SATURNO™

NARROW DIAMETER IMPLANT SYSTEM

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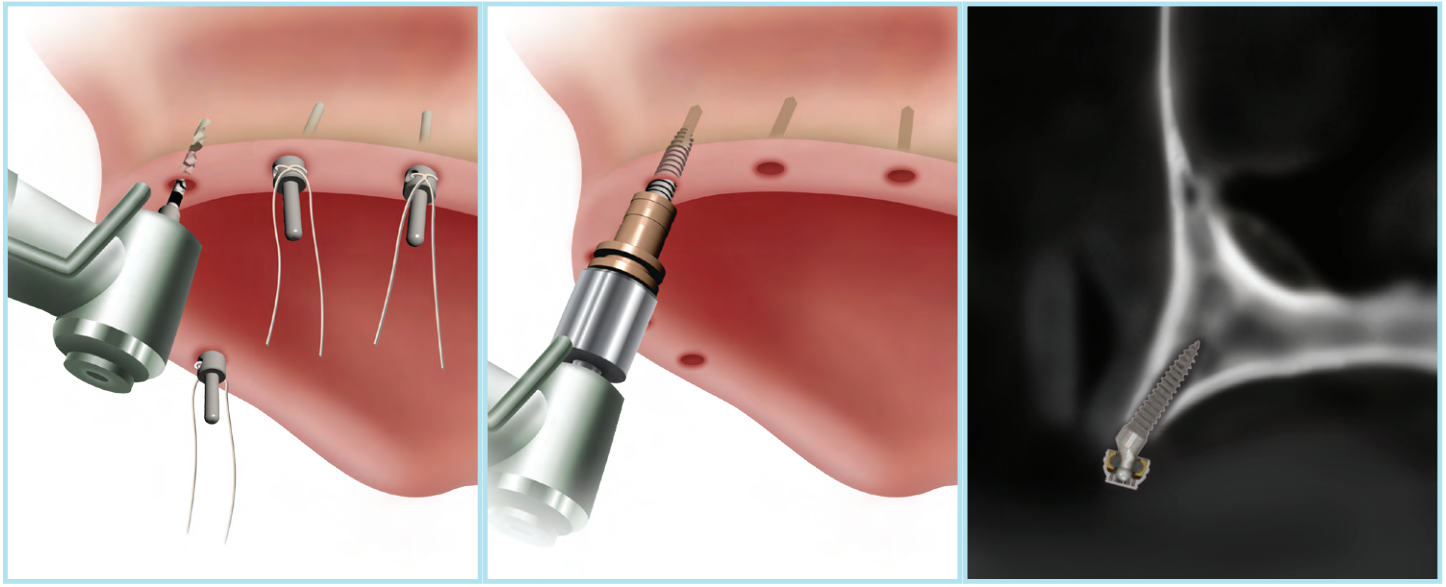


TECHNIQUE MANUAL

ZEST ANCHORS

THE SATURNO™ NARROW DIAMETER IMPLANT SYSTEM.

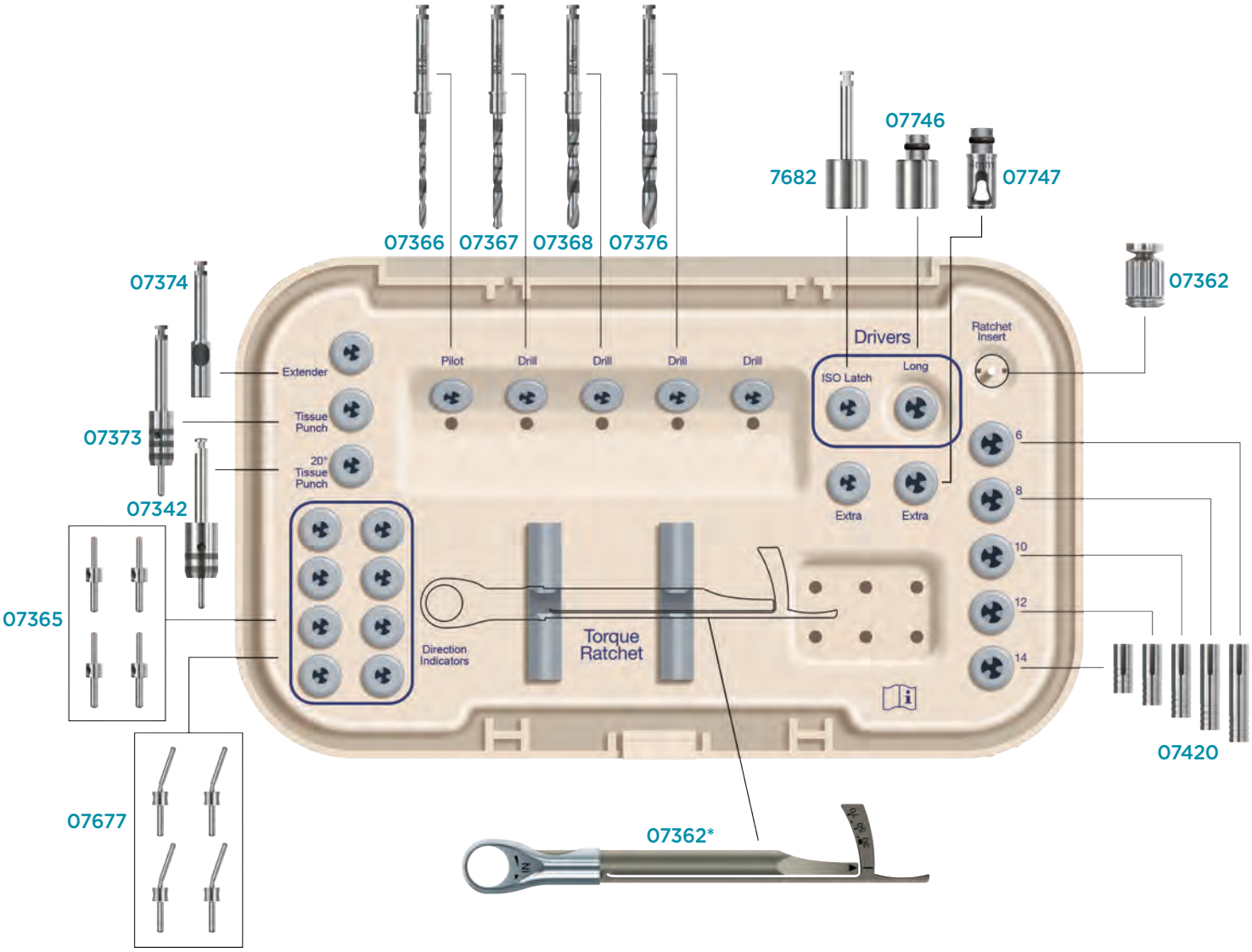
FOUR DECADES OF ATTACHMENT KNOWLEDGE INCORPORATED INTO NARROW DIAMETER OVERDENTURE IMPLANTS.

The SATURNO Narrow Diameter Implant System is comprised of 2.0, 2.4 or 2.9mm diameter endosseous dental implants (available in 10, 12 and 14mm lengths).
A straight or 20° angled O-Ball Implant is available for each implant size.
The implant cuff heights are available in 2 or 4mm.

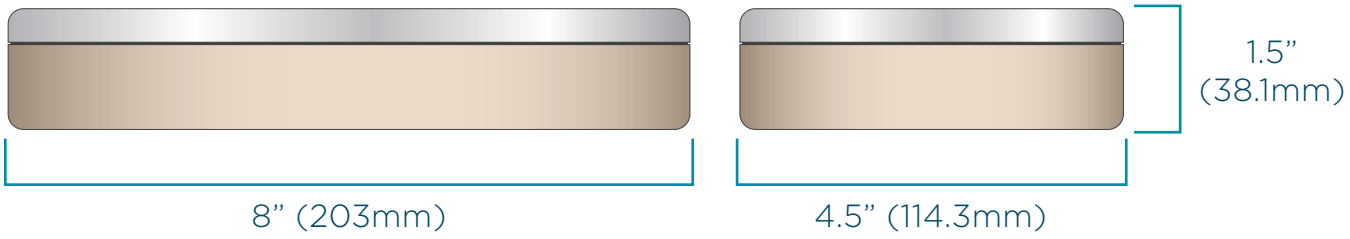
The SATURNO Implant is used to restore masticatory function for the patient and may be suitable for immediate function if sufficient primary stability of the implant is achieved at the time of placement. The final treatment option may be determined at the time of surgery as the clinicians must consider 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 clinicians.

IMPORTANT:

This document contains the most current instructions for use. Please read and retain.



KIT DIMENSIONS



*not included in kit purchase

TABLE OF CONTENTS

SATURNO™ IMPLANT FEATURES AND BENEFITS

1 SATURNO Angled O-Ball Implant allows for correction in challenging anatomical cases.

2 Progressive thread design that widens at the coronal portion providing primary stability.

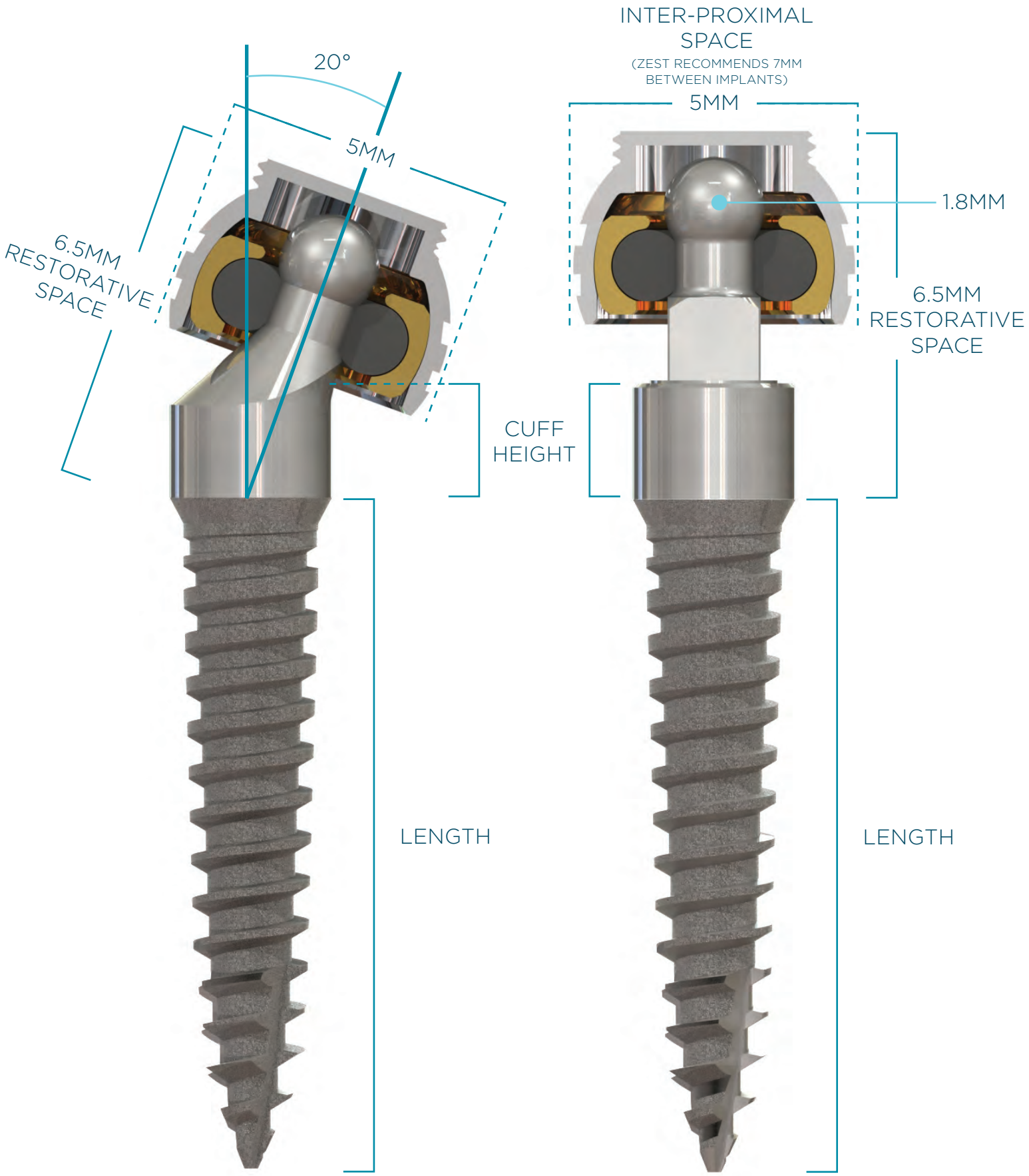
3 Proven RBM surface on entire length of implant.

4 SATURNO pivoting O-Ring race moves 15° in any direction within the denture cap, creating an aligned fit that is forgiving and patient-friendly.

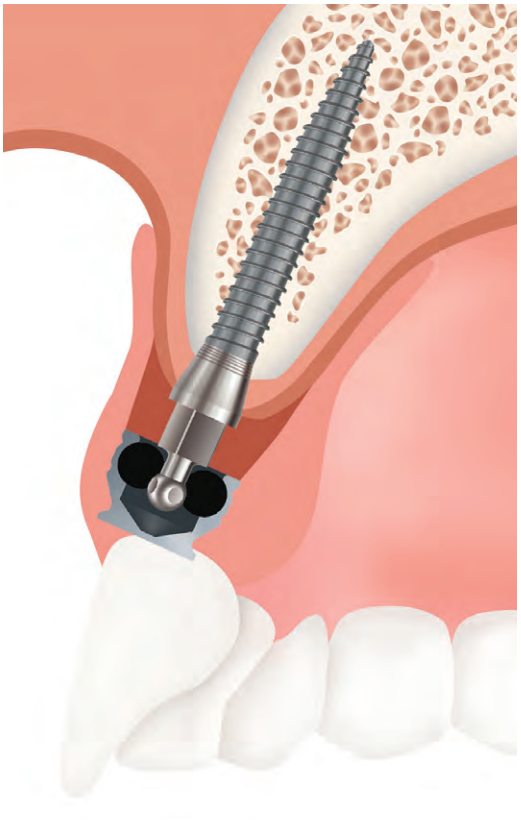
5 SATURNO implants are available in multiple diameters (2.0, 2.4, and 2.9mm), lengths (10, 12, and 14mm) and cuff height options (2 and 4mm).

