PANTHERA IMPLANT

OPERATIVE PROTOCOL

CAD-CAM sub™ subperiosteal IMPLANT

TABLE OF CONTENTS

1. Indications for Use
2. Step by Step Guide
3. Fabrication of the Models and Tooth Mounting
4. CBCT Scanning Protocol
5. Online Prescription
6. 3D Viewer
7. Surgical Protocol

7.1 Implant Preparation

7.2 Insertion of the Implant

7.2.1 Incision and Site Preparation

7.2.2 Insertion of the Subperiosteal

7.2.3 Tissue Extension to Cover the Guided Bone Regeneration (GBR)

7.2.4 Guided Bone Regeneration (GBR)

7.3 Closure with Addition of Sticky Bone

8. Recovery Time/Postoperative Precautions
9. Final Impression Technique
10. Instrument Kit

1. Indications for Use

The Panthera Dental CAD/CAM Subperiosteal Implant is intended to be used for the lower jaw in patients who are partially edentulous with Kennedy class I, II and III and with bone type of division C-h. The implant is designed for the mandible in situations of severe vertical bone atrophy. It is recommended that the patient have 7 mm of bone or less from the crestal bone level to the inferior alveolar canal.

IMPORTANT: There are several implant restoration options that can be screw retained or fixed with cement.

CONTRAINDICATIONS:

The Panthera Dental CAD/CAM Subperiosteal Implant is contraindicated for patients:

- Who are active smokers;
- Who are unfit for an oral surgical procedure;
- Who are allergic or hypersensitive to titanium TI6Al-4V and/or stainless steel;
- Who have an inter-arch distance inferior to 8 mm;
- Who have fewer than 6 remaining teeth, precisely from the 33 to the 43.

CAUTIONS:

To avoid failure, follow all guidelines included in this guide. Non-observance of the indicated limitations of use and surgical protocol may result in failure.

A close cooperation between Panthera Dental, the surgeon, the restorative dentist and the dental laboratory is strongly recommended for a successful treatment.

MANDATORY:

All surgeons must attend an approval training class to obtain permission to use the Panthera Dental CAD/CAM Subperiosteal Implant. As a unique product, no third party training can replace original and approved training by Panthera Dental. For a list of approved training centers, visit www.pantheraimplant.com.

2. Step by Step Guide

1. PATIENT ASSESSMENT

Verify if you patient is a good candidate for the CAD/CAM Subperiosteal Implant.

- Use the medical and dental questionnaire;
- Use the CBCT scan;
- Perform a complete oral examination.

2. PRIMARY IMPRESSION TECHNIQUE

A primary impression is made for the fabrication of a model of the remaining teeth and mucosa.

3. FABRICATION OF THE WAX -UP

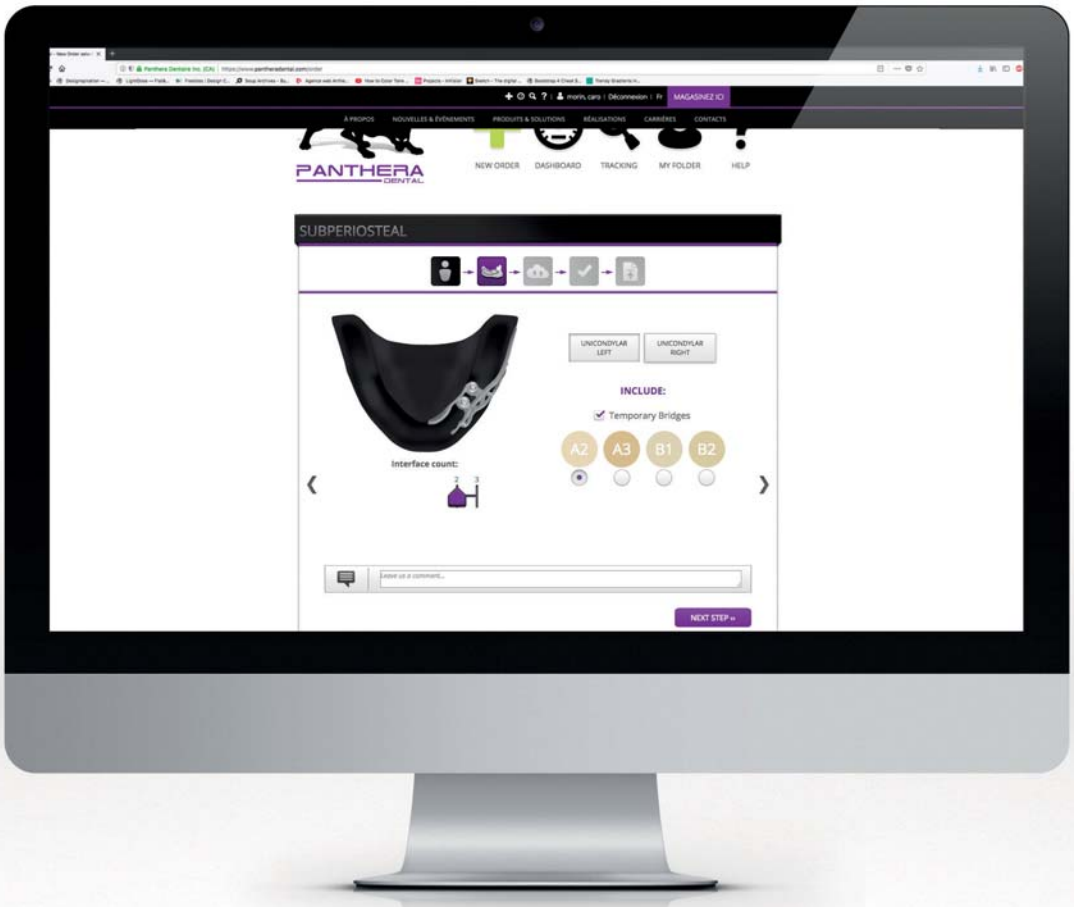
The wax-up is fabricated with the partner laboratory.

4. INTRA-ORAL TRY-IN

With your patient, perform an intra-oral try-in of the wax-up. Adjust the occlusion and other details where necessary.

5. CREATING THE PURCHASE ORDER

Go to **www.pantheraimplant.com** and follow the instructions to create a new purchase order.



Your shipment must include:

- The CBCT scan of your patient (no older than 3 months, otherwise run a new CBCT scan by following the scanning protocol)
- The stone model
- The adjusted wax-up

6. CASE DESIGN

Panthera's team gets to work and, with the help of its powerful software, draws your CAD/CAM Subperiosteal Implant.

Function and aesthetic criteria will be put forward to draw the perfect implant for your patient.

7. CASE VALIDATION

Directly on our website, you can validate your case and ask for adjustments if necessary.

8. MANUFACTURING AND DELIVERY

With cutting-edge technology 5-axis machines, your implants are manufactured in titanium with an accuracy of 5 µm.

Panthera partners with the best delivery services and will deliver your case in the shortest possible time.

9. SURGERY

With a simple protocol and custom tooling, it is time to perform the surgery and to proceed with the CAD/CAM Subperiosteal Implant insertion.

10. TEMPORARY

Optionally, a temporary will be provided to you by Panthera to be put in before the final restoration.

11. RECOVERY

For a period of 4 months, your patient must rest in order for the healing and osteointegration to take place.

12. FINAL IMPRESSION TECHNIQUE

Once your patient has fully recovered, a final impression is made with the new position of tissues.

13. FABRICATION OF THE RESTORATION

With your partner laboratory, fabricate the final restoration.

14. INSERTION

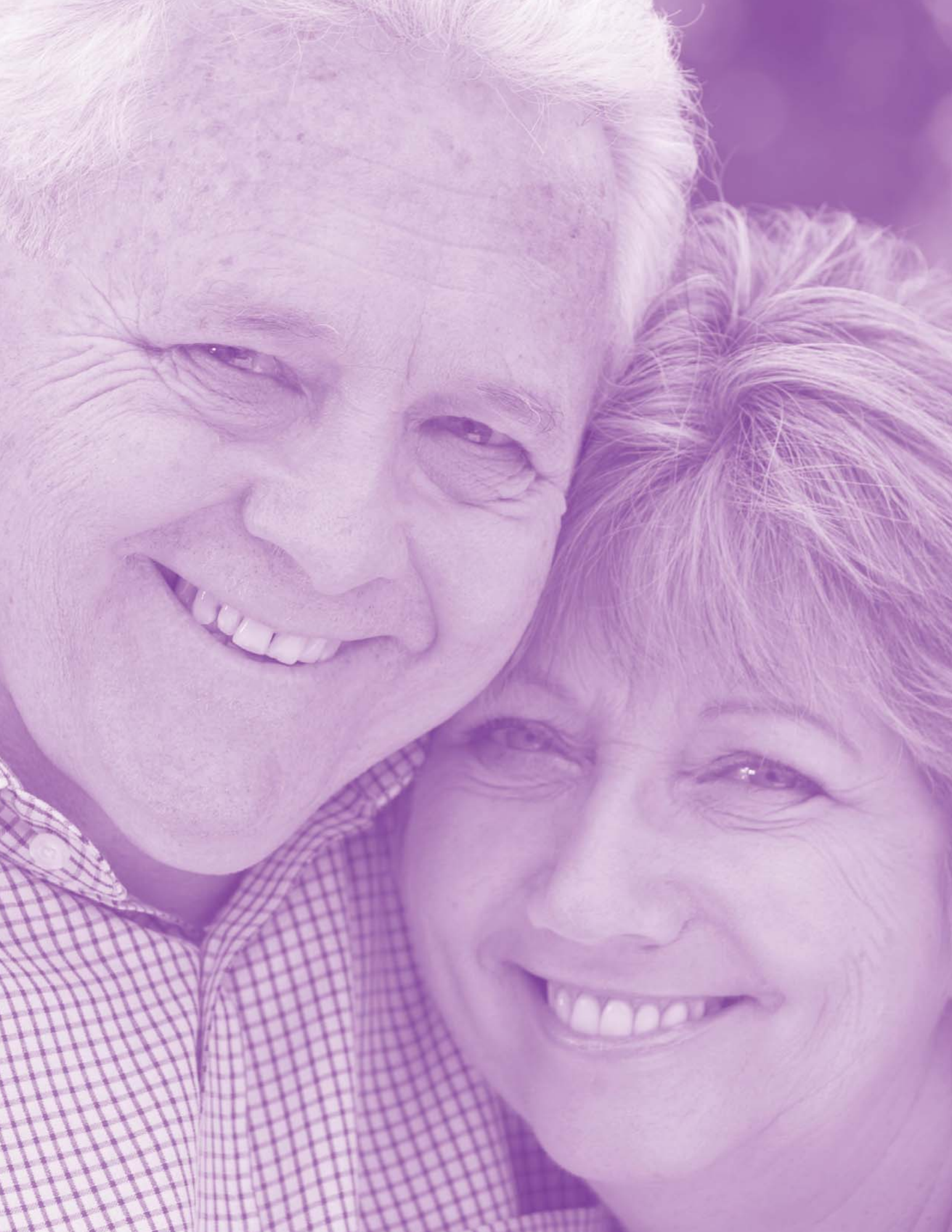
Finally, it is time to deliver your patient's eagerly awaited smile.

