Guide Right™

4.4 mm Depth Stop Crestal Sinus Elevation Drill Set

↻ Clockwise Rotation ↻

4 mm to 10 mm L

Instructions for Use

www.DePlaque.com

Sections

1. Unique Characteristics

- The sinus elevation drills are used to elevate the sinus membrane by moving autogenous bone from the patient's alveolar crest, lifting the sinus membrane, thereby providing room to place an implant.
- Additional bone grafting materials may be used along with the patient's bone to elevate the sinus membrane to provide more space to place implants that are longer, extending beyond the height of the alveolar crest.
- Single drill replacements are available if lost or worn out.

2. Clinical Advantages

- May be used in place of or with a lateral window, when a sinus elevation is required to place one or more longer implants extending above the floor of the sinus.
- Pre-cooled drills and aluminum drill blocks available to reduce morbidity.
- May reduce the risk of infection compared to a lateral window surgery.
- Allows implant placement within the sinus elevation.
- May reduce the cost and the procedure time.

3. Indications for Use

- Sinus elevation is recommended to facilitate placing implants of sufficient size to support a restoration in the maxillary posterior.
- Intended to move autogenous bone from the alveolar crest apically, while widening the osteotomy and lifting the sinus membrane.
- The autogenous bone particles are pushed up through the opening in the sinus floor beneath the membrane, as each progressive (larger diameter) drill removes bone from the inner wall of the osteotomy with a rotation.
- Rotating the drill pushes the bone apically to elevate the membrane.
- A Depth Probe can be used after each drill in the 1.5 - 2.2 mm gold series. Depth is completed when slight perforation through the bone at the sinus floor is felt.
- The drills **should NOT penetrate the bone at the floor of the sinus by more than 1 mm**, leaving the membrane intact.

4. Contraindications

- Symptoms or conditions where Crestal Sinus Elevation may not be advisable:
  - Presence of acute or chronic sinus infection or symptoms
  - Where there is less than 3 mm crestal bone height
  - Where the alveolar ridge width is less than 3 mm wider than the diameter of the implant
  - Patients with limited opening
  - When patients are required to remain on blood thinners
- Absolute contraindications:
  - Sinus neoplasms
  - Chronic polypous sinusitis
  - Mucocele
  - Severe allergic rhinitis
  - Paranasal sinus fungal infection
- Relative contraindications:
  - Sites for crestal bone thickness is less than 4 mm
  - Chronic maxillary sinusitis receiving otolaryngologic treatment
  - Very small size of the maxillary sinus
  - Mucous retention cyst
  - Maxillary sinus surgery history high incidence of failure and complications because the sinus is commonly filled with poorly vascularized scar tissue
- References available on page 39

4.4 mm

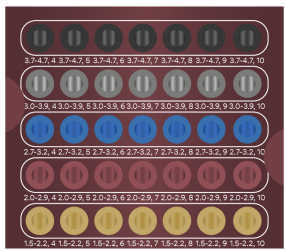
Depth Stop Crestal Sinus Elevation Drill Set

↺ Clockwise Rotation ↺

Crestal Sinus Elevation Drill Set

- The sinus elevation drills are used to elevate the sinus membrane by moving autogenous bone from the patient's alveolar crest, lifting the sinus membrane, thereby providing room to place an implant.
- Additional bone grafting materials may be used along with the patient's bone to elevate the sinus membrane to provide more space to place implants that are longer, extending beyond the height of the alveolar crest.
- Preferred grafting materials:
  - Soft collagen materials should be used to initiate the elevation along with the autogenous bone
  - Allograft particulate bone or Puros® used with Infuse®. Infuse binds to Puros because of the exposed collagen fibers, due to the special demineralization protocol
- Biologics can be used to enhance mineralization:
  - Gem 21S®
  - Infuse®

Storage Container



taper	taper	taper	taper	taper	taper	taper
3.7-4.7 mm	3.7-4.7 mm	3.7-4.7 mm	3.7-4.7 mm	3.7-4.7 mm	3.7-4.7 mm	3.7-4.7 mm
3.0-3.9 mm	3.0-3.9 mm	3.0-3.9 mm	3.0-3.9 mm	3.0-3.9 mm	3.0-3.9 mm	3.0-3.9 mm
2.7-3.2 mm	2.7-3.2 mm	2.7-3.2 mm	2.7-3.2 mm	2.7-3.2 mm	2.7-3.2 mm	2.7-3.2 mm
2.0-2.9 mm	2.0-2.9 mm	2.0-2.9 mm	2.0-2.9 mm	2.0-2.9 mm	2.0-2.9 mm	2.0-2.9 mm
1.5-2.2 mm	1.5-2.2 mm	1.5-2.2 mm	1.5-2.2 mm	1.5-2.2 mm	1.5-2.2 mm	1.5-2.2 mm
4 mm L	5 mm L	6 mm L	7 mm L	8 mm L	9 mm L	10 mm L

