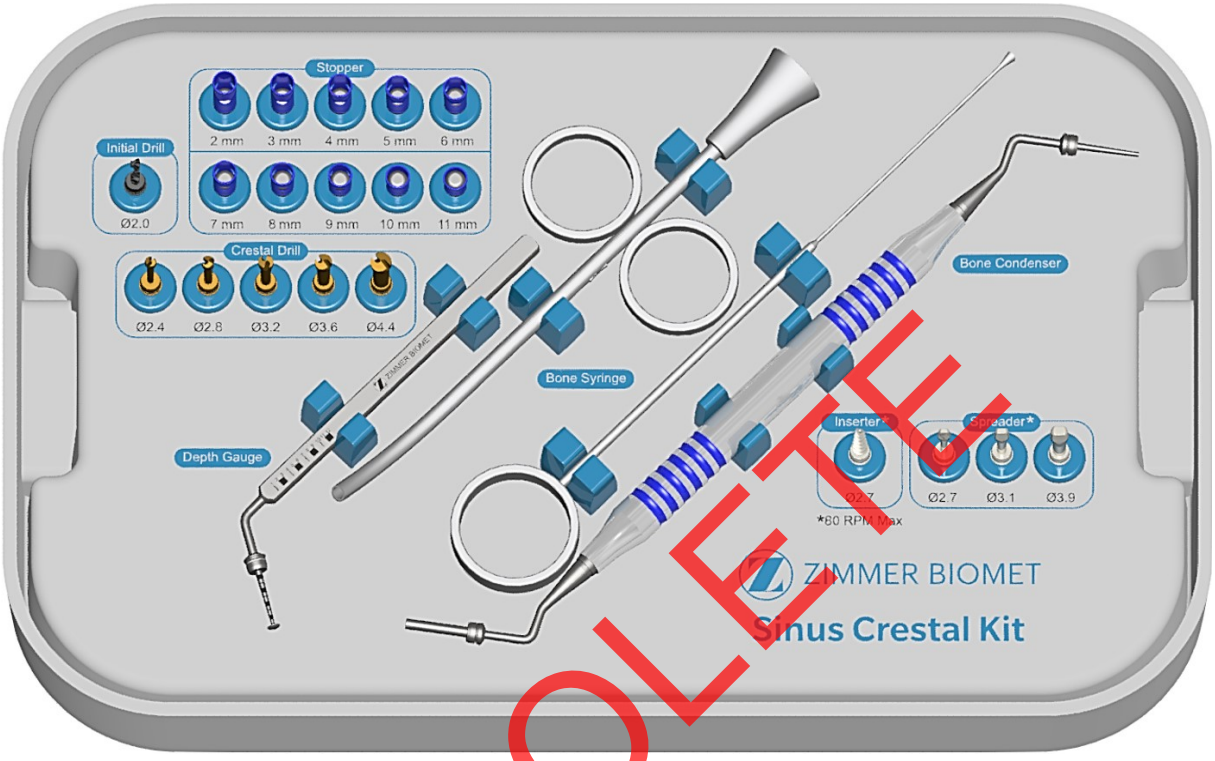
# Zimmer Biomet Sinus Crestal Approach (SCA) Kit Instructions for Use

**Description:**
The Sinus Crestal Approach Instrument Kit contains surgical instruments that are used to create osteotomy in order to access maxillary sinus floor, elevate the Schneiderian membrane and create space for placement of bone graft.






**Intended Use:**
Crestal maxillary subantral augmentation or "Sinus lift" procedure.

**Preparation for Use**

- Before using a Sinus Crestal Approach Instrument Kit and its components, the clinician performing this procedure should carefully study these instructions and fully comply with them. Before the procedure, the clinician must establish a treatment plan based on the patient's oral and other health conditions.
- Accurately assess the residual bone height of the maxillary posterior sinus floor, anatomical structure of the maxillary sinus, artery, nerve and lateral wall thickness through computed tomography (CT) and other appropriate imaging modalities, if required.
- After taking into consideration the condition of the patient, the instruments appropriate for the procedure must be prepared.
- This product is provided non-sterile. Accordingly, it should be used only after cleaning and sterilizing in an autoclave before and after each procedure. (Please refer to cleaning and sterilization instructions.)

