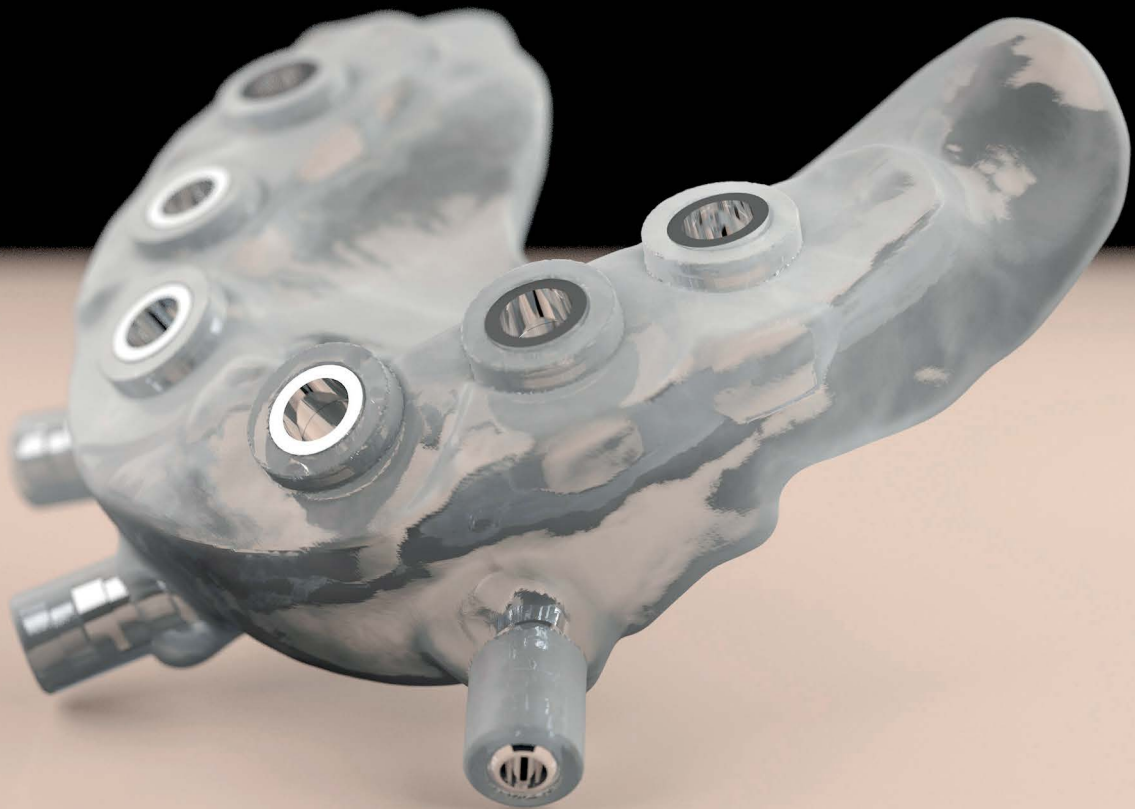

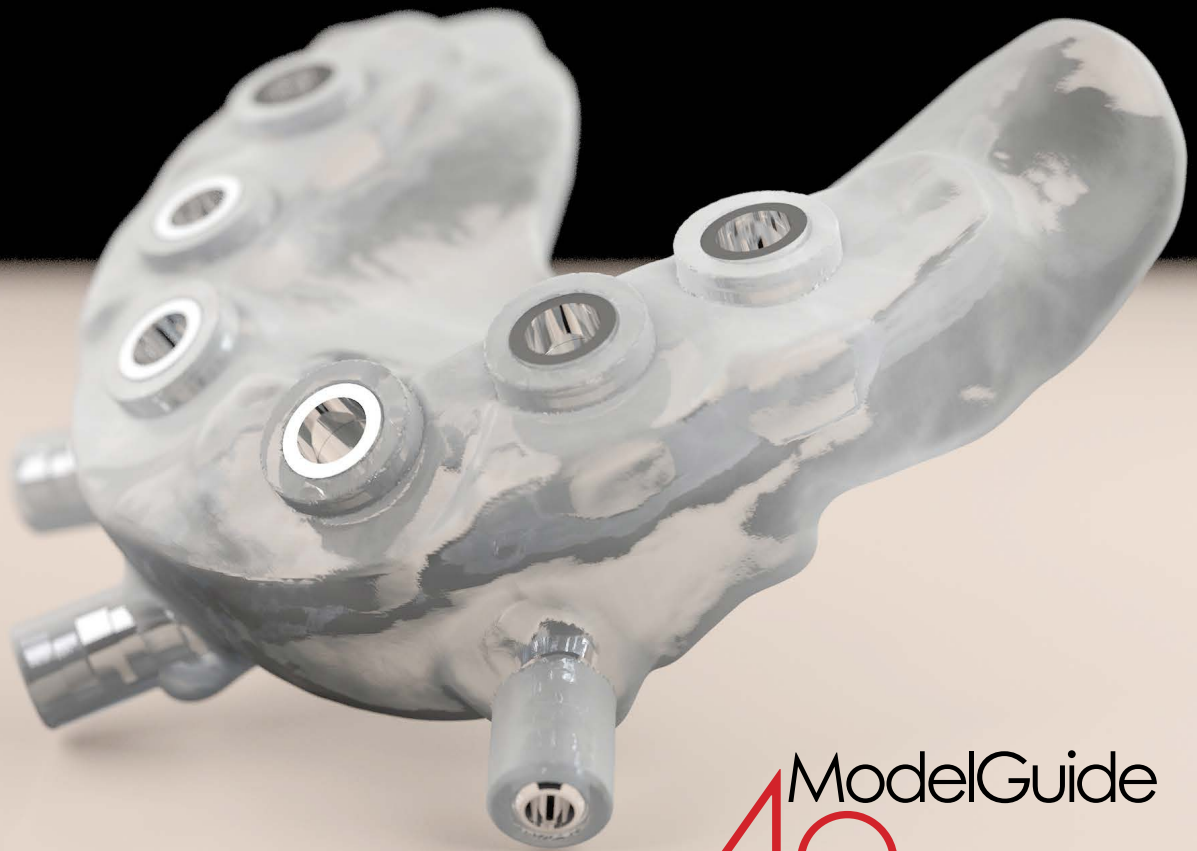


4.0 ModelGuide



SURGICAL

PROTOCOLS



ModelGuide
4.0 

ModelGuide is a method to create surgical guides for dental implant/prosthesis placement through software planning.

Through the implant design, the ModelGuide approach creates a customized surgical guide enabling the clinician to perform the implant/prosthesis placement in fully or partially edentulous patients in a safe, efficient and quick manner.

This very accurate surgical guide enables for results to be fully consistent with the software planning.

By using ModelGuide, all clinical decisions can be taken at the planning stage before the surgical procedure takes place.

As it enables a less invasive procedure while ensuring top level of accuracy, ModelGuide is the safest and most advanced guided surgery system now available.

This Clinical Practice Guideline illustrates the key steps for preparing, planning and performing a clinical case.

SURGICAL

PROTOCOLS

TRADITIONAL

ModelGuide
4.0



CASE HISTORY AND DENTAL VISIT

The case history is designed to collect all patient data in order to allow a correct diagnosis.

The dental visit aims to assess the general state of health of the mouth, preventive care, and the evaluation of operating spaces as a reduced oral opening may prevent the correct execution of the technique.



IMPRESSION AND CASTING MODELS

The impressions in the study can be detected with standard spoons or with those suitable for edentulous patients. From the precision impression the authorised laboratory creates the plaster Master model by eliminating the strong undercuts up to the arches. This model must be duplicated thus obtaining one free of undercuts.

In the event of post-extractives the areas of undercuts must be managed considering that the surgical guide will rest on the mucosa.



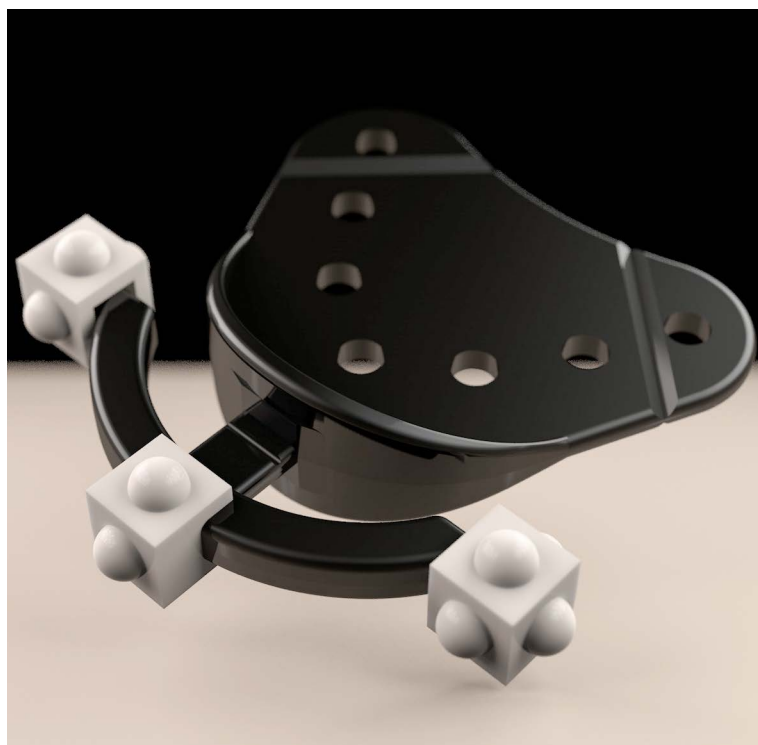
RADIOLOGICAL TEMPLATE CREATION

The radiological template must respond to the construction specifications learned by the technicians during the training course and must meet the specifications of the construction check list.

The cases which fall within the ModelGuideEasy (See annex D) protocol do not require the implementation of the radiological template.



Verification of correct positioning of the radiological template. If it is with dental support, using the appropriate inspection window, if it is resting on the mucous membranes it must have the widest possible extension.





UNIVERSAL ASSEMBLY OF STENT AND RADIOLOGICAL TEMPLATE

The template assembly technique consists in solidifying the radiological template and the Universal Stent with registration material which must be radiolucent (e.g. polyether).

In case it is necessary to acquire both arches two distinct radiological templates will be performed which will be assembled at the same time as the Universal Stent*.

It is also possible to remove the buccal portion and connect the arch containing the markers to the radiological template.

For cases falling within the ModelGuide Easy protocol the Universal Stent is positioned with the registration material directly on the arch considered.

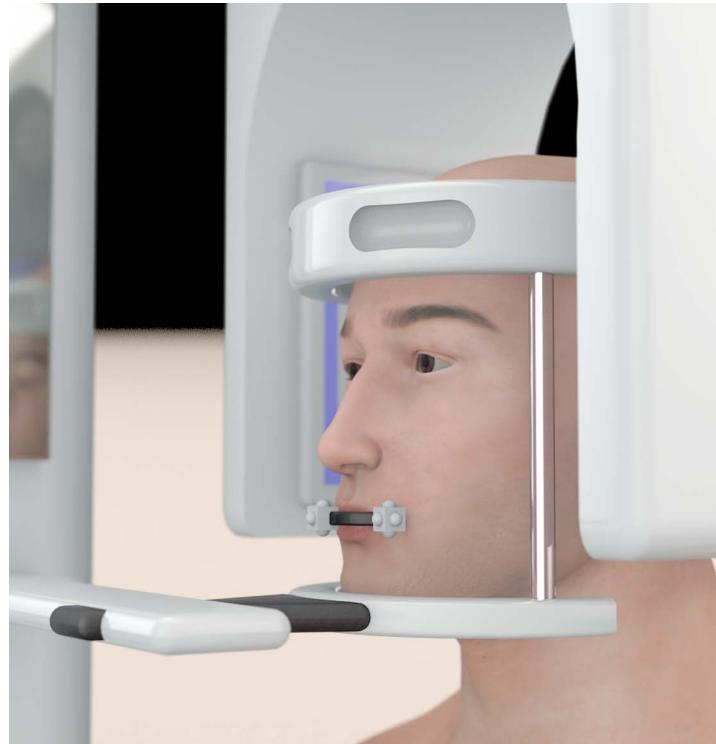
*The Universal Stent is to be regarded as disposable



CT ACQUISITION

The patient must be sent to the radiology centre equipped with the Universal Stent already fitted with the registration material, all accompanied by an adequate prescription containing instructions for the radiologist (*See annex B*).

