ENGLISH

Instructions for Use

LOCATOR F-Tx® Fixed Attachment System - The LOCATOR F-Tx Fixed Attachment System includes Abutment, Denture Attachment Housing, Processing Ball and three (3) levels of Retention Balls, Healing Cap, Impression Coping, Processing Cap, Abutment Analog, Waxing Cap, Polishing Cap, a Manual and a Latchlock Abutment Hex Driver Assembly tool, Retention Ball Hex Driver, and the seating and removal tools.

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

DESCRIPTION: The LOCATOR F-Tx Fixed Attachment System is an implant attachment for rigid connection of fixed, partial and full arch restorations on endosseous dental implants. The system enables the clinician to remove and re-seat the prosthesis when needed. The package contents include: 1 Abutment, 1 Denture Attachment Housing, 2 Black Processing Ball (1 attached to the Denture Attachment Housing and 1 additional), 1 Blue Low Retention Ball, 1 Tan Medium Retention Ball, 1 Green High Retention Ball, and 2 Block Out Spacers

INDICATIONS FOR USE - The LOCATOR F-Tx Fixed Attachment System is designed to support fixed full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function.

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

CONTRAINDICATIONS - Not appropriate for single tooth restorations. Not appropriate where a resilient connection is required. Not appropriate for use on an implant with divergence greater than 20 degrees (from vertical). Not appropriate for a unilateral bridge.

Dental implants should not be used in patients with serious medical problems or in a poor general state of health. Patients with medical problems such as uncontrolled bleeding disorders, drug or alcohol abuse, weakened immune system, or uncontrollable endocrine disorders should be carefully evaluated prior to treatment.

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 F-Tx Fixed 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 F-Tx Fixed 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 F-Tx Fixed 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 might be damaged or the product sterility compromised when the packaging becomes damaged. 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.

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.

The use of this or any dental restorative product requires that the clinician be thoroughly familiar with the product and the method for its use and application. They must also be familiar with all instruments and surgical/restorative procedures required, including device sterilization. The clinician must use reasonable judgment in deciding when and where to use the product. This should include a complete assessment of the patient prior to performing any procedure.

The clinician should also determine if the patient has a metal allergy to titanium alloy (6Al-4V) in which case, use of the system may be contraindicated.

Care should be taken when utilizing small components as they can be dropped and contaminated, ingested or aspirated. Components must be assembled and maintained as described in this document.

Parafunctional habits, such as bruxism or clenching may result in overloading, loosening or improper fitting of the components, causing them to fracture and/or fail during normal use.

SINGLE-USE DEVICES - The LOCATOR F-Tx Fixed Attachment System components with the exception of the tools and instruments (seating and removal tool and drivers) are Single-Use devices. 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 surgical instruments and tools of the LOCATOR F-Tx Fixed Attachment 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 F-Tx Seating & Removal Tool and other surgical instruments (abutment and Retention Ball drivers) 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 Seating & Removal tool or other instruments becomes worn or damaged, obtain a replacement device.

CLEANING OF MULTI-USE DEVICES - Reusable tools and instruments should be cleaned according to applicable instructions from the device manufacturer.

(i) Disassemble the instruments. Disassembly not required for drivers. **(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, repeat cleaning steps above until instrument or tool is clear of residual debris. **(v)** Remove excess moisture from the instruments with a clean, absorbent, non-shedding wipe.

STEAM 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.
All Attachment System components contained in the Abutment vial are supplied ***STERILE***(subjected to gamma irradiation). Healing Cap, Impression Coping, Abutment Driver and Retention Ball Driver are provided NON-STERILE and must be sterilized prior to use.
Sterilization Prep - Stainless steel or other metal instruments may be sterilized by Autoclave sterilization using the following parameters. Disassembly not required for drivers or pre-assembled Denture Attachment Housings and Impression Copings with Processing Balls. Use an FDA cleared autoclave bag or wrap. Sterilize the F-Tx Fixed Attachment System components and devices according to the following parameters:

Cycle Type	Description	Tools & Instrument Part Number	Temperature	Exposure Time	Drying Time
Gravity	LOCATOR F-Tx tools and Instruments	10028-01, 10029-01, 10030-01, 10032-01, 10036-01, 10037-01, 10039-01, 10042-01, and 10043-01	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 assessment, the clinician should select the appropriate restorative components, including abutments that

accommodate the desired gingival tissue thickness and place the appropriate Retention Balls for each quadrant of the prosthesis.