15. CONTROL AND VERIFICATION

Control the gingival response after the insertion and check the occlusion. Eliminate malocclusion forces outside the axis.

16. SUBSEQUENTLY

Then, you will simply have to perform an annual dental checkup and cleaning.



3. Fabrication of the Models and Teeth Set-Up

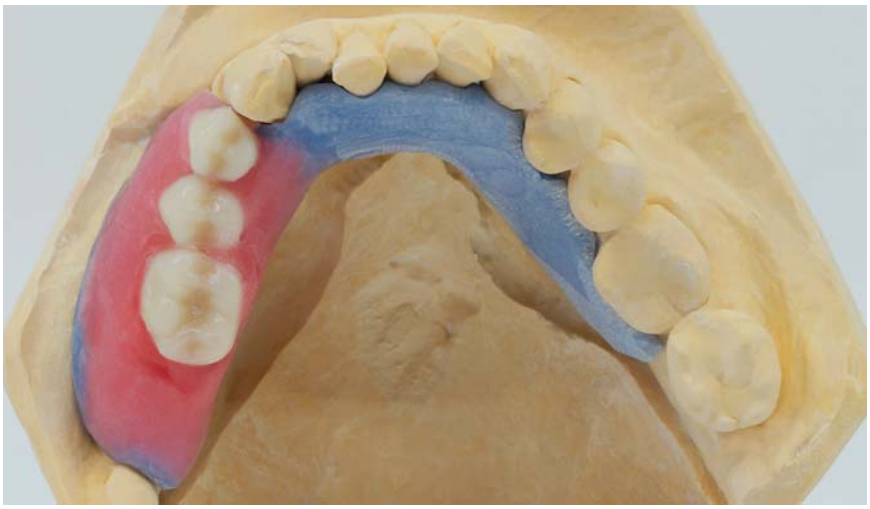
Ask your partner dental laboratory to fabricate the stone models from your impressions. The use of a quality dental stone is advisable. The color of the stone does not matter.

Upper model example

Lower model example

Models will be mounted on an articulator in order to build a wax-up of the artificial teeth on a baseplate designed by your laboratory.

Side view exemple



Top view exemple

IMPORTANT: Request a quality set-up because the wax-up will be the baseline for the final restoration.

4. CBCT Scanning Protocol

Preamble

This procedure aims to provide guidelines for imaging with a computed tomography scanner (CT scanner) for the design and fabrication of CAD/CAM Subperiosteal Implants.

Patient Preparation

The Subperiosteal Implant sits directly on the patient's bone. This part of the scan is thus the most important. It is recommended to remove all removable prostheses from the patient's mouth for the scan. Moreover, metallic parts cause image artefacts. It is strongly recommended to remove all removable parts that contain metal.

Patient Position

The mouth of the patient must be kept slightly open in order to avoid occlusion of the teeth. Non radiopaque objects such as cotton rolls can be used to maintain the position stable during the scan. Position the head of the patient so that the occlusal plane of the mandible is parallel to the floor.

Visual Range

The visual range of the computed tomography scanner must allow complete coverage of the area that will be used to position the implant. The Subperiosteal Implant will be implanted in the posterior part of the mandible and up to the ramus. It is important to make sure that this area is covered by the scan.

OPTION 1

Option 1 represents the ideal situation where the computed tomography scanner allows for a visual range that covers the entire mandible.

OPTION 2

Option 2 must be used if the computed tomography scanner does not allow for a full visual range of the complete mandible. For a unilateral implant, the visual range must cover only the side where the implant will be placed. For a bilateral implant, it will be necessary to run two scans, one covering the right side, and the other one covering the left side.

Image Resolution

The Subperiosteal Implant manufacturing technology makes it possible to produce highly accurate implants. To begin the work, it is therefore necessary to have high resolution images. It is a crucial element to produce an implant that will fit the bone well. The highest possible resolution will allow greater accuracy of the implant.

Axis	Résolution
x	≤ 0.3 mm
y	≤ 0.3 mm
z	≤ 0.6 mm

Minimum acceptable threshold

IMPORTANT:
The lower the number, the better.

Image Contrast

The image contrast enables the easiest possible separation of bones from the rest of the image. It is another essential aspect to ensure implant accuracy. The image contrast is primarily obtained through the type of reconstruction filter used to create the images. The best results are obtained by using a filter that favors bones. This filter promotes sharp transitions between bones and soft tissues. The following image represents a good example of what should be obtained.

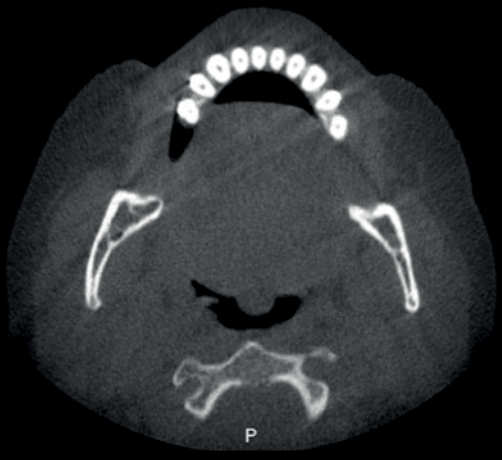


Image Exportation

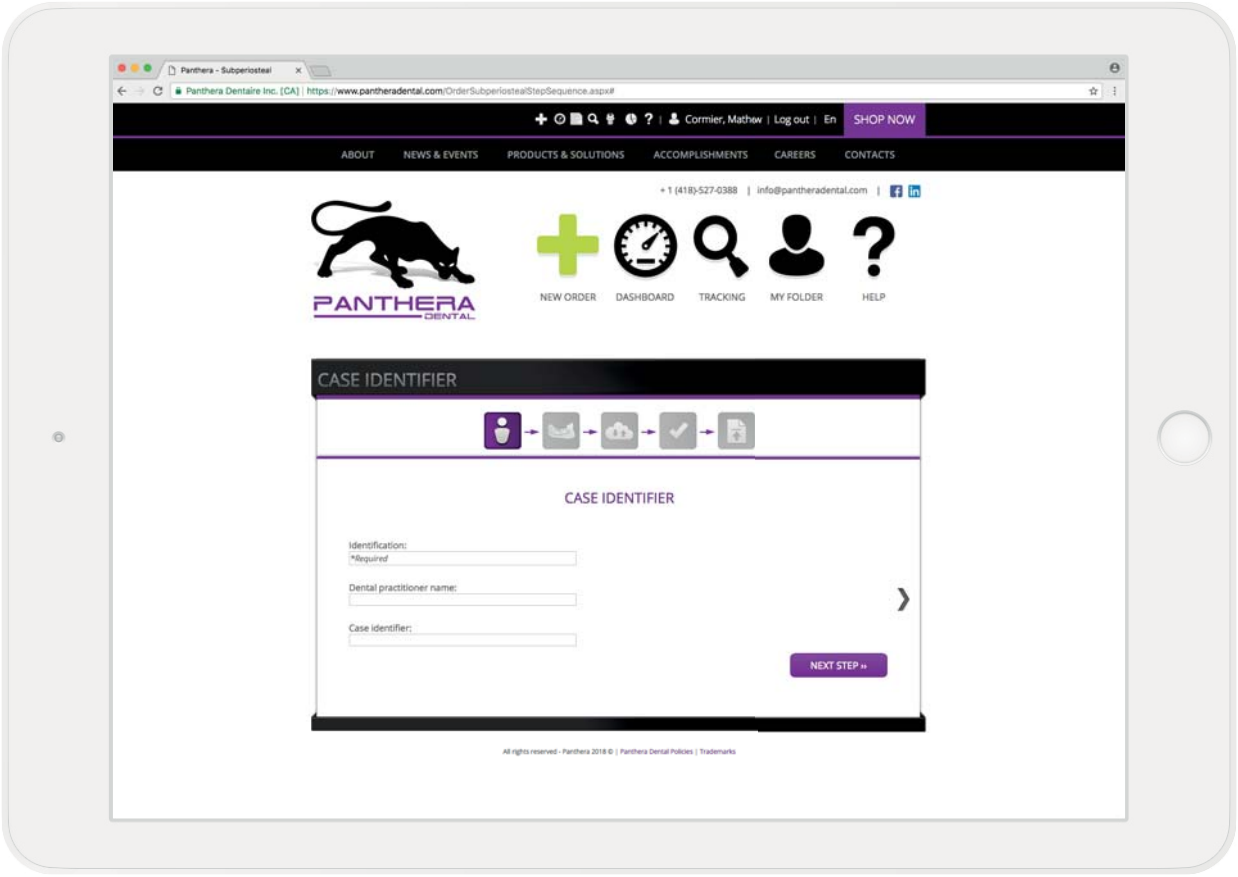
Images from the computed tomography scanner (CT scanner) must be exported in DICOM (.dcm) format. Images must be saved in such a way that one file corresponds to a slice unit of the CT scan. If there are 400 slice units, there will be 400 files.

5. Online Prescription

The Panthera Implant Online Prescription is a simple way to order your CAD/CAM Subperiosteal Implant. It helps prevent possible mistakes by making sure you provide all the mandatory information required to manufacture your patient's implant.

STEP 1 : IDENTIFICATION

At this step, you are required to provide your name and your patient's name.

