

RealGUIDE

UNIVERSAL OPEN SYSTEM

Procedure Manual



This manual is aimed exclusively at clinical professionals and is not a substitute for RealGUIDE guided surgery courses. For further details on the courses please refer to the TEAM TRAINING PROGRAM (downloadable from the www.3diemme.it website).

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I would like a simple and reliable procedure based on an open system for all implant platforms, customised according to my needs



Doctor

I would like an advanced diagnostics platform, which manages any examination in DICOM format, that can be distributed to Doctors to complete my diagnosis with a simple surgery planning protocol



Radiologist

I would like an open system, which can be interfaced with my prosthetic modelling systems and CAD/CAM that allows me to design and produce surgical guides and prosthesis based on the Doctor's planning



Dental technician

I would like minimally invasive surgery with fast post-operative recovery and foreseeable aesthetic results



Patient





“We shall not cease from exploration,
and the end of all our exploring
will be to arrive where we started
and know the place for the first time”
Thomas S. Eliot

COMPANY PROFILE

3DIEMME Srl is a services Company aimed at Professionals and Companies to provide advice and design in the technical and biomedical field. Since 2006 the company has worked in the dental and maxillofacial sector supporting Doctors and Dental technicians worldwide in managing clinical cases with minimally invasive and digital technologies.

Among the major services offered by 3DIEMME we highlight the following:

Development and customisation of medical software (3Diagnosys®)

Management of guided surgery procedures using the RealGUIDE technique

Application of rapid prototyping technologies and CAD/CAM in the biomedical field

Support in the preparation of scientific papers and presentations at medical conferences

MISSION

3DIEMME can provide the Customer (Doctor, Dental technician or Industry) a personalised solution for specific needs: ranging from the complete product (software and hardware) to specialised services (software customisation, virtual modelling and multi-material rapid prototyping).

Unlike competitors, 3DIEMME can prove the use of its Technology directly on actual problems of the Customers, illustrating the operation of each step to achieve the desired Solution, thanks to the possibility of visiting the production department of the Company and assist the practical manufacturing of Products to be used immediately in solving actual clinical cases.

VISION

To be the reference company for the digital management of minimally invasive surgery via the implementation of software that integrates all the information required for the Patient's customised rehabilitation in one open system.

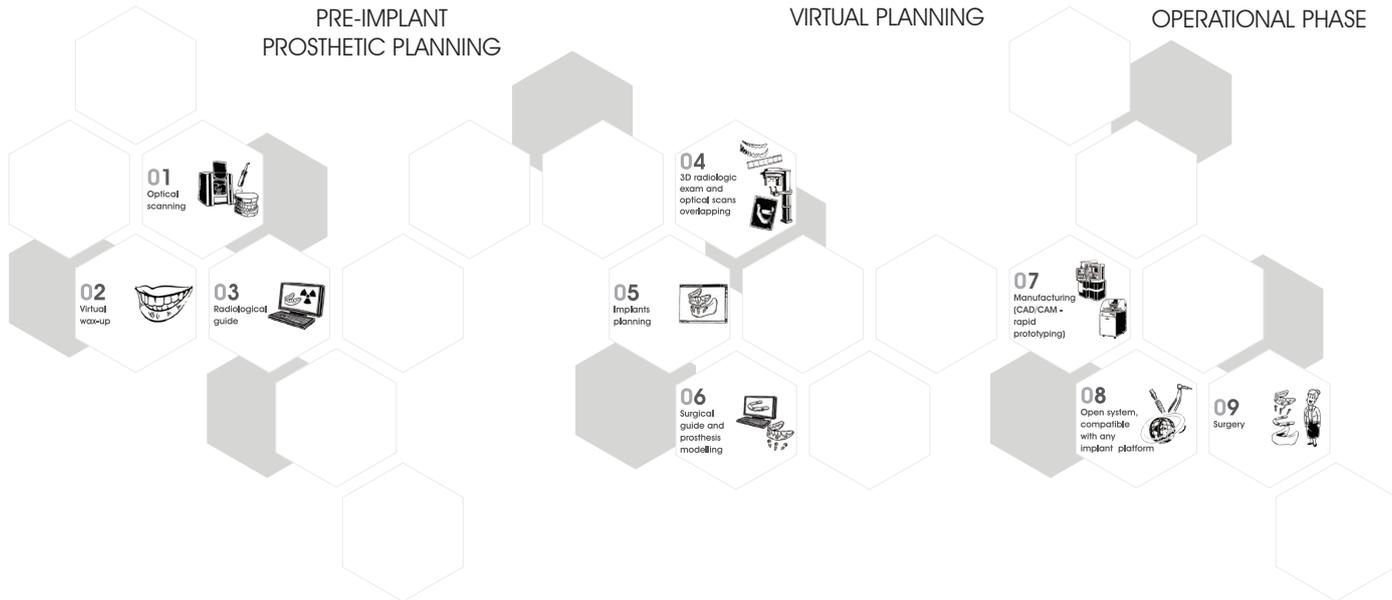
The scope of 3DIEMME is to provide the best solution to integrate the prosthetic planning (from scanners and laboratory modelling software) with the clinical treatment (from diagnosis to computer-assisted bone regeneration to achieve the prosthetic implant and biologically driven design) and implement the resulting project via any CAD/CAM or RP technology available on the Market.

The RealGUIDE procedure is a technique of guided surgery based on the following principles:

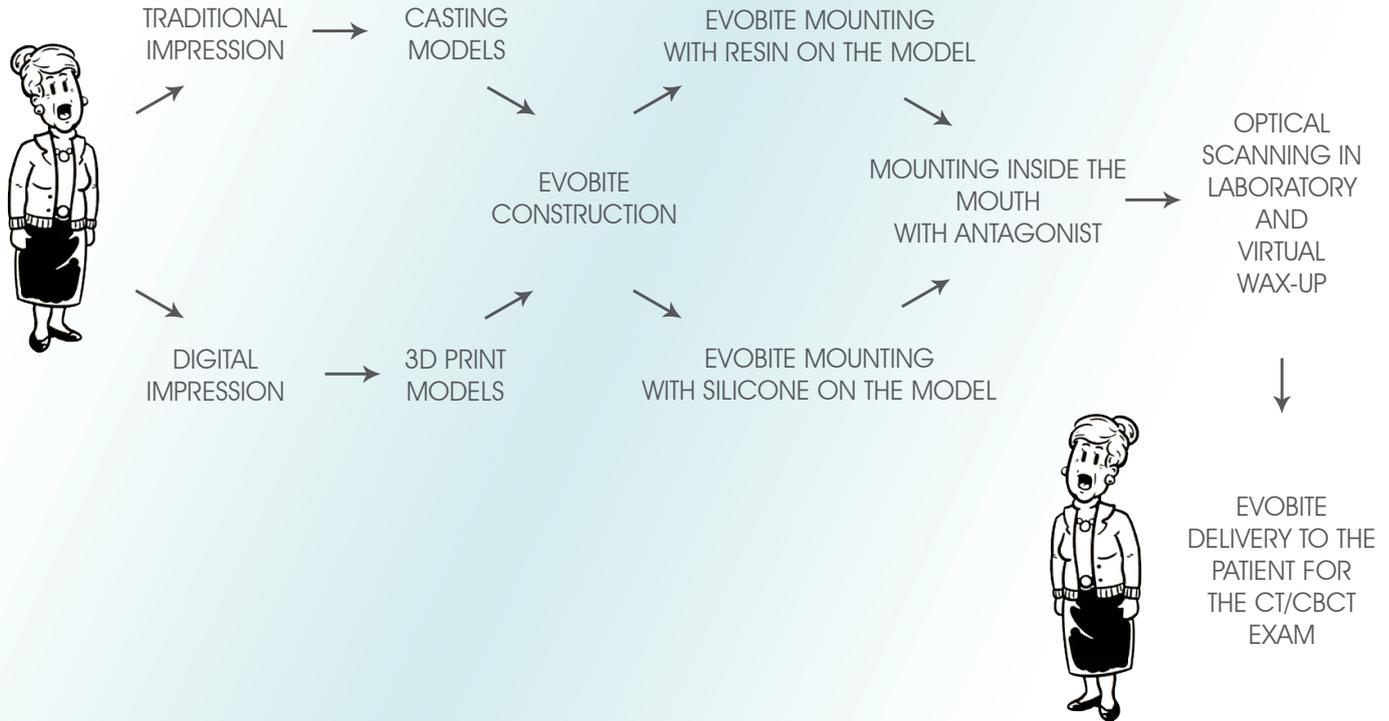
- Accurate three-dimensional reconstruction of the Patient by integrating data from X-rays and optical scanning of plaster models or intra-oral scans
- Use of certified software (3Diagnosys) which, in a simple and intuitive way, allows the Clinician to make a complete pre-implant diagnosis and create a virtual surgery plan
- Using the latest CAD/CAM and rapid prototyping technology for the automatic transfer of the treatment plan to a customised

surgical guide and a work model with implant analogs housing to be mounted in the articulator for the construction of temporary prosthesis

