100% Made in ITALY

GLOBALWIN

IMPLANT SYSTEM

GUIDED SURGERY PROTOCOL

CREA-3D® GUIDED SURGERY

BIOSAFIN

Partner of

cefla Making Your Life Better.

CONTENTS

BIOSAFIN Partner of cefla Making Your Life Better.

CREA GUIDED SURGERY 3D Guided Surgery

PATIENT'S FIRST AND SURNAME

☐ Upper Arch ☐ Lower Arch

☐ Crea 3D Guided Surgery ☐ Real Guide5.0

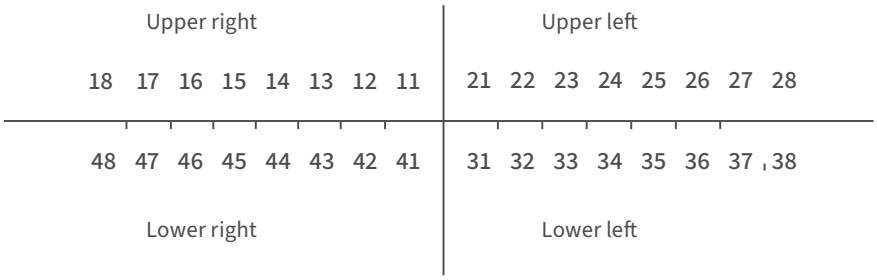
Implants preference and Connection type:

Upper Arch ☐ Cement-retained ☐ Screw-retained

☐ Immediate loading ☐ Not immediate loading

PROJECT GUIDELINES:

POSSIBLE EXTRACTIONS TO BE PERFORMED:



Equipment Required: ☐ Only Surgical Guide ☐ Surgical Guide + Perforated Model

☐ Surgical Guide + Perforated Model + Temporary

Requested delivery date:

Surgery Date:

Request for Guided Surgery KIT hire ☐ YES ☐ NO

NOTES

DATE

SIGNATURE

GLOBALWIN IMPLANT SYSTEM

Specialised Company

BIOSAFIN specialises in the manufacture and sale of devices and instruments for implantology and oral surgery, dental aligners and tailored digital dentistry services.
Research and Development is at the heart of our business, and we aim to achieve high product performance through the development of innovative scientific and technological content, while constantly improving Quality.
The evolutionary path of the BIOSAFIN implant ranges is founded on the scientific evidence cited in the extensive Bibliography of Studies and Publications available to dental professionals.

Scientifically and clinically tested product quality

Since 1995, BIOSAFIN been used with great success by dental practices and professional clinics with diverse needs according to the type of user and procedure.
The certified quality of the products – which all undergo a strict 1:1 production check – and the proposed solutions, always relevant in meeting the needs of patients, provide dental surgeons with maximum peace of mind.
The solid scientific background in which the devices are developed, allows for combining technological innovation and compatibility, thus avoiding demanding changes in operative procedures or costly replacements of materials for the dental surgery Team.

Company certifications

BIOSAFIN is certified to:

ISO 9001 standard, which verifies the entire work process from start to finish, further demonstrating compliance with quality standards considered optimal for the protection of the product User – the Professional – and the end user – the Patient.

ISO 13485 specifically relevant to the quality of Medical Devices.
The quality standards required for Certification are periodically examined and reviewed.

Customer Support and After-Sales Service

BIOSAFIN has specific dedicated resources for technical support during the initial stages when starting out in Guided Surgery, for the software installation and subsequent training stages.
Our ONE SHOT + direct support from our company Product Specialist package is available for Dentists wishing to approach this technique for the first time with no obligation.
BIOSAFIN makes the **CREA Digital Centre**, available for users of the Globalwin implant system, with specialised expertise for dentists practising Guided Surgery at their own clinics.
A direct link with the Company, which is always available to discuss the best approach with you.

GLOBALWIN Guided surgery

The Globalwin Guided Surgery Protocol is the result of validated clinical experience: once the anatomical conditions and health of the patient have been verified, Globalwin implants can be inserted safely and predictably using a **SURGICAL GUIDE**.

The system allows you to predict the exact position of the implants before surgery. This information is transferred to a 3D-printed model so that the provisional prosthesis can be designed and made in advance, meaning it is available on the day of the procedure and even before the actual implants and any abutments are fitted.
With CREA 3D Guided Surgery software it is possible to consider alternative restoration solutions, simulate various prosthetic solutions and thoroughly examine the individual functional and aesthetic parameters.

CREA 3D Guided Surgery is an advanced system that uses a radiological diagnostic program to read and digitally process CBCT or CT scans and superimpose DICOM radiological diagnostic files onto STL files from an existing prosthetic modelling program or optical scans of existing prostheses.

With the same program, it is possible to plan the virtual positioning of the Globalwin implants and corresponding abutments in accordance with the virtual mock-up of the prosthetic component.
With the GUIDED technique, turnaround times for implant-supported prosthetic restorations are considerably reduced compared with the usual standard surgical procedures, and the procedure is less invasive since there is no need to elevate a periosteal flap, with the benefit of improving the post-surgical period.

CREA-3D Guided Surgery software

CREA-3D GUIDED SURGERY SOFTWARE is a CE-certified class IIA medical device and a system that enables you to create a virtual simulation of implant position directly on your computer.
Plan the best position, identify the mandibular nerve and other important anatomical structures, plot panoramic views and sections of the bone model, view the three-dimensional model of the bone and be able to calculate its density.
The software has a user-friendly operating interface that is intuitive in sequencing and guiding the clinician to make an immediate 3D reconstruction of the anatomical regions involved.
The planning of the implants is accompanied by detailed reports and straightforward and intuitive video tutorials to guide the clinician in the use of the software. After it is planned and approved, we can request the moulding and production of the surgical guide from the BIOSAFIN CREA Digital Centre.

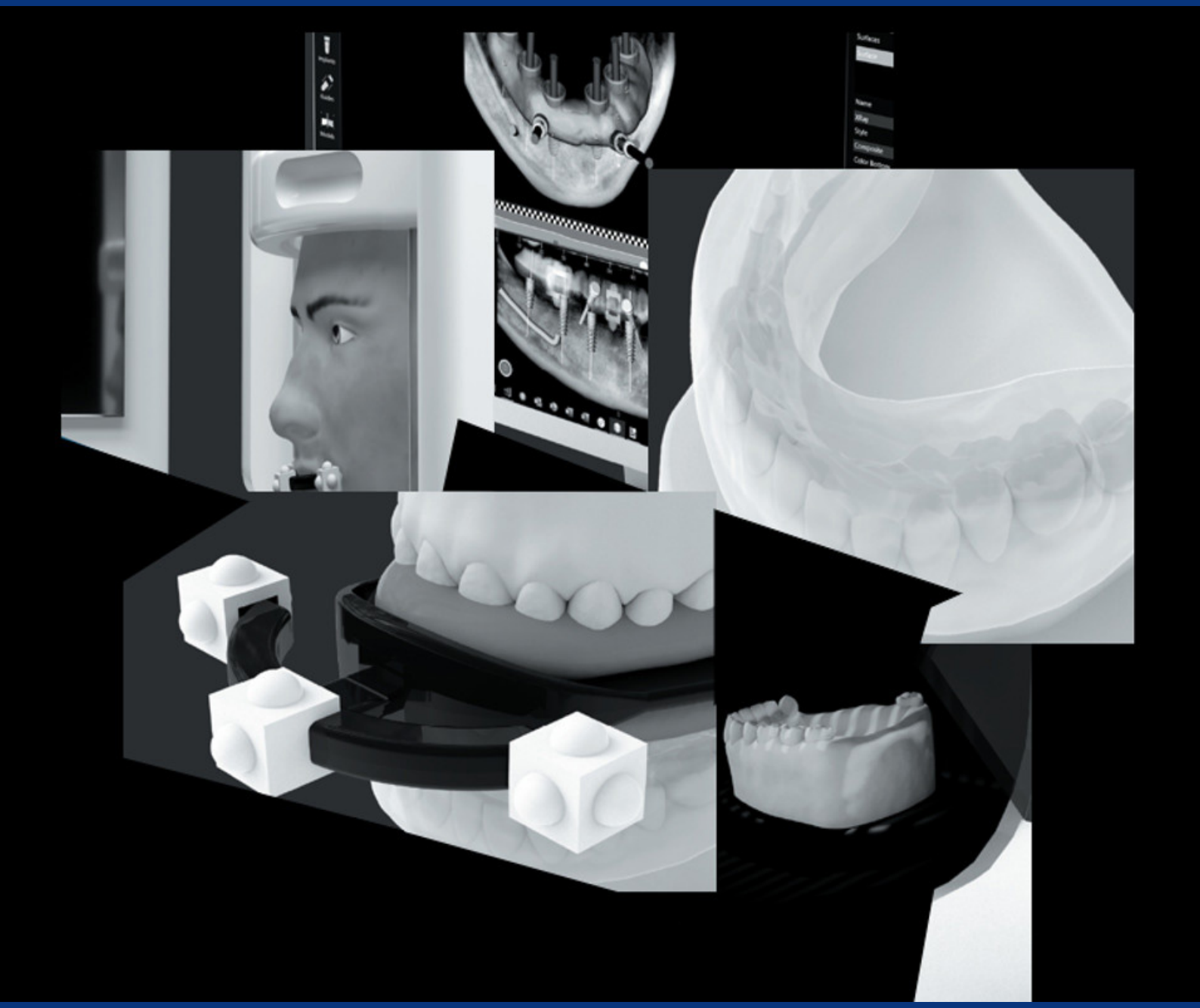
Technical requirements for use of CREA-3D Guided Surgery Software

HARDWARE REQUIREMENTS:
Intel Core i7 processor or higher recommended (or compatible processors).
RAM: minimum 8GB or more.
Video card: Accelerated 3D graphic with the driver OpenGL 3.2 or later, latest-generation of Nvidia recommended (minimum resolution 1280×1024).
Internet connection to activate the licence and perform periodic checks
Minimum Operating System: Windows 10 Pro (54 bit) Recommended Windows 10 Pro (64 Bit) CREA 3D Guided Surgery from BIOSAFIN creates 3D images from:
• CT/CBCT/MRI in standard DICOM format (re. the patient's anatomical structure)
• STL files from intra-oral or desktop scanners (re: radiographic landmark, impression model, prosthetic wax-up of the patient).

