

INSTRUCTIONS FOR USE

LOCATOR® TORQUE & THUMB KNOB WRENCH KIT (20Ncm and 30Ncm)

DESCRIPTION: The LOCATOR® Torque & Thumb Knob Wrench Kit (Zest order #04391) contains a 20Ncm Torque Wrench, a Thumb Knob Wrench, and a 15mm LOCATOR® Square Drive Torque Wrench Driver Insert. The LOCATOR® 30Ncm Torque & Thumb Knob Wrench Kit (Zest order #09020) contains a 30Ncm Torque Wrench, a Thumb Knob Wrench, and a 15mm LOCATOR® Square Drive Torque Wrench Driver Insert.

IMPORTANT: This document contains the most current instructions for use. Please read and retain.

INTENDED USE:

20Ncm Torque & Thumb Knob Wrench Kit: The Kit is intended for use in tightening LOCATOR® Implant attachment abutments to a maximum recommended torque of 20Ncm.

30Ncm Torque & Thumb Knob Wrench Kit: The Kit is indicated for use in tightening LOCATOR® Implant attachment abutments to a recommended optimum torque of 30Ncm.

CONTRAINDICATIONS:

20Ncm Torque & Thumb Knob Wrench Kit: The LOCATOR® Torque & Thumb Knob Wrench Kit cannot be used for implant abutments that require torque tightness greater than 20Ncm.

30Ncm Torque & Thumb Knob Wrench Kit: The LOCATOR® 30Ncm Torque & Thumb Knob Wrench Kit cannot be used for implant abutments that require torque tightness greater than 30Ncm.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed dentist.

NOTICE TO USERS IN THE EUROPEAN UNION

Any serious incident that has occurred in relation to the device(s) in which this Instructions for Use applies should be reported to the manufacturer identified in this Instructions For Use and the competent authority of the Member State in which the user and/or patient is established.

STORAGE AND HANDLING

The Torque & Thumb Knob Wrench Kit (20Ncm and 30Ncm) in its undamaged, original packaging is not subject to any special considerations for storage or handling (during transport and storage).

WARNINGS & PRECAUTIONS

Product should be inspected for integrity prior to use. Product from damaged packaging should not be used on patients. In the event that the packaging is damaged, the damaged packaging (with the product) should be returned to the manufacturer and a replacement will be provided only if damage to packaging is caused by product shipment.

As dental instruments are susceptible to damage and wear, they should be inspected before each use. Any reusable instrument should be replaced if damage or wear is present to ensure proper functionality. The number of uses will vary and depends on a variety of factors including but not limited to bone density encountered, handling, proper cleaning, autoclave exposure, and storage conditions (do not store tools or instruments wet). Over time, repeat sterilization may affect appearance and visibility of markings.

MULTI-USE DEVICES

The Torque & Thumb Knob Wrench Kit (20Ncm and 30Ncm) is designed for multiple uses and is provided NON-STERILE. Reusable tools and instruments must be sterilized prior to first use on patients and cleaned and sterilized prior to reuse. Follow the instructions provided here within for proper sterilization of non-sterile components, and the instructions for cleaning and resterilization process of reusable components. If the Torque & Thumb Knob Wrench Kit (20Ncm and 30Ncm) becomes worn or damaged, obtain a replacement device.

CLEANING AND STERILIZATION: The LOCATOR® Torque Wrench (20Ncm and 30Ncm), Thumb Knob Wrench, and 15mm LOCATOR® Square Drive Torque Wrench Driver Insert are all supplied NON-STERILE. All four items may be sterilized by steam autoclave or Chemclave® following the sterilizer manufacturer's recommended procedure. Sterilize the LOCATOR® Torque Wrench with the handle in the "broken" position, or manually "break" the handle after sterilization to assure it is working freely, then reset the handle. Prior to cleaning and sterilization disconnect the Square Drive Torque Wrench Driver Insert from the Thumb Knob Wrench, or disconnect the Driver Insert from the (20Ncm or 30Ncm) Torque Wrench.

Per the manufacturer's suggested cleaning and sterilization process:

- Brush instruments carefully with a nylon cleaning brush with soap and water or use a disinfectant wipe.
- After scrubbing, rinse instruments thoroughly under running water.
- Use a non-shedding and disposable cloth for cleaning and drying equipment.
- Dry instruments to prevent carryover of contaminated wash water into the sterilizer.
- Visually inspect instruments for residual debris or blood after cleaning and repeat if necessary.
- Steam sterilize for 20 minutes at 135°C (275°F)

Re-sterilizable instruments should be dried completely and stored in a clean and dry location at normal room temperature. Prior to instrument use, the exterior of any sterilized packaging should be inspected for integrity. Care must be exercised in the handling of wrapped or autoclave bagged instrument kits or instruments to prevent damage to the sterile barrier. If damage to the sterile barrier is observed, resterilization is recommended for reusable devices only.

CAUTIONS FOR STERILIZATION:



- Do not use "Flash Sterilization" techniques
- Do not exceed 275° F (135° C).
- Clean torque wrench thoroughly before sterilizing to prevent staining.