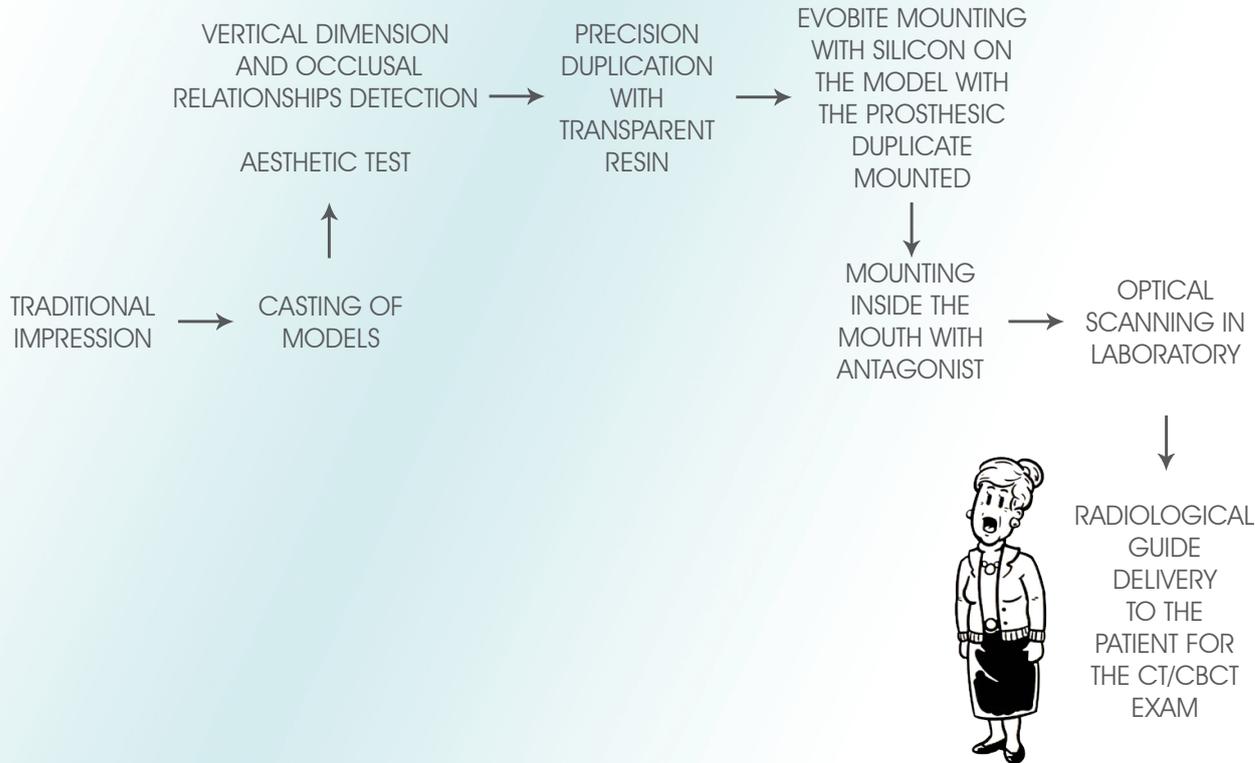
- Management of any type of implant rehabilitation intervention (partial, total and post-extraction edentulism) and bone regeneration (graft anatomical modelling)
- Open system and completely applicable to any implant platform, which can be fully integrated with the laboratory prosthetic modelling open software for the virtual design of the provisional starting from the implant planning of the Doctor exported in STL format



PARTIAL EDENTULISM



TOTAL EDENTULISM

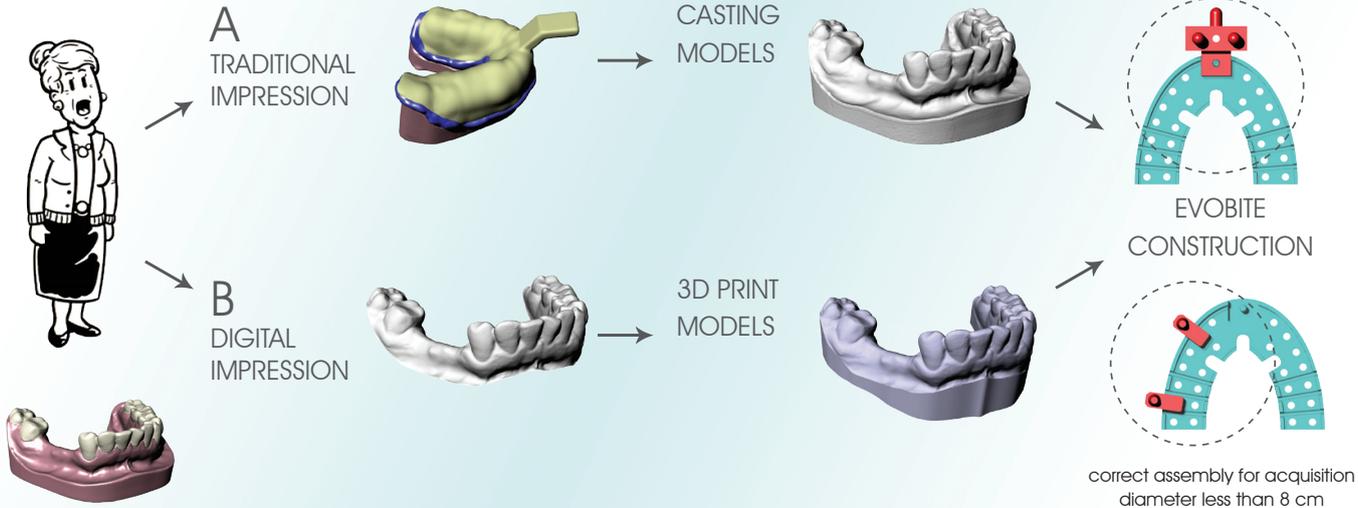


- Arch to operate, antagonist and centric
- Material:
 - If teeth are stable: silicone (polyether or similar polysiloxanes)
 - If teeth are not stable: alginate (after removal or splinting)
- Maximum extension, non-functionalised (anatomical)

Reproduce the exact situation of the mouth at the time of surgery

Extra-hard plaster model casting (no imperfections or bubbles)

- Fix the 3DMarkers to the bite according to the diagram below and glue them with a drop of cyanoacrylate
- Measure the bite on the model and if necessary shorten and fit it to the dimensions of the arch. It is advisable for the bite to reach the molars (not over)



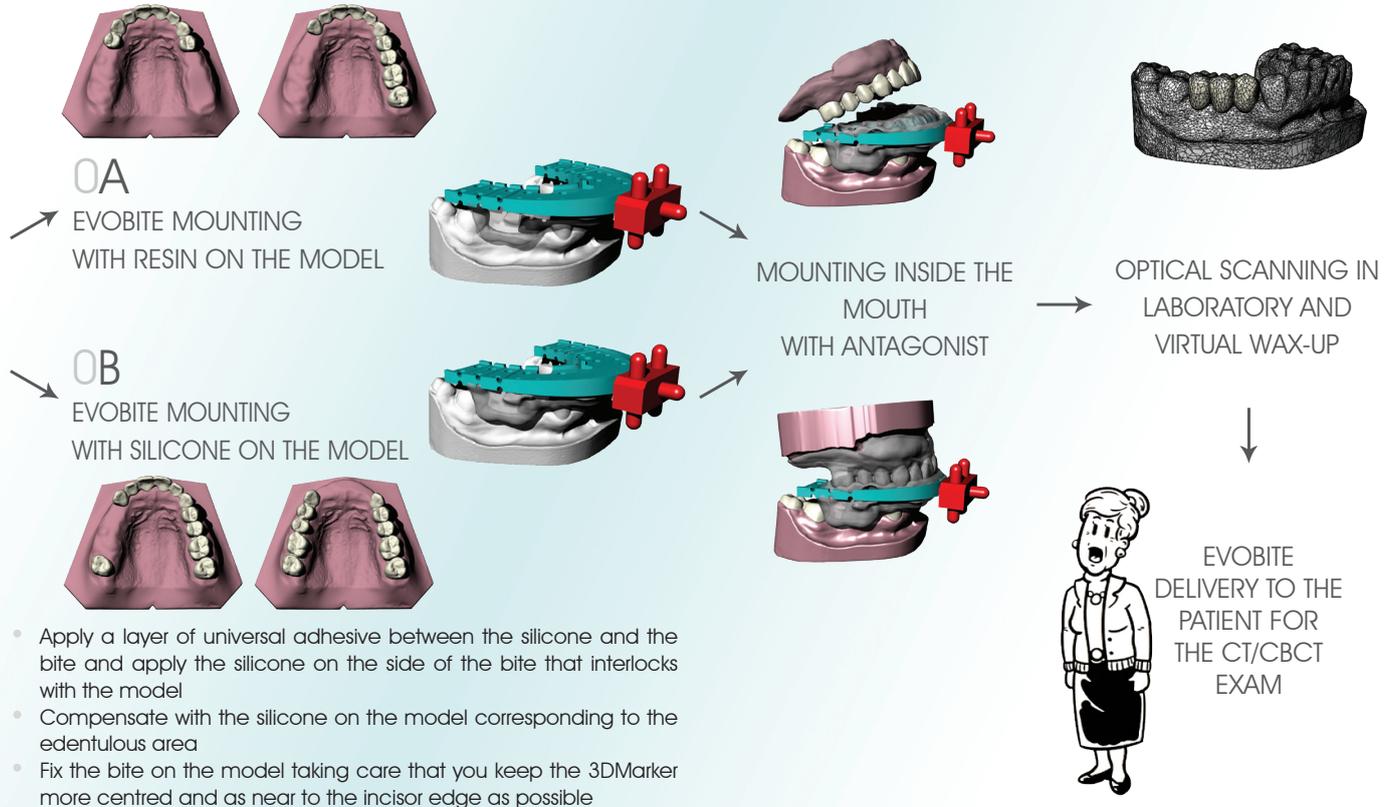
- Arch to operate, antagonist and centric
 - Maximum extension, without holes
- Reproduce the exact situation of the mouth at the time of surgery

