3D SYSTEMS

# VSP® Orthognathics
Virtual Surgical Planning

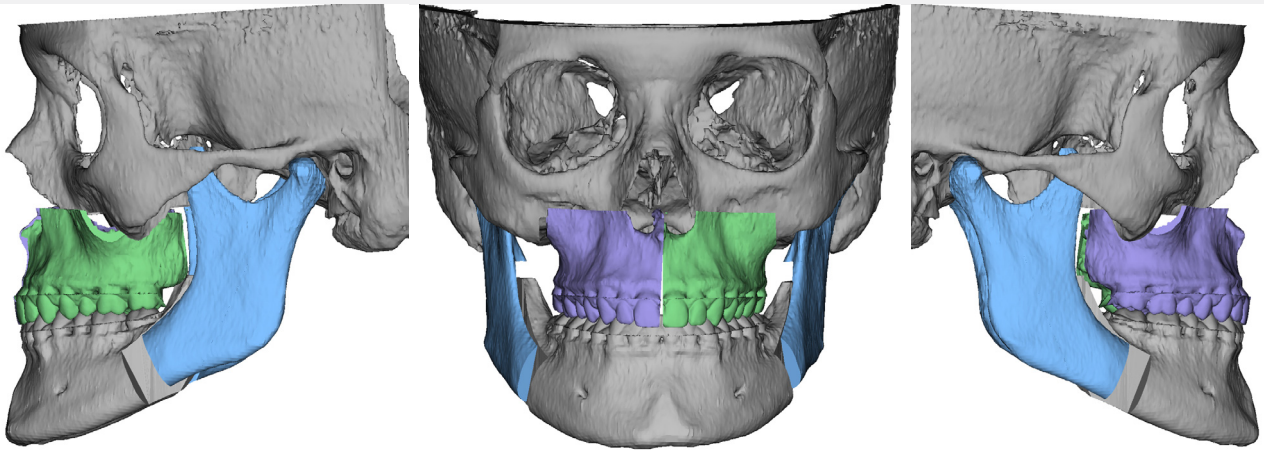
## CASE REPORT

### Surgeon and Patient Information

| | | | |
|---|---|---|---|
| Surgeon Name: | Dr. Edward Zebovitz | Patient Name: | Diana McKay |
| Email Address: | drz@drzebovitz.com | Surgery Date: | 8-12-2020 |
| Phone Number: | (301) 352-6311 | Rep Name: | Jonathan Hoehing |
| WO#: | 136842 | Rep Contact: | jonathan.hoehing@stryker.com |

### Simulated Virtual Surgical Plan

Segmental LeFort I and BSSO



### Surgeon Agreement

With respect to the patient case described above (the "Case"), I, the undersigned, request that 3D Systems, Inc., ("3DS"), provide certain products including, without limitation, templates, tools, surgical splints, guides and/or anatomical models (collectively, the "Products") and certain virtual surgical planning services (the "Services") for use in connection with the Products. I hereby acknowledge and agree as follows in connection with the Case:

- I have prepared the virtual surgical plan (the "Plan") for the Case and am solely responsible for the decisions made in the Plan and the surgical planning process.
- I hereby approve and accept the Products and Services provided by 3DS in connection with the Case and certify no changes are required.
- I acknowledge that, unless otherwise agreed in writing between myself and 3DS, all Products will be delivered non-sterile and that I am solely responsible for cleaning and sterilizing such Products prior to use.
- I have reviewed the Terms and Conditions set forth on the last page of this Case Report which are incorporated herein and agree to be bound by such Terms and Conditions.

Surgeon Signature

Date

Please copy this page, sign and date, and email or fax it to 3D Systems, Inc. Please note that if this Surgeon Agreement is not formally accepted prior to the surgery for the Case but the Products and Services are accepted, you nevertheless agree to pay for the Products and Services and to be bound by the Terms and Conditions.

| Rev | Rev Date | Reason for Revision |
|---|---|---|
| IR | 08/11/2020 | |
| | | |
| | | |
| | | |

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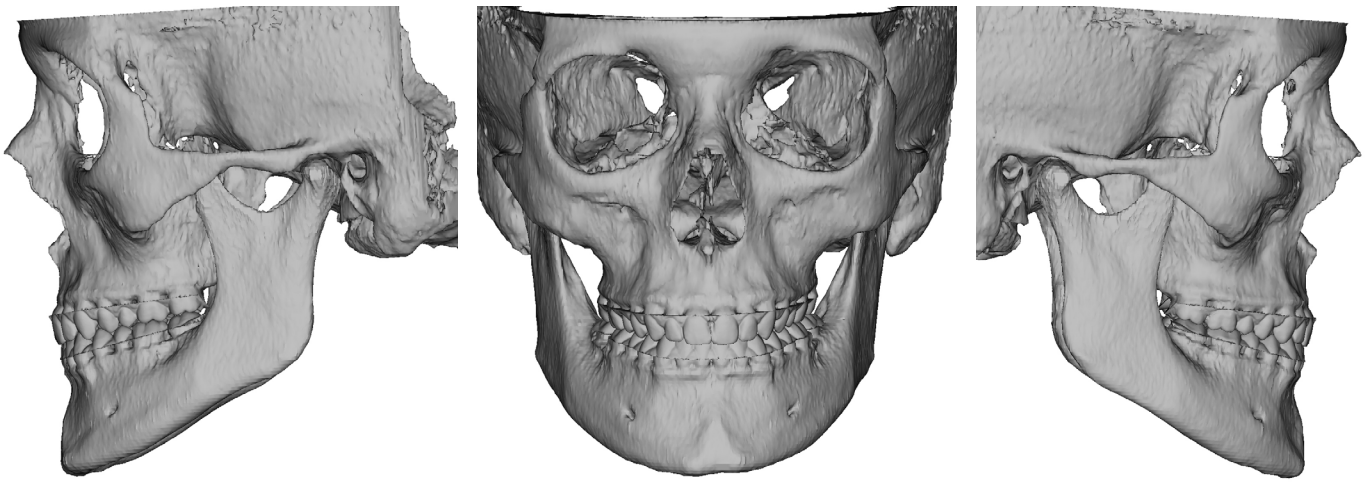
# Movement Summary

Below is a list of bony and occlusal anatomical landmarks and their summarized movements from preoperative position (with mandible auto-rotated close) to simulated postoperative position.

