

Low Torque Driver

Manufacturer:



Smart Denture Conversions, LLC
 56 Hunter St
 Suite 320
 Apex NC, 27511
 855-550-8787
www.SmartDentureConversions.com

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:

The Smart Denture Conversions’ Low Torque Driver is used to deliver the Separable Fastener to the multi-unit abutment, Lab Analog and/or Coating Mandrel, without the risk of "overdriving", causing separation of the PEEK Cap from the Threaded Post. The table below summarizes the items:

Name	Part Number	Compatible Separable Fastener	Driver	Material	# of Uses
Low Torque Driver, SDC	TTD-001	ASF-001, ASF-001L, ASF-002, ASF-002L, ASF-005, ASF-005L	SDC	300 Series Stainless Steel, Unfilled PEEK (Poly-Ether Ether Ketone) and Titanium alloy - Ti-6Al-4V (90% Ti, 6% Al, 4% V)	Single
Low Torque Driver, TiLobe (Quad Drive)	TTD-002	ASF-003, ASF-003L	Keystone TiLobe		
Low Torque Driver, Paltop (IHex)	TTD-003	ASF-004, ASF-004L	Keystone Paltop		

Indications for Use:

The Low Torque Driver is designed for use with tightening Separable Fasteners to a high enough torque to hold the TiBase to the multi-unit abutment, Lab Analog, or Coating Mandrel, but not too much to prematurely separate the Separable fastener. The Low Torque Driver also has an intended use to unscrew (loosen) Separable Fasteners and Press-On Caps as needed. The Low Torque Driver is designed to slip at a predefined torque when rotated in the clockwise direction and to act like a standard one-piece driver in the counterclockwise direction (full torque). The supplied Low Torque Driver is intended for a single patient. 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.

Test the low torque driver prior to each use following the directions listed below

1. Grasp the knurled collar with your dominant hand.
2. Lightly grasp the extended drive shaft with your other hand.
3. Slowly rotate the collar in the clockwise direction and the shaft should start to spin in your other hand. While still rotating the collar, grasp the shaft tighter until you prevent it from spinning. This should take a minimal amount of force (around 0.7oz-in). If the shaft cannot be easily prevented from spinning with force applied, the Low Torque Driver is damaged and should be replaced.

Low Torque Driver

4. Slowly rotate the collar in the counterclockwise direction and the shaft should start to spin in your other hand. While still rotating the collar, grasp the shaft tighter and you should not be able to prevent the shaft from spinning. If you can prevent the shaft from spinning with the collar, the Low Torque Driver is damaged and should be replaced.

Note: The Low Torque Driver must be properly aligned with the axis of the Separable Fastener to ensure the proper amount of torque is transferred while tightening. Failure to properly align the axis' can cause the Separable Fastener to be over tightened and separate. If the TiBase comes loose, the Separable Fastener has come apart. To correct this, ensure the top of the threaded section of the Threaded Post is flush with the top of the MUA. This can be done either by hand or by using the Retrieval Tool in a contra angle. With the Threaded Post at the proper height, the Peek Cap can simply be pressed back on, then turned clockwise slightly to ensure a snug fit.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Low Torque Driver 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:

- The Low Torque Driver is designed for use with Smart Denture Conversions' Separable Fasteners and Press-On Caps and should not be used to tighten or loosen any other items, including Prosthetic Screws. Use of the Low Torque Driver in Prosthetic Screws and other non-compatible products can cause damage to the Low Torque Driver and/or other components.
- 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 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.

Low Torque Driver

- If, due to unfavorable anatomical conditions, the 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:

All Smart Denture Conversion LLC 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 LLC 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.

Low Torque Driver

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
Low Torque Driver 1PK	LTD	TTD-001	+D990LTD0
Premium Starter Kit, SDC	PSK	TTD-001	+D990PSK0
Starter Kit, SDC	SK	TTD-001	+D990SK0
Premium Starter Kit, Straumann	PSK-ST	TTD-001	+D990PSK-ST0
Starter Kit, Straumann	SK-ST	TTD-001	+D990SK-ST0
Premium Starter Kit, Tilobe	KDTL-PSK	TTD-002	+D990KDTL-PSK0
Starter Kit, Tilobe	KDTL-SK	TTD-002	+D990KDTL-SK0
Premium Starter Kit, Paltop	KDIH-PSK	TTD-003	+D990KDIH-PSK0
Starter Kit, Paltop	KDIH-SK	TTD-003	+D990KDIH-SK0
Premium Starter Kit, Biohorizons	BHHD-PSK	TTD-001	+D990BHHD-PSK0
Starter Kit, Biohorizons	BHHD-SK	TTD-001	+D990BHHD-SK0
Torque Driver 1PK, ZimVie	ZV-LTD	TTD-001	+D990ZV-LTDO
Premium Starter Kit, TSV	ZVTS-PSK	TTD-001	+D990ZVTS-PSK0
Premium Starter Kit, Low Profile	ZVLP-PSK	TTD-001	+D990ZVLP-PSK0
Recharge Kit w/ Tall Spare Parts, TSV	ZVTS-RK	TTD-001	+D990ZVTS-RK0
Recharge Kit w/ Tall Spare Parts, Low Profile	ZVLP-RK	TTD-001	+D990ZVLP-RK0

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:













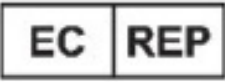












Please visit www.SmartDentureConversions.com for the most up to date warranty information.

OBSOLETE

Low Torque Driver

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