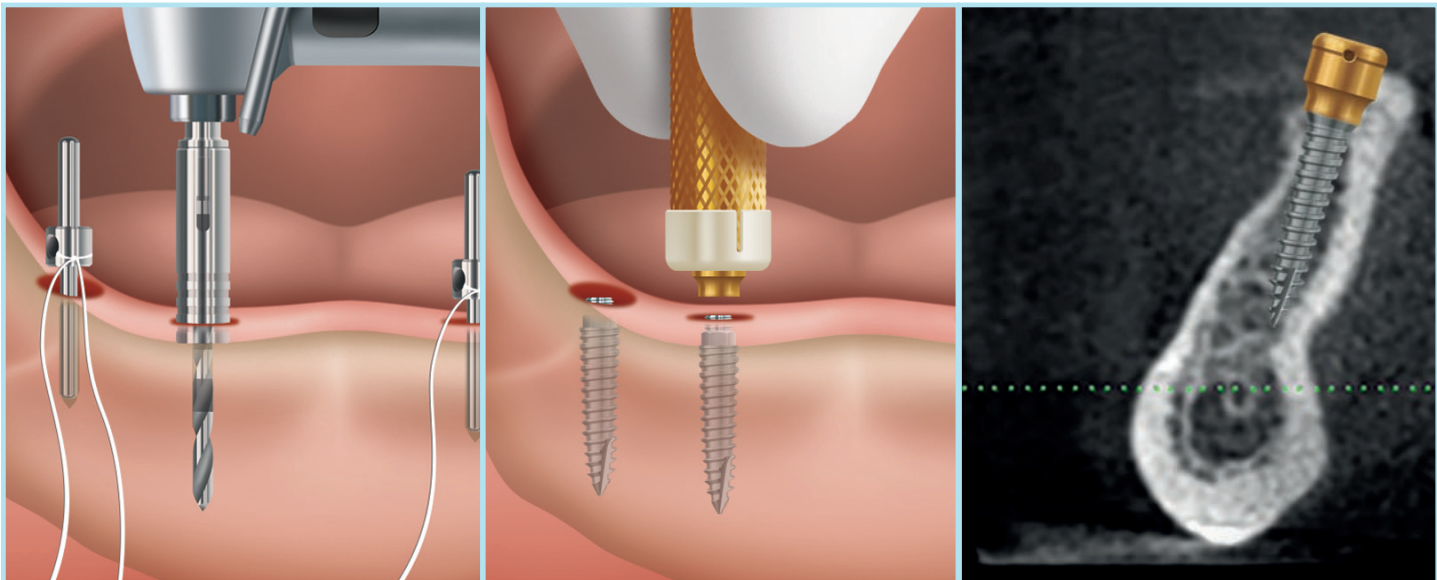



LOCATOR®
OVERDENTURE IMPLANT SYSTEM

THE LOCATOR® OVERDENTURE IMPLANT SYSTEM



TECHNIQUE MANUAL



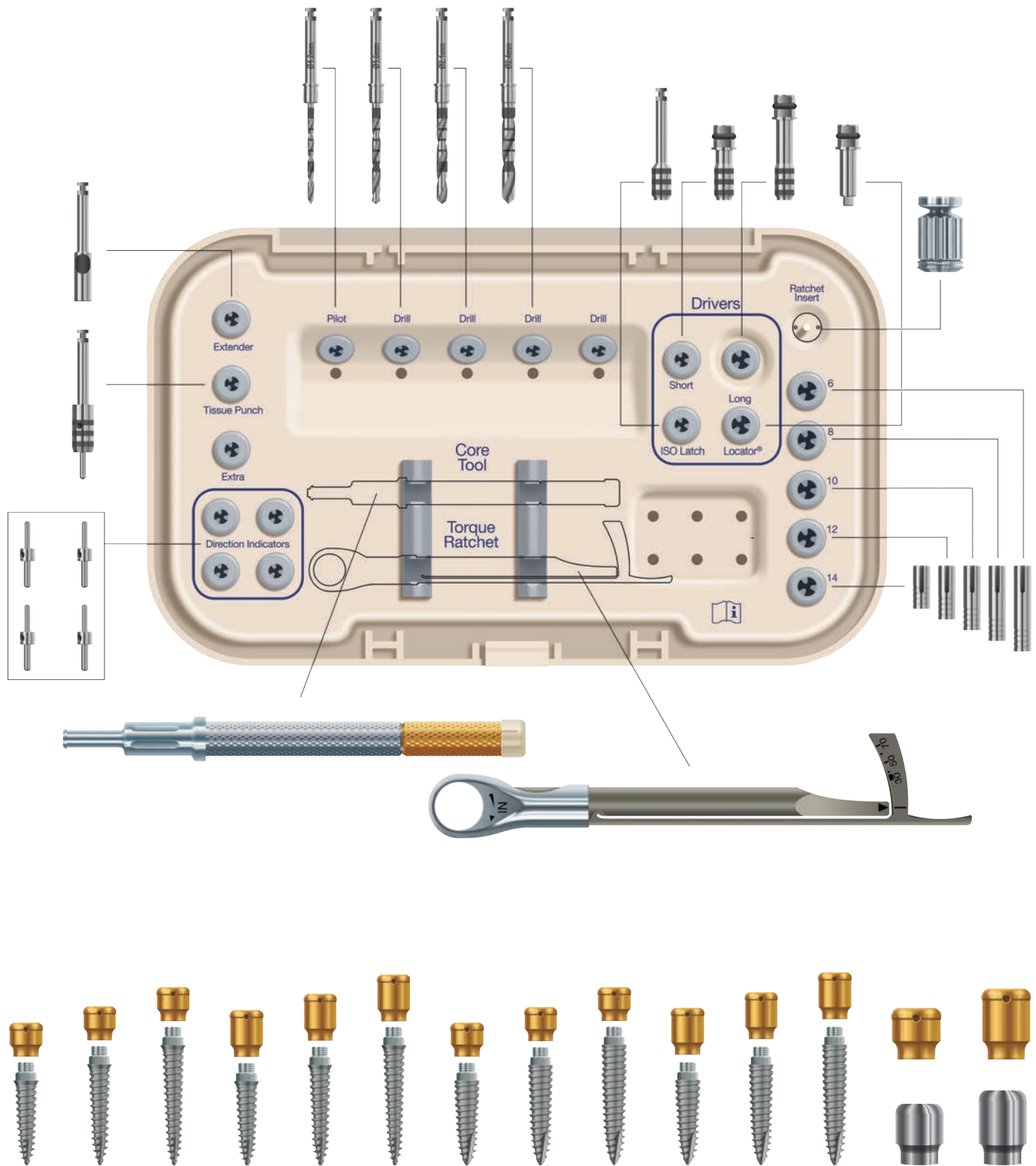
THE LOCATOR® OVERDENTURE IMPLANT SYSTEM.

FOUR DECADES OF ATTACHMENT
KNOWLEDGE INCORPORATED
INTO OVERDENTURE IMPLANTS.

The LOCATOR Overdenture Implant (LODI) System is comprised of 2.4 and 2.9mm diameter dental implants (available in 10, 12 and 14mm lengths) with a detachable LOCATOR Abutment that is available in a 2.5 and 4mm cuff height. The LODI 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. The final treatment option may be determined at the time of surgery as the clinician must consider the quality of supporting bone and initial insertion torque values of the implants. Immediate function is determined on a case-by-case basis and at the discretion of the clinician.

IMPORTANT: THIS DOCUMENT IS DESIGNED TO SERVE AS A REFERENCE GUIDE FOR DENTAL CLINICIANS USING ZEST ANCHORS PRODUCTS. IT IS NOT INTENDED TO BE A SUBSTITUTE FOR PROFESSIONAL TRAINING AND EXPERIENCE. PLEASE REFER TO THE INSTRUCTIONS FOR USE FOR FURTHER INFORMATION.

THE LOCATOR® OVERDENTURE IMPLANT (LODI) SYSTEM



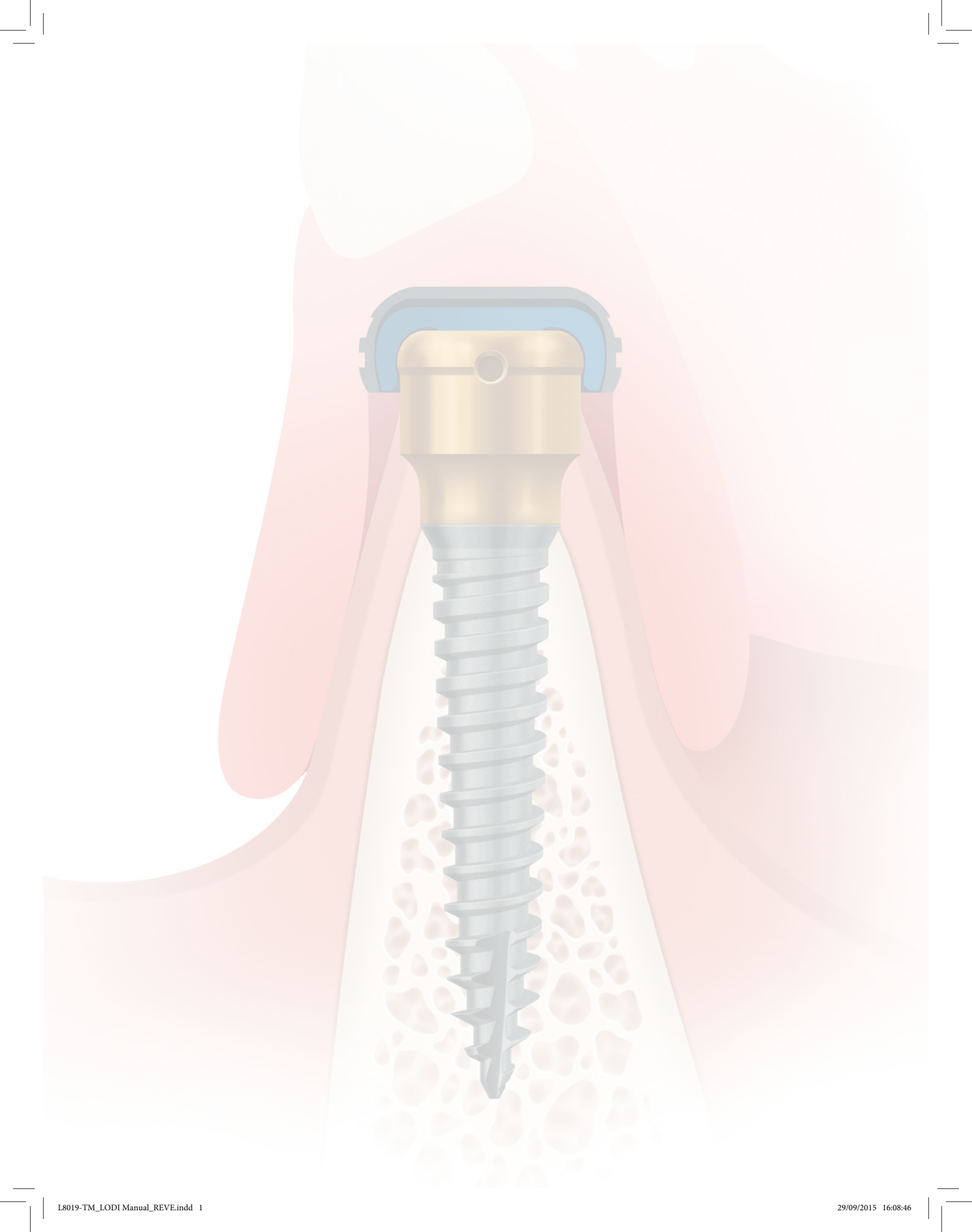


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THE LOCATOR® OVERDENTURE IMPLANT (LODI) SYSTEM OVERVIEW

1 The LOCATOR Retention Insert self-aligns and pivots inside the Denture Attachment Housing providing a genuine resilient connection that holds-up to patient mastication forces while providing attachment durability

2 The LOCATOR Abutment's dramatically reduced vertical height provides patient comfort when the denture is removed, as well as increased denture strength as compared to O-Ball attachments

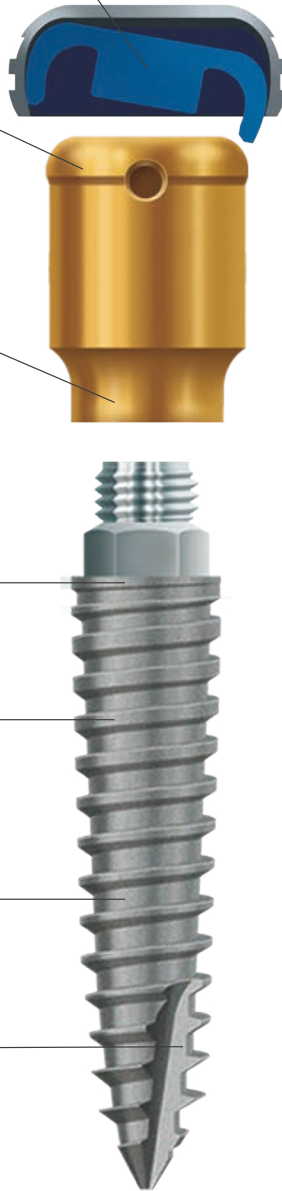
3 LOCATOR Abutment is available in 2.5 and 4mm cuff heights for implant placement flexibility, attachment interchangeability and replacement should wear occur over time