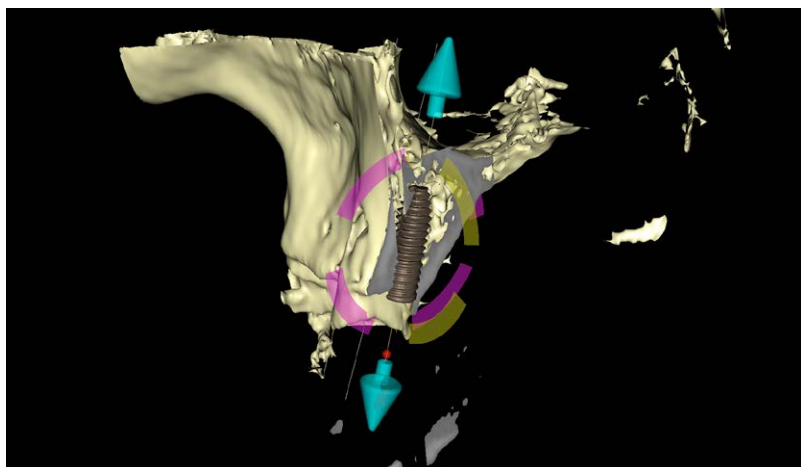
The request for a CT or conebeam exam in the arch/and interest can be prescribed provided that the radio-opaque markers present on the Universal Stent are also obtained



SOFTWARE DESIGN

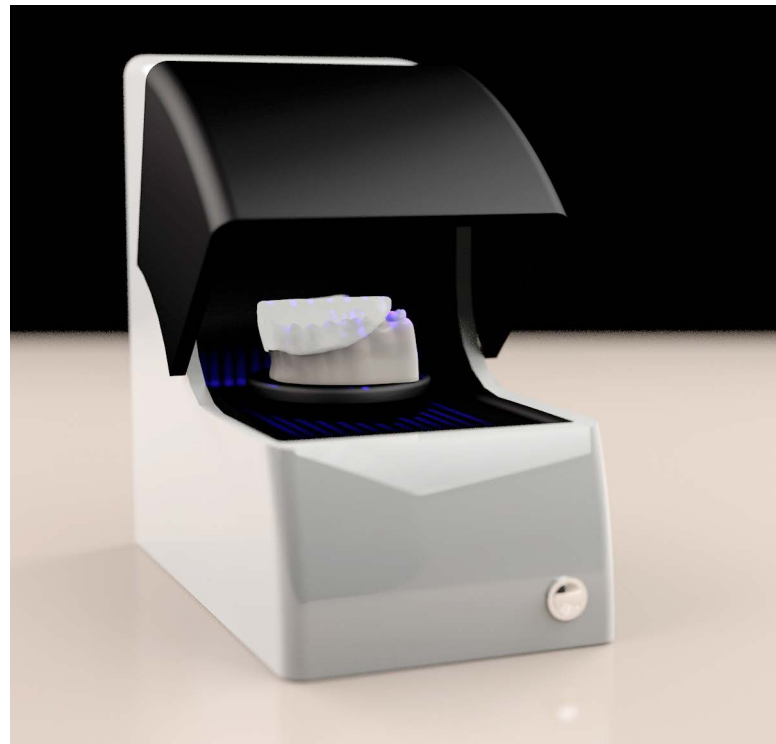
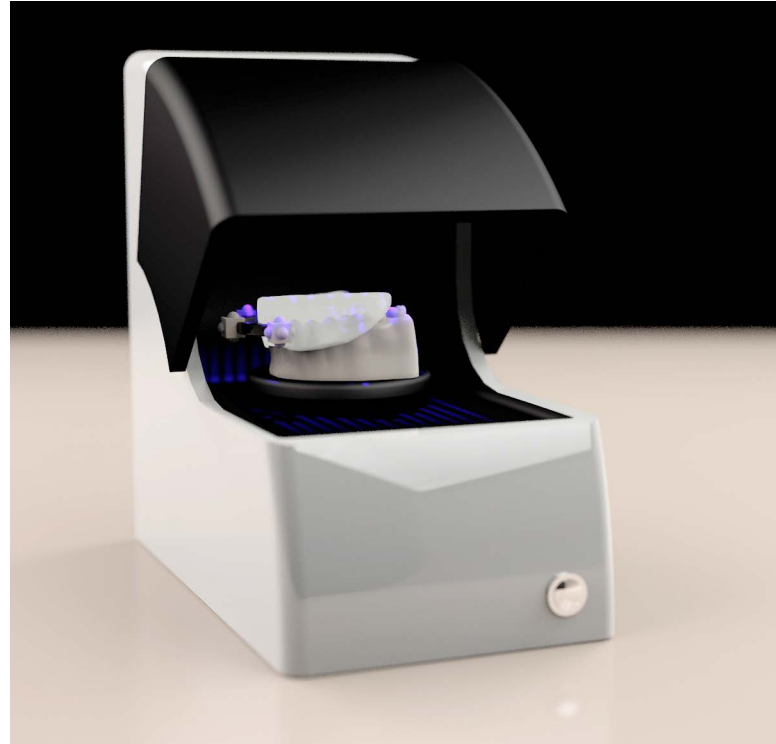
The CT EXAM must be obtained by the design software (Implant 3D and derivatives), so as to develop the case.

Once the virtual design has been completed, the surgical project must be exported onto a CD ROM.

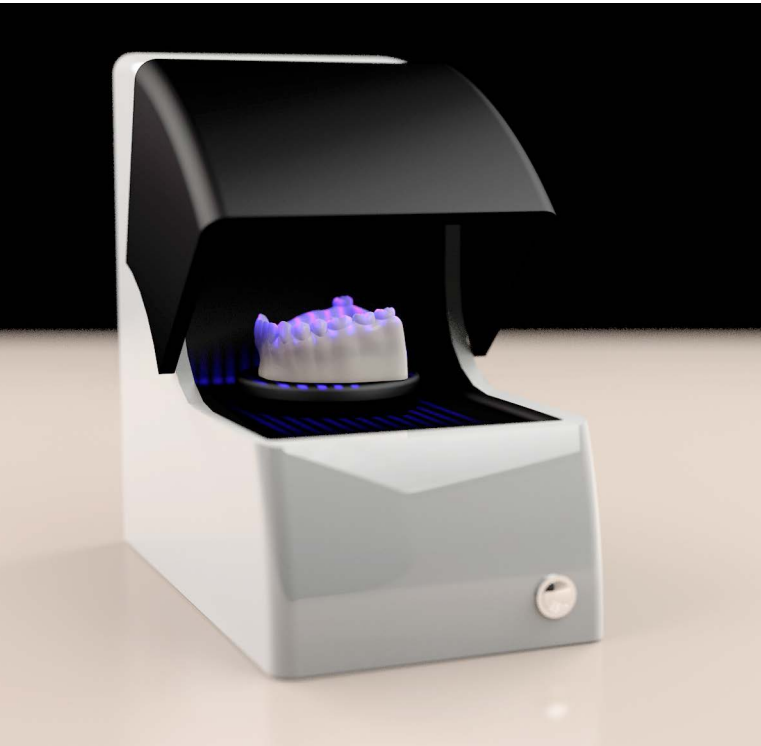


OPTICAL SCANS

If the study is equipped with optical scanner it will not be necessary to send the material but simply to send the STL file scan related to the plaster model together with the implant project.



TRADITIONAL 5



The following scans must be performed and sent:

- Plaster model with radiological template and Universal Stent positioned
- Plaster model with radiological template positioned
- Plaster model

For cases falling within the ModelGuide Easy protocol the scan of the plaster model with the Universal Stent and the scan of just the plaster model will suffice.

BioOrd

The order of the surgical guide must be made online through the portal BioOrd (clienti.bio-nova.eu).

If the study is equipped with optical scanner the order is completed by telematic systems.

If the study is not equipped with a scanner, the shipping package must be prepared, which must contain the radiological template assembled with the Universal Stent, the project files on CD ROM, the master model, the duplicate model, the order form and the check list stamped and signed.



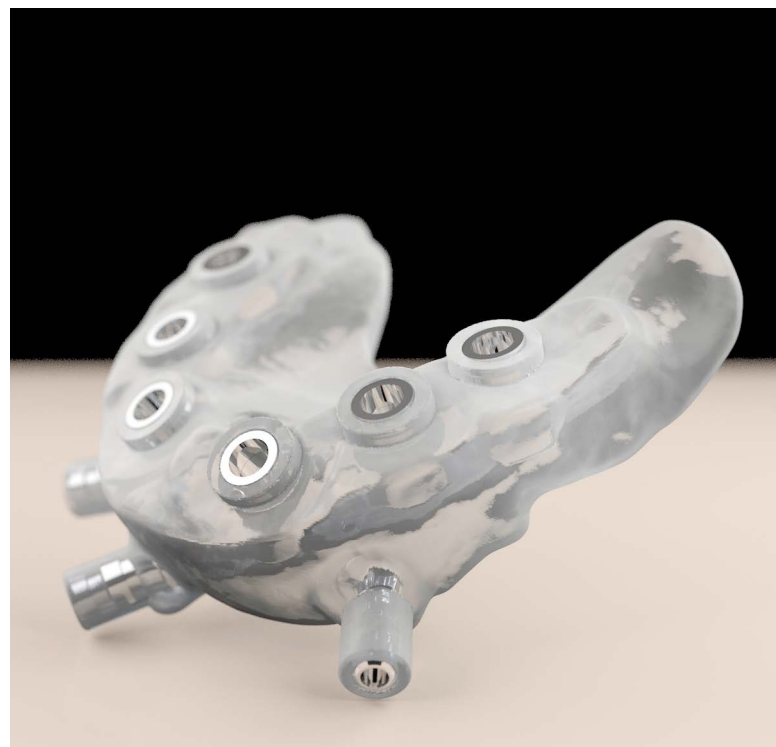
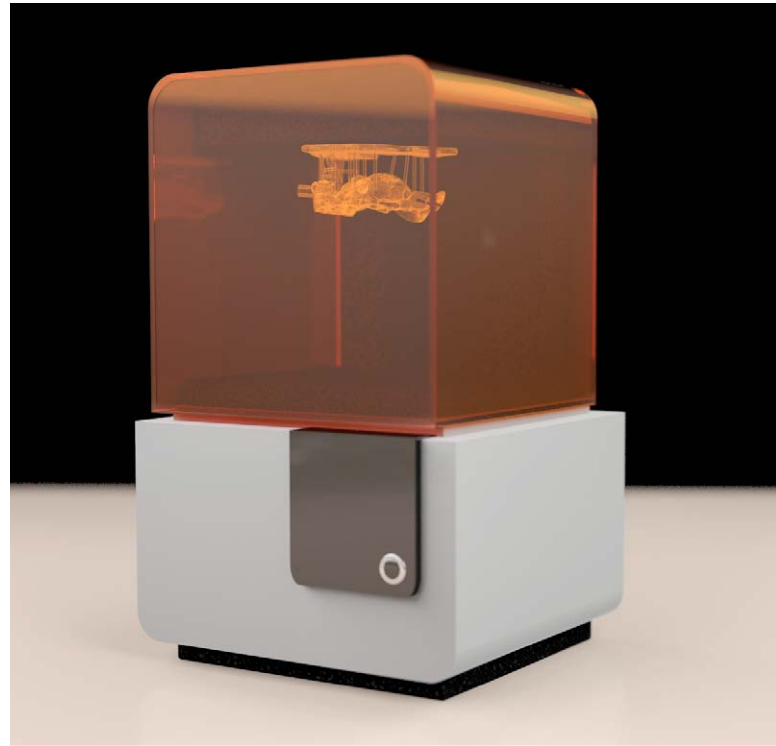
TRADITIONAL 6

After inserting the order it is necessary to wait for the arrival of the express courier who will collect the material for the manufacture of the surgical guide.