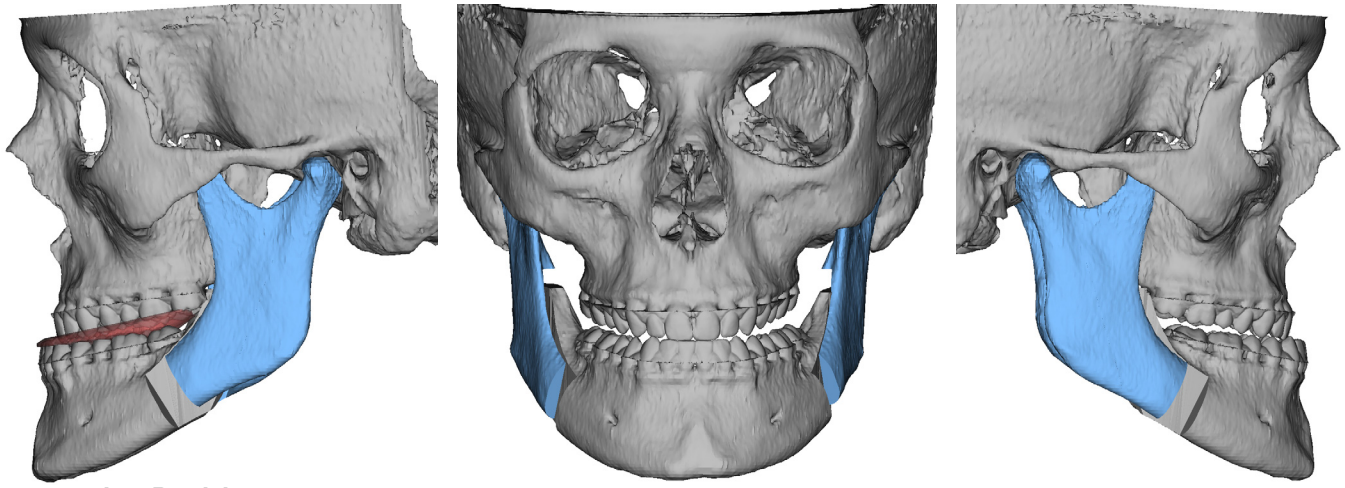
| Point | Name | Anterior/Posterior | Left/Right | Up/Down |
|---|---|---|---|---|
| ANS | Anterior Nasal Spine | 7.90mm Anterior | 1.35mm Left | 3.17mm Up |
| A | A Point | 8.73mm Anterior | 1.14mm Left | 2.84mm Up |
| ISU1 | Midline of Upper Incisor | 11.00mm Anterior | 0.50mm Left | 3.00mm Up |
| U3L | Upper Left Canine | 10.88mm Anterior | 0.92mm Left | 2.00mm Up |
| U6L | Upper Left Anterior Molar (mesiobuccal cusp) | 10.61mm Anterior | 1.22mm Left | 0.00 |
| U3R | Upper Right Canine | 11.15mm Anterior | 0.24mm Left | 3.07mm Up |
| U6R | Upper Right Anterior Molar (mesiobuccal cusp) | 10.89mm Anterior | 0.30mm Left | 1.85mm Up |
| ISL1 | Midline of Lower Incisor | 10.47mm Anterior | 0.70mm Left | 4.41mm Up |
| L6L | Lower Left Anterior Molar (mesiobuccal cusp) | 10.11mm Anterior | 0.79mm Left | 1.00mm Up |
| L6R | Lower Right Anterior Molar (mesiobuccal cusp) | 10.19mm Anterior | 0.77mm Left | 1.88mm Up |
| B | B Point | 12.43mm Anterior | 0.56mm Left | 4.31mm Up |
| Pog. | Pogonion | 15.32mm Anterior | 0.33mm Left | 4.94mm Up |