4 Proven RBM roughened surface on the entire length of the implant

5 Progressive thread design that widens at the coronal portion providing primary stability when immediate loading may be indicated

6 Available in 2.4 and 2.9mm diameters and 10, 12 or 14mm lengths for placement in all ridges

7 Self-tapping design for ease of implant insertion and increased implant stability



ALL INCLUSIVE PACKAGE CONTAINS

- 1 Implant
- 1 LOCATOR Abutment
- 1 LODI Processing Pack

Each Processing Pack has what you need to select retention levels and address draw correction; improving ease of denture placement and removal



Cuff Heights
2.5 or 4mm



Implant Diameters
2.4 or 2.9mm



LODI Male
Processing Pack

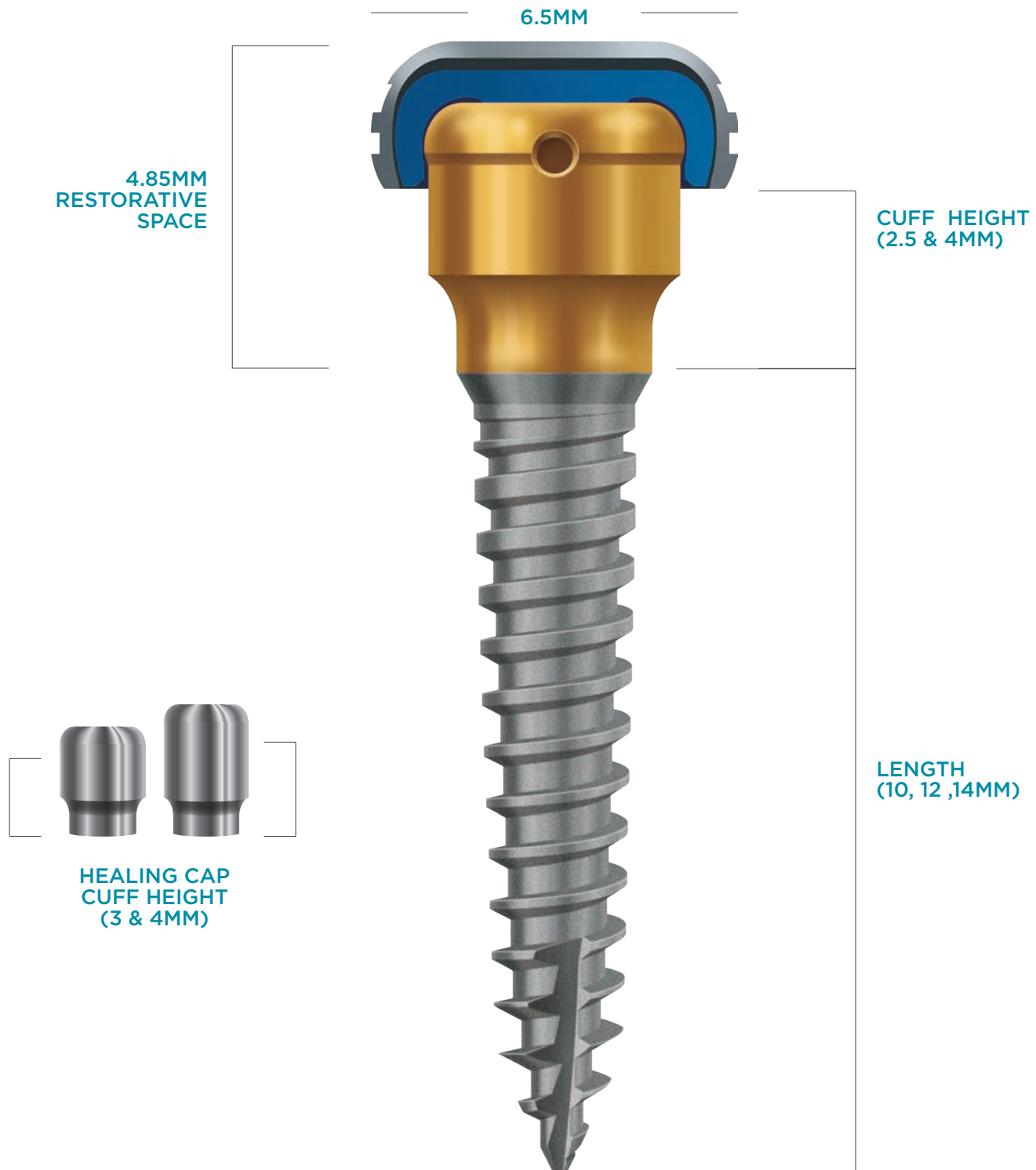
INCLUDED IN THE PROCESSING PACK



LODI DIMENSIONS

INTER-PROXIMAL SPACE

(ZEST RECOMMENDS 7MM BETWEEN IMPLANTS)

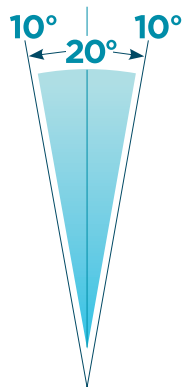
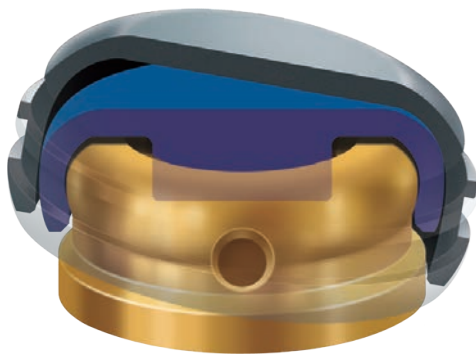


LOCATOR[®] STANDARD & EXTENDED RANGE INSERTS

THE MAGIC IS IN THE PIVOT, IT ALLOWS FOR A RESILIENT CONNECTION OF THE PROSTHESIS AND PREVENTS DAMAGE TO INSERTS DURING INSERTION.

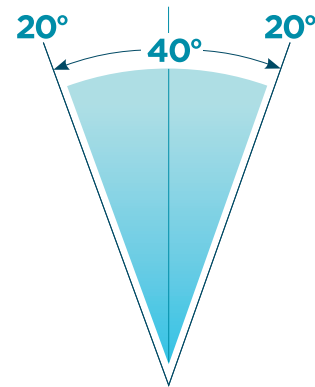
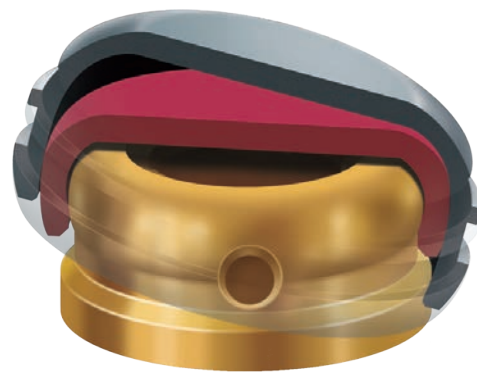
STANDARD INSERTS

Dual retention to maximize stability and pivoting action that accommodates up to 20° divergence between two implants.



EXTENDED RANGE INSERTS

Pivoting action accommodates up to 40° of total divergence between two implants.



Extra Light Retention



Light Retention



Regular Retention



Zero Retention



Extra Light Retention



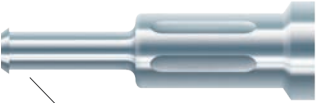
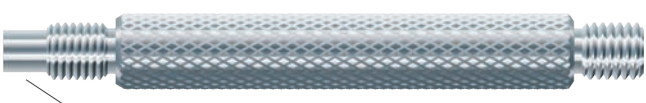
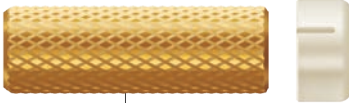
Light Retention



Regular Retention

LOCATOR® 3-IN-1 CORE TOOL

This convenient tool is used to carry and place the LOCATOR Abutment onto the implant, and for removal and insertion of the Inserts from/into the Denture Attachment Housing. In order to achieve 30Ncm of torque, the Abutment Driver portion of the tool is compatible with various types of insert drivers.

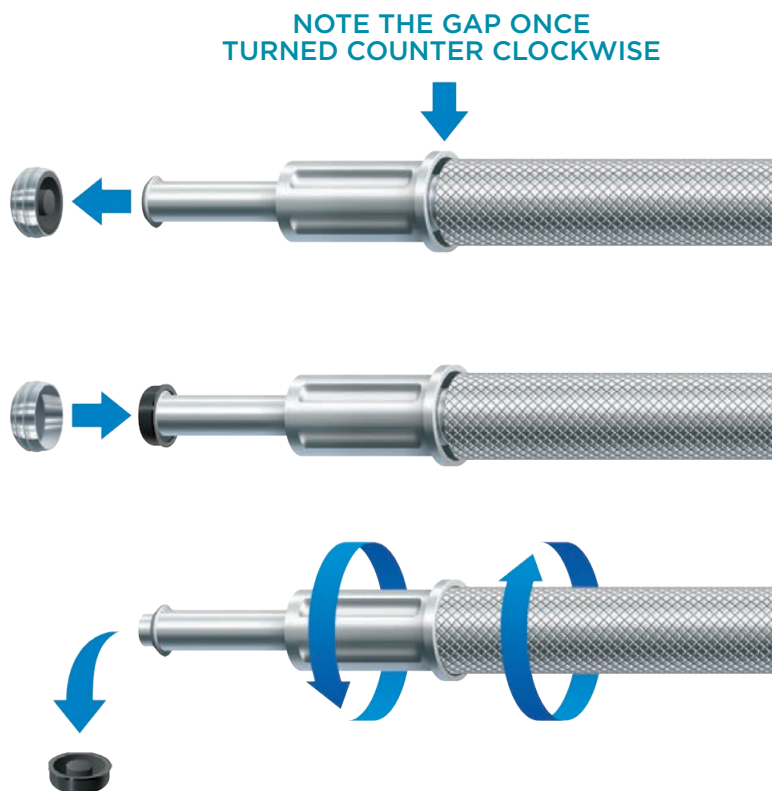
<p>REMOVAL TOOL</p>  <p>1</p> <p>REMOVAL</p> <p>The Insert Removal Tool has a sharp edge on the end to engage and remove the insert from the Denture Attachment Housing.</p>	<p>INSERTION TOOL</p>  <p>2</p> <p>INSERTION</p> <p>The Insert Seating Tool is used to seat the LOCATOR Insert.</p>	<p>ABUTMENT DRIVER & SLEEVE</p>  <p>3</p> <p>PLACEMENT</p> <p>The Abutment Driver with the Abutment Holder Sleeve carries the Abutment securely and places it onto the implant.</p>
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Loosen the Insert Removal Tool a full 3 turns counter clockwise (you will see a visible gap).

To remove a LOCATOR Insert from the Attachment Housing, simply insert the tip into the Housing/Insert assembly and push straight into the bottom of the Insert. Then, tilt the tool so that the sharp edge of the tip will grab hold of the Insert and pull it out of the Denture Attachment Housing.

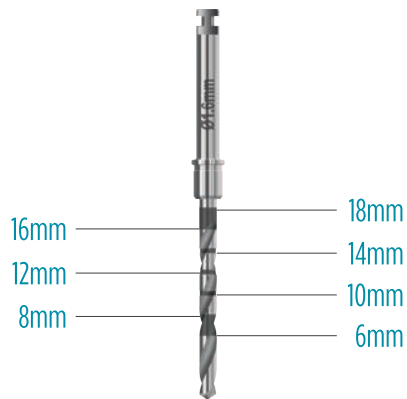
To disengage the Insert from the tip of the Core Tool; point the tool down and away from you and tighten the Removal Tool clockwise back onto the Core Tool. This will activate the removal pin and disengage the Insert from the tip of the Removal Tool.

Separate the Removal Tool section from the LOCATOR Core Tool and use the Seating Tool end to place a new Insert into the empty Denture Attachment Housing.