**Sterilization Instructions**

1. This product is provided non-sterile and must be sterilized prior to use by a pre-vacuum or a gravity autoclave.
2. Assembled components must be organized in the tray in order to improve the effectiveness of the sterilization.
3. Using a surgical wrap, wrap the tray, seal it with autoclave tape and sterilize using the below parameters.

Recommended Steam Sterilization Conditions

| Cycle Type | Temperature | Exposure Time (minimum) |
|---|---|---|
| Gravity Steam Sterilization | 132°C | 15 minutes |

If regional or national sterilization requirements are stricter than the conditions provided above, the stricter requirements must be followed.

- In order to effectively carry out high-pressure steam sterilization, the use of biological indicators at regular intervals must be considered. (Dry heat sterilization or chemical sterilization is not recommended.)
- If the above sterilization conditions are exceeded, it is possible that the plastic and metal components may be damaged. The sterilization device must be adjusted to ensure that the recommended temperatures are not exceeded.

**Methods for Use**

1. Expose the crestal bone at the planned osteotomy site. After accurately assessing the residual bone height of the sinus floor, mark the osteotomy location with the 2mm initial drill provided in the kit.

2. Utilize the radiograph to determine the appropriate drilling depth. Select a stopper that allows for drilling 1mm less than the residual bone height. Place that Stopper on the 2.0 mm initial drill to enable drilling up to the inferior cortical wall. Note: The marked length of the Stoppers indicates the depth of drilling, not the length of the Stoppers. Utilize the drill with sufficient irrigation. The drill is typically operated at 800-1200 RPM. The use of cutting tools is recommended up to 50 times.

3. Select the appropriate final diameter Crestal Drill based on implant size and bone density.

4. Use a stopper on the smallest diameter crestal drill that allows for drilling 1 mm shorter than the bone height and drill using sufficient irrigation. For safety, drill in 1 mm depth increments using a Stopper with the Crestal Drill.

    a) If the sinus inferior cortical wall does not perforate when the stopper reaches the crestal bone, change to the next Stopper with 1 mm increment and continue drilling.

5. You may tactically feel perforation in the inferior cortical wall. Once the cortical wall has been perforated, enlarge the osteotomy by drilling with sequentially larger diameter crestal drills (with the same stopper) keeping in consideration the final diameter crestal drill, which is based on the implant size and bone density.

6. Measure the residual bone height with the depth gauge. Carefully insert the end of the depth gage into the osteotomy and hang its end inside the sinus wall to measure the residual bone height. Note: Do not insert the depth gauge more than l mm into the sinus.

7. Close the patient's nostrils and ask the patient to gently blow through the nose to determine if the Schneiderian membrane has been punctured.

    a) If there is a tear in the Schneiderian membrane, utilize an osteotome or other blunt instrument to gently insert a hydrated resorbable collagen barrier membrane into the sinus cavity to form a barrier between the perforation and the graft material.

8. If there is no tear in the Schneiderian membrane or if a barrier membrane has been placed over a perforation, insert the bone graft material, which has been prepared using the method(s) identified in the Instructions for use, into the sinus cavity using the Bone Syringe

included in the kit. The bone syringe shall be assembled and the bone graft entered through the tip.

9. Place a Stopper (depth equal to original bone height) on the Bone Condenser and gently concentrate the particulate graft material with care to avoid puncture of the Schneiderian membrane. The volume of required bone graft material will be based on the desired height of Schneiderian membrane elevation.

10. Use the Bone Inserter with a stopper (to allow for a depth of 1mm less than the original bone height) to advance the bone graft material further into the sinus cavity. Note: Operate the drill no faster than 80 RPM. To increase Schneiderian membrane elevation, insert at least 0.3cc of bone graft material into the receptor site.

11. Choose a spreader based on the size of osteotomy. Spread the bone laterally in the sinus area wall by using a spreader with a suitable stopper. Do not use a speed faster than 80 RPM for the Bone Spreaders.