# Virtual Planning Work Flow

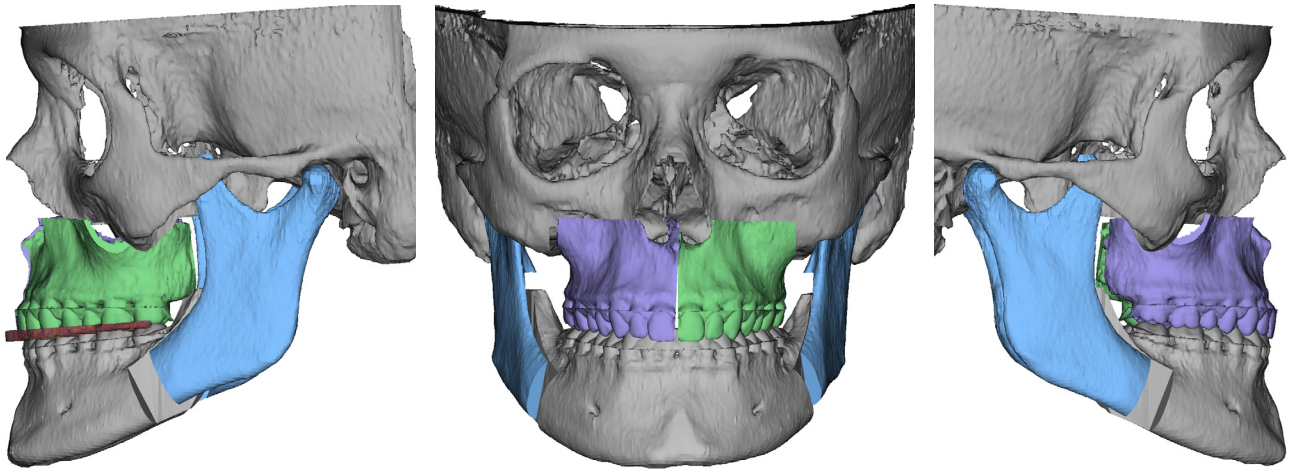
## Preoperative Position



## Intermediate Position

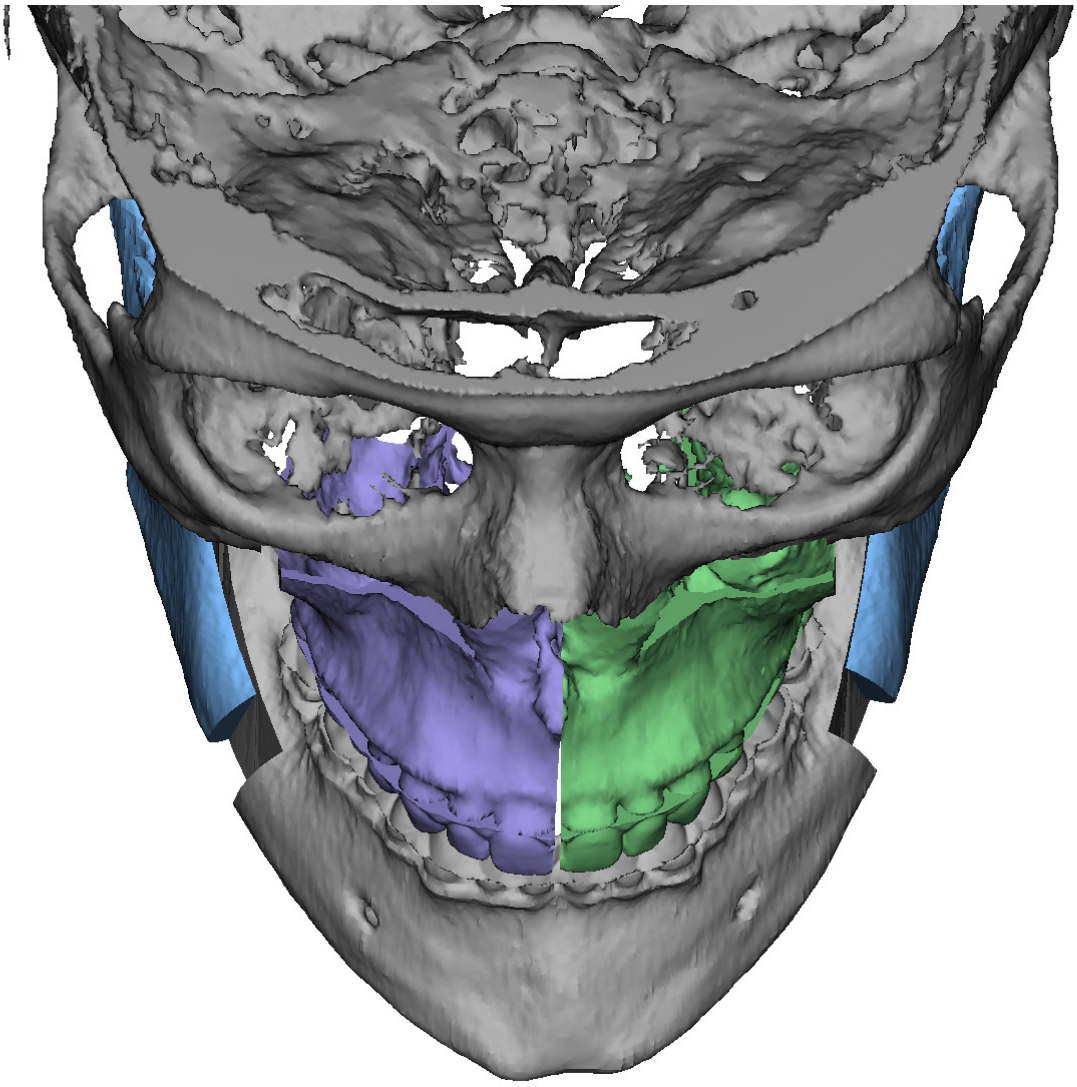


## Postoperative Position



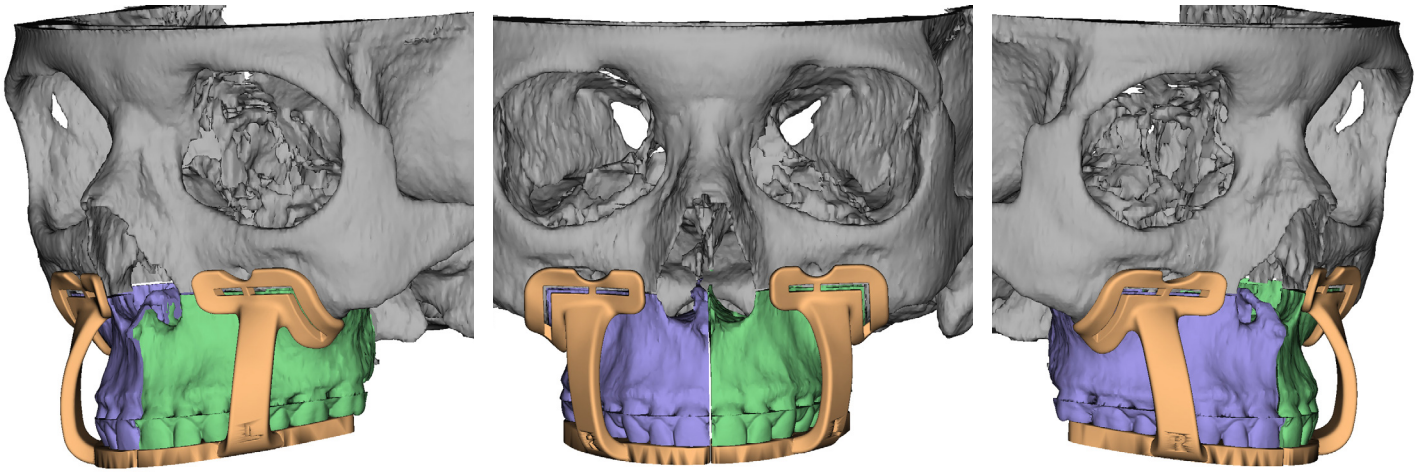
When using a protocol that does not include stone models physically present at 3D Systems, final fit verification of Orthognathic Splints is the responsibility of the surgeon prior to use.