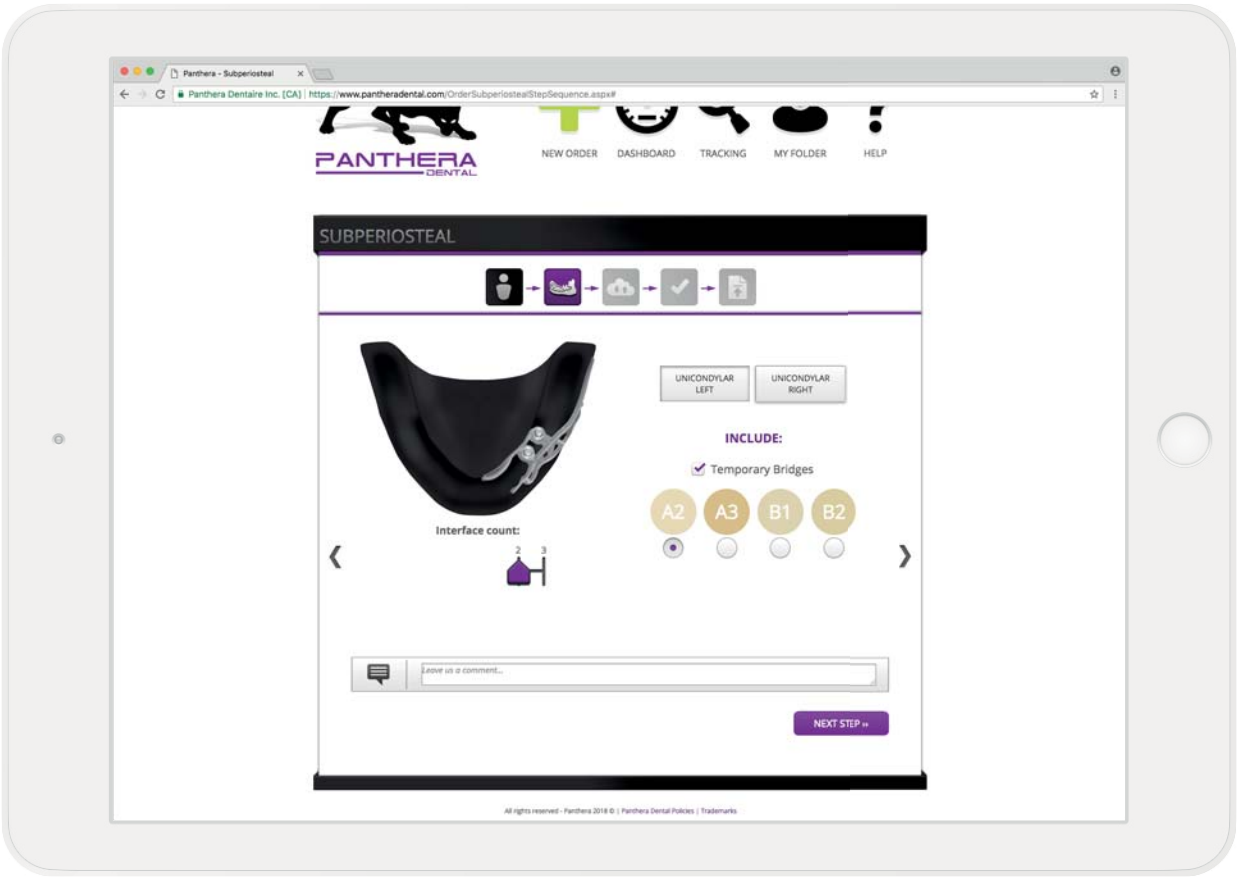


STEP 2 : DESIGN DETAILS

You now have to select the left, the right or both sides by clicking on one or both options, in accordance with the Subperiosteal Implants required for your patient.

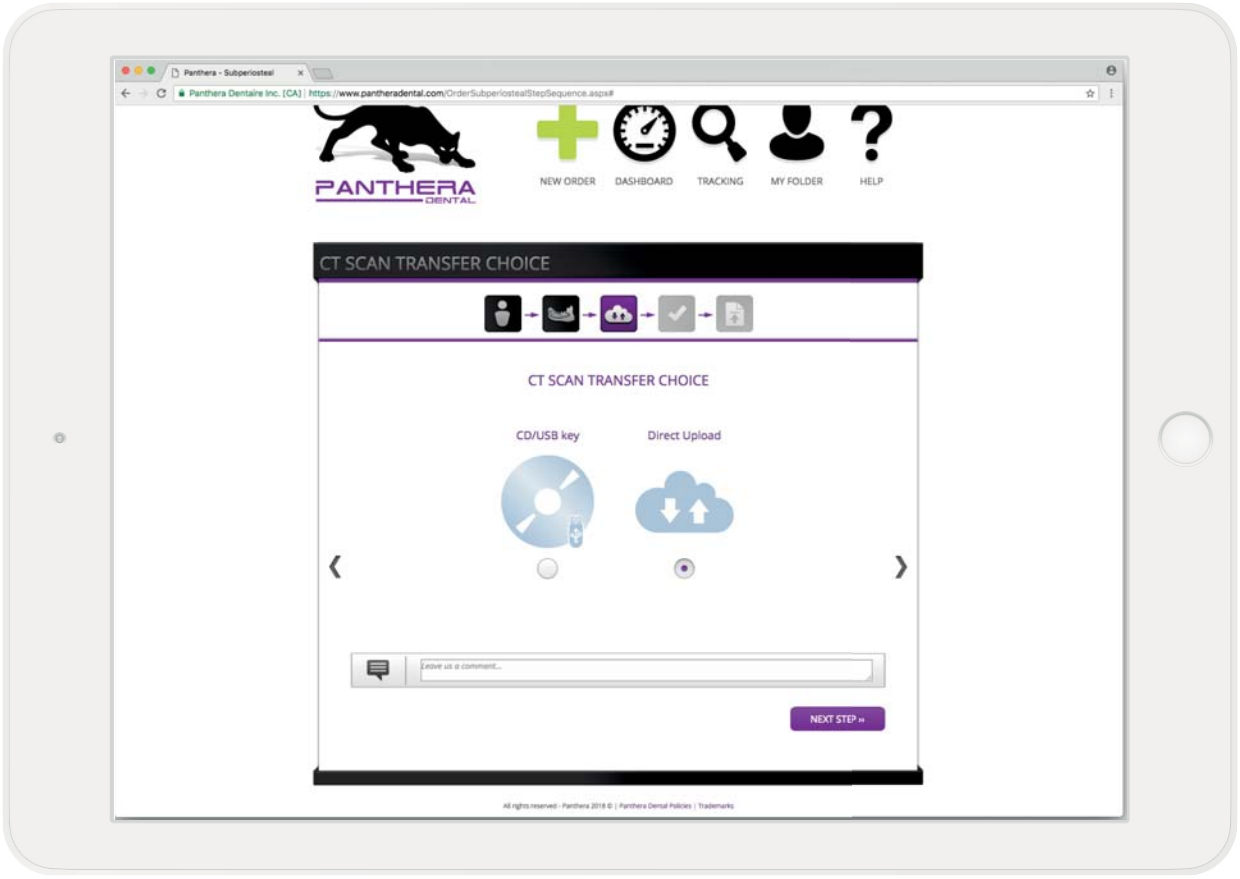
Once done, you can choose if you want 2 or 3 interfaces for the restoration. The jaw represents the lower arch of a patient.

Lastly, you can select among 4 color choices depending on your needs for the temporary bridge.



STEP 3 : CT SCAN TRANSFER METHOD

You must select if you will send a physical copy of the CT scan (either on a CD or a USB key) or if you will upload the files using our upload system. If you select “CD/USB Key”, you will move on to the next step; if you select “Direct Transfer”, you will be prompted to use a tool to upload your files. Make sure you provide all the files from the scan.

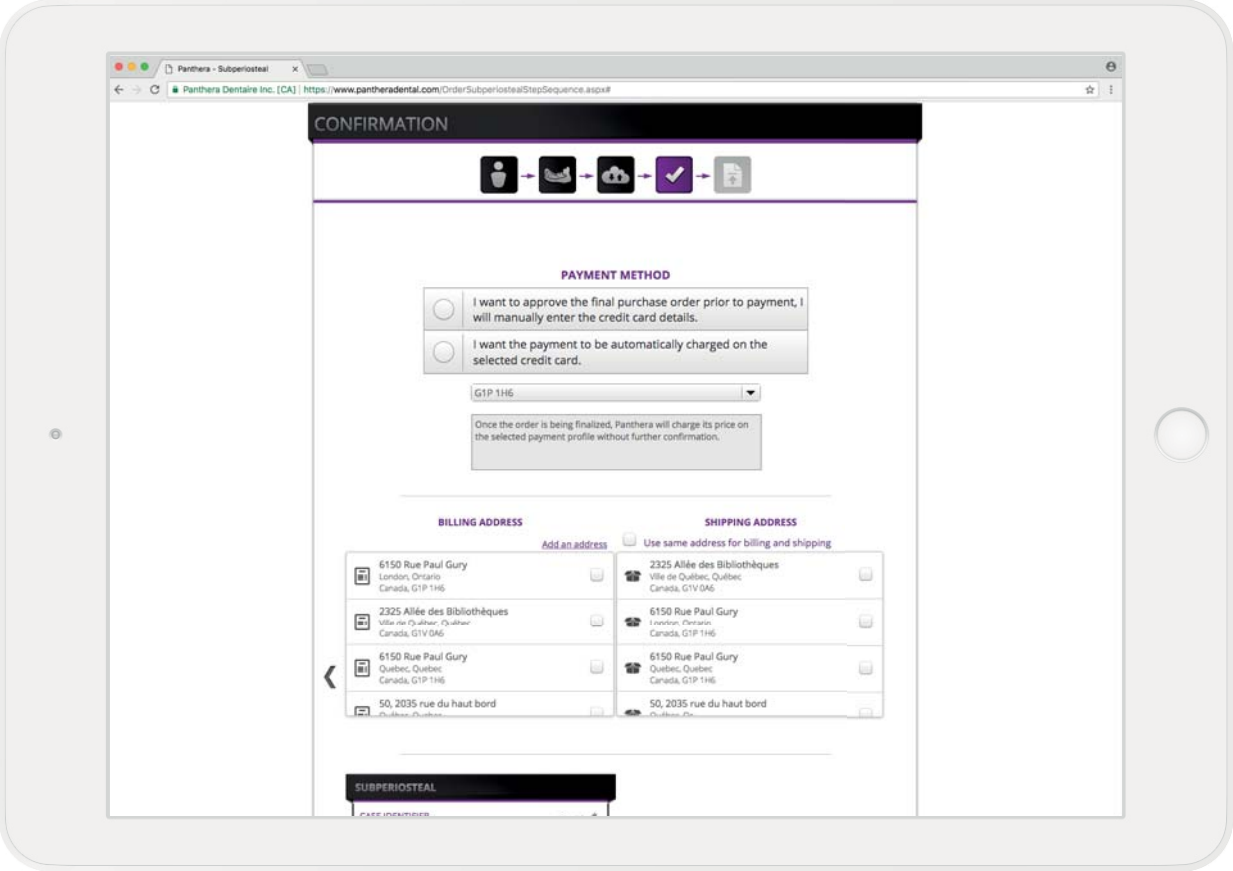


IMPORTANT: For scanning guidelines, please refer to page 16 of this book, section 4: CBCT Scanning Protocol.