Case Planning:
A minimum of four (4) implants are required to support a prosthesis with cross arch stabilization.
(i) Ensure the prosthesis extends at least 2mm past the most posterior Abutments to allow the Removal Loop to engage for prosthesis removal. **(ii)** Ensure the length of any cantilever is no more than **one time (1x) the Anterior/Posterior spread**. For Bruxers/Clenchers cantilevers of no more than 0.5 times (0.5x) the Anterior/Posterior spread. **(iii)** The proper selection of the cuff size is imperative when pre-planning a case. The minimum Attachment height requirement is 5.6mm. The choice of restorative material may require more vertical clearance.
NOTE: The LOCATOR F-Tx Seating and Removal Tool is required and MUST be used when seating the prosthesis; otherwise, Retention Balls may not fully engage leading to dislodgement.

FOR IMMEDIATE LOAD - ALL implants must have primary stability (≥35Ncm)
(i) Actual torque value required to achieve primary stability varies with implant systems and patient case; more than 35Ncm may be required to achieve primary stability. **(ii)** Follow soft diet protocol during the osseointegration period. **(iii)** Prosthesis removal should be avoided during osseointegration.

TEMPORARY/SHORT TERM RESTORATIONS
RETENTION BALL SELECTION *(for Immediate Load)*:
(i) Four Implants: All Medium (Tan) Retention Balls. (ii) Five + Implants: Medium (Tan) Retention Balls on the anterior and posterior cantilevers and Low (Blue) or Medium (Tan) on remaining Abutments.

	Anterior Abutments	**Posterior Abutments**	**All Other Abutments**
Four (4) Implants	Medium (Tan)	Medium (Tan)	N/A
Five or More (5+) Implants	Medium (Tan)	Medium (Tan)	Medium (Tan) or Low (Blue)

NOTE: Avoid using High (Green) Retention Balls if removal is likely during osseointegration period.

FINAL/LONG TERM RESTORATIONS
RETENTION BALL SELECTION *(for Long Term Restoration):*
(i) Four Implants: All High (Green) Retention Balls. (ii) Five + Implants: High (Green) Retention Balls on the anterior and posterior cantilevers and Medium (Tan) on all remaining Abutments.

	Anterior Abutments	**Posterior Abutments**	**All Other Abutments**
Four (4) Implants	High (Green)	High (Green)	N/A
Five or More (5+) Implants	High (Green)	High (Green)	Medium (Tan)

NOTE: Low (Blue) Retention Balls should not be used in a final restoration.

Abutment Attachment:
Each Abutment should be torqued according to the Implant manufacturer's guidelines using the F-Tx Abutment Driver. When the prosthesis is removed at recall appointments, the

Abutments should be checked for tightness and if needed, appropriately retightened to the proper value.

Impression and Stone Model Fabrication:
(i) Prior to seating the Impression Copings, ensure that the Black Processing Balls are hand tightened. **(ii)** Snap an Impression Coping onto each Abutment, ensuring each Impression Coping is seated properly. **(iii)** Align each Impression Coping to the orientation required by the prosthesis and as close to vertical as the prosthesis allows. **(iv)** Capture the position of the Impression Coping using standard impression technique. **(v)** Remove the tray and snap an Abutment Analog onto each Impression Coping. **(vi)** Pour a working model.

PROSTHESIS FABRICATION:

Laboratory Processing Technique:
(i) After the model is poured, replace the Impression Copings with the Denture Attachment Housings. **(ii)** Fabricate the prosthesis using standard laboratory techniques. A Waxing Cap may be used to facilitate the framework waxing process. **(iii)** A Processing Cap may be processed into the prosthesis for final cementation of the Denture Attachment Housing to the prosthesis, if the denture does not contain a metal framework. **(iv)** All recesses accepting the Denture Attachment Housings need to have mechanical retention grooves and should be sandblasted to increase bonding strength.
NOTE: (i) Use of any other ball besides the Processing Ball during lab fabrication may cause prosthesis damage. **(ii)** Laboratory pickup of the Denture Attachment Housings is not recommended.

Denture Attachment Housing Chair Side Pickup Technique:
(i) With the **Black** Processing Balls attached, snap a Denture Attachment Housing onto each Abutment, ensuring each Denture Attachment Housing is fully seated. **(ii)** Align each Denture Attachment Housing to the orientation required by the prosthesis. **(iii)** Drill recesses in the prosthesis to the appropriate depth and width to accommodate the Denture Attachment Housings and add relief vent holes. **(iv)** Secure the Denture Attachment Housing to the prosthesis using auto-polymerizing, light cure acrylic or composite resin.