- 3⅜" x 4¼" x 2¾"
- PVD Coated Stainless steel box
- Used to store and clean drills
- Silicone receptacle inserts to stabilize drills in storage container
- Contains drills with mm size indication inscribed for easy recognition
- Autoclavable, also can be placed in freezer for 1 hour prior to use for cold drilling protocol
- The metal box maintains the cold temperature of the drills when removed from the freezer, resulting in less damage to bone and less discomfort for the patient. Drills remain (below 10°C) cold for 25-35 minutes if placed on a cold ice pack.
- **The rotation direction is indicated on the box cover for each set of drills.**

Concave Plugger

- Included in the Depth Stop Crestal Sinus Elevation Drill Set
- 5 inches long with one concave tip at either end of the handle (marked at 2 mm intervals)
- Specifications:
  - One OD 2.5 mm tip
  - One OD 3.5 mm tip for larger openings
  - Each end is concave and is used to push additional graft material below the sinus membrane to elevate the membrane
  - The 2.5 mm tip of the plugger has an adjustable depth stop to prevent the plugger from being pushed beyond the level of the bone into the sinus cavity
  - **Only the *graft material*** should be pushed in to elevate the sinus
  - Caution: the adjustable depth stop may vibrate off during ultrasonic cleaning
- **Also sold separately**

Sinus Elevation Probe

- Included in the Depth Stop Crestal Sinus Elevation Drill Set
- Specifications:
  - The 2˚ tapered blunt tip is 1.5 mm diameter with 1 mm markings, 15 mm long
  - The probe tip is the same diameter as the 1.5 mm starting drill
- Use:
  - To check the depth of the osteotomy to see if the floor of the sinus has been breached, feeling **gently** after each drill is used
  - Do **NOT** puncture the membrane with the probe while checking it.
  - Sometimes it is difficult to feel the membrane. Do **NOT** assume that the membrane has been perforated. Check for perforation of the sinus membrane with the Valsalva maneuver.
  - A periodontal probe can also be used.

Gold Series

- Located in the **1st row** of the drill box
- 2˚ tapered from **1.5 mm to 2.2 mm** drill diameter
- Lengths: 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm
- 4.4 mm diameter depth stop
- Used with the 4.5 mm Guide Sleeve
- Used with the rotation direction indicated on the box cover at speeds of 600 to 800 RPM to reach the depth of the sinus membrane

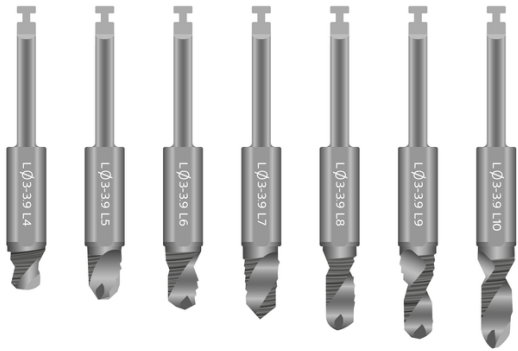
Rose Series

- Located in the **2nd row** of the drill box
- 2˚ tapered from **2.0 mm to 2.9 mm** drill diameter
- Lengths: 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm
- 4.4 mm diameter depth stop
- Used with the 4.5 mm Guide Sleeve
- Used with the rotation direction indicated on the box cover at speeds of 600 to 800 RPM to reach the depth of the sinus membrane

Blue Series

- Located in the **3rd row** of the drill box
- 2˚ tapered from **2.7 mm to 3.2 mm** drill diameter
- Lengths: 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm
- 4.4 mm diameter depth stop
- Used with the 4.5 mm Guide Sleeve
- Used with the rotation direction indicated on the box cover at speeds of 600 to 800 RPM to reach the depth of the sinus membrane

Silver Series



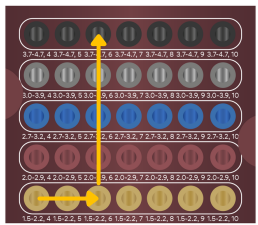
- Located in the **4th row** of the drill box
- 2˚ tapered from **3.0 mm to 3.9 mm** drill diameter
- Lengths: 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm
- 4.4 mm diameter depth stop
- Used with the 4.5 mm Guide Sleeve
- Used with the rotation direction indicated on the box cover at speeds of 600 to 800 RPM to reach the depth of the sinus membrane

