Instructions for Use

The **LOCATOR® Bar Attachment System and Bar Attachment Systems for Multi-Unit Abutments** includes: LOCATOR® Bar Abutments, Replacement Males, Denture Cap, Ancillary Processing Parts (analogs, impression coping, processing male, parallel post, processing spacer, block out spacer, and castable threaded insert), and Tools (paralleling mandrel, drill and tap holder, 1.7mm bar drill, 1.8mm bar drill, #2-56 bar tap, and 2.0mm bar tap).

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

DESCRIPTION

Bar Attachment: The LOCATOR® Bar Attachment System is a universal hinge, resilient attachment for bar splinted endosseous implants.

Bar Attachments for Multi-Unit Abutments: The LOCATOR® Bar Attachment Systems for Multi-Unit Abutments is a universal hinge, resilient attachment for connection to both angled and straight Multi-Unit Abutments. The bar splinted LOCATOR Implant Abutment for the angled Multi-Unit Abutment and the straight Multi-Unit Abutment is a two piece part that contains a castable Delrin Collar and the LOCATOR Abutment.

INDICATIONS FOR USE

Bar Attachment: The LOCATOR® Bar Attachment System is designed for use with overdentures or partial dentures, retained in whole or in part, by bar splinted endosseous implants in the mandible or maxilla.

Bar Attachment for Multi-Unit Abutments: The LOCATOR® Bar Attachment System is designed for use as a splinted bar attachment connector with angled or straight Multi-Unit Abutments in the mandible or maxilla for retaining overdentures.

CONTRAINDICATIONS

Not appropriate where a totally rigid connection is required. The use of a multi-unit on a narrow implant in the posterior is not recommended.

CAUTION

Federal (USA) law restricts this device to 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

The LOCATOR® Bar Attachment System and Bar Attachment System for Multi-Unit Abutments have 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® Bar System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

STORAGE AND HANDLING

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

WARNINGS AND PRECAUTIONS

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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® Bar Abutment is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue. Use of higher than recommended torque values could cause a fracture of the LOCATOR® Bar Abutment.

As tools are susceptible to damage and wear, they should be inspected before each use. Markings should be visible and legible. Any reusable tools 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 tool, 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 toward 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 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® Bar Attachment System components and Bar Attachment System for Multi-Unit Abutments components with the exception of the tools 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.

MULTI-USE DEVICES

The tools of the LOCATOR Bar Attachment System and Bar Attachment System for Multi-Unit Abutments 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® Tools such as the Core Tool, Drill & Tap Holder, Paralleling Mandrel 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 tool becomes worn or damaged, obtain a replacement tool.

CLEANING

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

(i) Disassemble the instruments. **(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 Replacement Males are sterilized/disinfected-all microorganisms including Clostridium sporogenes and Bacillus subtilis spores are eliminated, the Replacement Males 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 Bar 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 Bar Abutments, Tools and Instruments	09102, 09103, 09104, 09105, 09107, and All non-sterile titanium LOCATOR Bar 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® Bar Abutments based on the type of implant and diameter being used.

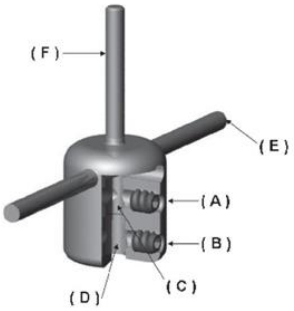
Using a calibrated torque wrench, tighten the LOCATOR® Bar Abutment to 30 Ncm or to the torque for an abutment screw recommended by the manufacturer of the implant system if that recommended torque is 35 Ncm or less. Use of higher torque values than recommended above could cause a fracture of the LOCATOR® Bar Abutment.

NOTE: For Implant Attachments with ≤ 1.4 mm thread (IDENTIFIED BY "≤ M1.4" SYMBOL ON LABEL): Hand tighten the LOCATOR Bar Abutment to the implant. Then, using a calibrated torque wrench, tighten

the LOCATOR® Bar Abutment to 20 Ncm. Use of higher torque values than recommended above could cause a fracture of the LOCATOR® Bar Abutment.