Each packaging must be reserved for only one case/patient.

Every single piece inside the shipping package must be individually protected.

Is it possible to receive the STL file of the surgical guide for printing in house or to directly receive the finished surgical guide, printed by Bionova with 3Dad ultra high resolution printers.



IMPLANT INTERVENTION

ANAESTHESIA

- It is important to avoid creating anaesthetic boluses that can prevent a proper housing of the guide.

GUM TISSUE REMOVAL

- Performed by means of a suitable Guided Gum Tissue Remover after having housed the guide.

THE SURGICAL OPERCOLUM

- The surgical guide should be removed to facilitate the removal of the operculum of the mucosa.

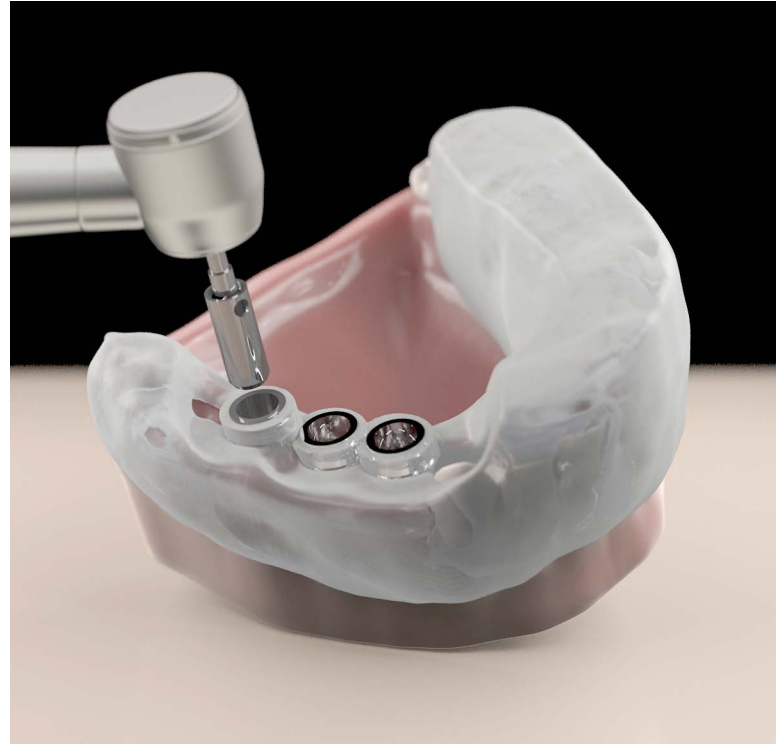
CRESTAL PREPARER

- Create the housing crestal plate of the implant head by removing all interference related to the progress of the alveolar crest.

CUTTER PASSAGE

- Starting from the first cutter of length 8 mm, the subsequent longer cutters work guided both by the bushes of the surgical guide and by 8 mm of the pilot cutter.

From the point of view of the sequence of the cutters we must consider that these may vary between the various types of implant and in relation to the quality of the bone in the implant site.





LAYING THE IMPLANT

- Special fitters screwed to the implant are used so as to bring the implant to the height while maintaining the insertion axis in line with the software project.

With these fitters it is also possible to trace the position of the connection system.

REMOVAL OF THE FITTERS AND OF THE FIXING SYSTEMS

PROSTHETIC PHASE

- If provided or fitting healing bolts or screws of the first surgical step.

IMMEDIATE LOADING

- The choice to perform an immediate loading is at the discretion of the professional performing the operation.

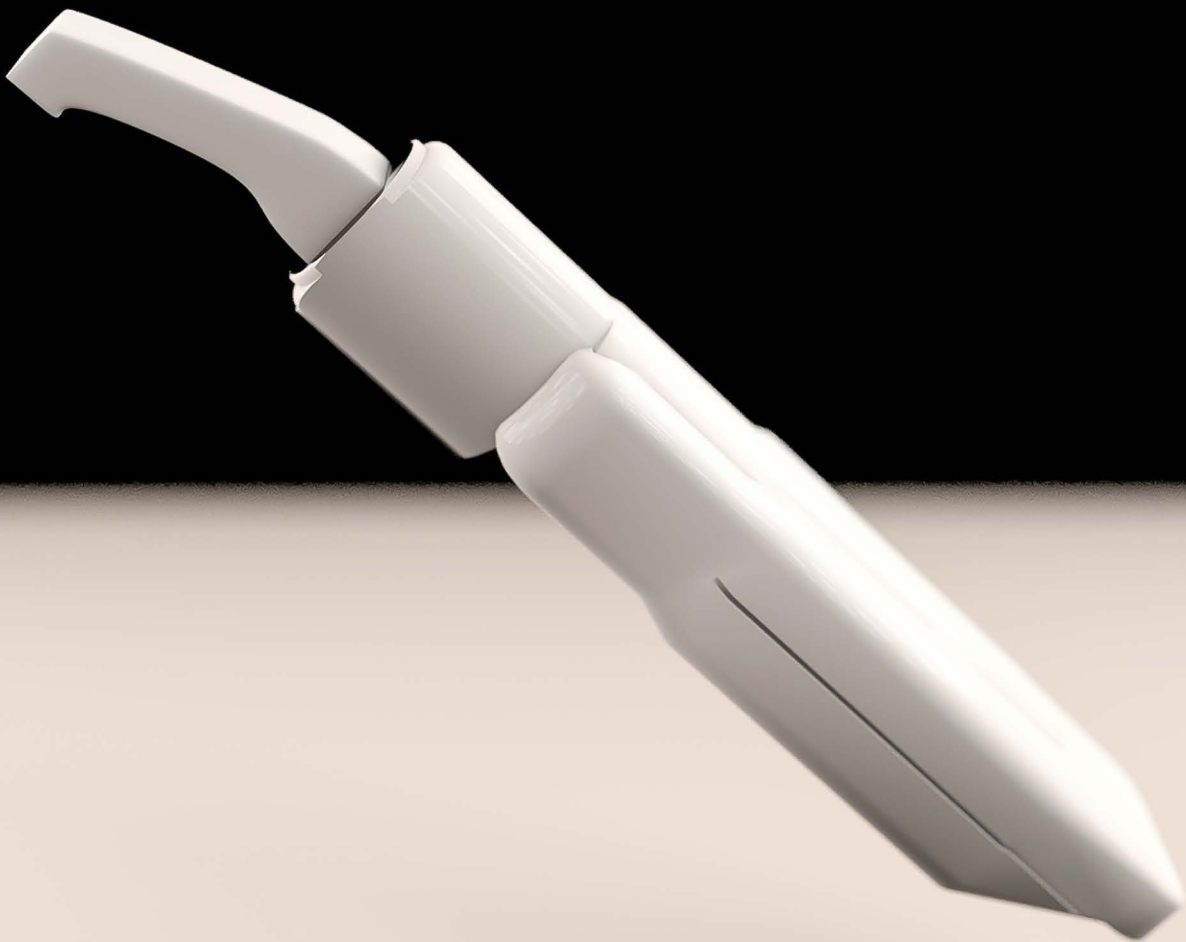
Certainly the ModelGuide technique, thanks to the option of making a temporary prebuilt prosthesis, can facilitate this therapeutic choice where the clinical conditions and literature data make it viable.



N.B. The guide must under no circumstance be sterilised with "hot" systems that may cause deformation. The guide should then be washed with sterile physiological solution before trying it in the oral cavity of the patient.

INTRAOURAL SCANNING

ModelGuide
4.0



INTRAORAL SCANNING 1

CASE HISTORY AND DENTAL VISIT

The case history is designed to collect all patient data in order to allow a correct diagnosis.

The dental visit aims to assess the general state of health of the mouth, preventive care, and the evaluation of operating spaces as a reduced oral opening may prevent the correct execution of the technique.

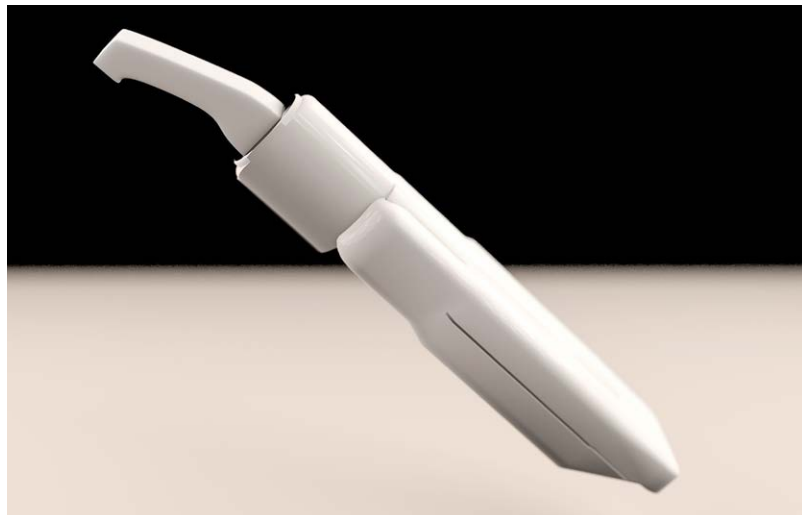


OBTAINING THE INTRAORAL SCAN

The digital process envisages the use of an intraoral scanner in order to improve accuracy and patient comfort.

The digital impression acquisition can be made only in cases of partial edentulism, with the objective of having a reasonable oral detection of soft tissues and of the dental surfaces.

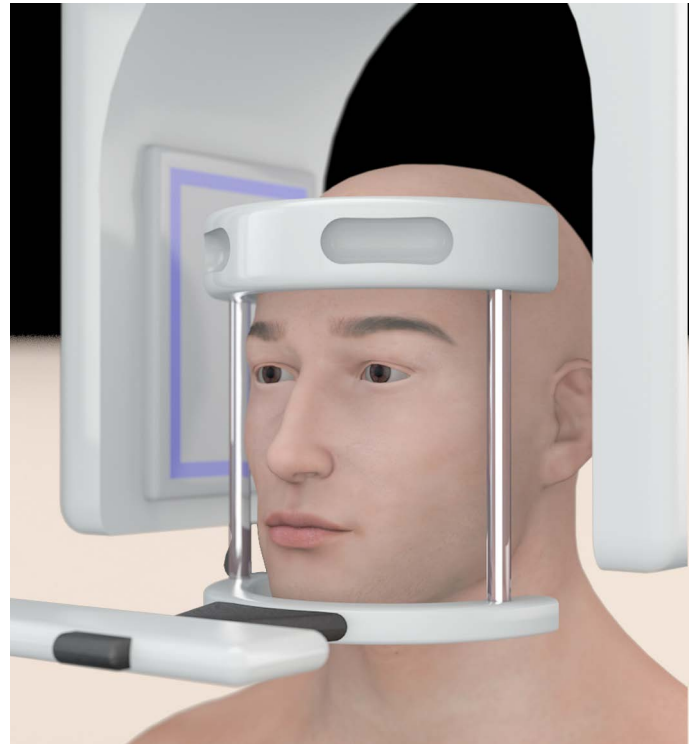
The Universal Stent must not be used during introral acquisition.



INTRAORAL 2 SCANNING

CT ACQUISITION

The CT EXAM must be performed acquiring images relating to the arch involved taking care in interposing suitable instruments between the two arches to prevent occlusion.