DRILLING DEPTH CONTROL & SEQUENCE EXAMPLES

DRILL LASER DEPTH MARKINGS



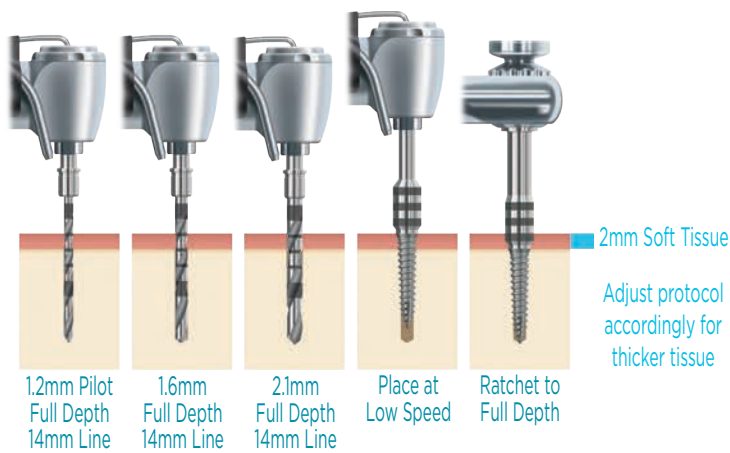
DRILL STOPS



PLACEMENT OF A 2.4MM X 12MM IMPLANT FLAPLESS SURGICAL PROCEDURE

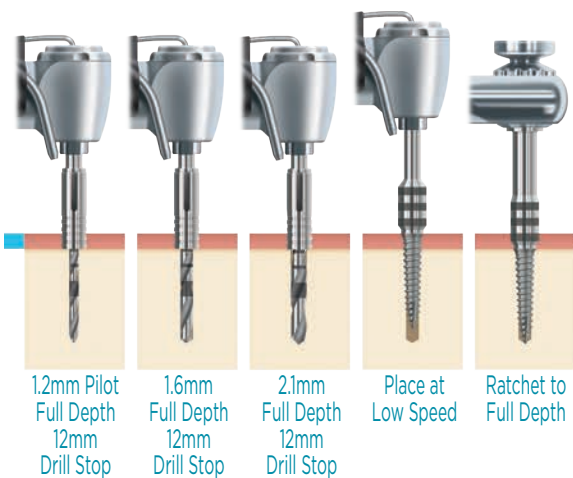
2.4MM LASER DEPTH MARKINGS

D1 BONE TYPE

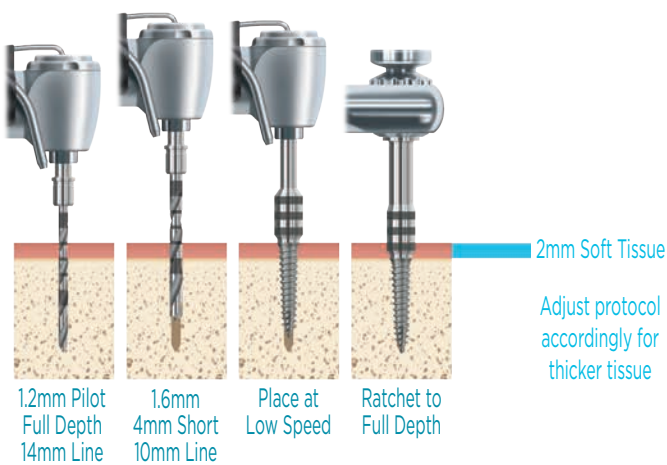


2.4MM DRILL STOPS

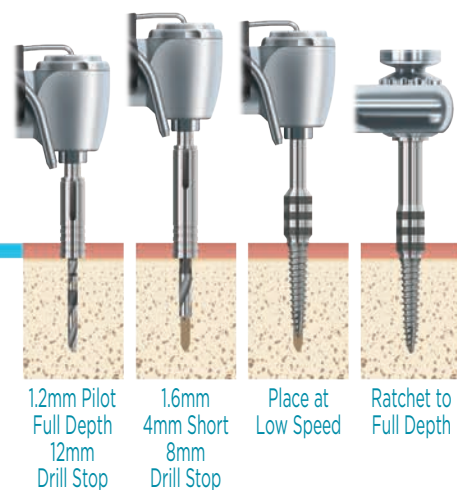
D1 BONE TYPE



D2/D3/D4 BONE TYPE



D2/D3/D4 BONE TYPE



DRILLING DEPTH CONTROL & SEQUENCE EXAMPLES (CONTINUED)

FINAL DRILL DIAMETER & DEPTH FOR VARIOUS BONE TYPES

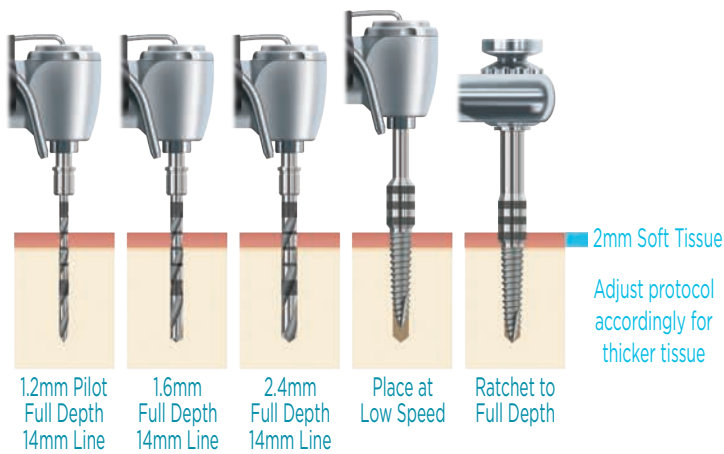
BONE TYPE	2.4MM IMPLANT DIAMETER		2.9MM IMPLANT DIAMETER	
	FINAL DRILL DIAMETER	DRILL DEPTH	FINAL DRILL DIAMETER	FINAL DRILL DIAMETER
D1	2.1mm	Full Depth	2.4mm	Full Depth
D2 / D3 / D4	1.6mm	Depth 4mm < Implant Length	2.1mm	Depth 4mm < Implant Length

Bone type is a general classification. The overall bone quality must be assessed by the clinician through treatment planning and at the time of surgery in order to create the appropriate osteotomy size to achieve the desired insertion torque.

PLACEMENT OF A 2.9MM X 12MM IMPLANT FLAPLESS SURGICAL PROCEDURE

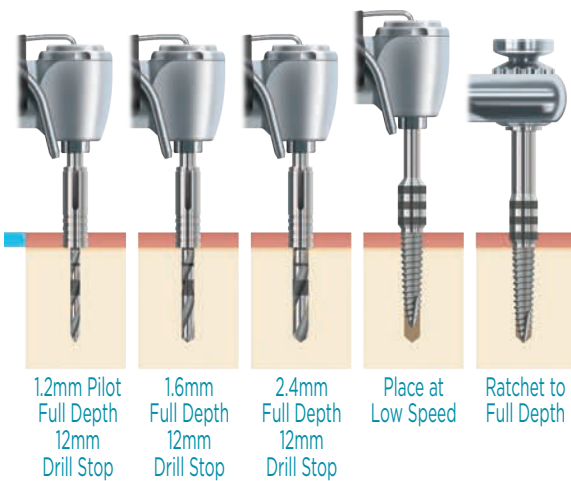
2.9MM LASER DEPTH MARKS

D1 BONE TYPE

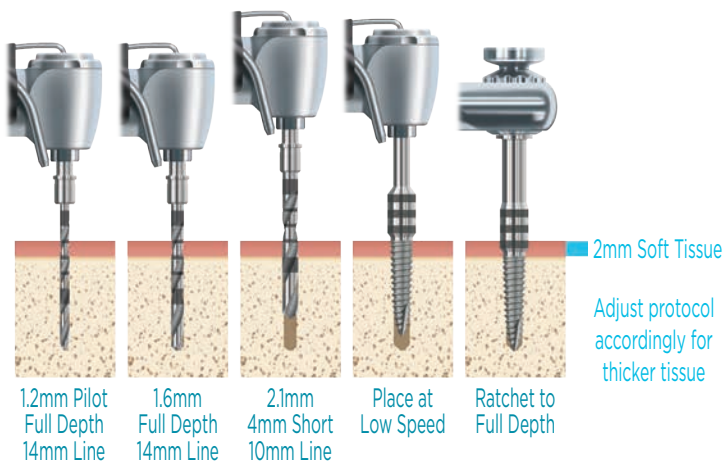


2.9MM DRILL STOPS

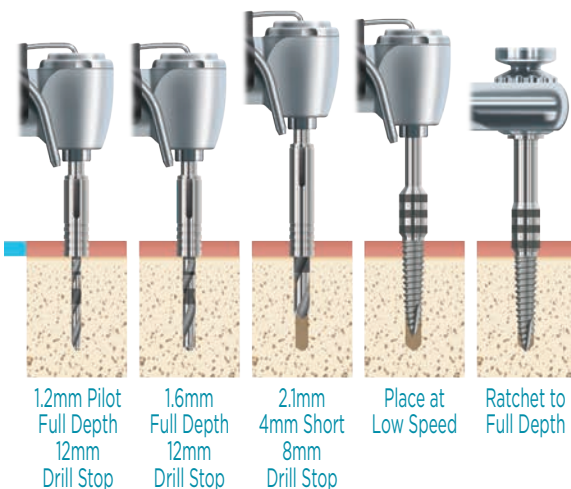
D1 BONE TYPE



D2/D3/D4 BONE TYPE

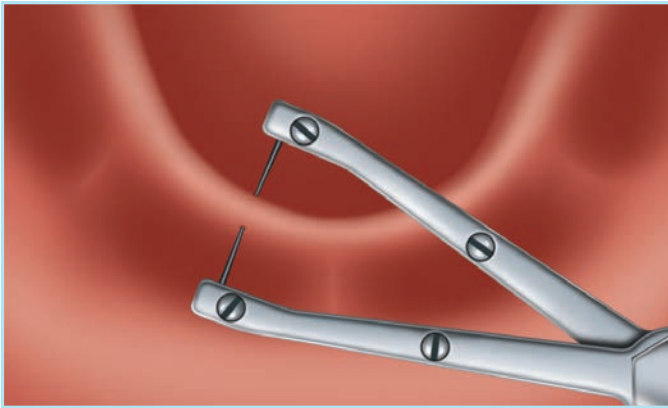


D2/D3/D4 BONE TYPE

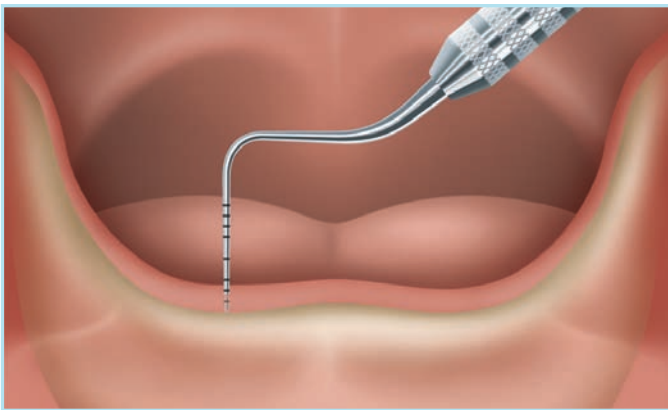


EXTERNAL IRRIGATION IS REQUIRED DURING THE DRILLING STEPS

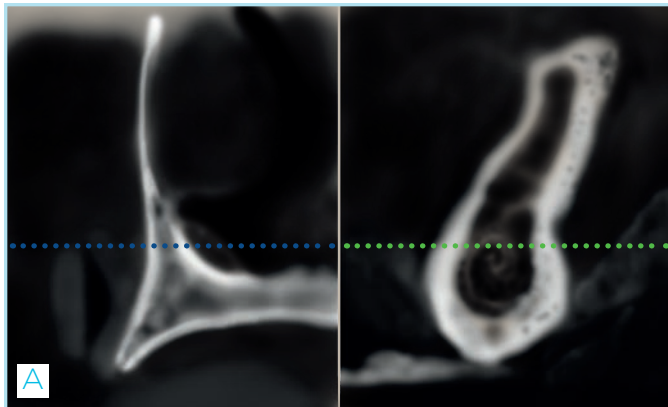
PRE-OPERATIVE TREATMENT PLANNING



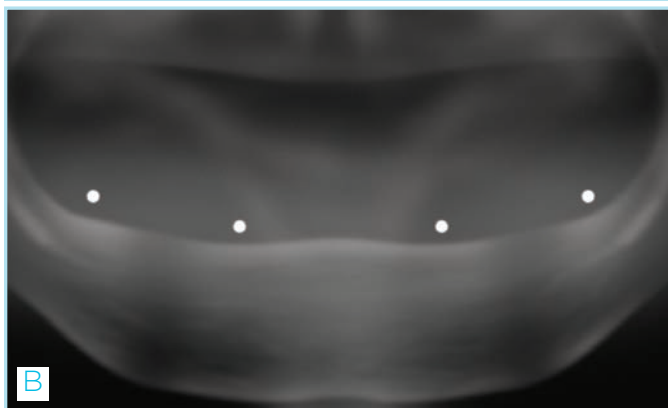
1 Evaluate available bone width at desired implant positions by using the index finger/thumb technique or a ridge mapping instrument (which can be purchased through most dental instrument companies).



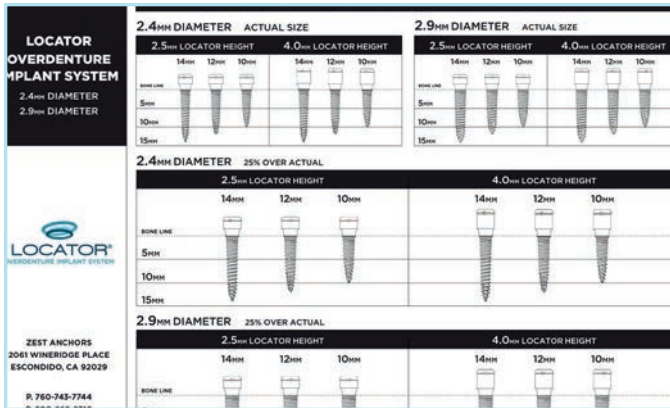
2 Measure gingiva height at each planned implant location using a periodontal probe to determine the proper LOCATOR® Abutment cuff height.



