EASY2FIX CATALOGUE

EASY2FIX SYSTEM

A Revolutionary Minimally Invasive Implant Integrated System for Edentulous

Despite advances in preventive dentistry, edentulism is still a major public health problem worldwide.
It has repercussions in self-esteem, eating and a severe decrease in the patient's quality of life. Most of the aging edentulous population is medically, financially and anatomically compromised. This doesn´t allow to carry out a standard rigorous conventional implant therapy, nor let implant dentistry serve the community as routinely as desired.

EASY2FIX, a unique dental implant system was developed to overcome the surgical trauma, the lack of adequate bone volume and its elevated cost by using small diameter guided implants with biomechanical enhanced primary stability, allowing immediate and long lasting denture stabilization.

The design has been validated by biomechanical testing and clinical randomized controlled trials published in international journals of implant dentistry.

Its survival rate is 97.8% and bone loss is 0.92 mm after 4 years.
If we eliminate frequent smokers from this study (more than 20 cigarettes/ day) the survival rate reaches 100%.

However, the most relevant publication in 2012, showed how this minimally invasive EASY2FIX System improved people's quality of life.

This system includes a new 3D surgical guide. This three-dimensional implant positioning in bone tissue with standard prefabricated guides does not require computerized scanners.

The procedure takes 15 minutes and there is no recovery period for the patient, allowing immediate function without the typical risks associated with other surgical implants, it provides a very precise standardized protocol, useful for general practitioners and beginners.

The EASY2FIX system, offering the most cost-effective solution in one dentist's session, is the perfect solution for edentulous patients.

EASY2FIX CATALOGUE

CFX-1320

EASY2FIX DENTAL IMPLANT 2.0mm 13mm L Prime

2.0 mm diameter dental Implant with screw shaped integrated abutment and square anti-rotational element.

The screw shaped abutment is designed for prefabricated bar attachment for implant splinting, or for ball attachment or straight abutment connection for restoration as a single unit.

FX-4000

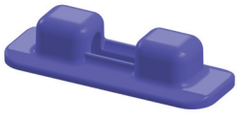
EASY2FIX CONNECTOR BAR (including Implant Screw Nuts)

Prefabricated connection bar for implant splinting, with integrated screws

FX-4032

EASY2FIX BAR RIDER

Fully metallic rider with spacer



FX-4035

EASY2FIX BAR PROTECTOR

Silicone bar protector, for undercuts protection during the acrylic relining of the removable prosthesis

PCFX-1320

EASY2FIX PREMIUM SET

The kit includes:

2 x EASY2FIX Implants CFX-1320
1 x EASY2FIX connector bar with integrated screws FX-4000
1 x Metallic rider with spacer FX-4032
1 x Easy2Fix bar protector FX- 4035

EASY2FIX CATALOGUE

FX-6200

EASY2FIX BALL ATTACHMENT

Dia : 2.25mm
H : 3.8mm

Used for retention of tissue supported over-dentures.
Hand tighten final torque.

CO-0620

NYLON INSERT STANDARD

For Metallic attachment housing CO-0630

CO-0621

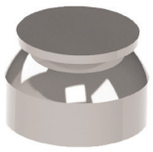
NYLON INSERT SOFT

For Metallic attachment housing CO-0630

CO-0622

NYLON INSERT HARD

For Metallic attachment housing CO-0630



CO-0630

METALLIC ATTACHMEN HOUSING

For Nylon insert housing.

FX-8000

EASY2FIX STRAIGHT ABUTMENT

Dia : 3.2mm
H : 5.0mm
Used for cemented restoration as a part of multiple unit restorations.
Hand tighten final torque.

CK-0030

EASY2FIX SURGICAL KIT

The EASY2FIX Surgical Kit, is used for EASY2FIX system placement.