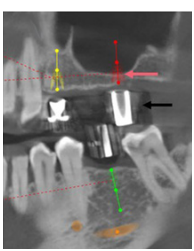
Black Series

- Located in the **5th row** of the drill box
- 2˚ tapered from **3.7 mm to 4.7 mm** drill diameter
- Lengths: 4 mm, 5 mm, 6 mm, 7 mm, 8 mm, 9 mm, and 10 mm
- Used for implant diameters greater than 4.7 mm
- Used without a Guide Sleeve for larger diameter implants
- Fits in 5.0 mm Guide Sleeves **only**
- Used with the rotation direction indicated on the box cover at speeds of 600 to 800 RPM to reach the depth of the sinus membrane

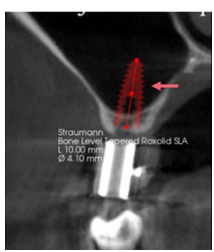
Crestal Sinus Elevation Protocol

- A case illustration:
  - Drilling is initiated 1.5 mm - 2.2 mm with the Depth Stop Drills in crestal bone approximately 5 - 6 mm thick.
  - **All drills are rotated in the direction indicated on the box cover** at 600 to 800 RPM, which results in pushing the bone particles upward, to lift the sinus membrane from the bony floor of the sinus. Higher speeds increase the risk of puncturing the membrane.
  - Once the floor of the sinus is reached, the drill flutes push the bone particles apically through the opening in the bone below the sinus membrane, **avoiding puncturing the membrane**.





The long axis of the virtual implant indicates the long axis of the Guide Sleeves do not need correction.

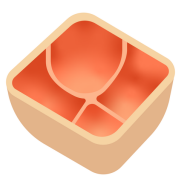


Alignment of the implant of the Diagnostic Guide Sleeve indicates no correction is necessary in the bucco-lingual plane.

Crestal Sinus Elevation Protocol

- The sequence is started with the gold drill series 1.5 - 2.2 mm drills.
- All drills are used with the rotation direction indicated on the box cover, therefore, pushing the bone particles upward to lift the membrane of the sinus cavity.
- The drills **increase in length by 1 mm**; starting with 4 mm and increasing to 5, 6 and 7 mm up to 10 mm.
- Once the osteotomy drill length opens up the bone below the sinus membrane, use the next larger diameter drill of the **same length or 1 mm shorter** for all the remaining drills used.
- The remaining drill diameters used or selected are dependent on the diameter of the implant to be placed.

Sinus Elevation Practice Model



- Two sinus elevation practice models are included with every drill set. (Additional models available on DePlaque.com)
- Instructions for use:
  - The 3 mm model site is too thin and will be perforated by the 4 mm drill and should not be used.
  - Use of the drill set is contraindicated on sites with 3 mm or less of crestal bone.
  - Follow the sinus elevation protocol using the sinus elevation practice models on the sites 4, 5, and 6 mm bone thickness.

Crestal Sinus Elevation Protocol

- Steps to completing a Crestal Sinus Elevation prior to implant placement:

1. A cone beam X-ray should be taken to determine the center of the alveolar ridge bucco-lingually. A surgical guide is highly recommended in making that determination.
2. From the cone beam image, estimate the thickness of the bone to determine the length of the initial drill to be used.
3. If the procedure is to be completed **flapless**, combine the thickness of the soft tissue (usually 2 - 3 mm) and the thickness of the alveolar bone.

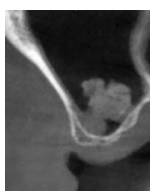
- *IF* there is any question about the thickness of the bone and soft tissue:
  - To be safe, start with the **shortest drill (4 mm)** and advance the length as needed, one millimeter at a time (5, 6, 7 mm), until the **bone is perforated** but **NOT the membrane**.
  - That **same length** of the drill that **perforates the bone, (not the membrane)** will be used for all the other larger diameter drills, so the diameter of the osteotomy increases and the drill depth does not increase.
  - Drills should **NOT** pass beyond the floor of the sinus; only the grafting materials should be used to elevate the membrane.

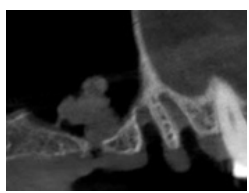
Crestal Sinus Elevation Protocol

4. Using a Thin Probe,
   - The **drill sequence is initiated** with the gold drill series 1.5 mm - 2.2 mm drills, using them up to the drill length that can be checked with a Thin Probe.
   - **Check the depth of the osteotomy** to see if the floor of the sinus has been breached by feeling if the drill has perforated the sinus floor after each drill is used.
   - The probing should be gentle to avoid perforation of the sinus membrane.