12. Spread out the bone graft material with the Bone Spreader after inserting every 0.2cc- 0.3cc volume of bone graft.

13. After the bone graft material has been fully placed into the maxillary sinus, proceed to immediate implant placement, if indicated. Follow the implant manufacturer's user guide for proper implant placement.

**Cleaning Instructions**

Surgical Instruments

1. After completion of the procedure, detach all surgical instruments from the tray, soak them in alcohol or a cleaner and rinse using conventional means.
2. After washing with distilled or tap water, remove any remaining traces of blood or foreign material. Use a syringe or pipe cleaner for difficult to wash areas.
3. Following the instructions provided by the enzyme cleaner manufacturer, dilute the enzyme cleaner using tap water and after ten minutes of ultrasonic washing, rinse using tap water for three minutes.
4. Completely remove the moisture by using a dry cloth or a warm-air circulator.

Kit Tray

1. Remove all visible foreign material using distilled or tap water and a soft brush. For areas that are hard to clean, use a syringe or pipe cleaner.
2. Following the instructions provided by the enzyme cleaner manufacturer, dilute the enzyme cleaner using tap water and soak for one minute. Afterwards, remove any remaining foreign material on all parts with a soft brush.
3. After washing, rinse for three minutes using tap water to remove the remaining enzyme cleaner.
4. Completely remove the moisture by using a dry cloth or a warm-air circulator.
5. Organize the dry surgical tools in the kit case and sterilize using the sterilization instructions.

**Maintenance and Storage**

- Dry and store instruments in a moisture-free environment. Failure to do so may result in corrosion or staining.
- Shelf-life and sterility of wrapped instrument cases are dependent on storage in a manner to avoid extreme temperature, moisture and/or other contamination.
- Care must be exercised in the handling of wrapped cases to prevent damage to the sterile barrier.
- Inspect the exterior of sterilized package before use. If a package is compromised, it should not be used, and should be reprocessed per the sterilization procedure.

**Precautions**

- Only healthcare professionals who have completed implant procedure education and training courses should use this product.
- For each patient, a procedure plan must be established after testing and analyzing for ailments, infectious disease, possible treatment for other ailments and presence of oral lesions.
- The healthcare professional must use the product only after becoming completely familiar with the instructions for use and the relevant warnings, and must select products that fit the treatment plan.
- Before each procedure, the instruments must be examined for wear and tear.
- Improper use may cause failure of the implant or post-surgical bone loss around the implant.
- Hydrogen peroxide is prohibited for disinfection and washing, as it could damage the TiN coating, laser markings and/or anodizing.

**Contraindications**

- Patients with active sinus disease
- Patients with serious internal ailments: endocrine ailments such as diabetes, circulatory ailments such as hypertension and ailments related to the immune system, blood or organs
- Patients receiving high-level radiation treatment
- Patients with malocclusions
- Patients with dry mouth
- Patients with poor oral health
- Patients with acute inflammatory conditions or patients who are at risk of infection
- Patients who are pregnant
- Patients who smoke
- Patients with blood clotting conditions or with severe cardiac conditions
- Patients who are allergic to titanium or stainless steel
- Patients with abnormal wound-healing
- Patients who are taking certain medications
- Patients who are susceptible to physical and mental stress caused by temporary use of specific medications
- Patients who are emotionally unstable due to alcohol addition, drug abuse and/or neurological or mental conditions
- Patients who have unrealistic expectations regarding the treatment plan
- Children still in skeletal growth phase



**Side effects**

- Using sound surgical techniques minimizes the risk of complications.
- Paresthesia due to nerve damage or malocclusion, infection, edema, hypodermic bleeding, pain, opening of the sutures, soft tissue ulcer and other localized adverse reactions may occur.
- Localized and general allergic reactions may occur.

**Labeling Symbols**
**CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician.**

| Symbol | Definition | Symbol | Definition |
|---|---|---|---|
|  | Catalog Number |  | Consult instructions for use<br>ifu.biomet3i.com |
|  | Batch Code |  | Non-Sterile |
|  | Date of manufacture |  | Prescription Only |
|  | Manufacturer | | |

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