CT-0801 - Ratchet
CT-S110 - 1.25mm Driver for Hex & Square ratchet
CD-1001 - Marking Drill
CD-C515 - Guided Drill Ø1.5mm
CD-5100 - Twist Drill Ø1.1mm
FX-0720 - EASY2FIX 3D Surgi-Guide Tool
FX-0705 - EASY2FIX Parallel Guide
FX-0320 - EASY2FIX Parallel Guide pin
CT-0580 - EASY2FIX Hand Driver Adaptor for ratchet
FX-0300 - EASY2FIX Motor Mount Driver

EASY2FIX CATALOGUE

CT-0801

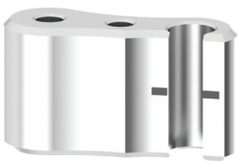
RATCHET (HANDWRENCH)

Used for implant installation

FX-0720

EASY2FIX 3D SURGI-GUIDE TOOL

3D surgical guide for determination the axial position of the implants with precise distance in between them for bar connection



FX-0705

EASY2FIX PARALLEL GUIDE

Parallel guide for insertion of the second Implant to correct vertical position

FX-0320

EASY2FIX PARALLEL GUIDE PIN

Screwed on the implant to hold parallel guide FX-0705

FX-0300

EASY2FIX MOTOR MOUNT DRIVER L=18mm

For installation EASY2FIX Implant with contra-angle hand piece or hand wrench.

EASY2FIX CATALOGUE

CT-0580

EASY2FIX HAND DRIVER ADAPTOR FOR RATCHET

From Hex 6.32mm to Square 4.05mm

Adaptor for hand wrench and Easy2fix motor mount driver FX-0300

CD-5100

TWIST DRILL

Dia: 1.1mm

CD-1001

STARTER DRILL

Dia: 1.5mm

CT-S110

1.25MM DRIVER FOR HEX & SQUARE RATCHET

For installation or removing the bar, ball attachment or abutments

FX-0321

LOCATION PIN

For fixing the parallel guide on the soft tissue

CD-C515

GUIDED DRILL

Dia: 1.5mm

Minimally Invasive Implant Integrated System for Edentulous- EASY2FIX

Despite advances in preventive dentistry, edentulism is still a major public health problem worldwide. It has repercussions in self-esteem, eating, and the ability to lead a dignified life. Most of the aging edentulous population is medically, financially and anatomically compromised. This doesn´t allow to carry out a standard rigorous conventional implant therapy, nor let implant dentistry serve the community as routinely as desired.

A new dental implant design was developed, overcoming the surgical trauma, the lack of adequate bone volume and its elevated cost by using small diameter guided implants with biomechanical enhanced primary stability, allowing immediate and long lasting denture stabilization. The design has been validated by biomechanical testing and clinical randomized controlled trials published in international journals of implant dentistry. Its survival rate is 97.8% and bone loss is 0.92 mm after 4 years.

If we eliminate frequent smokers from this study (more than 20 cigarettes/ day) the survival rate reaches 100%. However, the most relevant publication in 2012, showed how this minimally invasive EASY2FIX System improved people's quality of life.

This system includes a new 3D surgical guide. This three-dimensional implant positioning in bone tissue with standard prefabricated guides does not require computerized scanners. The procedure takes 15 minutes and there is no recovery period for the patient, allowing immediate function without the typical risks associated with other surgical implants, it provides a very precise standardized protocol, useful for general practitioners and beginners.

INTRODUCTION

Cortex Dental Implants Industries Ltd., was established by a group of clinicians, maxilla-facial specialists and opinion leaders which have worked and advised upon the developments of dental implants and rehabilitation solutions for several implant Companies.

Their combined multi-year experience have identified the surgical needs of doctors and practical clinical rehabilitation needs on a daily basis, have lead this group to create a leading team with engineering and marketing professionals.

This has lead to the combined effort of the exceptional and fast establishment of "Cortex". "Cortex" is a dynamic, innovative and qualitative company which has set its goals to place its self as one of the leading dental implant companies in the world in aspects of quality and the innovational solutions it offers to doctor's worldwide.

Cortex Implants Standards

The “Cortex” manufacturing plant operates in conformity with ISO QMS Standards, ISO 9001/2008 and EN ISO 13485/2012 (medical). “Cortex” has passed inspection of the European Notified Body (CE 0473) for approval of the design, manufacture, and quality assurance systems of Cortex
Implants, prosthetic components, and surgical tools. Cortex products are cleared for marketing in the USA as well.
At the present time, “Cortex” is also completing registration and regulatory procedures in a Large number of other countries.