STEP 4: PAYMENT AND SHIPPING

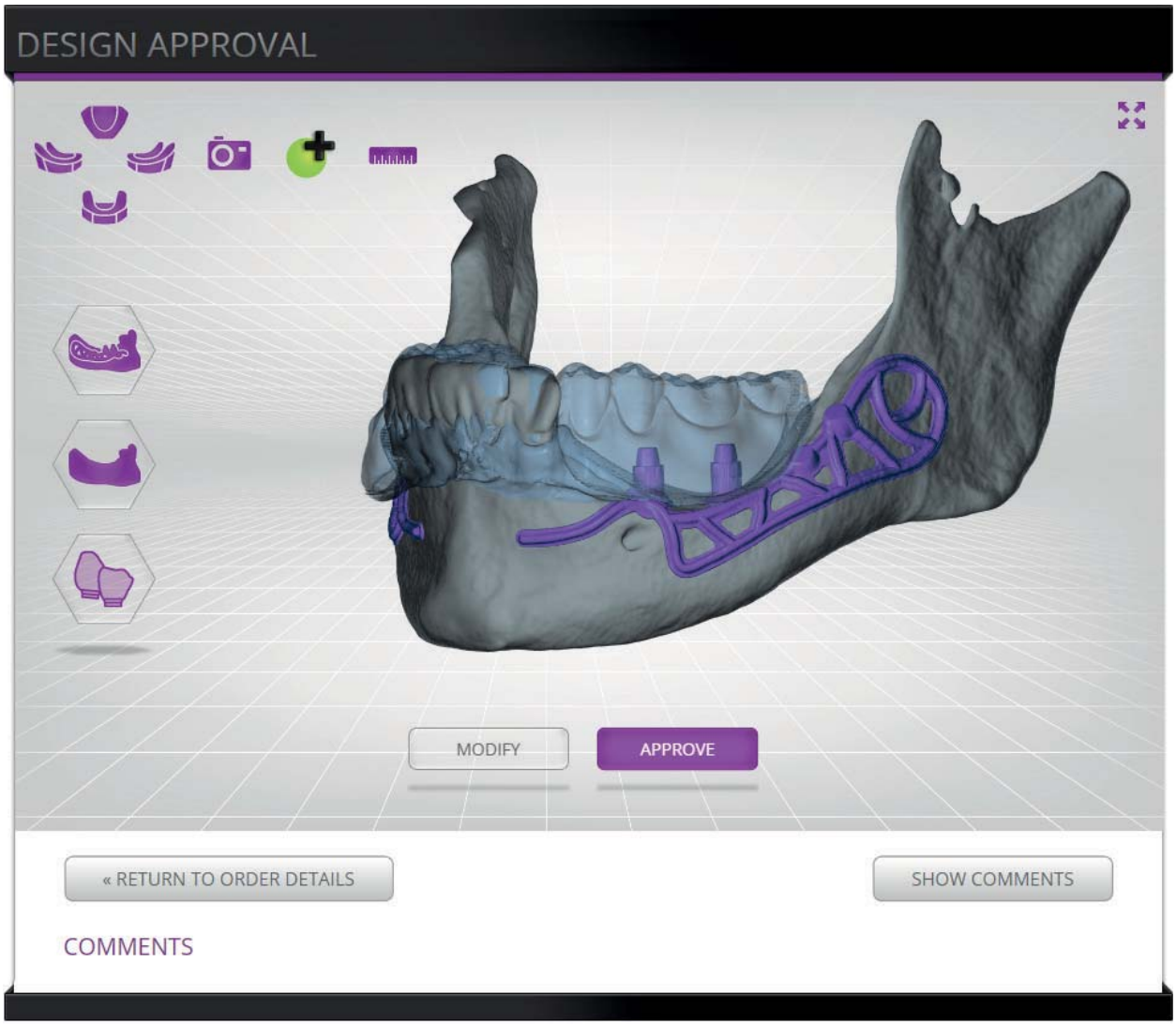
The final step is to provide us with the shipping and billing addresses.

As a first time customer, you will be asked to provide credit card information for payment prior to shipping; as a returning customer, you will be able to select a saved credit card and decide between an automatic payment and an approval option.



IMPORTANT: Panthera Dental only accepts credit card payments.

6. 3D Viewer



Tooth transparency

Bone transparency

SUB transparency

View options

Screenshot

Add comments

Measurements

New Features

You can now draw the modifications you want.

ON OFF Show/Hide comments

Delete comments

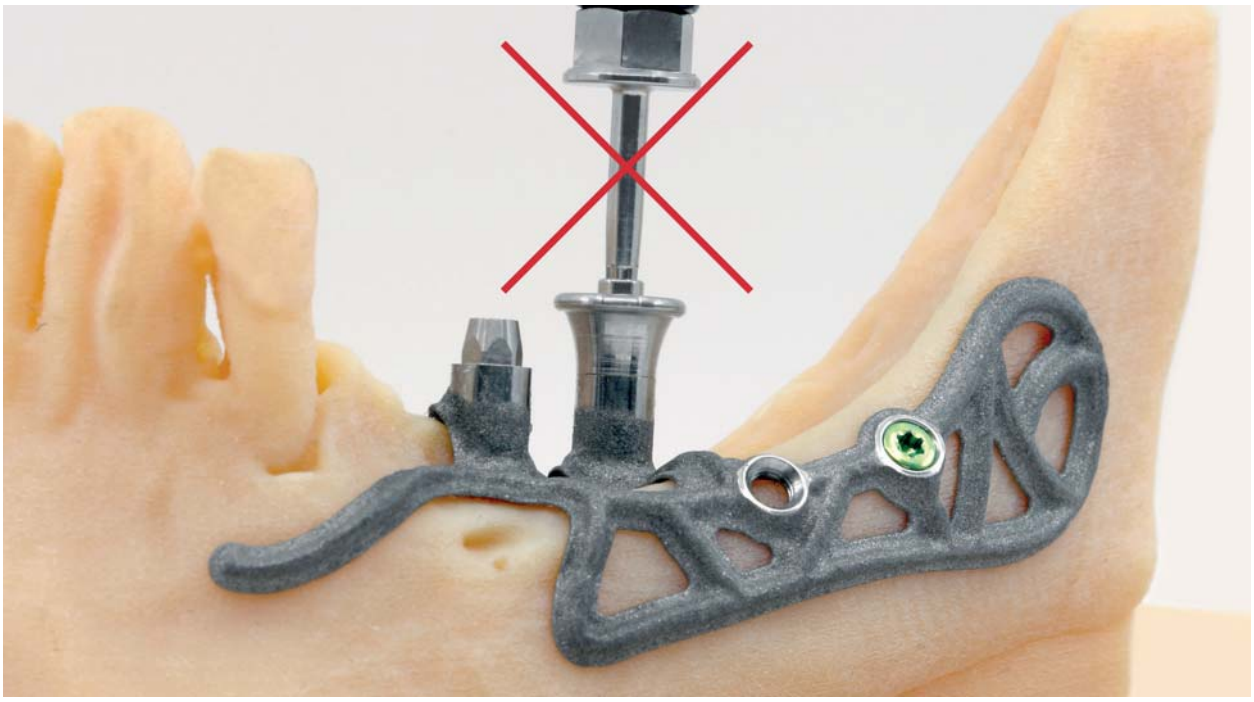
Trace on the model

Erase on the model

7. Surgical Protocol

7.1 PREOPERATIVE IMPLANT PREPARATION

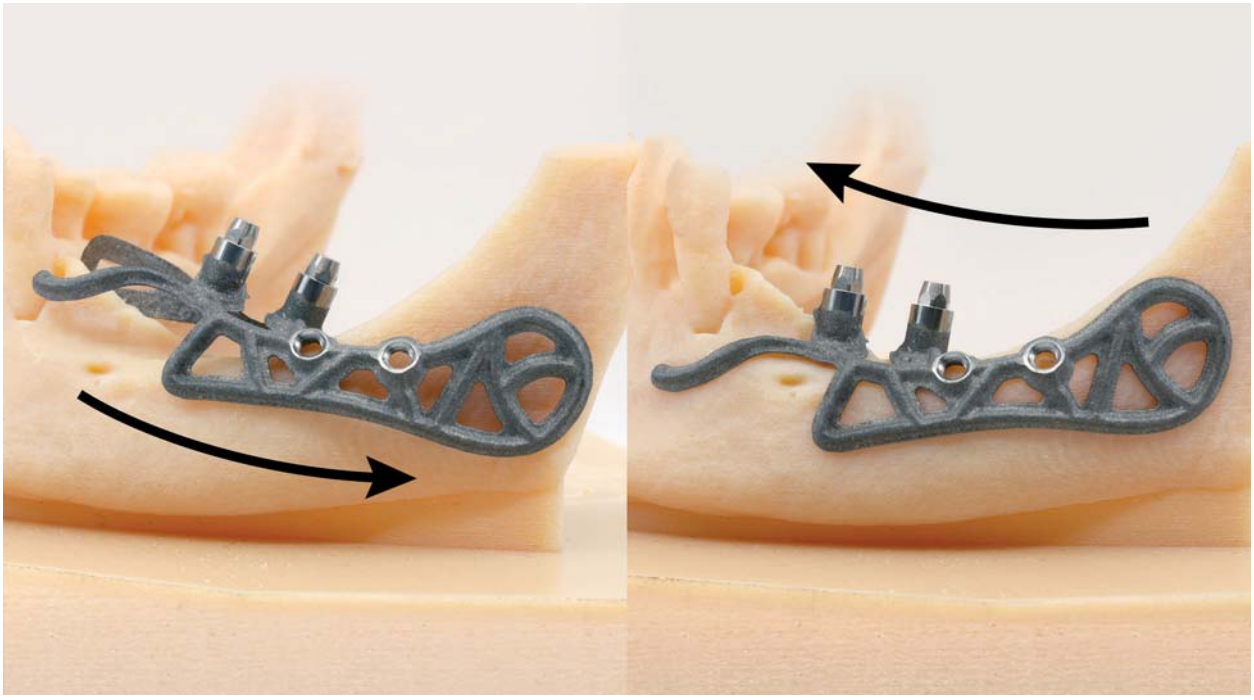
The Subperiosteal Implant is delivered clean with healing abutments in place.



IMPORTANT: DO NOT unscrew the healing abutments since they will be used to facilitate insertion.

IMPORTANT: Take the implant out of the bag and position it on the model delivered with the implant to familiarise yourself with the insertion axis.

The ideal insertion should be done by performing a distal translation followed by an anterior/mesial rotation.



Before sterilisation, the implant must be ultrasonically cleaned.

Finally, sterilise the implant and the drill bushing provided with it in an autoclave by using the same cycles as for surgical instruments

IMPORTANT: Do not use the chemiclave to sterilise the Subperiosteal Implant.

7.2 IMPLANT INSERTION

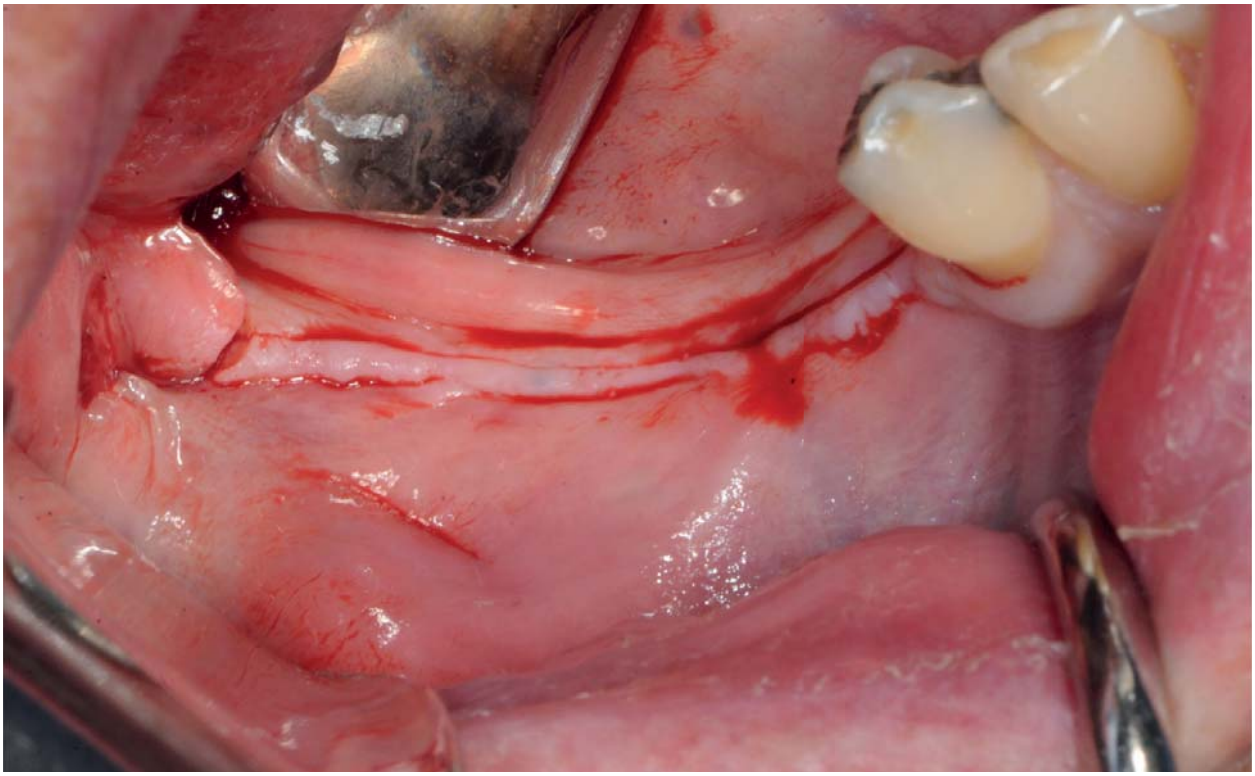
7.2.1 Incision and Site Preparation

With the help of a no. 15 blade, make a full-thickness crestal incision of the distal from the last tooth to the base of the retromolar pad by bisecting the keratinized gingiva.

