ENGLISH

Instructions for Use

The LOCATOR® Overdenture Implant System includes: Dental Implants, LOCATOR® Attachments and surgical, restorative and dental laboratory components.

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

DESCRIPTION - The LOCATOR Overdenture Implant System is comprised of a 2.4, 2.9, 3.5, 3.9, 4.4, or 4.9mm diameter endosseous dental implant (available in 10, 12, & 14mm lengths. 3.5, 3.9, 4.4, and 4.9mm diameter implants also available in 8mm length) with a detachable LOCATOR® universal hinge resilient attachment available in a 2.5, 3, 4, 5, or 6mm cuff height and healing cap for two stage surgery available in a 3 or 4mm cuff height. The processing pack includes a denture cap, processing insert, retention males, and a block out spacer. The surgical tools and instruments that are used with the LOCATOR Overdenture Implant System include: surgical drills (available in a Starter Drill, 1.6, 1.8, 2.1, 2.4, 2.6, 2.9, 3.2, 3.6, 4.1, and 4.6mm diameters), cortical drills (available in 3.3, 3.7, 4.3, and 4.8mm diameters) drill stops (available in 4, 6, 8, 10, 12, and 14mm lengths), drill extender, tissue punch, direction indicator, implant latch driver, implant drivers (short and long), implant overlay, kit orientation schematic and surgical trays (standard and premium). The LOCATOR Overdenture Implant System is used to restore masticatory function for the patient and may be suitable for immediate function if sufficient primary stability of the implant is achieved at the time of placement.

INDICATIONS FOR USE - The LOCATOR Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. Immediate loading is indicated when good primary stability has been achieved and with appropriate occlusal loading.

CONTRAINDICATIONS - Not appropriate where a totally rigid connection is required. Use of a single implant with divergence of greater than 20 degrees is not recommended. 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 - A person with an implant or abutment device of the Zest Dental LOCATOR® Overdenture Implant 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 Overdenture Implant System in its undamaged, original packaging is not subject to any special considerations for storage or handling (during transport and storage).

WARNINGS AND PRECAUTIONS - Practitioners must have adequate knowledge of dental implantology and education

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in overdenture restorations when handling the Zest Dental Solutions product to ensure they use the product safely as recommended in these instructions for use.

The products of the LOCATOR® Overdenture Implant System are made of various materials and patients should be evaluated for allergies or hypersensitivity to such materials prior to treatment. The LOCATOR® Implants and abutments are made from the titanium alloy Ti-6Al-4V. The abutments have a Titanium Nitride (TiN) coating. Restorative components are made from Ti-6AL-4V 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, silicone, Radel® (polyphenylsulfone), or coatings containing Titanium Carbon Nitride (TiCN), Aluminum Titanium Nitride (AlTiN), Diamond Like Carbon (DLC), Epoxy, or Enamel.

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 sterilized packaging must not be used on patients. In the event that the sterilized packaging for the LOCATOR Overdenture Implant is damaged, the damaged packaging (with the product) must be returned to the manufacturer and a replacement will be provided (if damage to sterilized packaging is caused by product shipment).

If the LOCATOR implants are subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue and / or localized bone failure.

As surgical instruments are susceptible to damage and wear, they should be inspected before each use. Any reusable instrument should be replaced if damage is present. 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 and instruments wet). Drills and cutting instruments will dull based on similar factors including bone density, handling, and use. Avoid application of excessive bending load on smaller diameter drills during the drilling procedure. The drill extender is to be used with surgical drills only and should not be used in high torque applications. When applicable to the surgical instrument, check the latch lock shank for wear to ensure the connection is not damaged. Over time, repeat sterilization may affect cutting efficiency and appearance. Any cutting edges should present a continuous edge and appear sharp. Markings should be visible and legible. Replace drills when wear is noticeable to avoid excessive heat being transferred to the surrounding bone during osteotomy preparation. For disposal of damaged drills and cutting instruments it is recommended to place them in a sharps disposal container to avoid possible injury. Used sharps disposal containers should be disposed of according to local community guidelines.