High definition 3D print of the STL file

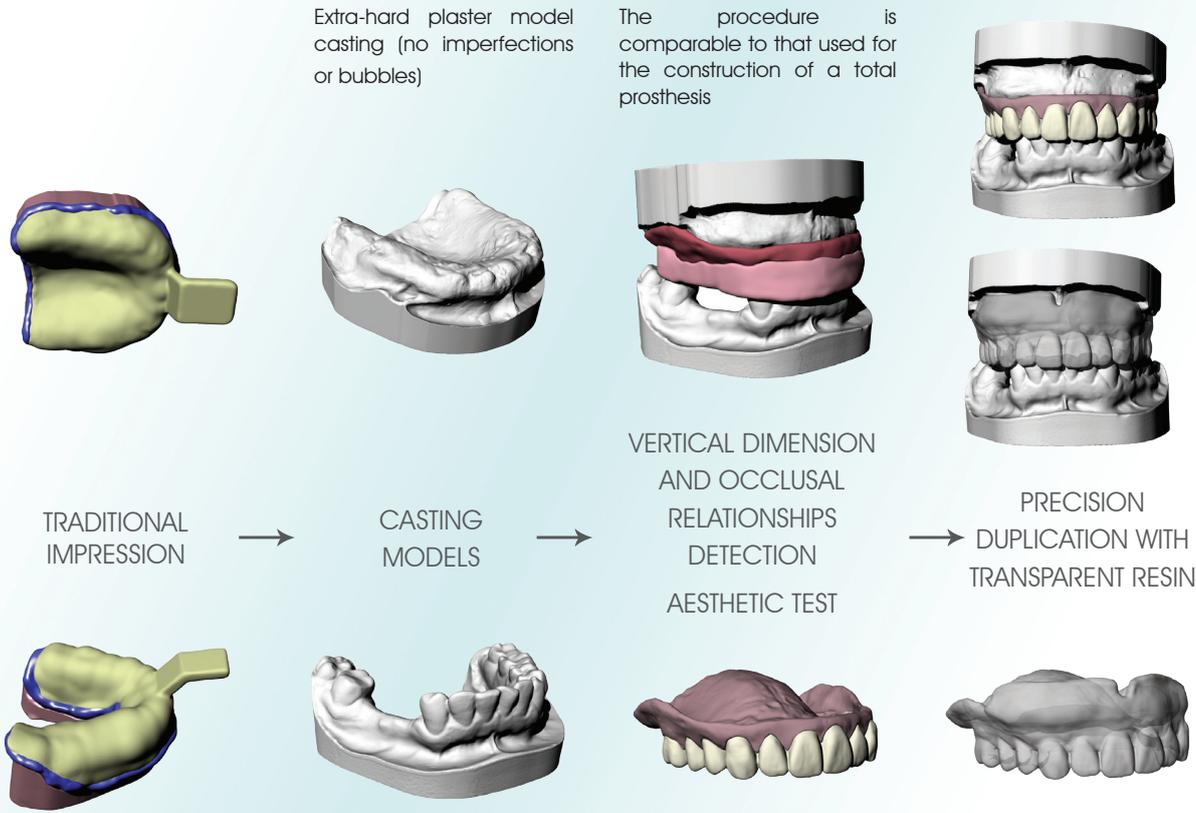
NOTE: THE COMPONENTS TO CONSTRUCT THE EVOBITE ARE DISPOSABLE

- Secure the Evobite with transparent and not radiopaque resin (orthodontic type) on the model, particularly compensating the space in line with the edentulous areas
- Keep the front 3DMarker more central and as near to the incisor edge as possible.

When hardened, position the bite on the patient and reline towards the antagonist with the same silicone supplied with the Evobite kit, taking care that you keep the bite steady (note: it is not a centric recording but a simple stabilisation key)



- Apply a layer of universal adhesive between the silicone and the bite and apply the silicone on the side of the bite that interlocks with the model
- Compensate with the silicone on the model corresponding to the edentulous area
- Fix the bite on the model taking care that you keep the 3DMarker more centred and as near to the incisor edge as possible



Extra-hard plaster model casting (no imperfections or bubbles)

The procedure is comparable to that used for the construction of a total prosthesis

TRADITIONAL IMPRESSION

CASTING MODELS

VERTICAL DIMENSION AND OCCLUSAL RELATIONSHIPS DETECTION
AESTHETIC TEST

PRECISION DUPLICATION WITH TRANSPARENT RESIN

- Arch to operate, antagonist and centric (raised)
- Material: silicone or alginate
- Maximum extension, non-functionalised (anatomical)

Reproduce the exact situation of the mouth at the time of surgery

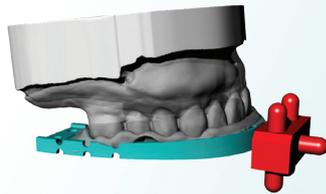
The duplicate of the aesthetic test must be precise and with transparent and NOT radiopaque material (orthodontic resin type), after having restored the vestibular flange

COMPATIBLE PROTOCOL

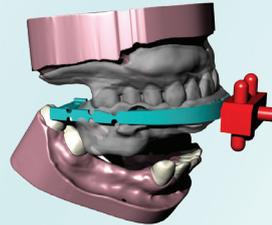
Although it is NOT recommended, if the patient has adequate removable prosthesis (from the aesthetic and functional aspect), proceed with its duplication after having relined it.

NOTE: THE COMPONENTS TO CONSTRUCT THE EVOBITE ARE DISPOSABLE

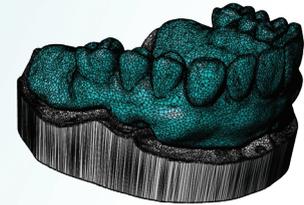
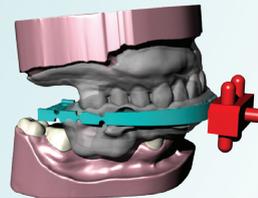
For the radiological guide to be stabilised, position the bite in the patient's mouth and reline towards the antagonist with the same silicone supplied with the Evobite kit, taking care that you keep the bite steady



→
EVOBITE MOUNTING WITH SILICON ON THE MODEL WITH THE PROSTHESIS DUPLICATE MOUNTED



→
MOUNTING INSIDE THE MOUTH WITH ANTAGONIST



↓
OPTICAL SCANNING IN LABORATORY

↓
RADIOLOGICAL GUIDE DELIVERY TO THE PATIENT FOR THE CT/CBCT EXAM



COMPATIBLE PROTOCOL

The RealGUIDE procedure is compatible with DUAL SCAN protocol (double scan) that consists of the insertion of radiopaque points in the prosthesis duplicate and double CBCT scan (patient with radiological template and radiological template only) to automatically overlap the scan of the prosthesis with the anatomy of the patient directly into the 3Diagnosis software. However, it is advisable to follow the standard procedure and use the Evobite even in cases of total edentulism

ALTERNATIVE PROTOCOL

Mounting the Evobite to the antagonist can also be performed in the articulator ONLY IF a RAISED centric was used during the initial phase. The same should be done in the case of guided surgery on two arches during the same operation





