TiBase

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:

Smart Denture Conversions' TiBases are picked up in the denture or prosthesis as an interface with the multi-unit abutment. They provide the screw seat for the Prosthetic Screw. Smart Denture Conversions' TiBases are offered in three formats and two heights, for a total of 6 TiBases. The table below summarizes the different types:

Name	Part Number	Approx Height	Material	# of Uses
Standard TiBase, SDC	SF-003	4.6mm	Titanium alloy - Ti-6Al-4V (90% Ti, 6% Al, 4% V)	Single
Tall TiBase, SDC	SF-004	6.1mm		
Standard TiBase, Paltop	PT-003	4.6mm		
Tall TiBase, Paltop	PT-004	6.1mm		
Standard TiBase, TSV	SF-012	4.6mm		
Tall TiBase, TSV	SF-012L	6.1mm		

Indications for Use:

TiBases are indicated for use with screw-retained multiple-unit abutments in the maxilla and mandible. Standard TiBases should be used when at least 75% of the TiBase can be embedded into acrylic during the pickup. When the tissue is not accommodating for Standard TiBases, Tall TiBases can be used for proper pickup. Smart Denture Conversions' TiBases are intended for single use. 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' TiBases 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:

- 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.

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- Always inspect components before use. Do not use damaged, deformed, corroded, or discolored components.
- Overtightening may cause the TiBase or other components to become deformed, broken or stuck on 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 components, follow-up treatment, incorrect impression resulting in incompatible restorations.
- Even if the product is used according to the instructions for use, the clinical outcome of dental treatment is influenced by multiple variables and may lead to any or all of the following complications: 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.
- Ensure that the abutment surface is clean before placing TiBases.
- 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.
- Observe specified torques.

Magnetic Resonance Imaging (MRI) Safety Information:

All Smart Denture Conversion 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 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 cleaned and sterilized by the user.

Sterilization is to be performed corresponding to the following scheme:

1. **Preparation for sterilization:** Place components in a sterilization pouch which is legally marketed (for the US market: FDA-cleared) for use with the recommended sterilization parameters. Every sterilization package must have a sterilization indicator and sterilization date.