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

SATURNO™ IMPLANT DIMENSIONS

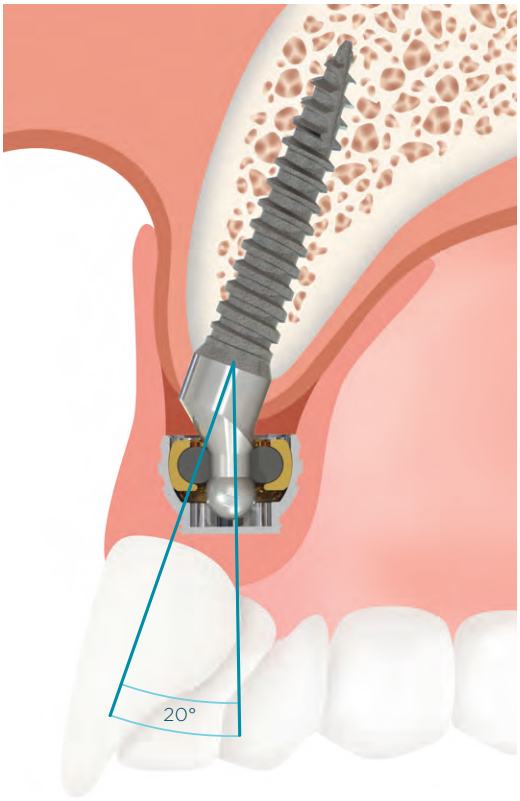


PIVOTING SATURNO™ O-RING ATTACHMENT

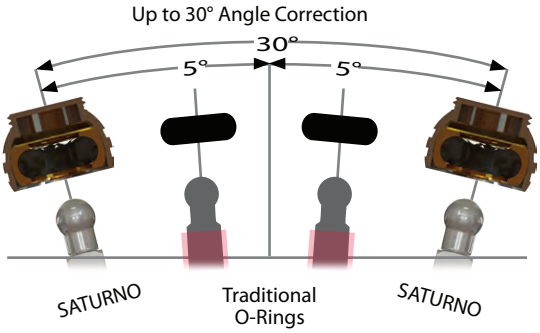


ANGLED IMPLANT VERSUS CONVENTIONAL STRAIGHT IMPLANT—

A FAR BETTER EMERGENCE ANGLE



EXTENSIVE LABORATORY TESTING HAS DEMONSTRATED SATURNO O-RING ATTACHMENT TO OUTPERFORM TRADITIONAL O-RINGS WHEN TESTED AT 15° OF DIVERGENCY.



SATURNO O-RING

ZEST SATURNO remains in excellent condition after 50,000 test cycles.

TRADITIONAL O-RING

Traditional O-Ring after 50,000 test cycles is non-functional.*

O-RING INSERTION TOOL

Allows for easy insertion of the O-Ring into the Denture Cap without damage to the O-Ring.

O-Ring inside insertion tool.

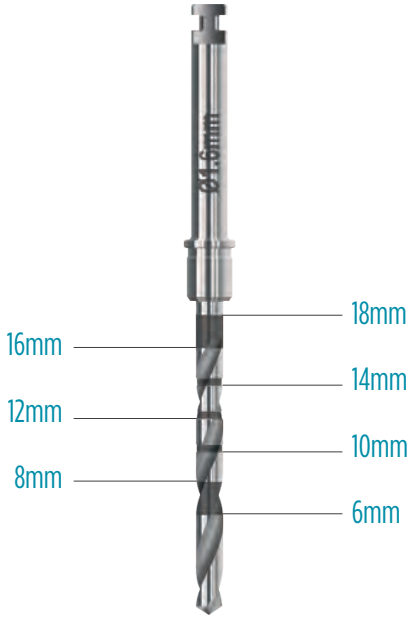
Placement of O-Ring inside attachment assembly.

O-Ring seated inside attachment assembly.

*Data on file

DRILLING DEPTH CONTROL

DRILL LASER DEPTH MARKINGS



DRILL STOPS

FINAL DRILL DIAMETER AND DEPTH FOR VARIOUS BONE TYPES

BONE TYPE	2.0Mm IMPLANT DIAMETER		2.4Mm IMPLANT DIAMETER		2.9Mm IMPLANT DIAMETER	
	FINAL DRILL DIAMETER	DRILL DEPTH	FINAL DRILL DIAMETER	DRILL DEPTH	FINAL DRILL DIAMETER	DRILL DEPTH
D1 Bone	1.2mm	Full Depth	2.1mm	Full Depth	2.4mm	Full Depth
D2/D3/D4 Bone	1.2mm	Depth 4mm less than implant length	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.

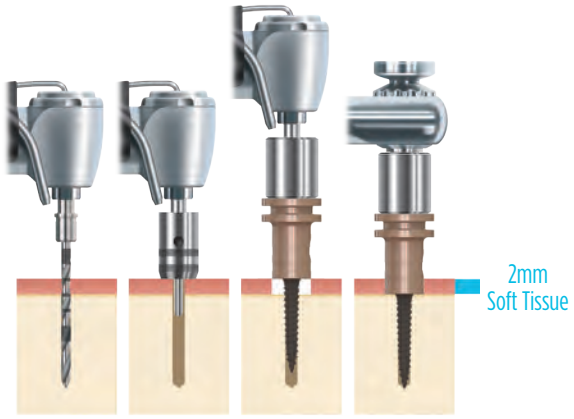
External irrigation is required during the drilling steps.

DRILLING SEQUENCE EXAMPLES

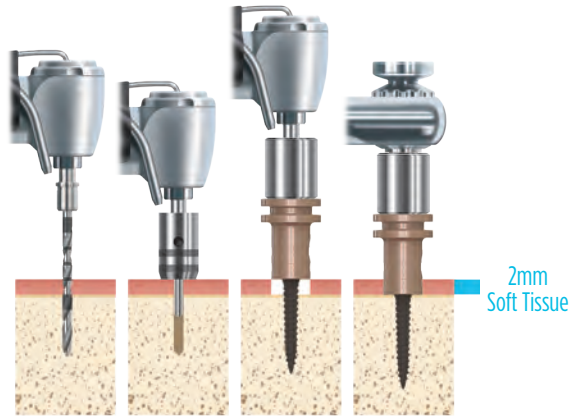
PLACEMENT OF A **2.0MM X 12MM** STRAIGHT AND 20° ANGLED O-BALL IMPLANT, FLAPLESS SURGICAL PROCEDURE

2.0MM STRAIGHT IMPLANT

D1 BONE TYPE

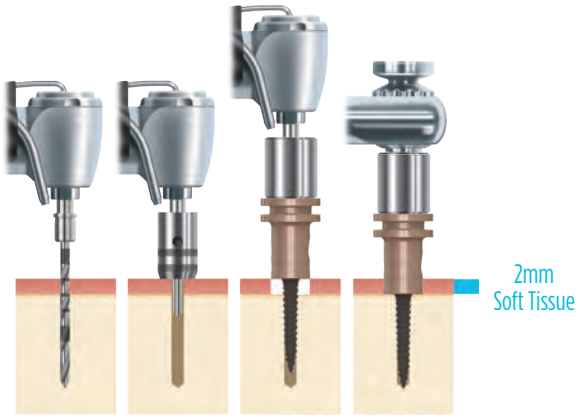


D2/D3/D4 BONE TYPE

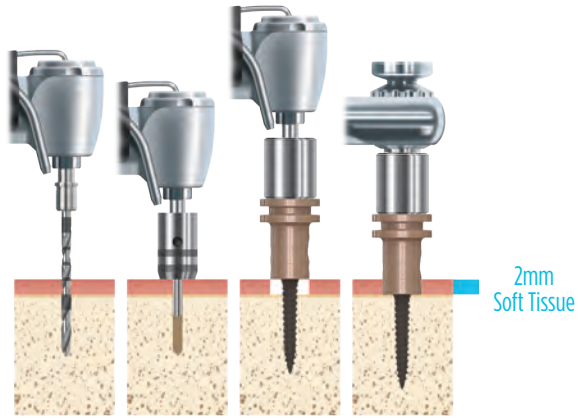


2.0MM 20° ANGLED IMPLANT

D1 BONE TYPE



D2/D3/D4 BONE TYPE



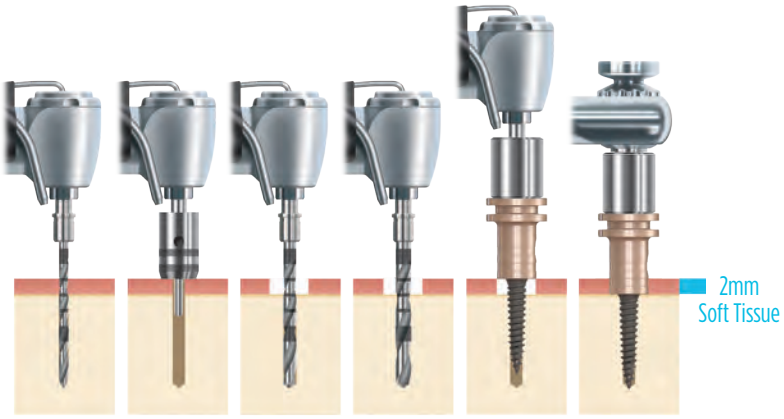
External irrigation is required during the drilling steps.

DRILLING SEQUENCE EXAMPLES
(CONTINUED)

PLACEMENT OF A **2.4MM X 12MM** STRAIGHT AND 20° ANGLED O-BALL IMPLANT, FLAPLESS SURGICAL PROCEDURE

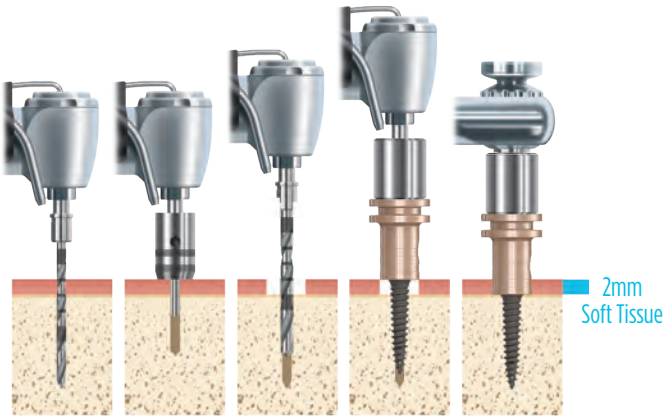
2.4MM STRAIGHT IMPLANT

D1 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | Tissue Punch to Crestal Bone | 1.6mm Full Depth 14mm Line | 2.1mm Full Depth 14mm Line | Place at Low Speed | Ratchet to Full Depth

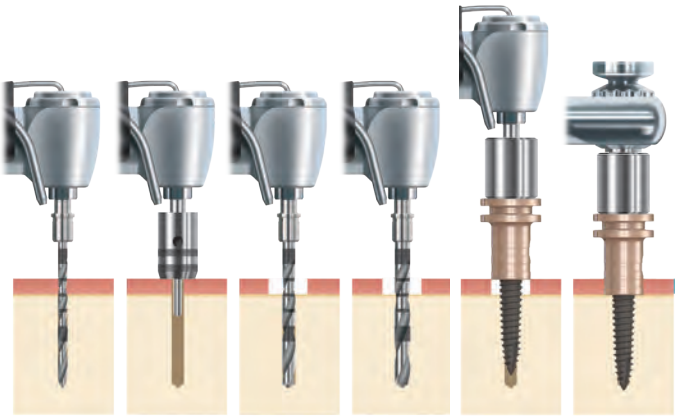
D2/D3/D4 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | Tissue Punch to Crestal Bone | 1.6mm 4mm Short 10mm Line | Place at Low Speed | Ratchet to Full Depth

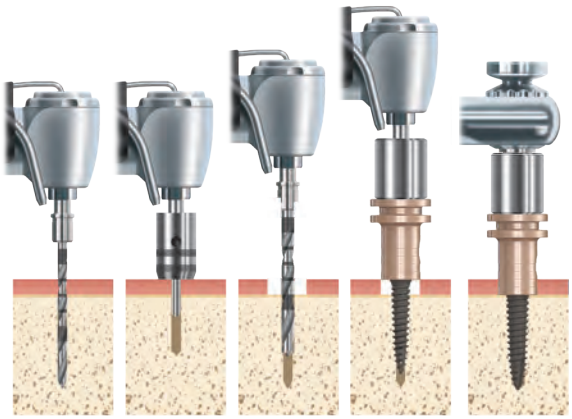
2.4MM 20° ANGLED IMPLANT

D1 BONE TYPE



1.2mm Pilot Full Depth 12mm Drill Stop | Tissue Punch to Crestal Bone | 1.6mm Full Depth 12mm Drill Stop | 2.1mm Full Depth 12mm Drill Stop | Place at Low Speed | Ratchet to Full Depth

D2/D3/D4 BONE TYPE



1.2mm Pilot Full Depth 12mm Drill Stop | Tissue Punch to Crestal Bone | 1.6mm 4mm Short 8mm Drill Stop | Place at Low Speed | Ratchet to Full Depth

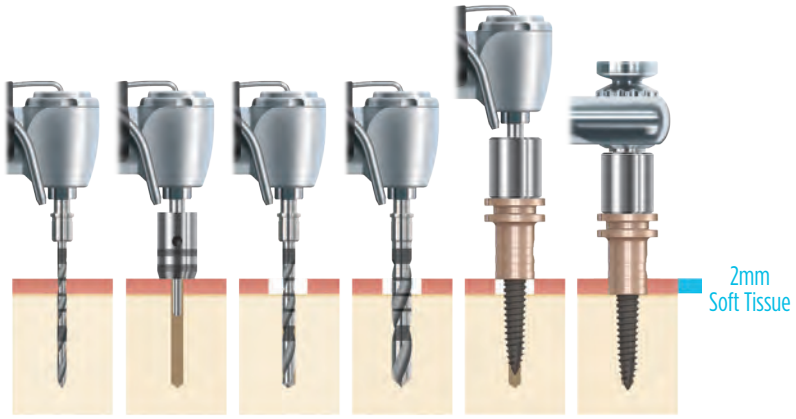
External irrigation is required during the drilling steps.