General Information

Read this manual carefully before starting the treatment. This manual should be used as a reference guide for clinicians and dental technicians to optimize the use of Cortex implants, surgical instruments and prosthetic components.

The procedures and guidelines presented in this Manual are not intended to be a substitute for formal implant surgical or restorative training for the clinician and the dental laboratory technician. It is the responsibility of the clinician and the dental laboratory technician to determine the final protocol and component selection.

IMPORTANT WARNING

Lack of adequate training is a major risk factor for the success of the implant procedure and might endanger patient’s health. Therefore, no implantation should be performed without prior adequate training by a certified institute.

CORTEX IMPLANT SELECTION

Cortex Dental Implants are manufactured from biocompatible titanium alloy.

All Cortex Implants feature the roughened surface.
For specific product description and net quantity refer to individual product labels.
Although final placement of a Cortex implant is up to the discretion of the implanting surgeon, Cortex has a recommended guideline.

Each case should be evaluated on placement, protocol and type of implant before the osteotomy is drilled. The availability of the different versions of Cortex Implants allows the clinician to weigh the advantages of each and choose the type best suited for each case. Cortex implant is recommended for placement at the crest of the ridge or slightly below.

Indication for use

EASY2FIX Dental Implants are indicated for stabilization of over-denture in completely edentulous patients.

The implant is a machined screw shape part made from Titanium alloy and has a thread like structure along its body that helps its placement in the jawbone in a firm and stable manner using the surgical tweezers for guided placement of the implants and fixation with prefabricated dolder bar for immediate loading.

Contraindications

The contraindications customary in oral surgery with other implant materials should be observed. These include patients on corticosteroids, anticoagulants or anticonvulsant and those receiving radiation or other immunosuppressive therapy.

Lactating or pregnant women are not candidates, nor are patients with abnormal laboratory values for BUN, creatinine or serum calcium.

Patients with diabetes or cardiovascular disease are contraindicated.

Hypertension above 170/110 mmHg, osteoporotic crush fractures, respiratory disease, thyroid or parathyroid disease should be excluded from treatment.

CORTEX IMPLANT SELECTION

Patients with diagnosed malignancy in the past five years and those with nodular enlargements, tenderness or unexplained lumps or masses of the head or neck should not be treated.

Implanting procedures should not be performed on people with active osteolitic, inflammatory or infectious processes in the implantation site.
Pregnancy, Hemophilia, Granulocytopenia or other bleeding problems, Osteoradionecrosis Patients receiving Biphosphonate treatment are in danger of bisphosphonate related osteonecrosis of the jaw (BRONJ). Poor patient motivation.

Psychiatric disorders that interfere with patient understanding and compliance with the necessary procedure. Unrealistic patient expectations Unattainable prosthodontic reconstruction. Inability of patient to manage oral hygiene. Patient hypersensitivity to specific component of the procedure.

Possible Contraindications

Chronic bleeding problems, psychological impairment, treatment with chemotherapeutic agents, metabolic bone or connective tissue diseases, treatment with corticosteroids, certain cardiac and vascular diseases, diabetes (uncontrolled), tobacco usage, chronic renal disease, poor patient oral hygiene, bruxism, alcoholism.

Temporary Contraindications

Systemic infection, local oral and respiratory infection
Anatomical or Pathological Contraindications:

- Insufficient alveolar bone width and height to surround the implant with at least one millimeter of bone.
- Inadequate bone height where proper implant placement would encroach within 2mm of the mandibular canal, sinus floor, etc.
- Malignancies

WARNINGS

The implant placement procedure should be done under aseptic conditions with specifically designed sterile surgical instruments. A surgical drill system with external irrigation is recommended for drilling the surgical site. The use 3D surgical guide and parallel guide are recommended to aid in implant placement and positioning with minimal invasive procedure.