With the help of a new no. 15 blade, make a 45 degree counterincision from the base of the retromolar pad to the external oblique line.

Continue by making a sulcular incision on the lingual side of the anterior teeth and to the midline, not including the interdental papillas.

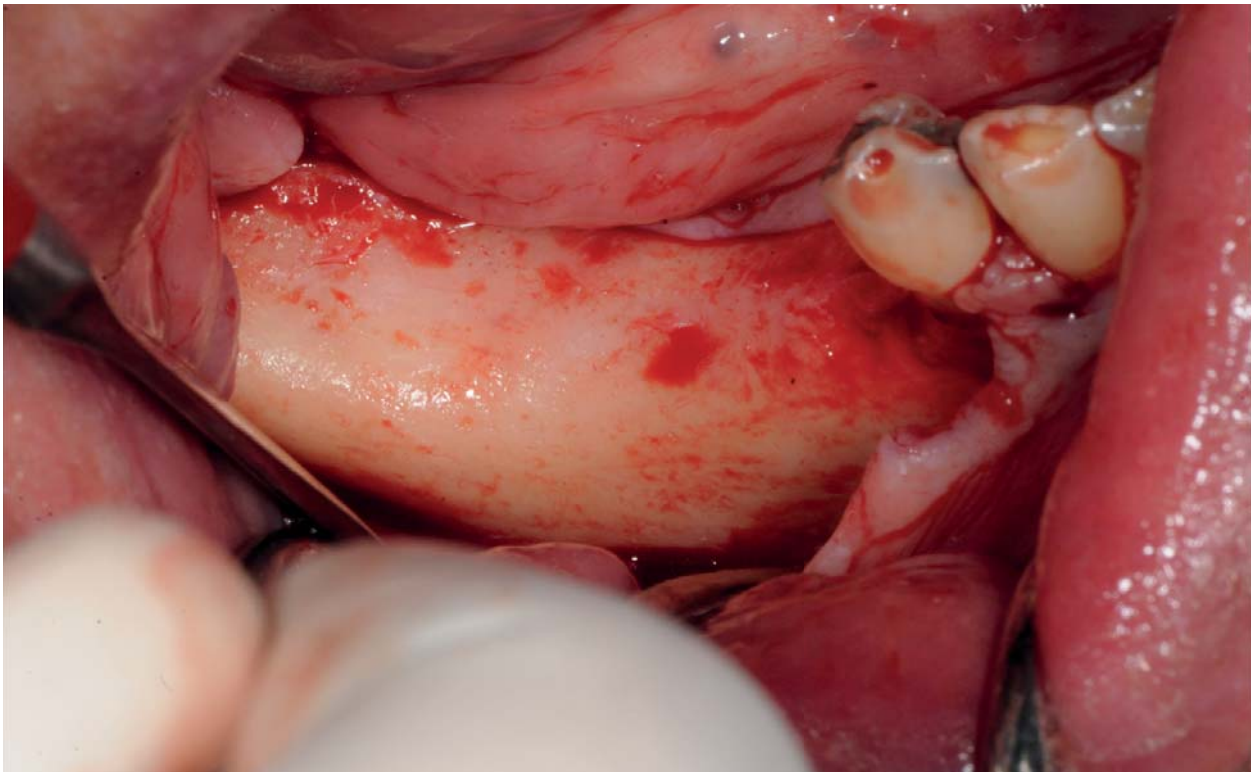
Complete this step with a sulcular incision on the buccal side of the two distal anterior teeth including the interdental papillas.



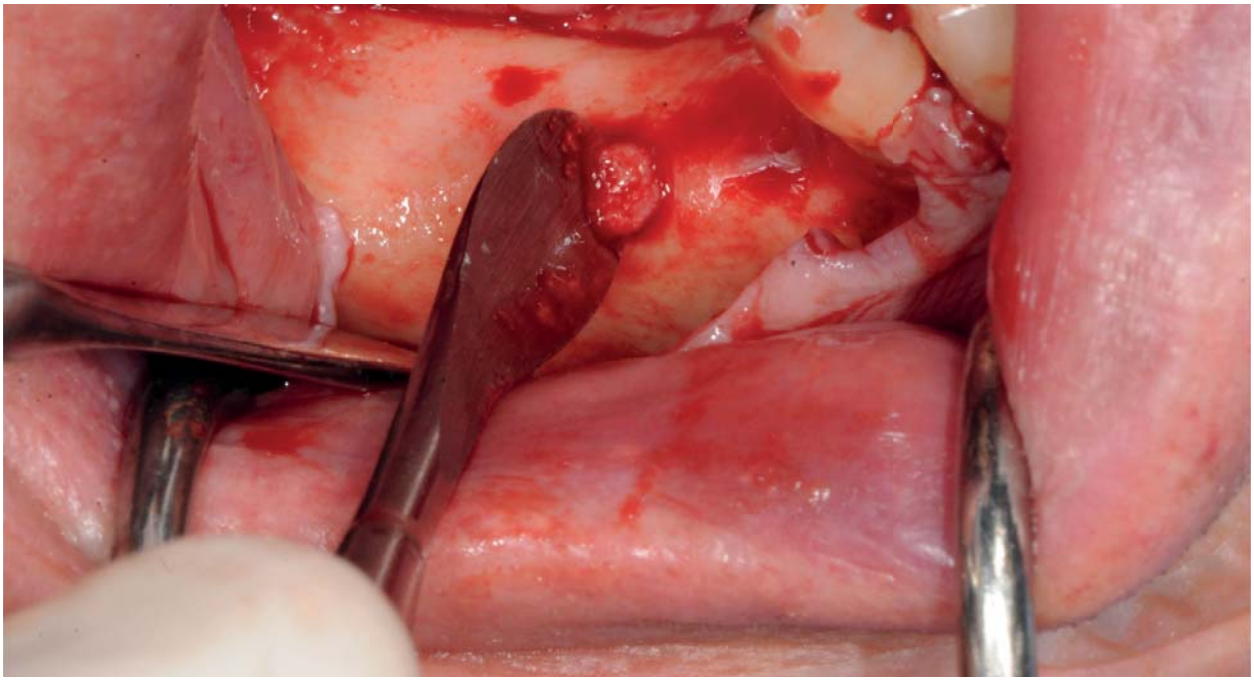
Using a 2/4 molt, elevate full-thickness flaps to the internal oblique line in posterior and apically into the anterior digastric fossa. During this step, it is important to avoid genial apophyses and the mylohyoid muscle.

With a periosteal elevator, elevate decorticate the full-thickness buccal flap beyond the external oblique line and up to the inferior ridge of the mandible in the facial artery groove area. Then, still in full thickness, clear to the insertion of the buccinator muscle without detaching it. Complete the flap by exposing the mental foramen.

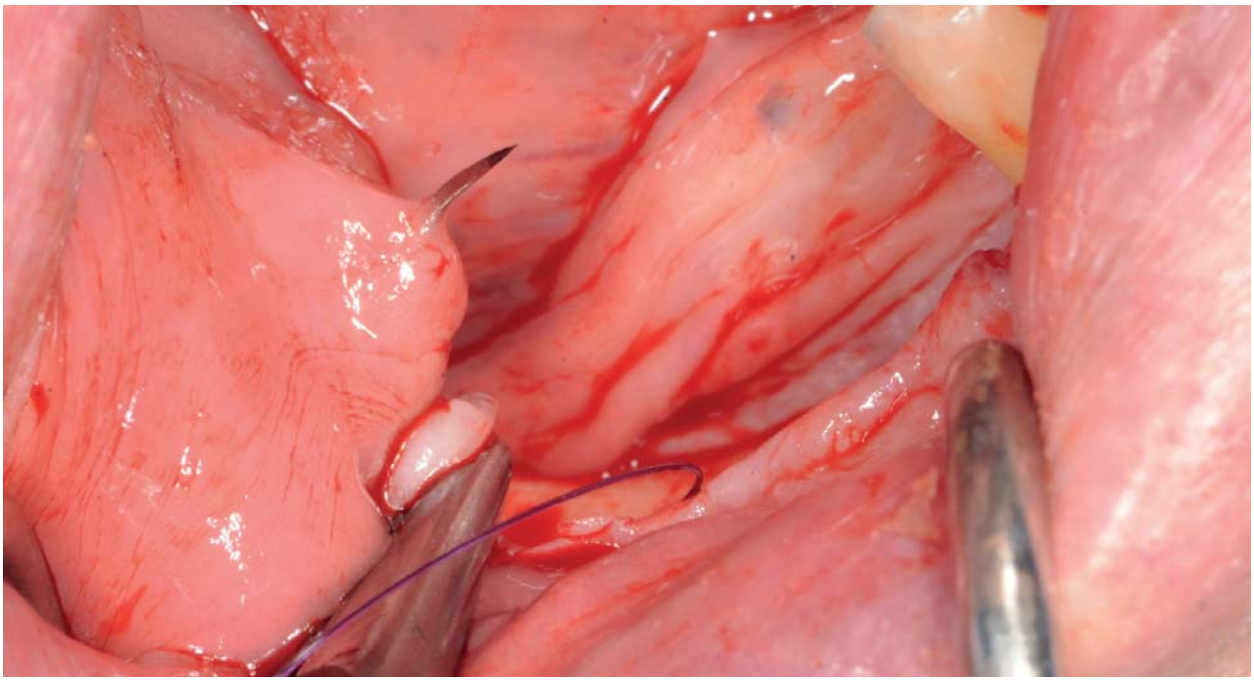
IMPORTANT: During flap elevation, always keep a bone contact with the instrument to avoid damaging the periosteum.



Before continuing, it is important to make sure that there is no residual fibrous tissue on the bone by scraping the bone with a raspatory.



With a 3/0 suture thread, fasten the buccal flap inside the jugal mucosa using a simple interrupted stitch.



7.2.2 Subperiosteal Insertion

Prior to the implant insertion, it is recommended to clean the surface of the bone with gauze soaked in sterile physiological solution.