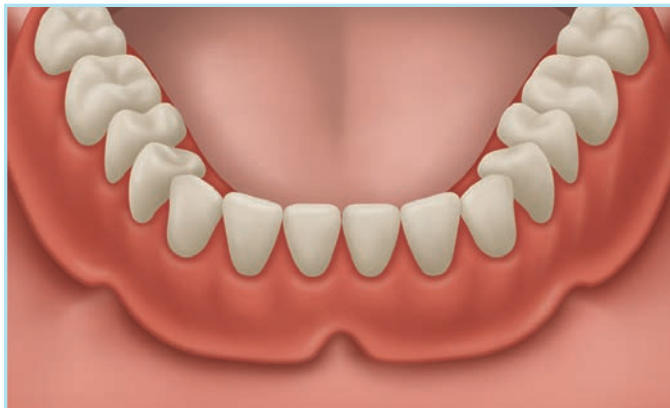
3A-3B A panoramic radiograph or CBCT with radiographic markers may be used to evaluate the bone topography and determine the appropriate implant positions.



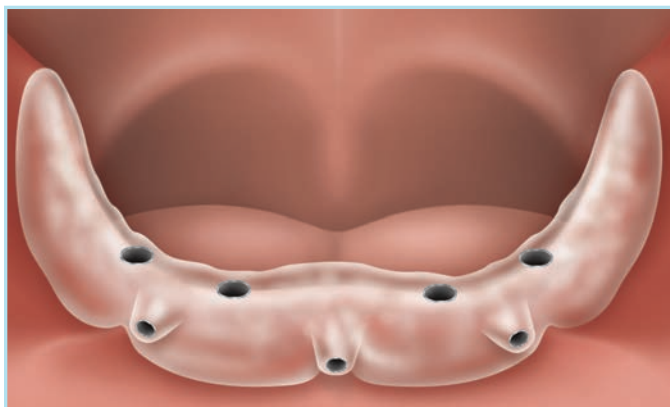
PRE-OPERATIVE TREATMENT PLANNING (CONTINUED)



4 Radiographic overlay templates are available from ZEST Anchors (L7012) to assist in choosing the correct implant size. ZEST recommends placement of the LOCATOR® Overdenture Implants where patients have at least 1mm of available bone around the circumference of the implant.



5 Determine if the patient's existing denture(s) will be used or if new ones will be fabricated. If a new denture is fabricated, follow the standard denture fabrication protocols. Instruct the patients to wear the new denture for a minimum of two weeks prior to implant placement.

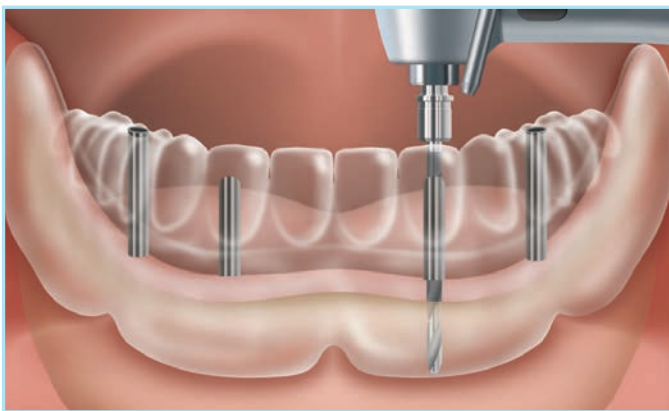


6 Optional: A surgical guide for implant placement may be fabricated prior to surgery.

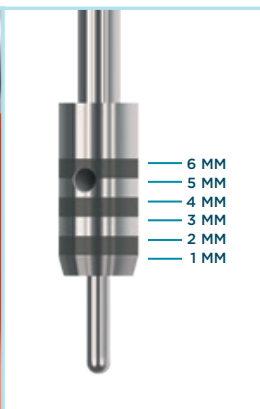
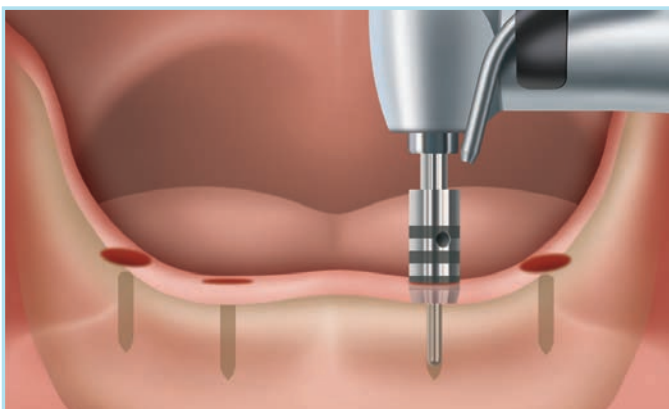
IMPLANT PLACEMENT

After patient selection and evaluation protocols have been completed, determine the number of implants required and discuss all treatment options with the patient. ZEST Anchors recommends a minimum of four implants to be placed in the mandible and six in the maxilla.

MANDIBULAR PLACEMENT OF FOUR **2.9MM X 10MM** IMPLANTS SHOWN IN TYPE D1 BONE

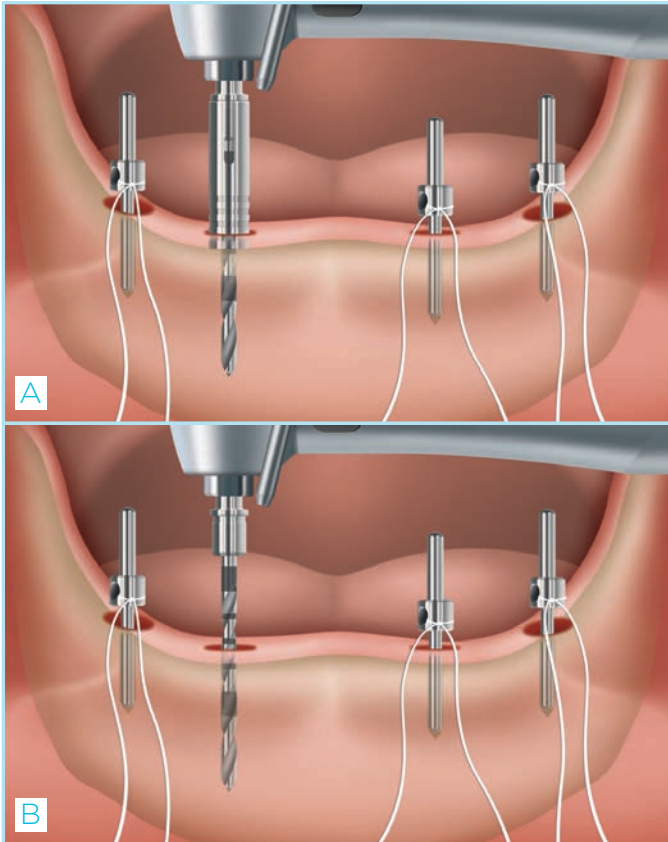


1 Using a surgical guide or by free hand, mark the implant osteotomy locations using the 1.2mm Pilot Drill (07366) to drill through the gingiva and into the bone crest 6mm. Note the gingival height. The recommended drilling speed is 800-1200rpm.



2 Remove the gingival cores at each site using the Rotary Tissue Punch (07373). Place the guide pin portion of the Rotary Tissue Punch into the pilot drill osteotomy and advance the drill unit to cut away the gingiva. Advance the Rotary Tissue Punch to the laser depth mark corresponding to the gingival height measurement. The recommended drilling speed is up to a maximum of 800rpm.

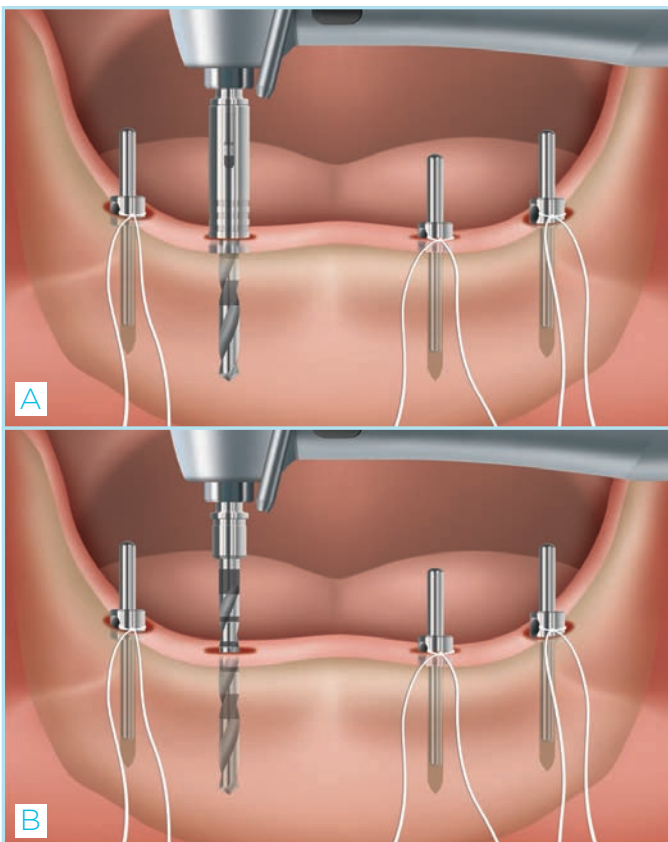
IMPLANT PLACEMENT (CONTINUED)



MANDIBULAR PLACEMENT OF FOUR **2.9MM X 10MM** IMPLANTS SHOWN IN TYPE D1 BONE (CONTINUED)

3A-3B Place the 1.2mm diameter (small) end of the Direction Indicator (07365) into the pilot drill osteotomies to verify the proper alignment. Attach the proper length Drill Stop onto the 1.2mm Pilot Drill according to the desired drilling depth.

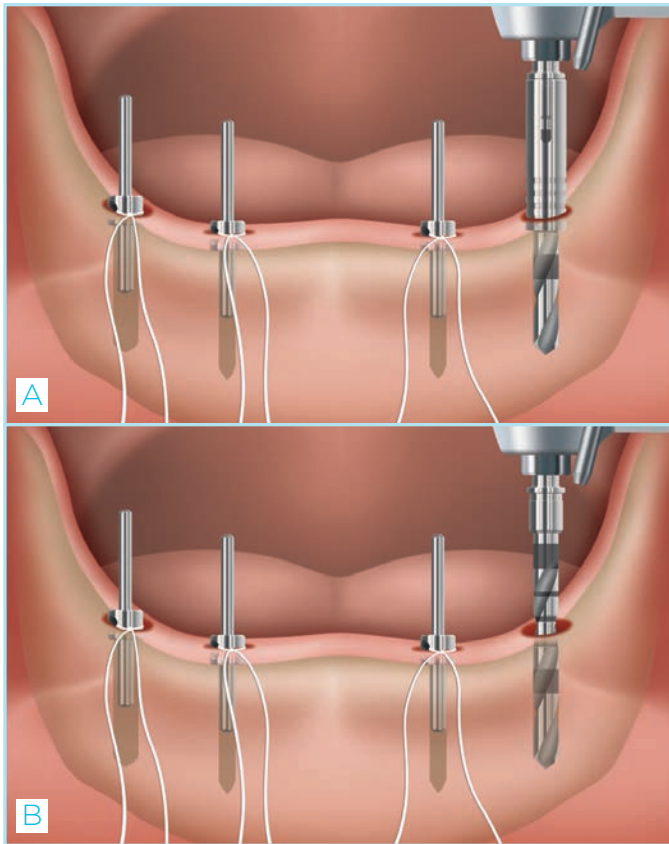
Alternatively, drill to the proper laser depth marking on the drill calculated by adding the implant length plus the gingival tissue height. The recommended drilling speed is 800-1200rpm. Continue osteotomy preparation to the desired depth at each implant site.



4A-4B Place the proper length Drill Stop onto the 1.6mm drill (07367) according to the desired drilling depth.

Alternatively, drill to the proper laser depth marking on the drill calculated by adding the implant length plus the gingival tissue height. The recommended drilling speed is 800-1200rpm. Continue osteotomy preparation to the desired depth at each implant site.

