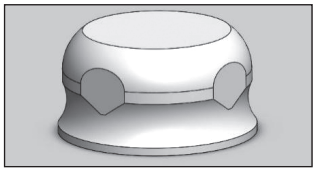
ZEST DENTAL SOLUTIONS

L9802-ZD Rev. C 2020-02

Instructions for Use:
LOCATOR® & LOCATOR R-Tx® Scan Body



INTENDED USE

The LOCATOR® Scan Body and LOCATOR R-Tx® Scan Body are reusable processing tools intended to represent the location, orientation and the space needed to create a recess in the denture that will later be used to retain the LOCATOR or LOCATOR R-Tx denture housing. The LOCATOR Scan Body and LOCATOR R-Tx Scan Body are designed to be used only with the corresponding Zest LOCATOR or LOCATOR R-Tx abutment in the oral cavity or abutment analog in a laboratory, by a trained professional.

DEVICE DESCRIPTION

The LOCATOR and LOCATOR R-Tx scan bodies are fabricated from polyetheretherkeytone (PEEK); the LOCATOR Scan Body is fabricated from natural PEEK that is tan in color, which distinguishes it from the LOCATOR R-Tx Scan Body. The LOCATOR and LOCATOR R-Tx scan bodies are designed to engage with the corresponding LOCATOR/LOCATOR R-Tx abutment or abutment analog, and are intended to be used in conjunction with a digital denture workflow.

ADDITIONAL NOTES / PRECAUTIONS

- The scan body undercut is designed to help mechanically retain the LOCATOR CAP / LOCATOR R-Tx denture housing within the denture and should not be removed in the software by the denture designer.
- Additional manual adjustments may need to be made in the software to ensure the proper dimensions are printed or milled.
- When used intraorally, ensure the implant has been fully integrated or placed with primary stability prior to engaging the Scan Body with the abutment to avoid compromised implant integration.
- Ensure Scan Body is securely attached to the abutment or abutment analog. An insecure Scan Body may result in an incomplete scan which will increase the amount of scanning time required.
- When performing the bite scan, the scan bodies must be protected with impression material or dental wax to ensure that damage does not occur to the scan body.
- Per standard procedure, verify that the denture is fully tissue supported prior to denture housing pickup.

PRODUCT LIFE TIME

The LOCATOR Scan Body and R-Tx Scan Body are designed for multiple uses. If a Scan Body is visually worn, damaged, or will not remain securely attached to the abutment or abutment analog, obtain a replacement Scan Body.

POINT OF USE PROCESSING

The Scan Body is supplied clean and NON-STERILE. Reusable tools and instruments must be sterilized prior to first use on patients and cleaned and sterilized prior to reuse. When removing the Scan Body from the initial packaging, the Scan Body must be cleaned prior to placement into the oral cavity, using the cleaning instructions as described below.

CLEANING

- Soak the Scan Body in enzymatic cleaning solution (mixed according to the manufacturer's instructions) by completely submerging the scan body for 20 minutes. Scrub the Scan Body using a soft-bristled, nylon brush until all soil has been removed.
- Remove the Scan Body from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes. Make sure to thoroughly flush internal crevices of the scan body that have difficult to reach areas.
- If additional cleaning is needed, place the Scan Body in a sonication bath (with enzymatic cleaning solution prepared according to manufacturer's instructions) making sure that the Scan Body is completely submerged, and sonicate for 10 minutes.
- Remove the scan body from the sonication bath, and rinse for 3 minutes making sure to thoroughly flush cleaning solution out of the crevices and/or difficult to reach areas.
- Remove excess moisture from the scan body with a clean, absorbent, non-shedding wipe.

REPROCESSING

Reusable tools must be cleaned first and sterilized prior to reuse. The validation procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biologic indicators, chemical indicators and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer according to an FDA or internationally recognized sterility assurance standard such as ANSI/AAMI ST79 or ISO 17665-1.

STERILIZATION

For gravity cycle, place Scan Body in an autoclave bag; and for Pre-Vacuum Cycle, double wrap Scan Body with autoclave wrap material and secure wrap with autoclave tape. Sterilize the Scan Body using the autoclave parameters listed below:

	Gravity Autoclave	Pre-Vacuum Autoclave
Temperature	132°C / 270°F	132°C / 270°F
Exposure Time	15 minutes	4 minutes
Drying Time	30 minutes	20 minutes

INTRAORAL SCANNING PROCEDURE

1. Install the selected LOCATOR or LOCATOR R-Tx abutment.
2. Select the Zest block out spacer for the Scan Body (Zest order number 08514).
3. Ensure that the seating surface of the abutment is clean, free of residue, and is dry.
4. Affix the block out spacer over the abutment and contacting the gingival tissue.
5. Inspect the Scan Body for any visual damage or wear.
6. Affix the Scan Body onto the abutment and ensure the scan body is securely fastened to the abutment.
7. Proceed with scanning following the software prompts and hardware IFU.
8. When the scan is complete, the Scan Body needs to be removed, cleaned, and sterilized before it can be used on the next case.
9. Notify denture designer that the undercut in the scan body geometry needs to remain.

LAB PROCESSING PROCEDURE

1. Install the selected LOCATOR or LOCATOR R-Tx abutment.
2. Ensure that the seating surface of the abutment analog is clean and free of residue.
3. Inspect the Scan Body for any visual damage or wear.
4. Affix the Scan Body onto the abutment analog and ensure the scan body is securely fastened.
5. Proceed with scanning following the software prompts and hardware IFU.
6. When the scan is complete, remove the Scan Body.

NOTICE TO USERS IN THE EUROPEAN UNION (EU)

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

Re-sterilizable Scan Bodies should be dried completely and stored in a clean and dry location at normal room temperature. Prior to use, the exterior of any sterilized packaging should be inspected for integrity. If damage to the sterile barrier is observed, resterilization is recommended.

DISPOSAL

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

GLOSSARY OF SYMBOLS

The following symbols may be found on product labeling:

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
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1	5.4.3
	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 and consult instructions for use	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
	Quantity	Indicates the number of items within the package	N/A	N/A
	Unique Device Identifier	Indicates a barcode as containing Unique Device Identifier information	ISO 15223-1	5.7.10
	Medical device	Indicates the item is a medical device	ISO 15223-1 (2019)	5.7.7
Rx only	Prescription Required	Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist	US Code of Federal Regulations, Title 21	801.15(c)(1)(i)(F)

Zest Anchors, LLC
2875 Loker Avenue East
Carlsbad • CA 92010 USA
(1) 760-743-7744
www.zestdent.com