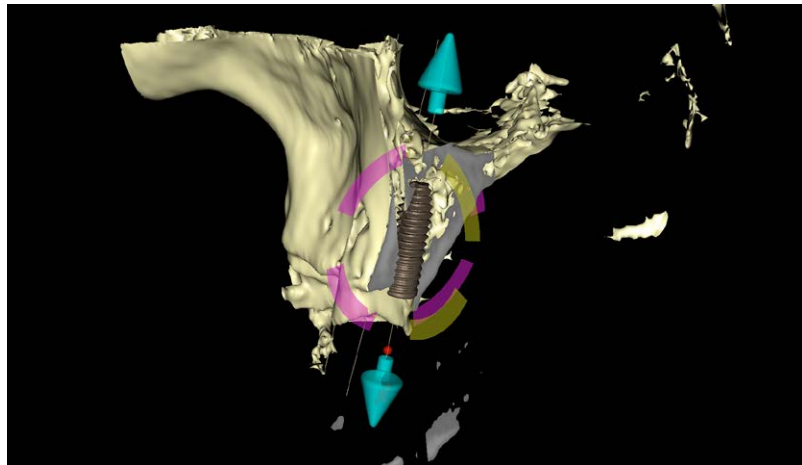
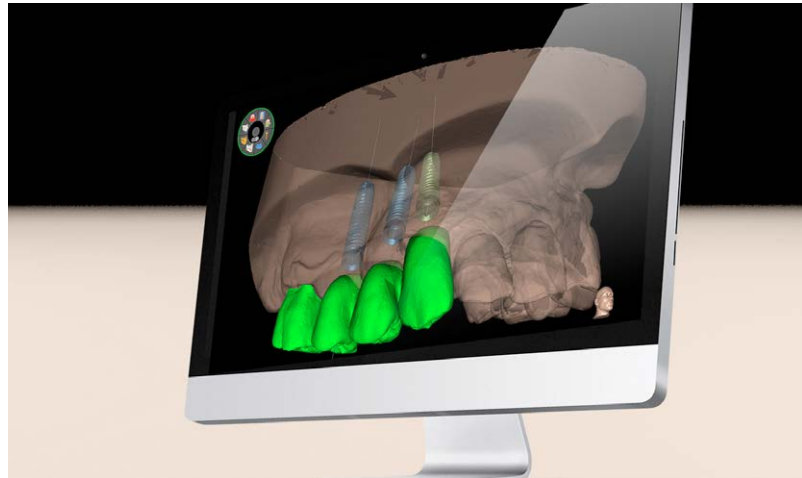
INTRAORAL SCANNING 3

CT ACQUISITION

The STL files deriving from the intraoral acquisition and CT acquisition must be imported within the design software in order to perform the alignment.

This step allows a correct implant planning having more anatomical information like the height of the mucosa.

The CT or conebeam exam must be acquired by the design software (Implant 3D and derivatives), so as to develop the case.



INTRAORAL SCANNING 4

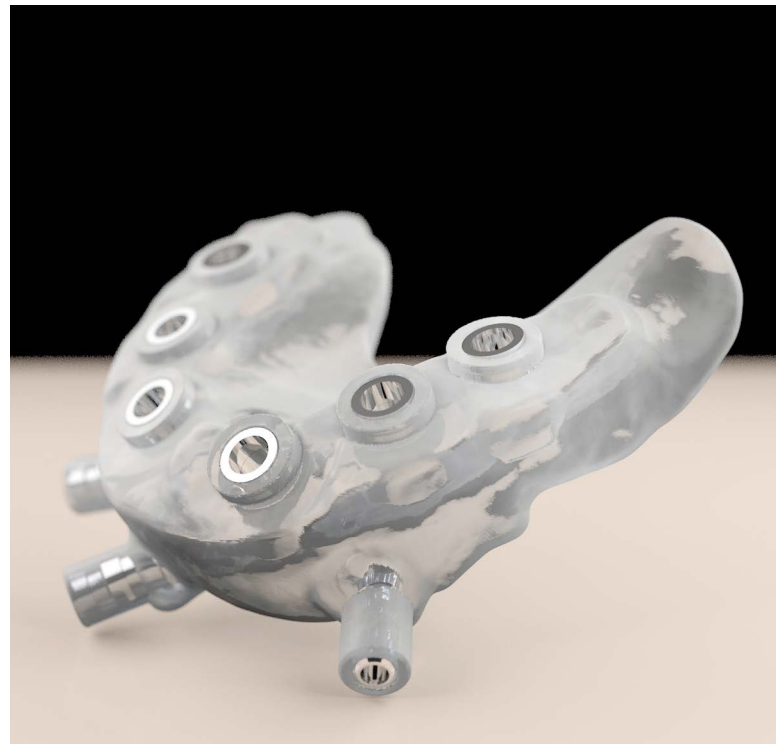
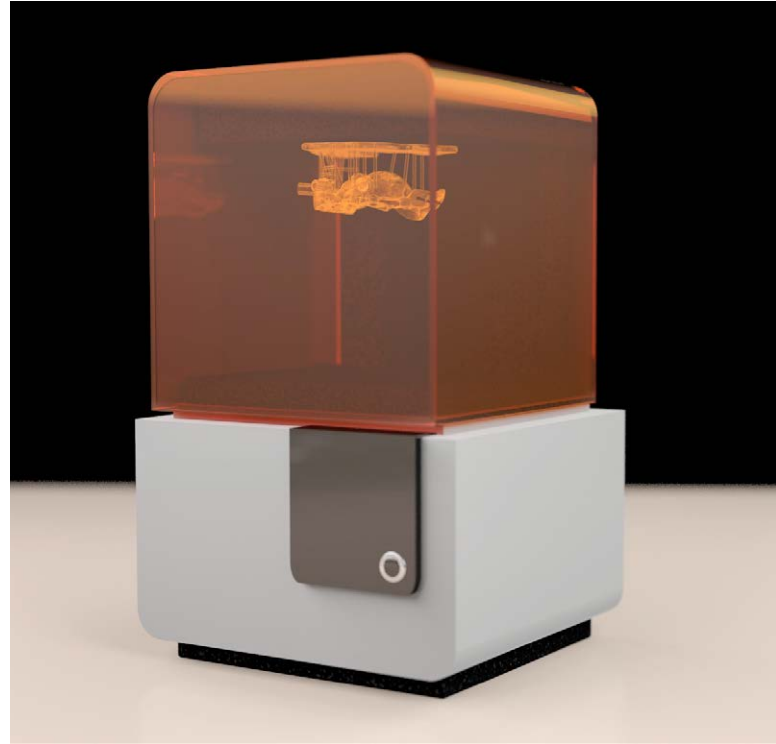
BioOrd

The order of the surgical guide must be made online through the portal BioOrd (clienti.bio-nova.eu).



INTRAORAL SCANNING 4

Is it possible to receive the STL file of the surgical guide for printing in house or to directly receive the finished surgical guide, printed by Bionova with 3Dad ultra high resolution printers.



INTRAORAL SCANNING 5

IMPLANT INTERVENTION

ANAESTHESIA

- It is important to avoid creating anaesthetic boluses that can prevent a proper housing of the guide.

GUM TISSUE REMOVAL

- Performed by means of a suitable Guided Gum Tissue Remover after having housed the guide.

THE SURGICAL OPERCOLUM

- The surgical guide should be removed to facilitate the removal of the operculum of the mucosa.

CRESTAL PREPARER

- Create the housing crestal plate of the implant head by removing all interference related to the progress of the alveolar crest.

CUTTER PASSAGE

- Starting from the first cutter of length 8 mm, the subsequent longer cutters work guided both by the bushes of the surgical guide and by 8 mm of the pilot cutter.

From the point of view of the sequence of the cutters we must consider that these may vary between the various types of implant and in relation to the quality of the bone in the implant site.



INTRAORAL SCANNING 5



LAYING THE IMPLANT

- Special fitters screwed to the implant are used so as to bring the implant to the height while maintaining the insertion axis in line with the software project.

With these fitters it is also possible to trace the position of the connection system.

REMOVAL OF THE FITTERS AND OF THE FIXING SYSTEMS

PROSTHETIC PHASE

- If provided or fitting healing bolts or screws of the first surgical step.

IMMEDIATE LOADING

- The choice to perform an immediate loading is at the discretion of the professional performing the operation.

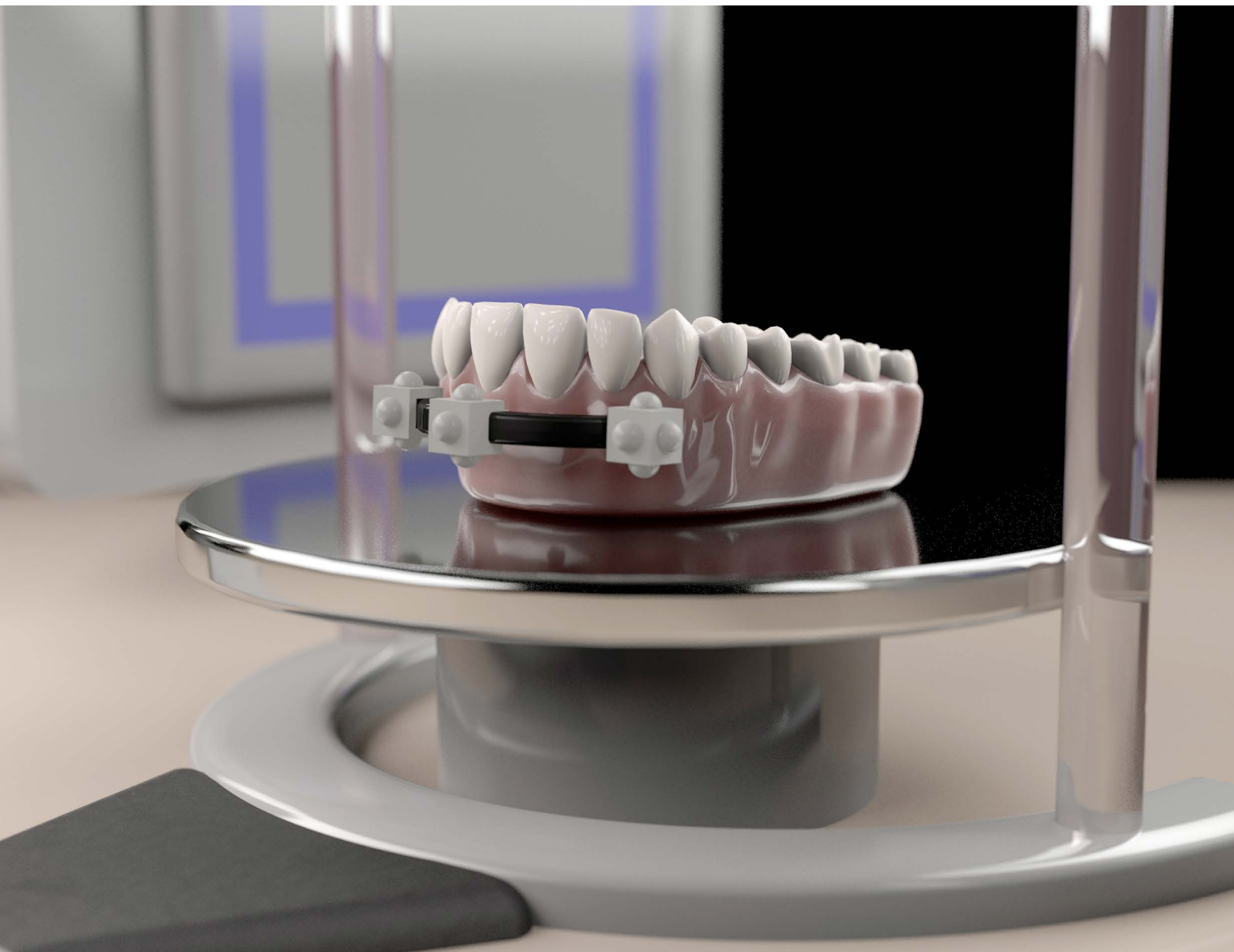
Certainly the ModelGuide technique, thanks to the option of making a temporary prebuilt prosthesis, can facilitate this therapeutic choice where the clinical conditions and literature data make it viable.



