ENGLISH

Instructions for Use

The LOCATOR R-Tx® Attachment System includes: LOCATOR R-Tx® Abutments, Retention Inserts, Denture Attachment Housing, Block Out Spacer, Ancillary Processing Parts (including Abutment Analog, Processing Spacer, Impression Coping), and Tools (including Retention Insert Tool, Hex Driver with Thumb Knob, and Hex Latch Driver).

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

DESCRIPTION - ***Implant Attachment:*** The LOCATOR R-Tx Attachment System is a universal hinge, resilient attachment for endosseous implants in the mandible or maxilla in order to restore masticatory function. The attachment system allows for the prosthesis to be removed and replaced by the patient.
LOCATOR R-Tx Retention Inserts:
Standard Range: The LOCATOR R-Tx standard inserts are designed for use with implants accommodating up to 30 degrees from vertical per implant, for a maximum of 60 degrees between implants. The standard inserts are available in Zero, Low, Medium, and High levels of retention.
Limited Range: The LOCATOR R-Tx Limited Range Retention Inserts are designed for use with parallel implants accommodating up to 5 degrees from vertical per implant for a maximum of 10 degrees between implants. The Limited Range Retention Inserts are available in Low, Medium, and High levels of retention.

INDICATIONS FOR USE - The LOCATOR R-Tx Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endosseous implants in the mandible or maxilla.

IMPLANT COMPATIBILITY: Visit https://www.zestdent.com/R-Tx_Compatibility for information on implant compatibility for the Locator R-Tx Attachment System.

CONTRAINDICATIONS - Not appropriate where a totally rigid connection is required. Use of an implant with divergence of greater than 30 degrees from vertical is not recommended. Not appropriate to be used for a fixed restoration.

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.

MRI SAFETY INFORMATION - A person with an implant or abutment device of the Zest Dental LOCATOR R-Tx Attachment System may be safely scanned under the following conditions. A scanning environment under Normal Operating Mode, with a Static Magnetic Field Strength (Bo) of 1.5T or 3.0T, with a Maximum Spatial Field Gradient of 40 T/m (4,000 gauss/cm), and RF Excitation which is Circularly Polarized (CP). The Maximum Whole-Body specific absorption rate (SAR) is 2 W/kg and the Maximum Head SAR is 3.2 W/Kg, both under Normal Operating Mode. The Scan Duration limit is 2 W/kg whole-body average SAR for 60 minutes of continuous radio frequency (RF), (a sequence or back-to-back series/scan without breaks). Failure to follow these conditions may result in injury. NOTE: The presence of this device may produce an image artifact that can extend as far as approximately 23.0 mm ± 0.5mm from the device, as observed in a nonclinical setting. The ± 0.5mm is the numerical value of the combined standard uncertainty.

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).

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WARNINGS & PRECAUTIONS - The products of the LOCATOR R-Tx Attachment System are made of various materials and patients should be evaluated for allergies or hypersensitivity to such materials prior to treatment. The abutments of LOCATOR R-Tx Implant Attachment System are made from the titanium alloy Ti-6Al-4V and have a Titanium Carbon Nitride (TiCN) coating. Restorative components are made from Ti-6AL-4V, 303 Stainless Steel and Nylon. During the treatment process patients may be exposed to instruments, tools, and processing components which may contain various grades of stainless steel, polyethylene, nitrile, or silicone. 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.
If the LOCATOR R-Tx abutment is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue.

As surgical instruments are susceptible to damage and wear, they should be inspected before each use. Markings should be visible and legible. 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. When applicable to the surgical instrument, check the latch lock shank or other connection feature for wear to ensure the connection is not damaged.

Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation towards good dental care, and anatomic acceptability prior to the placement of the implant attachments as part of restorative process is critical. Thorough evaluation of the patient's medical status and health history is mandatory. Treatment planning is vital to the success of the implant and prosthesis.

The use of this attachment system requires that the clinician be thoroughly familiar with the product and the method for its use and application. The clinician must also use reasonable judgment in deciding when and where to use the product.

Please follow the instructions for use from the manufacturer of each compatible implant system for implant placement and indicated range of divergence for abutments. Divergence up to 30° may not be indicated by the manufacturers of some of the compatible implant systems.