Improper techniques can cause implant failure and loss of bone.
No attempt should be made to alter or modify the implant body.
The use of electrosurgical or laser instruments around metallic implants and components is discouraged due to the electric and/or heat conductivity of the substrate metal.
Prosthetic components are for single use only. A previously used component should not be sterilized and used in a different patient.

CORTEX IMPLANT SELECTION

Reduction of the any prosthetic component intra-orally may transmit heat to the implant body and surrounding bone. Ample irrigation is necessary for cooling to preclude heat transfer.
It is very important to determine the local anatomy and suitability of the available bone for implant placement.
Case planning with adequate radiographs, direct palpation and visual inspection of the prospective implant site are necessary prior to treatment and implant use.

Forcing the implant into the osteotomy deeper than the depth established by the drills can result in: stripping the driver connection interface, stripping the driver, cold-welding of the mount-driver interface to the implant, or stripping the walls of the osteotomy that may prevent an effective initial implant fixation.

WARNING

Mishandling of small components inside the patients mouth carries a risk of aspiration and/or swallowing. Ensure that the patient has been informed regarding implant placement and restorative procedures, homecare and implant maintenance. The patient's expectations of the final result should be clearly defined.

Sterilization

All Cortex Implants are provided in sterile, gamma-irradiated packaging with a five- year shelf life. Refer to individual product labels for sterilization information; all sterile products are labeled 'STERILE.' Implants should not be used after the expiration date, as sterility cannot be assured. The inner vial and implant body are sterile unless the outer package seal has been damaged or opened.

If the implant becomes contaminated by the patient's body fluids or tissues, the implant cannot be used in another patient. The implant may not be cleaned or re-sterilized for use in another patient.

Do not attempt to decontaminate the implant by any in-office method. It is important to ensure all instrumentation, surgical hand-pieces, and equipment has been sterilized to prevent the possible contamination of the components, the surgical system, and thus, the patient. Always remove instrumentation from its packaging prior to sterilization.

Always run a system check to ensure that the surgical motor and its components are functioning properly. Backup equipment, implants and instrumentation are recommended in case of contamination or failure of equipment or instrumentation.

Surgical drills eventually become dull with use and require replacement.

Adverse Reactions

Complications that can occur include: infection, bone loss, patient discomfort, implant mobility, local soft-tissue degeneration, and unfavorable implant placement or alignment. Treatment for these reactions should follow standard dental procedures as would be indicated and applied for natural dentition. These would include pain medications, antibiotics, removal from function, removal of mobile implants, and soft tissue/bone debridement and augmentation.

Implant mobility, bone loss, or chronic infection may indicate implant failure. Any implant that appears to be failing should be treated as soon as possible. If removal of the implant is necessary, any soft tissue can be curetted from the implant site and then allowed to heal in the same manner as traumatic tooth extractions.

Unfavorable implant placement or alignment may be treated with either pre-angled or customized abutments. In the event that the implant is un-restorable due to unfavorable alignment or positioning, the implant may have to be left out of function or removed/replaced.

Storage and Handling:

Devices should be stored at room temperature. Refer to individual product labels and this manual for special storage or handling conditions.

Caution:

U.S. Federal Law restricts this device to be sold by or on the order of a licensed dentist or physician.

Treatment Planning

General Information:

These instructions will instruct practitioners in the use of EASY2FIX Implant System.
The success of any dental implant system depends upon proper use of the components and instrumentation.
This manual is not intended for use as a substitute for professional training and experience.

DATA COLLECTION

Examination and treatment planning

Patient Evaluation and Selection:

- Before any treatment, the patient must be informed about expected outcomes of preoperative examination and get an explanation about the treatment, including the expected results of the risks.

- Patients should sign an informed consent to indicate their acceptance of treatment.

- Patient status information should be registered, such as general medical contraindications, the surgical treatment, mental psychoses, alcohol and all of the information mentioned in instructions for use.

If the patient's medical history reveals an existing condition or signals a potential problem that may compromise treatment and/or the patient's well being, consultation with a physician is recommended.

Preoperative Planning:

Proper treatment planning, as well as the selection of the proper implant length and diameter, are crucial for long- term success of the implant and restoration.