2. **Sterilization:**

Method	Cycle	Temperature	Exposure Time*	Dry Time	Cooling Time	Reference
Steam	Dynamic Air Removal (Prevacuum)	132°C (270°F)	4min	20min	30min	ANSI/AAMI TIR12:2010
Steam	Gravity Displacement	121°C (250°F)	30min	30min	30min	
Steam	Gravity Displacement	132°C (270°F)	15min	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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Assembly and UDI 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
Standard TiBase 10-Pack	STB10PK	SF-003	+D990STB10PK0
Tall TiBase 10-Pack	TTB10PK	SF-004	+D990TTB10PK0
Premium Starter Kit, SDC	PSK	SF-003/SF-004	+D990PSK0
Starter Kit, SDC	SK	SF-003/SF-004	+D990SK0
Recharge Kit w/ Tall Spare Parts, SDC	RK	SF-003/SF-004	+D990RK0
Recharge Kit w/ POC, SDC	RKPOC	SF-003	+D990RKPOC0
Separable Fastener Assembly 10-pack with Drill kit	SFA10PKDK	SF-003	+D990SFA10PKDK0
Tall Spare Parts Kit, SDC	TSP	SF-004	+D990TSP0
Premium Starter Kit, Straumann	PSK-ST	SF-003/SF-004	+D990PSK-ST0
Starter Kit, Straumann	SK-ST	SF-003/SF-004	+D990SK-ST0
Recharge Kit w/ Tall Spare Parts, Straumann	RK-ST	SF-003/SF-004	+D990RK-ST0
Recharge Kit w/ POC, Straumann	RKPOC-ST	SF-003	+D990RKPOC-ST0
Tall Spare Parts Kit, Straumann	TSP-ST	SF-004	+D990TSP-ST0
Separable Fastener Assembly 10-pack with Drill kit, Straumann	SFA10PKDK-ST	SF-003	+D990SFA10PKDK-ST0
Premium Starter Kit, TiLobe	KDTL-PSK	SF-003/SF-004	+D990KDTL-PSK0
Starter Kit, TiLobe	KDTL-SK	SF-003/SF-004	+D990KDTL-SK0
Recharge Kit w/ Tall Spare Parts, TiLobe	KDTL-RK	SF-003/SF-004	+D990KDTL-RK0
Recharge Kit w/ POC, TiLobe	KDTL-RKPOC	SF-003	+D990KDTL-RKPOC0
Separable Fastener Assembly 10-pack with Drill Kit, TiLobe	KDTL-SFA10PKDK	SF-003	+D990KDTL-SFA10PKDK0
Tall Spare Parts Kit, TiLobe	KDTL-TSP	SF-004	+D990KDTL-TSP0
Premium Starter Kit, Paltop	KDIH-PSK	PT-003/PT-004	+D990KDIH-PSK0
Starter Kit, Paltop	KDIH-SK	PT-003/PT-004	+D990KDIH-SK0
Recharge Kit w/ Tall Spare Parts, Paltop	KDIH-RK	PT-003/PT-004	+D990KDIH-RK0
Recharge Kit w/ POC, Paltop	KDIH-RKPOC	PT-003	+D990KDIH-RKPOC0
Separable Fastener Assembly 10-pack with Drill kit, Paltop	KDIH-SFA10PKDK	PT-003	+D990KDIH-SFA10PKDK0
Tall Spare Parts Kit, Paltop	KDIH-TSP	PT-004	+D990KDIH-TSP0
Standard TiBase 10-Pack, Paltop (I-Hex)	KDIH-STB10PK	PT-003	+D990KDIH-STB10PK0
Tall TiBase 10-Pack, Paltop (I-Hex)	KDIH-TTB10PK	PT-004	+D990KDIH-TTB10PK0
Premium Starter Kit, BioHorizons	BHHD-PSK	PT-003/PT-004	+D990BHHD-PSK0
Starter Kit, BioHorizons	BHHD-SK	PT-003/PT-004	+D990BHHD-SK0
Recharge Kit w/ Tall Spare Parts, BioHorizons	BHHD-RK	PT-003/PT-004	+D990BHHD-RK0
Recharge Kit w/ POC, BioHorizons	BHHD-RKPOC	PT-003	+D990BHHD-RKPOC0
Separable Fastener Assembly 10-pack with Drill kit, BioHorizons	BHHD-SFA10PKDK	PT-003	+D990BHHD-SFA10PKDK0
Tall Spare Parts Kit, 0.05” Hex	FZMF-TSP	SF-004	+D990FZMF-TSP0
Premium Starter Kit, TSV	ZVTS-PSK	SF-003/SF-004	+D990ZVTS-PSK0
Premium Starter Kit, Low Profile	ZVLP-PSK	SF-012/SF-012L	+D990ZVLP-PSK0
Recharge Kit w/ Tall Spare Parts, TSV	ZVTS-RK	SF-003/SF-004	+D990ZVTS-RK0
Recharge Kit w/ Tall Spare Parts, Low Profile	ZVLP-RK	SF-012/SF-012L	+D990ZVLP-RK0

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Recharge Kit w/ POC, TSV	ZVTS-RKPOC	SF-003	+D990ZVTS-RKPOC0
Recharge Kit w/ POC, Low Profile	ZVLP-RKPOC	SF-012	+D990ZVLP-RKPOC0
Separable Fastener Assembly 10PK - Drill Kit Included, TSV	ZVTS-SFA10PKDK	SF-003	+D990ZVTS-SFA10PKDK0
Separable Fastener Assembly 10PK - Drill Kit Included, Low Profile	ZVLP-SFA10PKDK	SF-012	+D990ZVLP-SFA10PKDK0
Standard TiBase 10PK, TSV	ZVTS-STB10PK	SF-003	+D990ZVTS-STB10PK0
Standard TiBase 10PK, Low Profile	ZVLP-STB10PK	SF-012	+D990ZVLP-STB10PK0
Tall TiBase 10PK, TSV	ZVTS-TTB10PK	SF-004	+D990ZVTS-TTB10PK0
Tall TiBase 10PK, Low Profile	ZVLP-TTB10PK	SF-012L	+D990ZVLP-TTB10PK0

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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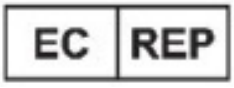
Symbols Glossary:

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