SINGLE-USE DEVICES - The LOCATOR R-Tx Attachment System components with the exception of the tools and instruments (insert tool and drivers) are single-use devices, and are provided non-sterile. Single-Use Devices must not be reused or re-sterilized. Reuse of a single-use device may cause harm to the patient in the transfer of blood, tissue, or saliva that may contain infectious disease. Single use devices may not function as intended if re-sterilized and may result in an improper surgical procedure and lead to improper function or failure of the device.
LOCATOR Inserts (Males): The inadvertent re-use of LOCATOR R-Tx nylon inserts could cause loss of retention of the overdenture due to wear from previous use or damage during removal with the LOCATOR Core Tool.

LOCATOR Abutments (Attachments): The inadvertent re-use of LOCATOR R-Tx Abutments could contain patient contamination build-up and subsequent wear of the retention feature. This would result in improper fit and function which cause the loss of retention of the prosthesis.

MULTI-USE DEVICES - The surgical instruments and tools of the LOCATOR R-Tx System are multi-use devices. Reusable tools and instruments must be sterilized prior to first use on patients and cleaned and sterilized prior to reuse.

TOOLS: The LOCATOR R-Tx Insert Tool and other surgical instruments are designed for multiple uses and are provided NON-STERILE. 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 Insert Tool or other instruments becomes worn or damaged, obtain a replacement device.

CLEANING - Reusable tools and instruments should be cleaned according to applicable instructions from the device manufacturer.
(i) Disassemble the instruments (i.e. Insert Tool). **(ii)** Soak the instruments in enzymatic cleaning solution (mixed according to manufacturer's instructions) by completely submerging them for 20 minutes. Scrub the components 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 the instruments that have difficult to reach areas. **(iv)** Visually inspect instruments and tools for cleanliness and presence of residual debris. If additional cleaning is needed, place instruments in ultrasonic cleaner (with enzymatic cleaning solution prepared according to manufacturer's instructions) making sure that they are completely submerged, and sonicate for 10 minutes. **(v)** Remove the instruments from the ultrasonic cleaner, 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
Tools and instruments provided non-sterile should be sterilized prior to use on patients. Reusable tools and instruments should be cleaned and sterilized prior to reuse on patients. The nylon males may be sterilized/disinfected using a liquid chemical sterilant as described below. Tools and instruments should be sterilized according to applicable instructions from the device manufacturer.

In order to ensure that the Inserts are sterilized/disinfected (all microorganisms including Clostridium sporogenes and Bacillus subtilis spores are eliminated), the Inserts must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature. **Note:** An FDA approved liquid chemical sterilant for critical devices that are heat-sensitive and incompatible with sterilization methods such as steam and gas/vapor/plasma low temperature processes may be used following the manufacturer's directions for the sterilization of the device.
Titanium abutments and stainless steel or other metal instruments may be sterilized by Autoclave sterilization using the following parameters. For gravity cycle, place components in autoclave bag; and for Pre-Vacuum Cycle, wrap the component with autoclave wrap material and secure wrap with autoclave tape. Wrap the components using a wrap that is FDA-cleared for the indicated cycles.

Cycle Type	Description	Tools & Instrument Part Number	Temperature	Exposure Time	Drying Time
Gravity	LOCATOR R-Tx Abutments, Tools and Instruments	08007, 08008, 30021-01, all non-sterile LOCATOR R-Tx titanium abutments	132°C / 270°F	15 Min	30 Min
Pre-Vacuum			132°C / 270°F	4 Min	20 Min

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. Single Use devices should not be resterilized.

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

PROSTHETIC PROCEDURES - Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate LOCATOR R-Tx Abutment based on the type of implant, diameter, and tissue height.

It is imperative that all bone and soft tissue be removed from the superior aspect of the implant body to guarantee complete seating of the Abutment.

Using the appropriate Hex Driver, seat the abutment to the implant and hand tighten. Finalize seating by using a calibrated torque wrench, tighten the LOCATOR R-Tx Abutment to 30 Ncm or to the

torque for an abutment screw recommended by the manufacturer of the implant/abutment system if that recommended torque is 35 Ncm or less. Use of higher torque values than recommended above could cause a fracture of the LOCATOR R-Tx Abutment.

NOTE: For Implant Attachments with ≤ 1.4 mm thread (IDENTIFIED BY "≤ M1.4" SYMBOL ON LABEL): Hand tighten the LOCATOR R-Tx abutment to the implant. Then, using a calibrated torque wrench, tighten the LOCATOR R-Tx Abutment to 20 Ncm. Use of a higher torque value than the maximum recommended 20Ncm could cause fracture of the LOCATOR R-Tx Abutment.