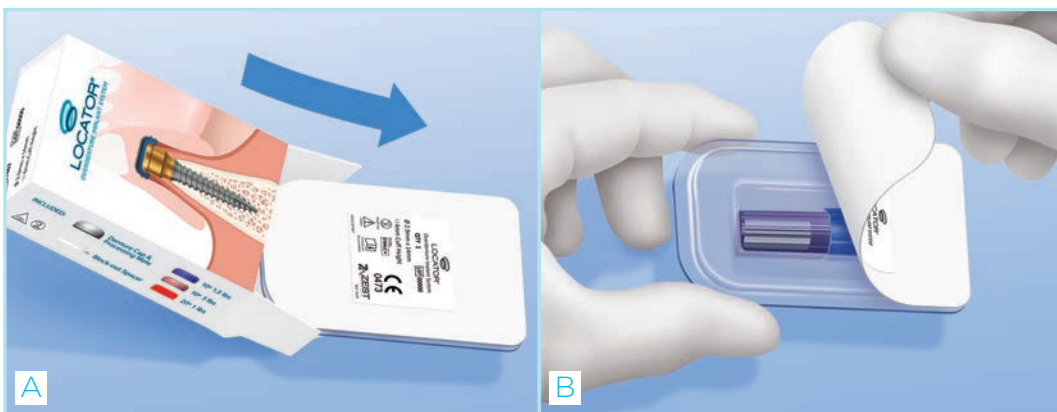
IMPLANT PLACEMENT (CONTINUED)



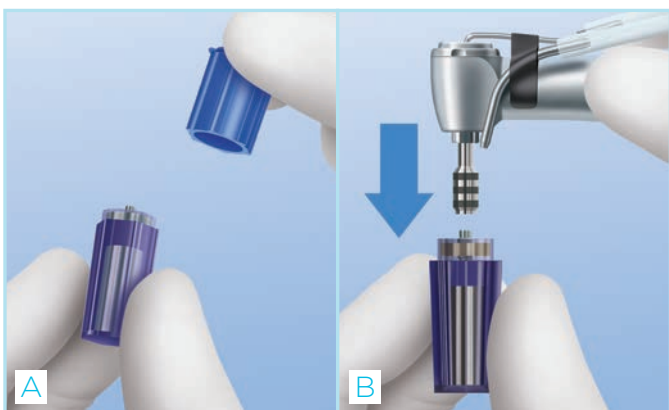
MANDIBULAR PLACEMENT OF FOUR 2.9MM X 10MM IMPLANTS SHOWN IN TYPE D1 BONE (CONTINUED)

5A-5B Place the 1.6mm diameter (large) end of the Direction Indicator into the osteotomies to verify proper alignment. Place the proper length Drill Stop onto the 2.4mm drill (0736) according to the desired drilling depth.

Alternatively, drill to the corresponding laser depth marking on the drill calculated by adding the implant length plus the gingival tissue height. The recommended drilling speed is 800-1200rpm. Continue osteotomy preparation to the desired depth at each implant site.

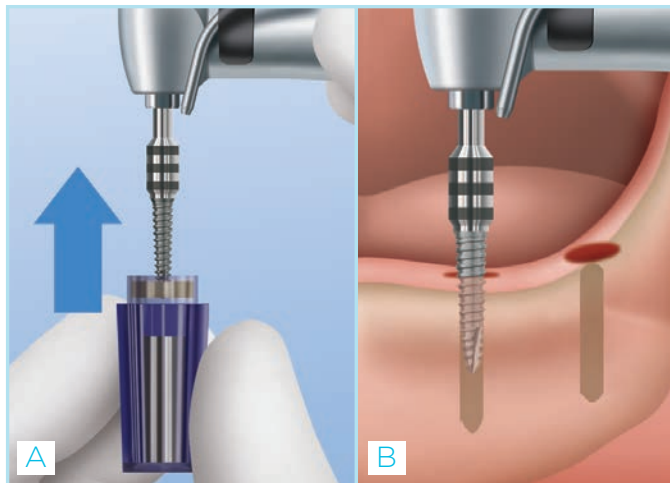


6A-6B Remove the implant package from the box and peel back the tyvek seal from the plastic tray. Place the sterile implant vial on the sterile tray. The contents of the plastic tray are sterile and should only contact components within the sterile field.



7A-7B Remove the cap from the implant vial and do not discard. The LOCATOR® Abutment is included in the cap. Set the drilling unit speed at 30rpm and the placement torque at 35Ncm. Place the Implant Latch Driver (07357) in the handpiece. Seat it onto the hex on the top of the implant and press down to engage securely. The bottom of the driver should contact the abutment seating surface and fully engage the entire length of the implant hex.

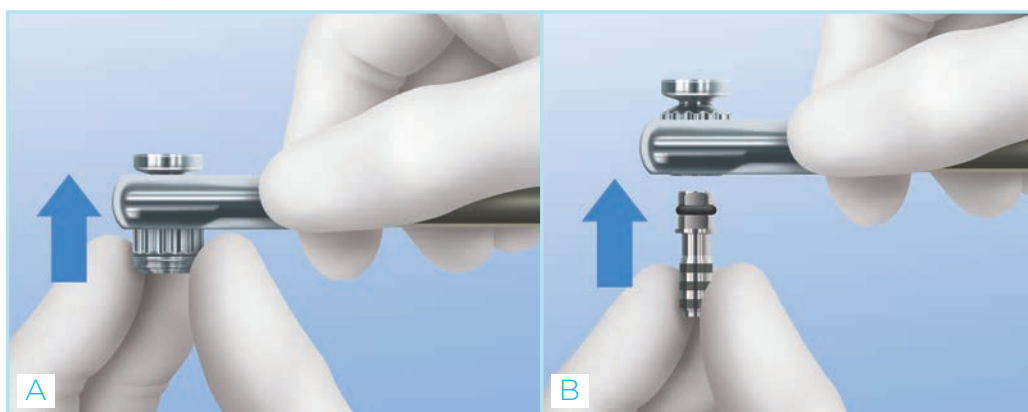
IMPLANT PLACEMENT (CONTINUED)



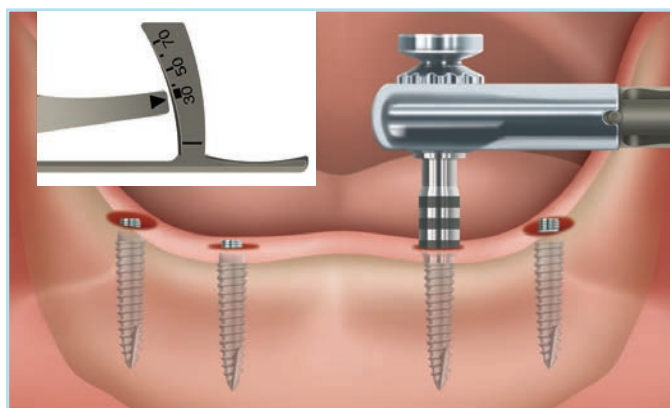
MANDIBULAR PLACEMENT OF FOUR
2.9MM X 10MM IMPLANTS SHOWN IN
TYPE D1 BONE (CONTINUED)

8A-8B Remove the implant from the vial. Carry the implant to the mouth, place it into the osteotomy and insert at 30rpm. Use Latch Driver to drive the implant three quarters (3/4) of the way into the osteotomy and finalize insertion with a Torque Indicating Ratchet Wrench (07362).

Warning: Do not use an implant that comes into contact with any non-sterile area. Replace with a new sterile implant.



9A-9B Assemble the Torque Ratchet Wrench Insert (07463) and the Torque Wrench (07362) to finalize seating. Short and long Implant Drivers (07360/07361) are available in the surgical kit.



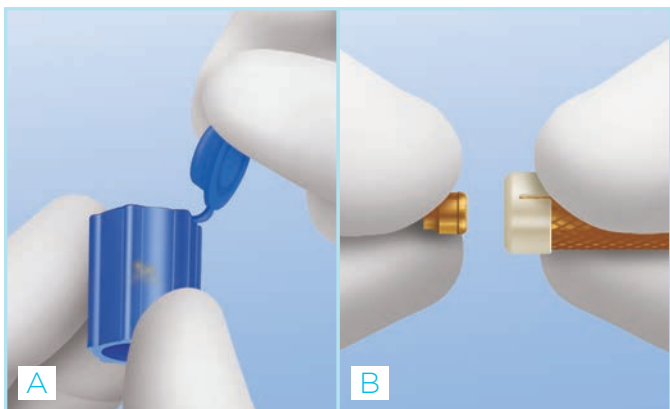
10 Engage the Implant Driver onto the hex on the top of the implant and verify that it is fully engaged. Slowly ratchet the implant to full depth. If final seating torque measures 30Ncm or above, the implant may be placed into immediate function at the discretion of the clinician, with the patient adhering to recommended post-surgical hygiene and care protocols. If the final seating torque measures below 30Ncm, relieve the denture acrylic and place a soft liner in the denture around the LOCATOR® Abutments during the implant integration period. If 70Ncm of torque is reached prior to full seating, the implant should be removed and the osteotomy should be enlarged.

LODI HEALING ABUTMENT & LOCATOR® ABUTMENT PLACEMENT



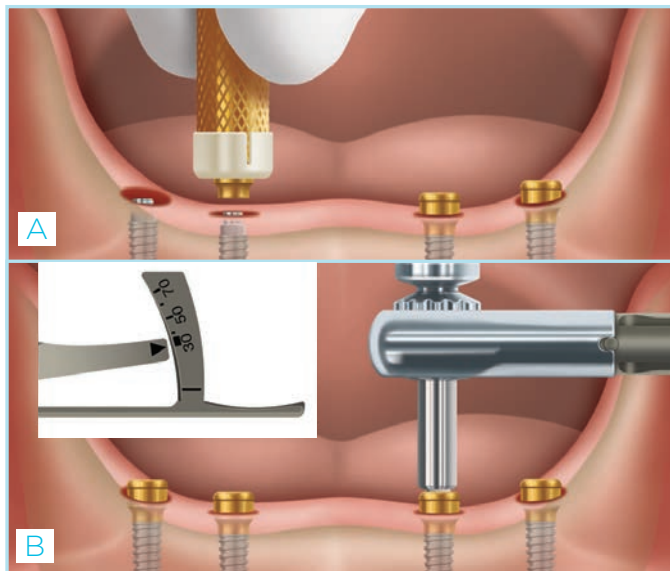
LODI HEALING ABUTMENT PLACEMENT

1 Optional: If the implant does not reach a final seating torque of 30Ncm, a Lodi Healing Abutment (07339 or 07340) is available. Use a 0.050 inch (1.25mm) Hex Driver and thread the Healing Abutment with the appropriate cuff height on the implant until finger tight. Relieve the denture acrylic and place a soft liner in the denture around the Lodi Healing Caps during the implant integration period.



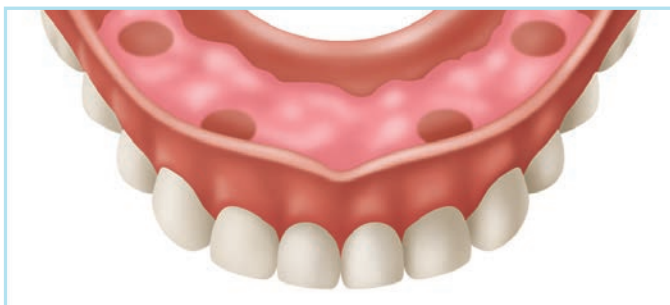
LOCATOR ABUTMENT PLACEMENT

2A-2B Open the flip cap on the top of the vial cap and remove the LOCATOR Abutment. Place the Abutment Holder Sleeve onto the LOCATOR Abutment Driver and insert into the tri-lobe channel of the LOCATOR Abutment.



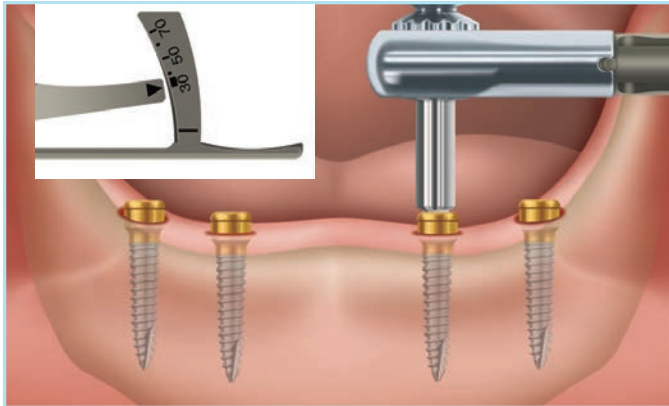
3A-3B Thread the LOCATOR Abutment onto the implant until finger tight. If the implant placement torque was 30Ncm or greater, the Abutments may be tightened to the recommended torque level of 30Ncm. If the implant placement torque did not reach 30Ncm, the Abutment should only be hand tightened. Assemble the LOCATOR Abutment Torque Driver Insert and the Torque Indicating Ratchet Wrench (07362) with LOCATOR Torque Wrench Driver (08926) and torque the attachments to 30Ncm.

Warning: Do not use the LOCATOR Abutment on top of the implant to further advance the implant into the osteotomy. If the implant needs to be placed deeper, remove the Abutment, re-engage the Implant Driver onto the implant and ratchet to desired depth.



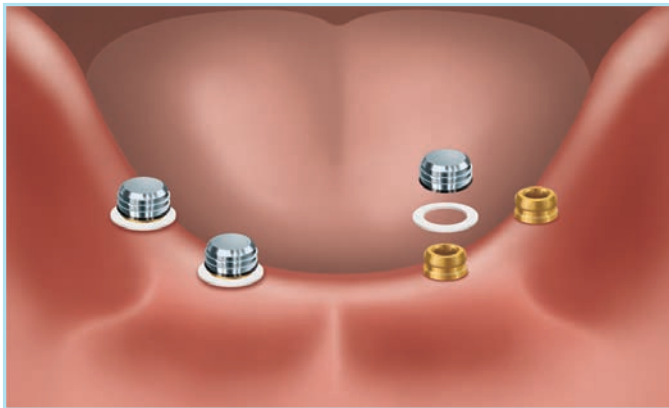
4 If the implant placement torque was 30Ncm or greater, follow the steps for processing the LOCATOR Denture Attachment Housings and Inserts into the denture. If the implant placement torque was less than 30Ncm, relieve the denture acrylic and place a soft liner in the denture around the LOCATOR Abutments during the integration period.

