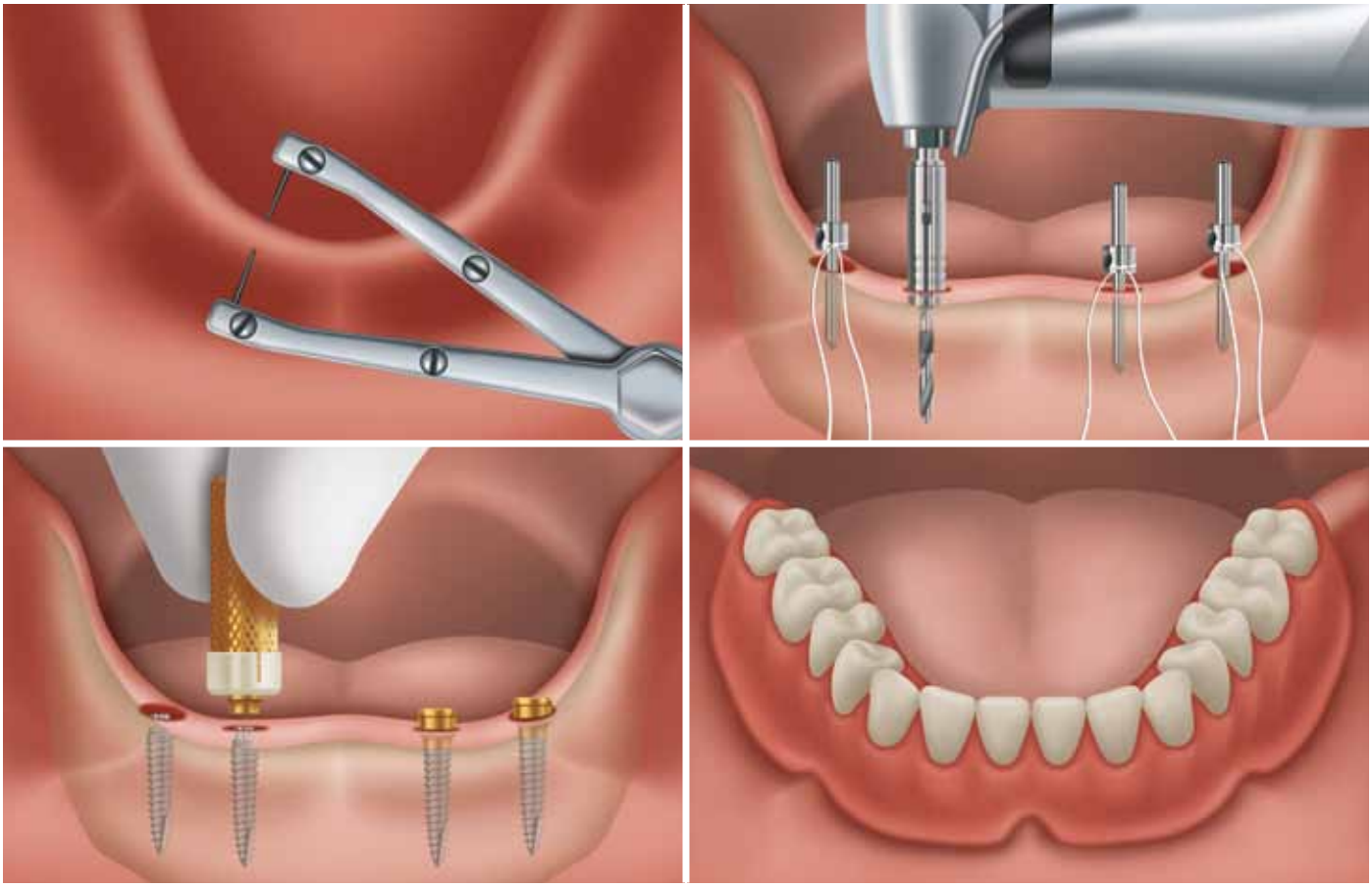
LOCATOR®
OVERDENTURE IMPLANT SYSTEM

THE LOCATOR® OVERDENTURE IMPLANT SYSTEM



TECHNIQUE MANUAL

ZEST ANCHORS

THE LOCATOR® OVERDENTURE IMPLANT SYSTEM.

FOUR DECADES OF ATTACHMENT KNOWLEDGE INCORPORATED INTO NARROW DIAMETER OVERDENTURE IMPLANTS.

The LOCATOR Overdenture Implant System (LODI) is comprised of 2.4mm and 2.9mm narrow diameter dental implants (available in 10, 12 and 14mm lengths) with a detachable LOCATOR Attachment that is available in a 2.5mm 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.

IMPORTANT: THIS DOCUMENT CONTAINS THE MOST CURRENT INSTRUCTIONS FOR USE. PLEASE READ AND RETAIN.

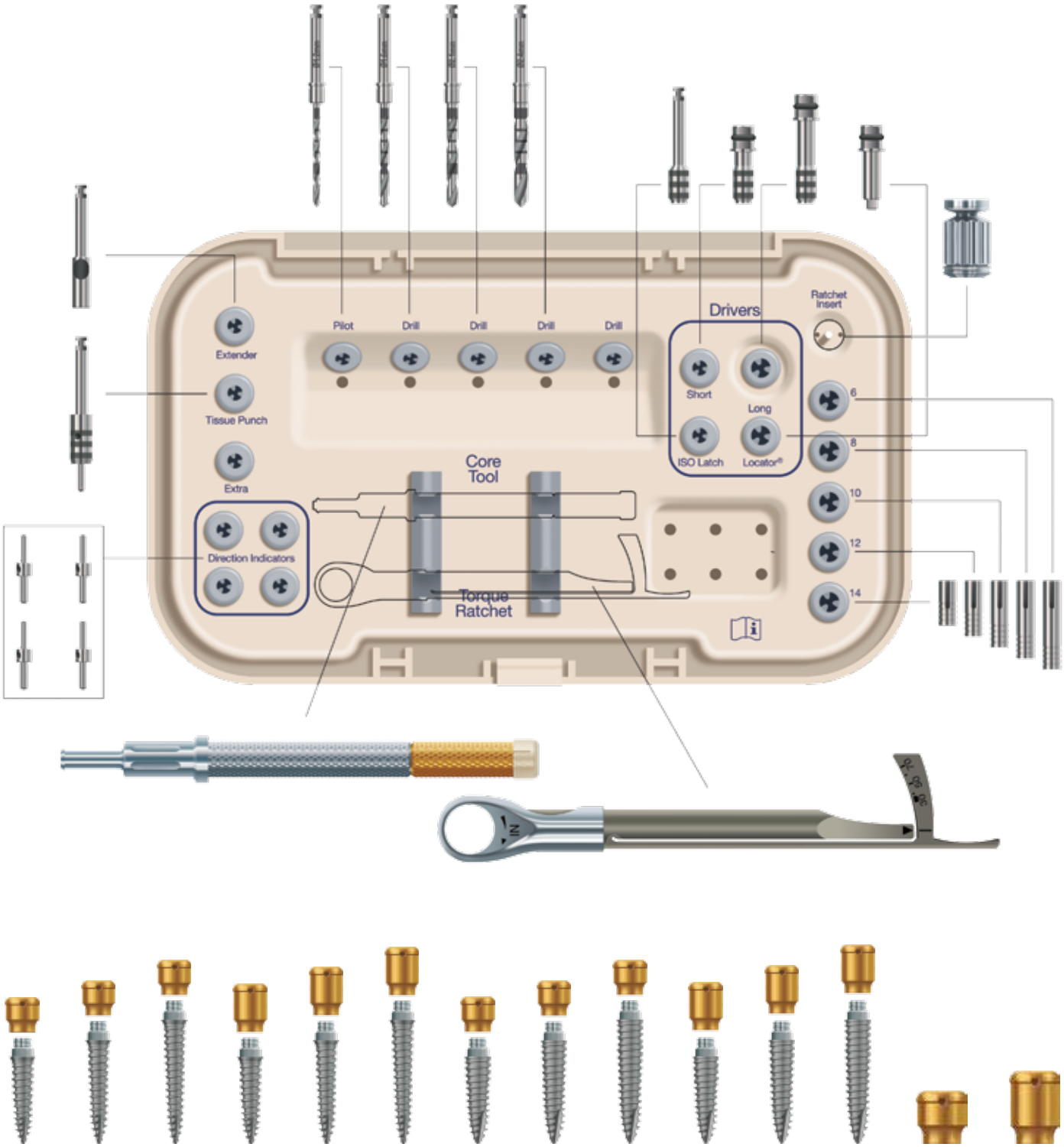

Extender
Tissue Punch
Extra
Direction Indicators
Pilot
Drill
Drill
Drill
Drill
Drivers
Short
Long
ISO Latch
Locator®
Ratchet Insert
6
8
10
12
14
Core Tool
Torque Ratchet

TABLE OF CONTENTS

LOCATOR® OVERDENTURE IMPLANT SYSTEM

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 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, 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 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 bands. 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 Attachment and together are supplied **STERILE** (subjected to radiation (gamma) as a means of sterilization).

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

The nylon males may be sterilized using a liquid chemical sterilant following the manufacturer's recommendations to achieve sterilization.

Note: The Liquid Chemical Sterilant must be approved for Sterilization not just high-level disinfection and must be compatible with nylon material.

LOCATOR® OVERDENTURE IMPLANT SYSTEM
(CONTINUED)

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.

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.