Impression and Stone Model Fabrication
(i) With the LOCATOR R-Tx Abutments torqued in place, snap the Impression Copings on the Abutments until they are seated firmly onto each Abutment. **(ii)** Proceed by taking an impression. **(iii)** Remove the tray and snap a Processing Analog into each intaglio of the Impression Coping. **(iv)** Capture the abutment position in stone using typical methods for fabricating a laboratory stone model.

Prosthesis Fabrication
(i) Seat the LOCATOR R-Tx Denture Attachment Housings with the Processing Inserts on each of the abutments. **(ii)** Fabricate the prosthesis using typical laboratory techniques. **(iii)** When delivering the prosthesis, use the lowest retentive level insert to begin with and increase the retention if needed.

Denture Attachment Housing Pickup Technique (Optional)
(i) Place a Block-Out Spacer around each Abutment and press down. **(ii)** Seat the LOCATOR R-Tx Denture Attachment Housings with the Processing Inserts on each of the abutments. **(iii)** Secure the Denture Attachment Housings to the prosthesis using auto-polymerizing or light cure acrylic or composite resin using a typical Denture Attachment Housing pickup technique.

Prosthesis Delivery
(i) Once the fit of the prosthesis is verified, remove the Processing Inserts from each Denture Attachment Housing. **(ii)** Replace them with the lowest retention level Inserts initially and increase the retention if needed. Firmly snap the prosthesis into place, ensuring that each Insert is fully engaged onto each Abutment.

HEALING PHASE
For delayed loading protocols: Relieve the denture to ensure the Abutments are not in contact with any denture acrylic. A soft liner may be added to the denture to ensure patient comfort during the healing phase.

PATIENT CARE
Good oral hygiene is vital to attachment success. The patient should be made aware of the following:

(i) The LOCATOR attachments must be thoroughly cleaned each day to prevent wear of the component due to plaque build-up. The patient should be instructed to use a soft nylon bristle or end-tufted toothbrush with a non-abrasive gel toothpaste to clean the Abutments and Inserts and floss to polish the Abutments. **(ii)** The coarse particles in abrasive toothpaste may scratch the surfaces of the Abutments and cause plaque accumulation. **(iii)** An irrigation system is recommended to flush out debris from the inside of the LOCATOR R-Tx Inserts. **(iv)** The Inserts are made of a soft plastic material (nylon) to allow the Overdentures to be removed/replaced regularly. Plastic materials are subject to wear as part of normal use and may require replacement. **(v)** Bruxism wears the LOCATOR abutments and may reduce the longevity of the Retention Inserts.

Patients should be instructed to maintain routine follow-up visits for hygiene and attachment function evaluation. Should a patient experience any discomfort or loss of retention of the overdenture, they should consult a dental professional.

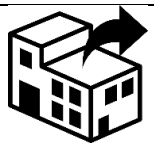
Follow-up visits are recommended at 6 month intervals. Abutments must be re-tightened at follow-up visits to the torque specifications outlined above. Failure to re-tighten abutments could lead to screw loosening

and abutment fracture. Patients should be examined for signs of inflammation around the implant abutments and for implant mobility.

Further Information
Traditional restorative protocols should be followed to process the attachments into the patient's overdenture. Standard overdenture care and maintenance should be followed in order to ensure the longevity of the restoration.

Explanation of Outer Packaging Label Symbols

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer	EN ISO 15223-1	5.1.1
	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community/European Union	EN 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
	Do not re-use	Indicates a medical device that is intended for one single use only, or for use on a single patient during a single procedure	EN ISO 15223-1	5.4.2
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	EN ISO 15223-1	5.4.3
 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
	Do Not Resterilize	Indicates a medical device that is not to be resterilized	EN ISO 15223-1	5.2.6
	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	EN ISO 15223-1	5.2.8
	European Mark of Conformity	Indicates device is in conformance with Medical Device Directive 93/42/EEC	MDD 93/42/EEC	Annex XII

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
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
≤M1.4 	≤M1.4 Metric Thread	Indicates abutment with a ≤1.4mm thread; only torque to 20Ncm.	None	IFU L8124-ZD
	Distributor	Indicates the entity distributing the medical device in the locale	ISO 15223-1	5.1.9
	Importer	Indicates the entity importing the medical device into the locale	ISO 15223-1	5.1.8
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions	ASTM F2503 EN 62570	Table 2

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