NB: hardware requirements may vary depending on ongoing progress in the technologies used and for this reason it is always recommended to contact Biosafin to find out the latest valid requirements.

SENDING OF FILES DIRECTLY VIA THE DEDICATED PORTAL
Both DICOM and standard STL files can be emailed directly to the company at ordini@biosafin.com or sent via the dedicated portal available at https://globalwin.eu/centrodigitale

PRELIMINARY INFORMATION



Operational guidelines for creating models and radiographic templates

• In cases of upper full-arch prosthetic restorations, radiographic templates should have the full palate. “Horseshoe-shaped” templates with reduced palates are not accepted.

• In the case of the production of full templates, it is necessary to create a lateral reinforcement box from transparent acrylic resin to provide greater resistance for the template on bending.

• The vestibulopalatal and vestibulolingual thickness in the anterior area should be at least 10mm and 15mm in the posterior quadrants. The palate should be 3-4mm

• In full templates the vestibular flanges must reach the fornices; in the partials, beyond the neck of the dental elements (blocking out undercuts where necessary).

• The correct amount of barium must be used: mix 20% barium sulfate + 80% transparent acrylic resin directly. Alternatively 50% Vivotac + 50% transparent acrylic resin may be used.

• Do not use coloured acrylic resins; the permitted colours are clear and white barium.

• The models must be made using Type IV scannable plaster.

• Remove the most prominent undercuts from the Master Model using only wax.

CAT acquisition protocol with Fiducial Markers - Universal Stents

Radiological Guide and Universal Stent
Always check the correct positioning of the radiological guide and the universal stent and make sure that the radiological guide is perfectly in contact with the surface of the tooth and the mucosa.

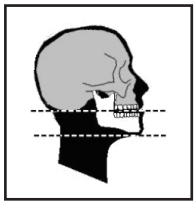
Maxilla: Scan the entire maxillary arch and the sinus regions. Ensure that all markers of the universal stent are visible on the scans.

Mandible: Scan the entire mandibular arch and the canal region. Ensure that all markers of the universal stent are visible on the scans.

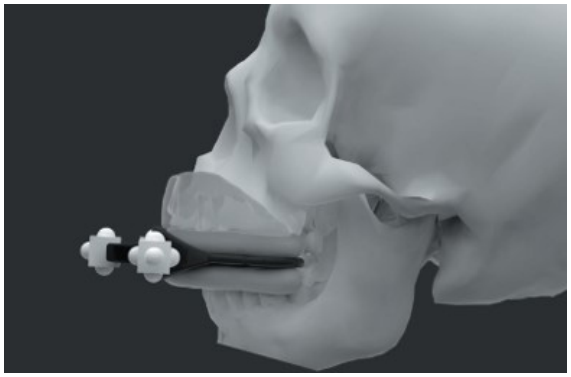
Maxilla & Mandible: In cases where the patient needs implant surgery on both arches, a single scan can be taken. Scan the entire maxillary and mandibular arch including the regions of the maxillary sinuses and mandibular canals. Ensure that all markers of the universal stent are visible on the scans.

Return the radiological guide, the universal stent and the CDROM containing only the axial images in DICOM 3.0 format to the patient at the end of the CT scan.
The axial images in DICOM 3.0 format must be saved in multi-file format.
In case of acquisition of both arches, save the axial sequence in two separate folders or on two CD-ROMs.

Post-extraction protocols: contact the Globalwin Guided Product Specialist for radiographic acquisition protocols for post-extraction cases, and they will analyse the case and provide personalised guidance.



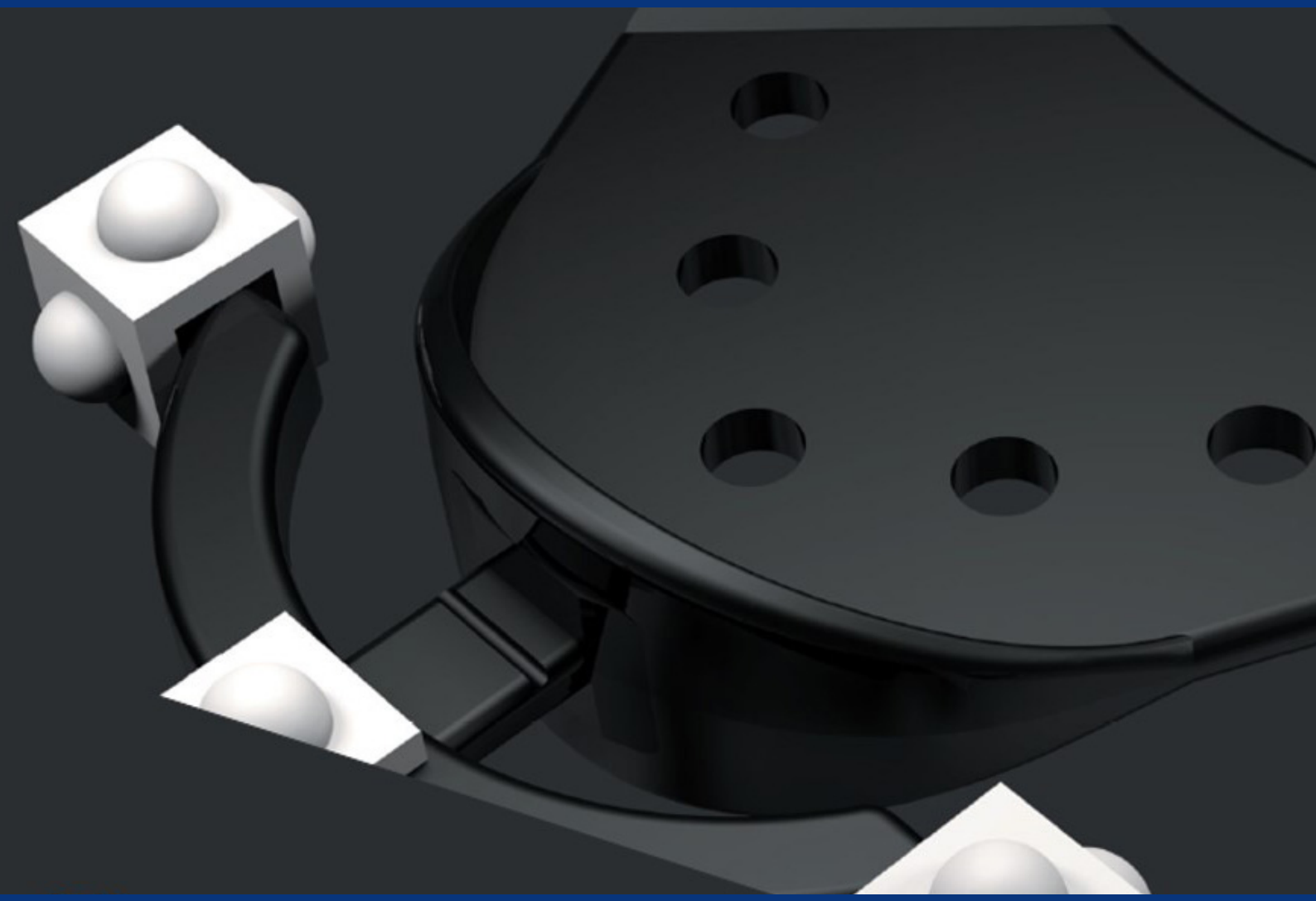
The horizontal CBCT centring line of the patient must be parallel to the masticatory plane.



Scanning parameters

Image size from 512x512 to 800x800
Gantry Tilt 0.0° Mandatory
0.25 to 1.00mm distance between the axials
DICOM 3.0 multi-file image format
No compression

STANDARD OPERATING PROTOCOL ANALOGUE PROCEDURE



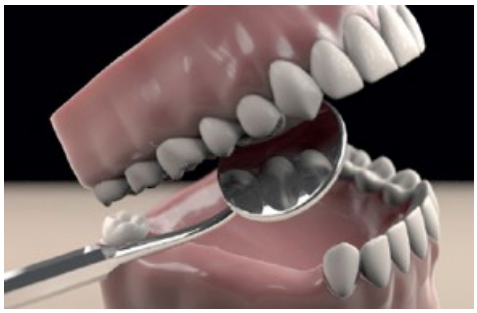
CREA-3D®
GUIDED SURGERY

1 MEDICAL HISTORY AND PRELIMINARY EXAMINATION OF THE PATIENT

Collect all patient data to allow a proper diagnosis.

Perform an accurate dental examination to assess the general state of the health of the mouth, evaluate preventive treatment and assess operating space.

A small mouth opening might prevent the technique from being performed properly.



2 IMPRESSION AND PRODUCTION OF PLASTER MODELS

Take the impressions of the two arches by using standard trays or with those for edentulous patients.