DIRECTIONS FOR USE - Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation towards good dental care, and anatomic acceptability prior to implant surgery is critical. Thorough evaluation of the patient's medical status and health history is mandatory. Panoramic and periapical radiographs, as well as thorough oral inspection and palpation are recommended to determine anatomical landmarks, dental pathology, and adequacy of bone. A cephalogram is suggested for totally edentulous patients. Any oral condition that adversely affects natural teeth, if uncorrected, will have an adverse effect on the success of the implants.

Small diameter implants should be avoided in the posterior region of the mouth whenever possible due to the higher mastication forces present. Periodontal disease, abnormal bone conditions, severe bruxism, cross-bite situations, and extenuating circumstances (e.g. excessive smoking, medical issues, etc) that may adversely affect the outcome must be evaluated and corrected if necessary, or use of the implant may be contraindicated.

SURGICAL PREPARATION - Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate implant (determine correct implant diameter and length based on bone type and patient anatomy; an implant overlay has been provided in the surgical kit to aid), restorative parts, and tools. Refer to drilling sequence section for further details. The clinician should also determine if the patient is allergic to any of the materials that will be used in the procedure as part of the pre-surgical treatment planning. If during patient evaluation, insufficient bone width and height, abnormal bone defects or contours are detected, then the placement of the implant may be contraindicated.

Patient motivation is a key factor in achieving success with any implant. The patient must be willing to practice the oral

hygiene necessary for implant maintenance. The clinician must provide the patient with information regarding proper care and maintenance of the implants. Also, they must inform the patient that conditions such as excessive smoking, improper/lack of maintenance may have adverse effects.

The use of this or any surgical implant 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 the instruments, and surgical procedures required (as described in this document). The clinician must also use reasonable judgment in deciding when and where to use the product.

SINGLE-USE DEVICES - The LOCATOR Overdenture Implant System is a single-use device, and the LOCATOR Overdenture Implant is provided 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. Zest Dental Solutions is not responsible for re-sterilized implants regardless of the re-sterilization method and/or party who re-sterilized.

LOCATOR Overdenture Implant: A previously used LOCATOR implant could contain patient contamination build-up. Therefore, the inadvertent re-use of this device could result in infection leading to lack of integration (of the implant to the bone).

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 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 Overdenture Implant 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 AND DRILLS: The LOCATOR Overdenture Implant System tools and drills 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 Overdenture Implant packaged together with the LOCATOR attachment are supplied STERILE (subjected to gamma irradiation) and must not be re-sterilized. All other restorative components, instruments, and replacement LOCATOR attachments (sold separately) are supplied NON-STERILE. Tools and instruments provided non-sterile should be sterilized prior to use on patients. Reusable tools and instruments should be cleaned according to applicable instructions from the device manufacturer. The nylon males may be sterilized/disinfected using a liquid chemical sterilant. In order to ensure that the nylon males are sterilized/ disinfected (all microorganisms including clostridium sporogenes and bacillus subtilis spores are eliminated) the nylon males must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.

Instruments and Individually Packaged Replacement Attachments

(i) Disassemble any instruments that can be disassembled according to manufacturers' instructions. **(ii)** Soak instruments in enzymatic cleaning solution (mixed according to manufacturers' instructions) by completely submerging them for 20 minutes. Scrub instruments 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 instruments (such as the tissue punch, drill extender, implant drivers, and disassembled core tool and ratchet torque wrench) that have difficult to reach areas. **(iv)** Place instruments in sonication bath (with enzymatic cleaning solution prepared according to manufacturers' instructions) making sure that they are completely submerged, and sonicate for 10 minutes. **(v)** Remove the instruments from the sonication bath, 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.