CT/CBCT
EXAM

EXPORT IN
DICOM FORMAT

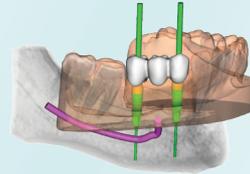
OVERLAPPED
DATA

VIRTUAL IMPLANT
PLANNING

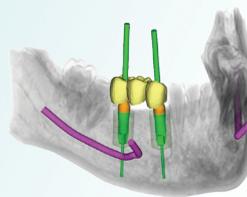
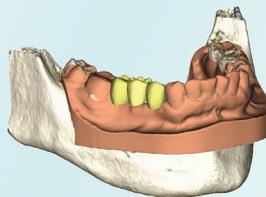
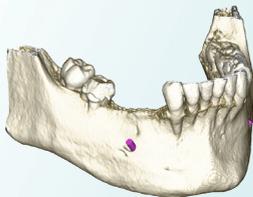
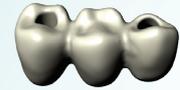
SURGICAL GUIDE AND
WORK MODEL
WITH HOLES FOR
IMPLANTS ANALOGS
MODELLING



ARCH OPTICAL SCANNING
AND DIAGNOSTIC WAX-UP
IN STL FORMAT



LABORATORY
PROSTHETIC
MODELLING



RADIOLOGICAL PROTOCOL

Once the perfect mouth fit of the radiological guide and the Evobite is verified, send the Patient to the Radiology Centre for the tomographic exam.

IMPORTANT: the Patient must be trained to properly position the radiological guide. Show the patient how to fit the guide and do some testing to make sure that the procedure is clear. The radiological guide MUST be preserved and returned to the studio.

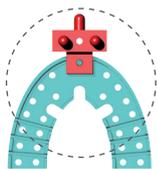
Patient positioning

- If possible, remove objects that may introduce artifacts in the images (jewellery, piercing, etc.)
- Make sure that the patient wears the radiological guide correctly
- Place the patient within the acquisition volume of the machine and make sure that he/she remains still during the capture of images

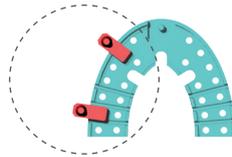
Suggested image capture settings

- Visual field (FOV: Field Of View): sections must have the same field of view that should include all relevant areas, especially the 3DMarkers related to the Evobite
- Capture all of the sections of an exam in the same direction and keep the space between the sections constant (less than or equal to the thickness of the single section)
- Perform a single capture of the Patient with the Evobite in position (it is not necessary to align the acquisition plane with the Evobite)
- Make sure that the 3DMarkers are completely included in the capture volume, as seen in the images below

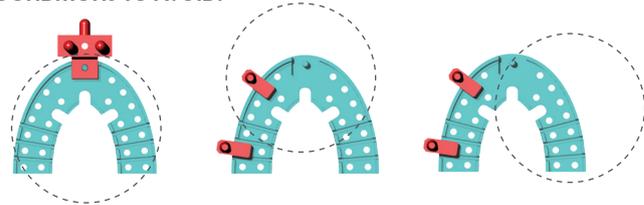
COMPLETE ARCH



HALF ARCH



CONDITIONS TO AVOID:



Exporting images

- Recommended export matrix: 512 x 512 pixels for each image (3Diagnosis can still import matrices of any size)
- Section thickness: use the thinnest available (possibly less than a mm)
- Reconstruction algorithm: use the algorithm with the highest resolution available (Bone or High Resolution)
- Image format: export axial images in uncompressed DICOM 3 format (standard). It is also advisable to export files in series and not compressed into a single file

If the Patient is sent to a Radiological Centre affiliated with 3DIEMME (complete list at www.3diemme.it), specify in the request that the images can be sent directly to 3DIEMME for faster processing.

A copy of this protocol can be found on the 3DIEMME website (www.3diemme.it) and attach a copy to the exam request that the Patient will give to the Radiologist.

OVERLAPPING DATA

OPTICAL SCAN PROCEDURE OF THE MODELS

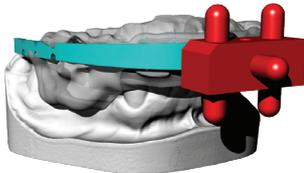
The models can be scanned by any laboratory scanner that allows the files to be exported in STL format.

1. Mount the model on the model holder clamp so that it is very stable
2. Perform the scan by paying particular attention to include all anatomical areas, including posterior areas and fornices (if present in the model)
3. Remove the model holder from the scanner and
 - a. FOR PARTIAL EDENTULISM: mount the Evobite while making sure it is secured and there is no risk of it moving during the model holder positioning procedure, and scan (like scanning a wax-up) with particular attention paid to the 3DMarkers regions
 - b. FOR TOTAL EDENTULISM: first mount the resin duplicate of the aesthetic test and perform the optical scan (prosthesis scan), then mount the Evobite (without removing the duplicate) and perform another optical scan (Evobite scan) with particular attention paid to the 3DMarkers regions
3. Export scans in separate STL files, with objects placed in the same reference system (i.e. opening the files together you have to be able to see them correctly mounted like on the original models)

PARTIAL EDENTULISM

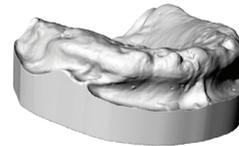


model scan

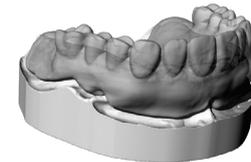


model scan with
Evobite

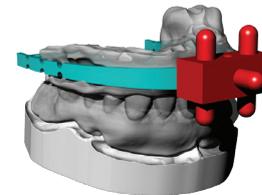
TOTAL EDENTULISM



model scan



model scan
with prosthesis

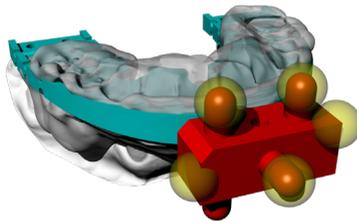


model scan
with prosthesis and Evobite

OVERLAPPING PROCEDURE OF STL FILES WITH THE DICOM EXAM

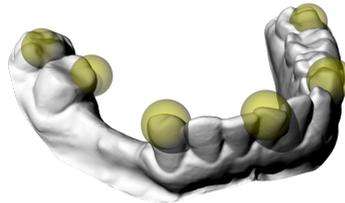
Depending on the STL data available, overlap the STL files with the DICOM dataset in the 3Diagnosys software according to the following alternative protocols (refer to the 3Diagnosys video tutorials for the detailed description):

STANDARD RealGUIDE PROCEDURE



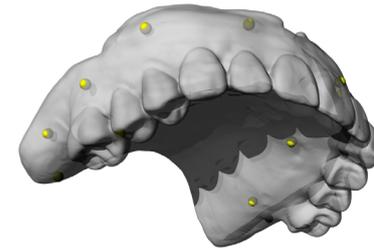
Using the 3DMarker as overlapping element of the STL files with the CT/CBCT exam (recommended)

DIRECT OVERLAPPING ON THE ANATOMY



Using dental elements as overlapping elements of the model or intra-oral scan with the CT/CBCT exam

CBCT DOUBLE SCAN PROTOCOL

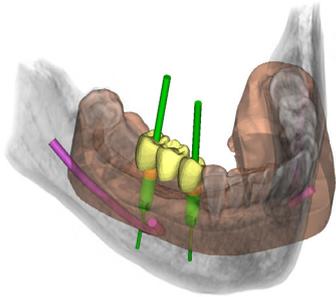


Using radiopaque points inserted in the patient's prosthesis duplicate to overlap the DICOM data related to the CT/CBCT of the prosthesis duplicate with the patient's CT/CBCT exam with the prosthesis in the mouth. In this case, the software will automatically search the reference points in the two dataset and overlap the prosthetic part with the anatomical regions directly

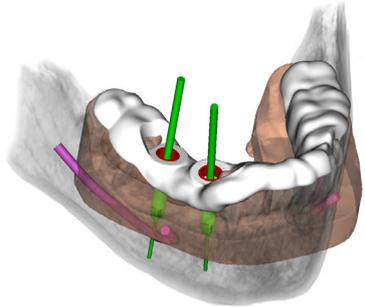
VIRTUAL MODELLING

The virtual project of the implants is used for the modelling stage of the surgical guide, the model with the holes correspondent to the implants analogs of the selected implant and the pre-modelling of the provisional prosthesis.