N.B. The guide must under no circumstance be sterilised with "hot" systems that may cause deformation. The guide should then be washed with sterile physiological solution before trying it in the oral cavity of the patient.

DOUBLE SCAN

ModelGuide
4.0



DOUBLE 1 SCAN

CASE HISTORY AND DENTAL VISIT

The case history is designed to collect all patient data in order to allow a correct diagnosis.

The dental visit aims to assess the general state of health of the mouth, preventive care, and the evaluation of operating spaces as a reduced oral opening may prevent the correct execution of the technique.



DOUBLE 2 SCAN



ACQUISITIONS

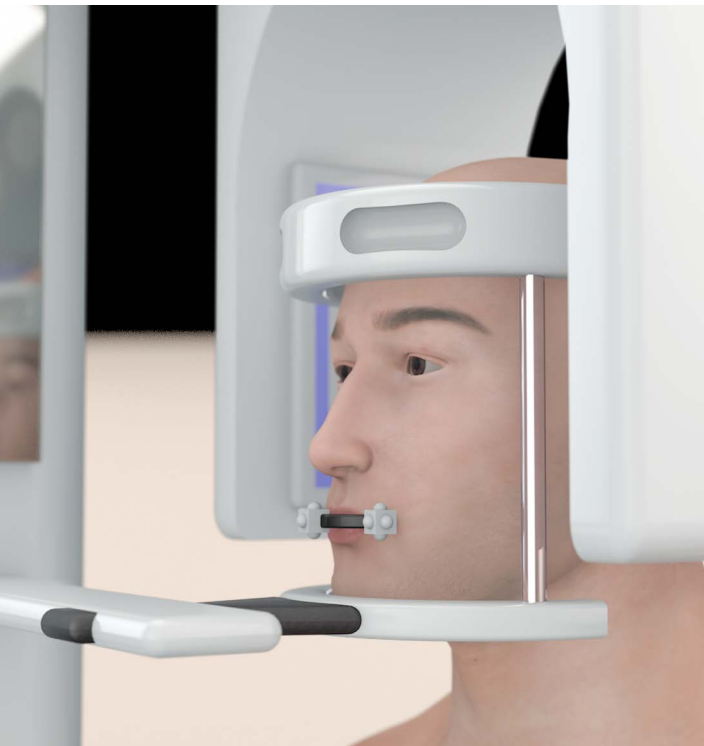
The protocol of the double scan is provided only for cases of total edentulism.

1ST ACQUISITION

If the study has a CT or a cone beam, the prosthesis itself can be connected to the Universal stent that will be removed after the second acquisition.

If the patient already has a total prosthesis which is appropriate for the treatment plan the same must be transformed into the scanning prosthesis.

This process is done by applying radiopaque balls (or other radiopaque markers) directly on the flanges of the prosthesis arranged in a staggered manner and in a minimum number of 5 units in the outer part and 3 units in the inner part.



DOUBLE 3 SCAN

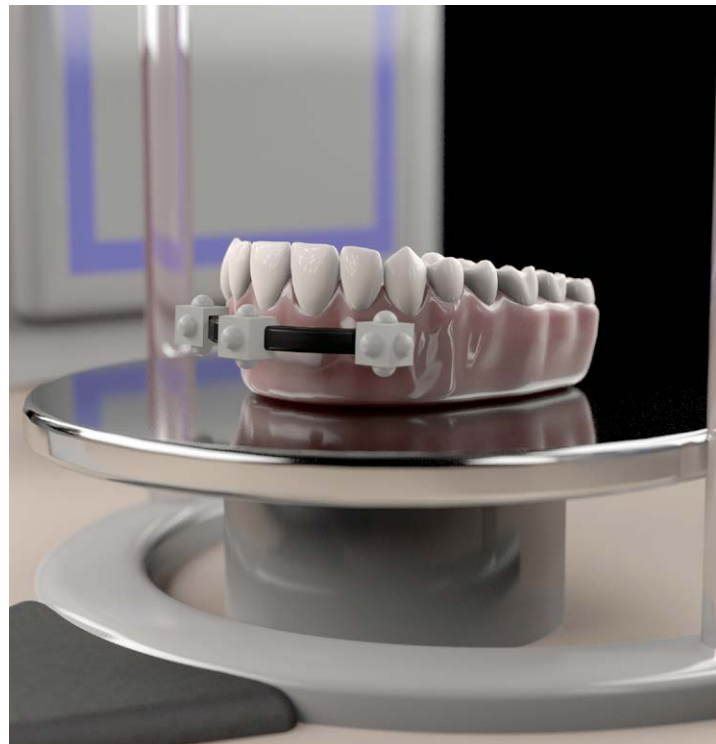
ACQUISITIONS

2° ACQUISITION

CT acquisition of the prosthesis congruous with Universal Stent.

Or

CT acquisition of the prosthesis congruous with the radiopaque markers.



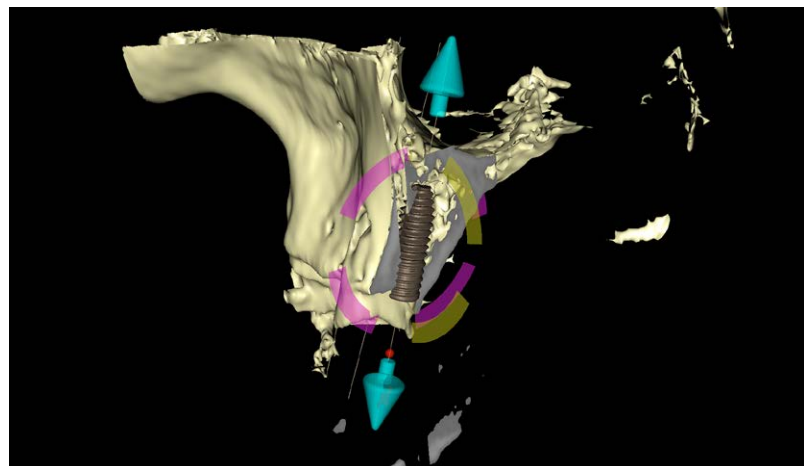
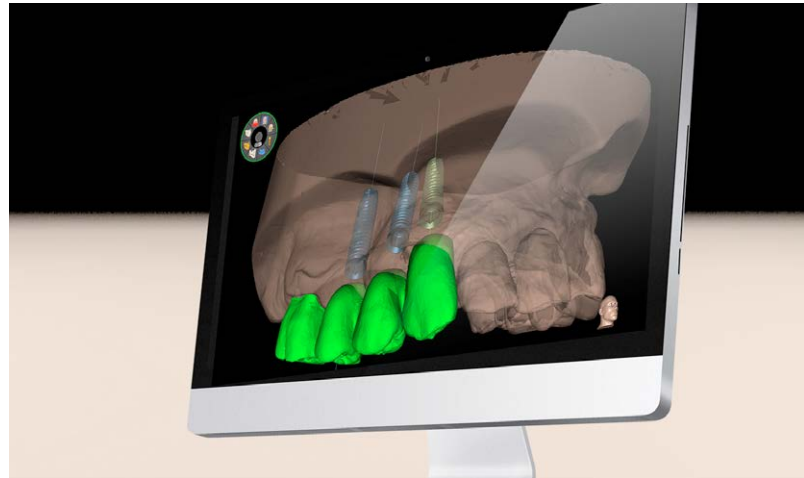
DOUBLE 4 SCAN

PROGETTAZIONE SOFTWARE

Both CT acquisitions must be imported within the design software in order to perform the alignment.

This step allows a correct implant planning having more anatomical information like the height of the mucosa.

The CT or conebeam exam must be acquired by the design software (Implant 3D and derivatives), so as to develop the case.

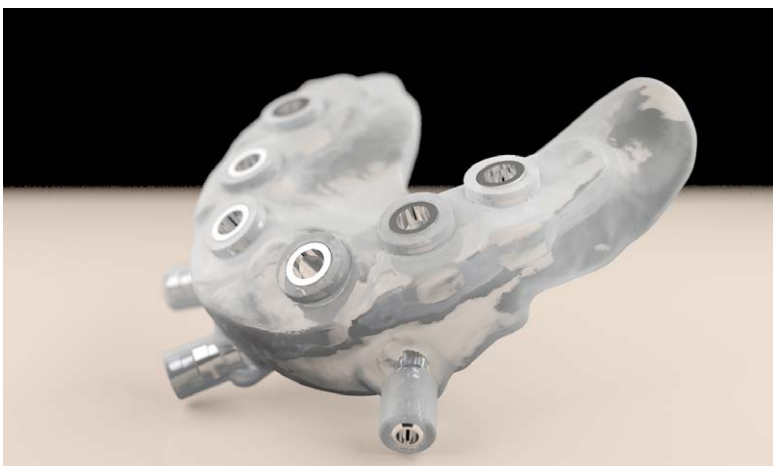
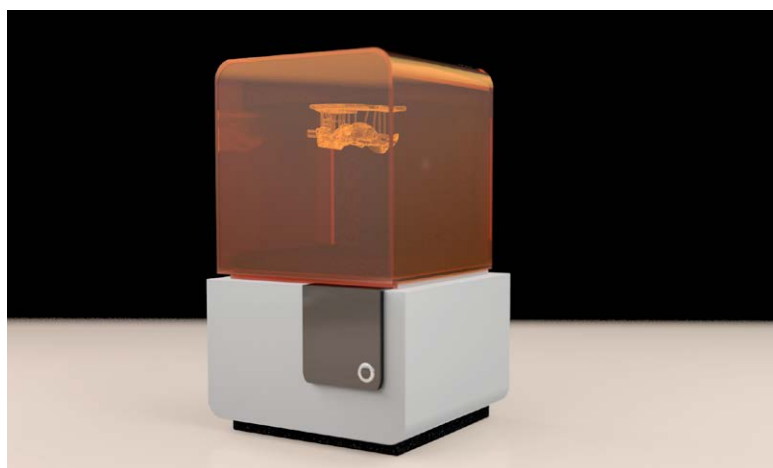


DOUBLE 5 SCAN

BioOrd

The order of the surgical guide must be made online through the portal BioOrd (clienti.bio-nova.eu).

Is it possible to receive the STL file of the surgical guide for printing in house or to directly receive the finished surgical guide, printed by Bionova with 3Dad ultra high resolution printers.



DOUBLE 6 SCAN

IMPLANT INTERVENTION

ANAESTHESIA

- It is important to avoid creating anaesthetic boluses that can prevent a proper housing of the guide.

GUM TISSUE REMOVAL

- Performed by means of a suitable Guided Gum Tissue Remover after having housed the guide.

THE SURGICAL OPERCOLUM

- The surgical guide should be removed to facilitate the removal of the operculum of the mucosa.

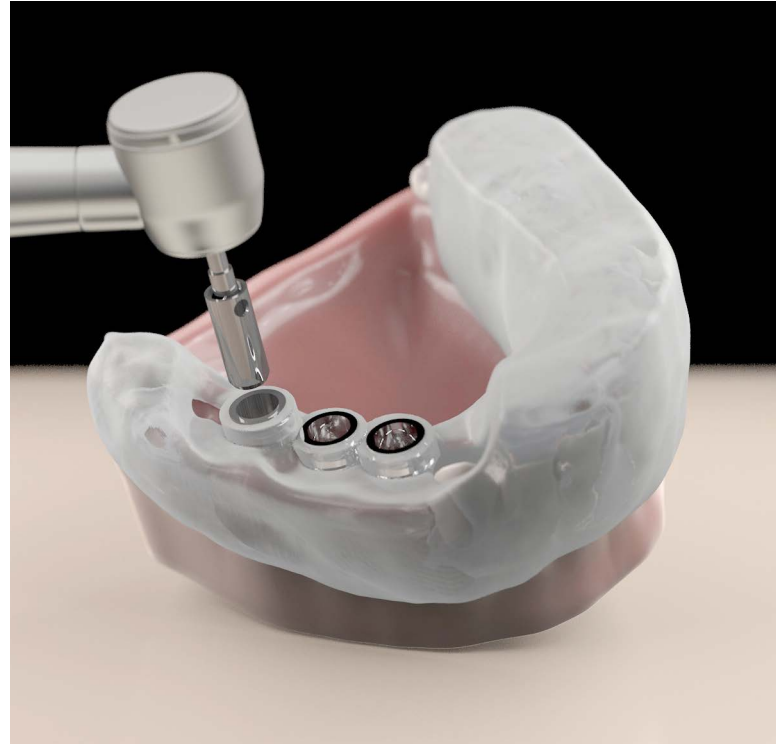
CRESTAL PREPARER

- Create the housing crestal plate of the implant head by removing all interference related to the progress of the alveolar crest.

