory procedures. 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.

Indications for Use:

Prosthetic Screws are intended for use in conjunction with endosseous dental implants to replace one or more missing teeth (e.g. edentulism) by retaining the prosthesis and/or abutment to the dental implant in the maxilla or mandible of the oral cavity. This product is indicated for Any adult patient who has a "hopeless" tooth (or teeth) requiring extraction or has had a tooth extracted or "lost", or has a congenitally missing tooth.

Contraindications:

It is contraindicated to using Low Profile 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.

Clinical Benefits:

The Retaining Screws aid in restoring masticatory function by retaining the prosthesis and abutment assembly to the dental implant.

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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.
- 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.

Target Patient Population:

Any adult patient who has a “hopeless” tooth (or teeth) requiring extraction or has had a tooth extracted or “lost” or has a congenitally missing tooth.

Intended Users:

The Dental Clinician, General Practitioner (DDS) dentist, Dental Assistant, Laboratory Technician or specialist such as a Periodontist or Oral Surgeon, are the intended users.

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.

U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician.

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

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.

The following precautions are required before or during treatment:

- Smart Denture Conversion Products should only be used by trained professionals. The surgical and restorative techniques required to properly utilize these products are highly specialized and complex procedures. Improper technique, incorrect size selection, improper design, excessive force application and/or use of damaged product or packaging can lead to damaged drive feature, damaged threads, damaged screw hex, seating issues, device loosening/dislodgment, device fracture, rust/corrosion, product wear/degradation, implant failure, loss of supporting bone, restoration fracture, ingestion and/or aspiration, and can lead to the patient being subjected to additional surgical procedures, anesthetics, and associated risks.

Magnetic Resonance Imaging (MRI) Safety Information:



MR Conditional

Non-clinical testing has demonstrated Low Profile Prosthetic Screws are MR Conditional. A patient with this device can be safely scanned in an MR system meeting the following conditions:

- Static magnetic field of 1.5 T and 3.0 T
- Maximum spatial field gradient of 3,000 gauss/cm (30 T/m)
- Maximum MR system reported, whole body averaged specific absorption rate (SAR) of 2 W/kg (Normal Operating Mode)

Under the scan conditions defined above, the Low Profile Prosthetic Screws are expected to produce maximum temperature rise of less than 4°C at 3.0 T and 3°C at 1.5 T after 15 minutes of continuous scanning.

In non-clinical testing, the image artifact caused by the device extends radially up to 2.7 cm and 2.2 cm from the implant when imaged with a gradient echo-pulse sequence and 3.0 T and 1.5 T MRI systems, respectively.

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. Smart Denture Conversions recommends the following sterilization parameters for wrapped items:

Steam gravity sterilization method (gravity-displacement cycle) - Minimum exposure of fifteen (15) minutes timing at a temperature of 270º-275°F (132-135ºC)* or

Pre-vacuum sterilization method (dynamic-air-removal cycle) - Minimum exposure of four (4) minutes, four (4) pulses timing at a temperature of 270º-275°F (132-135ºC)*

**Post sterilization, devices should be thoroughly dried for 30 minutes.*

Do not re-sterilize or autoclave components.

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.

Potential Adverse Events:

Potential adverse events associated with the use of restorative products may include: magnetically induced displacement force, torque and radio frequency heat induced bone necrosis following magnetic resonance exposure, soft tissue irritation/damage; presence of metallic debris; foreign body reaction; failure to integrate; loss of integration; infection as reported by an abscess, fistula, suppuration, inflammation, gingival recession, radiolucency; gingival hyperplasia; fracture; ingestion and/or, aspiration and can lead to the patient being subjected to additional surgical procedures, anesthetics, and associated risks.

Reporting Problems:

The user and/or patient should report any suspected serious incident related to the device by informing the manufacturer and the competent authority of the member state in which the serious incident has occurred.

Storage, Handling and Transportation:

SDC Restorative product within this IFU do not have any special storage, preparatory treatment or handling requirements.

Disposal:

All used implants and instruments are a potential biohazard, since they may be contaminated with blood or other body fluids, bone or other tissue. Handle and dispose these products in accordance with accepted medical practice and with applicable local, state and national laws and regulations. Any sharp objects should be disposed of immediately after use into a sharps container conforming to EN ISO 23907-1 or equivalent following the requirements in 2010/32/EU directive or equivalent national laws. The sharp edge must not be bent or broken and should be re-sheathed prior to disposal.

Basic Product Information:

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

SDC SKU	SDC Description	ZimVie SKU	ZimVie Description
ZVLP-PS1PK	Prosthetic Screw, Low Profile	LPCGSH	Gold-Tite® Retaining Screw, 0.048 Hex

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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.

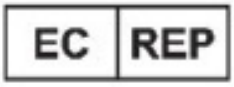
Warranty:

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