PROCESSING LOCATOR® DENTURE ATTACHMENT HOUSINGS & INSERTS INTO THE DENTURE



DIRECT TECHNIQUE: CHAIRSIDE PROCESSING (NEW OR EXISTING DENTURE)

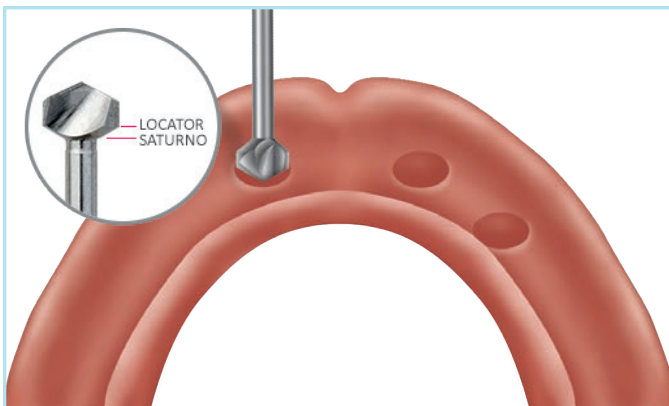
1 Torque the LODI Abutments to 30Ncm using an assembled Torque Indicating Ratchet Wrench and Insert.



2 Place a White Block Out Spacer Ring around each Abutment and press it down to the tissue. Place a Denture Attachment Housing with a Black Processing Insert inside of it and place the Housing/Insert assembly onto each Abutment, pressing down firmly.

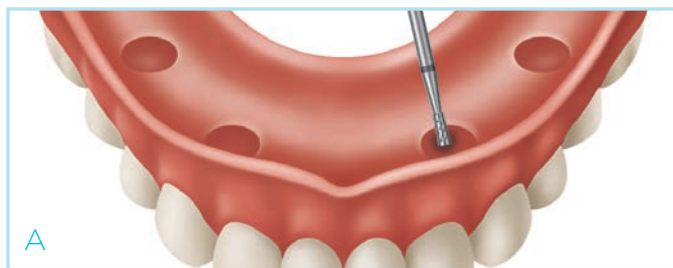


3 Apply fit check marking paste inside of the denture. Insert it into the mouth in position over the Denture Attachment Housings to mark areas where the denture will need to be relieved to allow space for the Attachment Housing to be picked up.



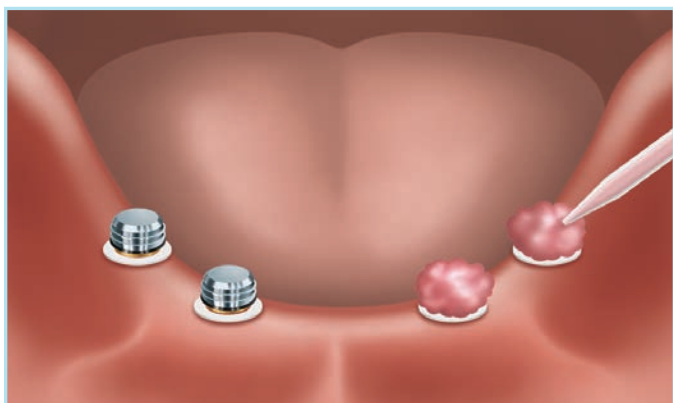
4 Relieve the areas marked with a CHAIRSIDE® Recess Bur (09756). ZEST recommends using slight pressure to get the tip of the Bur started followed by a straight downward motion to create the desired recess site. This efficient Bur has distinct depth landmarks which indicate where to stop when drilling for the Denture Attachment Housing.

PROCESSING LOCATOR® DENTURE ATTACHMENT HOUSINGS & INSERTS INTO THE DENTURE (CONTINUED)

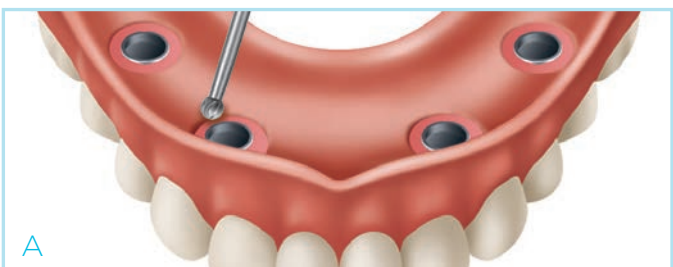


DIRECT TECHNIQUE: CHAIRSIDE PROCESSING (CONTINUED)

5A-5B Use the CHAIRSIDE® Undercut Bur (09577) to cut an undercut around the circumference of the relief areas for mechanical retention. Cut lingual/palatal vent windows in the denture with the CHAIRSIDE Vent Bur (09578) to visualize full seating and for excess material to vent.

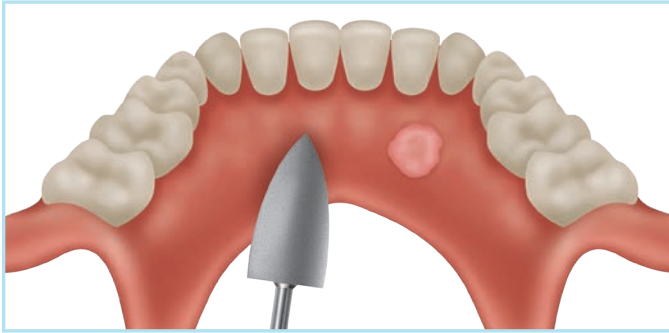


6 Dry the Denture Attachment Housings. Apply a small amount of CHAIRSIDE Attachment Processing Material (09566) around the circumference of each cap. Place CHAIRSIDE Material into the relief areas of the denture and seat it over the Housings and onto the tissue. Maintain the denture in very light occlusion, without compression of the soft tissue while the acrylic sets. Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and wear of the Inserts. The set time of the material from the time the material is mixed, to the time it is set is five (5) minutes; working time is one (1) minute, forty-five (45) seconds.

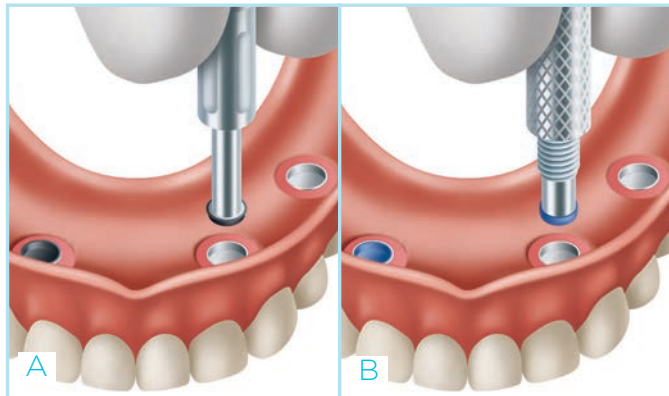


7A-7B Disengage the denture from the attachments and remove from the mouth. Verify that the Denture Attachment Housings have been securely processed into the denture. Fill any voids and light cure. The material will bond to itself and will cure within 30 seconds with light application. Use the CHAIRSIDE Trim (09579) and Grind Burs (09583) to remove any excess acrylic material remaining in the denture.

PROCESSING LOCATOR® DENTURE ATTACHMENT HOUSINGS & INSERTS INTO THE DENTURE (CONTINUED)



8 Use the CHAIRSIDE® Polish Bur (09580) to create a smooth finish in and around the denture.

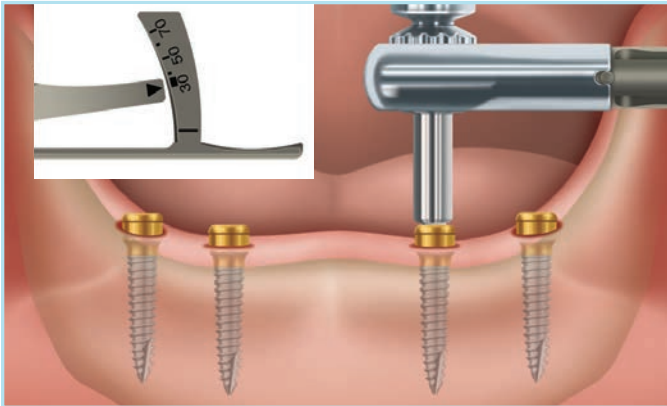


9 See the LOCATOR 3-In-1 Core Tool instructions on page (5). Remove the Black Processing Insert using the Removal Tool. Place the selected final Retention Insert into each Denture Attachment Housing using the Insertion Tool. Insert the lowest retentive option during try-in.



10 Seat the denture and press down to engage the Retention Insert on the LOCATOR Abutments and verify the occlusion. Instruct the patient on how to remove and insert the denture. If the retention is not satisfactory, remove the Inserts and replace with the next level of retention. See the Insert retention chart on page (4). Instruct the patient on proper home care maintenance and required recall visits.

PROCESSING LOCATOR® DENTURE ATTACHMENT HOUSINGS & INSERTS INTO THE DENTURE (CONTINUED)

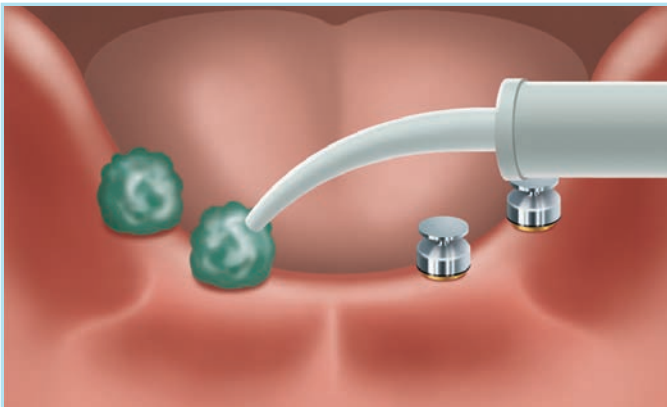


INDIRECT TECHNIQUE: LABORATORY PROCESSING

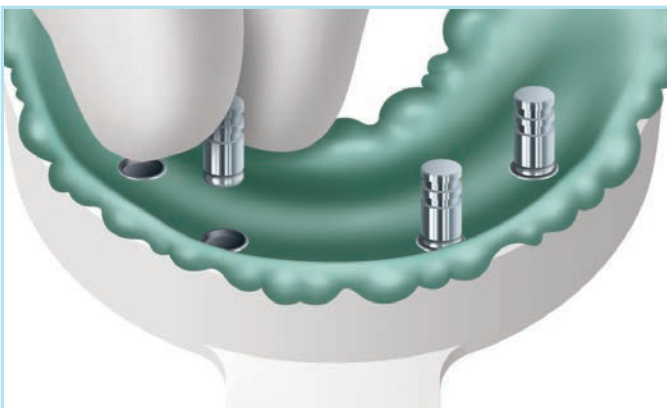
1 Torque the LOCATOR Abutments to 30Ncm using an assembled Torque Indicating Ratchet Wrench and LOCATOR Torque Wrench Driver Insert (08926).



2 A stock or custom impression tray may be used. Ensure that each recess has enough space for the height of the LOCATOR Impression Copings (08505).



3 Place a LOCATOR Impression Coping on each Abutment and press down firmly. Syringe a medium body impression material around the circumference of each coping. Fill the impression tray and insert it over the copings and onto the tissue. Allow the material to set. Remove the impression and verify that there are no draws in the impression.



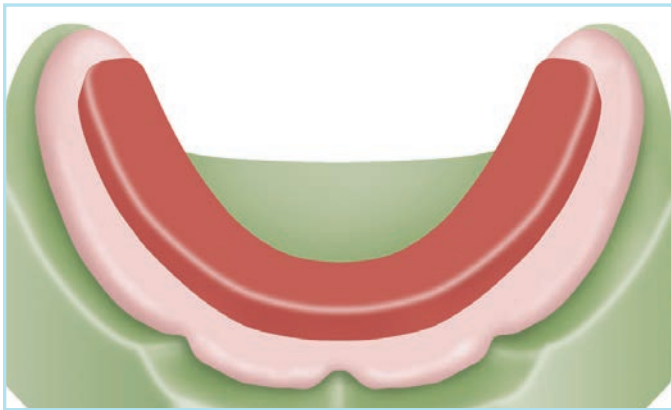
4 Press the LOCATOR Analogs (08530) into each Impression Coping and send the impression to the laboratory.