DRILLING SEQUENCE EXAMPLES
(CONTINUED)

PLACEMENT OF A **2.9MM X 12MM** STRAIGHT AND 20° ANGLED O-BALL IMPLANT, FLAPLESS SURGICAL PROCEDURE

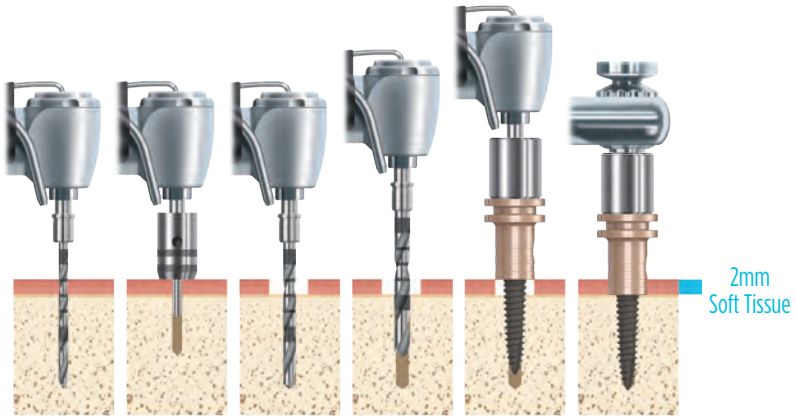
2.9MM STRAIGHT IMPLANT

D1 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | Tissue Punch to Crestal Bone | 1.6mm Full Depth 14mm Line | 2.4mm Full Depth 14mm Line | Place at Low Speed | Ratchet to Full Depth

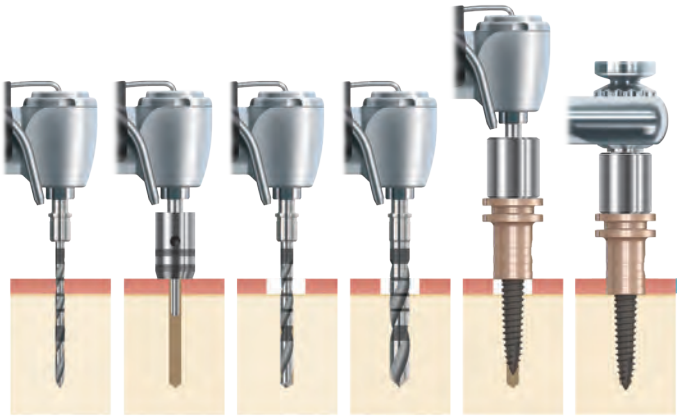
D2/D3/D4 BONE TYPE



1.2mm Pilot Full Depth 14mm Line | Tissue Punch to Crestal Bone | 1.6mm Full Depth 14mm Line | 2.1mm 4mm Short 10mm Line | Place at Low Speed | Ratchet to Full Depth

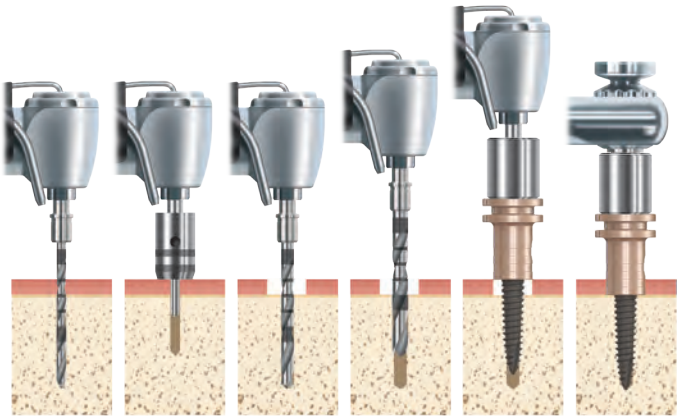
2.9MM 20° ANGLED IMPLANT

D1 BONE TYPE



1.2mm Pilot Full Depth 12mm Drill Stop | Tissue Punch to Crestal Bone | 1.6mm Full Depth 12mm Drill Stop | 2.4mm Full Depth 12mm Drill Stop | Place at Low Speed | Ratchet to Full Depth

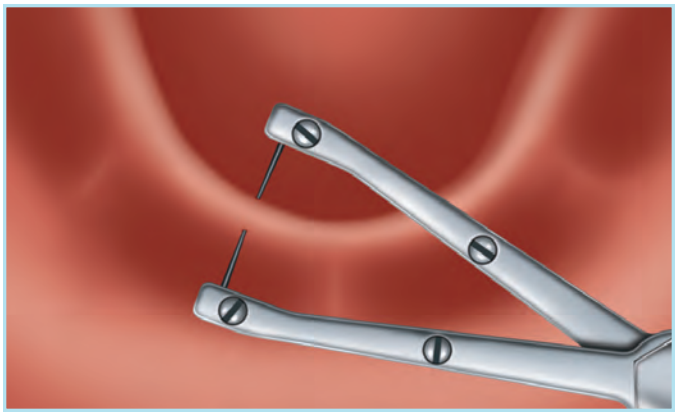
D2/D3/D4 BONE TYPE



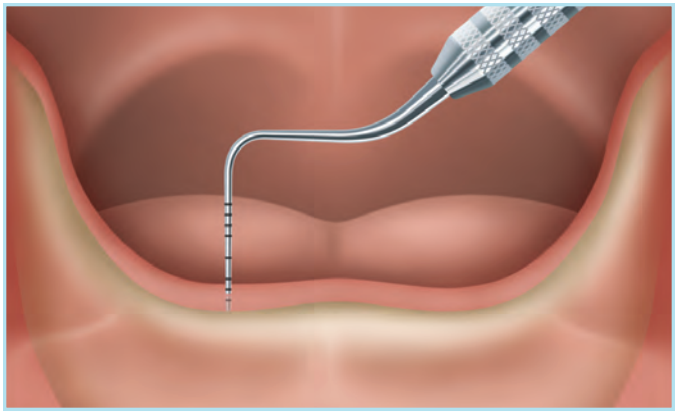
1.2mm Pilot Full Depth 12mm Drill Stop | Tissue Punch to Crestal Bone | 1.6mm Full Depth 12mm Drill Stop | 2.1mm 4mm Short 8mm Drill Stop | Place at Low Speed | Ratchet to Full Depth

External irrigation is required during the drilling steps.

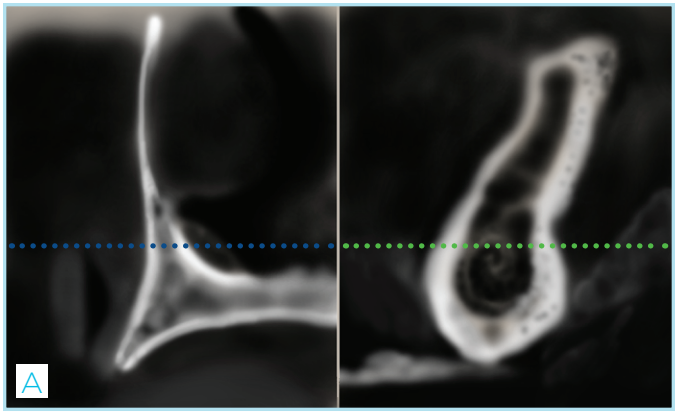
PRE-SURGICAL TREATMENT PLANNING

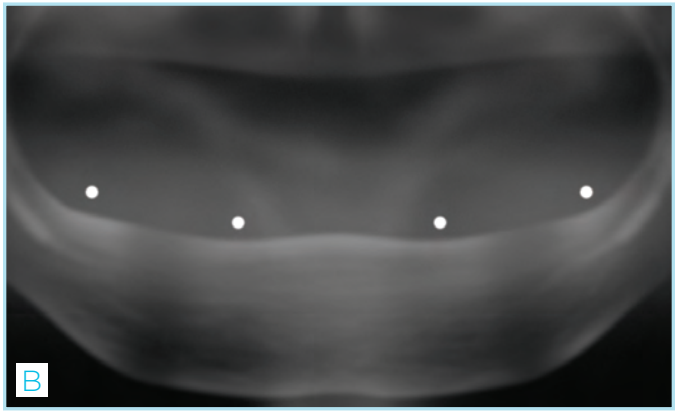


1 Evaluate available bone width for implant positions by using the index finger/thumb technique or a ridge mapping instrument (which can be purchased through most dental instrument companies).



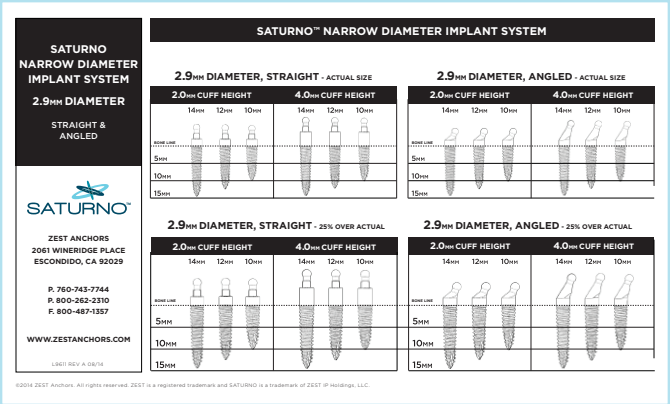
2 Measure the gingival height at each planned implant location using a perio probe to determine the proper SATURNO™ Implant cuff height.



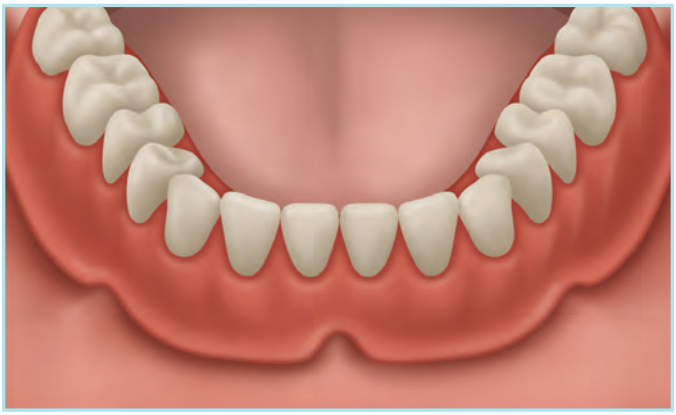


3A-3B A panoramic radiograph or CBCT with radiographic markers may be used to evaluate the bone topography and determine the appropriate implant positions.

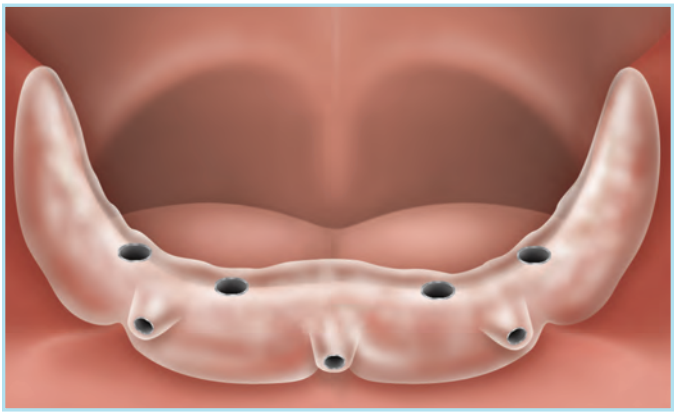
PRE-SURGICAL TREATMENT PLANNING
(CONTINUED)



4 Evaluate the angulation of available bone in comparison to the denture tooth position to determine if the use of a straight or 20° Angled O-Ball Implant is required at each planned implant location. Radiographic overlay templates are available from ZEST Anchors (L9611) to assist in choosing correct implant size. ZEST recommends placement of the SATURNO™ 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 a new one will be fabricated. If a new denture is fabricated, follow the standard denture fabrication protocols. Instruct the patient to wear the new denture for a minimum of 2 weeks prior to implant placement.



6 **OPTIONAL STEP:** A surgical guide for implant placement may be fabricated prior to surgery.