Ask your assistant to unpack the implant from its sterile bag and, with hemostatic forceps, grip the implant by its two healing abutments.

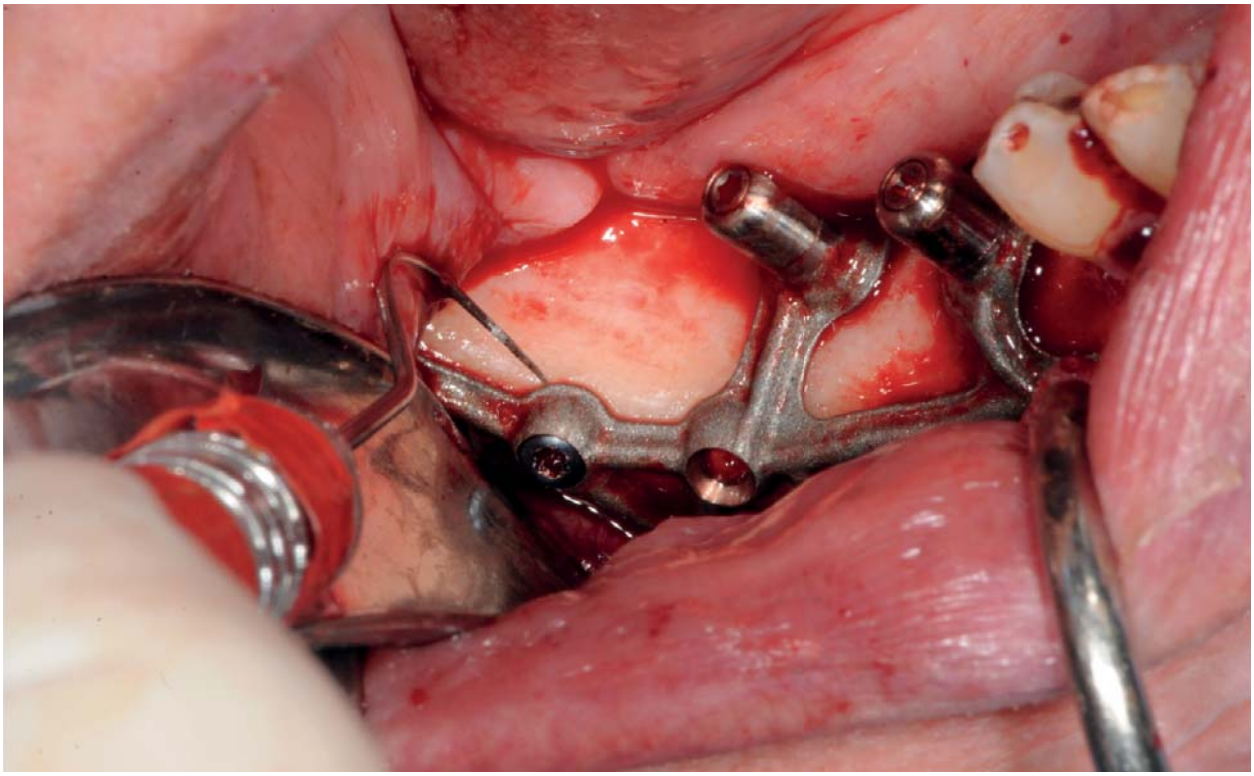
IMPORTANT: Avoid touching the subgingival portion of the implant during the insertion procedure.

Insert the Subperiosteal Implant under the envelope flap with a distal translation movement followed by an anterior rotation.

IMPORTANT: It is strongly recommended, as indicated at step 7.1, to have previously familiarised yourself with the insertion since it can differ slightly from one patient to another depending on the residual bone morphology.

Check the adaptation of the implant to the bone with the help of an explorer by probing around the entire subperiosteal.

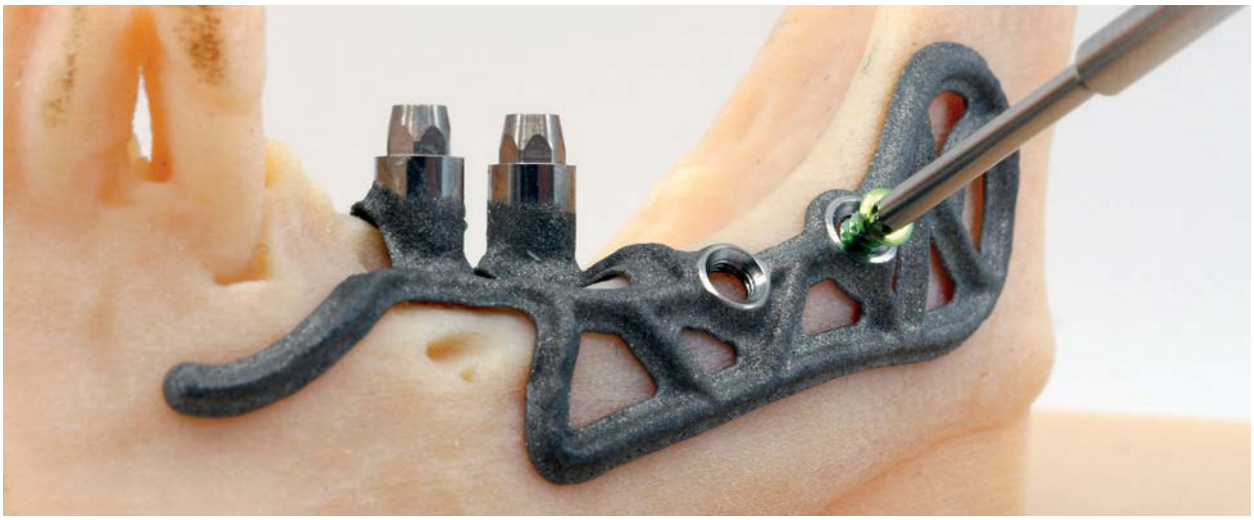
If the adaptation is not perfect, grip the implant again with hemostatic forceps and reposition it until it is in perfect position.



Screw the drill bushing in one of the fastening screw holes.

Use the supplied 1.1 mm diameter drill and pierce through the entire thickness of the cortex ending at the corticocancellous junction.

IMPORTANT: During this step, it is important to evaluate the thickness of the cortical bone for the choice of the fastening screw.



Unscrew the drill bushing and proceed with screwing the fastening screw. Use the long-handled screwdriver provided in your instrument kit.

Choose the screw according to your evaluation in the previous step. Screws of 5 mm and 6 mm lengths are available.

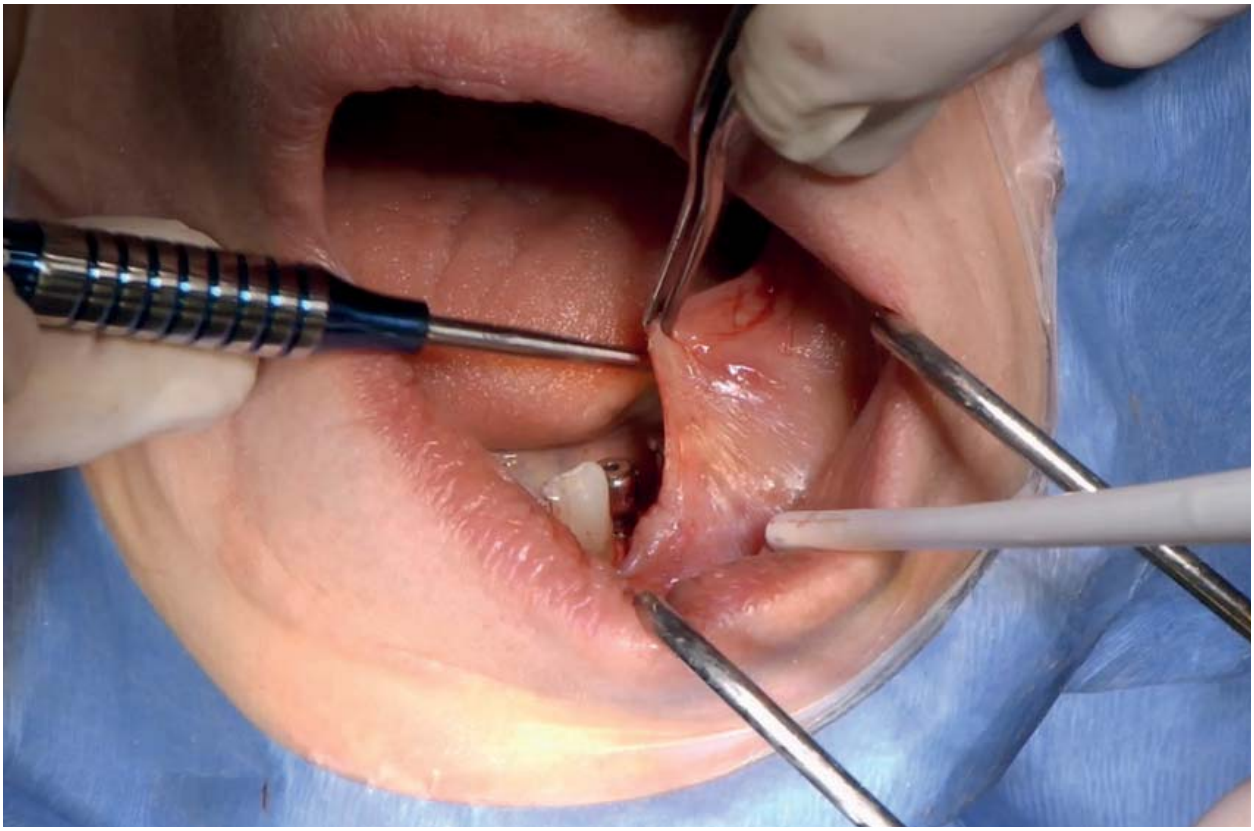
Grasp the implant once again with hemostatic forceps and verify the primary stability of the implant.

If there is any doubt about stability, put in a second fastening screw by following the same protocol used previously.

7.2.3 Tissue Extension to Cover the Guided Bone Regeneration (GBR)

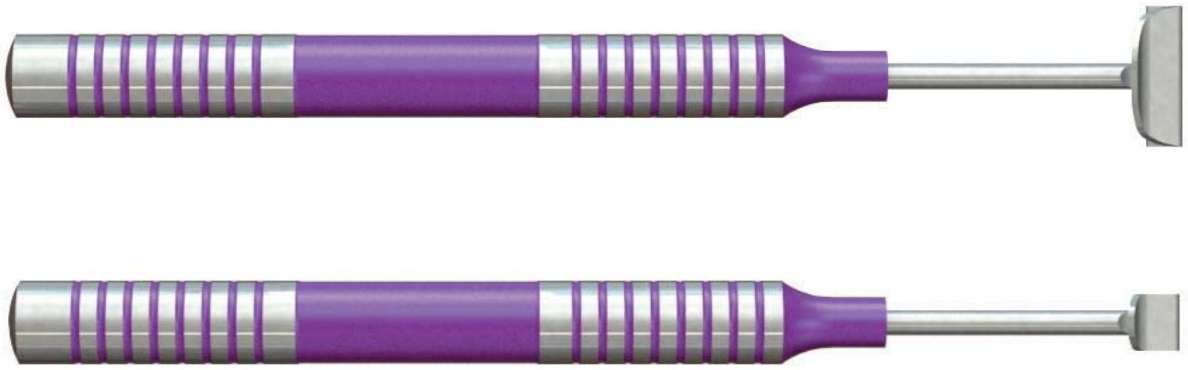
Cut the suture holding the buccal flap.