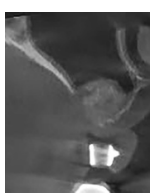
Caution: Do not puncture the sinus membrane with the probe. This should be checked with the Valsalva Maneuver or a periapical X-ray.

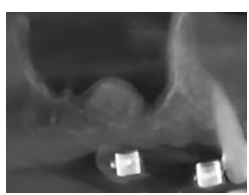
An example of a membrane that has been perforated and the particles have randomly been pushed through the membrane. NOTE: the particles appear loosely compacted rather than dense.





Loosely packed granules at the time of elevation with negative Valsalva maneuver.





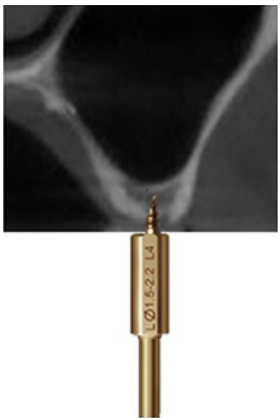
2 months CT shows congealed graft appearance ready for additional grafting.

Crestal Sinus Elevation Protocol

5. Elevating the sinus membrane

- *IF* the gold 1.5 mm - 2.2 mm x 4 mm L drill has **NOT perforated the sinus floor**:
  - Use the next 1 mm longer gold drill (1.5 mm - 2.2 mm x 5 mm L) to continue drilling 1 mm deeper.
  - Check **gently** with the Thin Probe again to feel if the bone has been perforated. It will feel soft with less resistance.
  - Do **NOT** puncture the membrane with the Sinus Elevation Probe while checking it.
  - Continue using the next 1 mm longer gold drill (1.5 mm - 2.2 mm x 6 mm L) to increase the depth by another mm. Check the site again with the probe to see if the bone has been perforated and the membrane has been reached.
  - Sometimes it is difficult to feel the membrane. Do **NOT** assume that the membrane has been perforated.
- The drills should **NOT** penetrate the floor of the sinus by more than 1 mm.
- The Valsalva Maneuver is the best way to check for a perforation.

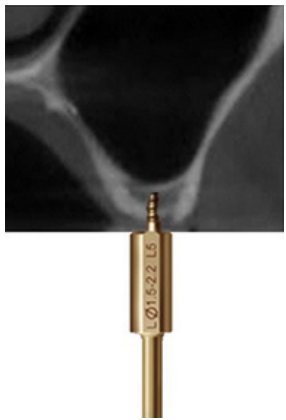
Sinus Elevation Illustration



4 mm L
1.5 x 2.2 mm taper

Step 1

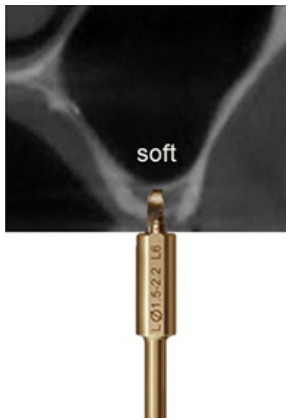
Use gold 4 mm L drill to **depth check for perforation of sinus floor**.



5 mm L
1.5 x 2.2 mm taper

Step 2

Use gold 5 mm L drill to **depth check for perforation of sinus floor**.



6 mm L
1.5 x 2.2 mm taper

Step 3

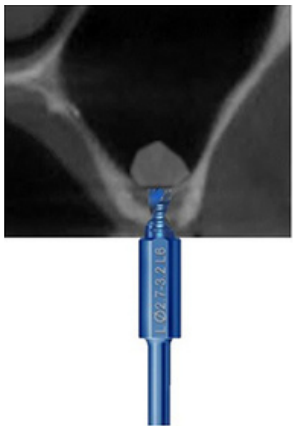
Use gold 6 mm L drill to depth check for perforation of sinus floor. *IF* it feels soft, it is the **correct working length for remaining drills**.

Sinus Elevation Illustration

6 mm L
2.0 x 2.9 mm taper

Step 4

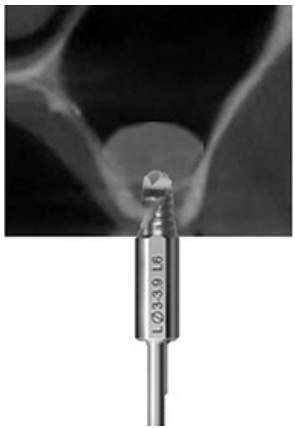
Use rose 6 mm L drill to push crestal bone to elevate the sinus membrane.



6 mm L
2.7 x 3.2 mm taper

Step 5

Use blue 6 mm L drill to push additional bone from the osteotomy wall.