Before an implant can be selected, the anatomical foundation available to receive the implant must be carefully assessed. Several steps should be taken to complete the evaluation:

1.CLINICAL EXAMINATION

Clinical examination of the oral cavity can provide important information about the health of the soft tissue at the proposed implant site.
Patient examination includes a clinical and radiographic examination and evaluation of general condition of the patient's health.
Soft and hard tissues should be carefully examined.

The patient should demonstrate an adequate dimension of attached mucosa or keratinized tissue at the site selected for implantation.
Data collection should include dental history, restorative status and occlusion.

CT scan is recommended in most cases.
Radiographic examination should provide information about anatomy, pathology, quality and quantity of bone.

6. PRE-OPERATIVE HANDLING

- The clinician's should be familiar with the CORTEX EASY2FIX system, surgical and prosthetic protocols for efficient and accurate installation.
- Initial preparation of the patients should be done prior the implant surgery.
- Premedication of 2g of amoxicillin one hour before implant placement prophylactically and 500mg every 8h post treatment for one week is given based on individual indications and according to literature up-dates. Allergic patient may be given 600 mg of clindamycin one hour before implant placement prophylactically and 150 mg every 6h post treatment for one week.
- Proper sterilization of the room and surgical instruments should be carried out prior to the procedure.
- Local anesthesia is given by infiltration technique.
- Mouth rinsing should be carried out with 0.2% chlorhexidine solution for 1 minute before surgery.

CLINICAL CLASSIFICATION FOR EASY2FIX

Classification	Surgical Approach
Class I Alveolar ridge ≥ 4mm width (x-ray, mapping with tweezers). Bone height ≥14 mm (x-ray). Keratinized tissue 3mm.	Class I Surgical Approach Follow the surgical protocol of E2F.
Class II Alveolar ridge < 4mm (x-ray, mapping with tweezers). Bone height ≥14 mm (x-ray) Some keratinized tissue on the ridge.	Class II Surgical Approach Incision from 4.2 to 3.2 zone and mini flap elevation. Bone Preparation lingual of the alveolar crest, if necessary carry out a bone osteotomy. Follow the surgical protocol of E2F. Suturing with reabsorbable sutures before bar connection.
Class III Atrophied alveolar ridge Bone height < 14 mm. Some or no keratinized tissue on the ridge. No possibility to use the bone gauge tweezers due to low mouthfloor depth.	Class III Surgical Approach Incision from 4.2 to 3.2 zone and mini flap elevation. Drill using the tweezers in an open position with direct visibility of the jaw bone. Use wider & shorter implants (3 x 10) (4 x 8) Free hand preparation and insertion of the first implant. Follow the surgical protocol of E2F, without the tweezers. Suturing with reabsorbable sutures.

INSTRUMENTATION

Cortex Instrumentation

All Cortex surgical instruments are provided non-sterile. Always remove the instruments from the packaging prior to sterilization. Inspect the surgical instrumentation to ensure sterility and functionality. For example, drills will become dull after many uses.

Always have a backup drill sterile and available. Cortex recommends drill replacement after 20 osteotomies depending on bone density.

Cortex Surgical Kit

Cortex EASY2FIX Surgical Kit holds all the instrumentation needed to place the EASY2FIX implants. Tools and drills can be purchased separately, depending on the clinician's preference.

Cleaning Procedure for Surgical Trays and Instrumentation

1. Disassemble the surgical kit and wash the tray using a detergent solution. Rinse the tray with water and dry thoroughly.
2. Place the instruments in a beaker of detergent solution and sonicate for approximately 10 minutes. Rinse thoroughly.
3. Remove any visible debris or bone fragments with a soft bristle brush. Rinse thoroughly.
4. Rinse the instruments with ethyl alcohol (do not use IPA isopropyl alcohol) to remove soap residue and minerals. (This is important to help prevent corrosion and spotting.)
5. Blot the instruments with a towel and allow to air dry completely.
6. Return the instruments to the appropriate locations in the surgical tray.
7. Wrap the kit in a double-layer of autoclave-wrap.
8. Sterilize the kit according to the "Sterilization Table"

CAUTION

Do not remove the surgical kit from the autoclave until the dry cycle is complete.