DEVELOPMENT OF PLASTER MODELS

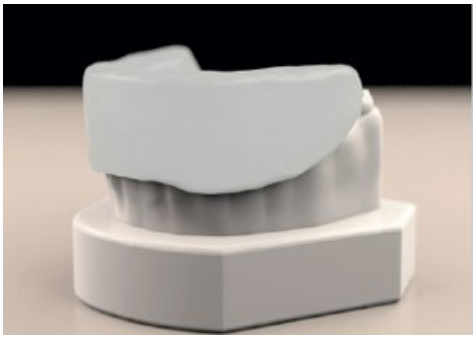
From the precision impressions, make the master models in Type IV scannable plaster, eliminating the most prominent undercuts up to the fornices and ensuring the complete absence of chipping and/or breakage.

The models should also have bevelled edges to facilitate the correct design of the surgical guide.

3 CREATION OF THE RADIOGRAPHIC TEMPLATE

Create the radiographic template carefully, respecting the construction specifications that require the use of transparent resin, ensuring a minimum thickness of 3 mm and maximum extension over the entire model.

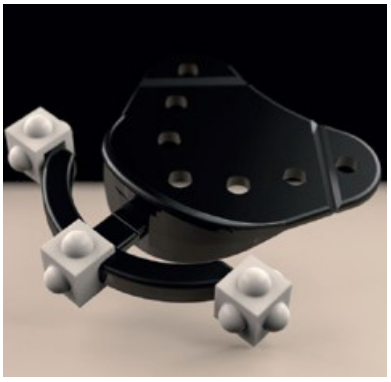
In the presence of an existing and excellent functionalised prosthesis, it is possible to make the radiographic template by duplicating it and respecting the construction specifications indicated in the previous point.



CHOOSING AND PURCHASING FIDUCIAL MARKERS - APPLYING TO THE MODEL

Acquire Fiducial Markers that are suitable for the technique in question, choosing between preformed and ready-to-use models or those that require the intervention of the dental technician to be applied to the radiographic template.

4A OPTION OF PREFORMED FIDUCIAL MARKERS - UNIVERSAL STENT 3.0

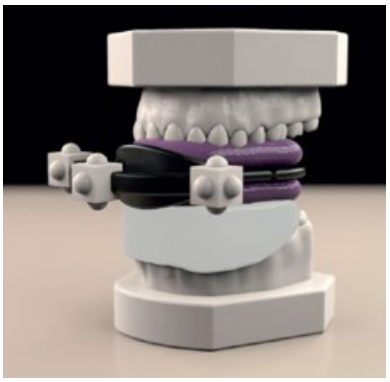


Indicated for total edentulism, extensive and bilateral edentulism, and in all cases where metal is present in the arch to be rehabilitated.

Minimum recommended FOV 10 x 10.

Apply specific radiotransparent material (e.g. polyether) to the UNIVERSAL STENT and build a suitable indicator for repositioning.

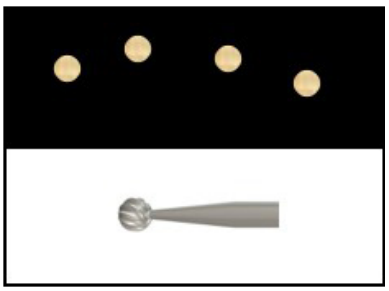
ASSEMBLY OF UNIVERSAL STENT AND RADIOGRAPHIC TEMPLATE



Place the two plaster models on the articulator and place the RADIOGRAPHIC TEMPLATE with the UNIVERSAL STENT and its REPOSITIONING INDICATOR on the arch involved in the procedure, verifying correct occlusion.

If it is necessary to scan both arches, two distinct radiological templates will be made, which will be assembled at the same time as the universal stent.

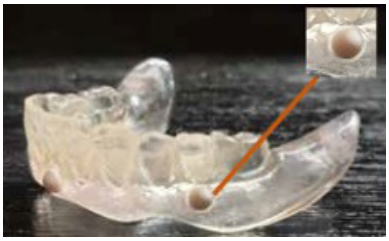
4B FIDUCIAL MARKER OPTION FOR MANUAL APPLICATIONS - RADIOPAQUE SPHERES



Indicated for total edentulism, extensive and bilateral edentulism, where there is no metal in the arch to be rehabilitated.

Patients who have problems tolerating fiducial markers.

Minimum recommended FOV 10 x 10.



On the flanges of the vestibular area (minimum 3) and palatal area (minimum 2) of the radiographic template, with a 3mm Ø round bur, make staggered notches for the quartz balls to be bonded and attached up to their equator.

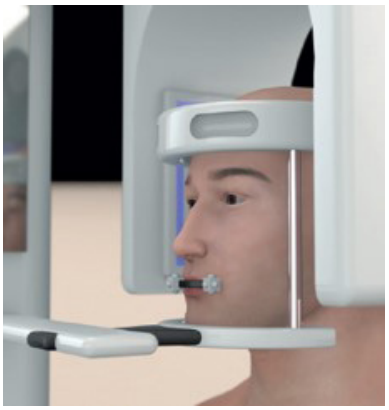
Use specific radiotransparent material (e.g. polyether) to build a suitable distancer/indicator for repositioning.

RADIOGRAPHIC TEMPLATE ASSEMBLY WITH QUARTZ SPHERES

Place the two plaster models on the articulator and place the RADIOGRAPHIC TEMPLATE with radiopaque spheres and its REPOSITIONING DISTANCER/INDICATOR on the arch involved in the procedure, verifying correct occlusion.

If it is necessary to scan both arches, two distinct radiological templates will be made, which will be assembled at the same time as the repositioning distancer/indicator.

5 CT SCANNING - PRELIMINARY CHECK



Place the radiographic template, fiducial markers (option 4A or 4B) and corresponding repositioning indicator in the patient's mouth and check the correspondence in relation to what is obtained on the articulator.

CT ACQUISITION

If suitable equipment is available, perform the CT or cone beam examination directly in the surgery after placing the radiographic template, the chosen fiducial marker (between option 4A or 4B) and the repositioning indicator in the patient's mouth.

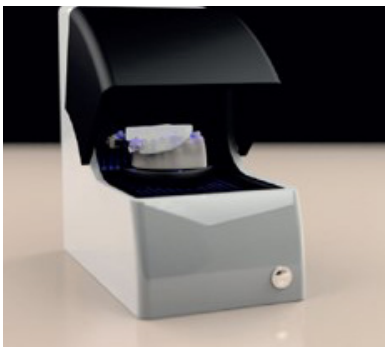
Alternatively, send the patient to an imaging centre with the appropriate prescription containing instructions for the radiologist and with the radiographic template, fiducial markers chosen and repositioning indicator.

6 OPTICAL SCANNING

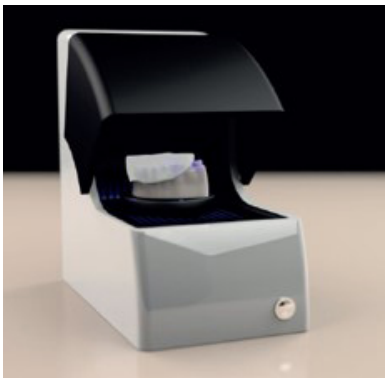
If the dental practice or laboratory used by the clinician is equipped with an optical scanner, it can directly perform the following three scans and generate the corresponding files in STL format.

Otherwise, the plaster models, the selected fiducial marker and the repositioning indicator can be physically sent to the BIOSAFIN CREA DIGITAL CENTRE, which will directly perform the three scans and generate the STL files, which will be necessary for implant planning together with the cone beam.

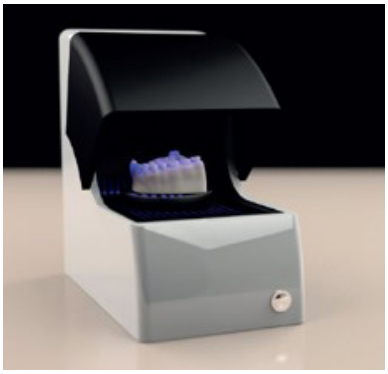
SCAN A: Scan the plaster model + radiographic template + Universal Stent positioned correctly (If using option 4B with radiopaque spheres, this initial scan is not necessary).



SCAN B: Scan the plaster model + radiographic template in place. This scan is always necessary even if you use option 4B with radiopaque spheres.



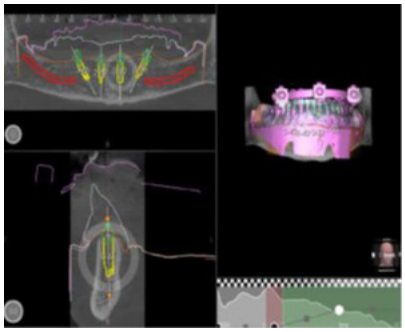
SCAN C: Scan the plaster model alone.



NB: all scans must be taken and oriented with the same axis of reference.

7 VIRTUAL PATIENT CREATION AND IMPLANT PLANNING WITH CREA-3D GUIDED SURGERY SOFTWARE

Create the virtual patient after having transferred the Cone Beam file and the STL file from the optical scanning into CREA 3D Guided Surgery.
Start the 3D design, defining the correct positioning of the implants (see paragraph on design)



STANDARD OPERATING PROTOCOL DIGITAL PROCEDURE

(ONLY FOR PARTIAL EDENTULOUS CASES)

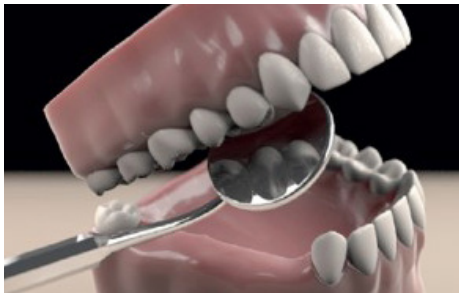
CREA-3D®
GUIDED SURGERY

1 MEDICAL HISTORY AND PRELIMINARY EXAMINATION OF THE PATIENT

Collect all patient data to allow a proper diagnosis.