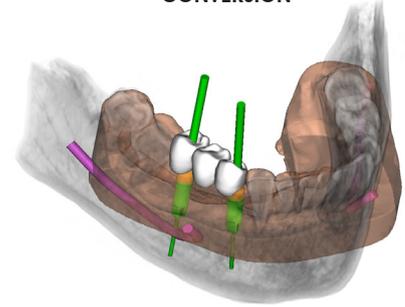
IMPLANT PLANNING



SURGICAL GUIDE



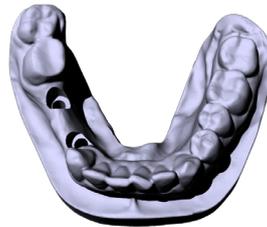
PROVISIONAL WAX-UP
CONVERSION



The result of the procedure therefore consists of all the components needed for minimal invasion and immediate rehabilitation of the patient:



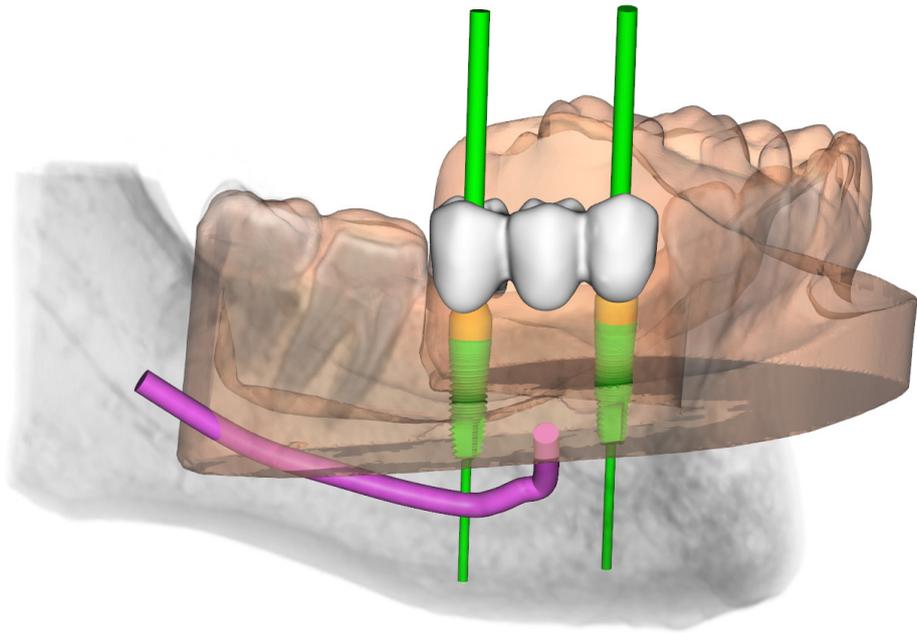
SURGICAL GUIDE



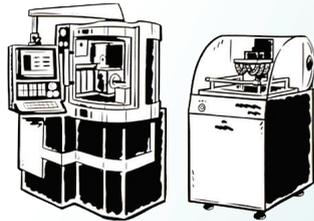
MODEL FOR ARTICULATOR



PROVISIONAL PROSTHESIS



PRODUCTION



- SURGICAL GUIDE
- WORK MODEL
- PROVISIONAL PROSTHESIS
- SURGICAL OCCLUSAL INDEX



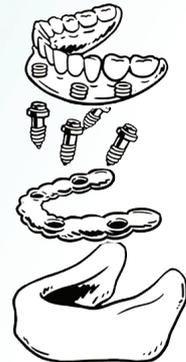
CHECKING THE
GUIDE INSIDE THE
MOUTH OF THE
PATIENT BEFORE
SURGERY



REALGUIDE
SURGICAL
KIT



SURGERY



SURGICAL GUIDE



- Made of biocompatible material (for temporary use, Class I in accordance with Rule 5 of Annex IX, Directive 93/42/EEC)
- Including metal guide sleeves, dedicated to the RealGUIDE kit or compatible kits (full list of the compatible kits can be found on the 3DIEMME website)
- Cold sterilisation

WORK MODEL



- Model with implant analogs holes, suitable for mounting in the articulator
- High quality and surface finishing
- Complete with the patient's name and indication of the size of the implants to be positioned

The resulting STL files can be used for production, by means of rapid prototyping and CAD/CAM technologies of all the components required for the transfer of the virtual design in the patient's mouth, and in particular:

- Construction of the **SURGICAL OCCLUSAL INDEX**: after mounting the work model and the surgical guide in the articulator, make a occlusal index in silicone with the same rise used for the initial centric
- Constructing the **PROVISIONAL PROSTHESIS** : from the virtual modelling (integrated with the implants planning, exported from 3Diagnosis), milled with the CAD/CAM technologies available

DRILL STOPS
 3DM626.1
 3DM626.15
 3DM626.2



MANUAL SCREWDRIVER
 3DM617



SQUARE CONNECTOR
 3DM612



EXTENSION FOR RATCHET
 3DM623



CYLINDRICAL BONE MILL
 3DM627



MUCOTOME
 3DM607



COUNTER-ANGLE SCREWDRIVER
 3DM618



TAPERED BONE MILL
 3DM628



START DRILL
 3DM621



DEPTH DRILLS
 3DM613.23.85
 3DM613.23.10
 3DM613.23.115
 3DM613.23.13
 3DM613.23.16



TORQUE WRENCH
 3DM611



OPENING GAUGE
 3DM622



FIXATION PINS DRILLS
 3DM610



FIXATION PINS
 3DM609



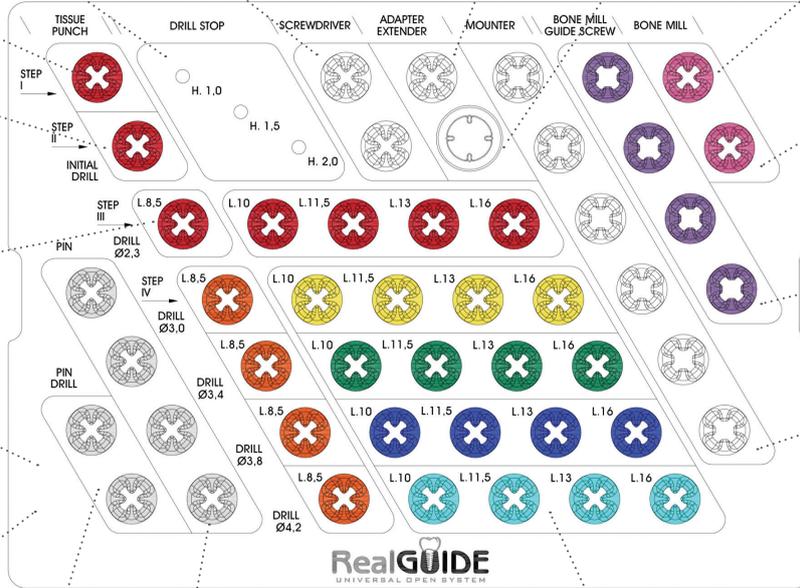
CALIBRATED DRILLS

3DM613.30.85	3DM613.34.85	3DM613.38.85	3DM613.42.85
3DM613.30.10	3DM613.34.10	3DM613.38.10	3DM613.42.10
3DM613.30.115	3DM613.34.115	3DM613.38.115	3DM613.42.115
3DM613.30.13	3DM613.34.13	3DM613.38.13	3DM613.42.13
3DM613.30.16	3DM613.34.16	3DM613.38.16	3DM613.42.16

GUIDE SCREWS FOR BONE MILL
 3DM629 (series)



IMPLANT MOUNT
 3DM606 (series)



PREPARATION DIAGRAM

The preparation diagram of the implant site is shown below as an example, for an implant of $\varnothing 4 \times 11.5$ mm. Refer to the table on page 24 and the description of the various steps of the surgical procedure on page 26 for further details.





OPENING GAUGE - 3DM622

The opening gauge of the mouth simulates the maximum dimensions of the RealGUIDE kit drills and must be used BEFORE manufacturing the radiological guide since it allows the maximum length of the implant to be determined according to the opening degree of the patient's mouth, especially in the rear sections. Mount the gauge on the surgical handpiece and turn the hex tip until the notch corresponding to the length of the implant estimated for the surgical site is seen; then simulate the insertion of the drills in the mouth (with the handpiece stationary) to verify the dimensions of the head of the handpiece.

The size of the hexagon at the base of the gauge coincides with the diameter of the guide sleeve, incorporated in the surgical guide and is useful to check the dimensions of the sleeve between the dental elements.



MUCOTOME - 3DM607

This tool performs a mucotomy of a diameter of 4.1 mm before the passage of the drills in flapless surgery. In case of little keratinised gingival tissue, it is not recommended to use the mucotome but to make a flap in line with the implant site.



FIXATION PINS DRILL - 3DM610

The fixation pins drill cuts at the tip and is bevelled at the edges. The drill should pass completely through the sleeve to guarantee that the pin grips firmly.



FIXATION PIN - 3DM609

The fixation pin fixes the surgical guide in position. The pin must be pushed all the way.