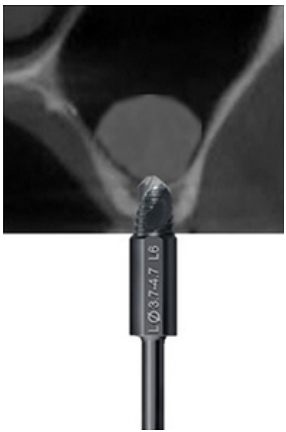
6 mm L
3.0 x 3.9 mm taper

Step 6

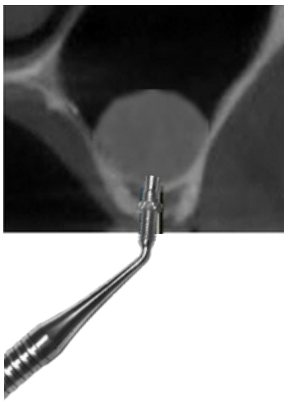
Use silver 6 mm L drill to push additional bone from the osteotomy wall.

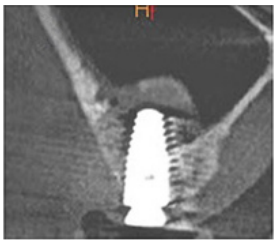
The opacity of the material used is usually less than what is illustrated above.

Sinus Elevation Illustration



6 mm L
3.7 x 4.7 mm taper





In this case, a 4.8 mm bone level tapered implant was placed after the 6 mm L 3.0 - 3.9 mm silver drill.

Step 7

Use black 6 mm L drill to enlarge the osteotomy diameter for a larger diameter implant.

Step 8

Concave Plugger is used to push additional graft material below the sinus membrane. (Grafting materials see: page 28)

Step 9

Implant diameter is coordinated with the diameter of the last drill used.

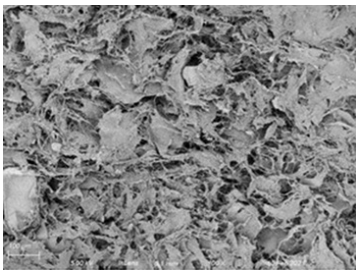
Crestal Sinus Elevation Protocol

6. Verifying the membrane status:
   - To verify an intact membrane, the sinus membrane can be checked using the ***Valsalva Maneuver***: pinching the patient's nose and having them try to blow their nose (mouth open) while watching to see if any bubbles escape from the osteotomy site. If no bubbles or blood escape, most likely the membrane has not been perforated.
7. After testing with the Valsalva Maneuver, *IF* the membrane has been perforated:
   - Select the 1 mm shorter drill series as the working length. Use the larger diameter drills, 1 mm shorter in length (rose, blue, silver, black), until you reach the final diameter needed.
   - Cut an OsteoGen® Plug (OPS625-10 Slim) into small particles.
   - Using the Concave Plugger (small end), compress pieces (one piece at a time), and place in the opening of the osteotomy. Check again for perforation of the sinus membrane with the Valsalva Maneuver.
   - Continue to increase the sinus elevation with more of the collagen or bone product until you have reached desired implant length. Check the site with the periapical X-ray prior to placing the implant.
   - *IF* the **sinus membrane opening remains**, terminate the procedure and let it heal for 3-4 weeks before restarting crestal sinus elevation using 1 mm shorter drills.
   - Patient post op instructions: Do not use straws or suction for 1 week.

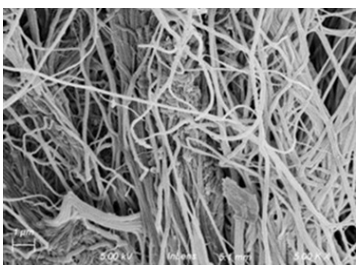
Crestal Sinus Elevation Protocol

8. Adding additional grafting materials:
   - The initial particles should be soft collagen material.
   - Example: The Impladent OsteoGen® Plug - 10 mm x 20 mm or 6 mm x 12 mm is cut lengthwise into pieces.
   - Each piece should be cut into smaller sections (3 - 4 mm lengths) (see: page 29) and using cotton pliers to insert the pieces one or two at a time through the osteotomy with the 2.5 mm or 3.5 mm tip of the Concave Plugger. The drill tip nor the plugger tip should be pushed beyond the floor of the sinus.
   - If pushing the material into the opening seems difficult with the plugger, use the last drill series again (rose, blue, silver) to push the material in further with rotary motion.
   - If Bone Morphogenetic Protein-2 (BMP2) Infuse® Medtronics 50-100 µg is used with 0.3-0.4 ml sterile water, delay placement 15 minutes prior to insertion of the collagen.
   - Collagen or particulate allograft bone can be placed in the osteotomy to elevate the sinus. **Infuse® will not bind with Bio-Oss or mineralized allograft alone**.
   - GEM 21S® (Geistlich Pharma North America, Inc.) can be used to enhance mineralization and shorten the implant integration time.
   - A periapical or cone beam X-ray should be taken prior to implant placement to view the dimensions of the sinus elevation. The length of the implant should not exceed the height of the sinus elevation.