Polishing Technique:
A Polishing Cap should be used to protect the Denture Attachment Housing interfacing surfaces during polishing procedures. Remove the Black Processing Balls and replace them with the Polishing Caps using the dedicated Retention Ball Hex Driver. Eye Protection must be worn during this procedure. Secure the Polishing Caps and proceed with the polishing procedure. When finished, unscrew the Polishing Caps and replace them with the Black Processing Balls.

Prosthesis Delivery - Prior to seating the final prosthesis intra-orally, verify the fit on the model first.
(i) Once prosthesis fit, function, phonetics and esthetics have been verified intra-orally, remove the Black Processing Balls from each Denture Attachment Housing. **(ii)** Thread the desired Retention Ball (**Green** High, **Tan** Medium or **Blue** Low) into each Denture Attachment Housing using the dedicated Retention Ball Hex Driver and lightly hand tighten. Take care not to strip the hex or threads. **(iii)** Follow the recommended Retention Ball guidelines outlined in Warnings and Precautions section above. **(iv)** Carefully place the prosthesis over the Abutments, taking care not to bend or damage the Retention Balls. Align the two most posterior Retention Balls over the Abutments, and engage them into the

abutments, first with firm hand pressure, and then using the F-Tx Seating and Removal Tool to fully seat them. **(v)** Pivot the prosthesis over the rest of the abutments and ensure that all Retention Balls are aligned within the Abutment cavities. Use firm hand pressure to start the seating process and follow up with the F-Tx Seating and Removal Tool to fully seat them. **(vi)** When highly angulated abutments are present, engage them first before engaging the rest of the Retention Balls. **(vii)** Have the patient bite on cotton rolls for further confirmation that the Retention Balls are fully seated.

HEALING PHASE:

Delayed Loading Protocols:

(i) If the F-Tx Abutments are to be seated at time of surgery, snap a Healing Cap onto the Abutment. **(ii)** Relieve the denture to ensure the Healing Cap is not in contact with any denture acrylic. **(iii)** A soft liner may be added in the recesses to ensure patient comfort during the integration phase.

Immediate Loading Protocols:

If a temporary prosthesis is to be delivered at the time of surgery, **Blue** Low, **Tan** Medium, or **Green** High Retention Balls may be used following the guidelines outlined in the Prosthetic Procedures section above and at the discretion of the clinician.

NOTE: The removal of the prosthesis prior to full implant integration with High or Medium Retention Balls could cause implant failure.

PROSTHESIS MAINTENANCE (By Clinician)

(i) Routine maintenance visits may be conducted as required for hygiene and attachment function evaluation for both the Maxilla and Mandible. **(ii)** All F-Tx Abutment cavities must be checked and cleaned prior to reseating the prosthesis with the new Retention Balls. They must be free from **ALL** debris. **(iii)** When the prosthesis is removed at recall appointments, the Abutments should be checked for tightness and if needed, appropriately retightened to the proper value. **(iv)** Retention Balls are single use only and all must be replaced each time the prosthesis is disengaged from the abutments.

NOTE: Use of plastic instruments is recommended for scaling and cleaning. Do not use metal instruments, which may cause scratches on the Abutment surface. Examine the patient for signs of inflammation around the Abutments and for implant mobility. Should a patient experience any discomfort or loss of retention of the overdenture, they should consult a dental professional.

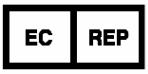
PATIENT CARE

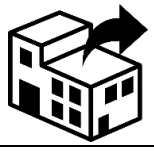
Good oral hygiene is vital to Attachment System success. The LOCATOR F-Tx Fixed Attachment System must be thoroughly cleaned each day to prevent plaque build-up. The patient should be instructed to use a soft nylon bristle or end-tufted toothbrush and super-floss to clean the Abutments. Non-abrasive toothpaste is recommended.

Further Information

Traditional restorative protocols should be followed to process the attachments into the patient's overdenture. Standard hybrid denture 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 / Annex A.15
	Do Not Resterilize	Indicates a medical device that is not to be resterilized	EN ISO 15223-1	5.2.6
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	EN ISO 15223-1	5.2.4
	Use-by date	Indicates the date after which the medical device is not to be used	EN ISO 15223-1	5.1.4
	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
	Distributor	Indicates the entity distributing the medical device in the locale	ISO 15223-1	5.1.9