PROCESSING LOCATOR® DENTURE ATTACHMENT HOUSINGS & INSERTS INTO THE DENTURE (CONTINUED)

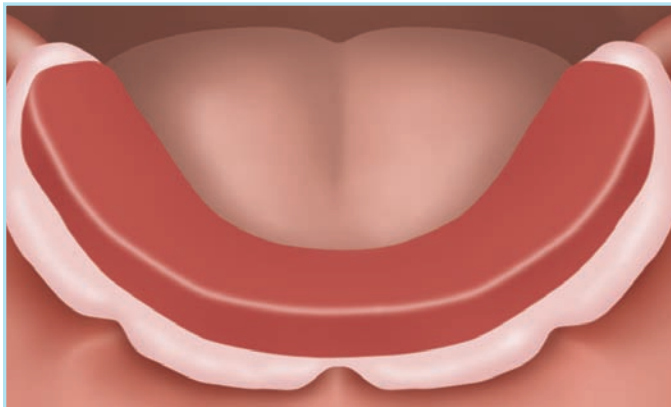


LABORATORY PROCESSING

5 Verify that the Analogs are secure in the Impression Copings and pour a model.

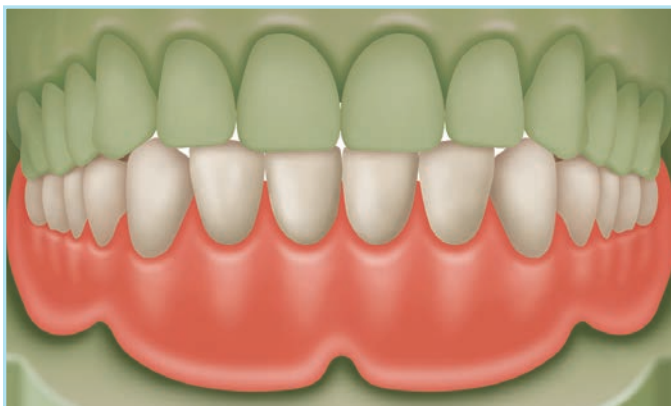


6 Fabricate the baseplate and wax rim on the cast for the bite registration. The Denture Attachment Housings with Black Processing Inserts may be processed into the baseplate to provide stabilization during record making and try-in.



BITE RECORDS

7 Place the bite block into the mouth and record the jaw relation. Take an impression of the opposing arch and pour the cast. Select a shade for the denture teeth.



LABORATORY STEP

8 Articulate the models and proceed with the denture teeth set up.

PROCESSING LOCATOR® DENTURE ATTACHMENT HOUSINGS & INSERTS INTO THE DENTURE (CONTINUED)



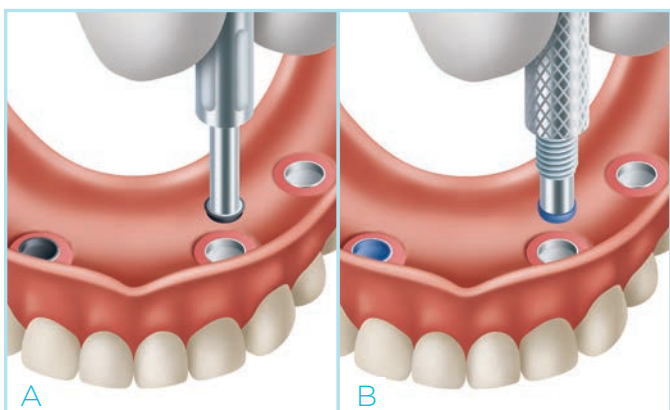
DENTURE TRY IN

9 Place the try-in denture into the mouth and verify the fit, attachment engagement, esthetics, phonetics, and occlusion.

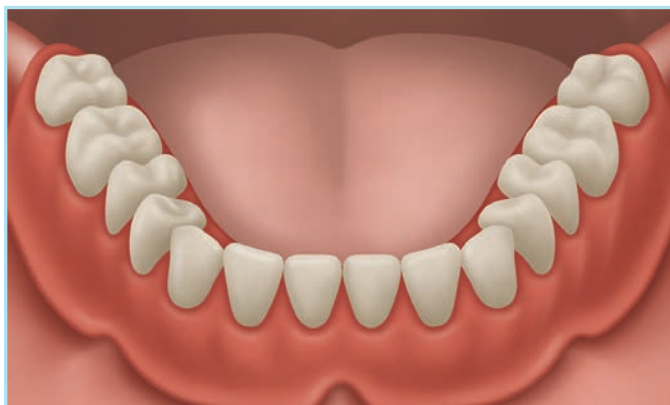


LABORATORY STEP

10 Finalize and flask the denture for processing. Separate the flask and boil away all wax. Place the Denture Attachment Housings with Black Processing Inserts on the Analogs and press down firmly. Place the cast back into the flask and verify that there is no contact with the teeth. Close the flask and process the denture. Remove the denture from the flask, finish, and polish.



11A-11B See the LOCATOR 3-In-1 Core Tool instructions on page (5). Remove the Black Processing Insert using the Insert Removal Tool. Place the selected final Insert into each Denture Cap using the Insertion Tool. Insert the lowest retentive option during try-in. See the Insert retention chart on page (4).



PROSTHESIS DELIVERY

12 Seat the denture in the mouth and press down to engage the Retention Inserts on the LOCATOR Abutments and verify the occlusion. Instruct the patient on how to remove and seat the denture. If the retention is not satisfactory, remove the Inserts and replace with the next level of retention. See the Insert retention chart on page (4). Instruct the patient on proper home care maintenance and required recall visits.

IMPORTANT INFORMATION ABOUT THE LODI SYSTEM & SURGICAL INSTRUMENTATION

INDICATIONS

The LOCATOR® Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla.

CONTRAINDICATIONS

Not appropriate where a totally rigid connection is required. Use of a single implant with divergence greater than 20° 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, titanium allergy or uncontrollable endocrine disorders should be carefully evaluated prior to treatment.

CAUTION

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

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). Only sterile titanium or stainless instruments/tools should be used to handle and deliver the implant to the surgical site.

SINGLE-USE DEVICES

The LOCATOR Overdenture Implant System is a single-use device.

LOCATOR Overdenture Implant: A previously used LOCATOR Overdenture 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 Retention Inserts: The inadvertent re-use of LOCATOR Retention Inserts could cause loss of retention of the overdenture due to wear from previous use or damage during removal with the LOCATOR Core Tool.

LOCATOR Abutments: The inadvertent re-use of LOCATOR Abutments could contain patient contamination build-up and subsequent wear of the retention features. This would result in the device to perform with improper fit and function which would result in loss of retention of the prosthesis.

STERILIZATION

The LOCATOR Overdenture Implant is packaged with the LOCATOR Abutment and together are supplied **STERILE** (subjected to radiation (gamma) as a means of sterilization).

All other restorative components, instruments, and replacement LOCATOR Abutments (sold separately) are supplied **NON-STERILE**.

The nylon Retention Inserts may be sterilized/disinfected using a liquid chemical sterilant. In order to ensure that the nylon Inserts are sterilized/disinfected (all microorganisms including Clostridium sporogenes and Bacillus subtilis spores are eliminated), the nylon Retention 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 (not just high-level disinfection) of the device.

CLEANING INSTRUCTIONS FOR INSTRUMENTS AND INDIVIDUALLY PACKAGED REPLACEMENT ATTACHMENTS

- 1** Disassemble any instruments that can be disassembled according to manufacturers' instructions.
- 2** 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.
- 3** 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.

Note: Use of a syringe or water jet will improve flushing of difficult to reach areas.

IMPORTANT INFORMATION ABOUT THE LODI SYSTEM & SURGICAL INSTRUMENTATION (CONTINUED)

CLEANING INSTRUCTIONS FOR INSTRUMENTS AND INDIVIDUALLY PACKAGED REPLACEMENT ATTACHMENTS (CONTINUED)

4 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.

5 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.

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

SURGICAL TRAY CLEANING INSTRUCTIONS

1 Rinse the tray and tray insert with tap water.

2 Place the Surgical Tray and 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 Insert to soak in the cleaning solution for 20 minutes making sure that they are completely submerged.

3 Remove the Surgical Tray and 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 solution residue.

4 Remove excess moisture from the Surgical Tray and Insert with a clean, absorbent, and non-shedding wipe.

INSPECTION AND MAINTENANCE OF CLEANED INSTRUMENTS

1 Carefully inspect each instrument to ensure that all visible contamination has been removed. If contamination is noted, repeat the cleaning process. Please note that if during inspection of instruments, you see signs of wear, damage, or unrecognizable color change, replace the instrument.

2 Reassemble multi-part instruments and check them for proper function (LOCATOR® Core Tool and the Torque Indicating Ratchet Wrench). Reference the IFU that comes with each of these parts and subsequent sections of this document for the proper assembly process.

STEAM STERILIZATION INSTRUCTIONS

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

1 Place all instruments into the surgical tray.

2 For gravity cycle, place Surgical Kit 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.

Note: LOCATOR Core Tool and Torque Indicating Ratchet Wrench should be disassembled prior to steam sterilization.

AUTOCLAVE STERILIZATION PARAMETERS

CYCLE TYPE	PART NUMBER	DESCRIPTION	TEMPERATURE	EXPOSURE TIME	DRYING TIME
GRAVITY	7421	STANDARD SURGICAL KIT	132°C / 270°F	15 MINUTES	30 MINUTES
	7422	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	132°C / 270°F	4 MINUTES	20 MINUTES

IMPORTANT INFORMATION ABOUT THE LODI SYSTEM & SURGICAL INSTRUMENTATION (CONTINUED)

TORQUE INDICATING RATCHET WRENCH CLEANING PROCEDURES

Intended Use: A dental torque wrench for placement and adjustment of dental implants, attachments, attachment screws and prosthetic screws during oral surgery and prosthetic procedures. **Scale Unit:** Ncm.

WARNING: Device must be autoclaved prior to use. This device must not be cleaned using hydrogen peroxide.

1 Cleaning: Press the Ratchet Insert to remove it from the head of the wrench, and remove the head by pressing a finger into the recess and gently pulling the head. The three separated parts are now ready for cleaning using the following procedure:

Soak torque wrench parts in enzymatic cleaning solution (mixed according to manufacturer's instructions) by completely submerging it for 20 minutes. Scrub torque wrench parts using a soft bristled, nylon brush until all soil has been removed.

Remove the torque wrench parts from the enzymatic cleaning solution and rinse in tap water for a minimum of 3 minutes.

Place torque wrench parts in sonication bath (with the enzymatic cleaning solution prepared according to manufacturer's instructions) making sure they are completely submerged, and sonicate for 10 minutes.

Remove the torque wrench parts from the sonication bath, and rinse in water 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 torque wrench parts with a clean, absorbent, and non-shedding wipe.

Sterilization: Autoclave/steam gravity sterilize for 25 minutes at 132 °C, dry for 30 minutes. For pre-vacuum cycle, autoclave/steam sterilize for 4 minutes at 132°C with drying time of 20 minutes.

Note: Drying times may vary according to load.

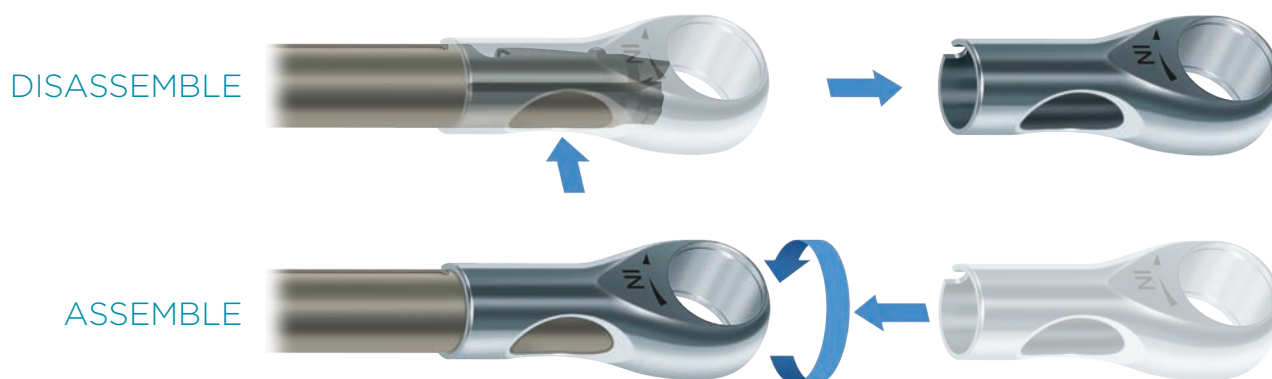
2 After sterilization, attach the head of the wrench to the body by pushing the components together and turning them in opposite directions until there is an audible click.

3 Push the Ratchet Insert into the wrench until there is an audible click. The arrow on the head of the wrench shows the direction in which the wrench is functioning.

4 Insert an appropriate driver and turn the wrench in the direction of the arrow until the desired torque is achieved.

WARNING: Before each use, make sure that the functionalities are intact and that the first line on the scale aligns with the arrow. The arm of the torque wrench must not go beyond the end of the scale, as this could result in inaccurate readings. If the torque wrench is used as an ordinary wrench, without using the torque scale, then it may not be subjected to a load of more than 80Ncm.

WARNING: If overloaded, dropped, or mishandled, the wrench must no longer be used since correct function can no longer be guaranteed.



IMPORTANT INFORMATION ABOUT THE LODI SYSTEM & SURGICAL INSTRUMENTATION (CONTINUED)

WARNINGS AND PRECAUTIONS

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

Product (implant/attachment) from damaged sterilized packaging must not be used on patients.

In the event that the sterilized packaging for the LOCATOR Overdenture Implant System 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).

The drill extender is to be used with surgical drills only and should not be used in high torque applications.

Avoid application of excessive bending load on smaller diameter drills during drilling. Drills will dull based on many factors including bone density, handling, autoclave exposure, etc. Replace drills when wear is noticeable to avoid excessive heat being transferred to surrounding bone during osteotomy preparation.

Do not use the LOCATOR Abutment on top of the implant to further advance the implant into the osteotomy. If the implant needs to be placed deeper, remove the Abutment, re-engage the Implant Driver onto the implant and ratchet to desired depth.