SURGICAL TRAY CLEANING INSTRUCTIONS (CONTINUED)

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 Re-assemble 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

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

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.

3 Autoclave Sterilization Parameters are listed below:

CYCLE TYPE	TEMPERATURE	EXPOSURE TIME	DRYING TIME
GRAVITY	121°C / 250°F	50 MINUTES	15 MINUTES
PRE-VACUUM	132°C / 270°F	4 MINUTES	20 MINUTES

TORQUE INDICATING RATCHET WRENCH CLEANING

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 driver 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 submered, 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.

Sterilzation: Autoclave/steam gravity sterilize for 50 minutes at 121ºc, dry for 15 minutes. For pre-vacuum cycle, autoclave/steam sterilize for 4 minutes at 132ºC 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.

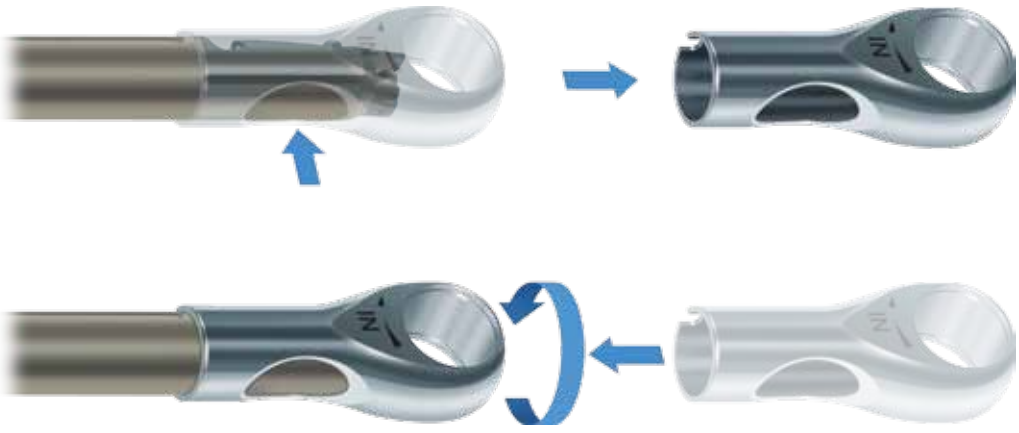
3 Push the driver into the wrench until there is an audible click. The arrow on the head of the wrench shows the direction in which the wrench is functioning.

4 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 sujected to a load of more than 80Ncm.

WARNING: After overloading or if dropped or in other ways mishandled, the wrench must no longer be used since correct function can no longer be guaranteed.

Please refer to the LOCATOR Overdenture Implant System Technique Manual available from the manufacturer or your distributor for detailed surgical procedure instructions. It is also available online at www.zestanchors.com



WARNINGS AND PRECAUTIONS

The LOCATOR Overdenture Implant System has not been evaluated for safety and compatibility in the MR environment. The LOCATOR Overdenture Implant System has not been tested for heating or migration in the MR environment.

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.

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. Panaromic 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.

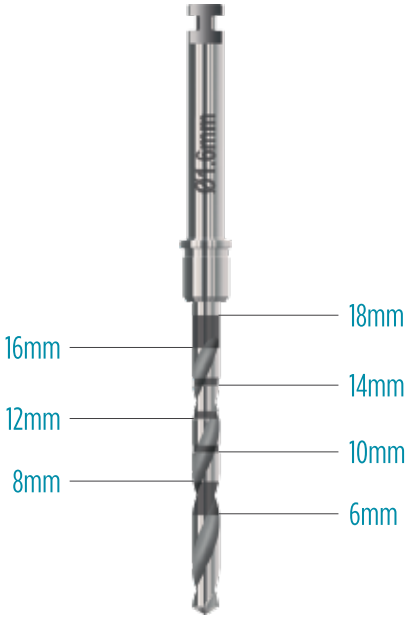
Based on the results of the patient's pre-surgical assessment, the clinician should select and order the appropriate implant (determine correct implant diameter and length based on bone type), restorative parts, and tools. Refer to Drilling Sequence section for further details. The clinician should also 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.

DRILLING DEPTH CONTROL

DRILL LASER DEPTH MARKINGS



DRILL STOPS

FINAL DRILL DIAMETER AND DEPTH FOR VARIOUS BONE TYPES

BONE TYPE	2.4MM IMPLANT DIAMETER		2.9MM IMPLANT DIAMETER	
	FINAL DRILL DIAMETER	DRILL DEPTH	FINAL DRILL DIAMETER	DRILL DEPTH
D1	2.1mm	Full	2.4mm	Full
D2 / D3	1.6mm	Depth 4mm less than implant length	2.1mm	Depth 4mm less than implant length
D4	1.6mm	Depth 4mm less than implant length	2.1mm	Depth 4mm less than implant length

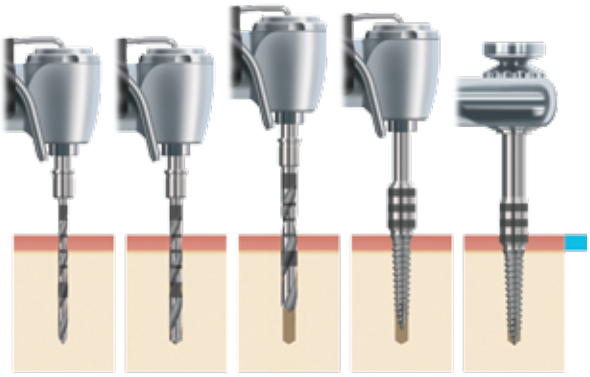
Bone type is a general classification. The overall bone quality must be assessed by the clinician through treatment planning and at the time of surgery in order to create the appropriate osteotomy size to achieve the desired insertion torque.

DRILLING SEQUENCE EXAMPLES

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

2.4MM LASER DEPTH MARKINGS

D1 BONE TYPE

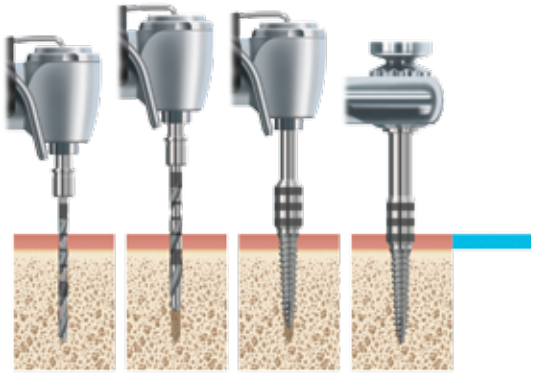


1.2mm Pilot Full Depth 14mm Line | 1.6mm Full Depth 14mm Line | 2.1mm Full Depth 10mm Line | Tap Speed Until Stop | Ratchet to Full Depth

D2/D3 BONE TYPE

1.2mm Pilot Full Depth 14mm Line | 1.6mm 4mm Short 10mm Line | Tap Speed Until Stop | Ratchet to Full Depth

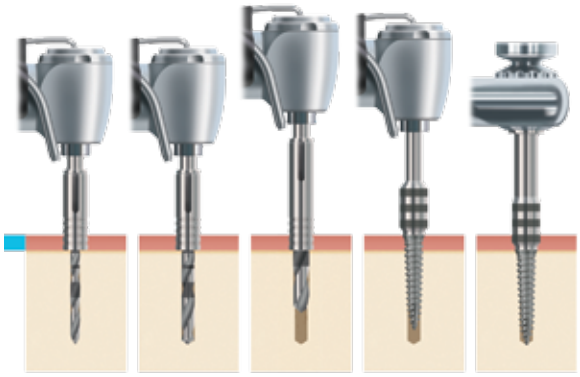
D4 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | 1.6mm 4mm Short 10mm Line | Tap Speed Until Stop | Ratchet to Full Depth

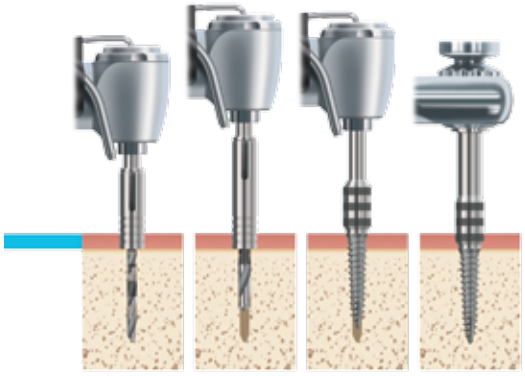
2.4MM DRILL STOPS

D1 BONE TYPE



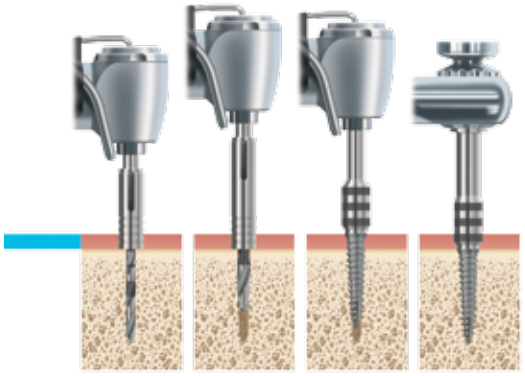
1.2mm Pilot Full Depth 12mm Drill Stop | 1.6mm Full Depth 12mm Drill Stop | 2.1mm Full Depth 8mm Drill Stop | Tap Speed Until Stop | Ratchet to Full Depth