CUTTER PASSAGE

- Starting from the first cutter of length 8 mm, the subsequent longer cutters work guided both by the bushes of the surgical guide and by 8 mm of the pilot cutter.

From the point of view of the sequence of the cutters we must consider that these may vary between the various types of implant and in relation to the quality of the bone in the implant site.



DOUBLE 6 SCAN



LAYING THE IMPLANT

- Special fitters screwed to the implant are used so as to bring the implant to the height while maintaining the insertion axis in line with the software project.

With these fitters it is also possible to trace the position of the connection system.

REMOVAL OF THE FITTERS AND OF THE FIXING SYSTEMS

PROSTHETIC PHASE

- If provided or fitting healing bolts or screws of the first surgical step.

IMMEDIATE LOADING

- The choice to perform an immediate loading is at the discretion of the professional performing the operation.

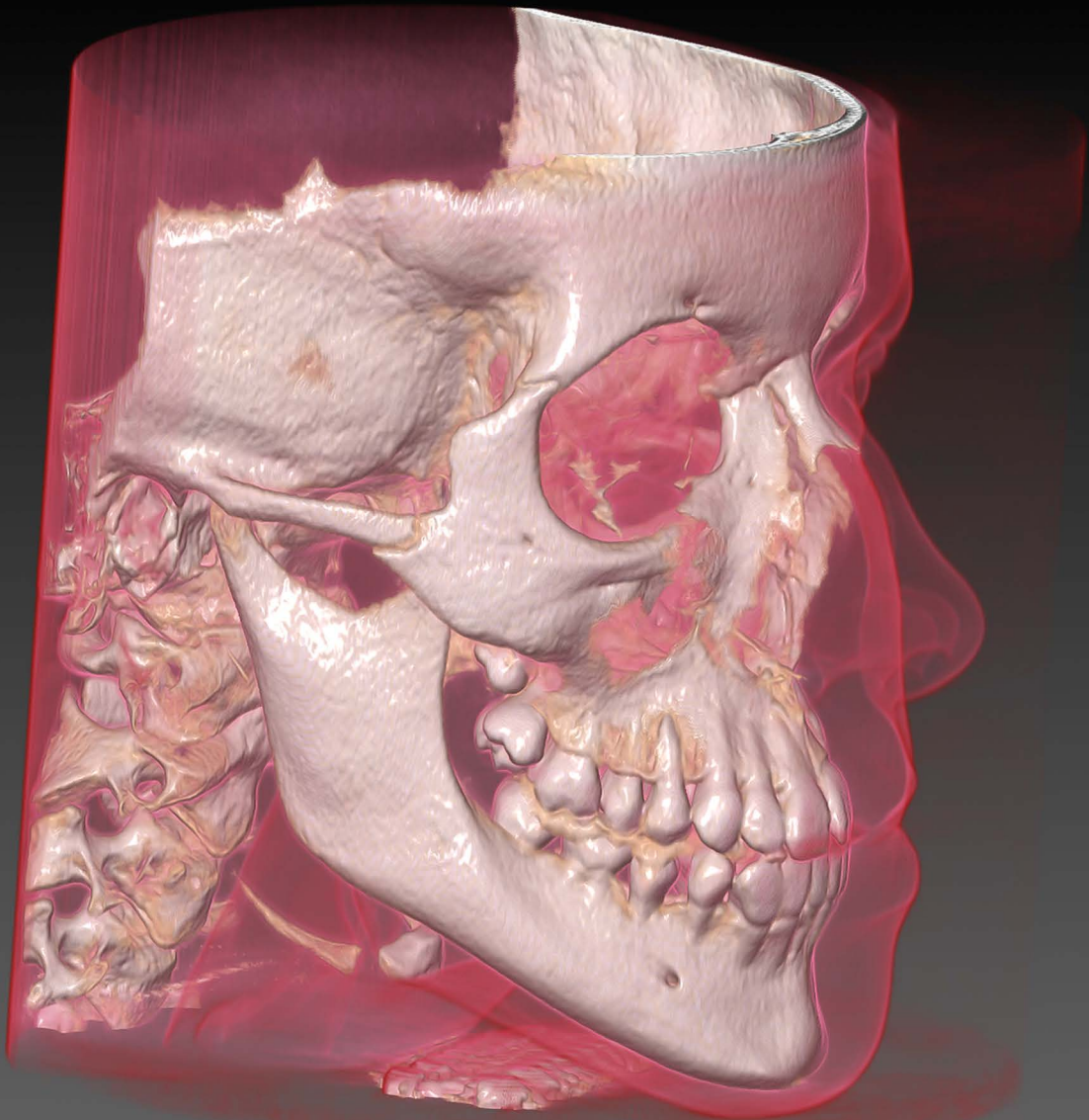
Certainly the ModelGuide technique, thanks to the option of making a temporary prebuilt prosthesis, can facilitate this therapeutic choice where the clinical conditions and literature data make it viable.



N.B. The guide must under no circumstance be sterilised with "hot" systems that may cause deformation. The guide should then be washed with sterile physiological solution before trying it in the oral cavity of the patient.

BONE SUPPORT

ModelGuide
4.0



BONE SUPPORT 1

CASE HISTORY AND DENTAL VISIT

The case history is designed to collect all patient data in order to allow a correct diagnosis.

The dental visit aims to assess the general state of health of the mouth, preventive care, and the evaluation of operating spaces as a reduced oral opening may prevent the correct execution of the technique.



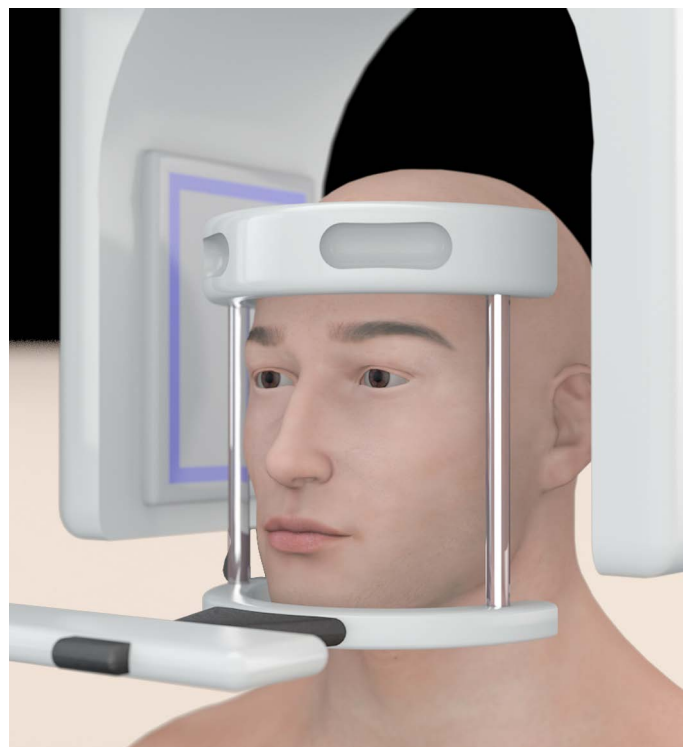
BONE 2 SUPPORT

ACQUISITION

The choice of using a surgical guide with bone support is at the discretion of the dentist.

The dentists in charge of the assessment of the case and the use of such a surgical guide, like in the presence of severe atrophies of the superior maxilla or in cases of post extractives with deep recesses or in regenerative cases.

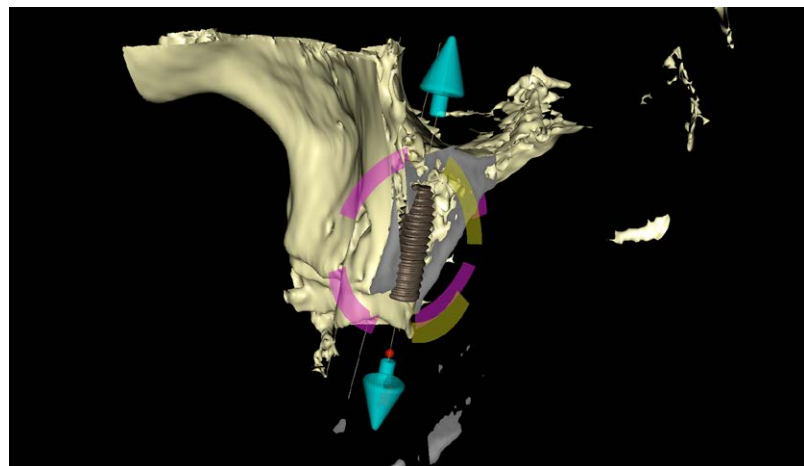
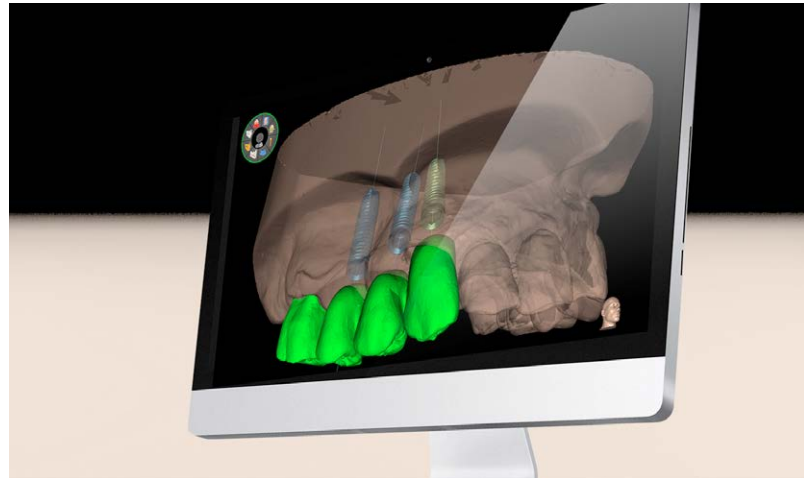
The CT exam must be performed acquiring images relating to the arch involved taking care in interposing suitable instruments between the two arches to prevent occlusion.



BONE SUPPORT 3

SOFTWARE DESIGN

The CT or conebeam exam must be acquired by the design software (Implant 3D and derivatives), so as to develop the case.