Surgical Tray Cleaning Instructions

(i) Rinse the surgical tray and tray insert with tap water. **(ii)** Place the surgical tray and tray insert in enzymatic cleaning solution (mixed according to manufacturers' instructions) and wipe off soil with a clean, absorbent, non-shedding wipe. Allow the surgical tray and tray insert to soak in the cleaning solution for 20 minutes making sure that they are completely submerged. **(iii)** Remove the surgical tray and tray insert from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes. Make sure to thoroughly flush each piece to completely remove cleaning residue. **(iv)** Remove excess moisture from the surgical tray and tray insert with a clean, absorbent, and non-shedding wipe.

Steam Sterilization Instructions - The validation procedures require the use of FDA-cleared sterilizers, sterilization trays, sterilization wraps, biologic indicators, chemical indicators and other sterilization accessories labeled for the sterilization cycle recommended. The health care facility should monitor the sterilizer according to an FDA recognized sterility assurance standard such as ANSI/AAMI ST79:2006.

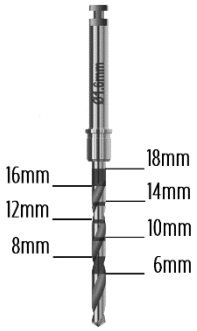
Tools and drills (instruments) may be sterilized by autoclave sterilization using the following parameters. Prior to sterilization, surgical kits are to be populated per L7013 or L8053 (kit orientation schematic). Additional drills, listed below, are to be sterilized separately from the 7421 and 7422 surgical kits. 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, re-sterilization is recommended for reusable devices only. Single use devices should not be re-sterilized.

Surgical Kits: For gravity cycle, place in a 10"x 15" autoclave bag; and for pre-vacuum cycle, double wrap the kit with autoclave wrap material and secure wrap with autoclave tape.

Additional Drills: For gravity cycle, place in an autoclave bag; and for pre-vacuum cycle, double wrap drills with autoclave wrap material and secure wrap with autoclave tape.

Autoclave Sterilization Parameters are listed below:

Cycle Type	Part Number	Description	Temperature	Exposure Time	Drying Time
Gravity	7421, 7561	Standard Surgical Kit	132°C / 270°F	15 Minutes	30 Minutes
	7375, 7369, 7370, 7377	Additional Drills			
	7422, 7564	Premium Surgical Kit	132°C / 270°F	25 Minutes	30 Minutes
Pre-Vacuum	7421	Standard Surgical Kit	132°C / 270°F	4 Minutes	20 Minutes
	7422	Premium Surgical Kit			
	7375, 7369, 7370, 7377	Additional Drills			
	7561, 7564	Standard and Premium Surgical Kit			30 Minutes



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

SURGICAL and PROSTHETIC PROCEDURES

Preoperative Treatment Planning - Utilize radiographic imaging to examine the amount of available bone to determine

which implant diameter, length, quantity of implants and proper positioning.

Drilling Protocol - Ample amounts of irrigation should be used during drilling steps. Drill to the proper laser depth marking on the drill for the implant selected per the drilling sequence in the table and shown in the picture below. Continue osteotomy preparation to the appropriate drilling depth at each implant site. The use of this or any surgical implant 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 the instruments, and surgical procedures required (as described in this document). The clinician must also use reasonable judgment in deciding when and where to use the product.

Implant ø (mm)	Bone Density	DRILLS											CORTICAL DRILLS			
		Starter	1.6	2.1	2.4	2.6	2.9	3.1	3.2	3.6	4.1	4.6	3.3	3.7	4.3	4.8
2.4	D1	o	●	●	o											
	D2, D3, D4	o	◓	o												
2.9	D1	o	●		●	o										
	D2, D3, D4	o	●	◓	o											
3.5	D1	o	●		●				●				o			
	D2, D3, D4	o	●		◓	o										
3.9	D1	o	●		●					●				o		
	D2, D3, D4	o	●		●		◓	o								
4.4	D1	o	●		●				●		●				o	
	D2, D3, D4	o	●		●					◓	o					
4.9	D1	o	●		●				●			●				o
	D2, D3, D4	o	●		●				●		◓	o				

Key: ●Full implant depth ◓4mm short of full implant depth oOptional

NOTE: ***Recommended drilling speed is 800-1200 RPM. Do not to exceed a maximum of 800 RPM when utilizing the Tissue Punch.***