If the LOCATOR Overdenture Implant System is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue or localized bone failure. The use of other tissue grafting components or parts that are made from dissimilar metals should not be used in or near the implant.

Patient evaluation including the determination of the general health, oral hygiene habits and status, motivation toward 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 anatomic 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 implants.

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 procedure must be evaluated and corrected if necessary, or use of the implant may be contraindicated.

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), 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, 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.

OVERDENTURE INSERTION, REMOVAL, AND CLEANING GUIDELINES FOR THE CLINICIAN AND PATIENT

To reduce wear on LOCATOR® Abutments it is critical that clinicians and patients perform routine maintenance on both the LOCATOR Abutment, the Denture Attachment Housing and the Retention Insert. It is also important that patients understand the proper overdenture maintenance that should be performed at home to guard against retention loss of the Retention Inserts within the Denture Attachment Housing.

The following are guidelines to consider.

INSERTING AND REMOVING AN OVERDENTURE

To insert the overdenture, the patient should ensure he/she can feel that it is properly positioned above the LOCATOR Abutments prior to applying pressure. The patient should use both hands and simultaneously press down on each side to firmly snap the overdenture into place.

The patient should avoid biting the overdenture into place as this force will result in improper wear of the LOCATOR Abutment and may affect the longevity of the prosthesis.

The patient should remove the overdenture by placing one thumb under the left edge and one finger under the right edge of the overdenture rim and pull one side upward and the other side downward, simultaneously. They may also use their tongue to aid in removal of the lower overdenture. Once the overdenture is removed, a thorough cleaning is recommended.

CLEANING AN OVERDENTURE

Maintaining proper hygiene is vital to the success of an overdenture, helping it last longer and function properly. Similar to natural teeth, dental plaque will also form on the surface of an overdenture. If the plaque is not removed it will continue to accumulate. It is for this reason that the overdenture should be taken out for cleaning daily. Patients should follow these two simple steps daily for cleaning an overdenture.

1 Fill a washing basin with warm water to prevent fracture of the overdenture. Apply detergent onto a soft bristle toothbrush and thoroughly clean every surface of the overdenture.




2 Before bed each night, remove the overdenture and immerse in a cup of plain cold water.

ADDITIONAL NOTES OF CAUTION

Failure of the patient to follow oral hygiene protocols and appropriately care for the overdenture may also result in inflamed tissue around the implant, leading to the development of peri-implantitis. Throughout time, peri-implantitis may cause the implant to become mobile and fail. Please ask patients to consider the following when caring for their overdentures:

- Avoid using abrasive toothpaste to clean the overdenture. The coarse particles in the toothpaste may scratch the surfaces of the overdenture, enhancing the potential for plaque accumulation.
- Chewing tobacco will get caught in the Retention Inserts and scratch the Abutments, considerably reducing the life of the Abutments, retentive features of the Retention Inserts and ultimately may affect the dental implants.
- Do not soak the overdenture in bleach or any other products not designed for use with denture cleaning as these can harm the retentive feature of the Retention Insert, which may ultimately cause additional wear on the Abutment.
- If a denture cleaning solution such as Polident® and Efferdent® must be used, it is recommended that the denture be soaked for fifteen minutes or less.
- Brushing the Abutments increases wear; if the patient brushes their Abutments, they should visit the dentist for regular inspection and maintenance of the Abutments, Retention Inserts and Attachment Housings.
- Refrain from picking at the Abutments or Retention Inserts with toothpicks or other foreign objects.
- Refrain from eating without the overdenture in place as food will scratch the Abutment or Retention Insert and may result in failure of the dental implant. Food trapped in the Abutment's drive cavity can also result in improper seating.
- Oral rinse such as Listerine® mouthwash can be used safely without any poor effect on the Abutments or Retention Inserts.
- Do not wash the overdenture in the dishwasher.

EXPLANATION OF SYMBOLS ON OUTER PACKAGING LABELS

SYMBOL	EXPLANATION OF SYMBOL
	<p>CE Marking of Conformity with Notified Body Number (Use 0086 only on class IIa and higher risk class devices).</p>
	<p>European Authorized Representative</p>
	<p>Symbol for “CONSULT INSTRUCTIONS FOR USE”</p>
	<p>Symbol for “DO NOT REUSE” For single-use. Use only once.</p>
<p>Rx Only</p>	<p>Prescription Required. May be used as a substitute to the verbiage “Caution: Federal law (U.S.A.) restricts this device to sale by or on the order of a licensed dentist.”</p>
	<p>Symbol for “BATCH CODE” This symbol shall be accompanied by the manufacturer’s batch code or lot code. The batch/lot code shall be adjacent to the symbol.</p>
	<p>Symbol for “CATALOGUE NUMBER” The product catalogue number shall be after or below the symbol adjacent to it.</p>
<p>REF</p>	<p>Customer Reference Number if different than Zest Anchors Reference Number. (NOTE: This symbol is not a BS EN 980 symbol and will be used to distinguish between Zest Anchors and Customer Reference Numbers.)</p>
	<p>Symbol for “MANUFACTURER” This symbol shall be accompanied by the manufacturer name (ZEST Anchors) and address (2061 Wineridge Place, Escondido, CA 92029); adjacent to the symbol.</p>
	<p>Symbol for “NON-STERILE” This label applies to the non-sterile restorative accessories and tools (noted on the side of the packaging) and the replacement LOCATOR® implant attachments.</p>
	<p>Symbol for “STERILIZED USING IRRADIATION” NOTE: Refers to Implant/Attachment sterilized packaging only.</p>
	<p>Symbol for “USE BY” This symbol shall be accompanied by a date to indicate that the device should not be used after the end of the year, month shown. The date shall be expressed as four digits for the year and, two digits for the month; located adjacent to the symbol.</p>

THE ZEST ANCHORS 10 YEAR WARRANTY



THE ZEST ANCHORS LLC NARROW DIAMETER IMPLANT (“NDI”) WARRANTY: LOCATOR® OVERDENTURE IMPLANT (“LODI”) AND SATURNO™ NARROW DIAMETER IMPLANT (“SNDI”)

ZEST Anchors LLC (“ZEST”) is committed to providing quality products and dedicated to gathering feedback about its products. ZEST actively collects and reviews the feedback of users of our products in compliance with regulatory reporting requirements and to better help us understand market expectations and validate our products’ performance. The collection method ZEST utilizes for such feedback is the ZEST Product Experience Report (“PER”) form. The PER form is to be completed from information provided by the attending clinician to share their ZEST product experience.

Pursuant to the ZEST NDI WARRANTY, ZEST will replace covered LODI and SNDI products for a \$25 processing fee for each such qualifying covered implant that is returned (as such terms are defined below). Upon a request for replacement under the ZEST NDI WARRANTY, ZEST will send a replacement product once ZEST receives the returned product and completed PER form and confirms that the returned product is covered under the ZEST NDI WARRANTY. Upon shipment of the replacement product, ZEST will issue the customer an invoice at \$25.

ONLY DIRECT ZEST CUSTOMERS MAY MAKE A WARRANTY CLAIM. In order to make a claim under the ZEST NDI WARRANTY please return the items mentioned below in protective packaging and send these via a shipping method which enables the package to be tracked:

Printed copy of PER form completed from information provided by the attending clinician.

Explanted product(s) in sterile condition (NON-STERILE products will not qualify for replacement)

If a product failure or loss of integration has occurred, please additionally send relevant radiographs (these will not be returned unless specifically requested, please send copies)

Send shipment to: ZEST ANCHORS LLC
ATTN: Customer Service (US customers) or Wholesale Distribution
(Distributors/OEM Partners)
2061 Wineridge Place Escondido, CA 92029

If using the electronic form, please include the Tracking Number for the returned product package.

Download ZEST NDI Product Experience Report (PDF) AT
WWW.ZESTANCHORS.COM

ZEST ANCHORS (“ZEST”) NARROW DIAMETER IMPLANT (“NDI”) WARRANTY
(Valid as of May 1, 2015)

1. Warranty beneficiary and scope: ZEST Anchors LLC hereby warrants to the direct ZEST customer purchasing the NDI from ZEST (“Customer”) that the ZEST LOCATOR Overdenture Implant (“LODI”) and SATURNO Narrow Diameter Implant (“SNDI”), when implanted according to the respective ZEST LODI/SNDI Technique Manual and other written instructions provided by ZEST by a clinician (the “User”), will be free from any loss or lack of integration, fracture or other structural failure for the period of 10 years (“Warranty Period”) from the time of treatment by the User (collectively, the “ZEST NDI WARRANTY”). This warranty only applies to the Customer. Third parties, particularly patients, are not covered by the ZEST NDI WARRANTY and have no rights hereunder. Customers’ sole remedy and ZEST’S sole liability under this ZEST NDI WARRANTY is the replacement of the LODI/SNDI implant by ZEST as set forth herein. The ZEST NDI WARRANTY only covers the replacement of the LODI/SNDI implant and not any associated costs or expenses, including, but not limited to, chair time, laboratory fees and any other associated treatment.

2. ZEST Warranty conditions: In the event that any request for warranty service for an NDI is made by a Customer under the ZEST NDI WARRANTY during the Warranty Period, ZEST will replace such NDI with the same or substantially equivalent product subject to the terms and conditions herein. The replacement product will be sent upon receipt of the returned product and the completed PER form and confirmation that the product is covered

under the ZEST NDI WARRANTY. To qualify for coverage under the ZEST NDI WARRANTY, the claim must be made within the applicable Warranty Period by a Customer and all conditions below must be met. Once these requirements are satisfied, ZEST will send the replacement part(s) and charge the ZEST Customer a \$25 processing fee per unit. The following REQUIRED conditions must be met and documented in order for coverage of a returned NDI under this ZEST NDI WARRANTY:

- 1.** The LODI/SNDI was used exclusively with all components, connections, attachments and other technology provided by ZEST and not in combination with any other manufacturer’s products or technology;
- 2.** The LODI/SNDI is returned in sterile condition (or disinfected if delivered as such);
- 3.** The LODI/SNDI was implanted by a User and inspected and maintained in full compliance with the respective ZEST LODI/SNDI Technique Manual valid at the time of treatment and all other ZEST written instructions as well as recognized dental procedures, during and after the treatment;
- 4.** The patient had good oral hygiene which was monitored and documented by the User
- 5.** The LODI/SNDI was not subjected to damage caused by misuse, misapplication, accident, trauma or any other damage caused by external factors or the User, the patient or a third party;
- 6.** A completed and signed PER was completed and submitted no later than 10 days after the complaint is made. Customer is responsible to ensure that the PER is completed and submitted from information provided by the applicable User. Details of the incident are imperative to determine whether vigilance reporting is required to regulatory authorities.

3. Limits and limitations: This ZEST NDI WARRANTY is the only guarantee provided by ZEST and shall apply in addition to any warranty rights conferred under any written sales agreement executed by ZEST. The User remains free to claim rights against his supplier. EXCEPT AS SET FORTH HEREIN AND IN A WRITTEN SALES AGREEMENT EXECUTED BY ZEST, ZEST HEREBY DISCLAIMS ANY OTHER WARRANTIES, EXPRESS OR IMPLIED, WITH RESPECT TO LODI/SNDI OR ANY OTHER ZEST PRODUCTS, SERVICES OR INFORMATION, INCLUDING, BUT NOT LIMITED TO, ANY WARRANTY OF FITNESS FOR PURPOSE OR MERCHANTABILITY, OR NON-INFRINGEMENT OF THIRD PARTY RIGHTS, OR ANY WARRANTY BY COURSE OF PERFORMANCE OR OTHERWISE.

ZEST SHALL NOT BE LIABLE TO THE CUSTOMER, THE USER, THE PATIENT, OR ANY THIRD PARTY, FOR LOST EARNINGS OR PROFITS, DIRECT OR INDIRECT DAMAGES AS WELL AS COLLATERAL, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES, DIRECTLY OR INDIRECTLY RELATED TO LODI OR ANY OTHER ZEST PRODUCTS, SERVICES OR INFORMATION.

4. ZEST Warranty territory: This ZEST NDI WARRANTY applies worldwide to LODI/SNDI implants sold by ZEST, a ZEST affiliated company or an official distributor of ZEST on or after the validity date stated above.

5. Modification or termination: ZEST may modify or terminate this ZEST NDI WARRANTY at any time in whole or in part. Changes to, or the termination of the ZEST NDI WARRANTY, will not affect the warranty given for LODI/SNDI installed prior to the date of the change or termination.

LOCATOR OVERDENTURE IMPLANT (LODI) and SATURNO NARROW DIAMETER IMPLANT (SNDI) PRODUCT EXCHANGE POLICY

ZEST Anchors LLC understands that customers may need to adjust inventories of LOCATOR Overdenture Implant (LODI) and SATURNO Narrow Diameter Implant (SNDI) Products in order to achieve the correct mix of sizes to treat their patients. ZEST Anchors LLC will waive normal restocking fees (1:1 or greater) for exchanges during the first six months following the original purchase. Packaging cannot be written on or in any way adulterated. Shipping will still be the responsibility of the customer requesting the exchange.


LOCATOR[®]
OVERDENTURE IMPLANT SYSTEM



VISIT OUR WEBSITE AT
WWW.ZESTANCHORS.COM
TO PLACE ORDERS ONLINE
24 HOURS A DAY 7 DAYS A WEEK.



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