INSTRUMENTATION

CAUTION

The use of hydrogen peroxide or other oxidizing agents will cause damage to the surface of the instruments. Towel or air-dry all instrumentation before sterilization. Drills and taps should be replaced when wear, a decrease in cutting performance, or signs of discoloration are noted. Cortex Dental Implants recommends replacement of drills after approximately 20 osteotomies, depending on bone density.

Sterilization Table

1. Autoclave 121 - 124° C (~250° F) 30 minute exposure / 30 minute dry time or 132 - 135° C (~270° 20 minute exposure / 30 minute dry time.

Do not exceed 140° C (284° F). Always use the dry cycle.

Each dental office is responsible for the proper, routine sterilization of instruments. All sterilization techniques should follow the unit manufacturer's guidelines.

Place all instrumentation and implants onto the sterile work field in the order they will be used. This makes for a natural progression through the case sequence.

The surgical kit is set up in this fashion. Follow the drilling sequence in this guide.

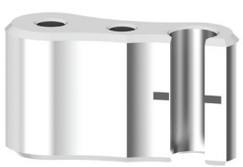
Surgical 3D Guide

A 3D surgical guide is used to indicate practical flapless boundaries for the placement of implants and prevent perforations of buccal or lingual plates.

This process helps to ensure functional placement of implants in pre-established distance and position.

Surgical Parallel Guide

Surgical parallel guide is used to indicate the vertical placement of implants to ensure functional placement of implants in correct vertical position for easy and passive connection of pre-fabricated bar.



SURGICAL STAGE

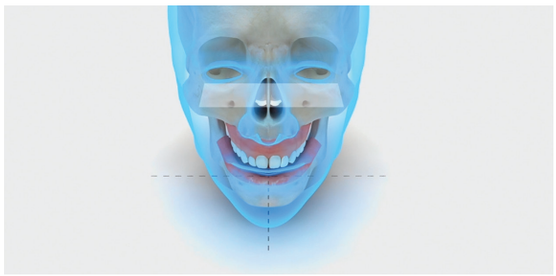
Surgical Procedures for Cortex EASY2FIX Implant Placement
Flapless surgery after administration of local anesthesia.
(It can be preformed also with raising a flap).

STEP 1

Set your hand piece to 1500 - 2000 rpm with irrigation.
Connect the hand piece Ø1.5mm Drill

STEP 2

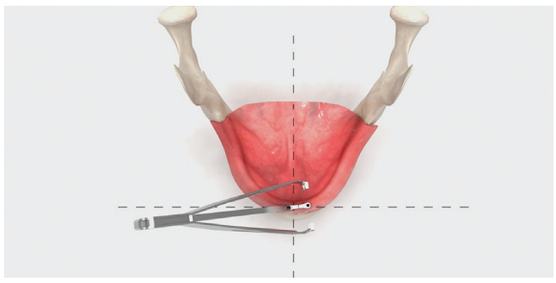
Mark the midline of the anterior mandible.



STEP 3

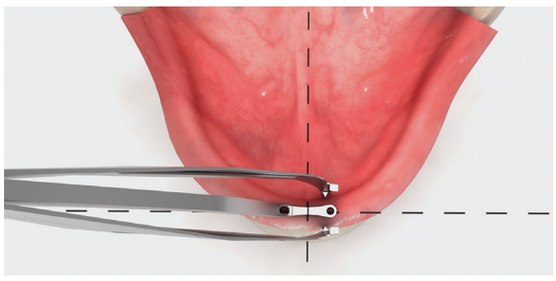
INFRONT of the patient, take the tweezer with your left hand and align the base centered mark with the mandibular midline.

This base should also be parallel to the bipupilar line.



STEP 4

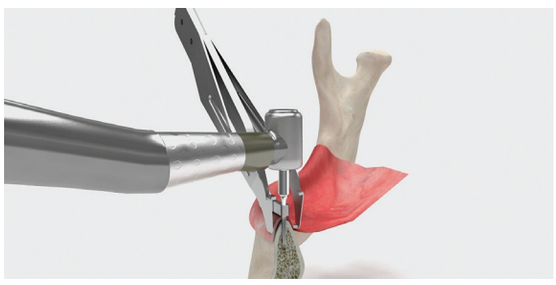
Press the arms together to determine the minimum thickness, lock the surgical guide by pressing your fingers.