Perform an accurate dental examination to assess the general state of the health of the mouth, evaluate preventive treatment and assess operating space.

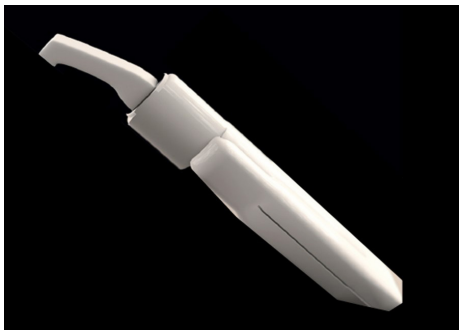
A small mouth opening might prevent the technique from being performed properly.



2 INTRA-ORAL SCANNING

The digital impression can be taken with an intra-oral scanner, but only in cases of partial edentulism and by taking an adequate scan of the soft tissues and tooth surfaces.

There is no need to use the universal stent when taking the images with an intra-oral scanner.

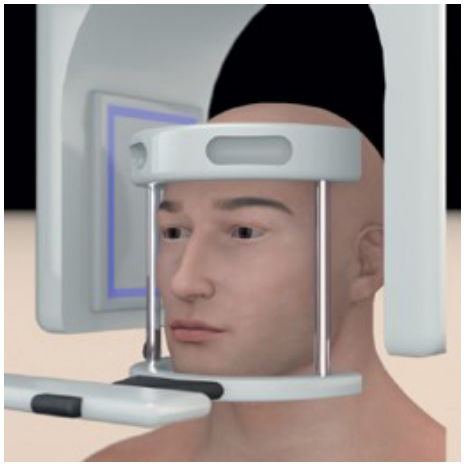


3 CREATION OF THE SEPARATOR FOR CT SCANNING

Create a special separator or use commercially available separators made with radiotransparent materials.

4 CT ACQUISITION

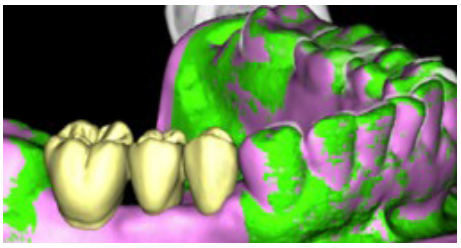
Perform the CT scan, acquiring the relevant images for the arch in question and distancing the two arches by placing the separator between them to avoid occlusion.



5 VIRTUAL CREATION OF THE DIAGNOSTIC WAX-UP

Dental practices or dental laboratories equipped with CAD software digitally create the diagnostic wax-up with the morphology of the missing teeth and perfect occlusion from the STL file generated by the intra-oral scan.

If you do not have CAD software, this can be requested from the Biosafin CREA Digital Centre.

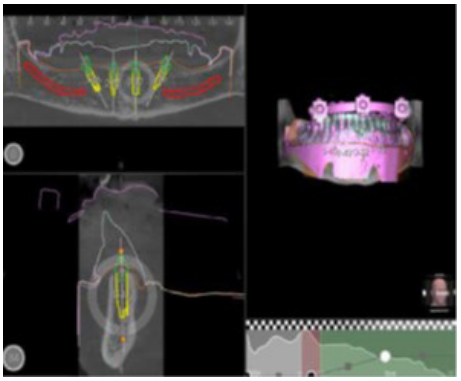


NB: all scans must be taken and oriented with the same axis of reference.

6 VIRTUAL PATIENT CREATION AND IMPLANT PLANNING WITH CREA 3D GUIDED SURGERY SOFTWARE

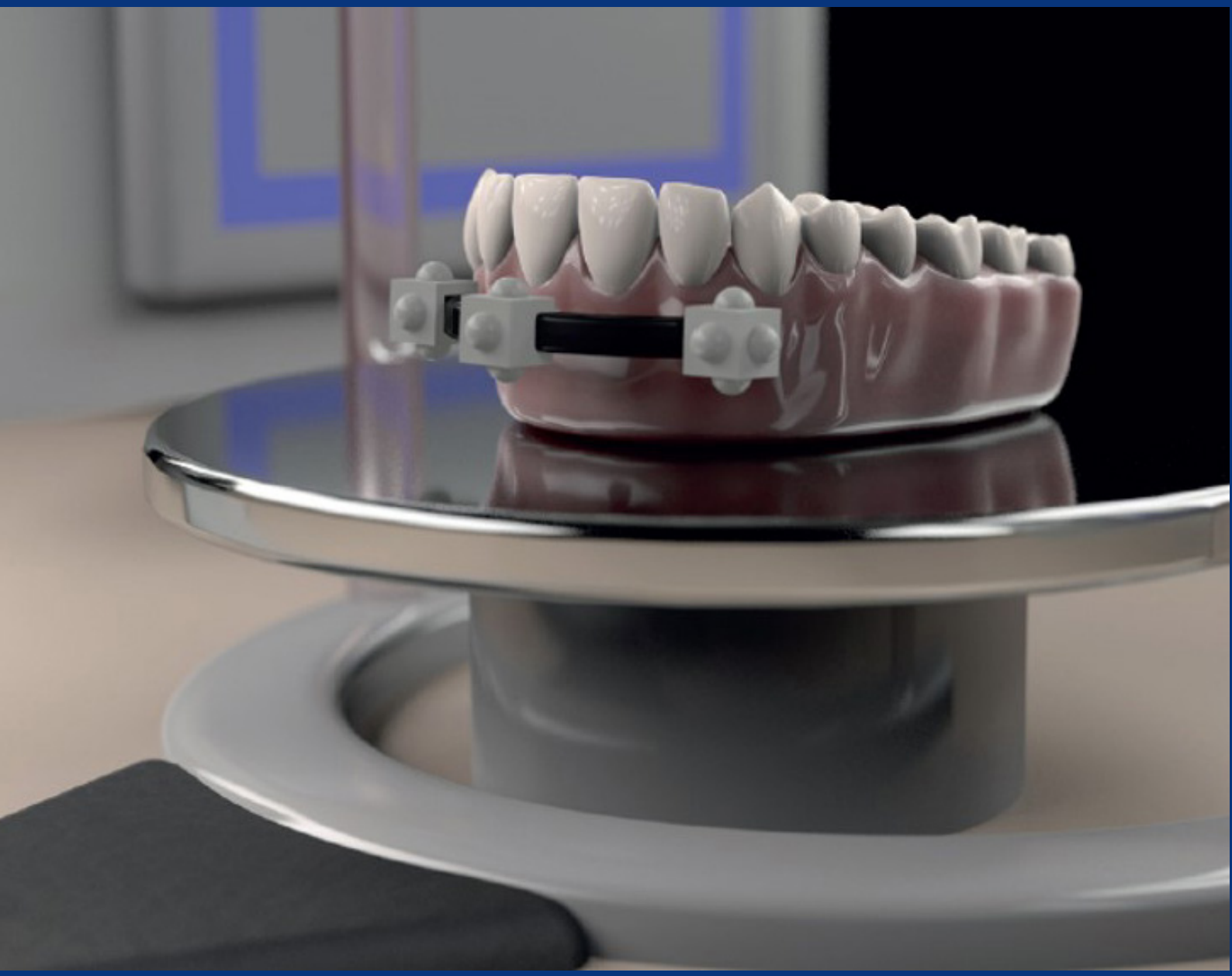
Import the STL files generated by the intra-oral scanning of the CAD diagnostic wax-up and the DICOM data of the CAT scan into the CREA 3D GUIDED SURGERY software and perform the alignment after creating the Virtual Patient.

Start the 3D design, defining the correct positioning of the implants (see paragraph on design)



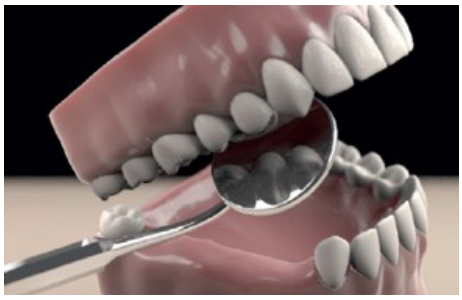
DOUBLE-SCANNING PROTOCOL

(ONLY FOR FULLY EDENTULOUS CASES)



CREA-3D®
GUIDED SURGERY

1 MEDICAL HISTORY AND PRELIMINARY EXAMINATION OF THE PATIENT

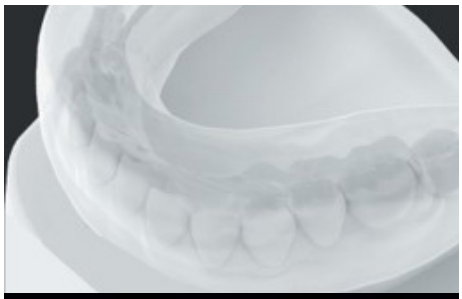


Collect all patient data to allow a proper diagnosis.

Perform an accurate dental examination to assess the general state of the health of the mouth, evaluate preventive treatment and assess operating space.

A small mouth opening might prevent the technique from being performed properly.

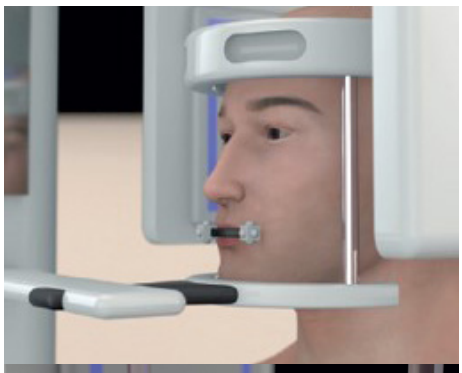
2 CREATION OF THE RADIOGRAPHIC TEMPLATE

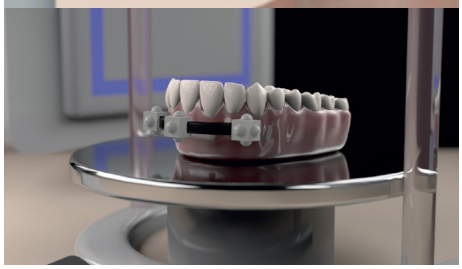


Create the radiographic template carefully, respecting the construction specifications that require the use of transparent resin, ensuring a minimum thickness of 3 mm and maximum extension over the entire model.