BONE 4 SUPPORT

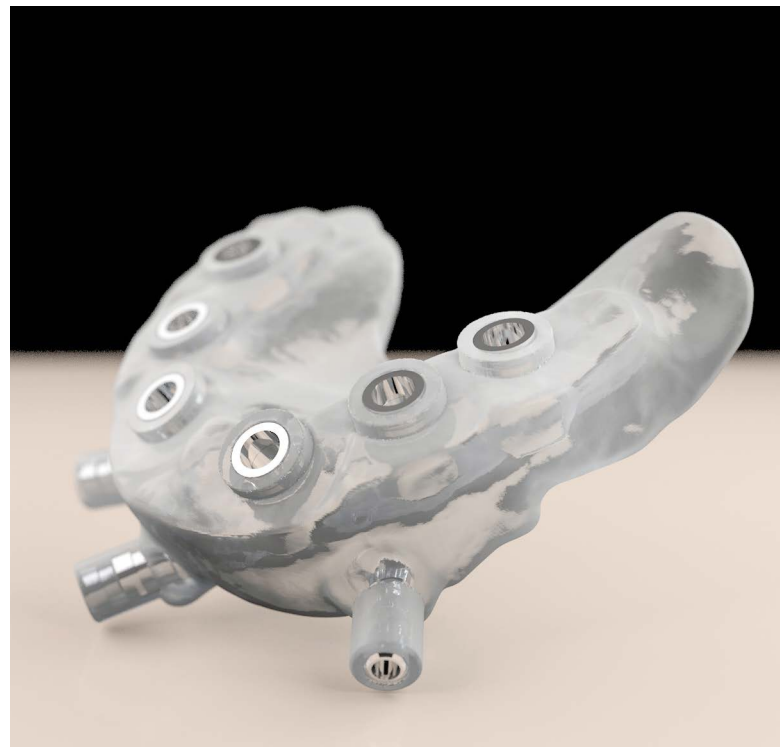
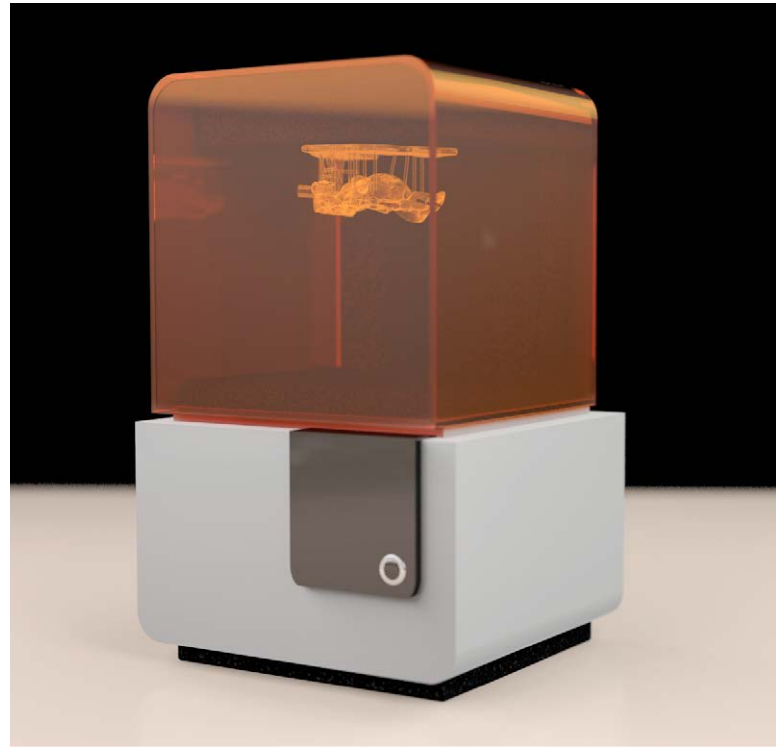
BioOrd

The order of the surgical guide must be made online through the portal BioOrd (clienti.bio-nova.eu).



BONE SUPPORT 4

Is it possible to receive the STL file of the surgical guide for printing in house or to directly receive the finished surgical guide, printed by Bionova with 3Dad ultra high resolution printers.



BONE 5 SUPPORT

IMPLANT INTERVENTION

ANAESTHESIA

- It is important to avoid creating anaesthetic boluses that can prevent a proper housing of the guide.

FLAP OPENING

- Make a cut to the gum area affected resulting in elevation of the flap in order to position yourself the surgical guide.

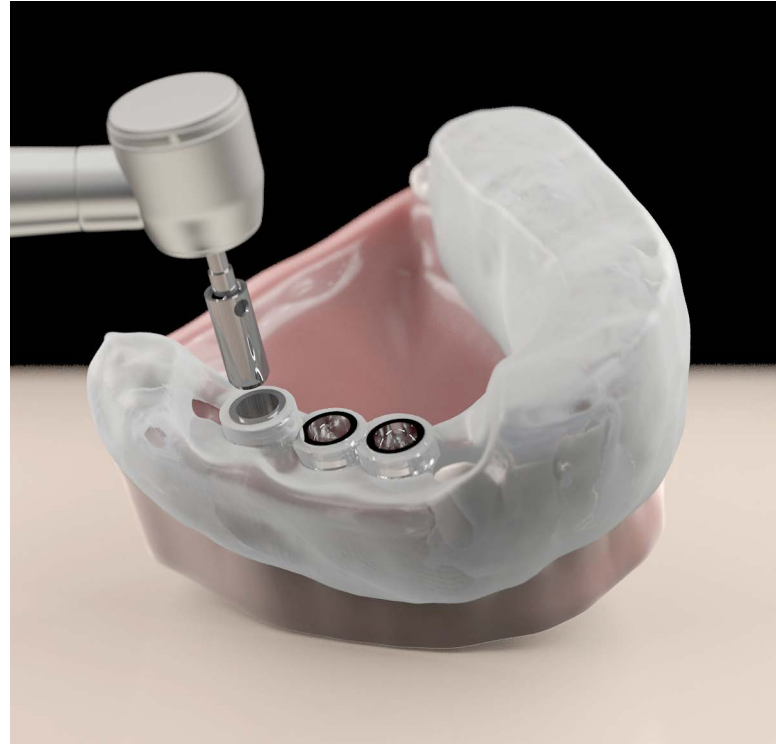
CRESTAL PREPARER

- Create the housing crestal plate of the implant head by removing all interference related to the progress of the alveolar crest.

CUTTER PASSAGE

- Starting from the first cutter of length 8 mm, the subsequent longer cutters work guided both by the bushes of the surgical guide and by 8 mm of the pilot cutter.

From the point of view of the sequence of the cutters we must consider that these may vary between the various types of implant and in relation to the quality of the bone in the implant site.



BONE 5 SUPPORT



LAYING THE IMPLANT

- Special fitters screwed to the implant are used so as to bring the implant to the height while maintaining the insertion axis in line with the software project.

With these fitters it is also possible to trace the position of the connection system.

REMOVAL OF THE FITTERS AND OF THE FIXING SYSTEMS

PROSTHETIC PHASE

- If provided or fitting healing bolts or screws of the first surgical step.

IMMEDIATE LOADING

- The choice to perform an immediate loading is at the discretion of the professional performing the operation.

Certainly the ModelGuide technique, thanks to the option of making a temporary prebuilt prosthesis, can facilitate this therapeutic choice where the clinical conditions and literature data make it viable.



N.B. The guide must under no circumstance be sterilised with "hot" systems that may cause deformation. The guide should then be washed with sterile physiological solution before trying it in the oral cavity of the patient.

CHECK LIST ORDER MODELGUIDE

VALID FOR: GUIDES UP TO 3 IMPLANTS, 4 IMPLANTS, OVER 4 IMPLANTS, BONE MODEL,
PERFORATED MODEL FOR ANALOGUES

This check list has the purpose of providing a valid help for the clinician in successfully completing all the steps necessary to issue the order ModelGuide Easy avoiding discomfort or delays.

TECHNICAL SECTION

- The impression was detected extensively and there are no streaks or distortions.
- Alginates or polyethers were used for cases of partial edentulism while polyethers or polysulphides were used for cases with mobile prostheses. The plaster models (master and duplicate), radiological template were entrusted to a ModelGuide authorised dental technician.
- The strongest undercuts were removed from the master model using only and exclusively wax, this model was used to manufacture the duplicate template.
- The ModelGuide authorised Dental Technician together with the radiological template and the plaster models also delivered the duly completed "Check list of radiological template production".

CT SCAN

- During the radiological template fixing step - Universal Stent with closing bite of the patient registration material was used (for example polyether) abundantly on both sides of the Universal Stent.
- Clear instructions were given to the patient on how to wear the radiological guide assembled to the Universal Stent during the CT scan.
- The technician who performed the CT scan on the patient followed the directions on the "CT acquisition protocol".

SOFTWARE DESIGN

- Subsequently to importing the DICOM files inside the implant simulation software the markers of Universal stents were checked to be visible.
- From the various views of the software no visible deformations of the scanned area were found during the CT EXAM.
- In the case of mandibular arch the associated channels were plotted and the collision-closeness with the implants present was assessed. In the case of maxillary arch the position of the implants with respect to the maxillary sinuses was assessed.
- The bone density around each implant was evaluated.
- The "mucosa depth" was assessed (not greater than 5 mm to avoid the bushing-mucosa precontact during the surgical guide positioning).
- The distances between bushings were evaluated and there are no overlaps or contacts between bushings.
- The position of the bushings has been evaluated with respect to the dental elements, avoiding collisions both with the surgical guide in place and in the guide positioning and removal phase
- The locking pins were positioned along the flanges of the guide and not outside in the "vacuum", the tips of the pins reach into the bone but not pass through it. The orientation of the pins, in particular the section angle, is such as to allow an easy operation during the intervention.
- The implant project was exported from the software and burned onto CD-ROM or copied to the USB stick. The burning or copy process has been verified.

CHECK LIST ORDER MODELGUIDE

VALID FOR: GUIDES UP TO 3 IMPLANTS, 4 IMPLANTS, OVER 4 IMPLANTS, BONE MODEL,
PERFORATED MODEL FOR ANALOGUES

This check list has the purpose of providing a valid help for the clinician in successfully completing all the steps necessary to issue the order ModelGuide Easy avoiding discomfort or delays.

ORDER

- The BioOrd portal was used to issue the order.
- In the compilation of the order, if present, the following have been indicated: the number of pins used, the number of post-extractives and all the dental elements that will be extracted were listed in the notes.
- In the event of a request for perforated model for analogues this has been specified in the compilation of the order and the size of the analogues used were given.
- The order form was printed, and was signed and stamped.
- In the case where, after issuing the order on the BioOrd portal, the material to be sent to Bionova is not yet ready, it was specified in the order notes indicating day, time and location of the availability for the withdrawal of the material.
- The package to be sent to Bionova contains: master model, duplicate of the master model, radiological template joined to the Universal Stent, CD-ROM drive or USB key of the implant project, "Radiological guide production check list", order form stamped and signed.
- The label with the printable address from the BioOrd portal was affixed on the package to be sent to Bionova or it has been affixed manually (Bionova s.r.l. - Via Trieste 4 - 19020 Follo SP).

ANNEX B

CT SCAN PROTOCOL

Name or Patient ID

Dental Practice

Note

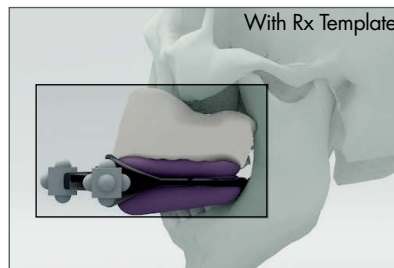
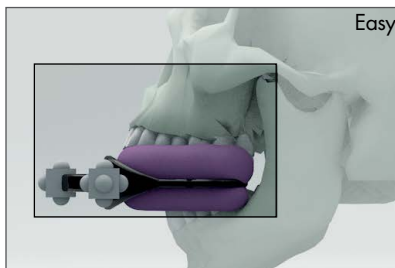
Date

Radiological Template & Universal Stent

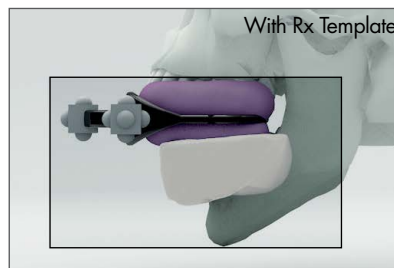
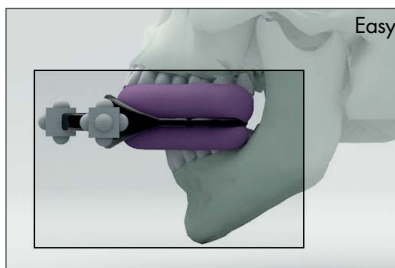
Please check that the Radiological Template & Universal Stent are seated properly and check that the Radiological Template make good contact with the gums and teeth surface.