Impression and Stone Model Fabrication: Indirect Technique
(i) After the bar of choice has been fabricated, divest, finish and polish the cast bar. **(ii)** Finger tighten the Bar Tap manually into the Drill and Tap Holder. **(iii)** Use the Bar Tap to manually chase and clean the internal threads of each Replacement Male. NOTE: Use tapping fluid while cutting the threads into the bar to reduce the chance of breaking the tap off in the Abutment. **(iv)** With the LOCATOR® Bar Abutments torqued in place, snap the Impression Copings on the Bar Abutments until they are seated firmly. **(v)** Proceed by taking an impression. **(vi)** Remove the tray and snap an Analog into each intaglio of the Impression Coping. **(vii)** Capture the Bar Abutment position in stone using standard methods for fabricating a laboratory stone model.

Additional Instructions For Use of Bar Drill & Tap Holder:



(i) Make sure that all Set Screws (A) (two) and (B) (two) are unthreaded to the point where they are first visible above the body of the Drill and Tap Holder tool. **(ii)** Insert the appropriate Locator Bar Drill (1.7mm Bar drill for 2.0mm thread, No. 09102 or 1.8mm Bar Drill for 2-56 thread No. 09103) into channel (C). **(iii)** Using the Allen Wrench provided, tighten only the two Set Screws (A) across from each other in the upper portion of the Holder tool, locking the drill in place. **(iv)** The .092 shank (F) of the Drill & Tap Holder is designed to fit into the hand piece of a milling unit in the dental laboratory. **(v)** After drilling is completed, loosen the two Set crews (A) and remove the drill. **(vi)** Insert the appropriate Locator Bar Tap (2.0mm Bar Tap for 2.0mm thread, No. 09104 or 2-56 bar Tap for 2-56 thread, No. 09105) into channel (D). **(vii)** Using the Allen wrench provided, tighten only the two Set Screws (B) across from each other in the lower portion of the Holder tool, locking the tap in place. **(viii)** Insert Tap Handle (E) into either of the two cross holes in the upper portion of the Holder tool to assist with the forward and back tapping motion. One half turn back for every one turn in, is required for proper tapping of the drilled hole. The use of tapping fluid while cutting the threads is required to reduce the chance of breaking the tap off in the preparation. **(ix)** After tapping is completed, remove the Tap Handle (E) and loosen the two Set Screws (B) to remove the tap.
WARNIG: At no time shall the power be turned on with the tap handle in place or at any time during the tapping process.

Prosthesis Fabrication
(i) Seat the LOCATOR® Denture Caps with the Processing Males on each of the Bar Abutments. **(ii)** Fabricate the prosthesis using standard laboratory techniques. **(iii)** When delivering the prosthesis, use the lowest retentive level Replacement Male to begin with and increase the retention if needed.

Denture Cap Pickup Technique (Optional)
(i) Place a Block-Out Spacer around each Bar Abutment and press down. **(ii)** Seat the LOCATOR® Denture Cap with the Processing Male on each of the Bar Abutments. **(iii)** Secure the Denture Caps to the prosthesis using auto-polymerizing or light cure acrylic or composite resin pickup technique. **(iv)** NOTE: Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and premature wear of the Replacement Male.

Prosthesis Delivery
(i) Once the fit of the prosthesis is verified, remove the Processing Males from each Denture Cap using the Core Tool. **(ii)** Replace them with the lowest retention level Replacement Males initially and increase the retention if needed. Firmly snap the prosthesis into place, ensuring that each Replacement Male is fully engaged onto each Bar Abutment.

HEALING PHASE

For delayed loading protocols: 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® Bar 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 toothpaste to clean the Abutments. **(ii)** The coarse particles in abrasive toothpaste may scratch the surfaces of the Bar Abutments and cause plaque accumulation. **(iii)** An irrigation system is recommended to flush out debris from the inside of the LOCATOR® Replacement Males. **(iv)** The Replacement Males 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 attachments and may reduce the longevity of the Replacement Males.

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. Bar Abutments must be re-tightened at follow-up visits to the torque specifications outlined above. Failure to re-tighten Bar Abutments could lead to screw loosening and Bar 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 Bar 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 <u>NOT BITE</u> their Overdentures into place as this force will result in improper wear of the Abutments, including the Replacement Males 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	EN ISO 15223-1	5.1.1

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SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
EC REP	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
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
	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 / 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
	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	Annex XII
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

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SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
≤M1.4 	≤M1.4 Metric Thread	Indicates abutment with a ≤1.4mm thread; only torque to 20Ncm.	None	IFU L8102-ZD
	Distributor	Indicates the entity distributing the medical device in the locale	ISO 15223-1	5.1.9

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