D2/D3 BONE TYPE



1.2mm Pilot Full Depth 12mm Drill Stop | 1.6mm 4mm Short 8mm Drill Stop | Tap Speed Until Stop | Ratchet to Full Depth

D4 BONE TYPE



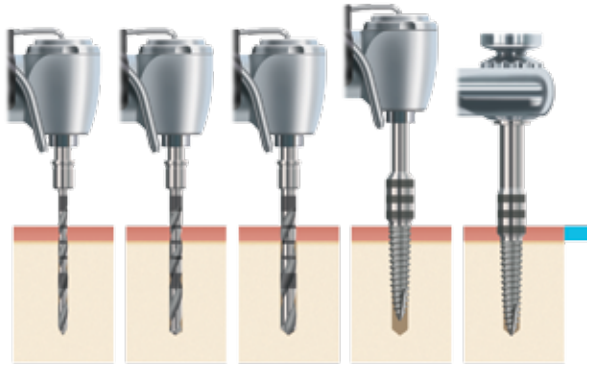
1.2mm Pilot Full Depth 12mm Drill Stop | 1.6mm 4mm Short 8mm Drill Stop | Tap Speed Until Stop | Ratchet to Full Depth

DRILLING SEQUENCE EXAMPLES
(CONTINUED)

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

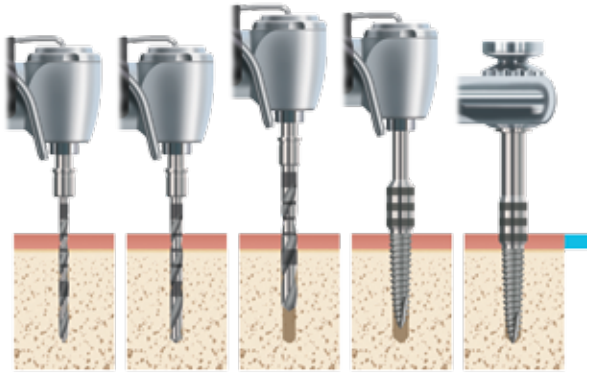
2.9MM LASER DEPTH MARKINGS

D1 BONE TYPE



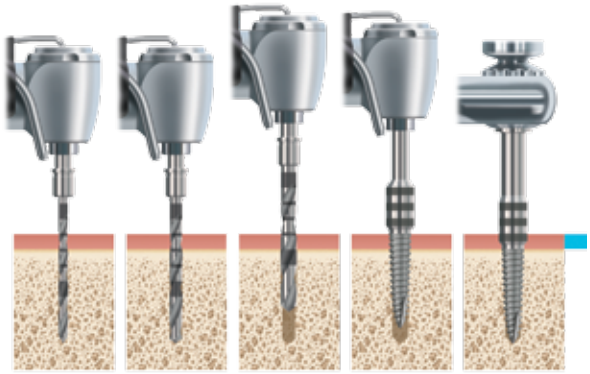
1.2mm Pilot Full Depth 14mm Line | 1.6mm Full Depth 14mm Line | 2.4mm Full Depth 14mm Line | Tap Speed Until Stop | Ratchet to Full Depth

D2/D3 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | 1.6mm Full Depth 14mm Line | 2.1mm 4mm Short 10mm Line | Tap Speed Until Stop | Ratchet to Full Depth

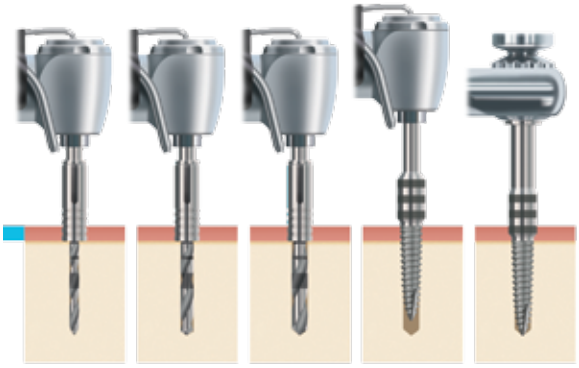
D4 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | 1.6mm Full Depth 14mm Line | 2.1mm 4mm Short 10mm Line | Tap Speed Until Stop | Ratchet to Full Depth

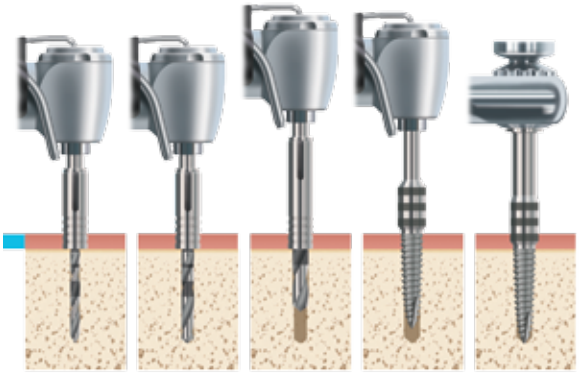
2.9MM DRILL STOPS

D1 BONE TYPE



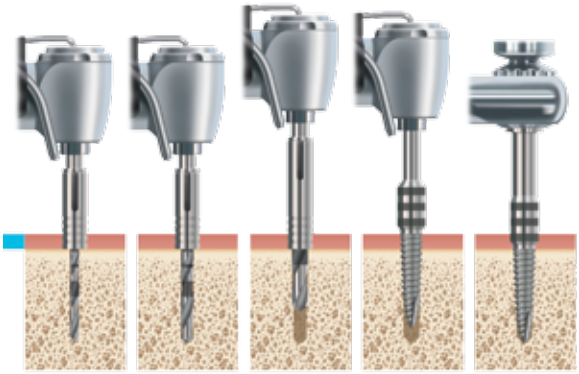
1.2mm Pilot Full Depth 12mm Drill Stop | 1.6mm Full Depth 12mm Drill Stop | 2.4mm Full Depth 12mm Drill Stop | Tap Speed Until Stop | Ratchet to Full Depth

D2/D3 BONE TYPE



1.2mm Pilot Full Depth 12mm Drill Stop | 1.6mm Full Depth 12mm Drill Stop | 2.1mm 4mm Short 8mm Drill Stop | Tap Speed Until Stop | Ratchet to Full Depth

D4 BONE TYPE

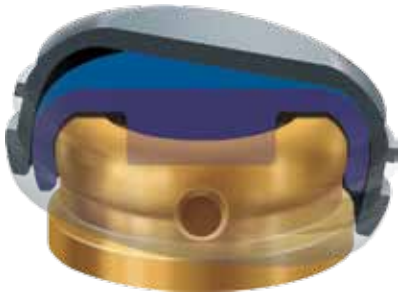


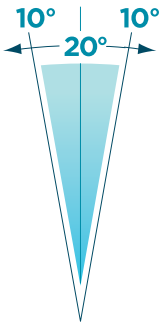
1.2mm Pilot Full Depth 12mm Drill Stop | 1.6mm Full Depth 12mm Drill Stop | 2.1mm 4mm Short 8mm Drill Stop | Tap Speed Until Stop | Ratchet to Full Depth

LOCATOR® MALES & EXTENDED RANGE MALES

LOCATOR MALES

The unique Dual Retention innovation provides the LOCATOR Attachment with a greater retention surface area than ever before available with other attachments.



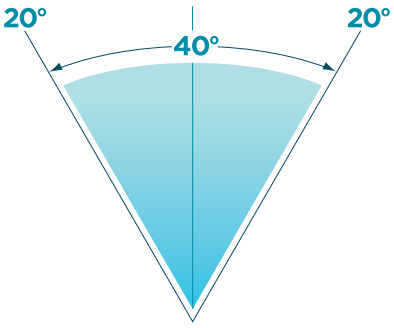


1.5 lbs 3 lbs 5 lbs

Dual retention, pivoting action provides resiliency to maximize stability and longevity.

EXTENDED RANGE MALES

Allows you to restore a non-parallel implant with up to 20 degrees of angulation. This calculates to an extensive 40 degrees of divergence between two implants.



0 lbs 1 lbs 2 lbs 4 lbs

Extended Range Male's pivoting action allows for insertion with up to 40° total divergence.

A LODI MALE PROCESSING PACK IS INCLUDED WITH EACH IMPLANT

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

LODI Male Processing Pack

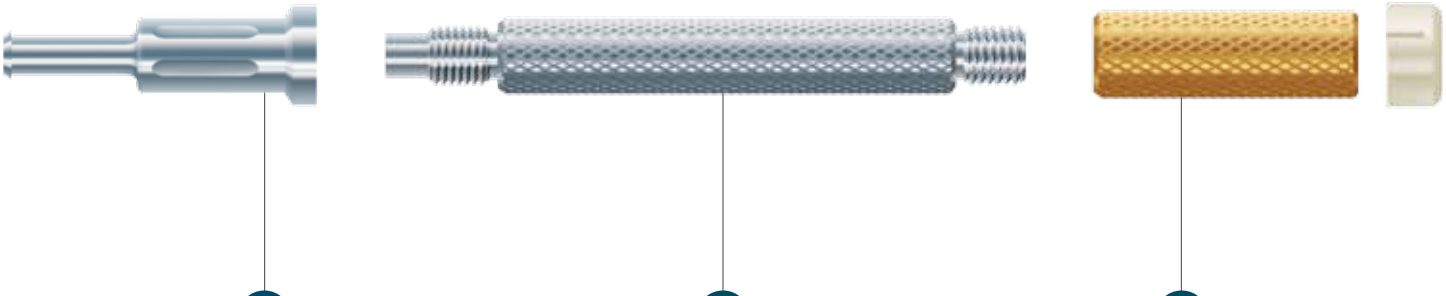
Denture Cap | Blue 1.5 lbs | Pink 3 lbs | Red 1 lbs

Spacer Ring

LOCATOR® CORE TOOL

LOCATOR CORE TOOL

The LOCATOR Implant Attachment System features a Core Tool that contains 3-tools-in-1. This convenient tool is used to carry and place the LOCATOR Attachment onto the implant, remove the LOCATOR Male, and insert the male into the LOCATOR Denture Cap. Insert drivers for various types of torque wrenches are available to achieve 30Ncm of torque.