# Bird's Eye View

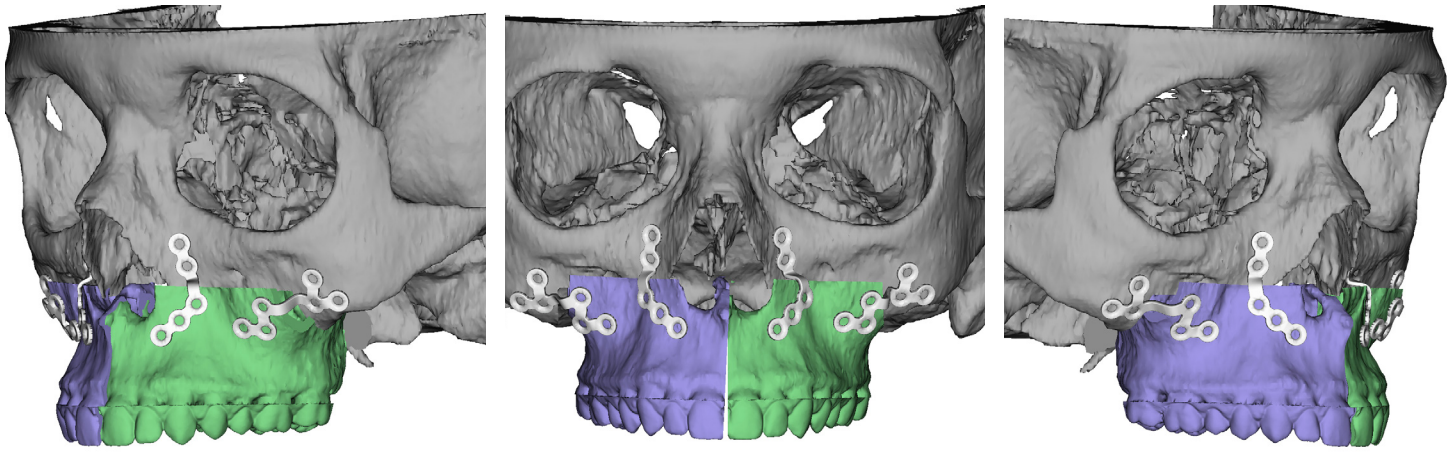


# LeFort Marking Guides and Stryker Customized Plates

## Marking Guides

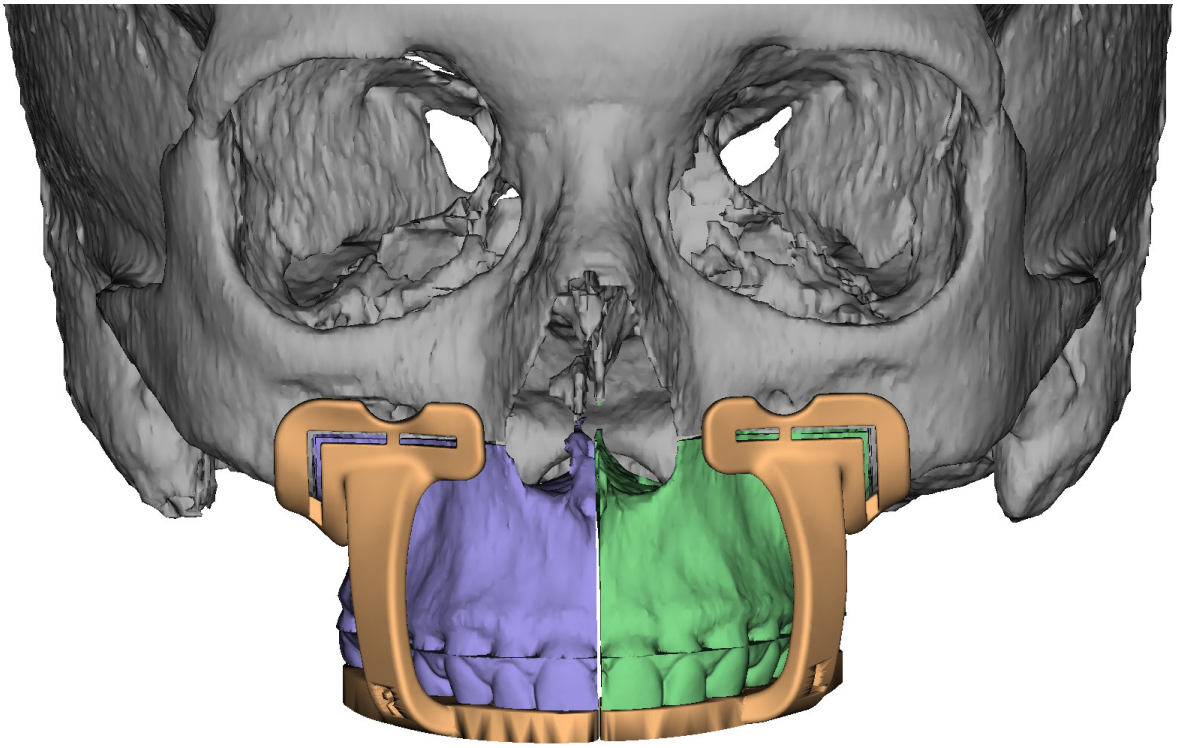


## Stryker Customized Plates - # 2007211019