STEP 5

Use the 1.5 diameter drill and prepare the 32 zone through the cylinder guide until the hand piece reaches the guide.

repeat the movement in and out twise and pull out the drill while it is still rotating.



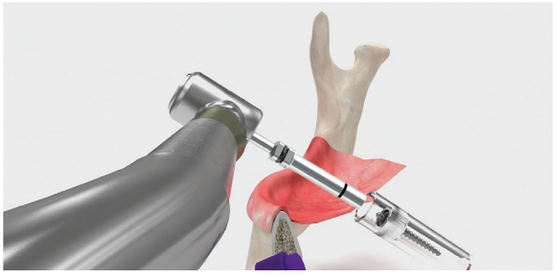
SURGICAL STAGE

STEP 6

Adjust the control unit's speed to 20rpm/15Ncm and shut down the irrigation.
Connect the implant driver to the hand piece.

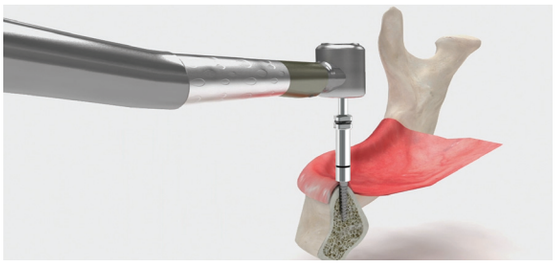
STEP 7

Open the vial in a horizontal position and take the implant with the implant driver. Remove it slowly from the vial and deliver it to the prepared 32 site.



STEP 8

Insert the implant until the edge of the implant driver touches the mucosa or slightly above it. If the implant rotation stops before reaching the final position, disconect the motor mount from the hand piece, and finish the insertion by using the ratchet and the adaptor.



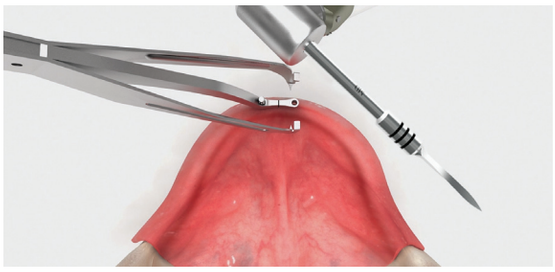
STEP 9

Remove the implant driver, place the 1.5 guided drill in the hand piece and adjust the speed between 1500 and 2000 rpm, activate the irrigation.

SURGICAL STAGE

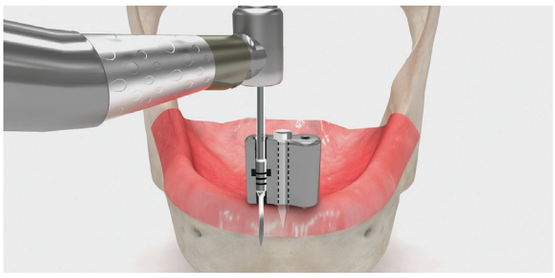
STEP 10

Fix the parallel pin on the inserted implant head. BEHIND the patient, take the tweezer with your left hand, place the larger hole of the tweezer on the parallel pin, press the tweezer's arms and lock it.
With the 1.5 sear drill prepare the 42 zone through the second hole and remove the tweezer.



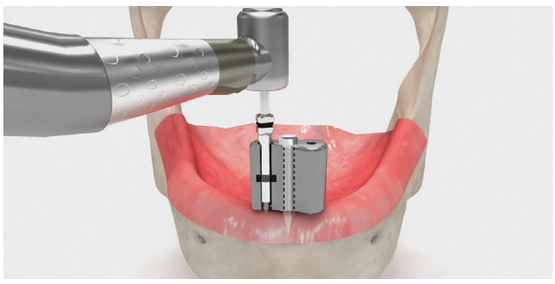
STEP 11

Place the implant parallel guide over the pin. Lock the guide with the locking pin in the center by pushing it into the crest. Hold it in place and drill the second hole for the 42 implant by using the long drill.