1

REMOVAL

The Male Removal Tool has a sharp edge on the end to catch and remove the male from the Denture Cap.

2

INSERTION

The Male Seating Tool is used to seat the LOCATOR Male.

3

PLACEMENT

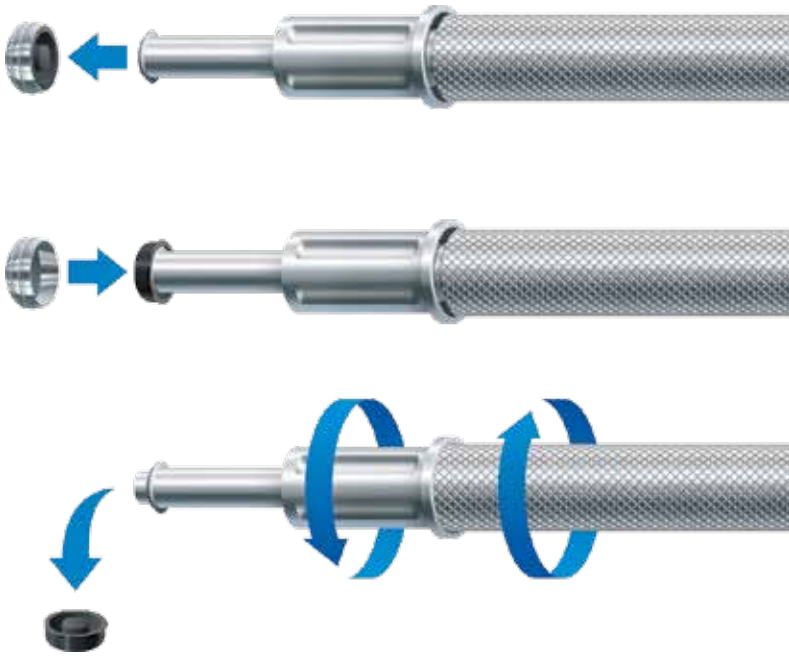
The LOCATOR Abutment Driver with the Abutment Holder Sleeve carries the attachment securely and places it onto the implant.

Loosen the Male Removal Tool a full 3 turns counter clockwise (you will see a visible gap).

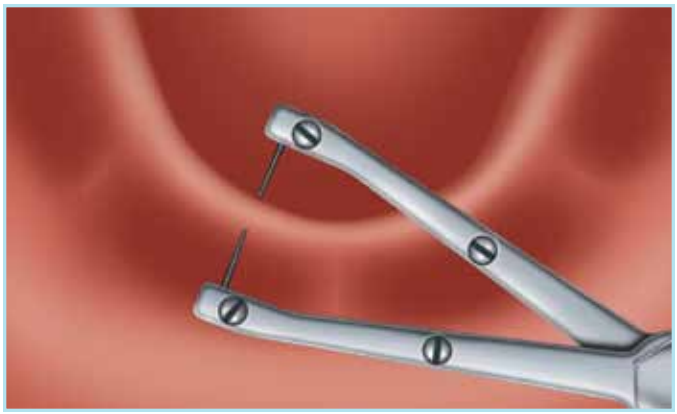
To remove a LOCATOR nylon male from the Denture Cap; simply insert the tip into the cap/male assembly and push straight in to the bottom of the nylon male. Then tilt the tool so that the sharp edge of the tip will grab hold of the male and pull it out of the Denture Cap.

To discard the nylon male from the tip on the Core Tool; point the tool down and away from you and tighten the Male Removal Tool clockwise back onto the Core Tool. This will activate the removal pin and dislodge the nylon male from the tip end of the Male Removal Tool.

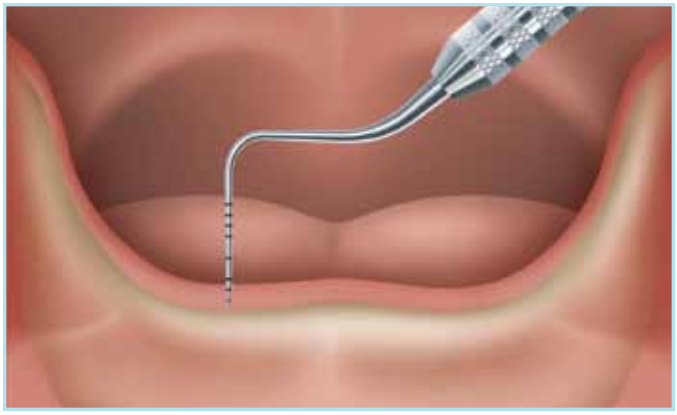
Separate the Male Removal Tool section from the LOCATOR Core Tool and use the Male Seating Tool end of the remaining two sections to place a new nylon male into the empty Denture Cap.



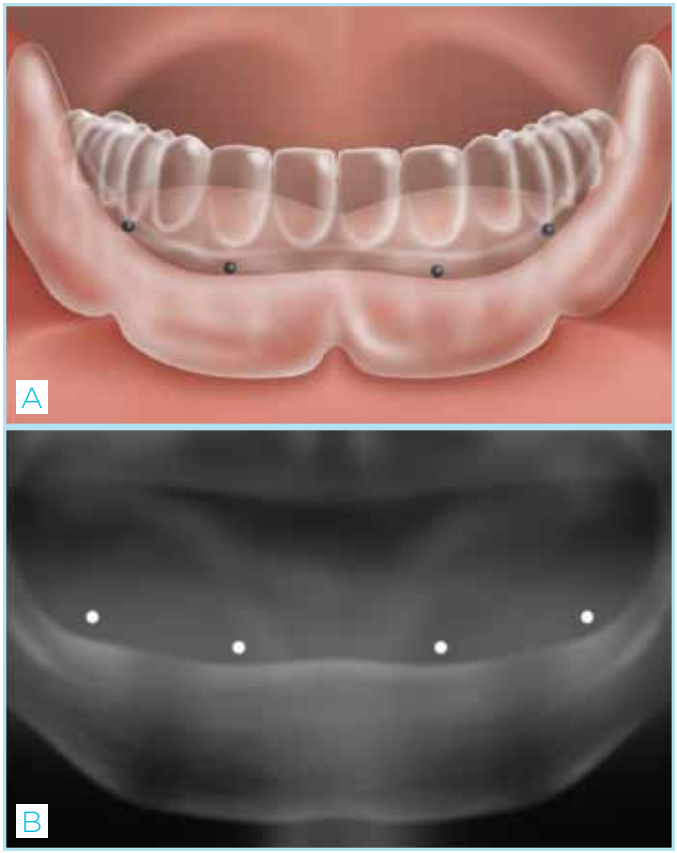
PRE-SURGICAL TREATMENT PLANNING



1 Evaluate available bone width for implant positions by using the index finger/thumb technique or a ridge mapping instrument.



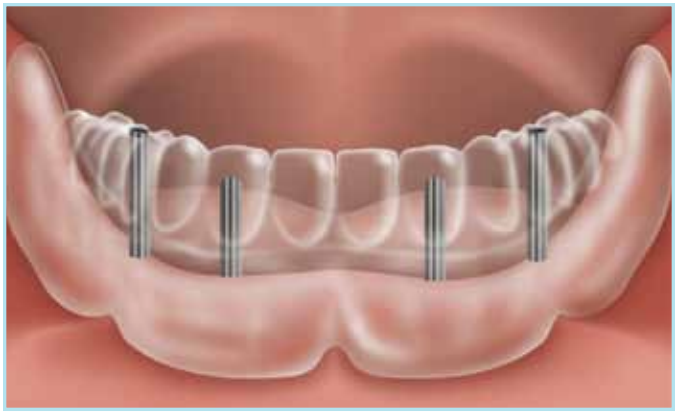
2 Measure the gingiva depth at each implant location using a perio probe to determine the proper depth measurement line on the osteotomy preparation drills and to select the LOCATOR® Attachment cuff height of either 2.5mm or 4mm.



3A-3B Radiograph the arch using a panoramic radiograph or CBCT to determine available bone height for implant positions. A radiographic template with measurement balls may be fabricated to assist with determining dimensions.

PRE-SURGICAL TREATMENT PLANNING
(CONTINUED)

4 Determine if the patient's existing denture(s) will be used or if new ones will be fabricated. If a new denture is made, follow the conventional process. Have the patient wear the new denture for 2 weeks prior to implant placement.

