Manual Torque Wrench

Manufacturer:

Smart Denture Conversions, LLC
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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:

The Manual Torque Wrench is used for inserting and removing dental screws with a defined torque. The table below summarizes the product:

Name	Driver Compatibility	Material	# of Uses
Manual Torque Wrench, Omnibut	4mm Square	Stainless Steel	Multi-Use

Intended Use/Indications for Use:

The Manual Torque Wrench is intended to tighten SDC Prosthetic Components with 4mm square screwdrivers. Torque is applied by the bending rod. The torque locations for 15, 25 and 35 Ncm are noted on the wrench.

Manul Torque Wrenches are indicated for reuse. Devices are intended to be reprocessed until they do not work as intended. For more specific information on specific Omnibut process steps, please refer to the Technique manual located on the website www.SmartOnX.com.

Contraindications:

It is contraindicated to using Smart Denture Conversions' Manual Torque Wrench 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:

- Torque reading should always be done directly from the top.
- 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 Torque Wrench 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.
- 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:

Smart Denture Conversion products within the scope of this IFU are used in the operatory with transient patient contact, and do not remain in the body. 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.

Preparation:

Treatment Instructions/Warnings

To avoid damage, do not use metal brushes or cleaning sponges. Only use cleaning and disinfectant solutions with a pH value of between 4.5 and 10. The wrench is not sterile when delivered and must be cleaned and sterilized before it is used.

Restriction Regarding Re-preparation

The end of the product’s service life is normally determined by wear and damage caused during use and by incorrect handling.

Preparations for Cleaning

Clean the wrench under cold running water using a soft brush to remove all visible soiling. Ensure that all openings and cavities are thoroughly rinsed. Do not allow blood and other soiling to dry on.

Cleaning Instructions:

Manual

Ultrasonic cleaning bath: Place the device into a wire basket, in order to avoid acoustic shadows. Clean for 3 minutes in an ultrasonic cleaning bath (35-40 kHz) at a temperature of 40°-50°C with an enzymatic cleaning solution. Ensure that the wrench is completely immersed in the water, without the formation of any bubbles.

Rinse with clear, cold water; if possible, use deionized water. Dry the wrench with a lint-free cloth and blow dry with compressed air.

Automatic

Securely apply the cleaned ratchet to the carrier. Do not overload the carrier. Start the program. After rinsing, chemical cleaning starts at 40°-60°C. Residues from the cleaning process must be reliably removed in the subsequent rinsing phase. Avoid damage to the material from neutralizing reagents. Thermal disinfection is achieved at 90°-95°C. The subsequent treatment with deionizing water is followed by adequate drying. Remove the ratchet from the device immediately after the program ends.

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.

Torque Wrenches shall be inspected before each reuse to ensure that the integrity and performance continues to be maintained. Torque Wrenches 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 Torque Wrench does not engage properly with compatible surgical or prosthetic components.

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)	134°C (273°F) 137°C MAX	3-4min	10min

*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.

Immediately after use, the products must be put in cold water (<40°C). Do not use hot water (>40°C) or cleaning agents, as this may cause fixation of residues on the product, which can affect the success of the subsequent processing steps.

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.

Calibration:

We recommend annual calibration of the wrench.

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.

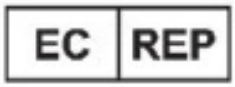
Warranty:

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
	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