STEP 12

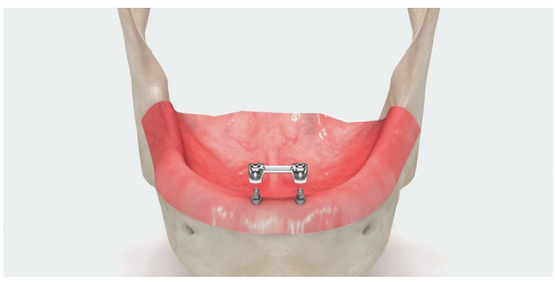
Insert the second implant through the parallel guide until the line at the motor mount matches the line on the implant parallel guide.

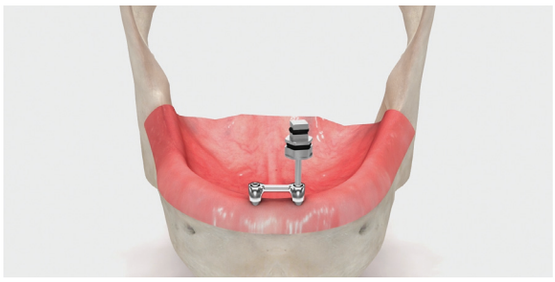


STEP 13

Remove the parallel guide and the Parallel Guide Pin, place the bar on the head of the inserted implants and attach the micro screws.

Fix the screw with the 1.25mm Driver, torque 20 N/cm place the bar protector.

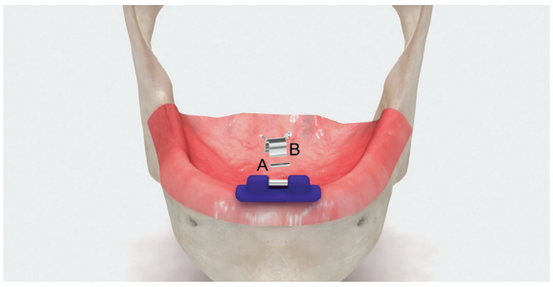




SURGICAL STAGE

STEP 14

Place the metal spacer (A) on the upper side of the bar and then clip-on the rider (B) on top of it.



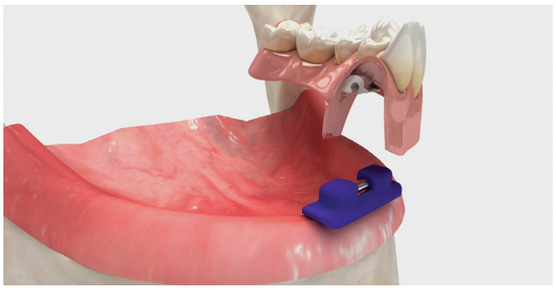
STEP 15

Remove the necessary acrylic from the anterior base of the removable prosthesis to make room for the bar protector and the Metallic rider.
Test the prosthesis to determine a passive fit without disturbance on occlusion.

STEP 16

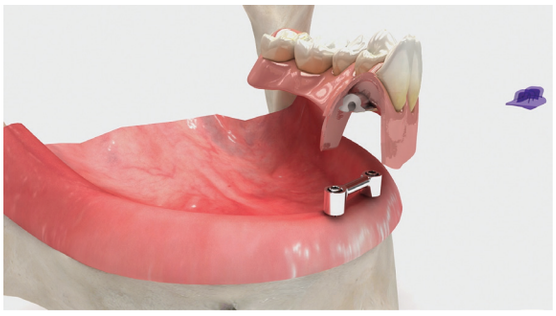
Refill the cavity with the least amount possible of self-cure acrylic, mainly in the Metallic rider zone.

Place the prosthesis and ask the patient to bite.



STEP 17

After acrylic polymerization, remove the prosthesis. Then remove the undercuts and refine the margins with acrylic.



STEP 18

It is recommended to reline the old denture posteriory to prevent any pressure on the dolder.