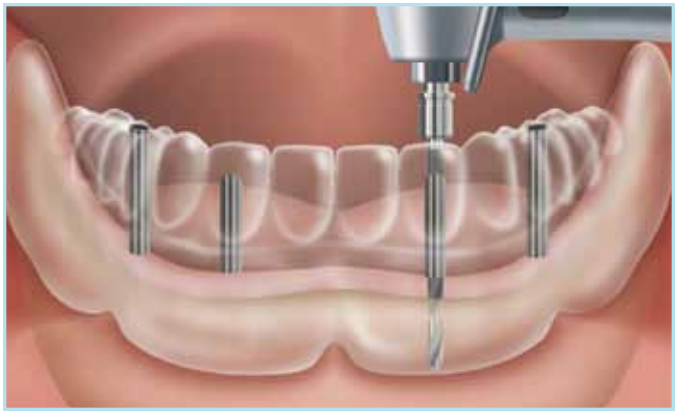


5 A surgical guide for implant placement may be fabricated from the patient's existing or new denture prior to surgery.

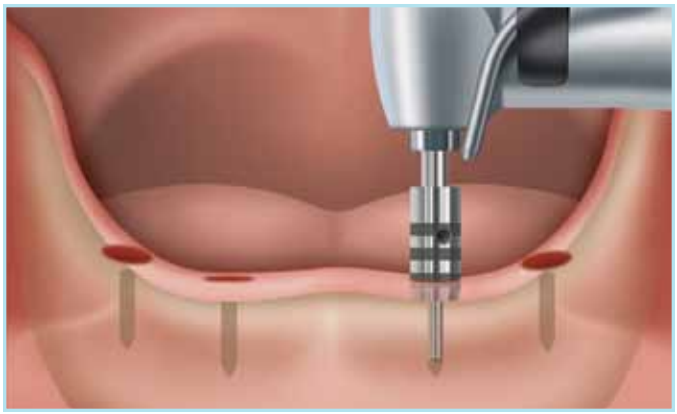
IMPLANT PLACEMENT

After patient selection and evaluation protocols have been completed, the number of implants required is determined and discussed with the patient. The patient's denture is then fabricated or modified, followed by identification of appropriate implant sites. For mandibular placement, the position of the nerve and bone quality must be taken into consideration. For maxillary placement, bone volume, bone quality and sinus location must be taken into consideration.

EXAMPLE IS PLACEMENT OF FOUR **2.9MM X 10MM** IMPLANTS IN TYPE D1 BONE

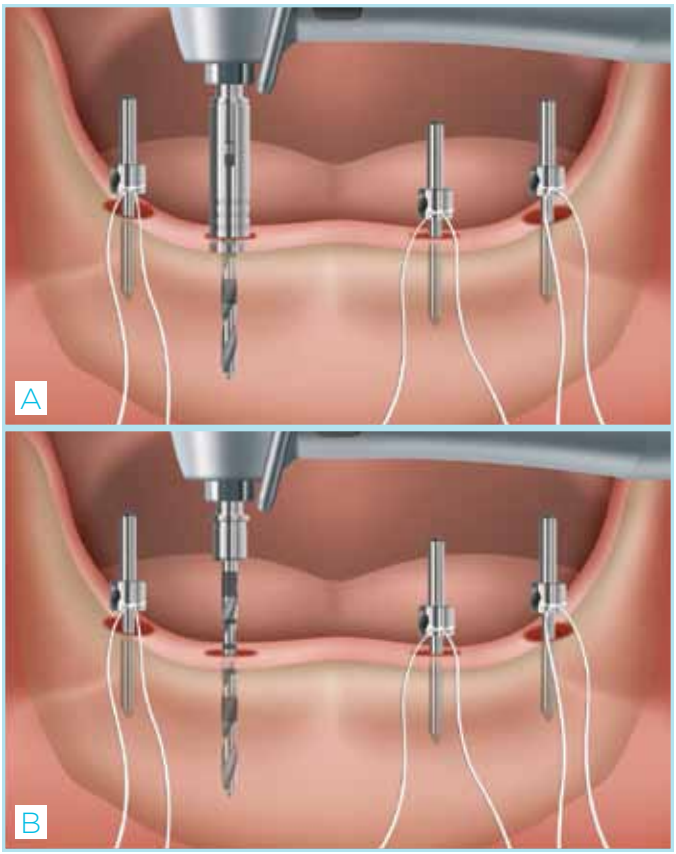


1 Using the surgical guide or by free hand, mark the implant osteotomy locations by drilling through the gingiva and into the bone crest approximately 6mm using the 1.2mm Pilot Drill. Note the gingival depth. The recommended drill speed is 1200-1500 rpm.



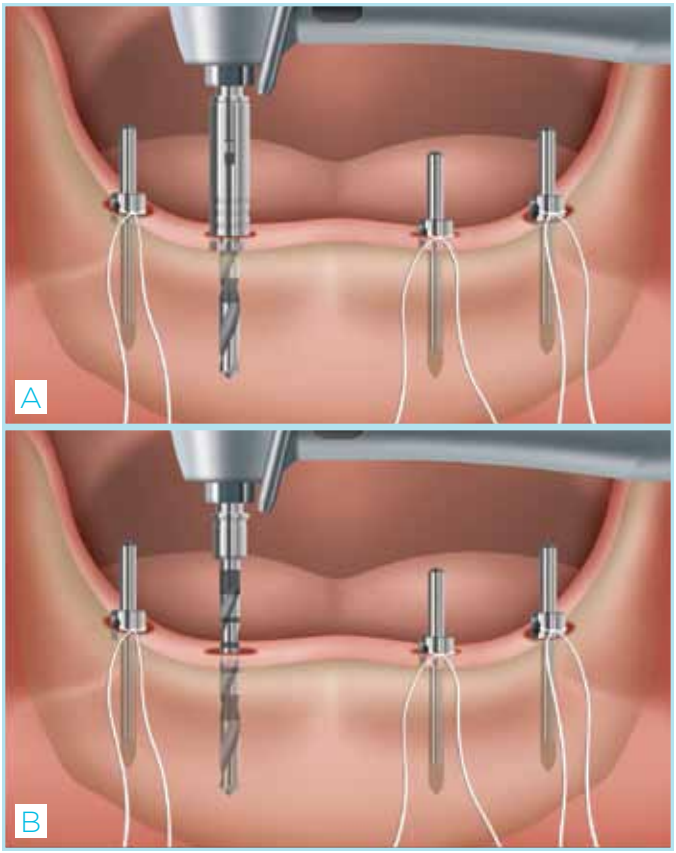
2 Remove the gingiva cores at each site using the Rotary Tissue Punch. Place the guide pin portion into the pilot holes and rotate to cut away the gingiva. Rotate the Tissue Punch to the laser depth mark indicated from the gingiva depth measurement. The recommended speed is up to a maximum of 800 rpm.

IMPLANT PLACEMENT
(CONTINUED)



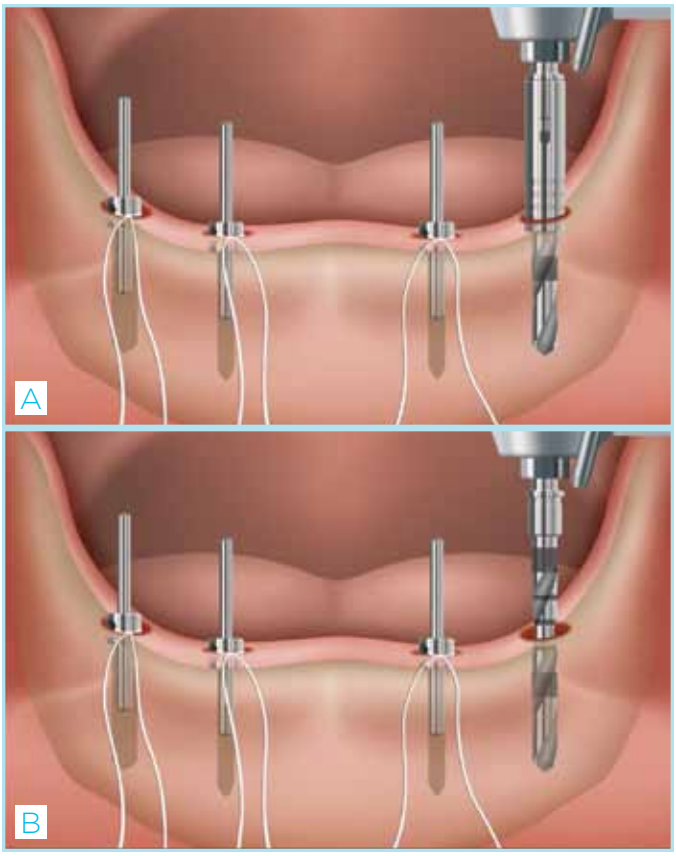
EXAMPLE IS PLACEMENT OF FOUR **2.9MM X 10MM** IMPLANTS IN TYPE D1 BONE • CONTINUED

3A-3B Place the 1.2mm diameter (small) end of the Direction Indicator into the pilot drill osteotomies to verify the proper angulation. Place the proper length drill stop onto the 1.2mm Pilot Drill according to the desired drill depth. Or, drill to the proper laser depth marking on the drill calculated by adding the desired drill depth and tissue depth. The recommended drill speed is 1200-1500 rpm. Continue osteotomy preparation to the desired depth at each implant site.



