

ENGLISH

Instructions for Use

LOCATOR® Root Attachment System (incl. Retrofit for ERA® Root Attachment)

Includes: LOCATOR® Root Attachments), Retention Inserts, Denture Attachment Housing, Ancillary Processing Parts (i.e. analogs, processing spacer, block out spacer, parallel post, etc), and Tools.

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

DESCRIPTION

Root Attachment:

Universal hinge, resilient attachment for endodontically treated roots.

Retrofit for ERA® Root Attachment

Universal hinge, resilient attachment converts worn or damaged standard sized ERA® attachments to new LOCATOR® attachments for endodontically treated roots.

INDICATIONS

The LOCATOR® Root Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by endodontically treated roots in the mandible or maxilla.

CONTRAINDICATIONS

Not appropriate where a totally rigid connection is required.

Retrofit for ERA® Root Attachment

Not appropriate for Micro ERA® sized attachments or where a totally rigid connection is required.

CAUTION

Federal (USA) law restricts this device to sale by or on the order of a licensed dentist.

MRI SAFETY INFORMATION

The LOCATOR® Root Attachment System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the LOCATOR® Root Attachment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

WARNINGS AND PRECAUTIONS

Product from damaged packaging must not be used on patients. In the event that the packaging is damaged, the damaged packaging with the product must be returned to the manufacturer and a replacement will be provided only if damage to packaging is caused by product shipment.

If the LOCATOR® Abutment is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue.

Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation toward good dental care, and anatomic acceptability prior to the placement of the

attachments as part of restorative process is critical. Thorough evaluation of the patient's medical status and health history is mandatory.

The use of the Root 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.

Treatment planning is vital to the success of the implant and prosthesis.

SINGLE-USE DEVICES

The LOCATOR® Root Attachment System components with the exception of the Tools are single-use devices and Single-Use Devices must not be reused or re-sterilized.

TOOLS: The following LOCATOR® Tools Core Tool, Spotface Diamond Bur, Pilot Drill, are designed for multiple uses. If the tool becomes worn or damaged, obtain a replacement tool.

CLEANING

- Disassemble the instruments.
- 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.
- 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.
- 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.
- 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.
- Remove excess moisture from the instruments with a clean, absorbent, non-shedding wipe.

STERILIZATION

Wrap the components using a wrap that is FDA-cleared for the indicated cycles. All components and instruments are supplied NON-STERILE.

The Core Tool may be sterilized by autoclave sterilization using the following parameters:

	Gravity Autoclave	Pre-Vacuum Autoclave
Temperature	132°C	132°C
Exposure Time	15 minutes	4 minutes
Dry Time	30 minutes	20 minutes

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.

PROSTHETIC PROCEDURES

Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate LOCATOR® Root Abutment.

- Prepare and measure study casts to determine space available in the root for the LOCATOR Abutment. Width of root surface must be equal to or exceed 4.0 mm.
- Decoronate the root and perform endodontic therapy. Remove the desired depth of gutta percha following standard clinical procedure.
- Finish contouring of roots; final reduction should place root surface supra-gingival within 1 mm of gingiva.
- Size the canal using the Pilot Drill and spotface the root surface with the Diamond Bur to a depth where a full 360 degree recessed seat first appears on the occlusal surface of the root.
- Cement LOCATOR® Abutment in place with a composite resin or adhesion material.

Prosthesis Fabrication

- Seat the LOCATOR® Denture Attachment Housings with the Processing Inserts on each of the LOCATOR Abutments.
- Fabricate the prosthesis using typical laboratory techniques.
- 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)

- Place a Block-Out Spacer around each LOCATOR Abutment and press down.
- Seat the LOCATOR® Denture Attachment Housings with the Processing Inserts on each of the LOCATOR Abutments.
Secure the Denture Attachment Housings to the prosthesis using auto-polymerizing or light cure acrylic or composite resin pickup technique.

Prosthesis Delivery

- Once the fit of the prosthesis is verified, remove the Processing Inserts from each Denture Attachment Housing using the Core Tool.
- 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.

PATIENT CARE

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

- The LOCATOR® Attachments must be thoroughly cleaned each day to prevent plaque build-up and the patient should use a soft nylon bristle or end-tufted toothbrush with a non-abrasive toothpaste to clean the Abutments.
- The coarse particles in abrasive toothpaste may scratch the surfaces of the Abutments and cause plaque accumulation.
- An irrigation system is recommended to flush out debris from the inside of the LOCATOR® Inserts.

- 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.
- Bruxism wears the Locator attachments 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.

Inserting and Removing the Overdentures

The patient should be instructed on how to properly insert the overdenture. The patient should make sure they can feel that it is positioned over the LOCATOR Abutments prior to applying pressure. The patient should use both hands and press down one each side and firmly snap the overdenture into place.

CAUTION: THE PATIENT MUST NOT BITE their overdentures into place as this force will result in improper wear of the LOCATOR Abutments, including the Retention Inserts in the overdenture. The patient must remove the overdenture by placing their thumbs under the edges of the overdenture rim and pulling each side upward/downward simultaneously. Use of their tongue may aid in removal. Once removed, a thorough cleaning is recommended.

Cleaning your Implant Retained Overdenture










Instruct the patient to follow the protocol below to ensure the longevity of their overdenture.

1. Fill a washing basin with some warm water to prevent fracture of the overdenture. Apply non-abrasive toothpaste onto the soft bristle toothbrush and thoroughly clean every surface of the overdenture.
2. Each night, remove overdenture and immerse in a cup of plain water

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	Symbol Description
	"Symbol for BATCH CODE" (Lot #)
	Symbol for "MANUFACTURER"
	Symbol for "CATALOGUE NUMBER"
	Symbol for "CONSULT INSTRUCTIONS FOR USE"
 www.zestdent.com/eifu	Consult Electronic Instructions for Use
	Symbol for "NON-STERILE"
	Symbol for "DO NOT REUSE"
RxOnly	Prescription Required.
	CE Marking (Use 2797 only on class IIa and higher risk class devices).
	European Authorized Representative