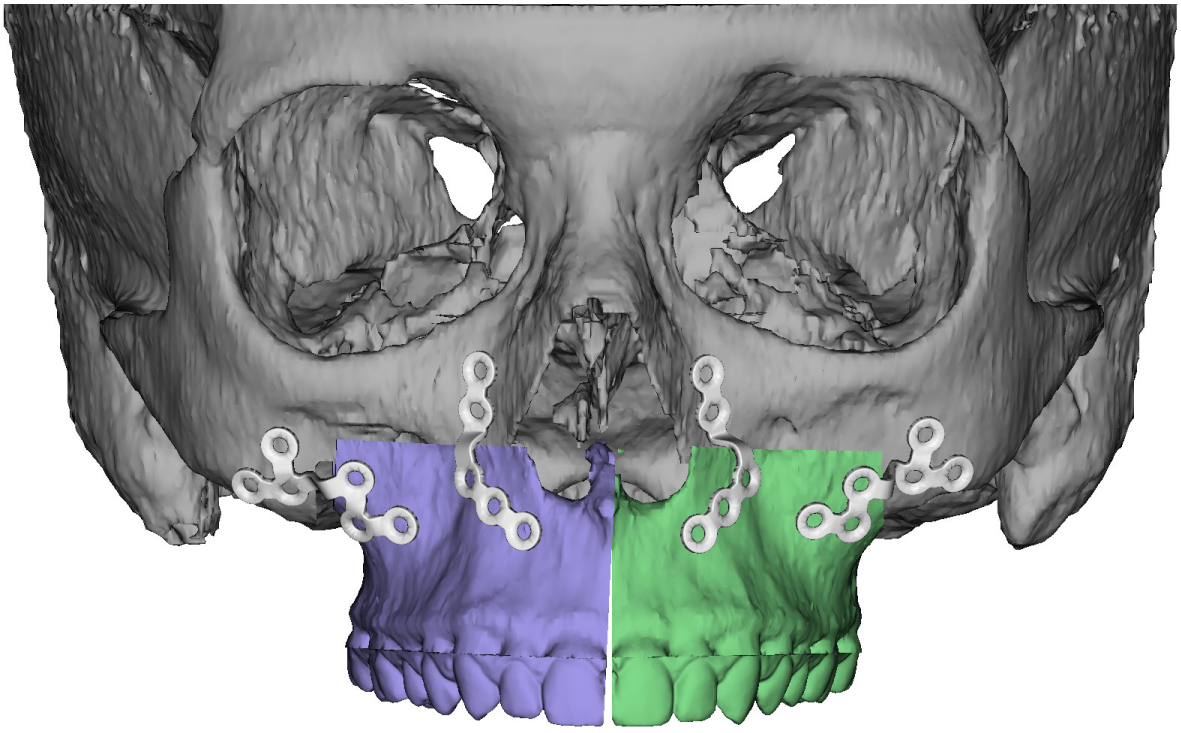


More information about
LeFort Facial iD Guides

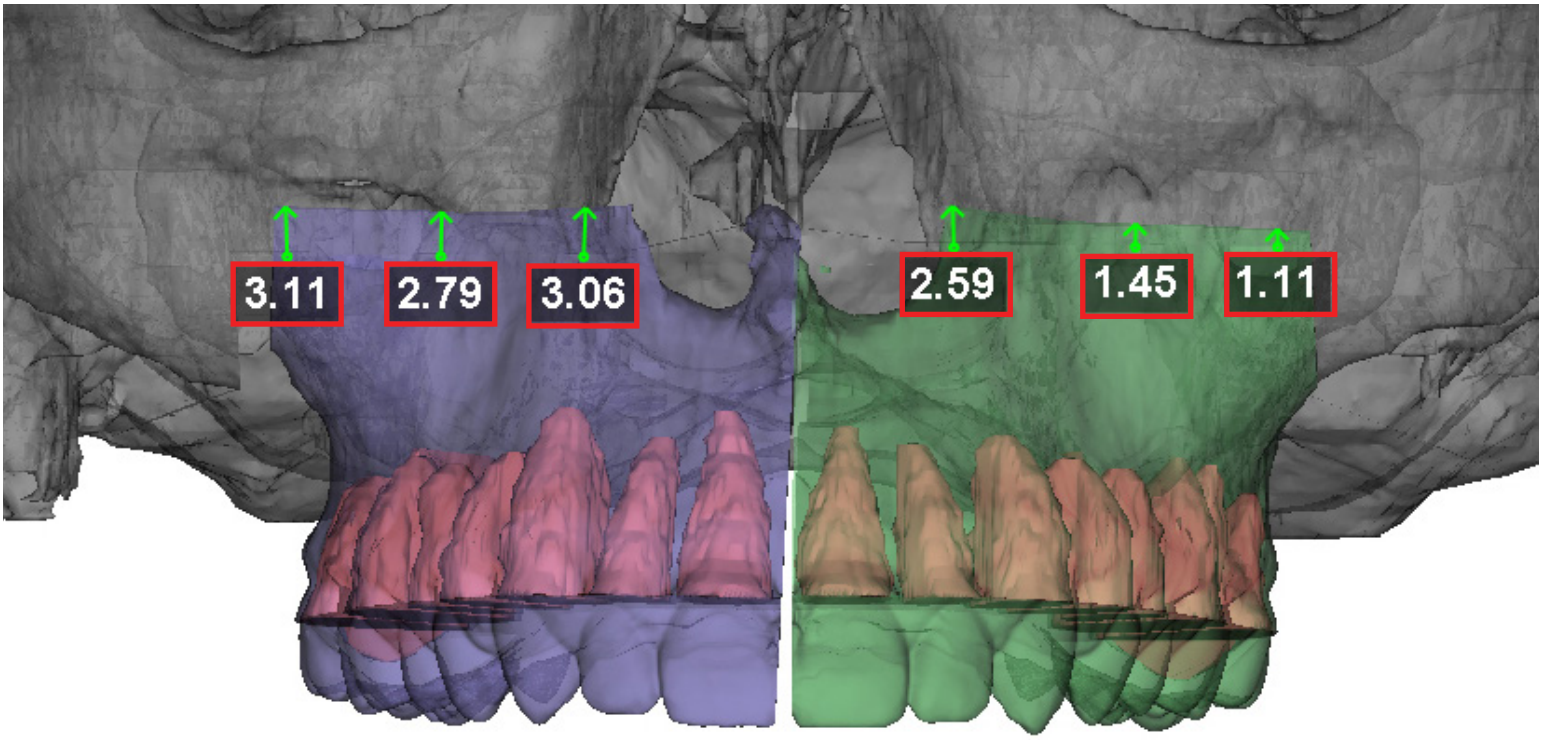
# Fixation and Predictive Holes for Stryker Customized Plates



There are no fixation holes.