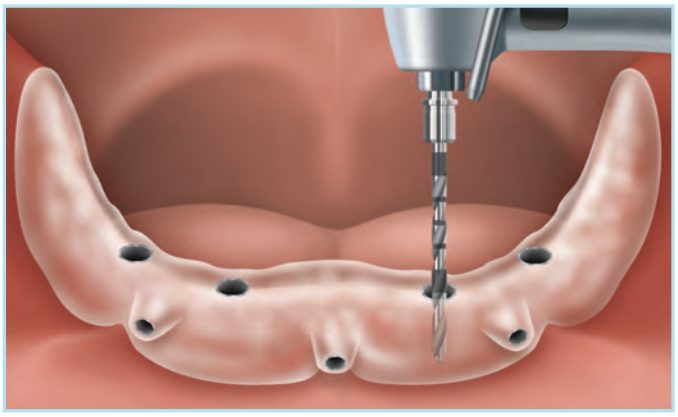
IMPLANT PLACEMENT (STRAIGHT O-BALL)

After patient selection and evaluation protocols have been completed, determine the number of implants required and discuss all treatment options with the patient.

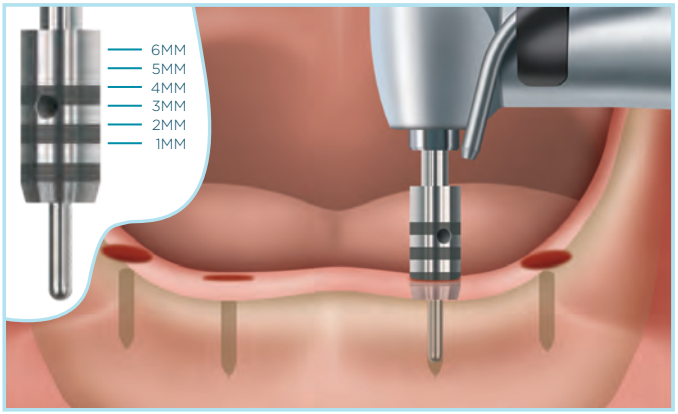
ZEST Anchors recommends a minimum of 4 implants be placed in the mandible and 6 in the maxilla for maximum retention. The patient's denture will then be fabricated or retrofitted. Bone topography, bone density and anatomical landmarks must be considered during preoperative planning.

MAXILLARY PLACEMENT OF 4 STRAIGHT 2.9MM × 12MM,
2MM CUFF HEIGHT O-BALL IMPLANTS

SHOWN IN TYPE D1 BONE

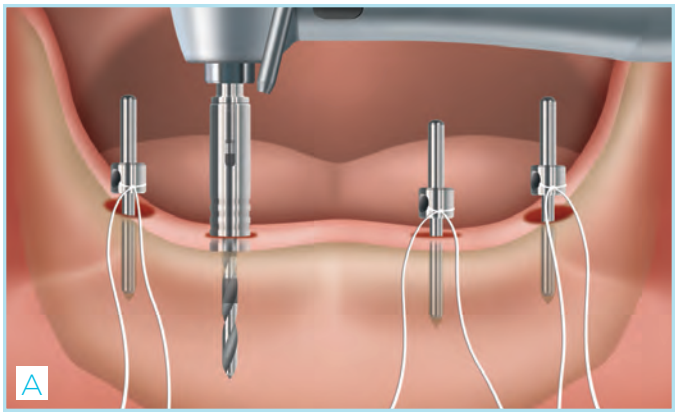


1 Using a surgical guide or by free hand, mark the implant osteotomy locations using the 1.2mm Pilot Dril to drill through the gingiva and into the bone crest 6mm. Note the gingival height. The recommended drilling speed is 800-1200Rpm.

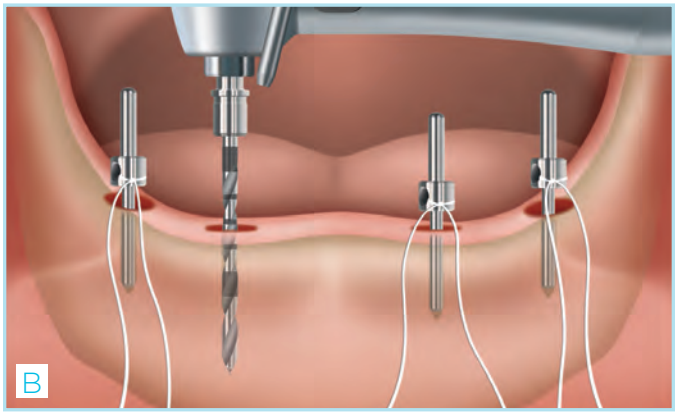


2 Remove the gingival cores at each site using the Rotary Tissue Punch by placing the guide pin portion into the pilot holes and rotate to cut away the gingiva. Rotate the Rotary Tissue Punch to the laser depth mark corresponding to the depth measurement.
The recommended drilling speed is up to a maximum of 800Rpm.

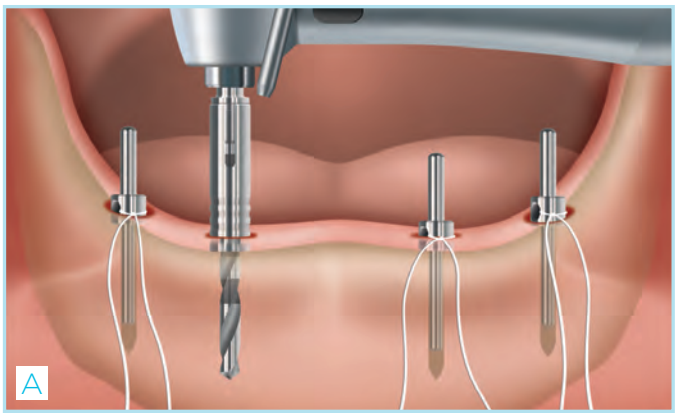
IMPLANT PLACEMENT (STRAIGHT O-BALL)
(CONTINUED)



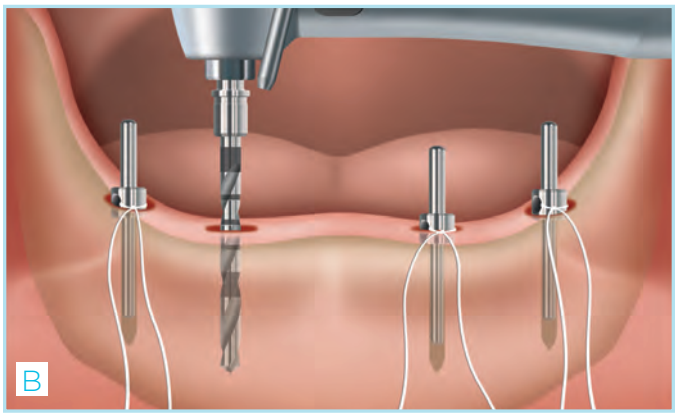
3A-3B Place the 1.2mm diameter (small) end of the Direction Indicator into the pilot drill osteotomies to verify the proper alignment. Attach the proper length drill stop onto the 1.2mm Pilot Drill according to the desired drilling depth.



Alternatively, drill to the proper laser depth marking on the drill calculated by adding the desired drilling and tissue depths. The recommended drilling speed is 800-1200Rpm. Continue osteotomy preparation to the desired depth at each implant site.

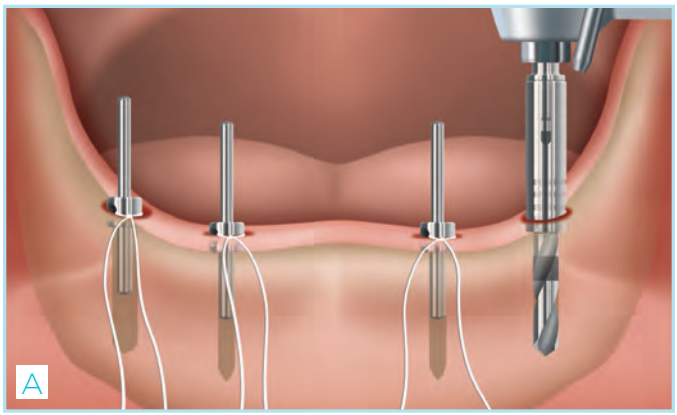


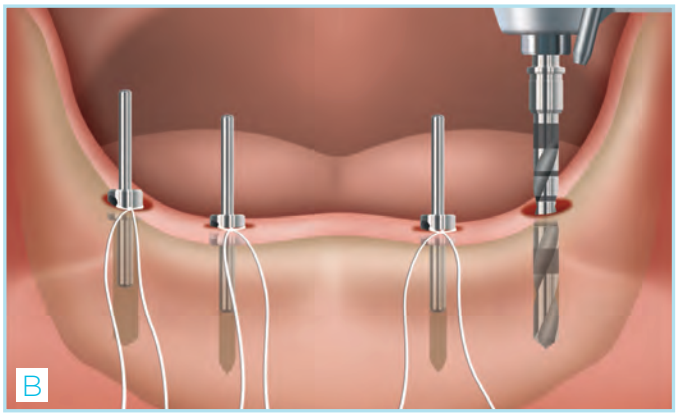
4A-4B Place the proper length drill stop onto the 1.6mm drill according to the desired drilling depth.



Alternatively, drill to the proper laser depth marking on the drill calculated by adding the desired drilling and tissue depths. The recommended drilling speed is 800-1200Rpm. Continue osteotomy preparation to the desired depth at each implant site.

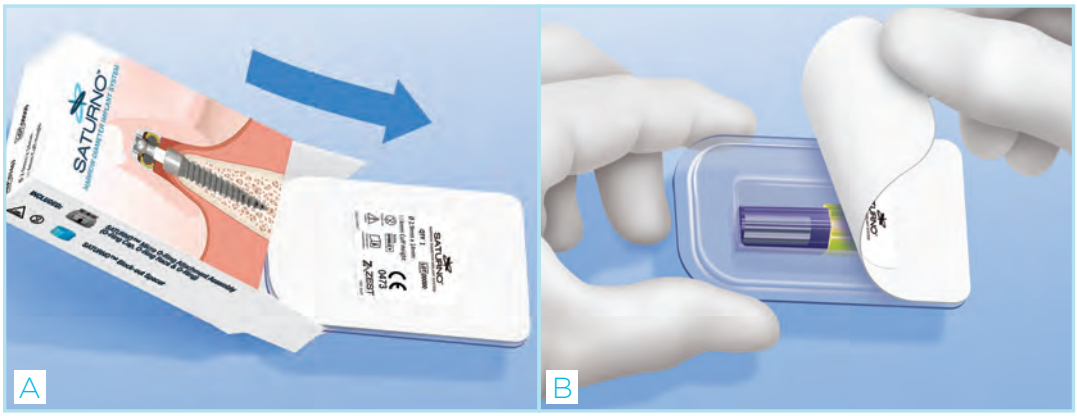
IMPLANT PLACEMENT (STRAIGHT O-BALL)
(CONTINUED)



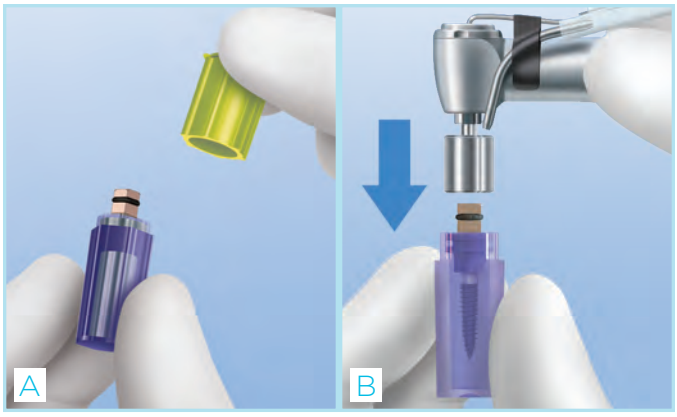


5A-5B Place the 1.6mm diameter (large) end of the Directional Indicator into the osteotomies to verify the proper alignment. Place the proper length drill stop onto the 2.4mm drill according to the desired drilling depth.

Alternatively, drill to the corresponding laser depth marking on the drill calculated by adding desired drilling and tissue depths. The recommended drilling speed is 800-1200Rpm. Continue osteotomy preparation to the desired depth at each implant site.

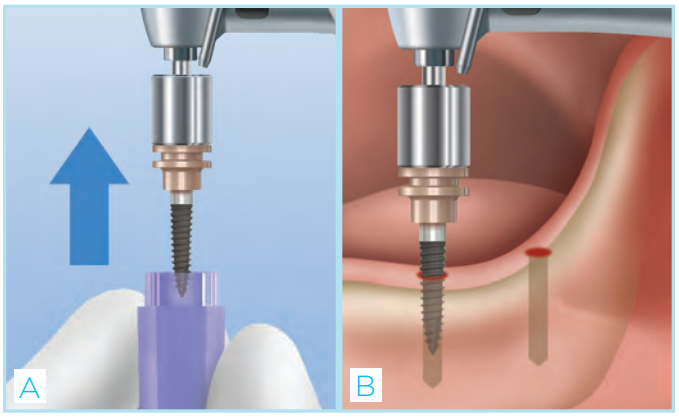


6A-6B Remove the implant package from the box and peel back the tyvek seal from the plastic tray. Place the sterile implant vial on the sterile tray. The contents of the plastic tray are sterile and should only contact components within the sterile field.



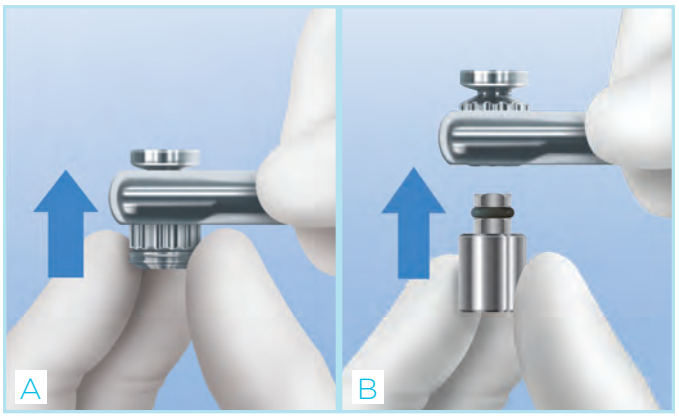
7A-7B Remove the cap from the implant vial. Set the drilling unit placement torque at 35Ncm. Place the SATURNO™ Implant Latch Driver in the handpiece and seat the Latch Driver onto the square of the SATURNO Implant Mount and press down to engage securely.