If the patient already has a full prosthesis that suits the treatment plan, it can be used as a radiographic template, unless it contains radiopaque or metallic material that could affect the success of the scan.

3 SCANNING





The double scanning protocol involves two alternative approaches and both involve only 2 scans.

OPTION 1 - FIDUCIAL MARKER - UNIVERSAL STENT:

1st SCAN

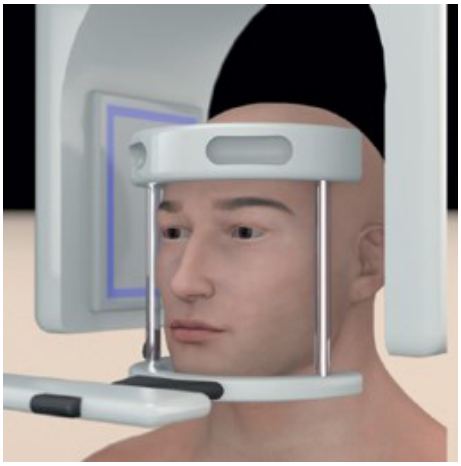
Position the previously prepared radiographic template in the patient's mouth and fit the universal stent properly.

Perform the CBCT scan internally in the practice if equipped with a CT or cone beam, or externally by sending the patient at to an imaging centre with the appropriate instructions.

2nd SCAN

Correctly position the universal stent onto the radiographic template and take a second CT scan, resting them on a NON-radiopaque support.

OPTION 2 - FIDUCIAL MARKER - RADIOPAQUE SPHERES:



1st SCAN

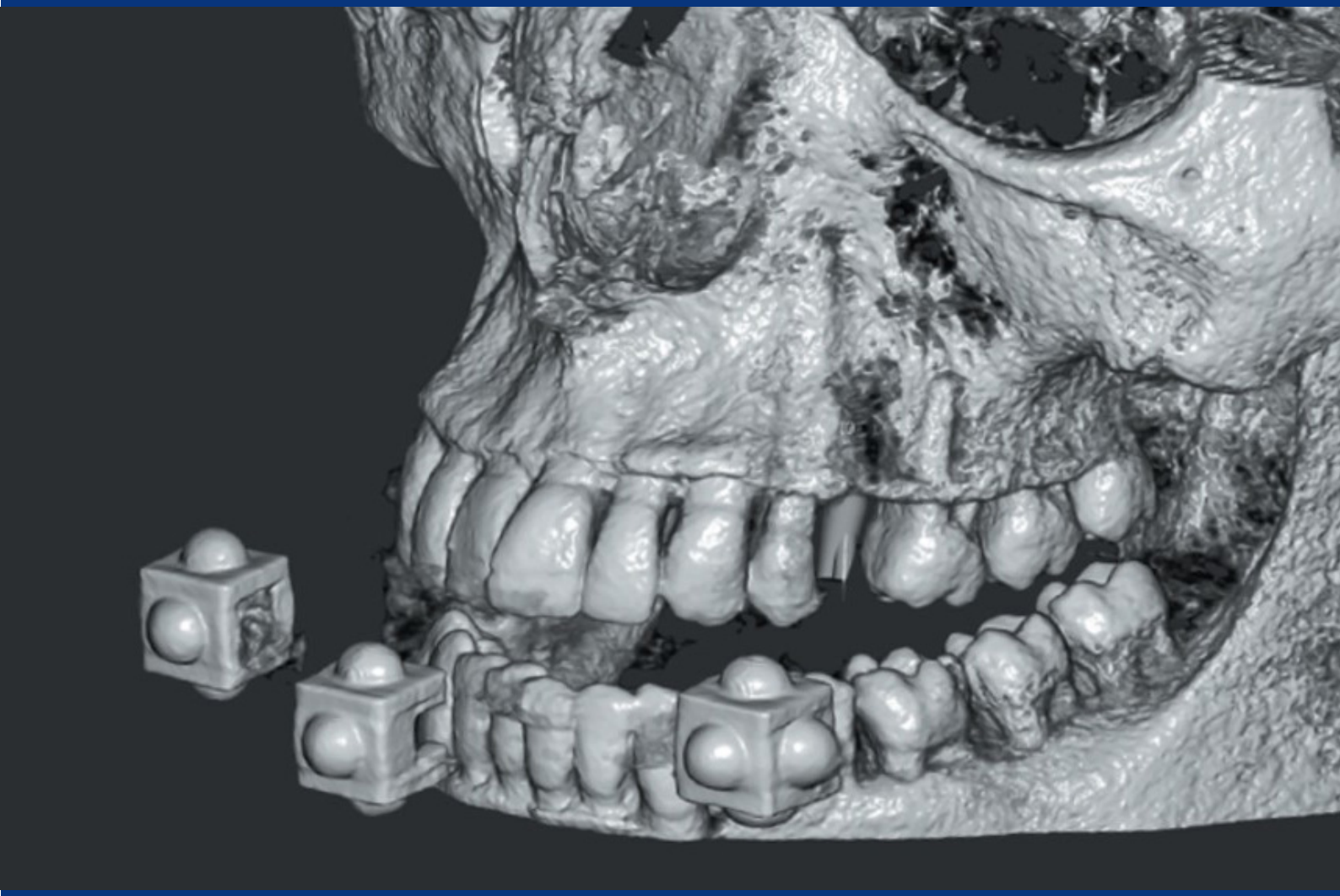
Position the previously prepared radiographic template in the patient's mouth and fit the occlusal separator properly.

Perform the CBCT scan internally if equipped with a CT or cone beam, or externally by sending the patient at to an imaging centre with the appropriate instructions.

2nd SCAN

Perform the second CT scan of the radiographic template alone, including radiopaque spheres, resting it on a NON-radiopaque support.

MATCHING AND CREATION OF VIRTUAL PATIENT



CREA-3D®
GUIDED SURGERY

The virtual patient can be created by the clinician in their own surgery if they own the CREA 3D Guided Surgery software (virtual planning of implant placement) or it can be requested from the BIOSAFIN CREA Digital Centre as an additional service.

The CREA-3D software works with any device that generates DICOM files and allows the anatomical regions involved in the surgical and prosthetic rehabilitation to be reconstructed immediately in 3D.

To create the Virtual Patient it will be necessary to first import the CBCT file in DICOM 3 Axial format into the CREA 3D Guided Surgery software **(please note: the radiologist normally exports the exam in Viewer format)** and the other STL files generated by the previously performed scans (in relevant cases, also the diagnostic wax-up files) depending on the type of protocol adopted.

PLASTER MODEL PROTOCOL

• CT - STL (Universal Stent + model + radiographic template)

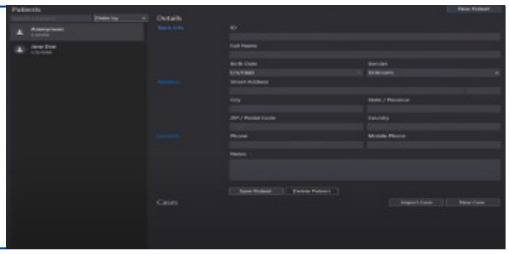
DIGITAL PROTOCOL

• CT- STL arch (in the case of intra-oral scanning)- STL diagnostic wax-up

DOUBLE-SCANNING PROTOCOL

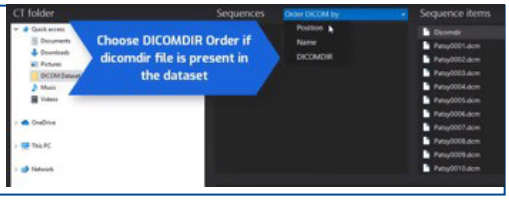
• CT (patient + prosthesis + Universal Stent) - CT (prosthesis + Universal Stent)

Launch software and create a new patient by filling in all patient information and personal details fields for the patient.