START DRILL - 3DM621

The start drill removes the mucosa cut by the mucotomy and prepares the cortical bone for the passage of the first drill. The start drill is inserted through the surgical guide all the way.



DRILL STOPS 3DM626.1 - 3DM626.15 - 3DM626.2

The drill stops are available in 3 heights: 1.0 - 1.5 - 2.0 mm and are mounted completely on all the drills that you wish to reduce the perforation depth. Thanks to the reduction rings, implants that are between 5.5 and 16 mm long can be guided with the same drills kit.



DEPTH DRILLS - 3DM613.23.85 - 3DM613.23.10 - 3DM613.23.115 - 3DM613.23.13 - 3DM613.23.16

The depth drills guarantee the initial preparation (2.3 mm diameter) of the implant site for implants that are 8.5 - 10 - 11.5 - 13 - 16 mm long. Vary the preparation length by inserting the reduction rings on the cylindrical part of the drill (3DM626 series) completely. The visible notches in line with the guide cylinder are placed at a distance of 1 mm between them and provide a visual indication of the correct assembly of the rings to the drill.

Example: guide an Implant of 14 mm in length by inserting the 2 mm reduction ring (3DM626.2) on the 16 mm drill (3DM613.23.16)

Inserting implants up to 13 mm in length: first use the 8.5 mm drill (3DM613.23.85) and then the drill corresponding to the length of the implant to be inserted.

Inserting implants longer than 13 mm: use the 8.5 mm drill (3DM613.23.85), then the 11.5 mm drill (3DM613.23.115) and then the drill corresponding to the length of the implant to be inserted.

Example: the sequence to insert a 10 mm implant is 3DM613.23.85 - 3DM613.23.10; the sequence to insert a 16 mm implant is 3DM613.23.85 - 3DM613.23.115 - 3DM613.23.16



CALIBRATED DRILLS

3DM613.30.85 - 3DM613.30.10 - 3DM613.30.115 - 3DM613.30.13 - 3DM613.30.16 - 3DM613.34.85 - 3DM613.34.10 - 3DM613.34.115 - 3DM613.34.13 - 3DM613.34.16 - 3DM613.38.85 - 3DM613.38.10 - 3DM613.38.115 - 3DM613.38.13 - 3DM613.38.16 - 3DM613.42.85 - 3DM613.42.10 - 3DM613.42.115 - 3DM613.42.13 - 3DM613.42.16

The calibrated drills complete the implant site preparation, which as to be managed according to the length of the implant and bone density. As in the case of depth drills, it is mandatory to first use the 8.5 mm drill, then the drill corresponding to the length of the implant to be inserted, up to 13 mm, inserting the 11.5 mm drill for implants that are longer than 13 mm.



IMPLANT MOUNT - 3DM606 (series)

The implant mount (driver) connects to the implant by means of the clamping screw and goes in the direction and to the depth of the implant through the surgical guide. Thanks to the hex reference on the implant mount you can also check the position of the connection of the implant through the surgical guide. Check the list of available implant connections on the 3DIEMME website.



MANUAL SCREWDRIVER - 3DM617

Manual screwdriver to tighten the screw of the implant driver.



COUNTER-ANGLE SCREWDRIVER - 3DM618

Screwdriver to tighten the screw of the implant driver with connection to the handpiece.



TORQUE WRENCH - 3DM611

Torque wrench for manual insertion of the implant, set for torque between 10 and 70 Ncm (refer to the technical documentation attached to the torque wrench for more information).



SQUARE CONNECTOR - 3DM612

Connector for guiding the implant driver with surgical handpiece.



EXTENSION FOR RATCHET - 3DM623

Extension for connection between the torque wrench and the implant driver.



GUIDE SCREWS FOR BONE MILL - 3DM629 (series)

Implant connection safety screws and bone mill guide to be inserted AFTER removing the surgical guide.



CYLINDRICAL BONE MILL - 3DM627

Used to remove the residual crestal bone to correctly position the straight abutments. To be used AFTER removing the surgical guide.



TAPERED BONE MILL - 3DM628

To be used AFTER the cylindrical bone mill to correctly position the angled abutments.

SEQUENTIAL DIAGRAM FOR POSITIONING A $\varnothing 4 \times 11.5$ mm IMPLANT



SEQUENTIAL DIAGRAM FOR POSITIONING A $\varnothing 3.75 \times 12$ mm IMPLANT



RealGUIDE KIT DRILLS SEQUENCE

IMPLANTS		SLEEVE	Mucotome [800 rpm]	START DRILL (800 rpm)	Depth drills [800 rpm] ø 2.3					Preparation drills [800 rpm] ø 3.0								
					CODE					CODE								
Implant diameter [mm]	Length [mm]	Code	ONLY FOR FLAPLESS SURGERY		3DM	3DM	3DM	3DM	3DM	3DM	3DM	3DM	3DM	3DM	3			
					613.23.85 ø 2.3 x 8.5	613.23.10 ø 2.3 x 10	613.23.115 ø 2.3 x 11.5	613.23.13 ø 2.3 x 13	613.23.16 ø 2.3 x 16	613.30.85 ø 3.0 x 8.5	613.30.10 ø 3.0 x 10	613.30.115 ø 3.0 x 11.5	613.30.13 ø 3.0 x 13	613.30.16 ø 3.0 x 16	613			
ø 3.3 - 3.4	8.5	3DM604CAD1	3DM607	3DM621	X					X								
	10				X	X			X	X								
	11.5				X		X		X		X							
	13				X			X		X		X						
	16				X		X		X		X		X					
ø 3.7 - 3.8	8.5							X				X						
	10				X	X					X							
	11.5				X		X				X							
	13				X			X			X							
	16				X		X		X		X							
ø 4.1 - 4.2	8.5							X				X						
	10				X	X					X							
	11.5				X		X				X							
	13				X			X			X							
	16				X		X		X		X							
ø 4.5 - 4.8	8.5							X				X						
	10				X	X					X							
	11.5				X		X				X							
	13				X			X			X							
	16				X		X		X		X							

NOTE:

This Protocol refers to the preparation sequence for D1 type bone according to the scale of Misch

Depending on the bone density (detectable even through the 3Diagnosis software functions), the Doctor may decide on the diameter of the final drill, based on his own clinical experience and depending on the geometry of the implant, for a possible under-preparation of the surgical site in order to increase the stability of the implant.

Preparation drills [800 rpm] ø 3.4						Preparation drills [800 rpm] ø 3.8					Preparation drills [800 rpm] ø 4.2					IMPLANT MOUNT [20 rpm - 50 Ncm]
CODE						CODE					CODE					
3DM 613.34.85	3DM 613.34.10	3DM 613.34.115	3DM 613.34.13	3DM 613.34.16	3DM 613.38.85	3DM 613.38.10	3DM 613.38.115	3DM 613.38.13	3DM 613.38.16	3DM 613.42.85	3DM 613.42.10	3DM 613.42.115	3DM 613.42.13	3DM 613.42.16	Code	
ø 3.4 x 8.5	ø 3.4 x 10	ø 3.4 x 11.5	ø 3.4 x 13	ø 3.4 x 16	ø 3.8 x 8.5	ø 3.8 x 10	ø 3.8 x 11.5	ø 3.8 x 13	ø 3.8 x 16	ø 4.2 x 8.5	ø 4.2 x 10	ø 4.2 x 11.5	ø 4.2 x 13	ø 4.2 x 16		
	X															
	X	X														
	X		X													
	X			X												
	X		X		X											
	X				X											
	X				X	X										
	X				X			X								
	X				X		X		X							
	X				X					X						
	X				X					X	X					
	X				X					X		X				
	X				X					X			X			
	X				X					X		X		X		

3DM606 series

The following illustrates the surgical procedure performed with the instruments discussed above. In order to preserve the vitality of the bone it is important to thoroughly perfuse the surgical area with sterile saline solution at 4°C during surgical manoeuvres.

ANAESTHESIA

It is advisable to avoid anaesthetic infiltration in keratinised mucosa to prevent dimensional changes that may affect the positioning accuracy of the surgical guide. Therefore, it is advisable in the maxilla to perform plexus anaesthesia in the vestibular fornix and nerve block at the greater palatine foramen and nose palatine foramen, whereas in the mandible perform plexus anaesthesia (or possibly truncal at the lower alveolar nerve) and infiltration at the tongue level.

POSITIONING OF THE SURGICAL GUIDE

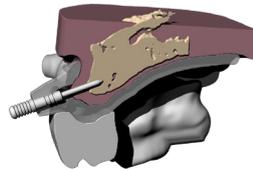
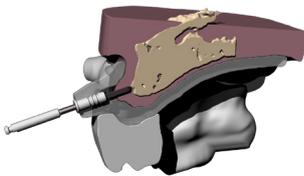


Place the surgical guide making sure it is stable, in case of a surgical guide with fixation pins, interpose the silicone occlusal bite between the arches and make the patient occlude firmly to ensure the position and stability of the surgical guide.