IMPLANT PLACEMENT (STRAIGHT O-BALL)
(CONTINUED)

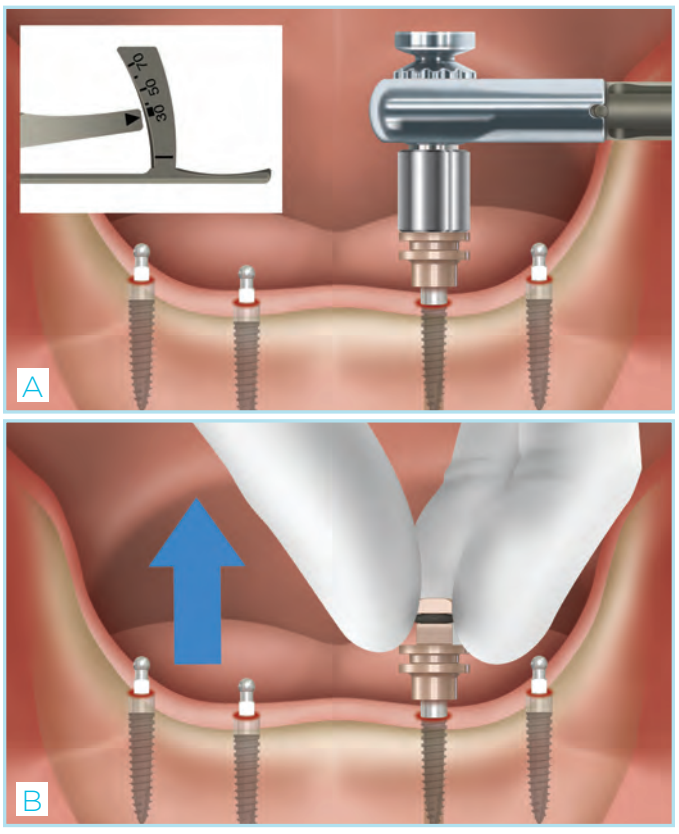


8A-8B Remove the implant from the vial, carry it to the mouth, place the implant into the osteotomy and insert at 30Rpm. Use the Latch Driver to drive the implant three quarters (3/4) of the way into the osteotomy and finalize insertion with a Torque Indicating Ratchet Wrench.

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



9A-9B Assemble the Torque Ratchet Wrench Insert and the SATURNO™ Implant Driver into the Torque Wrench and finalize seating. Alternatively, the Torque Indicating Ratchet Wrench Insert may be used to remove the implant from the vial and carry it to the mouth to begin threading into the osteotomy by hand.



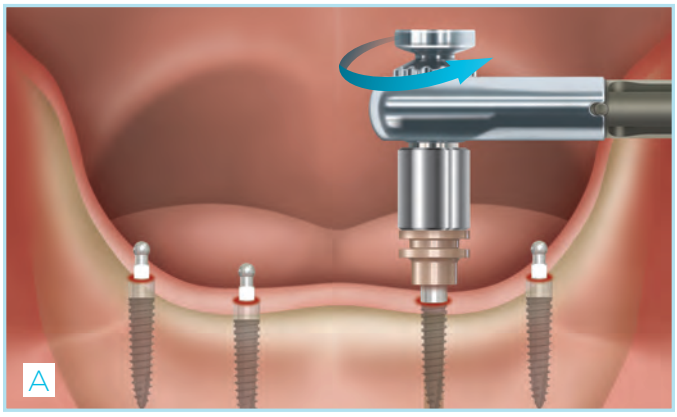
10A-10B Engage the Implant Driver onto the Implant Mount and verify that it is securely engaged. Slowly ratchet the implant to full depth. Remove the implant mount carefully by pulling in a vertical direction. If final seating torque measures 30Ncm or above, the implant may be put into immediate function 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 SATURNO Ball Attachments during the integration period. If 70Ncm of torque is reached prior to full seating, the implant should be removed and the osteotomy should be enlarged.

Please refer to processing the Saturno Denture Cap into the denture on page 21.

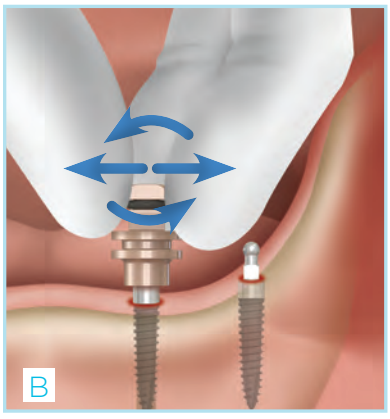
IMPLANT PLACEMENT REMOVAL OF THE IMPLANT MOUNT (STRAIGHT O-BALL)

Due to the tight manufacturing tolerances and possible higher implant insertion torque values in dense bone, at times, the Implant Mount will become very snug on the implant. The binding of two components will make it difficult to passively remove the Implant Mount.

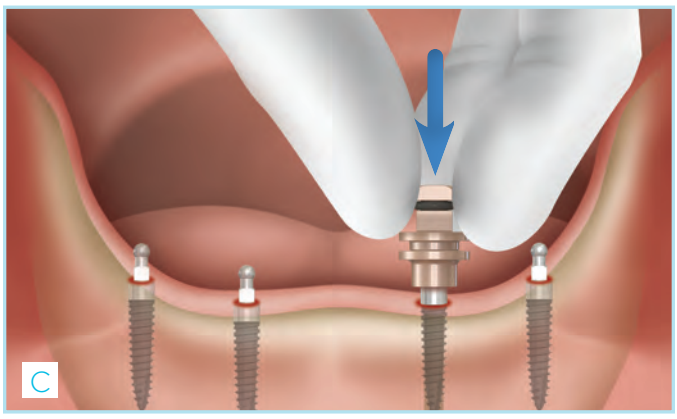
If the Implant Mount is difficult to remove. please follow these steps:



a. Reengage the Implant Mount with the torque wrench assembly in a counter-clockwise direction and slightly, turn the wrench counter-clockwise to release the bind between the Implant Mount and the SATURNO™ Implant.



b. Remove the torque wrench assembly from the Implant Mount and gently move the Implant Mount to confirm that it is free from any bind and that it is released.



c. Once you ensure the release of the Implant Mount from the Implant, proceed by pulling the Implant Mount in a vertical direction while following the trajectory of the straight O-Ball.

IMPLANT PLACEMENT (20° ANGLED O-BALL)

Please refer to pre-surgical treatment planning steps on pages 9 & 10.

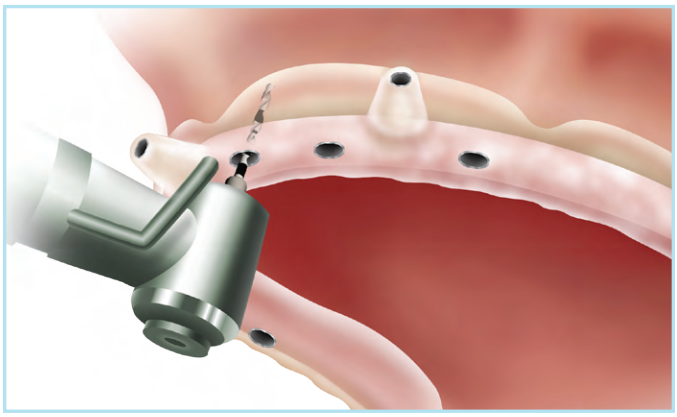
MANUAL PLACEMENT OF THE IMPLANT IS RECOMMENDED. INSERTION WITH A HANDPIECE IS NOT ADVISED.

After patient selection and evaluation protocols have been completed, determine the number of implants required and discuss all treatment options with the patient.

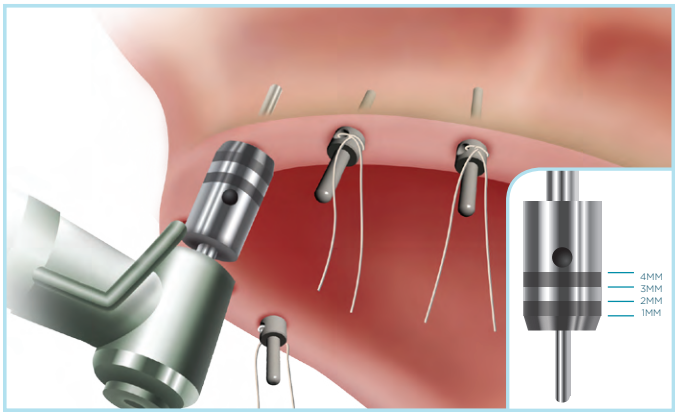
ZEST Anchors recommends a minimum of 4 implants be placed in the mandible and 6 in the maxilla for maximum retention. The patient's denture will then be fabricated or retrofitted. Bone topography, bone density and anatomical landmarks must be considered during preoperative planning.

MAXILLARY PLACEMENT OF 4 20° ANGLED O-BALL 2.9MM × 12MM, 2MM CUFF HEIGHT AND 2 STRAIGHT 2.9MM × 12MM, 2MM CUFF HEIGHT IMPLANTS

SHOWN IN TYPE D3/D4 BONE



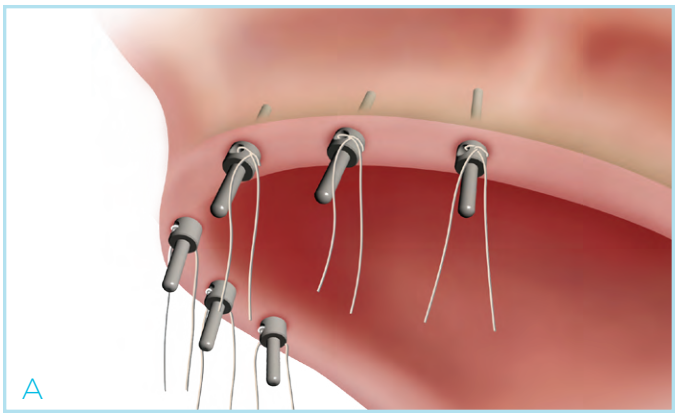
1 Using a surgical guide or by free hand, mark the implant osteotomy locations using the 1.2mm Pilot Drill and drill through the gingiva and into the bone crest approximately 6mm. Note the gingival depth. The recommended drilling speed is 800-1200Rpm.

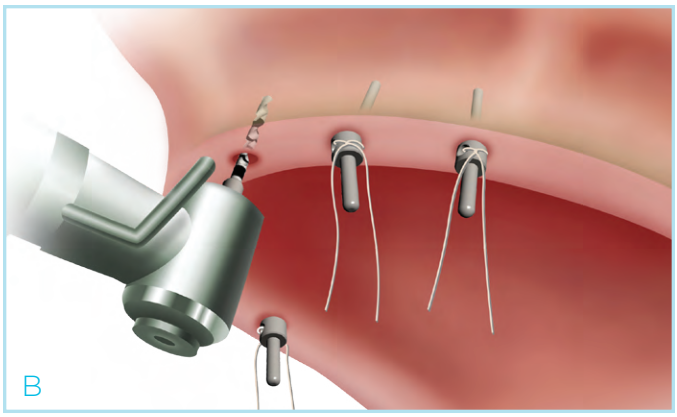


2 Remove the gingival cores at each site using the Tissue Punch specifically for the 20° Angled O-Ball Implant by placing the guide pin portion into the Starter Drill holes and rotate to cut away the gingiva. Rotate the Tissue Punch to the laser depth mark corresponding to the gingiva depth measurement. The recommended drilling speed is 800Rpm.

NOTE: Reference the drill laser depth marking guide for flapless surgery and the drilling sequence chart on page 5 for each implant diameter and the various bone densities.

IMPLANT PLACEMENT (20° ANGLED O-BALL)
(CONTINUED)

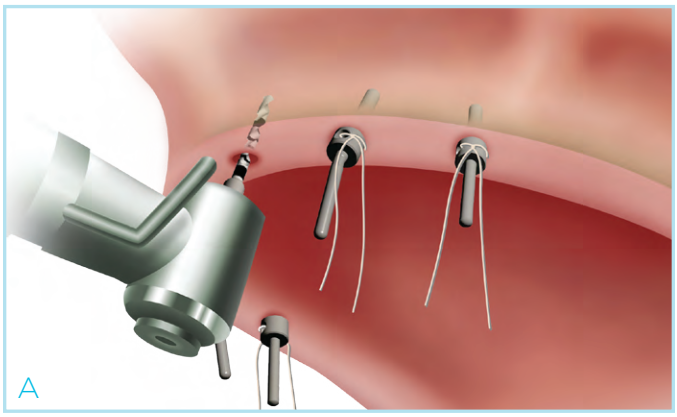


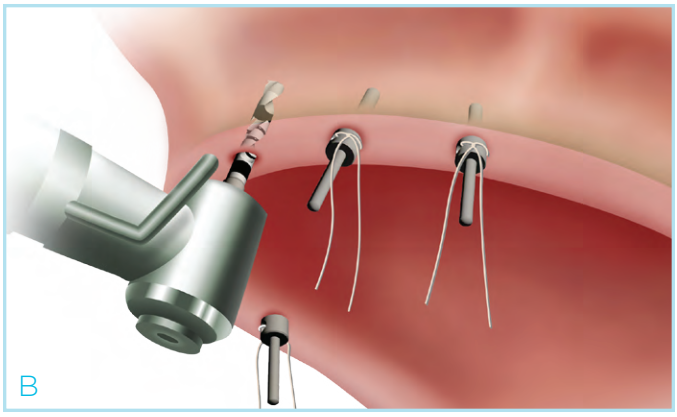


3A-3B Place the 1.2mm diameter end of the 20° Angled Direction Indicator into the osteotomy and verify the proper emergence. If an angled implant is not required, follow the steps for the straight technique on page 13.