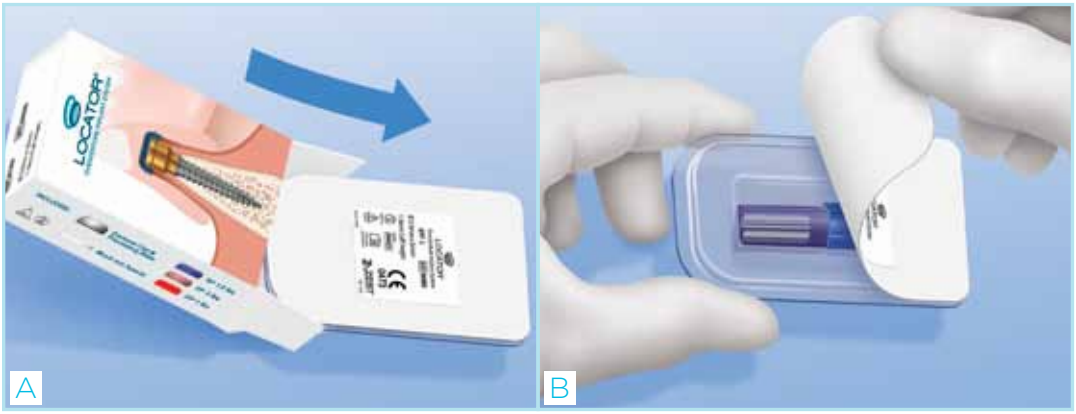
4A-4B Place the proper length drill stop onto the 1.6mm drill according to the desired drill depth. Or, drill to the proper laser depth marking on the drill calculated by adding the desired drill depth and tissue depth. The recommended drill speed is 1200-1500 rpm. Continue osteotomy preparation to the desired depth at each implant site.

IMPLANT PLACEMENT
(CONTINUED)

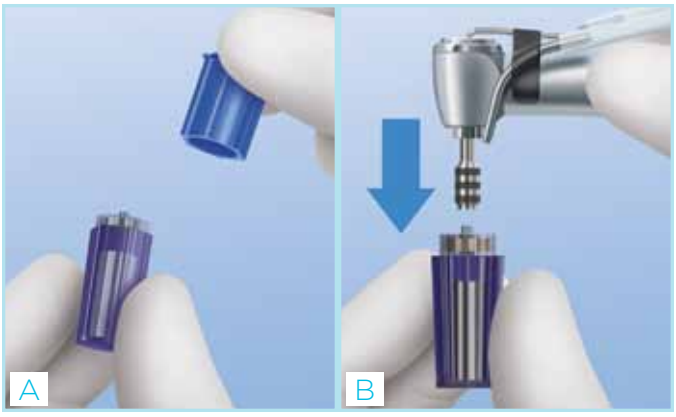


EXAMPLE IS PLACEMENT OF FOUR **2.9MM X 10MM** IMPLANTS IN TYPE D1 BONE • CONTINUED

5A-5B Place the 1.6mm diameter end of the Directional Indicator into the osteotomies to verify the proper angulation. Place the proper length drill stop onto the 2.4mm drill according to the desired drill depth. Or, drill to the proper laser depth marking on the drill calculated by adding desired drill depth and tissue depth. The recommended drill speed is 1200-1500 rpm. 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. Drop the implant vial on the sterile tray. The contents of the plastic tray are sterile and should only contact components within the sterile field.

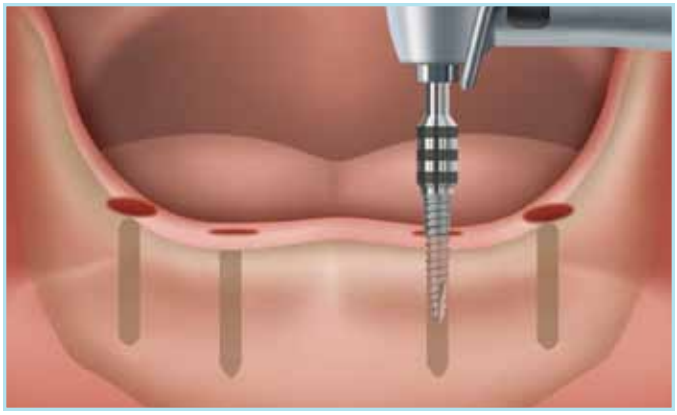


7A-7B Remove the cap from the implant vial and do not discard. The LOCATOR® Attachment is in the cap. Set the drilling unit speed at 50rpm and the placement torque at 35Ncm. Place the Implant Driver in the handpiece. Insert the Implant Driver onto the hex on the top of the implant and press down to frictionally engage. The bottom of the driver should contact the attachment seating surface and fully engage the entire length of the implant hex.

IMPLANT PLACEMENT
(CONTINUED)

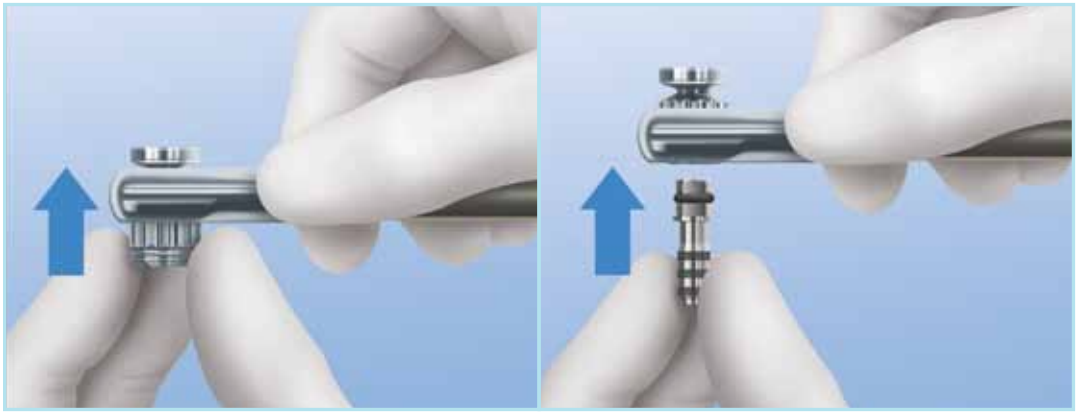
EXAMPLE IS PLACEMENT OF FOUR **2.9MM X 10MM** IMPLANTS IN TYPE D1 BONE • CONTINUED

8 Remove the implant from the vial in a straight out motion.

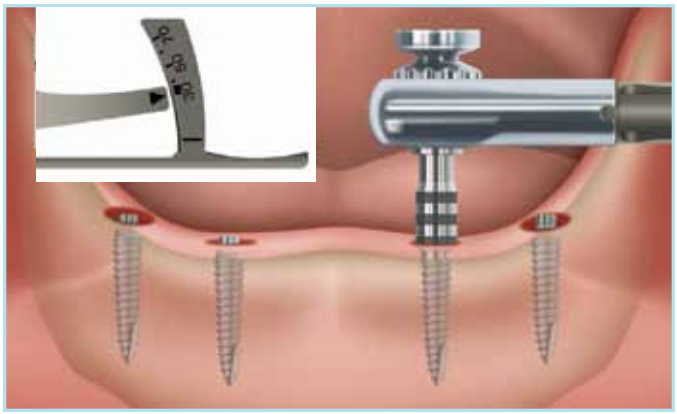


9 Carry the implant to the mouth, place it into the osteotomy and tap into place at 50 rpm. Avoid sudden movement and/or touching an external object which may dislodge the implant from the driver.

Warning: Discard and do not use an implant that has been dropped in a non-sterile area and replace with a new sterile implant.

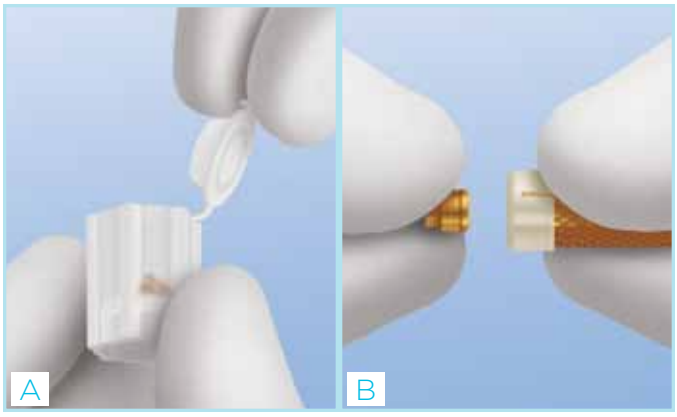


10A-10B When the drilling unit stops tapping the implant, place the Torque Indicating Ratchet Wrench Insert into the Torque Ratchet Wrench. Place the Implant Driver (short or long) into the insert.

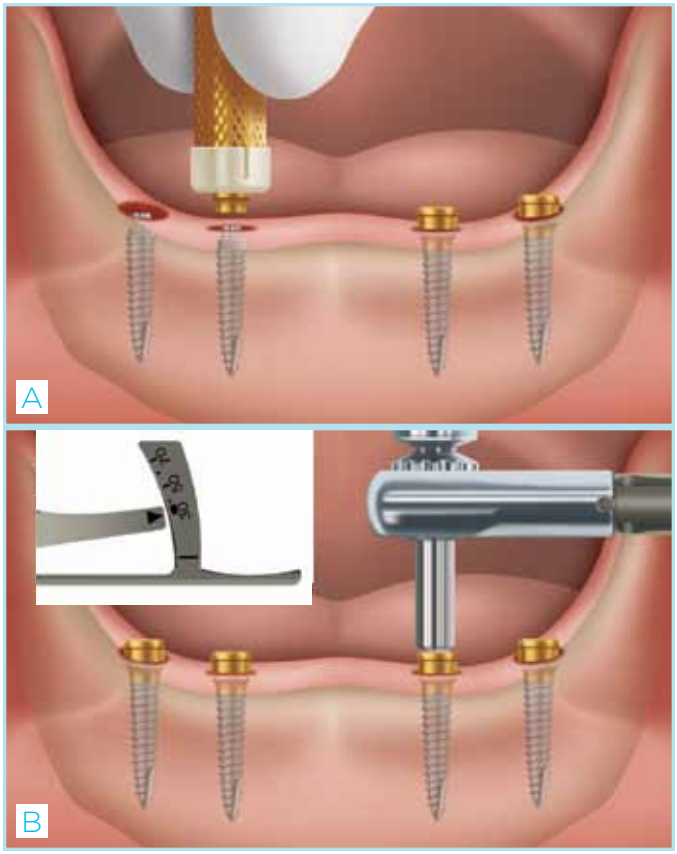


11 Position the Implant Driver onto the hex on the top of the implant and verify that it is fully engaged. Slowly ratchet the implant to full depth. If final seating torque measures 30Ncm or above, the implant may be immediately loaded at the discretion of the clinician. If the final seating torque measures below 30Ncm, the denture acrylic should be relieved and a soft liner placed around the LOCATOR® Attachments during the integration period. Implant insertion torque should not exceed 70Ncm. If 70Ncm of torque is reached, prior to full seating, the implant should be removed and the osteotomy should be enlarged.