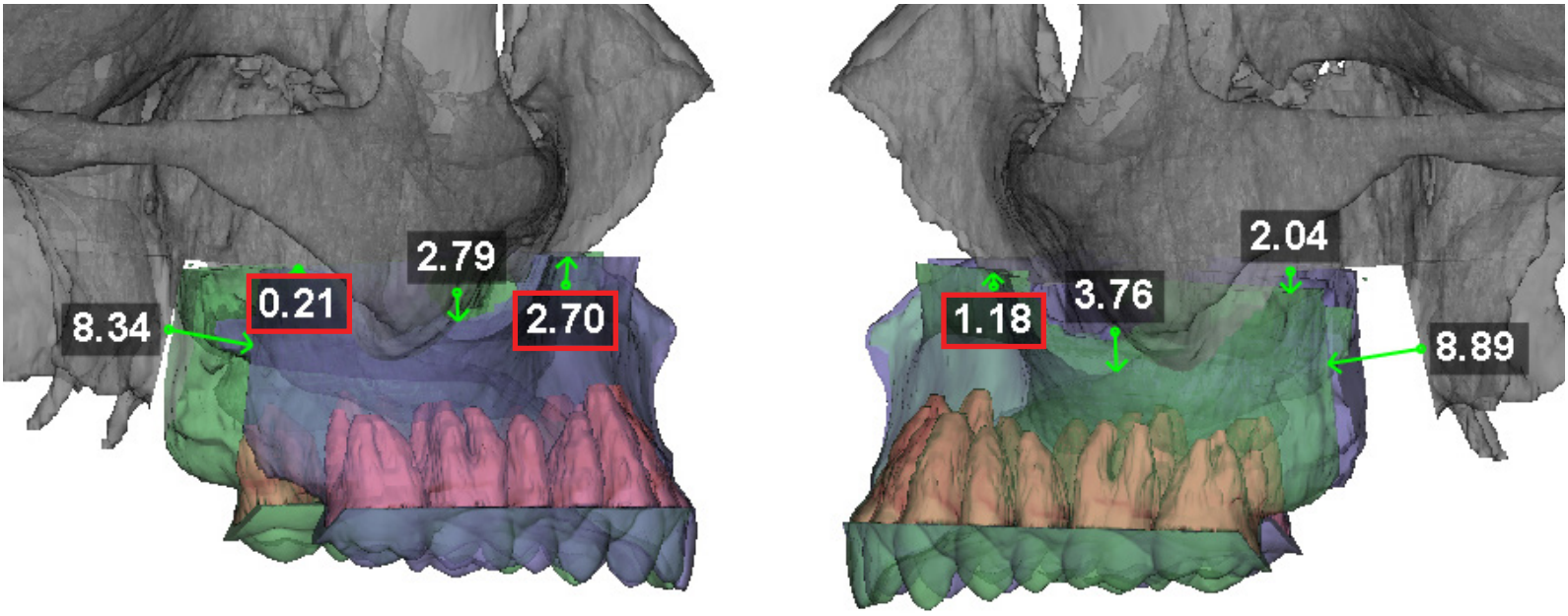


# LeFort Overlap Analysis

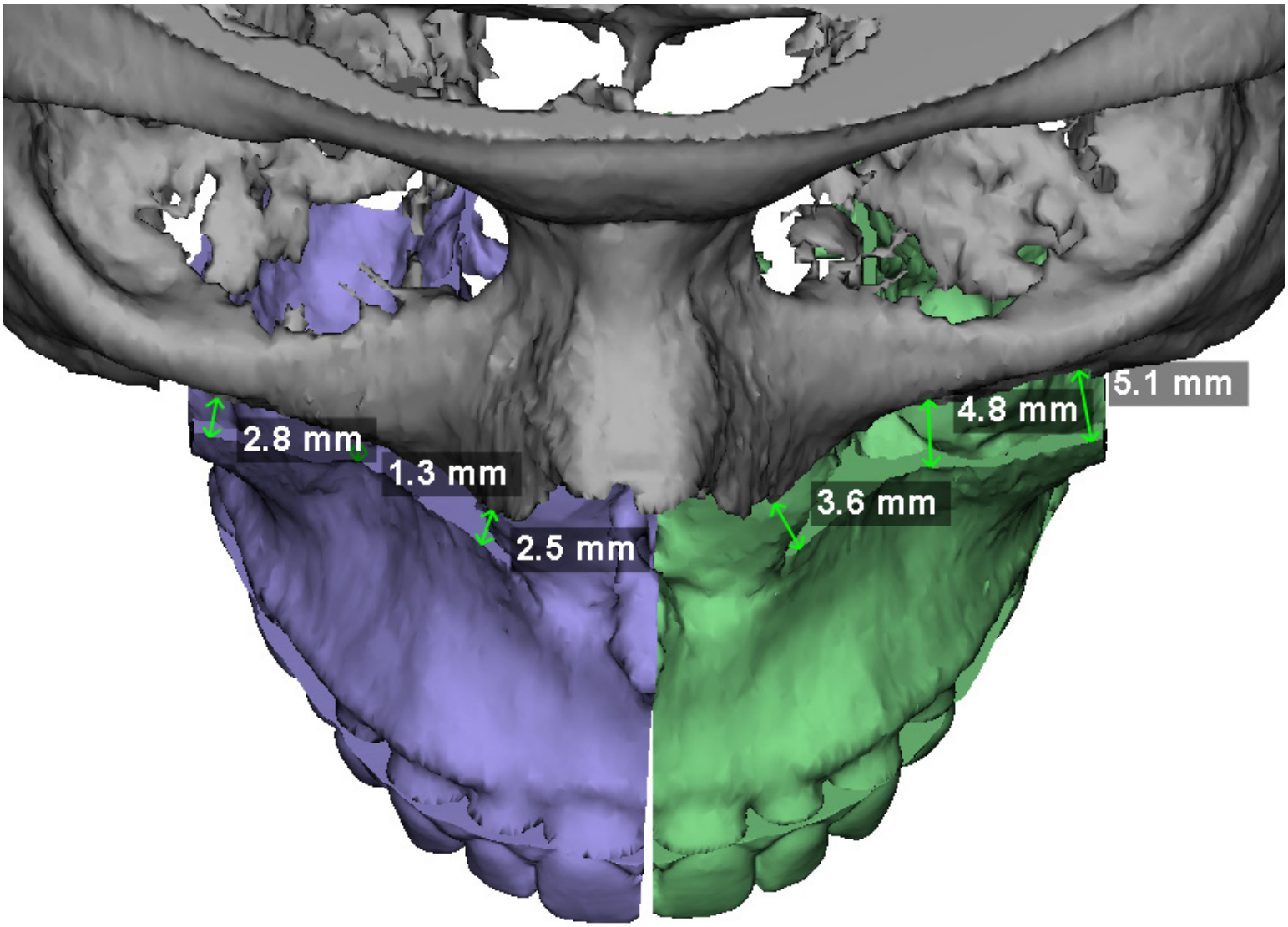



Measurements outlined in red indicate an overlap.

Measurements are approximate.

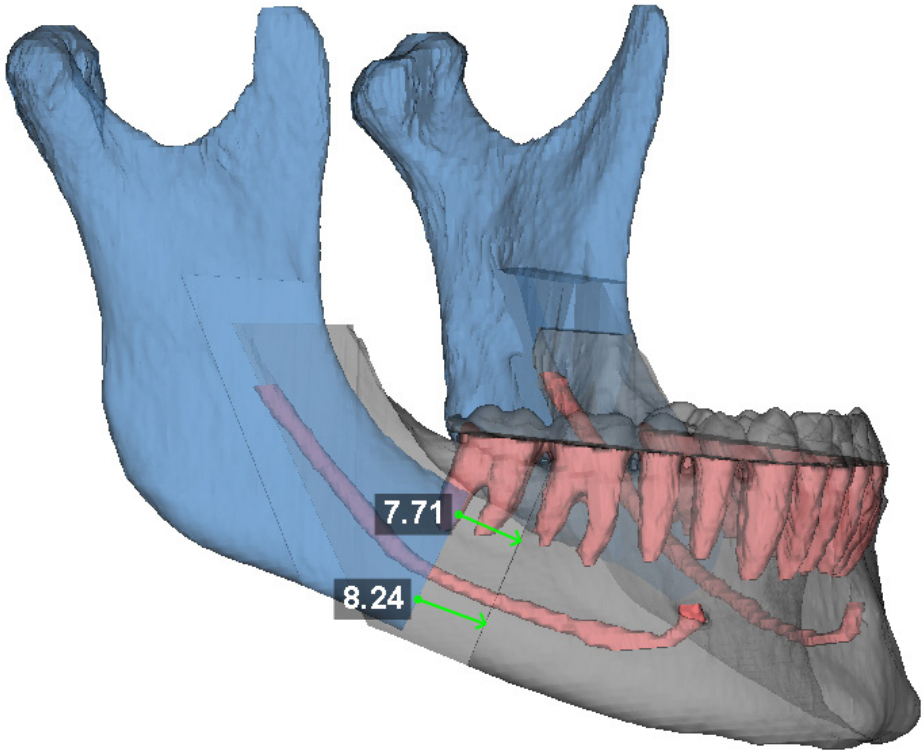


# LeFort Advancement

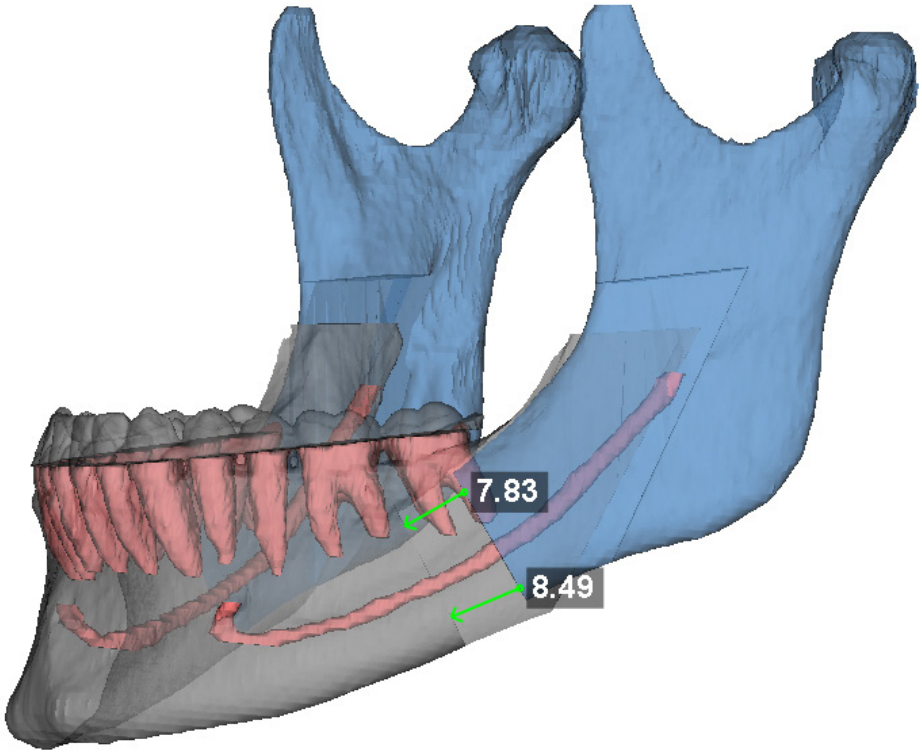



Measurements are approximate.