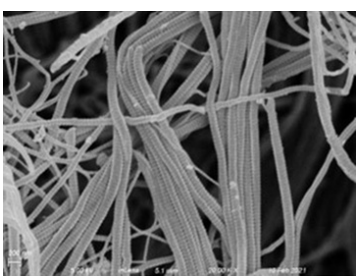
Grafting Materials Used With BMP2



- Low magnification
- SEM of OsteoGen® where calcium apatite particles can be observed between the collagen fibers



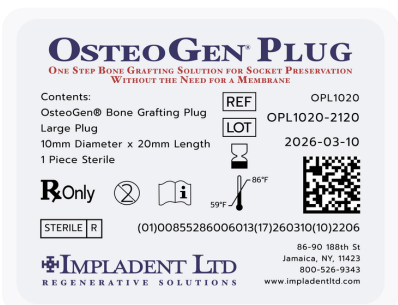
- Higher magnification
- SEM of OsteoGen® illustrating the collagen fibers necessary to bind the Infuse® (BMP2) 15 minutes prior to use



- Highest magnification
- SEM of OsteoGen® illustrating the cross banding of the collagen fibers necessary to bind the Infuse® (BMP2)

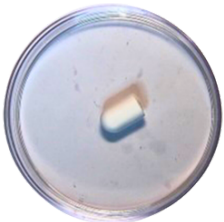
Additional Grafting Materials

- Biologics can be used to speed up the rate of mineralization of the collagen.
- **Avoid Gelfoam®** (does not contain collagen).
- BMP2 by Infuse® (Medtronics) is the Guide Right™ preferred biologic to add to a collagen substrate, to enhance the rate of mineralization above the membrane.
- Infuse® (Medtronics) 50-100 µg can be added to enhance the mineralization of the collagen-rich material. (Another alternative product: GEM 21S® by Geistlich)
- Without the use of biologics, the mineralization rate takes 6 months or more.



Mechanism of Action for rhBMP-2/ACS*	
1. Implantation	rhBMP-2/ACS is implanted.
2. Chemotaxis	Migration of Mesenchymal Stem Cells and other bone-forming cells to the site of implantation.
3. Prolification	rhBMP-2/ACS provides an environment where stem cells multiply prior to differentiation.
4. Differentiation	rhBMP-2 binds to specific receptors on the stem cell surface signaling them to differentiate into osteoblasts.
5. Bone Formation + Angiogenesis	Osteoblasts respond to local mechanical forces to produce new mineralized tissue replacing the ACS. New blood vessel formation is observed at the same time.
6. Remodeling	The body continues to remodel bone in response to the local environmental and mechanical forces, resulting in normal trabecular bone.

OsteoGen® Plug 1020



OsteoGen® Plug 1020

Section the OsteoGen® Plug in quarters lengthwise using ACE Southern's Smith Wire Cutting Scissors, 1 Blade Serrated, small (SKU# 0800213-EA)

Application of 50 µg BMP2 in 0.40 ml sterile H2O for 15 minutes prior to application, or use GEM 21S® in liquid form added to the collagen

Adding the Infuse® (BMP2) or GEM 21S® softens the material

Cut each piece to smaller pieces for the elevation of the sinus membrane

OsteoGen® Plug 1020

Each piece of collagen-based material OsteoGen® with or without a biologic is placed with college pliers and pressed in with the Concave Plugger.

Concave Plugger

The adjustable depth stop can be used to prevent over insertion of the plugger tip.

Crestal Sinus Elevation Protocol

9. Use of Surgical Guides and Sinus Elevation:
   - A Surgical Guide is recommended for sinus elevations **without flap reflection**.
   - Lab fabricated or printed surgical guides can be utilized with ID 4.5 mm Guide Sleeves to center the osteotomy and sinus elevation (bucco-lingually) in the alveolus with simultaneous implant placement.
   - The Guide Right™ Surgical Guide protocol is illustrated on page 35.

