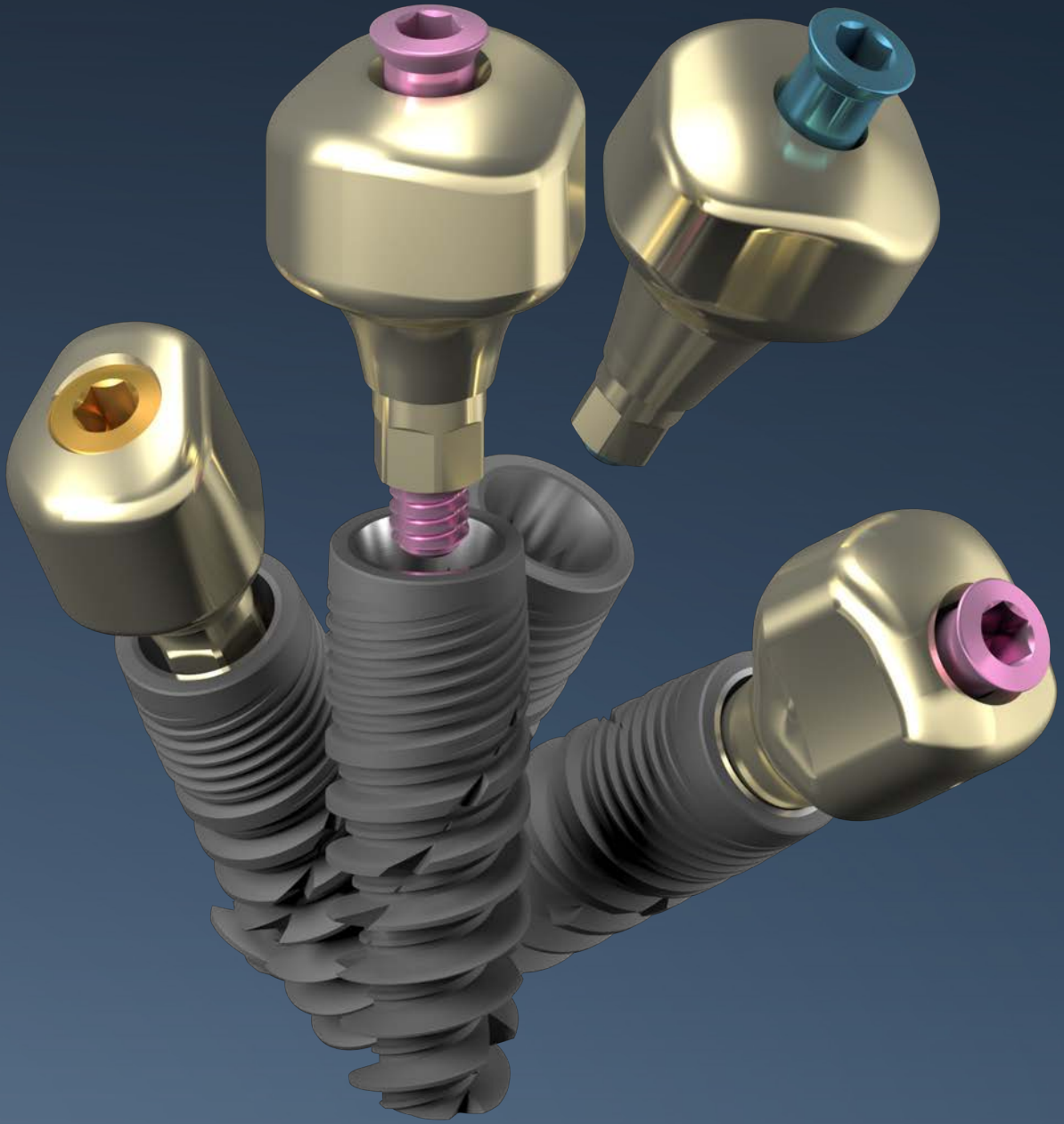


PROFILE DESIGNER

iphysio[®]



INSTRUCTION MANUAL

Healing - Impression - Temporary

Distributed by

LYRA[™]

TABLE OF CONTENTS

I.	Warning	p.4
II.	General information	p.5
	1. iphysio® concept	p.5
	2. Packaging and storage of parts	p.6
	3. Precautions for Use	p.7
	4. Warranties	p.7
III.	Selection of the iphysio® Profile Designer	p.8
	1. Choice of shape and height	p.8
	2. Use of trial abutments	p.9
IV.	Placement of the iphysio® Profile Designer	p.11
V.	Impression taking on Profile Designer iphysio®	p.13
	1. Digital impression	p.13
	2. Silicone impression	p.14
VI.	Temporisation on the iphysio® Profile Designer	p.15
VII.	The key design points of the final prosthesis in the laboratory	p.18

I. WARNING

The iphysio® concept must be used by a practitioner who has been previously trained in dental implantology techniques and under aseptic conditions suited to this type of intervention.