Click on ‘create new case’ and then click on ‘import DICOM’ to open the window and select the relevant file

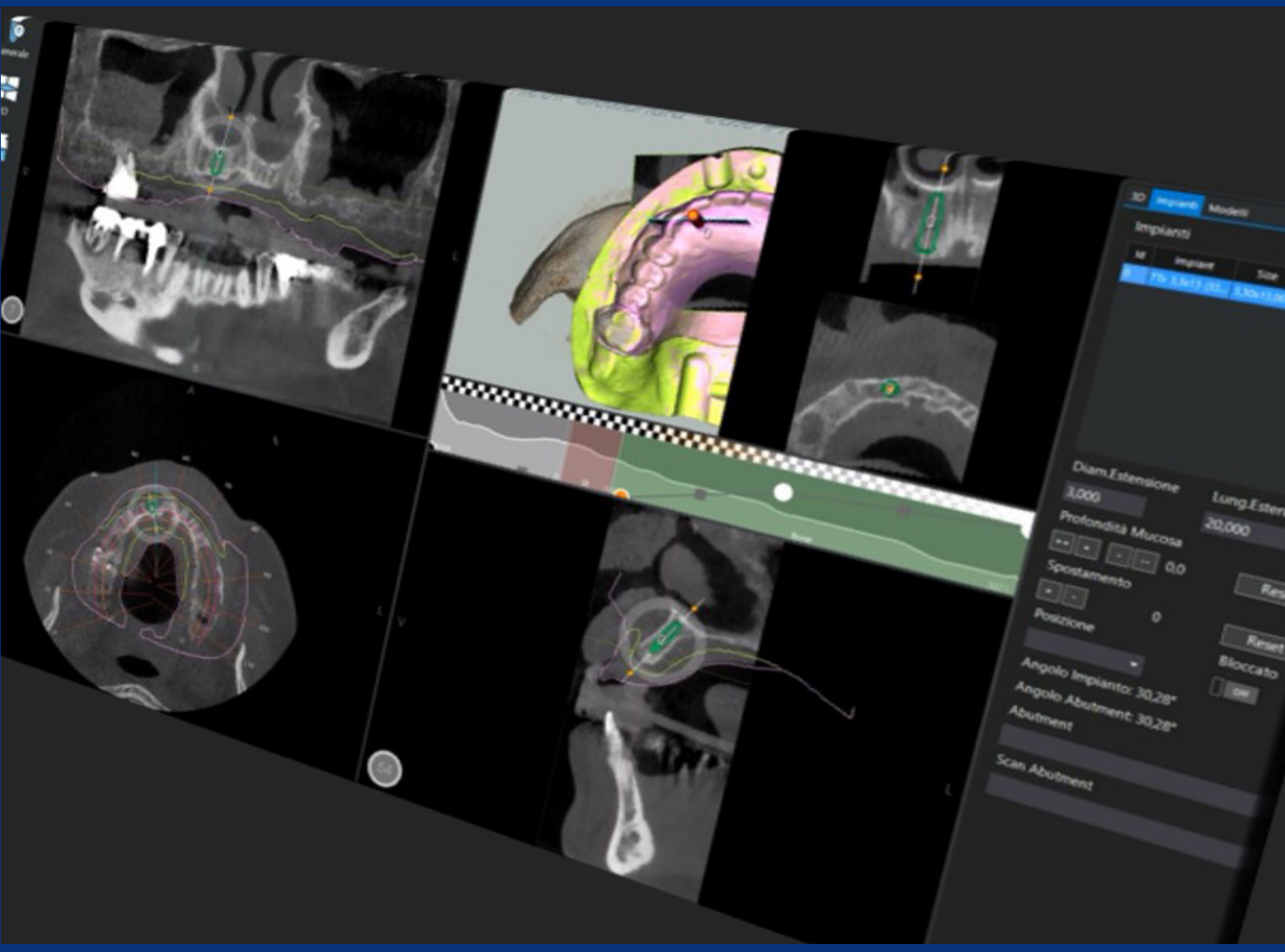
Select the DICOM folder and in the dataset window, select DICOMDIR



Import the case, confirm and adjust the axial view.

Once the DICOM files has loaded and been adjusted, return to the file selection menu and click on STL Dataset folder to import the STL files for the previously performed scans uploaded onto the computer.
Import and perform matching.

SOFTWARE-GUIDED PLANNING

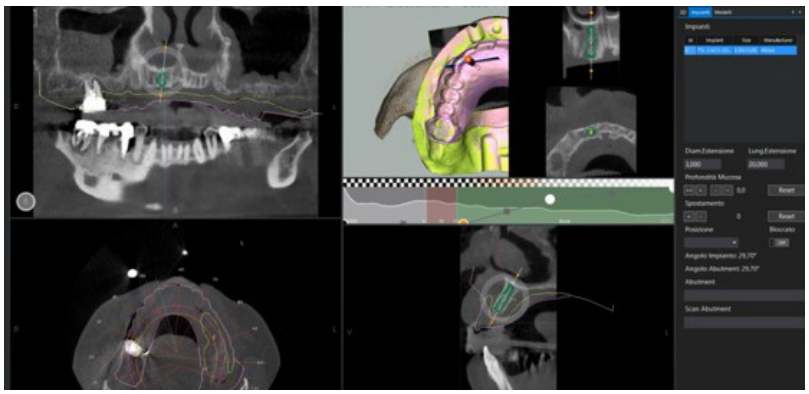


After the initial 3D assessment of the condition of the bone and mucosa available and having identified and highlighted any critical points to consider, proceed to plan the optimum position for the implants. To carry out the planning, select the type, diameter and length of the implant chosen for the procedure from the library and position it virtually in the area to be rehabilitated.

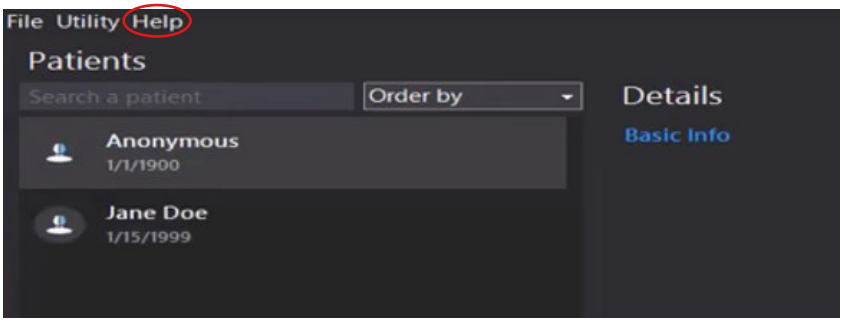
The correct positioning of the implant must always start from a careful and accurate prosthetic restoration design and requires adequate bone availability to promote healing and osseointegration.

Implant planning with 3D Guided Surgery Software makes it possible to also virtually simulate the placement of the prosthetic abutment and evaluate aspects such as favourable and more aesthetic prosthetic accesses or establish the ideal prosthetic abutment in advance, according to the available mucosa.

Implant planning in 3D allows invasion of previously highlighted critical areas to be avoided with the aid of the virtual tools in the software and thus enables interventions performed to always be safe and predictable.



For more details on the use and the functions of the software, see the Help/Help area of the menu (see image below)



SOFTWARE AND SERVICES

CREA 3D Viewer Guided Surgery Software (Single-user)	M03013DML-CRE-V
CREA 3D Planning Guided Surgery Software (Single-user)	M03013DML-CRE
CREA 3D Planning Guided Surgery Software and Design 3D* Guide Module (Single-user)	M03013DML-CRE + M03013DML-CRE-GD
Design 3D Guide Module* (Single-user) (Reserved for owners of CREA 3D Planning who wish to extend software functionality)	M03013DML-CRE-GD
Virtual Patient creation	C3DVP
Pre-planning	C3DOS
Pre-planning/Project Review CREA centre	C3DOSP
Pre-planning/Project Review Opinion Leader	C3SOSOL
Optical Scanning of Models + Export in STL format	C3DES

GLOBALWIN GUIDED SURGERY KIT

CREA-3D®
GUIDED SURGERY

GUIDED SURGERY KIT INSTRUMENTS

Item Code	Description
STD0G	Mucotome for guided surgery
STD16G	6mm-long Pilot drill for guided surgery
DSD12	12mm-long Short manual screwdriver for torque wrench
DSD16	16mm-long Short manual screwdriver for torque wrench
HSD20	20mm-long Contra-angle screwdriver
HMG	Contra-angle adaptor for Guided Surgery with MTRG series instruments
ADEXG	Extension for Guided Surgery for use with the ADMTRG adaptor
STD28G	Drill for guided surgery Ø: 2.2/2.6 mm - L: 8 mm
STD210G	Drill for guided surgery Ø: 2.2/2.6 mm - L: 10 mm
STD2115G	Drill for guided surgery Ø: 2.2/2.6 mm - L: 11.5 mm
STD213G	Drill for guided surgery Ø: 2.2/2.6 mm - L: 13 mm
STD215G	Drill for guided surgery Ø: 2.2/2.6 mm - L: 15 mm
STD38G	Drill for guided surgery Ø: 2.6/3.0 mm - L: 8 mm
STD310G	Drill for guided surgery Ø: 2.6/3.0 mm - L: 10 mm
STD3115G	Drill for guided surgery Ø: 2.6/3.0 mm - L: 11.5 mm
STD313G	Drill for guided surgery Ø: 2.6/3.0 mm - L: 13 mm
STD315G	Drill for guided surgery Ø: 2.6/3.0 mm - L: 15 mm
STD48G	Drill for guided surgery Ø: 3.0/3.4 mm - L: 8 mm
STD410G	Drill for guided surgery Ø: 3.0/3.4 mm - L: 10 mm
STD4115G	Drill for guided surgery Ø: 3.0/3.4 mm - L: 11.5 mm
STD413G	Drill for guided surgery Ø: 3.0/3.4 mm - L: 13 mm
STD415G	Drill for guided surgery Ø: 3.0/3.4 mm - L: 15 mm
STD58G	Drill for guided surgery Ø: 3.4/3.8 mm - L: 8 mm
STD510G	Drill for guided surgery Ø: 3.4/3.8 mm - L: 10 mm
STD5115G	Drill for guided surgery Ø: 3.4/3.8 mm - L: 11.5 mm
STD513G	Drill for guided surgery Ø: 3.4/3.8 mm - L: 13 mm
STD515G	Drill for guided surgery Ø: 3.4/3.8 mm - L: 15 mm
STD68G	Drill for guided surgery Ø: 3.8/4.2 mm - L: 8 mm
STD610G	Drill for guided surgery Ø: 3.8/4.2 mm - L: 10 mm
STD6115G	Drill for guided surgery Ø: 3.8/4.2 mm - L: 11.5 mm
STD613G	Drill for guided surgery Ø: 3.8/4.2 mm - L: 13 mm
STD615G	Drill for guided surgery Ø: 3.8/4.2 mm - L: 15 mm
BP35G	Guided Cortical Drill Ø 3.40
BP37G	Guided Cortical Drill Ø 3.65
BP43G	Guided Cortical Drill Ø 4.20
BP50G	Guided Cortical Drill Ø 4.90
STDPG	1.5 mm-long Pin drill for guided surgery
PGG	GLOBALWIN® Surgical stent fastening pin
DTW75	Torque wrench 10-75 Ncm
ADMTRG	DTW75 torque wrench adaptor for guided surgery
MMTRG	Mounter for guided surgery
GWGST	GLOBALWIN® Surgical tray for guided surgery