# Proximal Segment Overlap Analysis

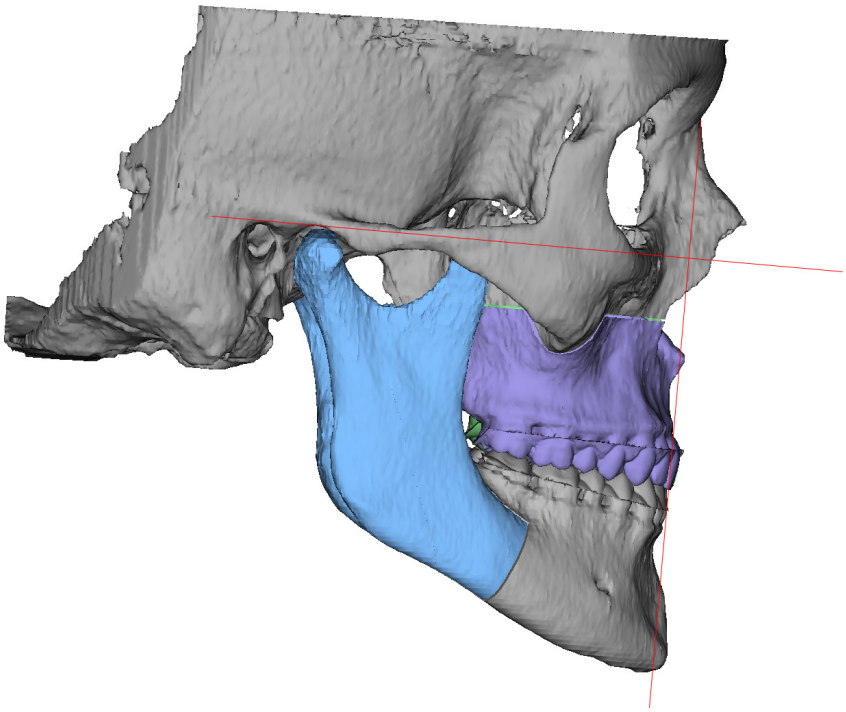



**Measurements outlined in red indicate an overlap.**
**Measurements are approximate.**

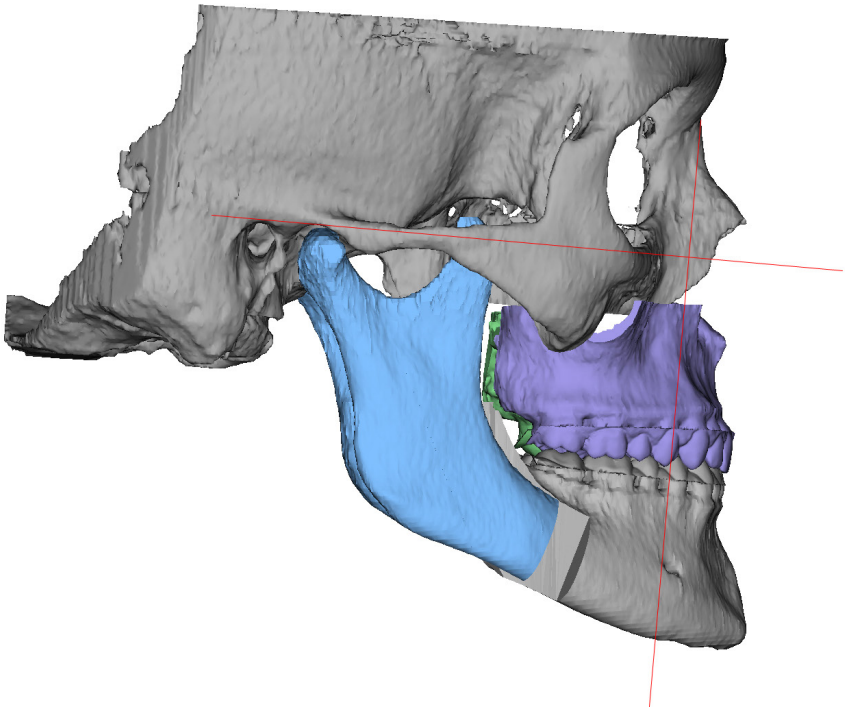


# Pogonion Nasion Perpendicular

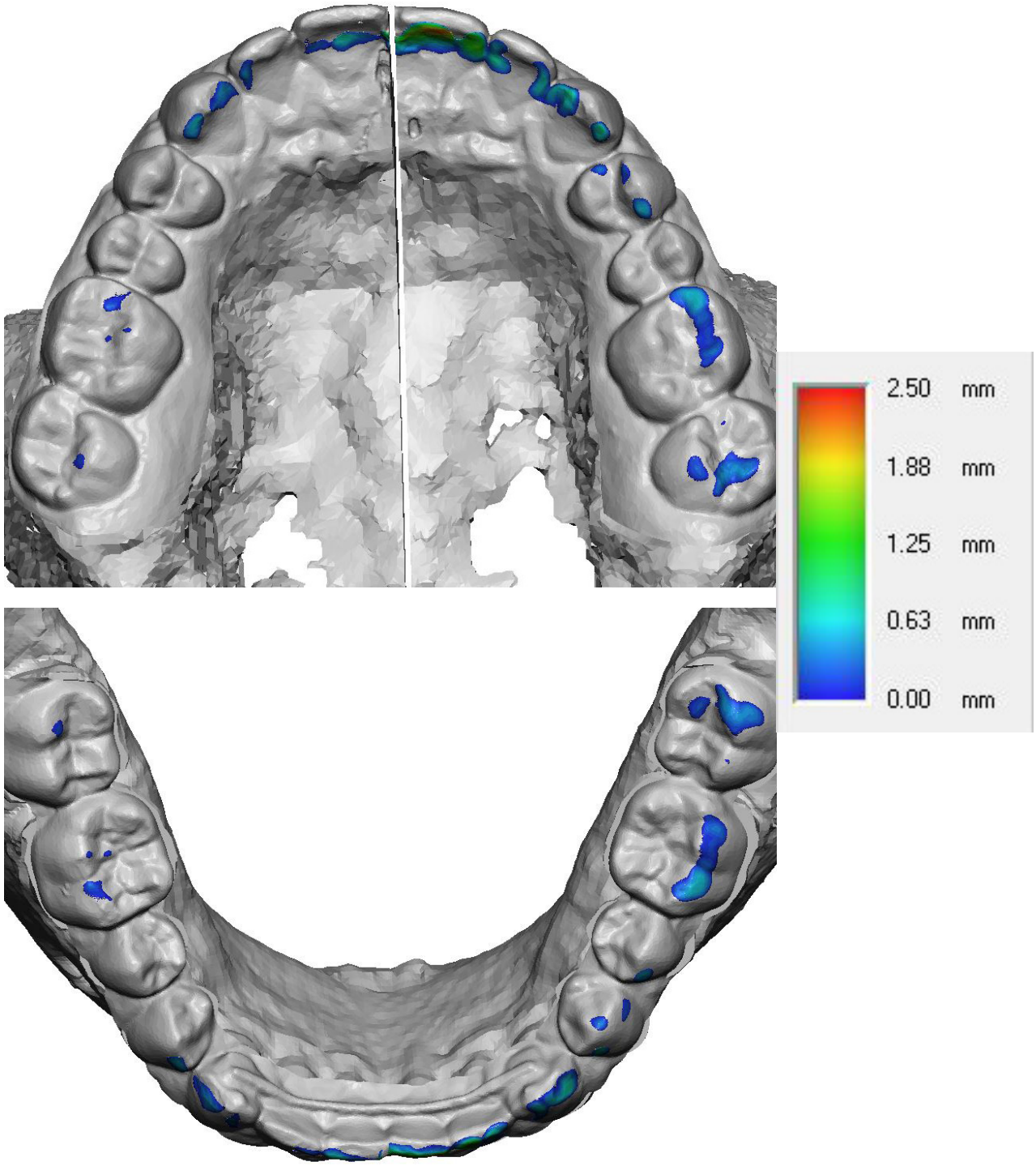
## Preoperative Position



## Postoperative Position



# Occlusal Overlap Color Map



# Terms and Conditions

## Indemnification

To the extent permitted by applicable law, I herby agree to indemnify and hold harmless 3DS, its officers, directors, employees, successors and assigns, from and against any and all liabilities, demands, claims, actions or causes of action, judgments, proceedings or investigations, losses, fines, penalties, damages, costs and expenses, including, without limitation, reasonable attorneys' fees (collectively, "Damages"), that may be sustained, suffered or incurred by any of them arising from, out of, in connection with, or by reason of (a) the death or injury of any person, or loss or damage to property, resulting from the Products used in connection with the Case if such Products were (i) fabricated in accordance with the patient data for the Case, including but not limited to any 3-D or other images (the "Patient Data") that were supplied to 3DS by me or my employees, agents or designees, or (ii) used by me or my employees, agents or designees in a manner not intended or sanctioned by 3DS, or (iii) altered, added to, or enhanced by me or my employees, agents or designees, (b) the negligence or willful misconduct of me or of my employees, agents or designees in the use of the Products, or (c) the design, plan and/or application or implementation of the Services.

## Limited Warranty of Products

3DS hereby warrants that upon delivery of the Products such Products will (i) be new and free from defects in material and workmanship, and (ii) conform to the Patient Data supplied to 3DS and the Plan. Notwithstanding the foregoing, the warranties given by 3DS for the Products are hereby limited as follows, and no warranty is given by 3DS with respect to any Products if any alterations, additions, or enhancements are made to the Products after delivery:

(a) 3DS is not responsible for the accuracy of the Patient Data. Any damages caused by the Products, or your inability use the Products, resulting from inaccurate, incomplete or poor quality Patient Data shall be your sole responsibility.

(b) Because of biological differences in individual patients, the Products cannot be, and are not, guaranteed to be 100% effective under all circumstances. In addition, because 3DS has no control of the condition under which the Products are used, nor any involvement in the diagnosis of the patient, the method of use or administration, or handling of the Products after delivery, 3DS cannot and does not warrant either a good result or against an ill effect to the patient following use or application of the Products. Final determination of the suitability of the Products for the use contemplated by you or your employees, agents and designees is your sole responsibility, and 3DS shall in no way be responsible for the suitability of the Products for any particular use or with any particular patient.