LOCATOR® ATTACHMENT PLACEMENT



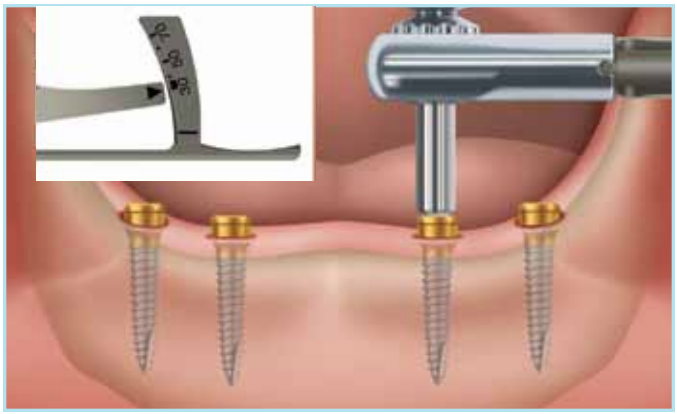
1A-1B Open the flip cap on the top of the vial cap and remove the LOCATOR Attachment. Place the Abutment Holder Sleeve onto the LOCATOR Abutment Driver. Place the attachment into the Abutment Holder Sleeve to securely carry it to the mouth.



2A-2B Thread the LOCATOR Attachment onto the implant until finger tight. If the implant placement torque was 30Ncm or greater, the attachments may be tightened to the recommended torque level of 30Ncm. If the implant placement torque did not reach 30Ncm, the attachments should only be hand tightened. Place the LOCATOR Attachment Torque Driver Insert into the Torque Ratchet Wrench. Insert the driver into the attachment and verify it is fully engaged. Torque the attachments to 30Ncm.

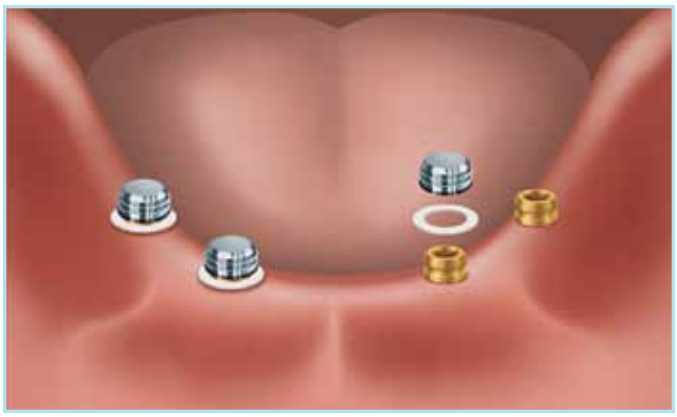
3 If the implant placement torque was 30Ncm or greater, the implants may at the discretion of the clinician be immediately loaded. Continue on with steps for processing the LOCATOR Denture Caps and Males into the denture. If the implant placement torque was less than 30Ncm, relieve the denture acrylic and place a soft liner in the denture around the LOCATOR Attachments during the integration period.

PROCESSING LOCATOR® DENTURE CAPS AND MALES INTO THE DENTURE



DIRECT TECHNIQUE: CHAIRSIDE PROCESSING (NEW OR EXISTING DENTURE)

1 If the implants were not immediately loaded, the LOCATOR Attachments must be torque tightened. Place the LOCATOR Abutment Torque Driver Insert into the Torque Ratchet Wrench. Insert the driver into the attachment and verify that it is fully engaged. Torque the attachments to 30Ncm.

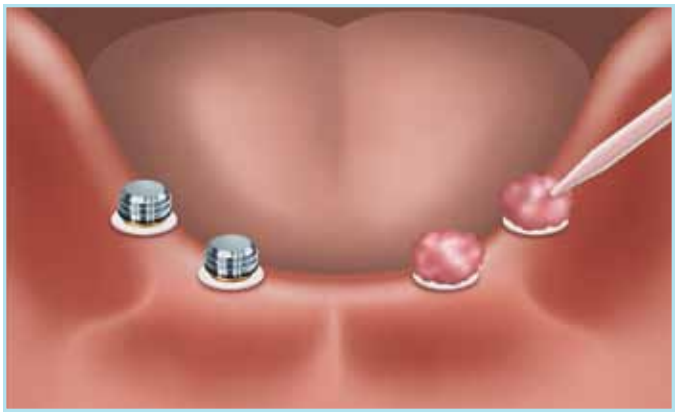


2 Place a White Block Out Spacer Ring around each attachment and press it down to the tissue. Place a Denture Cap with a Black Processing Male inside of it onto each attachment and press down firmly.

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

4 Relieve the areas marked with an acrylic bur. Try in the denture to verify that the Denture Caps are not in contact with the acrylic in any area. Cut lingual/palatal vent windows in the denture to visualize full seating and for an excess acrylic vent.

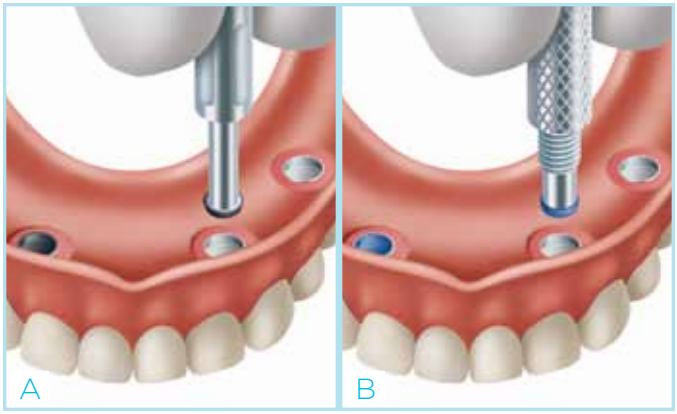
PROCESSING LOCATOR® DENTURE CAPS AND MALES INTO THE DENTURE (CONTINUED)



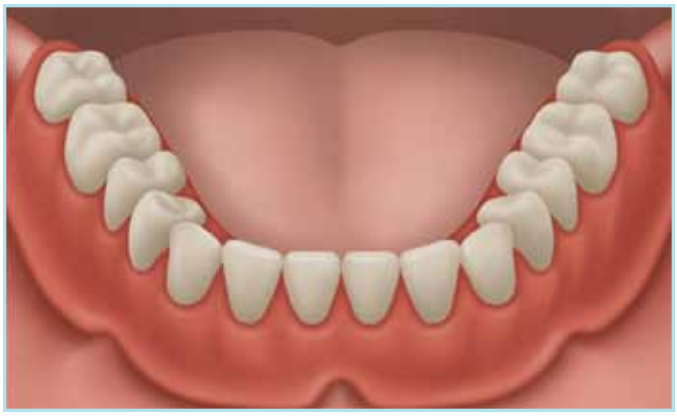
DIRECT TECHNIQUE: CHAIRSIDE PROCESSING (CONTINUED)

5 An autopolymerizing or light cure acrylic resin may be used to pick up the caps. Dry the Denture Caps. Apply a small amount of acrylic around the circumference of each cap. Place acrylic into the relief areas of the denture and seat it over the caps and onto the tissue. Have the patient close into occlusion and hold while the acrylic sets.

6 Disengage the denture from the LOCATOR Attachments and remove from the mouth. Verify that the Denture Caps have been securely picked up in the denture. Fill any voids and polish the denture.



7A-7B See the LOCATOR Core Tool instructions on page 10. Remove the Black Processing Male using the Male Removal Tool. Place the selected final male into each Denture Cap using the Male Insertion Tool. It is recommended to place the least retentive male to begin with. See the male retention chart on page 9.



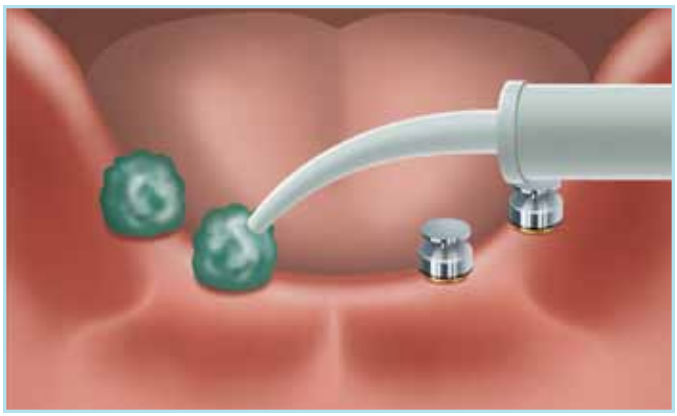
8 Place the denture in the mouth and press down to engage the males on the LOCATOR Attachments. Verify the occlusion. Instruct the patient on how to remove and insert the denture. If the retention is not satisfactory, remove the males and replace with the next level of retention. See the male retention chart on page 9. Instruct the patient on proper home care maintenance and required recall visits.