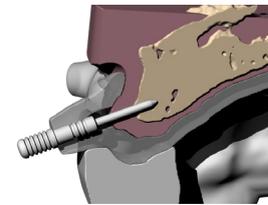
PAY PARTICULAR ATTENTION TO THIS STAGE AS POSITIONING THE GUIDE WRONGLY MAY AFFECT THE ENTIRE SURGICAL TREATMENT.

FIXING THE SURGICAL GUIDE

Insert the fixation pin drill (3DM610) in the vestibular sleeve, push until you feel contact with the bone and activate the motor, pressing on the handpiece up to the limit. Remove the drill and insert the fixation pin (3DM609). Repeat the operation for all the fixation pins. Check the stability of the guide before proceeding with the other steps.



DRILL AT FULL DEPTH

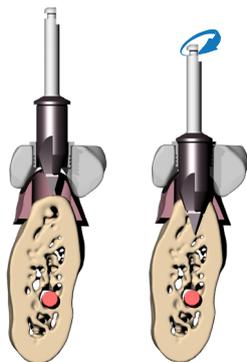


FIXATION PIN



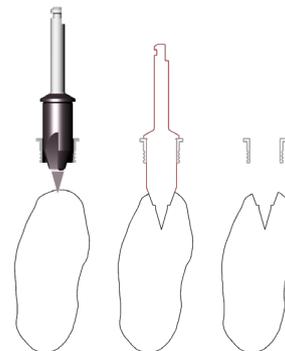
MUCOTOMY

Remove the occlusal bite and make a mucotomy by inserting the dedicated instrument (3DM607) through the sleeve of the surgical guide until you feel the mucotome make contact with the bone crest. The section of soft tissue can be removed through the sleeve with a special detacher or remove the guide to go directly to the gum, repositioning it at the end of the mucotomy using the silicone bite again.



INITIAL PREPARATION

Insert the start drill (3DM621) through the guide sleeve with the MOTOR OFF until the tip touches the bone, check the simultaneous engagement of the cylindrical part of the drill in the guide sleeve, and then begin the drilling phase at low speed (800 rpm). Pay particular attention to the insertion of the tip of this drill (perfectly aligned with the guide sleeve) as it directs the insertion of the subsequent drills. Verify that the gum cut during the mucotomy has been removed completely before drilling the implant site and flush it thoroughly to prevent the presence of mucosal tissue bring left in the implant site.



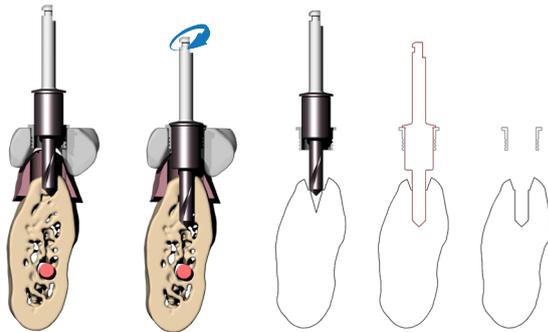
DEPTH PREPARATION

Begin the implant site preparation by inserting the (MANDATORY) first 8.5 mm depth drill (3DM613.23.85) in the guide sleeve of the surgical guide with the MOTOR OFF until the tip touches the bone; check the simultaneous engagement of the cylindrical part of the drill in the guide sleeve, and then begin the drilling phase at low speed (800 rpm). Depending on the length of the implant to be inserted, proceed with the next depth drill according to the following diagram:

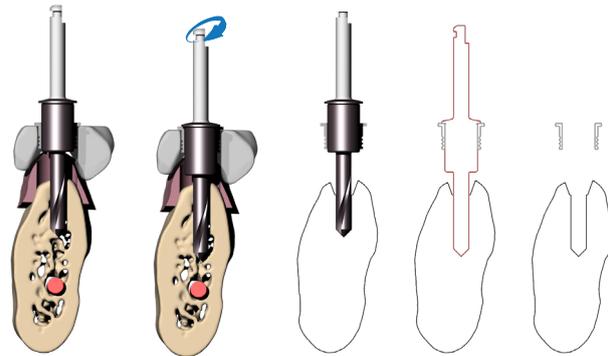
- Implants up to 13 mm in length: after using the 8.5 mm drill (3DM613.23.85), insert the drill corresponding to the length of the implant to be positioned (3DM613.23 series).
- Implants longer than 13 mm: after using the 8.5 mm drill (3DM613.23.85), insert the 11.5 mm drill (3DM613.23.115) and then the drill corresponding to the length of the implant to be positioned (3DM613.23 series).

If necessary, mount the drill stops (3DM626) corresponding to the length of the planned implant on the drill.

Drill the bone at full drill length and at low speed (800 rpm), thoroughly perfusing the implant site after each drilling phase to prevent the bone overheating.



DRILL
 \varnothing 2.3 x 8.5 mm
 3DM613.23.85

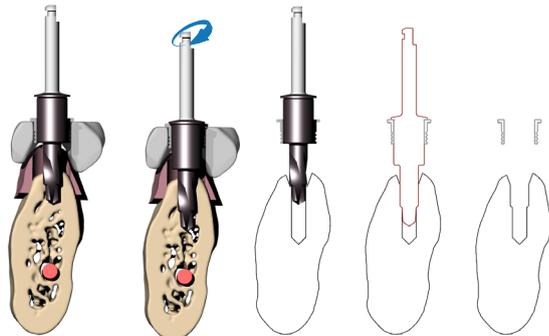


EXAMPLE OF USING THE DRILL
 \varnothing 2.3 x 11.5 mm
 3DM613.23.115

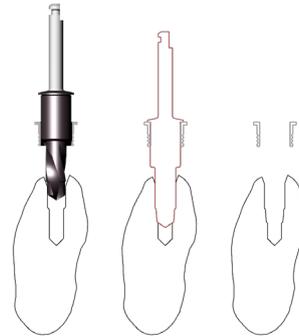
FINAL PREPARATION

Continue preparing the implant site using the preparation drills (3DM613 series), to be managed according to the length of the implant and the bone density. As in the case of depth drills, it is mandatory to first use the 8.5 mm drill, then the drill corresponding to the length of the implant to be inserted, up to 13 mm, inserting the 11.5 mm drill for implants that are longer than 13 mm (see the preparation diagram on page 24).

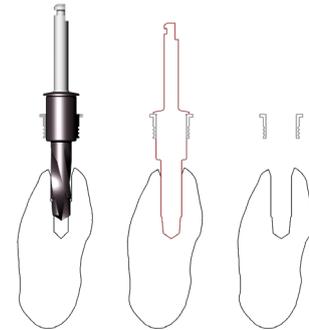
Insert the drill in the guide sleeve of the surgical guide with the MOTOR OFF until the insertion of the tip of the drill is felt to be entering the hole made in the bone by the previous drill. Verify the simultaneous engagement of the cylindrical part of the drill into the guide sleeve (DOUBLE GUIDE: of the tip in previous hole and of the cylindrical body in the guide sleeve), and then start drilling at low speed (800 rpm).



DRILL
ø 3.0 x 8.5 mm
3DM613.30.85



DRILL
ø 3.4 x 8.5 mm
3DM613.34.85



DRILL
ø 3.4 x 11.5 mm
3DM613.34.115

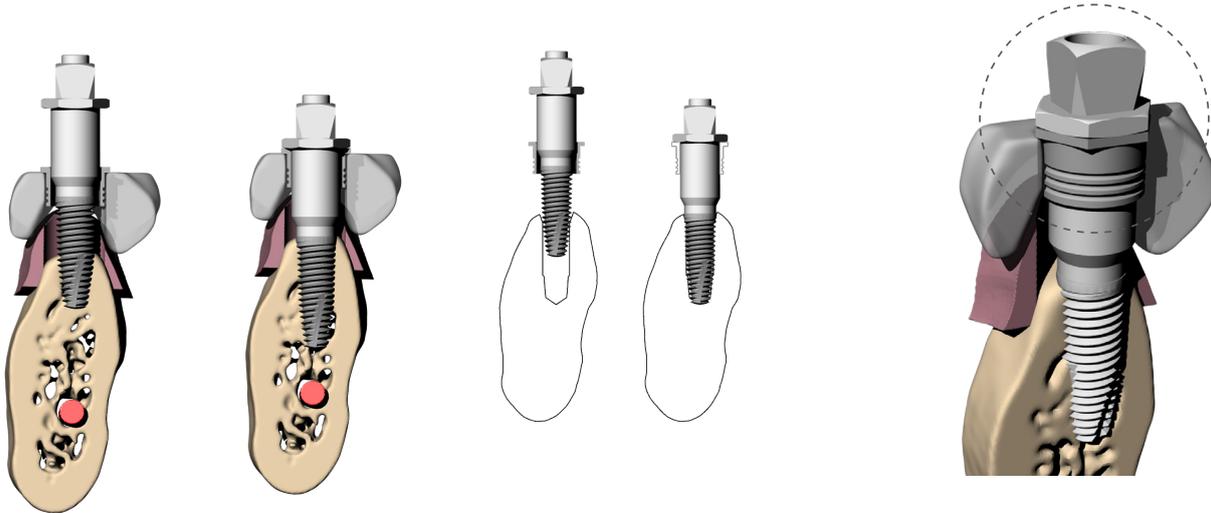
GUIDED IMPLANT POSITIONING

Once you create the implant site, position the implant using the appropriate 3DIEMME implant mount (3DM606 series).

