ENGLISH

Instructions for Use

The LOCATOR® Implant Attachment System and Attachment System for Multi-Unit Abutments includes: LOCATOR® Abutments, Retention Inserts, Denture Attachment Housing, Ancillary Processing Parts (including abutment analogs, processing spacer, block out spacer, parallel post, impression coping, black processing male), and Tools (including abutment driver assembly, square driver, torque wrench insert drivers, and angle measurement guide).

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

DESCRIPTION

Implant Attachment:

The LOCATOR® Implant 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.

Attachments for Multi-Unit Abutments:

The LOCATOR® Implant Attachment System for multi-unit abutments is a universal hinge, resilient attachment for connection to both angled and straight Multi-Unit Abutments.

INDICATIONS FOR USE

The LOCATOR® Implant 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.

CONTRAINDICATIONS

Implant Attachment:

Not appropriate where a totally rigid connection is required. Use of a single implant with divergence of greater than 20 degrees from vertical is not recommended.

Attachments for Multi-Unit Abutments:

Not appropriate 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 only.

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

The LOCATOR® Implant 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® Implant Attachment System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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STORAGE AND HANDLING

The LOCATOR® Implant Attachment System in its undamaged, original packaging is not subject to any special considerations for storage or handling (during transport and storage).

WARNINGS AND 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.

If the LOCATOR® Implant 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 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 anatomical 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 each of these attachment systems require 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.

SINGLE-USE DEVICES

The LOCATOR® Implant Attachment System components, with the exception of the tools and instruments, 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® Males: The inadvertent re-use of LOCATOR® nylon males could cause loss of retention of the overdenture due to wear from previous use or damage during removal with the LOCATOR® Core Tool.

LOCATOR® Attachments: The inadvertent re-use of LOCATOR® Attachments could contain patient contamination build-up and subsequent wear of the retention inserts. 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® Implant Attachment System are multi-use devices. Reusable tools and instruments must be cleaned and sterilized prior to reuse on patients

TOOLS: The LOCATOR® Tools 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.

CLEANING AND STERILIZATION
The LOCATOR® Implant Attachment System, and other restorative components, instruments, and replacement LOCATOR® Attachments (sold separately), tools and instruments are supplied NON-STERILE, and should be sterilized prior to use on patients.

CLEANING
- Reusable tools and instruments should be cleaned according to applicable instructions from the device manufacturer.
- Disconnect or 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.
- 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.
- 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
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.

Autoclave Sterilization Parameters are listed below:

Cycle Type	Description	Tools & Instrument Part Number	Temperature	Exposure Time	Drying Time
Gravity	LOCATOR® Abutments, Tools and Instruments	08260, 08280, 08317, 08913, 08914, 08916, 08926, 09530, 08927, 08929, all non-sterile LOCATOR® 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® 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 a calibrated torque wrench, tighten the LOCATOR® Abutment to 30Ncm or to the torque for an abutment screw recommended by the manufacturer of the implant/abutment system if that recommended torque is 35Ncm or less. Use of higher torque values than recommended above could cause a fracture of the LOCATOR® Abutment.

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

Impression and Stone Model Fabrication

- With the LOCATOR® Abutments torqued in place, snap the Impression Copings on the Abutments until they are seated firmly.
- Proceed by taking an impression.
- Remove the tray and snap an Analog into each intaglio of the Impression Coping.
- Capture the abutment position in stone using standard methods for fabricating a laboratory stone model.

Prosthesis Fabrication

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

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- 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 Abutment and press down.
- Seat the LOCATOR® Denture Attachment Housings with the Processing Inserts on each of the 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 (refer to IFU L8109 for additional instruction).
- 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:

- 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. 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.

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 Abutments prior to applying

pressure. The patient should use both hands and press down one each side and firmly snap the Overdenture into place.

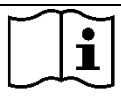
NOTE: The patient must not bite their Overdentures into place as this force will result in improper wear of the Abutments, including the Retention Inserts in the Overdenture. Remove the Overdenture by placing the thumbs under the edges of the Overdenture flanges and pulling each side upward/downward simultaneously. Use of the tongue may aid in removal. Once removed, a thorough cleaning is recommended.

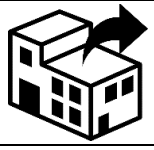
Cleaning your Implant Retained Denture
Instruct the patient to follow the protocol below to ensure the longevity of their Overdenture.

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	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directive 93/42/EEC	EN ISO 15223-1	5.1.1
	Authorized Representative in the European Community	Indicates the authorized representative in the European Community	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 use, 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

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	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
 YYYY-MM-DD	Use-by date	Indicates the date after which the medical device is not to be used	EN ISO 15223-1	5.1.4
	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
CE 2797	European Mark of Conformity	Indicates device is in conformance with Medical Device Directive 93/42/EEC	MDD 93/42/EEC	MDD 93/42/EEC Annex XII
CE	European Mark of Conformity	Indicates device is in conformance with Medical Device Regulation EU 2017/745	MDR 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 the Unique Device Identifier information	DIS 15223-1 (2019)	5.7.10
MD	Medical device	Indicates the item is a medical device	DIS 15223-1 (2019)	5.7.7
≤M1.4 	≤M1.4 Metric Thread	Indicates abutment with a ≤1.4mm 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

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