MISCELLANEOUS ACCESSORIES AND INSTRUMENTS

Item Code	Description
BGG50	GLOBALWIN® 5.0 mm Guided bushing
MMTRSG	Mounter for Guided Slim Connection

CBCT ANATOMICAL LANDMARKS

SGG30	Landmark spheres for Guided Surgery (3.0 mm)
US003-01	Universal stent pack of 1 (Anatomical landmarks for CBCT)
US003-03	Universal stent pack of 3 (Anatomical landmarks for CBCT)
US003-05	Universal stent pack of 5 (Anatomical landmarks for CBCT)
US003-10	Universal stent pack of 10 (Anatomical landmarks for CBCT)

SURGICAL STENTS

GGS01I	1 implant - Male Surgical Stent Lower - Bushings included
GGS01S	1 implant - Male Surgical Stent Upper - Bushings included
GGS02I	2 implant - Male Surgical Stent Lower - Bushings included
GGS02S	2 implant - Male Surgical Stent Upper - Bushings included
GGS03I	3 implant - Male Surgical Stent Lower - Bushings included
GGS03S	3 implant - Male Surgical Stent Upper - Bushings included
GGS04I	4 implant - Male Surgical Stent Lower - Bushings included
GGS04S	4 implant - Male Surgical Stent Upper - Bushings included
GGS05I	5 implant - Male Surgical Stent Lower - Bushings included
GGS05S	5 implant - Male Surgical Stent Upper - Bushings included
GGS06I	6 implant - Male Surgical Stent Lower - Bushings included
GGS06S	6 implant - Male Surgical Stent Upper - Bushings included
GGS07I	7 implant - Male Surgical Stent Lower - Bushings included
GGS07S	7 implant - Male Surgical Stent Upper - Bushings included
GGS08I	8 implant - Male Surgical Stent Lower - Bushings included
GGS08S	8 implant - Male Surgical Stent Upper - Bushings included
GGS17I	Additional Surgical Stent - Lower Bushings included
GGS17S	Additional Surgical Stent - Upper Bushings included

Surgical instruments and devices for implantology are supplied non-sterile. They must be disinfected and sterilised before use, as well as any before any subsequent use, after being washed thoroughly.

CLINICAL PROCEDURE AND PROTOCOLS

IMPORTANT INDICATIONS FOR GLOBALWIN IMPLANTS AND GUIDED SURGERY

Implant model	Suitability for guided surgery:	Guided Technique possible for implants up to diameter	Guided Technique possible for implants up to length	Clinical indication
Globalwin	Yes	3.75 mm	15 mm	Bone Level or Subcrestal
Globalwin	Yes	4.3 mm	15 mm	Bone Level or Subcrestal
Globalwin Slim	Yes	3.3 mm	15 mm	Bone Level or Subcrestal
Globalwin Slim	Yes	2.9 mm	15 mm	Bone Level or Subcrestal

GLOBALWIN SLIM IMPLANTS SURGICAL PROTOCOLS

Guided drilling protocol			
Implant diameter	Implant length	bone D1-D2-D4	Implant Driver
2.9	10 mm	2.2/2.6 (10-mm long drill)	MMTRSG
2.9	11.5 mm	2.2/2.6 (11.5-mm long drill)	MMTRSG
2.9	13 mm	2.2/2.6 (13-mm long drill)	MMTRSG
2.9	15 mm	2.2/2.6 (15-mm long drill)	MMTRSG

Implant diameter	Implant length	bone D2 - D4	bone D1	Implant Driver
3.3	10 mm	2.2/2.6 (10-mm long drill)	Cortical Drill BP35G	MMTRSG
3.3	11.5 mm	2.2/2.6 (11.5-mm long drill)	Cortical Drill BP35G	MMTRSG
3.3	13 mm	2.2/2.6 (13-mm long drill)	Cortical Drill BP35G	MMTRSG
3.3	15 mm	2.2/2.6 (15-mm long drill)	Cortical Drill BP35G	MMTRSG

GLOBALWIN GUIDED SURGERY

Guided drilling protocol					
Implant diameter	Implant length	bone D2 - D4		bone D1	Implant Driver
3.75	8 mm	2.2/2.6 (8-mm long drill)	Cortical Drill BP35G	Cortical Drill BP37G	MMTRG
3.75	10 mm	2.2/2.6 (10-mm long drill)	2.6/3.0 (8-mm long drill)	Cortical Drill BP37G	MMTRG
3.76	11.5 mm	2.2/2.6 (11.5-mm long drill)	2.6/3.0 (8-mm long drill)	Cortical Drill BP37G	MMTRG
3.77	13 mm	2.2/2.6 (13-mm long drill)	2.6/3.0 (10-mm long drill)	Cortical Drill BP37G	MMTRG
3.78	15 mm	2.2/2.6 (15-mm long drill)	2.6/3.0 (11.5-mm long drill)	Cortical Drill BP37G	MMTRG

Implant diameter	Implant length	bone D2 - D4				bone D1	Implant Driver
4.30	8 mm	2.2/2.6 (8-mm long drill)	2.6/3.0 (8-mm long drill)	Cortical Drill BP35G		Cortical Drill BP37G	MMTRG
4.30	10 mm	2.2/2.6 (10-mm long drill)	2.6/3.0 (10-mm long drill)	Cortical Drill BP35G	Cortical Drill BP37G	Cortical Drill BP43G	MMTRG
4.30	11.5 mm	2.2/2.6 (11.5-mm long drill)	2.6/3.0 (11.5-mm long drill)	Cortical Drill BP35G	Cortical Drill BP37G	Cortical Drill BP43G	MMTRG
4.30	13 mm	2.2/2.6 (13-mm long drill)	2.6/3.0 (13-mm long drill)	Cortical Drill BP35G	Cortical Drill BP37G	Cortical Drill BP43G	MMTRG
4.30	15 mm	2.2/2.6 (15-mm long drill)	2.6/3.0 (15-mm long drill)	Cortical Drill BP35G	Cortical Drill BP37G	Cortical Drill BP43G	MMTRG

The summary table shows the last drill to be used according to the type of implant and in relation to the type of bone found and whether it is necessary to use the cortical drill.

IMPLANT PROCEDURE

- Construction of the surgical guide positioning indicator
- Anaesthesia
- Mucotomy and marking tool
- Preparation of the ridge
- Drilling steps
- Placement of implant
- Removal of transporter and fastening systems

INDICATOROF THE SURGICAL GUIDE POSITIONING

Place the models on an articulator with the SURGICAL GUIDE received from the CREA Digital Centre and create a new positioning indicator to be used for correct positioning of it in the mouth (essential for the correct positioning of the surgical guide in fully edentulous patients).

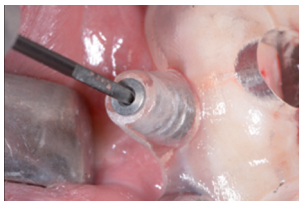
ANAESTHESIA

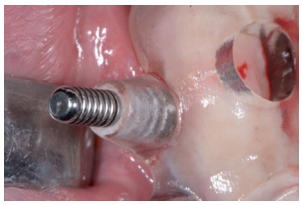
Implant surgery involves administration of a local infiltration anaesthetic locoregionally at the implant insertion site.

Infiltration around the palatal area too ensures a sound and complete anaesthetic action throughout the procedure. Make sure that no areas of submucosal accumulation of anaesthetic are created, since they could cause distension of the mucosa and thereby disrupt the proper fitting of the surgical guide.

SURGICAL GUIDE FITTING

With the aid of the previously prepared positioning indicator, place the surgical guide in the affected area and make sure that it sits stably and does not tilt.





FASTENING PIN PLACEMENT

Once the correct position of the surgical guide has been checked, it is fixed in place using the using the relevant fastening pin.

MUCOTOMY

Perform mucotomy with the aid of the specific mucotome (code STD0G).
With the micromotor stopped, first insert the mucotome into the surgical guide bushing. Only after this can you proceed to start up the mechanical rotation.
Completely remove the part of the mucosa that has been cut out and make sure that no residue is left in the alveolus.

INITIAL PREPARATION

Start preparation by inserting the corticotomy drill into the bushing of the surgical guide.

When contact with the bone is felt, start the micromotor and start the drilling stage at a low speed, between 150 and 400 revolutions/minute, depending on the patient's bone quality.

DEPTH PREPARATION

To prepare the desired depth fully, each of the drills D 2.2 - D 2.6 must be passed through in stages up to the one corresponding to the length of the implant to be inserted. The example in Figure 1 shows the preparation of depth of a 11.5mm long Globalwin implant, in which first 8mm long drills are passed through, and then 10mm and finally 11.5mm drills.

The drills must always be inserted into the bushing with the micromotor off until contact with the bone is felt and starting the motor to begin drilling only afterwards, at a speed between 150 and 400 revolutions/minute according to the bone quality of the patient.

Failure to follow these instructions could result in damage to the bushing and the surgical guide, affecting the surgery.