6. Recommended Sinus Elevation Cold Drilling Protocol

Benefits of Cold Drilling Osteotomies:

- Because the flapless protocols involve **serial drilling by increasing drill lengths at 1 mm intervals**, the drills are pre-cooled.
- Irrigation is not recommended nor required.
- After autoclaving, the drills should be pre-cooled by placing them in a refrigerator freezer for at least one hour prior to surgery.
- The sinus elevation protocol calls for **serial drilling** increasing the depth by 1 mm at a time (4, 5, 6, 7, 8, 9 & 10 mm lengths).
- Once the depth of the osteotomy is reached, the width of the osteotomy is increased by less than 1 mm with each increasing drill diameter. Using pre-cooled reverse twist drills, while elevating the bone to lift the sinus membrane, results in less trauma to the alveolar bone and discomfort to the patient.
- After the appropriate depth is reached (checked with a periodontal probe and the Valsalva maneuver), the osteotomy diameter is also increased in small steps, to remove a very small amount of bone pushed apically.
- The level of discomfort experienced by patients with a flapless protocol with cooled drills is significantly less than the discomfort reported with lateral window sinus elevation surgery.

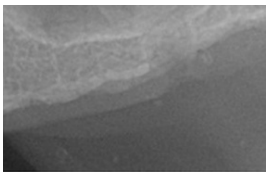
7. Factors Affecting Heat Generation During Implant Site Preparation

- "The success of endo-osseous implants is largely dependent on the bone viability post implant site preparation factor that affects the viability and vitality of the bone at implant site and that needs to be considered is the sensitivity of the bone to the heat generated during bone drilling. Heat generations during bone drilling is a frequent occurrence related to various factors such as bone density, irrigation system, drill sharpness, drilling depth, feed rate, drill wear and drilling speed, drilling load and many others."*
- "Drilling at a low speed has been proven to be advantageous over high speed drilling with irrigation. Others concluded temperature rise is also dependent on the force applied. Intermittent drilling is considered a better alternative than continuous drilling."**

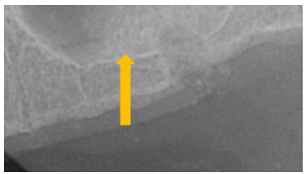
**SH Tehemar Factors Affecting Heat Generation During Implant Site Preparation: a Review of Biologic Observations and Future Considerations, J Oral Maxillofac Implants 1999; 14:130*

***RK Samra, R Showkat, Impact of Drilling Speed in Implantology: A Review J Pierre Fauchard Academy India Section), Vol 35 (30, DOI: 10.18311/pjfa/2021/27610, September 2021 p 78-86*

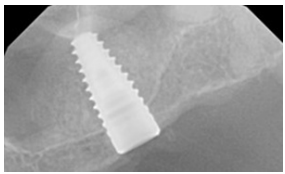
8. Recommended: Use of Surgical Guide



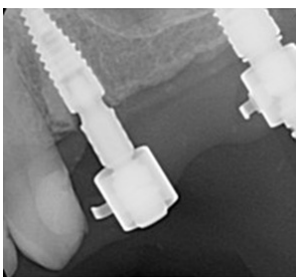
Osteotomy prior to placing OsteoGen® particles.



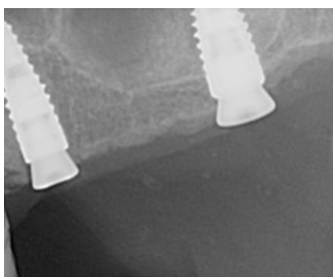
Osteotomy Post Graft
The OsteoGen® particles with 50 µg Infuse® appear to be slightly radio opaque and can be observed above the opening in the crest after insertion through the opening with the **Concave Plugger**.



The implant is inserted even with the alveolar crest and will be placed 2 mm deeper.

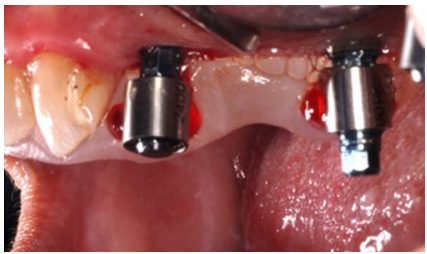


This PA X-ray was taken with the **Surgical Guide in place** to verify the implant positions. The distal fixture needs to be placed deeper.



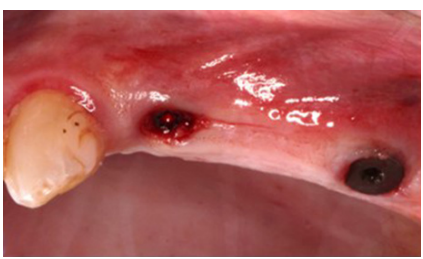
Both implants are placed deeper to allow placement of 2 mm healing abutments even with the tissue height.

8. Recommended: Use of Surgical Guide



4.8 mm implant and carriers placed through the Surgical Guide Sleeve indicate the positions of the implant placement and illustrate that carriers can be placed through the Guide Sleeve.