NOTE: Take care not to apply lateral force when using the 1.2mm drill.

Continue drilling the implant osteotomies using the 1.6mm Twist Drill. Drill to the depth indicated in the drilling sequence chart on page 8 while ensuring that all direction indicators are as parallel to one another as possible.
The recommended drilling speed is 800-1200Rpm.



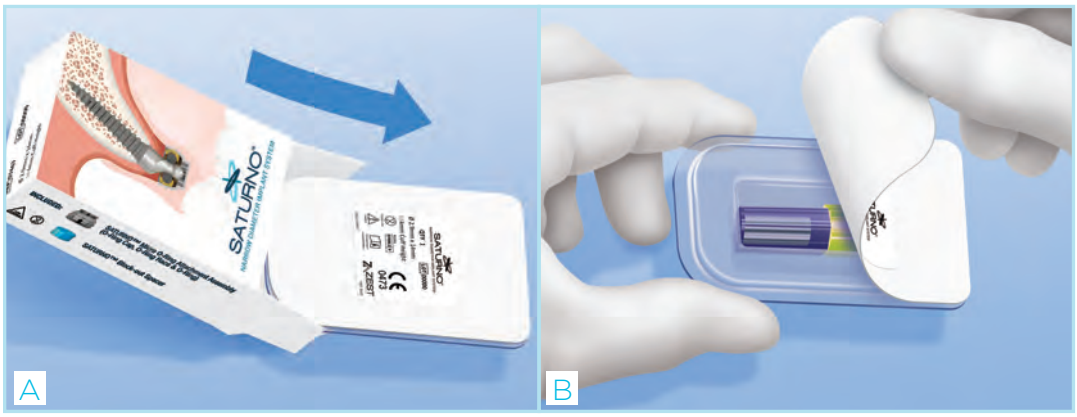


4A-4B Insert the 1.6mm diameter end of the 20° Angled Direction Indicator into the osteotomy and verify proper emergence. Ensure all implants are placed as parallel to one another as possible.

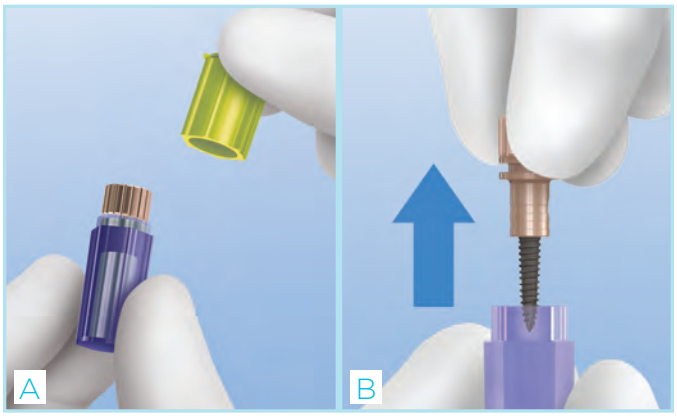
Continue drilling the osteotomies using the 2.4mm Twist Drill indicated in the drilling sequence chart on page 8.
The recommended drilling speed is 800-1200Rpm.

NOTE: Verify no two implants have more than 30° of divergence.

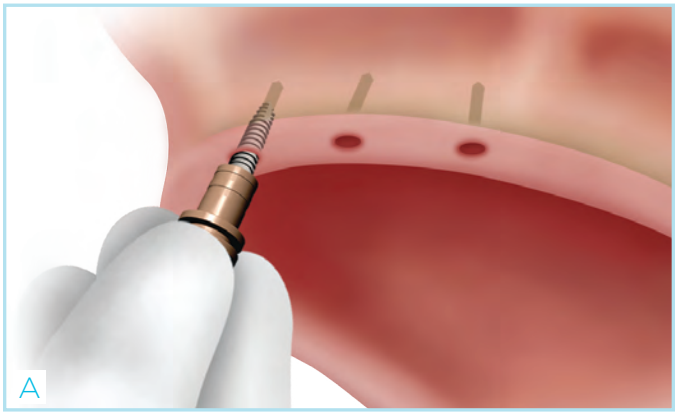
IMPLANT PLACEMENT (20° ANGLED O-BALL)
(CONTINUED)



5A-5B Remove the implant package from the box and peel back the tyvek seal from the plastic tray.



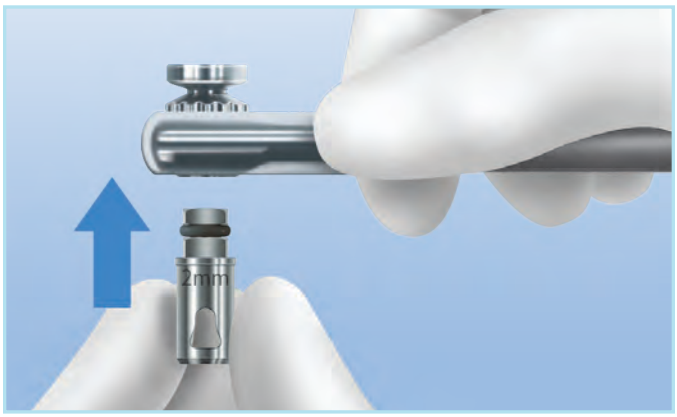
6A-6B Open the sterile implant vial over the sterile tray and remove the cap from the implant vial. Remove the implant from the vial in a straight, vertical motion.



7A-7B Manually insert the implant as far as the Carrier allows and remove the Implant Carrier carefully by pulling in a vertical direction while following the trajectory of the O-Ball as shown.

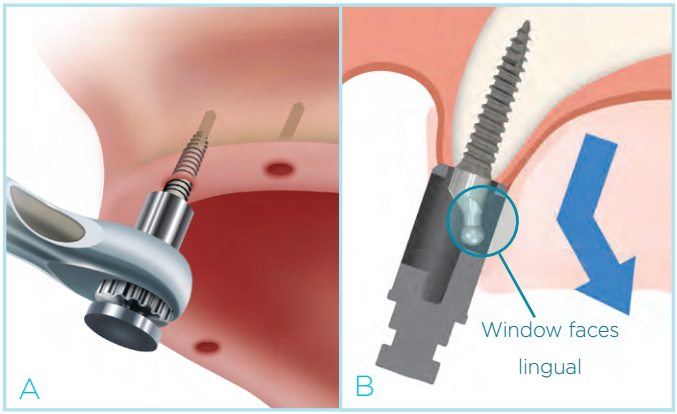
NOTE: Discard and do not use an implant that has been dropped in a non-sterile area and replace with a new sterile implant.

IMPLANT PLACEMENT (20° ANGLED O-BALL)
(CONTINUED)



8 Complete final insertion with a Torque Indicating Ratchet Wrench. Assemble the Torque Ratchet Wrench Insert and the 20° Angled Implant Direct Driver into the Torque Wrench and finalize seating.

NOTE: The Direct Driver is designed to fit both the 2 and 4mm cuff height Angled Implants. Ensure the Driver is properly aligned prior to inserting over the implant.



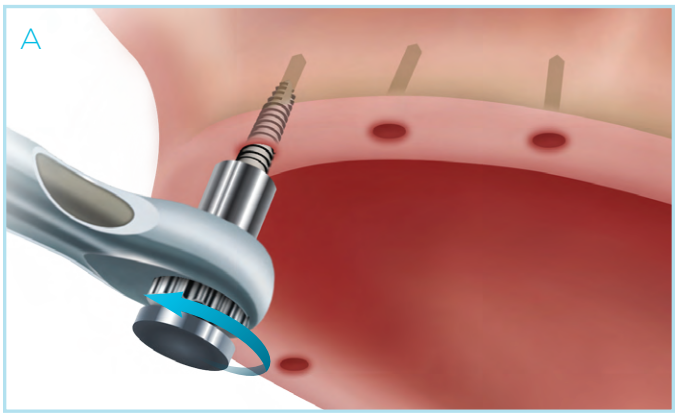
9A-9B Slowly ratchet the implant into the osteotomy and as the implant reaches full depth, ensure the Direct Driver window is positioned such that the trajectory of the O-Ball is in the desired position. Remove the Direct Driver carefully by pulling in a vertical direction while following the trajectory of the O-Ball.

If 70Ncm of torque is reached prior to full seating, the implant should be removed and the osteotomy should be enlarged. If final seating torque measures 30Ncm or above the implant may be immediately placed into function at the discretion of the clinician. If the final seating torque measures below 30Ncm, relieve the denture acrylic and place a soft liner in the denture around the SATURNO™ Ball Attachments during the integration period.

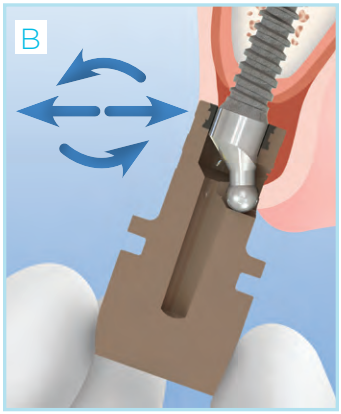
ADDENDUM - REMOVAL OF THE DIRECT DRIVER (SATURNO™ 20° O-BALL IMPLANT)

Due to the tight manufacturing tolerances and possible higher implant insertion torque values in dense bone, at times, the Direct Driver for the 20° O-Ball will become very snug on the implant. The binding of two components will make it difficult to passively remove the Direct Driver.

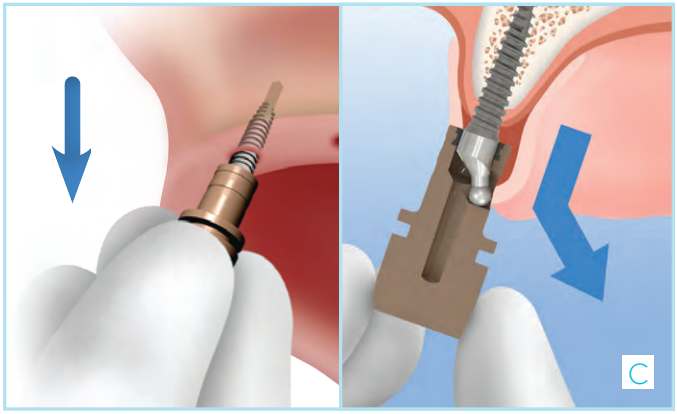
If the Carrier or Direct Driver is difficult to remove, please follow these steps:



a. Reengage the Direct Driver with the torque wrench assembly in a counter-clockwise direction and slightly, turn the wrench counter-clockwise to release the bind between the Direct Driver and SATURNO Implant.

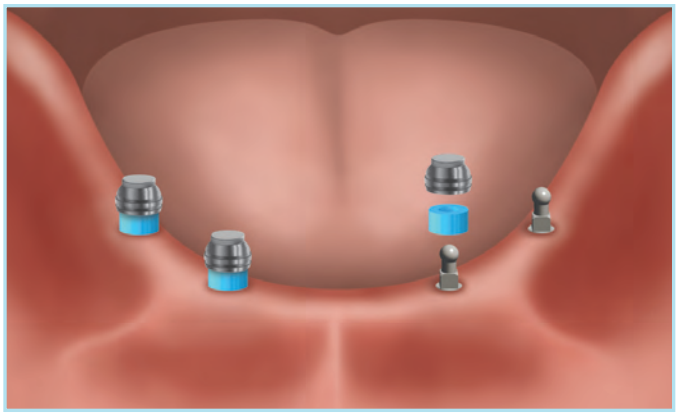


b. Remove the torque wrench assembly from the Direct Driver and gently move the Direct Driver to confirm that it is free from any bind and that it is released.



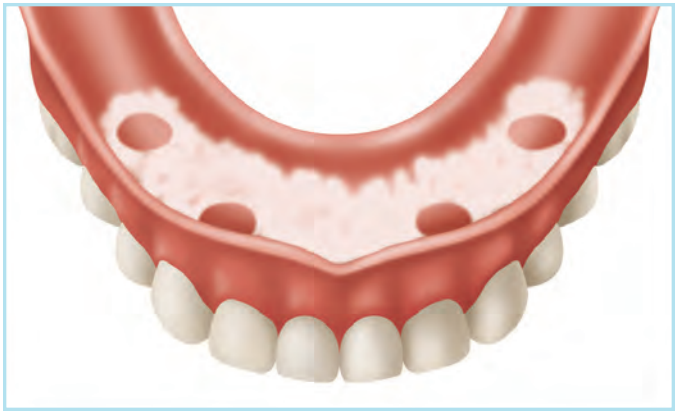
c. Once you ensure the release of the Direct Driver from the SATURNO Implant, proceed by pulling the Direct Driver in a vertical direction while following the trajectory of the straight O-Ball.