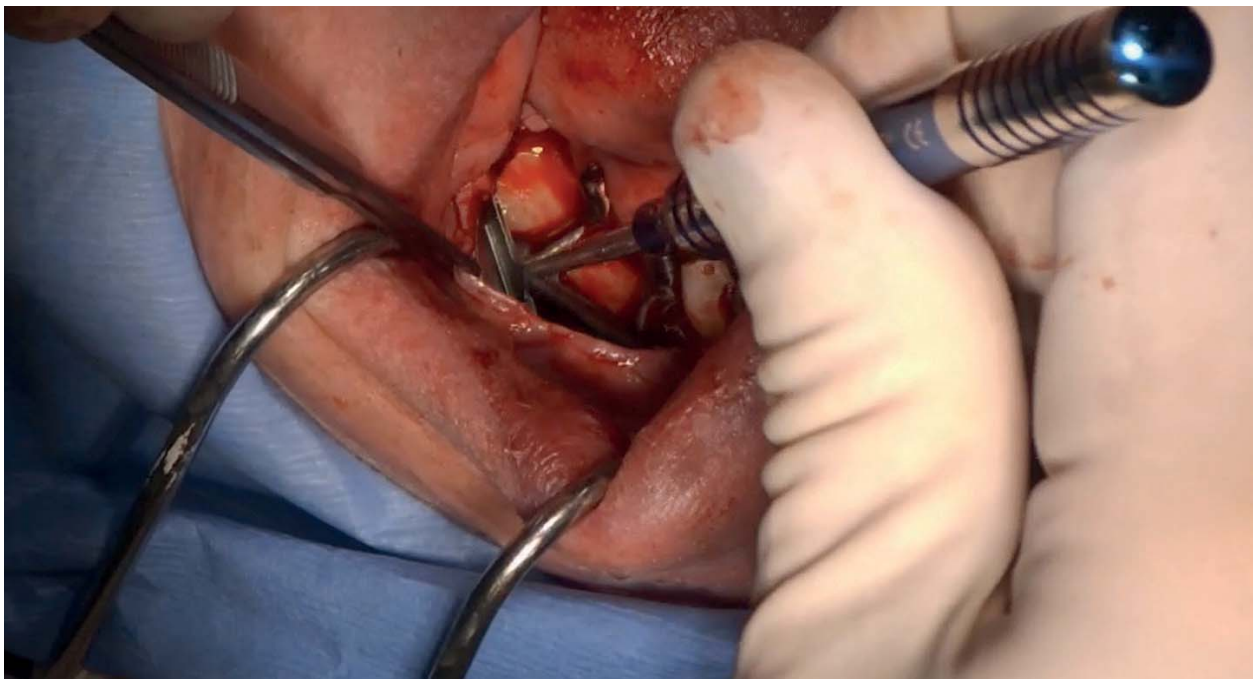
Keep tension on the buccal flaps, and then the lingual flaps, with the help of a two-in-on clip.



With the supplied brushes, scrape the periosteum to disorganize the collagen fibers and obtain a significant extension of the tissues for an eventual closing without tension.

IMPORTANT: Use the brush size best suited to the available space.





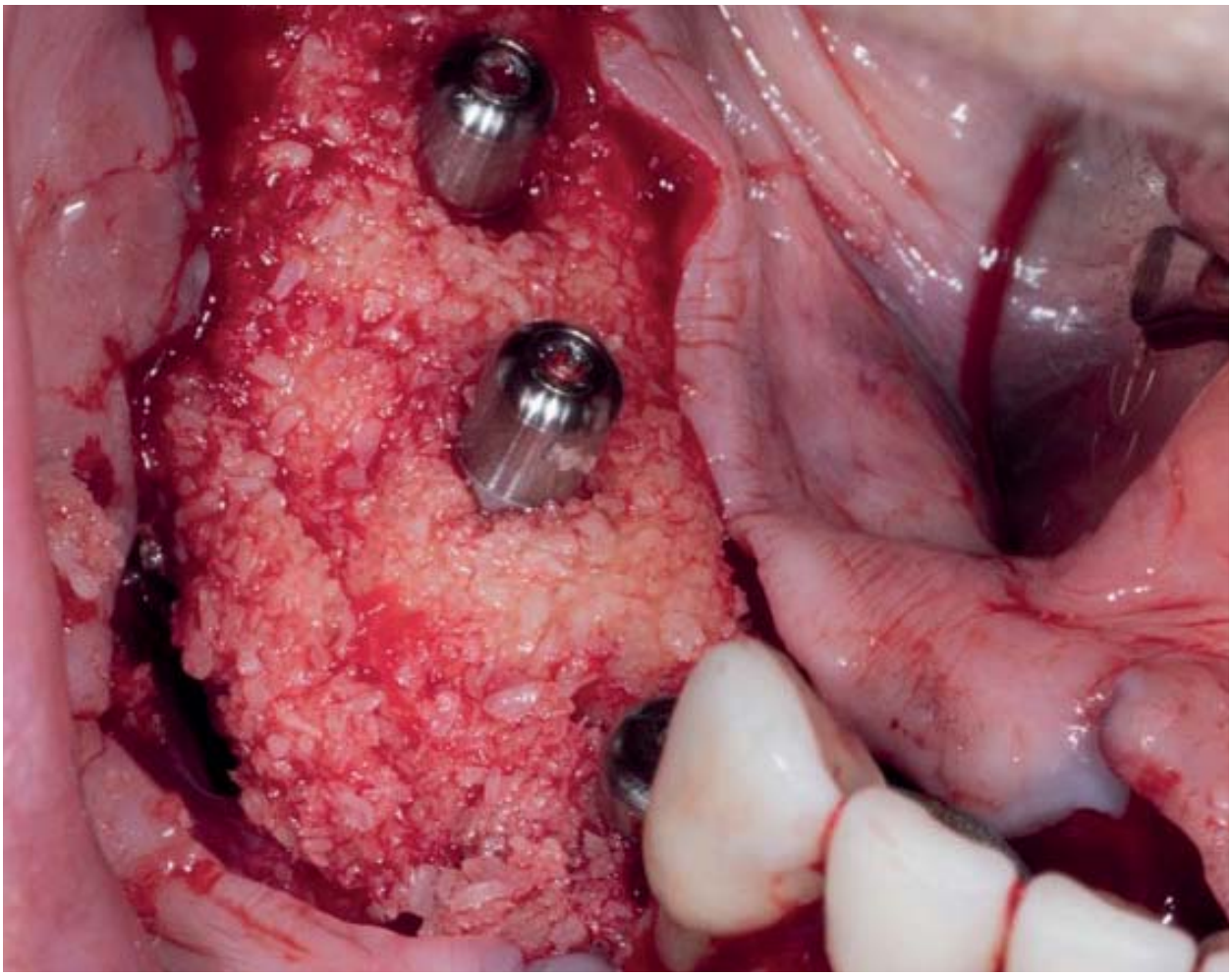
7.2.4 Guided Bone Regeneration (GBR)

Sticky Bone

In order to decrease the crown-implant ratio and increase gingival height, the rough surfaces of the abutments should be covered with sticky bone.

Sticky bone is allogenic bone mixed with liquid A-PRF.

Place the sticky bone around and between the implant abutments. Make sure to completely cover the entire height of the rough surfaces of the abutments.



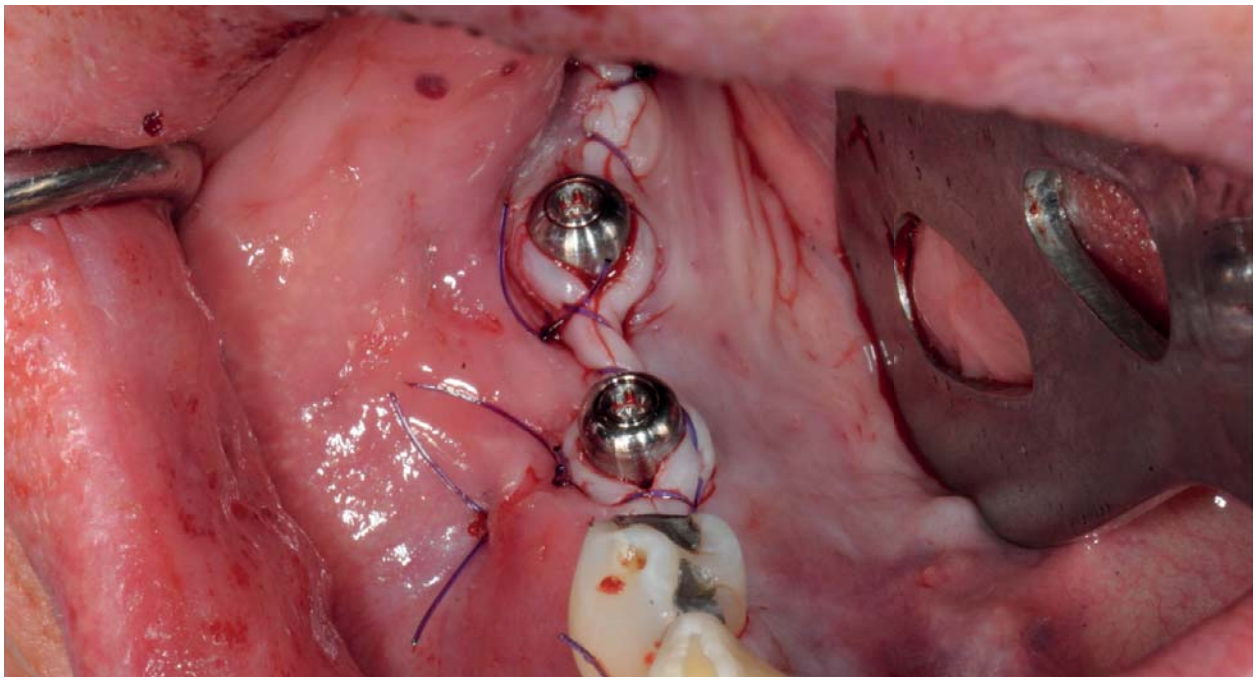
Subsequently, place the A-PRF membranes over the sticky bone and cover the whole GBR.

7.3. CLOSING

Use Glycolon 4/0 and make a vertical mattress suture at 10-12 mm apical from the primary incision line at the buccal of each abutment. Do not grab the lingual flap with the apical mattress and, instead, go around the healing abutments lingually. This technique makes it possible to avoid closing with tension and potential movements of the cheek with the primary incision line.

Afterwards, make a crestal mattress suture around the healing abutments including the lingual and buccal flaps of the primary incision line. Combining these two mattress stitches, crestal and apical, will allow you to thicken the vestibular soft tissues.

IMPORTANT: The success of this step is crucial to achieve optimal healing.