Occlusal View

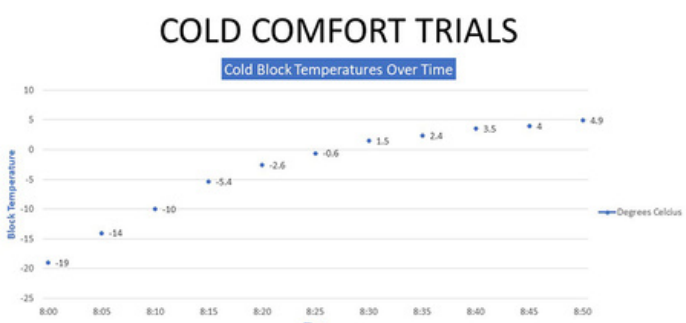


2 mm healing abutments were placed too close to the sites, illustrating the absence of the bone exposure where no flap was reflected. No sutures were placed.

9a. Maintenance Prior to First Time Use

- **STAGE 1: Light Cleaning and Rinsing** - Drill should be brushed and visually inspected for cleanliness, then dipped in detergent, rinsed and dried.
- **STAGE 2: Sterilization** - Drills should be placed in storage container and sterilized in an autoclave at 121 to 132°C (269.6°F) for a 30 to 40 minute duration in a standard approved sterilization wrap.
- **STAGE 3: During Use** - Aluminum drill blocks (provided), when placed in the freezer for 1 hour, will maintain cold temperatures for 30 minutes when used at room temperature and placed on a cooling pack.

Caution: Drills are not secured in the aluminum box and will fall out if the box is turned over.



9b. Cleaning + Storage of Drills After Use

- **STAGE 1: Cleaning** - Drills should be brushed and rinsed with detergent to remove any remaining blood or tissue. Complete visual inspection for cleanliness.
- **STAGE 2: Ultrasonic Cleaning** - Drills should be cleaned in an ultrasonic bath using appropriate enzymatic detergent (10% solution) following detergent manufacturer's instructions.
- **STAGE 3: Rinsing** - Drills should be rinsed with running water to completely remove detergent.
- **STAGE 4: Sterilization** - Drills should be replaced in storage container and sterilized in an autoclave at 132°C (269.6°F) for 30 minutes in a standard approved sterilization wrap.

9c. First-Time Surgical Use + Accessory Maintenance

- **STAGE 1: Light Cleaning and Rinsing** - Accessories should be rinsed under cold tap water. During the rinse, use an appropriately sized lumen brush to brush the lumen of the article and a soft-bristled brush to brush the exterior surface of the article.
- **STAGE 2: Preparation** - Prepare a detergent solution using Palmolive Dish detergent or comparative brand, using 1 tbsp per gallon of tap water. Brush the lumen of the article using appropriately sized lumen brush that has been wetted with the prepared detergent solution. Brush the exterior surface of the article using a soft-bristled brush that has also been wetted with the detergent solution.
- **STAGE 3: Ultrasonic Cleaning** - Prepare a detergent solution using Enzol or comparative brand in an ultrasonic unit, following the manufacturer's recommendation of 1 oz. per gallon using warm tap water. Immerse the articles in the detergent solution and allow them to sonicate for 5 minutes. While sonicating, ensure that there is no contact between articles. Rinse the articles under cold tap water. Allow the articles to air dry completely.
- **STAGE 4: Sterilization** - Accessories should be sterilized in an autoclave at 132°C (269.6°F) for a 30 minute duration in a standard approved sterilization wrap.

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11. Terms + Conditions of Sale

- CAUTION: Federal law restricts the sale of this device to or on the order of a licensed dentist.
- Treatment planning and clinical use of the Guide Right™ Drills and accessories are the responsibility of each individual clinician.
- **Surgeon preference and clinical judgment overrules the suggestive Guide Right Surgical protocol**. Guide Right™ strongly recommends completion of ADHERENCE to this manual.
- Guide Right™ is not responsible for incidental or consequential damages or liability relating to the use of the Guide Right™ Drills and accessories alone or in conjunction with other products other than replacement under warranty.
- Guide Right™ Drills and accessories are warranted for a period of thirty (30) days from the date of initial invoice.

12. Return Policy

- If you are not completely satisfied with your purchase for any reason, you may return it within 30 days for a full refund.
- TO INITIATE RETURN:
  - Contact DePlaque Customer Service at: (585) 924-3190 or customerservice@deplaque.com
  - Return in original container with all drills in original set up location.
  - Customer is responsible for secure packaging and return postage.
  - When returned within 30 days, original payment method will be credited.