The following instructions will guide you in the performance of the different phases to be implemented in order to carry out your implant treatments. They are accompanied by the most accurate advice possible. Nevertheless, the practitioner remains solely responsible for his/her different choices and decisions with regard to the feasibility of treatment. The technical specifications and clinical advice contained in this manual are given purely for information purposes with the aim of providing assistance, and may not give rise to any claim.

We have taken particular care with the design and manufacture of our products; we nevertheless reserve the right to make changes or improvements arising from new technical developments of our implant system. You will be notified of any change which has an impact on the operating method. Depending on the extent of these changes, a new manual will be submitted to you. In effect, on the back of your instruction manual, there is an index indicating the date of publication which allows us to check whether you are in possession of the latest updates. You may also consult our website to check which is the current version of this manual.

Reproduction and distribution of all or part of this work requires the prior approval of LYRA.

II. GENERAL INFORMATION



1. iphysio® concept

The iphysio® concept is a post-surgical protocol for the preservation of soft tissue and hard tissue, whilst maintaining flexibility for the choice of the final, cemented or screw retained prosthetic restoration.

The iphysio® Profile Designer is screwed into the implant during the 1st or the 2nd surgical stage. It remains in place throughout the healing process as well as during the taking of an impression irrespective of the implant sector, whether aesthetic or not. It is only removed once to place the final screw retained prosthesis.

- **Healing:** its anatomic shape fully meets with the morphology of the teeth to be replaced.
- **The taking of the impression:** it is possible with both digital and conventional impression techniques.
- **The temporary prosthesis :** its design makes it possible to adapt a temporary prosthesis in the aesthetics sector.

The iphysio concept also offers the possibility in the aesthetic zone to provide a supra-gingival temporary prosthesis on the Profile Designer without altering it.

	iphysio® Profile Designer	iphysio® Profile Designer
		
Utilisation	Anatomic healing Digital impression Silicone impression	Temporary prosthesis in the anterior sector

2. Packaging and storage of parts

Sterility and asepsis rules

The iphysio® Profile Designers are delivered sterile. A reference indicator shows the components' effective sterility on their packaging. The sterility is guaranteed for 5 years from the sterilisation. The standard expiry date is mentioned on the label.

Only an undamaged package can guarantee the products' imperviousness and sterility. Do not use products whose packaging may have been damaged or prematurely opened.

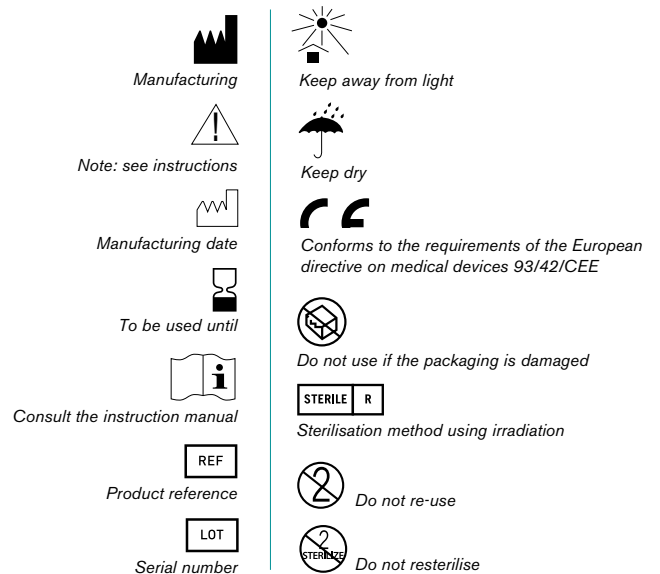
Our products have been designed so that their handling allows them to be maintained in sterile condition. It is therefore important to respect these in order not to compromise the standard asepsis conditions of implant practice.

The parts (temporary abutment and trial abutments) and instruments delivered non-sterile must be decontaminated and sterilised in the rooms according to a validated process.

Label

The Profile Designers and the associated parts of the iphysio® range are delivered with 1 main label and 2 removable labels clearly mentioning the trademark, reference and batch number (namely 3 labels):

- 2 labels for the implantology patient's file or his/her correspondent.
- 1 label for the patient.



Storage of parts

All the iphysio® components must be kept in a clean, dry and fresh place, far from any high-risk chemical product (solvents, detergents, etc.).

3. Precautions for Use

The iphysio® Profile Designer is a Class IIB healing abutment (according to European Union Directive 93/42/CEE) which conforms to current standards and bears the CE0459 marking. This is a sterile medical device designed for **single use only**.

The iphysio® Profile Designer owing to its screw retained design and its internal cavity which falls within the configuration of complex devices marked the recycling operations (of decontamination and sterilisation) more or less effective, bringing about non-quantifiable infectious and immunopathological risks.

Furthermore, the iphysio® Profile Designer plays the role of impression transfer. Any alteration in its upper surface shall be a source of inaccuracy at the time of the digital or physical repositioning of the implant analogue. In particular, in the case of digital scanning, the scratches on the scanned surface could cause artefacts making the identification of the iphysio® Profile Designer difficult or even impossible.