PROCESSING THE SATURNO™ DENTURE CAP WITH O-RING INTO THE DENTURE DIRECT TECHNIQUE

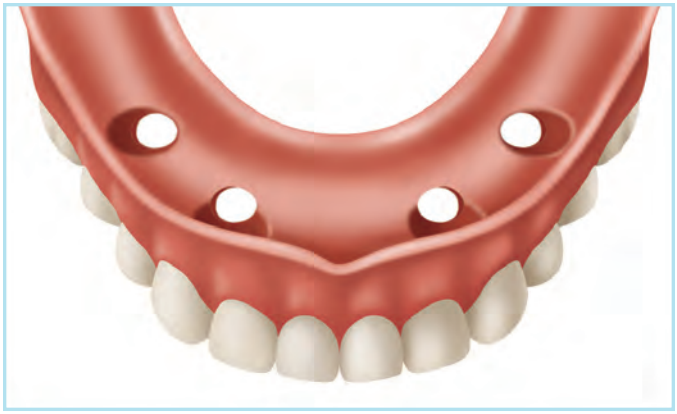


NEW OR EXISTING DENTURE

1 Slide the SATURNO™ Block Out Spacer over the ball attachment and press down until it stops. The Block Out Spacer may be cut to adjust the height. Place a Denture Cap with a Micro O-Ring inside of it onto each ball attachment and press down firmly.

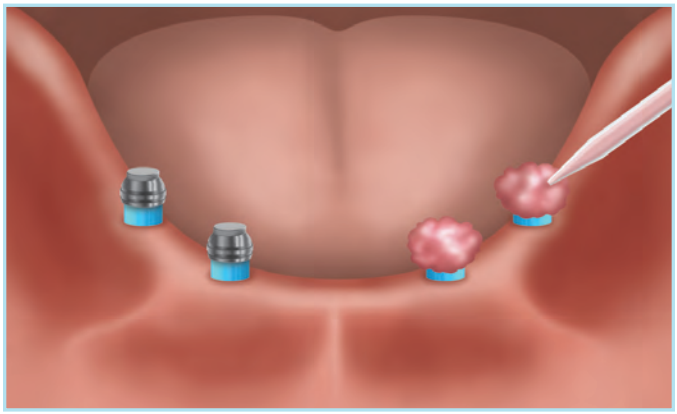


2 Apply fit check marking paste inside of the denture. Insert it into the mouth in position over the Denture Caps to mark the areas where the denture will need to be relieved to allow space for the caps to be picked up.



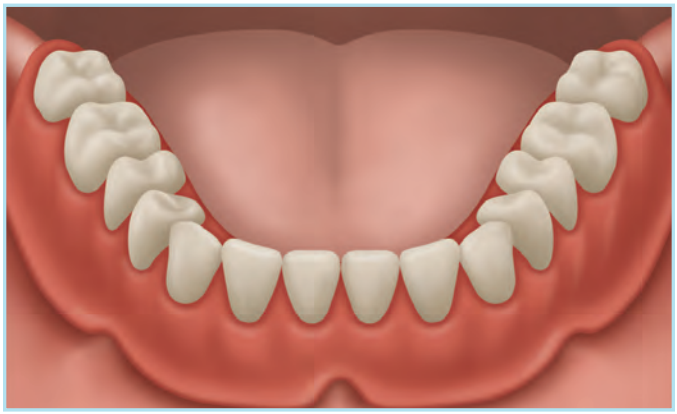
3 Relieve the areas marked and try in the denture to verify that the Denture Caps are not in contact with the acrylic. Drill lingual/palatal vent holes in the denture to visualize full seating and allow excess acrylic to vent. Cut an undercut below the intaglio surface of each Denture Cap relief area for added mechanical retention.

PROCESSING THE SATURNO™ DENTURE CAP WITH O-RING INTO THE DENTURE DIRECT TECHNIQUE (CONTINUED)



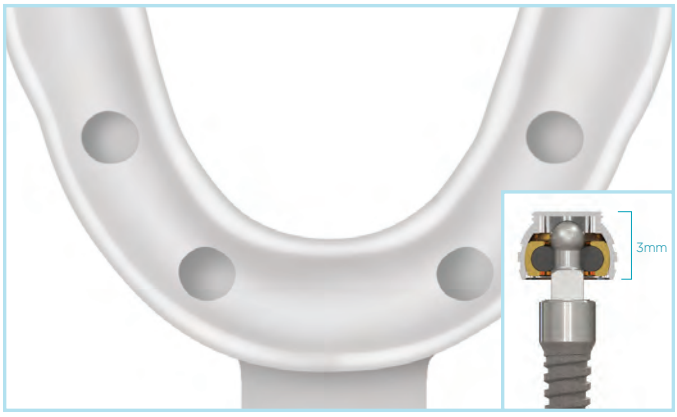
4 Dry the denture caps and apply a small amount of CHAIRSIDE® Attachment Processing Material around the circumference of each cap. Fill the recesses in the denture 2/3 of the way full with the CHAIRSIDE Material and seat over the caps. Have the patient bite into centric occlusion while the material sets. Do not allow the patient to over compress the denture on the soft tissue. Excessive occlusal pressure during the setting time may cause tissue recoil against the denture base and could contribute to dislodging and wear of the O-Rings. Please refer to CHAIRSIDE Attachment Processing Material IFU for set times.

5 Remove the denture from the mouth and verify that the Denture Caps have been securely processed into the denture. Fill any voids, cure and polish.

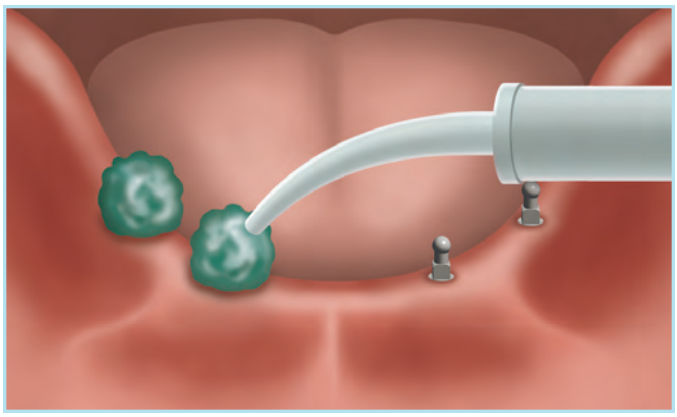


6 Seat the denture in the mouth and press down to engage the O-Rings on the ball attachments and verify the occlusion. Instruct the patient on how to remove and insert the denture. Instruct the patient on proper home care and inform them of required recall appointments.

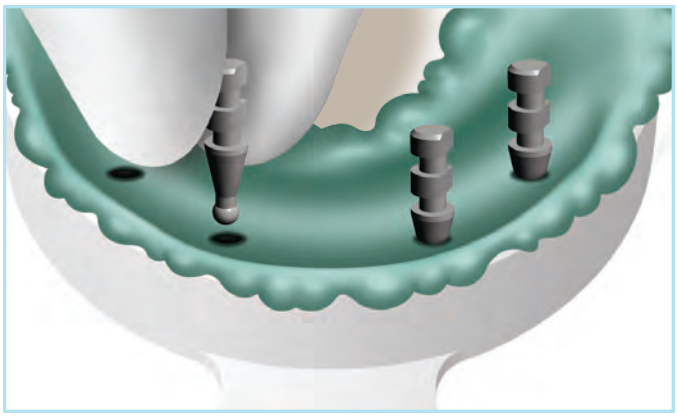
PROCESSING THE SATURNO™ DENTURE CAP WITH O-RING INTO THE DENTURE INDIRECT TECHNIQUE



1 A stock or custom impression tray may be used. Ensure on each recess that there is enough space for the height of the ball attachments.



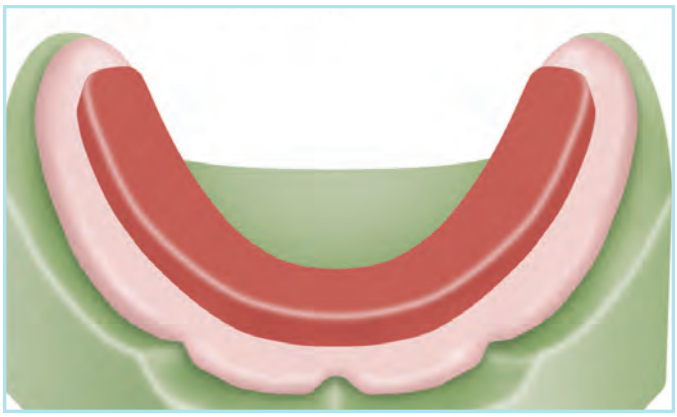
2 Syringe a medium body impression material around the circumference of each ball attachment. Fill the impression tray and insert it over the attachments and onto the tissue. Allow the material to set. Remove the impression and verify that there are no draws in the impression.



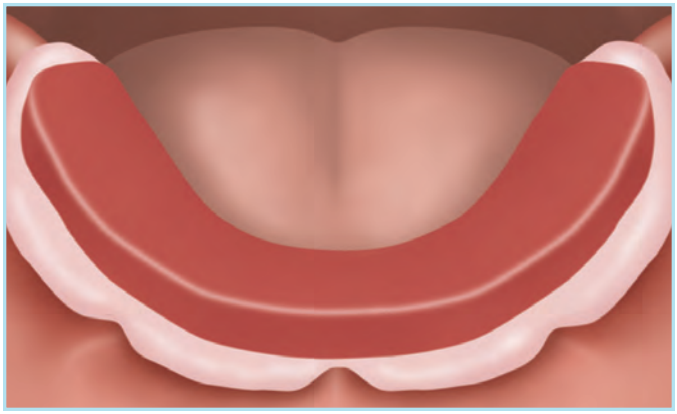
3 Press the SATURNO Lab Analogs into each intaglio of the ball attachment until you feel the ball engage. Send the impression to the laboratory.

PROCESSING THE SATURNO™ DENTURE CAP WITH O-RING INTO THE DENTURE INDIRECT TECHNIQUE (CONTINUED)

4 Verify that the analogs are secure in the impression material and pour a model.

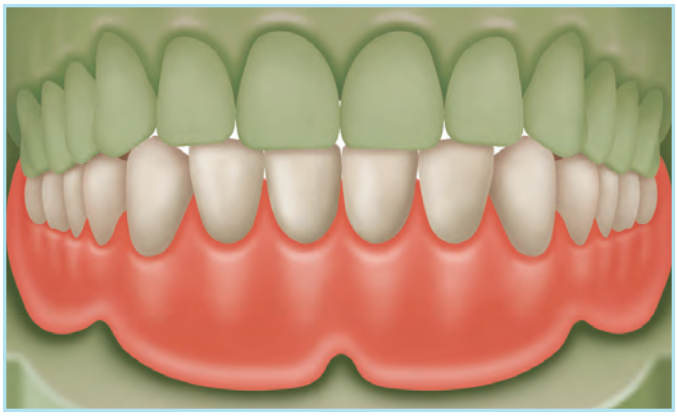


5 Fabricate the baseplate and wax rim on the cast for bite registration. Two of the denture caps with O-Rings may be processed into the baseplate to provide stabilization during record making and try in.



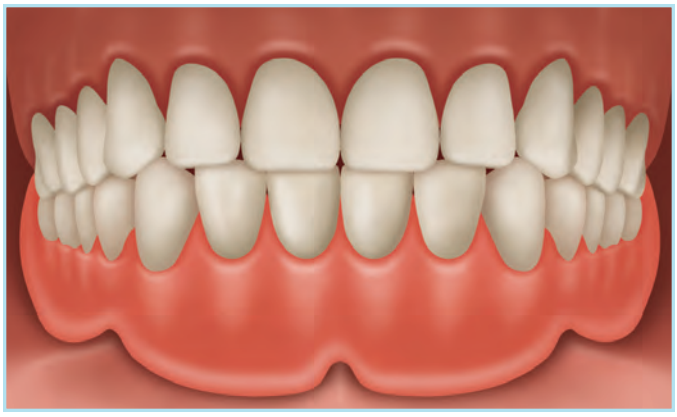
BITE RECORDS

6 Place the bite bloc 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.



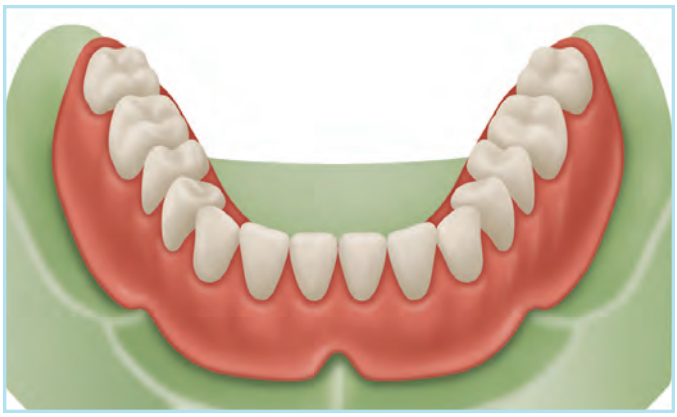
7 Articulate the models and proceed with the denture teeth set up.

PROCESSING THE SATURNO™ DENTURE CAP WITH O-RING INTO THE DENTURE (CONTINUED)

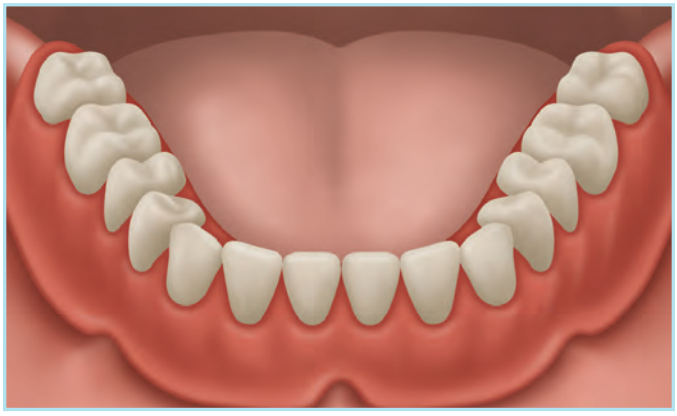


DENTURE TRY-IN

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



9 Finalize and flask the denture for processing. Separate the flask and boil away all wax. Slide the SATURNO Block Out Spacer over the balls on the analogs and press down until it stops. The Block Out Spacer may be cut to adjust the height. Place the SATURNO Denture Caps with O-Rings 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.