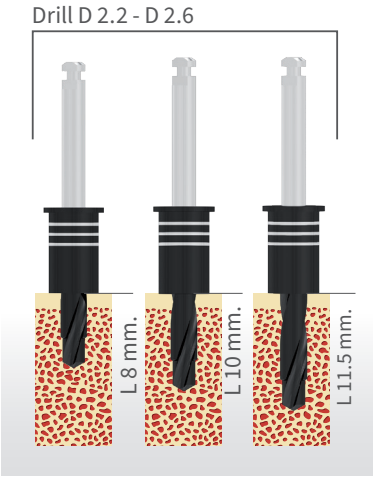


Fig. 1 (example of 11.5mm-long Globalwin implant depth preparation)

WIDTH PREPARATION

Continue to prepare the implant site using the larger diameter drills (refer to the Globalwin implant protocol table), maintaining the criterion for the usage in stages (for the length) that requires that you start with the 8mm-long drill up to that corresponding to the length of the implant to be inserted (see example in Figure 2). Always remember to insert the drills into the bushings with the motor off until you feel the contact with the bone and before starting the micromotor.

Set the drilling speed to between 150 and 400 revolutions/minute according to the bone quality of the patient

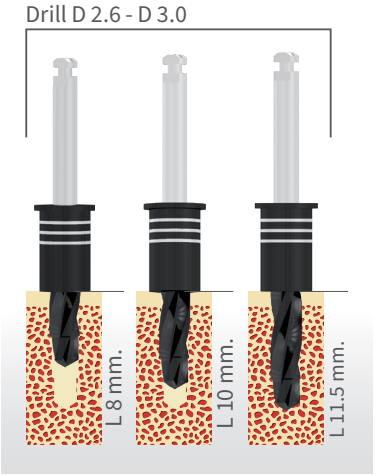


Fig. 2 (example of 11mm-long Globalwin implant width preparation)

CORTICAL PREPARATION

Complete the preparation of the implant site using the last drill indicated in the Globalwin surgical protocols.

Where the bone is particularly hard, Globalwin protocols require the use of cortical drills (see example in Figure 3).

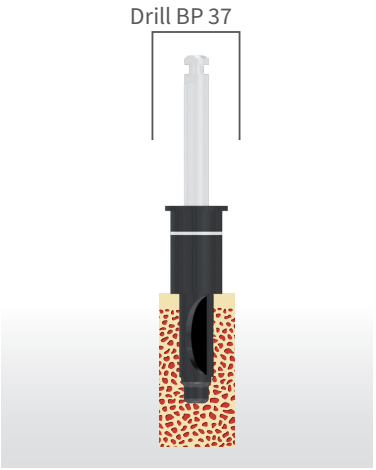


Fig. 3 (example of preparation of 3.8mm-diameter implant with cortical drill)

IMPLANT INSERTION

The placement of the implant involves the following steps:

1. Open the outer packaging first, then remove and open the inner blister and drop the sterile ampoule onto the surgical tray without touching it.

2. In completely sterile conditions, open the ampoule and screw the guided mounter specific to the type of connection onto the selected implant, as per the following chart:

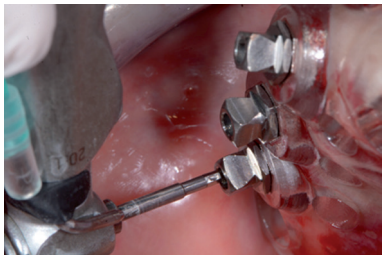
3. Remove the implant from the ampoule and place it in the prepared implant site and through the bushing of the surgical guide. This initial implant positioning operation can be performed manually with the use of the special adapter, or directly with the contra-angle of the micromotor, or with the surgical ratchet.

4. Continue and complete the insertion of the implant with the aid of the contra-angle or with the surgical ratchet and bring it into position up to the end by matching the hex on the mounter with the hex of the surgical guide bushing (see Figure 4). To obtain an ideal coupling, it is advisable to complete insertion with the ratchet.

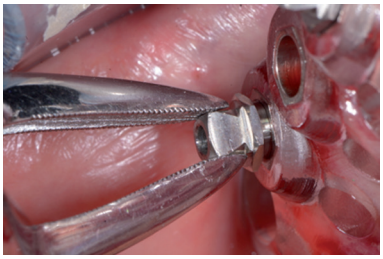
Fig. 4 Coupling of mounter and bushing hex.

REMOVAL OF THE SURGICAL GUIDE

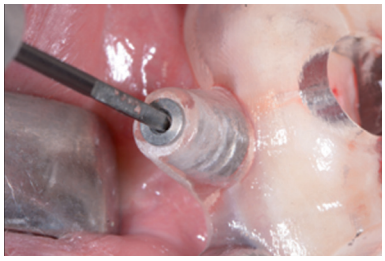
Once the implants have been inserted, remove the surgical guide by performing the following operations in order:



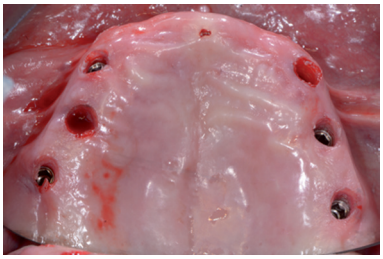
1. Unscrew all mounter-implant connection screws



2. Remove all mounters from the bushings of the surgical guide



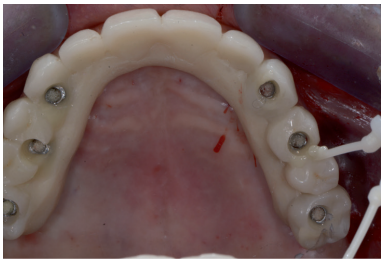
3. Remove fastening pins



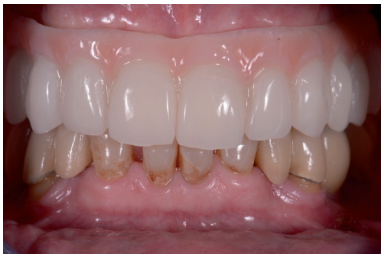
4. Remove the surgical guide

5. Take a post-intervention control x-ray

POSITIONING OF THE PROVISIONAL



Position and use the prosthetic components necessary to attach the provisional prepared previously by the dental technician if this has been planned during the virtual planning stage, verifying correct occlusion and respecting the rules on reduced functional load.



Otherwise, place the implant cover screws (in the cap of the ampoule that contained the implants used for surgery) and suture any flaps (recommended when immediate loading with a temporary prosthesis is not planned).

DISCHARGING THE PATIENT

Discharge the patient, scheduling monthly checks until osseointegration of the implants has occurred (4–6 months). When performing these check-ups, always check occlusion and torque of the prosthetic screws. Also, during the healing period, it is important to give the patient instructions for maintaining good oral hygiene correctly.

After osseointegration of the implants has taken place, take new impressions (using analogue or digital procedures) for the fabrication of the definitive prosthesis.

COMPLETION WITH DEFINITIVE PROSTHESIS

For a custom definitive prosthesis, you can use the customisation services of the BIOSAFIN CREA Digital Centre, which will create the ideal construction with the GUARANTEE of GLOBALWIN ORIGINAL CONNECTIONS.

CLEANING AND STERILISATION OF GLOBALWIN SURGICAL KIT

• **To clean with an ultrasonic bath** use a neutral detergent solution, following the manufacturer's instructions on dosage and time.

We recommend SEKUSEPT detergent or similar products at 1 measure per litre of water. Leave the instruments in the solution for at least 15 minutes and then proceed to ultrasonic cleaning for 15 minutes at 60°C.

At the drainage stage, check that all residue has been removed and repeat the cycle as necessary. Use demineralised water to prevent the formation of stains or smears on the instruments.

• **For manual cleaning** use a neutral detergent solution, following the manufacturer's instructions and brush with soft bristles under running water, making sure that any openings are not blocked. When finished, use distilled water for at least 4 minutes.

After rinsing, dry the devices thoroughly and when completely dry, place into pouches for sterilisation at 134°C for 45 minutes.

Proceed with the following stages:

• **Sterilisation** in autoclave (according to the manufacturer's instructions). Equipment should be placed in the autoclave after thorough rinsing and drying, since the autoclaving process increases the oxidising action of detergents.

• **Storage**: pouches containing sterilised instruments should be stored intact and opened at the time they are used. Before opening, check that they are still completely sealed and that they show no signs of damage. Check the shelf life of sterile packs.

Pouches should be stored in a dry place away from sunlight, water and sources of heat.

Always follow the sterilisation protocol for surgical and prosthetic instruments.

BIBLIOGRAPHICAL REFERENCES

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• R. Vinci1, +, M. Manacorda2, +, R. Abundo3, A.G. Lucchina4, A. Scarano5, C. Crocetta6, L. Lo Muzio7, E.F. Gherlone8 and F. Mastrangelo7,* Journal of Clinical Medicine 2020, 9, 774; doi:10.3390/jcm9030774.

• Pianificazione implantoprotesica digitale. Progettazione e realizzazione di riabilitazioni "full arch" a carico immediato. M. Manacorda, R. Vinci, F. Bova, E.F. Gherlone. Università Vita-Salute San Raffaele, Milano Corso di Laurea Magistrale in Odontoiatria e Protesi Dentaria - IRCCS Ospedale San Raffaele, Milano Dipartimento di Odontoiatria San Raffaele Dental Clinic. Dr. Os, gennaio 2016 - XXVII 01

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GLOBALWIN
IMPLANT SYSTEM

GLOBALWIN Medical devices are compliant with EC Directive 93/42 as amended

www.globalwin.eu

BIOSAFIN Partner of cefla Making Your Life Better.

BIOSAF IN is certified to:

ISO 9001, which certifies the entire work process, from start to finish, further demonstrating our compliance with quality standards considered optimal for the protection of product Users – Professionals – and end users – Patients.
ISO 13485 specifically relevant to the quality of Medical Devices.