Screwdrivers

Manufacturer:

Smart Denture Conversions, LLC
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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:

Screwdrivers

Screwdrivers are reusable stainless steel instruments which are used in conjunction with SDC screws and prosthetic components. Drivers are available in "Latch Type" (compatible to ISO 1997-1 Contra-angle handpieces) or "Square type" connections. At their active end, the driver geometry is appropriate for coupling to their corresponding screws/prosthetics components/abutments.

Omnibut Base Driver

Omnibut Base Drivers are used to tighten the Omnibut Abutment into an implant.

T6 Driver

T6 Drivers are available in various lengths and are used to tighten and loosen the Orientation Screw and Prosthetic Screws.

The table below summarizes the items:

Name	Compatible Parts	Maximum Torque	Material	Use Type
Spline Driver Bit Square Type	Omnibut Bases	35 Ncm*	Heat Treated 440C Stainless Steel	Multi-use
Spline Driver Bit Latch Type				
T6 Driver Bit, Square Type	Prosthetic Screw Orientation Screw	Prosthetic Screw: 15 Ncm Orientation Screw: 25 Ncm		
T6 Driver Bit, Latch Type				
T6 Long Driver Bit, Square Type				
T6 Long Driver Bit, Latch Type				

*Always refer to OEM implant recommended torque. See the Omnibut Instructions for Use (IFU-013) for compatible implant recommended torque.

Intended Use/Indications for Use:

Screwdrivers

Intended for use to tighten and/or loosen abutments and screws used to connect to dental implant system components. Screwdrivers are intended to be reprocessed until they do not work as intended. For more specific information on process steps, please refer to the Technique manual located on the website www.SmartOnX.com.

Note: The Screwdriver must be properly aligned with the axis of compatible parts prior driving prosthetic components.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Screwdrivers 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.

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Warning:

- Never exceed recommended maximum tightening torque in applicable instructions for use of the surgical or prosthetic component. Overtightening of the screw may lead to a screw fracture and/or damage of the component.
- 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.
- 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 indicated on the packaging.
- 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:

Smart Denture Conversion LLC Screwdrivers are tools that are used in the operatory with transient patient contact, and do not remain in the body. These products 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 Screwdrivers in the MR environment is unknown.

Cleaning Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for reuse. Prior to first and subsequent uses, the devices must be cleaned and sterilized by the user.

Smart Denture Conversions recommends the following procedure for cleaning and sterilization of the devices prior to each use.

<u>Initial Treatment at Point of Use Prior to Reprocessing:</u>

1. Discard single-use instruments and worn reusable instruments immediately after use.
2. Remove excess soil and debris from reusable devices to be reprocessed using absorbent paper wipes. Use a dental probe for soil and debris in cavities.
3. Rinse the devices with cold running tap water.

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Containment and Transportation/Shipping to Reprocessing Area:

4. After removal of excess soil and debris, store the devices in a container which is suitable to protect the devices during transportation and to avoid any contamination of personnel or the environment.
5. Transport the devices to the reprocessing area as soon as practical. If transfer to the processing area is likely to be delayed, consider covering the devices with a damp cloth or store it in a closed container to avoid drying of soil and/or debris.

   Note: Reusable devices should be reprocessed by initiating the prescribed automated or manual cleaning and drying procedures within 1 hour of use, to ensure the efficacy of the reprocessing.
6. If the devices are shipped to an outside facility for reprocessing, they must be contained in a transportation or shipping container which is suitable to protect the devices during transportation and to prevent contamination of personnel or the environment.

Manual Cleaning and Drying:

1. Immerse device for a minimum of 5 minutes in a sterile 0.9% NaCl solution.
2. Scrub the outer surfaces of the device with soft-bristled nylon brush for a minimum of 20 seconds until all visible soil is removed.
3. Flush the inner surfaces, lumina and cavities (where applicable) with 20 mL lukewarm enzymatic cleaning solution (e.g. Cidezyme ASP or Neodisher Medizym; maximum 45°C (113°F)) using an irrigation needle connected to a 20 mL syringe.
4. Brush the inner surfaces, lumina and cavities (where applicable) with appropriately sized bottle brush for a minimum of 10 seconds until all visible soil is removed.
5. Thoroughly rinse the outer surfaces and lumina of the device with cold running tap water for a minimum of 1 minute to remove all cleaning solutions.
6. Immerse the device in an ultrasonic bath containing 0.5% enzymatic cleaning agent (e.g. Cidezyme ASP or Neodisher Medizym) and treat for a minimum of 5 minutes at minimum 40°C (104°F)/ maximum 45° (113°F).
7. Flush the inner surfaces, lumina and cavities (where applicable) with 20 mL lukewarm tap water using an irrigation needle connected to a 20 mL syringe.
8. Thoroughly rinse the outer surfaces of the device with purified or sterile water for a minimum of 1 minute to remove all cleaning agent.
9. Dry with compressed air or clean and lint-free single use wipes.

Visual Inspection:

After cleaning and drying, inspect the device for unacceptable deterioration such as corrosion, discoloration, pitting or cracked seals, or if dental debris remains on the device. Properly discard any devices that fail the inspection.

Reuse Instructions:

Components are delivered non-sterile by Smart Denture Conversions and are intended for reuse. Prior to use, clean and sterilize the product following the instructions in the Cleaning and Sterilization Instructions section.

Screwdrivers shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Screwdrivers shall be discarded if any of the following criteria are met:

- If any wear, abrasion of the anodization, deformations or corrosion is visible on the component.
- If the screwdriver does not engage properly with compatible surgical or prosthetic components.

Sterilization Instructions:

Components are delivered non-sterile by Smart Denture Conversions. 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.

Basic UDI-DI Information:

The following table lists the Basic UDI-DI information for the devices described in this IFU.

Product	Catalog Number	Basic UDI-DI Number
Spline Driver Bit 1PK, Square Type	TDB-SP1PK-SQ	D990TDBSP1PKSQ0
T6 Driver Bit 1PK, Square Type	TDB-T61PK-SQ	D990TDBT61PKSQ0
T6 Long Driver Bit 1PK, Square Type	TDB-T6L1PK-SQ	D990TDBT6L1PKSQ0
Spline Driver Bit 1PK, Latch Type	TDB-SP1PK-LT	D990TDBSP1PKLT0
T6 Driver Bit 1PK, Latch Type	TDB-T61PK-LT	D990TDBT61PKLT0
T6 Long Driver Bit 1PK, Latch Type	TDB-T6L1PK-LT	D990TDBT6L1PKLT0

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.

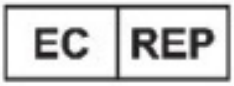
Warranty:

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
	Keep Dry		Consult Instructions for Use
RX Only	For Prescription Use Only		Keep Away from Sunlight
	Do Not Use if Packaging is Damaged		Caution, Consult Accompanying Documents