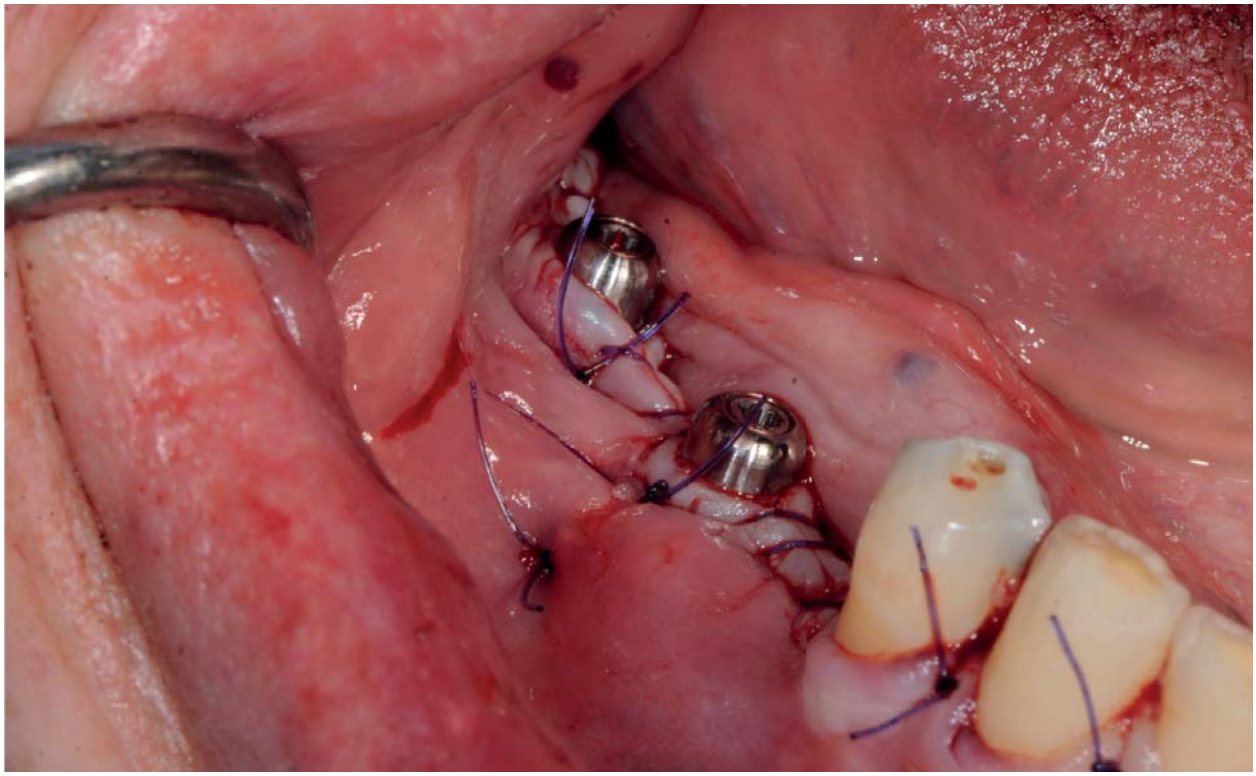


Still with Glycolon 4/0, use a simple continuous stitch to suture the distal counterincision line starting from the base of the retromolar pad.

Continue by using a simple continuous stitch to suture the primary incision line from the mesial to the distal.

Finally, complete with interpapillary interrupted stitches between the anterior teeth. Place gauze on the site with closed teeth for a duration of one hour in order to avoid hematoma formation.

IMPORTANT: Before releasing your patient, verify that the healing abutments are still securely screwed.



8. Postoperative Precautions

As with all implant surgeries, it is recommended to follow the pharmaceutical protocols and supply the patient with cortisone and prophylactic antibiotics pre-operatively, one hour before the intervention.

After the surgery, the patient will continue the cortisone and the analgesic as required.

For the first postoperative weeks, the patient is recommended to avoid hard foods at the surgical site.

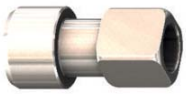
The recommended recovery time is 4 months following surgery, and this time interval must be respected before proceeding to the final prosthetic steps.

9. Final Impression Technique

The CAD/CAM Subperiosteal Implant is designed to be used with the open tray technique for final impression. The following procedure creates a model that represents the exact position of the prosthetic part of the implant and the soft tissue profile.

The procedure requires the following components and materials :

- SUB Open Transfer non-hex



- SUB Open Transfer M1.6 Screw

- SUB Analog

- SUB Driver Medium Assembly

IMPORTANT: The recommended impression material is polyvinylsiloxane.

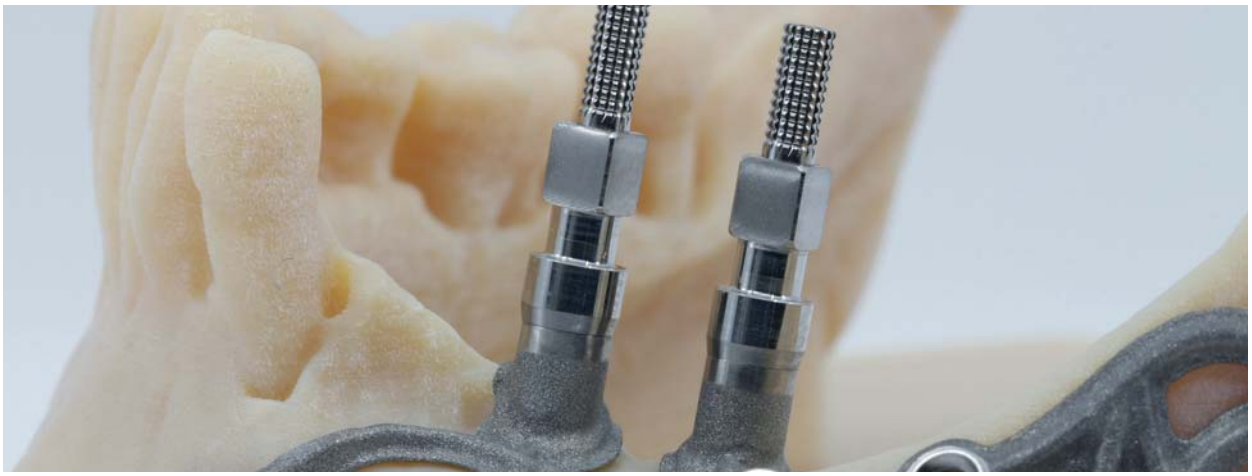
1. Removing the Healing Abutment

Remove the healing abutment using the provided screwdriver. Confirm that the prosthetic area is free of tissue or any other debris.

IMPORTANT: During this step, it is recommended to remove one healing abutment at a time and to replace it immediately with the impression coping.

2. Placing the Impression Coping

Place the impression coping on the prosthetic part and hand-tighten the screw.



3. Making a Full-Arch Impression

Try in the custom impression tray or modified stock tray to check that the coping screw protrudes through it without interference.

Syringe a medium or heavy body elastomeric impression material around the coping but make sure you leave the screw exposed. Load the tray with impression material and make the impression.

IMPORTANT: Before the material sets, make sure to wipe any impression material from the top of the screw so it remains exposed and accessible.

4. Removing the Coping Screw and Impression

After the impression material has set, remove the coping screw by hand or use the screwdriver, and remove the tray from the patient's mouth. Verify that the impression material is completely adapted around the coping. Reinstall the healing abutment immediately to prevent any collapsing of the soft tissues.

5. Sending your Impression to your Lab

Pack your impression properly and send it to your preferred dental laboratory.

Make sure to send the following:

- Impression with impression coping embedded in it
- Coping screw
- Bite registration
- Opposing model or impression
- Laboratory implant analogs
- Prescription with lab instructions

6. Lab Step – Assembling the Analog

Attach the implant analog to the impression coping in the impression and insert the coping screw through the access hole in the impression tray. Hand tighten.

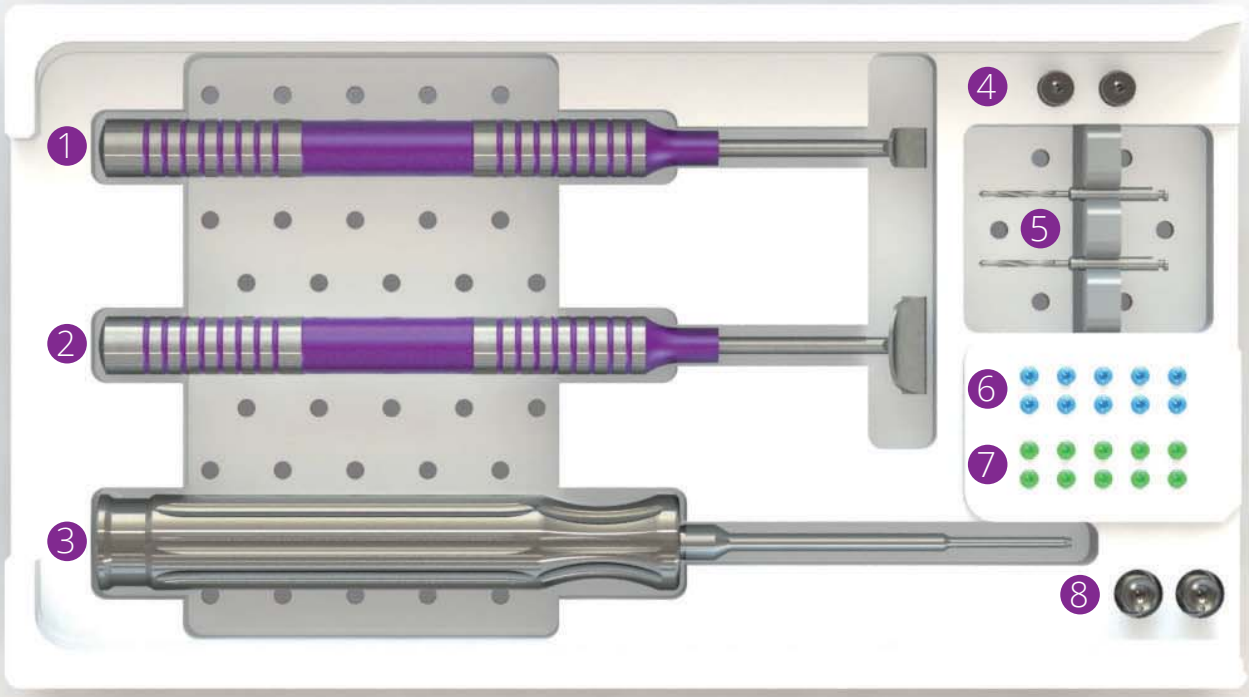
7. Lab Step – Making a Soft Tissue Model

Verify that the coping and analog assembly is properly connected. Apply lubricant where the soft tissue replica material is to be applied. Syringe a soft tissue replica material around the analog.

8. Lab Step – Fabrication

Fabricate a working model following the proper material instructions. Articulate according to normal laboratory procedures. Your case is ready for the final restoration fabrication.

10. Instrument Kit



1	38133	Regular Soft Brush
2	38134	Medium Soft Brush
3	38119	SUB T6 Screwdriver
4	38130	SUB Drill Bushing 1.1 mm
5	38131	SUB Drill Bit 1.1 mm Salvin
6	38115	SUB Bone Screw 5 x 0.9 mm
7	38116	SUB Bone Screw 6 x 0.9 mm
8	38128	SUB Driver Medium Assembly

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