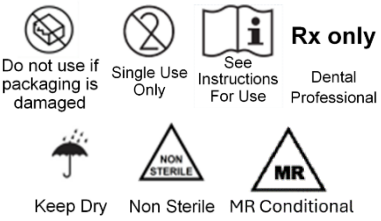
Instructions for Use (IFU)

Prosthetic Screw

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:

Prosthetic screws are pre-manufactured dental screws designed for fixing prosthetic restorations onto the implant abutment. An assortment of Prosthetic Screws is available for use with different prostheses or implant system components, depending on the dental implant platform or connection type. The table below summarizes the items:

Name	Part Number	Compatible TiBase	Driver	Material	# of Uses
Prosthetic Screw, Omnibut	OA-506	OA-003/OA-004	SDC T6	Titanium alloy – Ti-6Al-4V (90% Ti, 6% Al, 4% V)	Single
Prosthetic Screw, Unigrip	PS-001	SF-003/SF-004	Nobel (Unigrip)		
Prosthetic Screw, Straumann	PS-002	SF-003/SF-004	Straumann (SDS)		
Prosthetic Screw, TiLobe (Quad Drive)	PS-003	SF-003/SF-004	TiLobe		
Prosthetic Screw, Paltop (IHex)	PS-004	PT-003/PT-004	0.05” Hex		
Prosthetic Screw, BioHorizons	PS-005	SF-003/SF-004	0.05” Hex		
Prosthetic Screw, BioHorizons	PS-006	SF-003/SF-004	0.05” Hex		

*IFUs for PS-007 (Prosthetic Screw, TSV) and PS-008 (Prosthetic Screw, Low Profile) are available in IFU-021 and IFU-022, respectively. These IFUs are available on https://www.SmartOnX.com/ifus/. See page 5 herein for applicable SKUs.

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 any TiBase 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.

Omnibut Prosthetic Screws are indicated for use with Smart Denture Conversions’ Omnibut multi-unit abutment. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartOnX.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.

Warning:

- 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. Do not apply greater torque than recommended.
- 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 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.
- 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:

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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Device Name	Prosthetic Screws
Static Magnetic Field Strength (B0)	≤ 3.0T
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 SAR	2 W/kg (Normal Operating Mode)
Maximum Head SAR	Not evaluated for head landmark
Scan Duration	No specific constraints due to implant heating

Sterilization Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for single use. 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.

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
Prosthetic Screw 10PK, Unigrip	PS10PK	PS-001	+D990PS10PK0
Prosthetic Screw 10PK, Straumann	PS10PK-ST	PS-002	+D990PS10PKST0
Prosthetic Screw 10PK, TiLobe (Quad Drive)	KDTL-PS10PK	PS-003	+D990KDTLPS10PK0
Prosthetic Screw 10PK, Paltop (IHex)	KDIH-PS10PK	PS-004	+D990KDIHPS10PK0
Prosthetic Screw 10PK, BioHorizons	BHHD-PS10PK	PS-005	+D990BHHDPS10PK0
Premium Starter Kit, SDC	PSK	PS-001	+D990PSK0
Starter Kit, SDC	SK	PS-001	+D990SK0
Recharge Kit w/ Tall Spare Parts, SDC	RK	PS-001	+D990RK0
Recharge Kit w/ POC, SDC	RKPOC	PS-001	+D990RKPOC0
Separable Fastener Assembly 10-pack with Drill kit	SFA10PKDK	PS-001	+D990SFA10PKDK0
Premium Starter Kit, Straumann	PSK-ST	PS-002	+D990PSKST0
Starter Kit, Straumann	SK-ST	PS-002	+D990SKST0
Recharge Kit w/ Tall Spare Parts, Straumann	RK-ST	PS-002	+D990RKST0
Recharge Kit w/ POC, Straumann	RKPOC-ST	PS-002	+D990RKPOCST0
Separable Fastener Assembly 10-pack with Drill kit, Straumann	SFA10PKDK-ST	PS-002	+D990SFA10PKDKST0
Premium Starter Kit, TiLobe	KDTL-PSK	PS-003	+D990KDTLPSK0
Starter Kit, TiLobe	KDTL-SK	PS-003	+D990KDTLSK0
Recharge Kit w/ Tall Spare Parts, TiLobe	KDTL-RK	PS-003	+D990KDTLRK0
Recharge Kit w/ POC, TiLobe	KDTL-RKPOC	PS-003	+D990KDTLRKPOC0
Separable Fastener Assembly 10-pack with Drill Kit, TiLobe	KDTL-SFA10PKDK	PS-003	+D990KDTLSFA10PKDK0
Premium Starter Kit, Paltop	KDIH-PSK	PS-004	+D990KDIHPSK0
Starter Kit, Paltop	KDIH-SK	PS-004	+D990KDIHSK0
Recharge Kit w/ Tall Spare Parts, Paltop	KDIH-RK	PS-004	+D990KDIHRK0
Recharge Kit w/ POC, Paltop	KDIH-RKPOC	PS-004	+D990KDIHRKPOC0
Separable Fastener Assembly 10-pack with Drill kit, Paltop	KDIH-SFA10PKDK	PS-004	+D990KDIHSFA10PKDK0
Premium Starter Kit, BioHorizons	BHHD-PSK	PS-005	+D990BHHDPSK0
Starter Kit, BioHorizons	BHHD-SK	PS-005	+D990BHHDSK0
Recharge Kit w/ Tall Spare Parts, BioHorizons	BHHD-RK	PS-005	+D990BHHDRK0
Recharge Kit w/ Tall Spare Parts	BHHD-RKPOC	PS-005	+D990BHHDRKPOC0
Separable Fastener Assembly 10-pack with Drill kit, BioHorizons	BHHD-SFA10PKDK	PS-005	+D990BHHDSFA10PKDK0
Premium Starter Kit, Omnibut	PSK-OA	OA-506	+D990PSKOA0
Recharge Kit w/ Tall Spare Parts, Omnibut	RK-OA	OA-506	+D990RKOA0
Recharge Kit w/ POC, Omnibut	RKPOC-OA	OA-506	+D990RKPOCOA0
Separable Fastener Assembly 10-pack with Drill kit, Omnibut	SFA10PKDK-OA	OA-506	+D990SFA10PKDKOA0
Prosthetic Screw 10PK, Omnibut	PS10PK-OA	OA-506	+D990PS10PKOA0
Prosthetic Screw 1PK, Omnibut	PS1PK-OA	OA-506	+D990PS1PKOA0

*SKUs starting with ZVTS contain PS-007 (Prosthetic Screw, TSV) and instructions are available in IFU-021. SKUs starting with ZVLP contain PS-008 (Prosthetic Screw, Low Profile) and instructions are available in IFU-022. These IFUs are available on https://SmartOnX.com/ifus/.

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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.

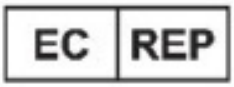
Warranty:

Please visit www.SmartOnX.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
	Do Not Use if Packaging is Damaged		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