(c) The Products, once delivered to you, are not in 3DS's control and will be put to uses under circumstances wholly unknown to 3DS. Any losses, injuries or Damages to persons or property caused by the alteration of, addition to, or enhancement to the Products after delivery are not the responsibility of 3DS.

This warranty is the exclusive warranty applicable to the Products. 3DS SPECIFICALLY DISCLAIMS ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. Some states do not allow disclaimers of implied warranties. In those states, the implied warranties expressed above shall be specifically limited in duration to ten (10) business days. Some states do not allow limitations on how long an implied warranty lasts. Where such limitations on the duration of implied warranties exist, the limitations on the duration stated in this section will not apply. In no event shall 3DS be liable to you for any special, consequential, incidental or indirect Damages, however caused, on any theory of liability. In addition, in no event shall 3DS's maximum liability to you exceed the amounts actually paid by you to 3DS for the Products and Services provided pursuant to the Surgeon Agreement to which these Terms and Conditions are attached.

## No Warranty for Services

To the extent permitted by applicable law, I acknowledge and understand that 3DS does not warrant and is not responsible for the outcome of any surgery as a result of the provision of the Services provided to me or my employees, agents or designees in connection with the Case.

## Release

To the extent permitted by applicable law and except as otherwise provided herein, I hereby waive and release 3DS from all Damages related to the Products and Services provided to me or my employees, agents or designees in connection with the Case.

## Important Use Information

℞ Only Federal Law (USA) restricts this device to sale by or on the order of a physician

**INDICATIONS FOR USE:** The VSP® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the VSP® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, templates, and surgical guides for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

**CONTRAINDICATIONS:** The outputs of the VSP® System and the associated case report should not be used if in any of the following occur:

Active infection is a contraindication for use of this device.

Significant changes to patient's anatomy have occurred since the medical scan used for product definition was obtained.

⚠ **WARNINGS:** To avoid mixups and associated serious injury, patient identification on templates and guides must be verified and confirmed against patient identification prior to use.

Device(s) are single use only and designed for use with a specific patient only. To avoid risk of infection and serious injury, do not attempt to re-clean or re-sterilize or in any way re-use VSP® System outputs.

Templates and guides are designed for a specific patient. To avoid the potential for serious injury, guide and templates should not be modified in any way.

Ensure cutting guides are firmly affixed to bony structures prior to use.

⚠ **PRECAUTIONS:** VSP®models, templates and guides are shipped in a non-sterilized state. To avoid possibility of infection, open, clean and sterilize per provided instructions before use.