Mount the 3DIEMME driver (check that the driver connection is correct according to the implant used BEFORE performing surgery) on the implant and tighten the connecting screw with a manual (3DM617) or handpiece (3DM618) screwdriver (max. 15 Ncm). If it is not possible to easily assemble the implant mount on the implant due to the presence of a pre-mounted driver, remove it and replace it with the 3DIEMME driver.

Insert the implant all the way through the guide sleeve using the square connector (handpiece-driver) (3DM612) or the torque wrench (3DM611) (max 50 Ncm). In case of difficulty in positioning due to excessive insertion torque of the implants, remove the implant and prepare with the drill that has a larger diameter or tap with a dedicated tool according to the surgical site. In the case of use of angled abutments it is important that the hexagon present in correspondence with the head of the driver aligns with the hexagonal profile of the sleeve inserted in the surgical guide.

Keep the driver in place while proceeding to the insertion of the next implant (to increase the stability of the surgical guide). In case of multiple implants, it is advisable to insert implants alternating the right site with the left site in order to avoid the surgical guide from possibly rotating with respect to the centre of gravity. Keep in position at most two or three drivers (depending on the number of implants to be inserted) to avoid generating excessive tension in the surgical guide.



ALIGNING HEXAGONS TO CORRECTLY POSITION THE IMPLANT CONNECTION

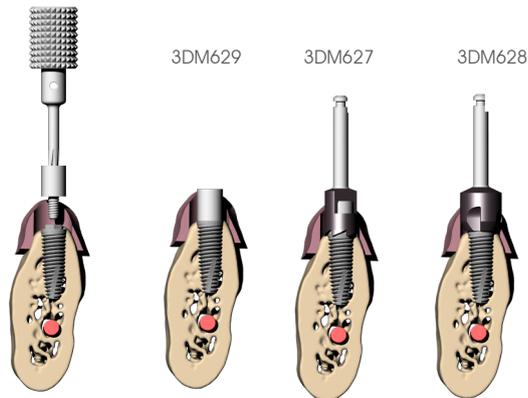
GUIDE REMOVAL

At the end of the insertion phase remove in the following order: the fixation pins of the surgical guide, the connecting screws and drivers inserted to remove the surgical guide.

Verify the possibility of the correct coupling of the prosthetic components correctly, thereby eliminating any excess soft tissue and residual bone crests that can interfere with the mounting of the abutments.

ADJUSTING THE BONE CREST

Mount the connection safety screw and bone mill guide (3DM629 series) (verify that the connection of the screw is correct according to the implant used BEFORE performing surgery); insert the cylindrical bone mill (3DM627), if straight abutments are used, with the motor off until engagement with the guide cylinder of the screw; then proceed at low speed until the stop is reached. It is recommended not to press the handle all the way and work with an oscillating movement so as not to over-tighten (indirectly) the protection screw making it difficult to remove it from the implant. If angled abutments are planned also use the tapered bone mill (3DM628) to allow the abutment to be housed adequately even in cases of irregular bone crests. Remove the protection screw when finished.



ASSEMBLY OF PROSTHESIS

Proceed with the installation of the prosthesis according to standard procedures.

CONDITIONS OF SALE

GENERAL ASSISTANCE (Italy Timezone)

From Monday to Friday from 8:30 to 12:30 and from 14:30 to 18:00 (except holidays):

Tel.: +39 031 7073353 Fax: +39 031 710284

For information related to order management, shipment and invoicing: segreteria@3diemme.it

For information on product sales and services: biomed@3diemme.it

For technical information on the products: biomed@3diemme.it

For technical assistance: info@3diemme.it , odontofec@3diemme.it

TERMS OF DELIVERY AND SHIPPING OF PRODUCTS

Product Delivery

The products and services provided by 3DIEMME S.r.l. are managed as follows:

GUIDED SURGERY and DIAGNOSIS

- 3DIAGNOSYS AND PLASTYCAD SOFTWARE LICENSES - installation within 2 working days
- SINGLE PATIENT 3DIAGNOSYS SOFTWARE GENERATION FROM DICOM DATA - 1 working day
- OVERLAP DICOM/STL VIA INTRA-ORAL OPTICAL SCAN OR DENTAL MODELS (AND/OR A RADIOLOGICAL MODEL/TEMPLATE SCAN) - 2 working days
- TECHNICAL ASSISTANCE FOR IMPLANT PLANNING - by appointment
- WORK MODEL 3D PRINT AND SURGICAL TEMPLATE (RealGUIDE CAD technique) - 6 working days

CONSUMABLES

- SURGICAL/DENTAL EQUIPMENT - 2 working days

MEDICAL PROTOTYPING

- BONE MODEL 3D PRINT FROM DICOM DATA - 4 working days
- 3D PRINT FROM STL FILE (orthodontic set-up, intra-oral scans, surgical guides) - 3 working days

STL FILE GENERATION FROM DICOM DATA

- DICOM DATA CONVERSION TO STL FILE - 2 working days
- BONE GRAFTING VIRTUAL MODELLING - by appointment after receiving the prescription form

Product shipment

Shipping is by courier (chosen by 3DIEMME S.r.l.), standard or express, at the expense of the Customer.

The goods will be sent in protective packaging in order to prevent damage being caused during transport.

3DIEMME S.r.l. is not responsible for shipment errors due to incorrect or incomplete information when provided by the Client when placing the order. In case of non-delivery for reasons attributable to the Customer, the goods will be resent at the expense of the latter.

Receiving the products

Upon delivery of the products to the Customer by the carrier assigned with their transport, the Customer, in the presence of the carrier, must check that the packaging used for transportation is intact, not damaged, wet or otherwise altered, even to the packaging material. Any anomalies must be immediately reported to the carrier and the delivery must be accepted with reservation.

The Customer must then check that the amount and type of products ordered correspond to that specified in the transport document; any discrepancy must be reported immediately by e-mail to 3DIEMME S.r.l. – segreteria@3diemme.it .

No complaints made after 24 hours that the products have been delivered will be accepted.

The times indicated are to be calculated from the date of the order confirmation that 3Diemme S.r.l. sends to the Customer and do not include the shipping service.

For orders placed after 14:00 hours (the delivery date of the courier/server mail will be considered), the 1st working day is that following the date of the order.

3DIEMME S.r.l. agrees to promptly notify the Customer of any changes in the delivery times.

CONDITIONS OF SALE

PAYMENT METHODS

The following payment options are available:

- with credit card ("E-SHOP" section on the 3DIEMME website)
- with advance bank transfer

Special payment terms can be granted in the case of continuous collaboration (for example, a single invoice is issued at the end of the month and payment is made by bank transfer 30 days after end of month), after discussing and agreeing with the Sales Manager of 3DIEMME S.r.l.

Lastly, financing conditions are available depending on the individual offers (to be discussed with the Sales Manager of 3DIEMME).

WE VALUE YOUR OPINION

3DIEMME S.r.l. provides its Customers with an efficient tool for the continuous improvement of the services and products offered. By letting us know any problems or comments you may have, you can help us improve our efficiency. Our Customer Assistance Service Tel.: +39 031 7073353 enters all the information you submit in our special Customer Loyalty program. Automatically, we activate various internal processes to evaluate or respond to your requests. We would be very grateful if you send us your suggestions or feedback. Thanks to your cooperation we will be able to implement useful action to constantly improve our service according to your satisfaction. If you wish, you may send us your suggestions at the following e-mail address: biomed@3diemme.it

INVOICING

An invoice will be issued for each order; therefore, please provide complete billing information when placing the order.

The invoice will then be sent via e-mail to the CUSTOMER in .pdf format. If not requested, no printed copy will be sent. It is the responsibility of the customer to print and keep the invoice according to all the necessary legal obligations of the specific Country.





3DIEMME srl - via Risorgimento 9 - 22063 Cantù CO - ITALY - tel +39 031 7073353 - fax +39 031 710284 - biomed@3diemme.it - www.3diemme.it