English

Instructions for Use: LOCATOR® CORE TOOL (with Abutment Holder Sleeve)

The LOCATOR® Core Tool (also referred to as the 3-in1 Core Tool) includes: Male Removal Tool, Male Seating Tool, and Abutment Driver with the Abutment Holder Sleeve.

NOTE: This document contains the most current Instructions for Use. Please read and retain.

INTENDED USE and DEVICE DESCRIPTION: The LOCATOR Core Tool is for use with the Locator Overdenture Implant System, and the LOCATOR Attachment System. The Core Tool is used to carry and place the LOCATOR Abutment onto the implant and for removal and insertion of the Males retention inserts from or into the Denture Cap. ***Male Removal Tool (removal tool): -*** *The Removal Tool* has a sharp edge on the end to engage and remove the male retention insert from the Denture Cap. ***Male Seating Tool*** *(also referred to as the insertion tool)****:*** *The Insertion Tool* is used to seat the LOCATOR Male retention insert. ***Abutment Driver and Sleeve:*** The *Abutment Driver* with the *Abutment Holder Sleeve* carries the Abutment securely and places it onto the implant. The Abutment Holder Sleeve for use with the LOCATOR Core Tool is available separately from the Core Tool in a 4 pack or 20 pack, (Zest catalog numbers 8394 and 8394-20). The removal tool and abutment driver are available separately as a replacement components (Zest catalog numbers 08397 and 08390 respectively).

CAUTION
Federal (USA) law restricts this device to the 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 LOCATOR R-Tx Attachment System 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 LOCATOR Core Tool 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 Core Tool or other instruments becomes worn or damaged, obtain a replacement device.

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Instruments and Individually Packaged Replacement Attachments

(i) Disassemble the Core Tool. **(ii)** Soak in enzymatic cleaning solution (mixed according to manufacturers' instructions) by completely submerging it for 20 minutes. Scrub instruments using a soft-bristled, nylon brush until all soil has been removed. **(iii)** Remove the instruments from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes. Make sure to thoroughly flush internal holes/crevices of instruments (such as the tissue punch, drill extender, implant drivers, and disassembled core tool and ratchet torque wrench) that have difficult to reach areas. **(iv)** Place instruments in sonication bath (with enzymatic cleaning solution prepared according to manufacturers' instructions) making sure that they are completely submerged, and sonicate for 10 minutes. **(v)** Remove the instruments from the sonication bath, and rinse for 3 minutes making sure to thoroughly flush cleaning solution out of the holes/crevices and/or difficult to reach areas. **(vi)** Remove excess moisture from the instruments with a clean, absorbent, non-shedding wipe.

STERILIZATION

The LOCATOR® Core Tool only in the disassembled state of the removal tool, seating tool, and abutment driver components may be sterilized by Autoclave or Dry Heat sterilization using the following parameters:

Cycle Type	Description	Tools & Instrument Part Number	Temperature	Exposure Time (Minutes)	Drying Time (Minutes)
Gravity	LOCATOR Core Tool and core tool components[1]	08390, 08393, 08397	132°C / 270°F	15	30
Pre-Vacuum			132°C / 270°F	4	20
Flash Cycle	LOCATOR Core Tool and core tool components[2]	08390, 08393, 08397	134°C / 273°F	6	20
Dry Heat	LOCATOR Core Tool and core tool components[1]	08390, 08393, 08397	170°C / 338°F	120 Minimum (2 Hours)	N/A
Steam (15-20 psig at sea level)	Abutment Holder Sleeve	08394	121°C / 250°F	40 Minimum	-

[1]The Core Tool must be in a disassembled state. Disassembled pieces can be placed in a single autoclave bag.

[2] The Core Tool must be in a disassembled state, with each disassembled piece placed in a separate autoclave bags.

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.

NOTE: The Abutment Holder Sleeve has been validated to withstand five (5) autoclave sterilization cycles using the specific parameter identified above for the Abutment Holder Sleeve only. The Sleeve may also be sterilized using a liquid chemical sterilant following manufacturer's instructions. The liquid chemical sterilant must be approved for Sterilization not just High-Level disinfection and it must be compatible with polysulfone material.

PROCEDURE FOR USE AND DISASSEMBLY OF CORE TOOL

NOTE: To use the driver with sleeve start with Step 1. To remove and replace the LOCATOR® Male start with Step 2

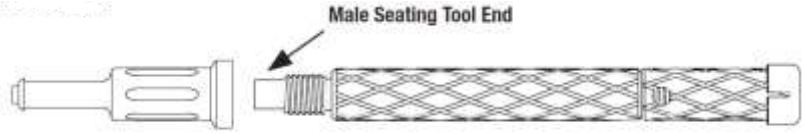
1. The sleeve (Zest catalog number 8394) slips onto the driver end of LOCATOR® Core-Tool, and is designed to hold a LOCATOR® Abutment onto the driver, allowing the driver/sleeve and abutment to be held vertically without abutment falling off the driver, making it easier to deliver the abutment to the patient's implant. In order to achieve 30Ncm of torque, the Abutment Driver portion of the tool is designed with a 1.25mm (.050") internal hex feature which is compatible with various types of restorative drivers.

2. Loosen the (8397) Male Removal Tool a full 3 turns counter clockwise (you will see a visible gap).

3. To remove a LOCATOR® nylon male from the titanium metal housing; simply insert the tip into the cap/male assembly and push straight in to the bottom of the nylon male. Then tilt the tool so that the sharp edge of the tip will grab hold of the male and pull it out of the cap.

4. To discard the nylon male from the tip on the Core Tool; point the tool down and away from you and tighten the Male Removal Tool clockwise back onto the Core Tool. This will activate the removal pin and dislodge the nylon male from the tip end of the Male Removal Tool.

5. Separate the Male Removal Tool section from the LOCATOR® Core Tool and use the Male Seating Tool end of the remaining two sections to place a new nylon male into the empty titanium metal housing.



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 Outer Packaging Label Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
EC REP	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community/European Union	ISO 15223-1	5.1.2
REF	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	EN ISO 15223-1	5.1.6
LOT	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	EN ISO 15223-1	5.1.5
XXXXX	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
NON STERILE	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

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SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	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
CE	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)
QTY	Quantity	Indicates the number of items within the package	N/A	N/A
UDI	Unique Device Identifier	Indicates as containing Unique Device Identifier information	ISO 15223-1	5.7.10
MD	Medical device	Indicates the item is a medical device	ISO 15223-1	5.7.7
	Distributer	Indicates the entity distributing the medical device in the locale	ISO 15223-1	5.1.9