SECTION A

15MM LOCATOR® SQUARE DRIVE TORQUE WRENCH DRIVER INSERT INSTALLATION: To install the 15mm LOCATOR® Square Drive Torque Wrench Driver Insert into the LOCATOR® Torque Wrench, push the square end of the Driver Insert into the square hole in the Torque Wrench. The square hole in the Torque Wrench is divided into eight positions, allowing the Driver Insert to be placed into it in 45 degree increments.

DRIVER ASSEMBLY FOR TIGHTENING AN IMPLANT ABUTMENT:

20Ncm Torque & Thumb Knob Wrench Kit: For tightening an implant abutment, place the Driver Insert into the underside of the Torque Wrench with the printed word "20Ncm" on the handle facing upward. Move the Torque Wrench handle in a clockwise direction.



30Ncm Torque & Thumb Knob Wrench Kit: For tightening an implant abutment, place the Driver Insert into the underside of the Torque Wrench with the printed word "30Ncm" on the handle facing upward. Move the Torque Wrench handle in a clockwise direction.

For loosening an implant abutment, use the same placement as in the tightening of implant abutment but rotate the handle in a counterclockwise direction. The Torque Wrench handle will not release in this direction.

SECTION B

OPERATION TO TIGHTEN AN ABUTMENT:

Place the square end of the Driver Insert into the Thumb Knob Wrench. Using finger pressure, tighten the abutment securely. Remove the Driver insert from the Thumb Knob Wrench and place it into the Torque Wrench. (Following the instructions in Section A). Support the head of the wrench with finger control while rotating the handle in a clockwise direction.

20Ncm Torque & Thumb Knob Wrench Kit: Slowly rotate the handle clockwise until the handle "breaks away", which produces the torque tightness of 20Ncm shown on the handle.

30Ncm Torque & Thumb Knob Wrench Kit: Slowly rotate the handle clockwise until the handle "breaks away", which produces the torque tightness of 30Ncm shown on the handle.

CAUTIONS FOR TIGHTENING:



- Do not apply any additional force to the handle after it "breaks away", because it will increase the torque value desired.
- Do not attempt to adjust the torque setting screw in the handle. If the torque does not appear to be correct, send the Torque Wrench in for accurate calibration.

SECTION C

OPERATION TO LOOSEN AN ABUTMENT:

Place the Driver Insert into the implant abutment to be loosened.

20Ncm Torque & Thumb Knob Wrench Kit: Place the Torque Wrench over the square end of the Driver Insert with the word "20Ncm" showing and the arrow pointing in a clock-wise direction on the top side of the handle.

30Ncm Torque & Thumb Knob Wrench Kit: Place the Torque Wrench over the square end of the Driver Insert with the word "30Ncm" showing and the arrow pointing in a clock-wise direction on the top side of the handle.

Rotate the handle in a counter-clockwise direction until the abutment is loose. *NOTE:* The Torque Wrench handle will not disengage when loosening an abutment. Remove the Torque Wrench from the Driver Insert. Using the Driver Insert by itself, unscrew the rest of the way by hand.

SECTION D

MAINTENANCE: Directly after use, spray the Torque Wrench with MicroMist® Spray or the equivalent through the open handle end to flush out debris and lubricate the wrench. Do the same for the open end of the Thumb Knob Wrench. Clean the Torque Wrench, Thumb Knob Wrench, and Driver Insert with a wet towel or disinfectant wipe. Rinse under hot tap water and wipe dry. Proceed with sterilization instructions.

CAUTIONS FOR MAINTENANCE:



- Do not submerge the Torque Wrench in any solution.
- Do not use an ultrasonic cleaner unit to clean the Torque Wrench.

SECTION E


















CALIBRATION: The Torque Wrench should be calibrated annually to ensure proper operation.

DISPOSAL

Dispose of used devices which pose a risk of infection according to facility clinical waste procedures and applicable local and state regulations.

Explanation of Packaging Label Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community/European Union	ISO 15223-1	5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	EN ISO 15223-1	5.1.6
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	EN ISO 15223-1	5.1.5
 www.zestdent.com/eifu	Consult Electronic Instructions for Use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1	5.4.3 / Annex A.15
	Caution	To indicate that caution is necessary when operating the device or control close to where the symbol placed, or to indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences	ISO 15223-1	5.4.4
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	EN ISO 15223-1	5.2.7
	Date of Manufacture	Indicates the date when the medical device was manufactured.	EN ISO 15223-1	5.1.3
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	ISO 15223-1	5.2.8
	European Mark of Conformity	Indicates device is in conformance with Medical Device Regulation EU 2017/745	MDR EU 2017/745	Annex V
Rx only	Rx only	Federal law restricts this device to sale by or on the order of a dentist only	US CFR Title 21	801.15(c)(1)(i)(F)

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Quantity	Indicates the number of items within the package	N/A	N/A
	Unique Device Identifier	Indicates as containing Unique Device Identifier information	ISO 15223-1	5.7.10
	Medical device	Indicates the item is a medical device	ISO 15223-1	5.7.7
$\leq M1.4$ 	$\leq M1.4$ Metric Thread	Indicates abutment with a ≤ 1.4 mm thread; only torque to 20Ncm.	None	IFU L8125-ZD
	Distributor	Indicates the entity distributing the medical device in the locale	ISO 15223-1	5.1.9