Patient positioning

*Maxilla: scan the entire maxillary arch and the maxillary sinuses region.
The CT volume should include all the radiopaque markings on the Universal Stent.*

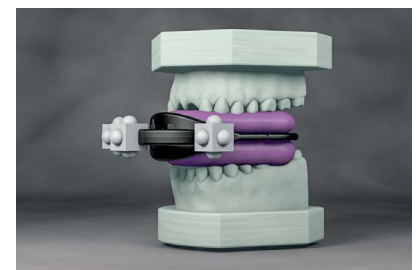
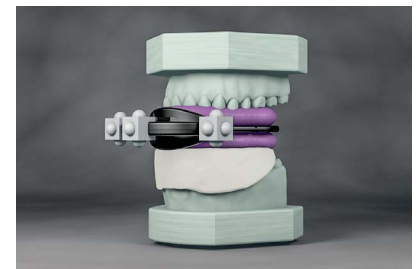
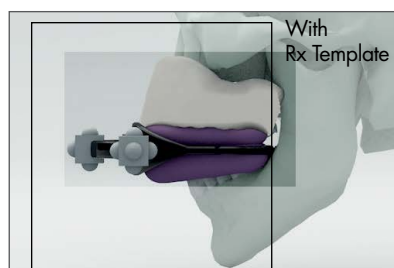
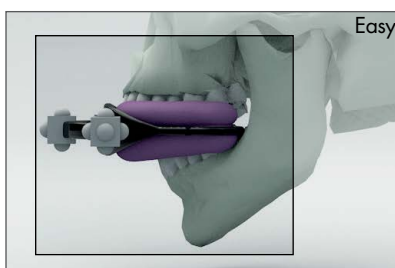


*Mandible: scan the entire mandibular arch and the mandibular canals region.
The CT volume should include all the radiopaque markings on the Universal Stent.*



Maxilla & Mandible: if the Patient needs an implant surgery for both jaws it is possible to perform a single scan. Scan the entire maxillary and mandibular arch including the maxillary sinuses region and the mandibular canals region.

The CT volume should include all the radiopaque markings on the Universal Stent.

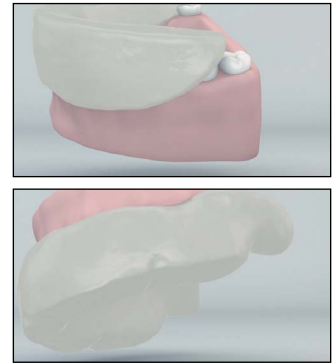


Scan Parameters

Pictures Size	from 512x512 to 800x800
Gantry Tilt	0.0° Mandatory
Axials thickness	from 0.25 to 1.00 mm
Image Format	DICOM 3.0 multfile
Compression	None

After CT scan please return to the Patient the Radiological Template, the Universal Stent and the CD-ROM with the axials images in DICOM 3.0 format (multifile). If both jaws were scanned please save the axials sequences in two separate folders or two CD-ROMs.

CHECK LIST FOR THE PRODUCTION OF THE RADIOLOGICAL TEMPLATE



The purpose of the production check list is to indicate the phases the ModelGuide licensee dental technician laboratory must go through to create the radiological guide. The check list should be filled-out by the laboratory that manufactures the radiological guide by check-marking the boxes and should be signed and delivered to the requesting dentist together with any template produced as confirmation of the proper execution of the protocol. The Dentist should enclose the check list when sending the material for the construction of the surgical guide.

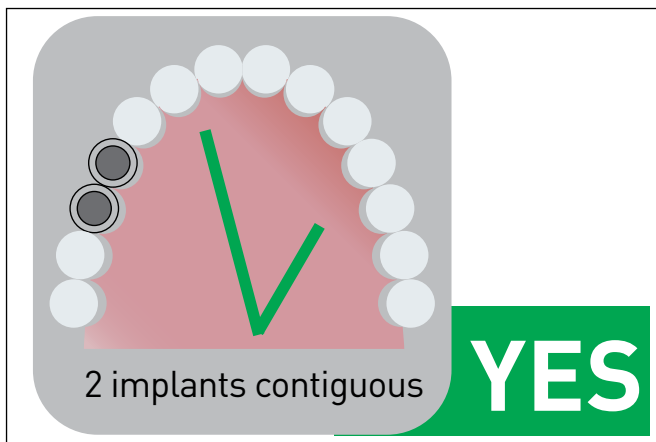
1. In cases of upper fully edentulous jaws, the radiological guides should have the entire palate. "Horseshoe" templates, with reduced palate are not accepted.
2. When creating full templates, it is necessary to create a reinforcement side box in transparent acrylic resin, to give major flexural strength to the template.
3. The vestibular-palatal and vestibular-lingual thickness in the front area should be at least 10 mm and 15 mm in the rear quadrants. 3-4 mm palate.
4. In full templates, the vestibular flanges must reach the arches, while in partial templates they must go over the teeth neck (unloading the undercuts, if necessary).
5. The Barium must be in the right amount: when mixing directly Barium Sulphate 20% with transparent acrylic resin 80%. An alternative is the use of Vivotac powder 50% + 50% transparent acrylic resin.
6. Do not use coloured acrylic resins; the allowed colours are transparent and white of the Barium.
7. The models should be created using class III plaster.
8. Remove the strongest undercuts from the Master Model using only and exclusively wax.
9. Make a duplicate model starting from the Master Model with undercuts already operated.

date

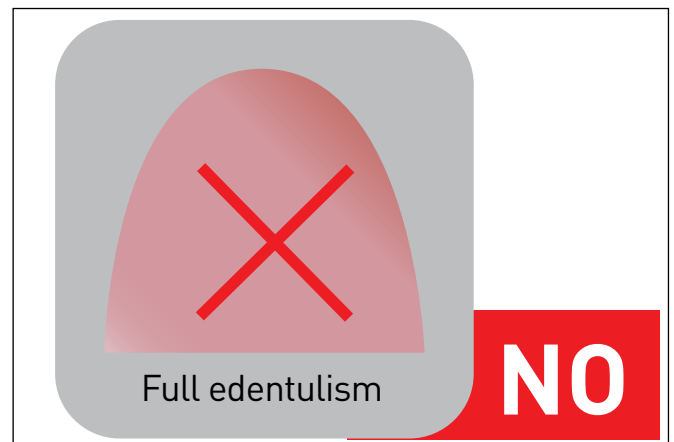
stamp and signature

BioOrd order number

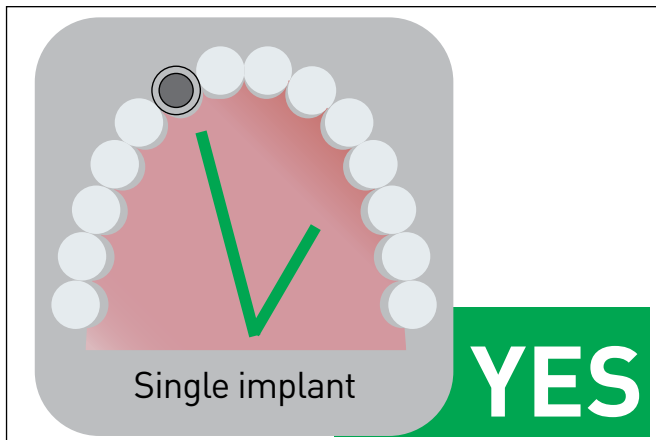
PROTOCOL LIMITATIONS MODEL EASY



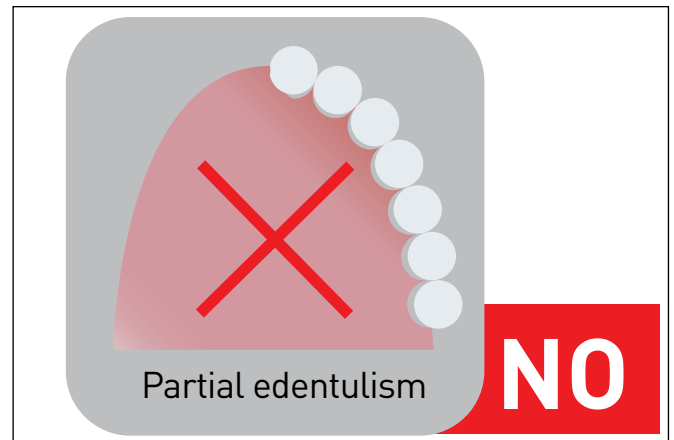
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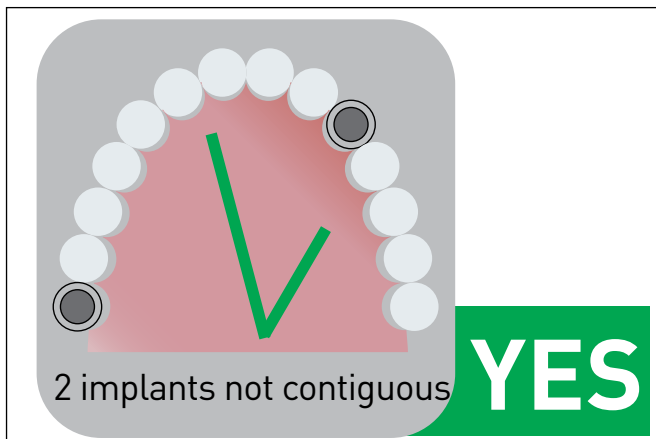
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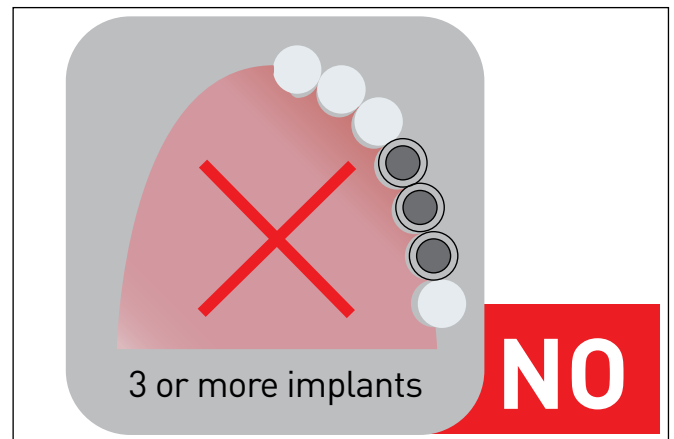
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E

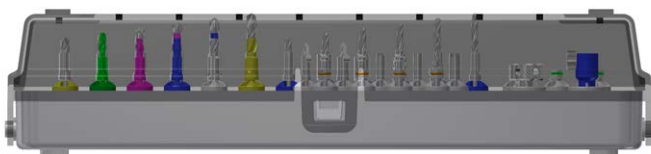


C

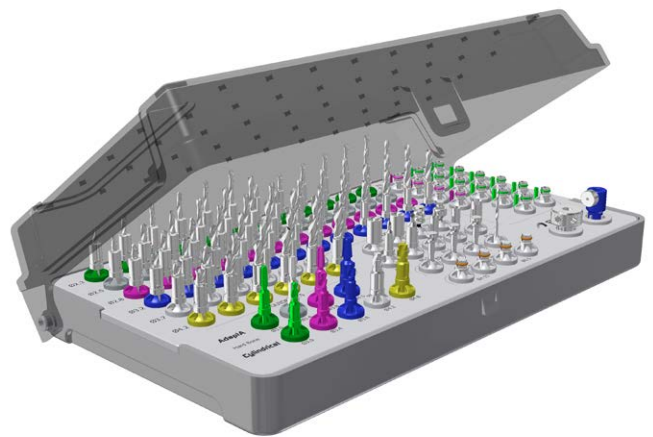


F

ANNEX E



Surgical Kit.



02 Surgical Kit.

ANNEX E



Tissue punch



Bone crestal drill



Drill



Drill neck
Pro Cylindrical - Adapta



Guided mounter + screw



Driver



Crestal pin



Lateral pin



Drill lateral pin



Extension



Extractor



Mount adapter for micromotor



Manual key + lever



Implant support



Dynamometric torque wrench