Implant Insertion - A LOCATOR Overdenture implant can be placed with a torque indicating ratchet or a surgical hand piece. The speed of insertion should not exceed 50rpm. Implant insertion torque should not exceed 70Ncm.
Follow the D2/D3/D4 drilling sequence prior to following the D1 drilling sequence. This offers the flexibility to adapt the drilling protocol to the patient's bone quality. For D1 bone density, an optional cortical drill may be used as the final drilling sequence step for the 3.5, 3.9, 4.4, or 4.9mm diameter implant.
If strong resistance occurs before the implant reaches its final desired position, rotate the implant counterclockwise and then continue to insert. Repeat until the final desired position is obtained. The next drill size up or cortical drill (if available) may also be used if strong resistance occurs before the implant reaches its final desired position.

Healing Phase - Zest Dental Solutions LOCATOR Overdenture implants may be suitable, within the defined indications, for immediate function if sufficient primary stability of the implant is achieved at the time of placement.
In the instance of immediate function: final seating torque of the implant must measure 30 Ncm or above. Implant insertion torque should not exceed 70Ncm. The abutment should be torqued to 30Ncm if insertion torque of the implant reaches a minimum of 30Ncm.
For delayed loading protocols: use a .050 inch (1.25mm) Hex Driver to deliver and thread the LOCATOR Overdenture Implant healing cap onto the implant until finger tight. Relieve the denture to ensure the healing cap is not in contact with any denture acrylic. A soft liner may be added to the denture to ensure patient comfort during the integration phase.

PATIENT CARE & RECALL APPOINTMENTS

Patient Care - Good oral hygiene is vital to attachment success.

(i) 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 and floss to clean 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 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 attachments and may reduce the longevity of the retention 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. 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. Cleaning is recommended.

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

(i) 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. **(ii)** Patients who soak their overdenture in a cleaning solution, must do so for 15 minutes only. Solutions such as Polident® and Efferdent® must be used. **(iii)** Do not soak overdentures overnight. Excessive soaking could negatively impact the Retention Inserts' performance.

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.

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Manufacturer	Indicates the medical device manufacturer	ISO 15223-1	5.1.1
	Authorized Representative in the European Community/ European Union	Indicates the authorized representative in the European Community/European Union	ISO 15223-1	5.1.2
	Catalogue Number	Indicates the manufacturer's catalogue number so that the medical device can be identified	ISO 15223-1	5.1.6

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Batch Code	Indicates the manufacturer's batch code so that the batch or lot can be identified	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	ISO 15223-1	5.4.2
	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use	ISO 15223-1	5.4.3
	Consult Electronic Instructions for Use	Indicates the need for the user to consult the instructions for use	ISO 15223-1	5.4.3 / Annex A.15
	Do Not Resterilize	Indicates a medical device that is not to be resterilized	ISO 15223-1	5.2.6
	Non-Sterile	Indicates a medical device that has not been subjected to a sterilization process	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	ISO 15223-1	5.1.4
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Country of manufacture	To identify the country of manufacture of products. The "CC" shall be replaced by either the two-letter country code or the three letter country code of the place where the product was originally made.	ISO 15223-1 ISO 3166-1	5.1.11
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened	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
	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)

SYMBOL	TITLE	EXPLANATORY TEXT	STANDARD	REFERENCE
	Quantity	Indicates the number of items within the package	N/A	N/A
	Unique Device Identifier	Indicates as containing Unique Device Identifier information	ISO 15223-1	5.7.10
	Medical device	Indicates the item is a medical device	ISO 15223-1	5.7.7
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation	ISO 15223-1	5.2.4
	Single *sterile* barrier system with protective packaging inside	Indicates a single *sterile* barrier system with protective packaging inside	ISO 15223-1	5.2.13
	MR Conditional	An item with demonstrated safety in the MR environment within defined conditions	ASTM F2503 EN 62570	Table 2