DELIVERY

10 Place the denture in the mouth and press down to engage the O-Rings on the O-Ball attachments. Verify the occlusion. Instruct the patient on how to remove and insert the denture, and also on proper home care and required recall appointments.

PATIENT CARE

Good oral hygiene is vital to the success of the restoration.
The O-Ball on SATURNO™ Implants must be thoroughly cleaned each day to prevent wear due to buildup of abrasive plaque. Instruct patients to use a soft nylon bristle or end-tufted toothbrush and non-abrasive gel toothpaste to clean the O-Balls. An irrigation system is recommended to flush out debris from the inside of the SATURNO Denture Cap.

RECALL APPOINTMENTS

Patients should schedule a follow up appointment at 6 weeks post op for any necessary adjustments and should maintain a three to four month recall for cleaning and maintenance of the overdenture attachment system. The surface of the SATURNO O-Ball and the sulcus area around the SATURNO Implant collar are the primary areas of concern. Use plastic instruments for scaling the O-Balls. Do not use metal instruments which may create scratches on the implant collar surface.

SATURNO™ MICRO O-RING REPLACEMENT

1 Use an explorer or similar dental instrument to remove the existing O-Ring.

2 The O-Ring Insertion Tool (8049) is designed to insert Micro O-Rings (3.5mm outside diameter, 1.8mm Ball) and/or Standard O-Rings (4.5mm outside diameter, 2.25mm Ball) into the SATURNO O-Ring Attachment titanium caps using the appropriate end of the Insertion Tool. **Only the Micro O-Rings should be used with the SATURNO Narrow Diameter Implant System.**

3 Lubricate the O-Ring Insertion Tool prior to use by dipping each end of the Insertion Tool handle tines into lubricant (Water Based lubricant). Insert the Insertion Tool handle tines into the respective ferrule. Slide the ferrule back and forth to lubricate the inside.

4 Place the appropriate O-Ring (Micro size) on a flat surface. Remove the O-Ring Ferrule (Micro size) and place the ferrule over the O-Ring, pressing gently (Figure 1). The O-Ring should be seated flat in the ferrule as shown in (Figure 2).

Figure 1

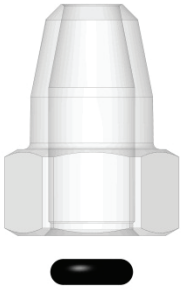
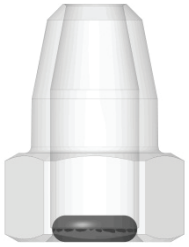


Figure 2

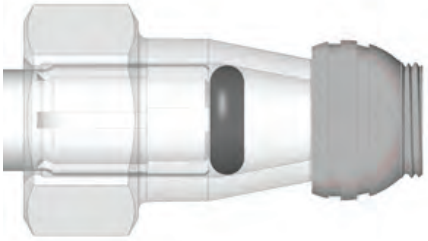


5 Place the loaded O-Ring Ferrule onto its respective end of Insertion Tool handle (spinning the handle as it goes in keeping the O-Ring flush with the end of the tool), and lock it onto the handle. The O-Ring will be advanced toward the tip of ferrule (Figure 3).

Figure 3

6 The O-Ring is ready to be inserted into the SATURNO O-Ring Attachment Cap in the denture. Place the tip of the O-Ring Insertion Tool into the Cap located in the denture (Figure 4).

Figure 4



O-Ring Insertion Tool Ferrule

SATURNO O-Ring Attachment Cap

7 Push the Insertion Tool handle to insert O-Ring into SATURNO O-Ring Attachment Cap in denture (Figure 5).

Figure 5

8 Once the O-Ring is fully inserted into the SATURNO O-Ring Attachment Cap, remove the O-Ring Insertion Tool from the Cap in denture.

INDICATIONS

The SATURNO Narrow Diameter Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. The SATURNO System is used to restore masticatory function for the patient and may be suitable for immediate function if sufficient primary stability of the implant is achieved at the time of placement.

CONTRAINDICATIONS

Not appropriate where a totally rigid connection is required. Use of a single straight implant with divergence of greater than 15° is not recommended. Use of a single 20° angled implant with divergence of greater than 30° 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.

Not for use with O-Rings other than the SATURNO Micro O-Ring.

CAUTION

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

STORAGE AND HANDLING

The SATURNO Narrow Diameter 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 steel instruments/tools should be used to handle and deliver the implant to the surgical site.

SINGLE-USE DEVICES

The SATURNO Narrow Diameter Implant is a single-use device.

SATURNO Narrow Diameter Implant: A previously used SATURNO Narrow Diameter 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).

SATURNO Micro O-Rings: The inadvertent re-use of SATURNO Micro O-Rings could cause loss of retention for the overdenture due to wear from previous use or damage during removal.

STERILIZATION

The SATURNO Narrow Diameter Implant is packaged and supplied ***STERILE*** (subjected to radiation (gamma) as a means of sterilization).

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

The O-Ring Insertion Tools (in the disassembled state only) may be sterilized/disinfected using a liquid chemical sterilant. In order to ensure that the nylon males are sterilized/disinfected (all microorganisms including *Clostridium sporogenes* and *Bacillus subtilis* spores are eliminated), the nylon males must be soaked for a minimum of 3 hours in the liquid sterilant at room temperature.

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.

Do not autoclave the O-Ring Insertion Tool with the SATURNO Surgical Kit.

PART DESCRIPTION	STERILIZATION METHOD	TEMPERATURE	DWELL TIME	DRY TIME
Blockout Spacer or Denture Cap	Steam – Gravity	132°C (270°F)	15 minutes	30 minutes
	Steam – Pre-Vacuum	132°C (270°F)	4 minutes	20 minutes

CLEANING INSTRUCTIONS FOR INSTRUMENTS

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 these 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 torque ratchet 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 a sonication bath (with enzymatic cleaning solution prepared according to manufacturers' instructions) making sure that these 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 Surgical 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 these 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 observed, repeat the cleaning process. Please note that if during inspection of instruments, there are signs of wear, damage, or unrecognizable color change, replace the instrument.

2 Reassemble the Torque Indicating Ratchet Wrench and check for proper function. Reference the IFU that is included with the part 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 (excluding the O-Ring Insertion Tool) into the surgical tray.

2 Double wrap the kit with autoclave wrap material and secure wrap with autoclave tape.

Autoclave Sterilization Parameters are listed below:

CYCLE TYPE	TEMPERATURE	EXPOSURE TIME	DRYING TIME
GRAVITY	132°C / 270°F	25 MINUTES	30 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 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.

NOTE: Drying times may vary according to load.

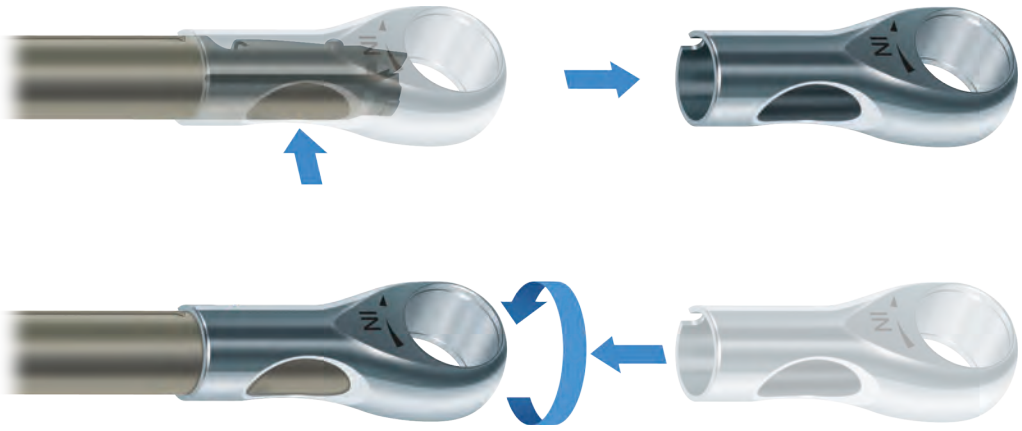
2 After sterilization, attach the head of the wrench to the body by pushing the components together and turning them in opposite directions until there is an audible click.

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 subjected 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.



WARNINGS AND PRECAUTIONS

The SATURNO Narrow Diameter Implant System has not been evaluated for safety and compatibility in the MR environment. The SATURNO Narrow Diameter Implant System has not been tested for heating, migration, or image artifact in the MR environment. The safety of the SATURNO NDI System in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

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

In the event that the sterilized packaging for the SATURNO Narrow Diameter Implant is damaged, the damaged packaging (with the product) must be returned to the manufacturer and a replacement will be provided (if damage to sterilized packaging is caused by product shipment).

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 SATURNO Narrow Diameter Implant is subjected to inappropriate loading conditions, there may be a potential risk of metal fatigue or localized bone failure.

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.

RETURN POLICY AND WARRANTY

ORDERING

Orders are accepted by internet, email, mail, fax, or phone. Regular business hours are 7:00am to 5:00pm PST (Pacific Standard Time). Orders received by 1:00pm PST can be shipped by ground the same day. Orders received by 3:00pm PST can be shipped by express. Institutional orders require a purchase order number.

PRICING

ZEST Anchors LLC makes every effort to maintain a competitive pricing structure. Pricing is subject to routine review and change without prior notice. All prices listed are in U.S. dollars.

TERMS AND BILLING

A) Credit Card: Payment at the time of order with VISA, AMERICAN EXPRESS, DISCOVER or MASTERCARD is necessary for customers not approved for open account billing or special financing offers.

B) C.O.D.: Delivery can also be made by C.O.D. freight collect.

C) Open Account: An open account can be established by completing a credit application and approval by ZEST Anchors LLC. The terms of orders purchased under open accounts are net 30 days.

D) Export Orders: Individual orders shipped outside the U.S. require payment in advance or a letter of credit.

E) Past Due Accounts: Past due balances will be subject to a 1.5% finance charge per month, amount equal to 18% per annum.

SHIPPING CHARGES

Merchandise is shipped prepaid by ZEST Anchors LLC with the cost added to the invoice, or freight collect with C.O.D. fee included in the case of C.O.D. shipments. Delivery is made using Fed Ex 2-day service unless ground, 3 day, or overnight rush service is requested.

LIMITED WARRANTY

ZEST Anchors LLC provides a limited warranty for its products, to the original purchaser, to be free from defects in workmanship and materials under normal use and service, for a period of one year from the date of purchase. ZEST Anchors LLC will, at its option, substitute the returned product that proves defective within the warranty period, with a similar product free of charge.

ZEST Anchors LLC continually strives to improve its products, and therefore, reserves the right to improve, modify, or discontinue products at any time without notice or incurring obligations. Purchaser assumes all risks and liability resulting from the use of ZEST Products, whether used separately or in combination with other products not of ZEST Anchors LLC manufacture.

POLICIES FOR SATURNO NARROW DIAMETER IMPLANT

ZEST Anchors LLC will not cover non-integration or loss of integration of a SATURNO Narrow Diameter Implant.

ZEST Anchors LLC will not cover the replacement of a SATURNO Narrow Diameter Implant if it is opened or dropped.

SATURNO NARROW DIAMETER IMPLANT PRODUCT EXCHANGE POLICY

ZEST Anchors LLC understands that customers may need to adjust inventories of SATURNO Narrow Diameter Implant 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.

RETURN POLICY – ALL OTHER ZEST ANCHORS LLC PRODUCTS

Please Observe the Following Guidelines:

A) Authorization for returns must be received from ZEST Anchors LLC prior to the return of any product. An authorized Return Material Authorization (RMA) number is required for all returns.

B) Shipping charges must be prepaid by the customer to accept a return shipment.

C) Returned products are subject to a $20 restocking fee for orders under $400. For orders $400 to $1,000, a $40 restocking fee will be applied. For orders exceeding $1,000, please contact your Customer Service Representative for the restocking fee.

D) Returned merchandise will be accepted within 90 days of purchase if product is in saleable condition (in its original unopened package and not marred by any added writing or over-labeling).

E) Returns will not be accepted after 90 days of purchase.

F) Non-returnable items include:

1) Merchandise retained beyond expiration date noted on the package.
2) Packages with broken seals or missing parts.
3) Used, damaged, or obsolete products will not be accepted for return.

EXPLANATION OF SYMBOLS ON OUTER PACKAGING LABELS

SYMBOL	EXPLANATION OF SYMBOL
CE 0086	CE Marking of Conformity with Notified Body Number (Use 0086 only on class IIa and higher risk class devices).
EC REP Wellkang Ltd 29 Harley St. W1G 9QR London U.K.	European Authorized Representative
	Symbol for **"CONSULT INSTRUCTIONS FOR USE"** NOTE: Product is provided with an Instructions For Use (IFU) and a Technique Manual.
	Symbol for **"DO NOT REUSE"** For single-use. Use only once.
Rx Only	**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."**
LOT	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.
REF	Symbol for **"CATALOGUE NUMBER"** The product catalogue number shall be after or below the symbol adjacent to it.
REF	**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.)
	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.
	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.
STERILE R	Symbol for **"STERILIZED USING IRRADIATION"** NOTE: Refers to Implant/Attachment sterilized packaging only.
	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.

SATURNO™

NARROW DIAMETER IMPLANT SYSTEM

TO RECEIVE INFORMATION ABOUT

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