PROCESSING LOCATOR® DENTURE CAPS AND MALES INTO THE DENTURE (CONTINUED)

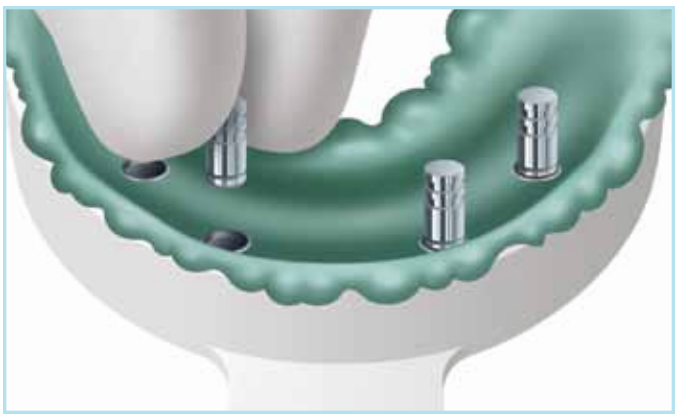
INDIRECT TECHNIQUE: LABORATORY PROCESSING (APPT. 1)

1 If the implants were not immediately loaded, the LOCATOR® Attachments must be torque tightened. Place the LOCATOR Abutment Torque Driver Insert into the Torque Ratchet Wrench. Insert the driver into the attachment and verify that it is fully engaged. Torque the attachments to 30Ncm.

2 A stock or custom impression tray may be used. Ensure on each that there is enough space for the 4mm height of the LOCATOR Impression Copings.

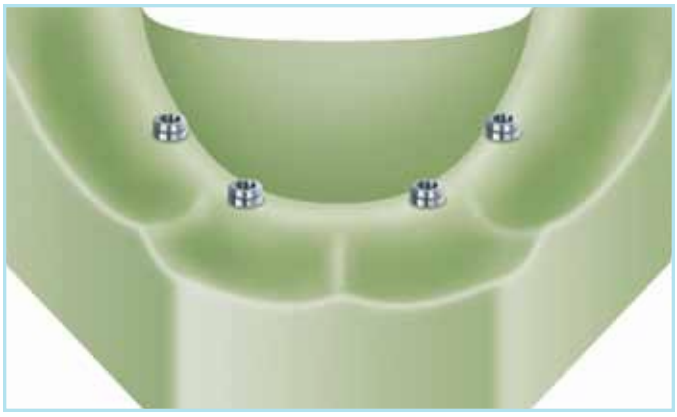


3 Place a LOCATOR Impression Coping on each attachment and press down firmly. Syringe a medium body impression material around the circumference of each coping. Fill the impression tray and insert it over the copings and onto the tissue. Allow the material to set. Remove the impression and verify that the copings have been securely picked up inside of it.



4 Press the LOCATOR Analogs into each impression coping. Send the impression to the laboratory.

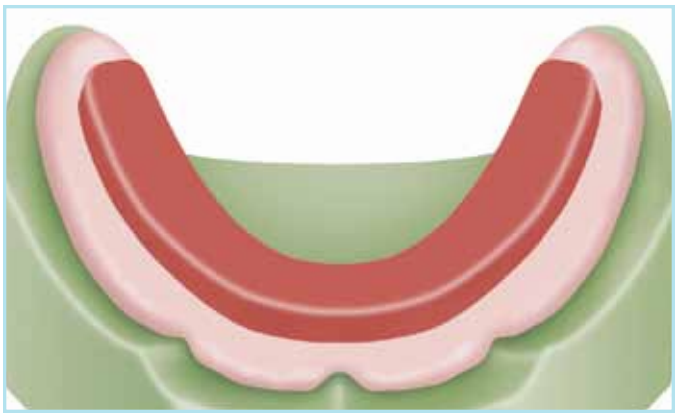
PROCESSING LOCATOR® DENTURE CAPS AND MALES INTO THE DENTURE (CONTINUED)



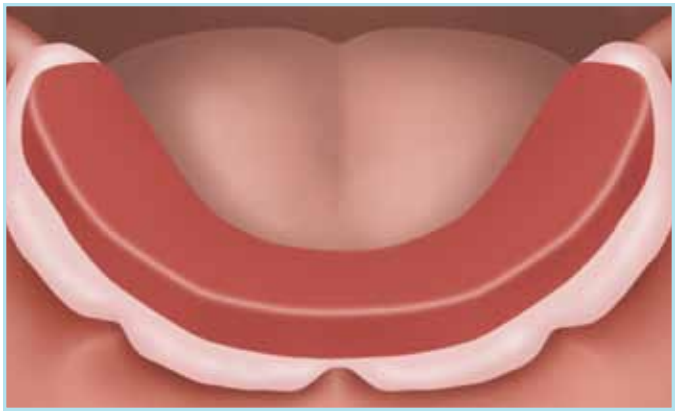
INDIRECT TECHNIQUE: LABORATORY PROCESSING (CONTINUED)

LAB STEP 1

1 Verify that the analogs are secure in the impression copings. Pour die stone into the impression to fabricate the master cast.



2 Fabricate the baseplate and wax rim on the cast for the bite registration. The Denture Caps with Black Processing Males may be processed into the baseplate to provide stabilization during record making.



BITE RECORDS (APPT. 2)

1 Place the wax rim into the mouth and make the bite records. Take an impression of the opposing arch and pour the cast. Select a shade for the denture teeth.

LAB STEP 2

1 Articulate the master cast with the opposing using the bite records. Set the denture teeth on the baseplate and fabricate a wax denture for try in.

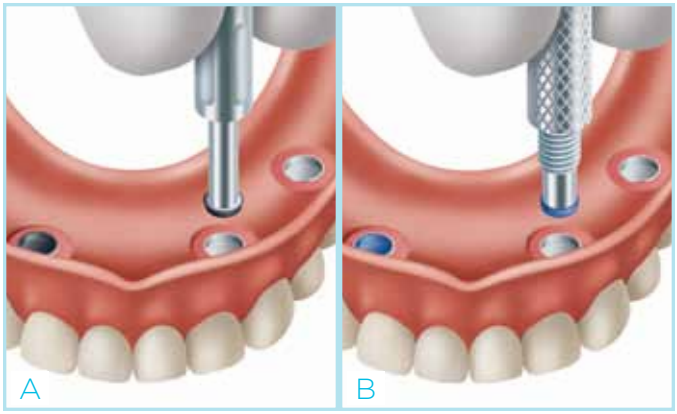
PROCESSING LOCATOR® DENTURE CAPS AND MALES INTO THE DENTURE (CONTINUED)

DENTURE TRY IN (APPT. 3)

1 Place the wax denture into the mouth and verify the esthetics, phonetics and occlusion.

LAB STEP 3

1 Wax and flask the denture for processing. Separate the flask and boil away all wax. Place the Denture Caps with Black Processing Males 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.



2A-2B See the LOCATOR Core Tool instructions on page 10. Remove the Black Processing Male using the Male Removal Tool.Place the selected final male into each Denture Cap using the Male Insertion Tool. It is recommended to place the least retentive male to begin with. See the male retention chart on page 9.

DELIVERY (APPT. 4)

1 Place the denture in the mouth and press down to engage the males on the LOCATOR Attachments. Verify the occlusion. Instruct the patient on how to remove and insert the denture. If the retention is not satisfactory, remove the males and replace with the next level of retention. See the male retention chart on page 9. Instruct the patient on proper home care maintenance and required recall visits.

EXPLANATION OF SYMBOLS ON OUTER PACKAGING LABELS

SYMBOL	STANDARD	EXPLANATION OF SYMBOL	LOCATION OF SYMBOL
	ISO 980	Symbol for **"DO NOT REUSE"** For single-use. Use only once.	**ON THE FOLLOWING LABELS:** **1)** L9127-XXXX **2)** L7409-XXXX **3)** L9108-XXXX
	ISO 980	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.	**ON THE FOLLOWING LABELS:** **4)** L9127-XXXX **5)** L7409-XXXX **6)** L9108-XXXX **7)** L9115-07420 **8)** L9912-07362 **9)** L9109-XXXX
	ISO 980	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.	**ON THE FOLLOWING LABELS:** **10)** L9127-XXXX **11)** L7409-XXXX **12)** L9108-XXXX **13)** L9115-07420 **14)** L9912-07362 **15)** L9109-XXXX
	ISO 980	Symbol for **"STERILIZED USING IRRADIATION"** **NOTE:** Refers to Implant/Attachment sterilized packaging only.	**ON THE FOLLOWING LABELS:** **16)** L9127-XXXX **17)** L7409-XXXX
	ISO 980	Symbol for **"CATALOGUE NUMBER"** The product catalogue number shall be after or below the symbol adjacent to it.	**ON THE FOLLOWING LABELS:** **18)** L9127-XXXX **19)** L7409-XXXX **20)** L9108-XXXX

NOTES

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