We recommend using a safety thread or placing a dental dam at the back of the mouth when handling the components to prevent them from accidentally falling into the throat of the patient.

4. Warranties

In the case of non-osteointegration of the implant following the use of an iphysio® Profile Designer, you must inform your sales consultant or the after-sales service about this, so that we can analyse the causes of this failure and take the necessary corrective actions.

An exchange may take place in the case where a product fault is involved; if the failure results from poor analysis of the clinical case, an operating protocol not suited to this case, the use of worn drills or any other reason not pertaining to the quality of our products, the warranty cannot be taken into account.

III. SELECTION OF THE IPHYSIO® PROFILE DESIGNER

1. Choice of shape and height

During the healing phase the iphysio® Profile Designer makes it possible to shape the future profile of the prosthetic emergence whilst awaiting stabilisation of the gingival height.

It is necessary to have defined prior the gingival depth of the prosthetic margin and desired emergence profile in order to be able to select the most appropriate Profile Designer.

Lingual or palatal side



Vestibular side

• **4 shapes** have been developed in accordance with the position of the teeth and depending on the implant brand and model :



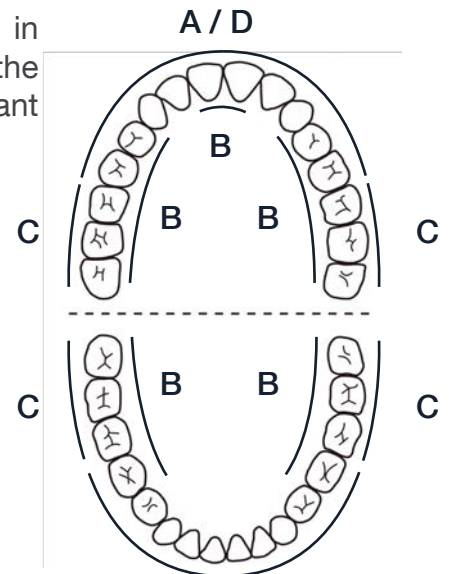
Shape A

Incisor, canine and premolar



Shape C

Molars



Shape B

Premolars, molars and maxillary central incisors



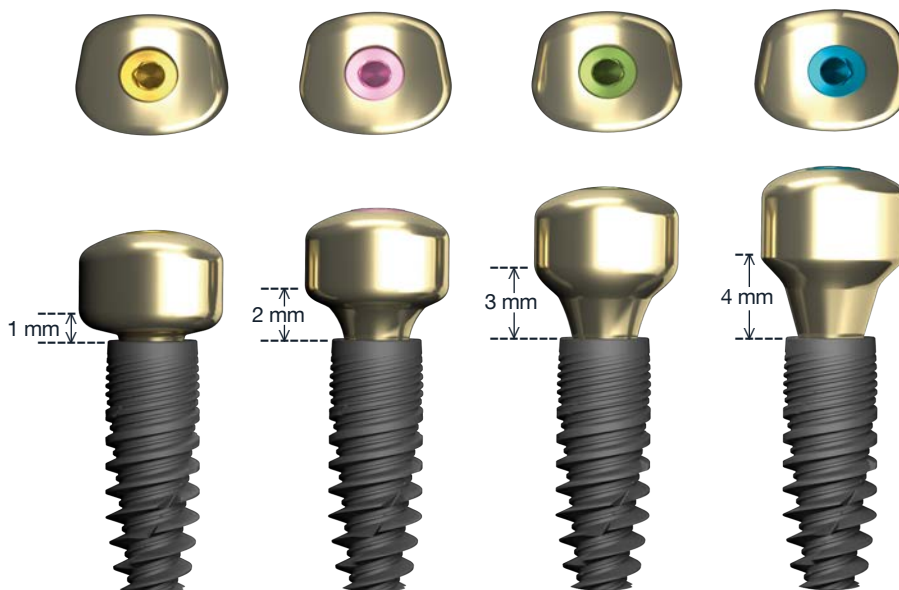
Shape D

Incisor and premolar

A / D

NB: The Profile Designers may be oriented differently depending on the anatomy of the tooth to be replaced or the mesiodistal space available between the iphysio® Profile Designers or the teeth.

• **4 supra-implant heights** are available depending on the implant brand and model.



Selecting the most suitable Profile Designer shape and height for the various implant brands is detailed in the “Range and References” document which is downloadable online from the website www.iphysio.dental

2. Use of iphysio® trial abutments

The trial abutments are exact replicas of the iphysio® Profile Designers.

Their design and practical handling will simplify the selection of the iphysio® Profile Designer which is best suited to the shape of the tooth to be replaced.

- In order to facilitate the identification of their height, the trial abutments have an identical colour code to that of the iphysio® Profile Designer fixation screws.
- The A, B, C or D shape is indicated by laser marking on the side of the trial abutment.

Contrary to the iphysio® Profile Designers, the trial abutments are reusable after their cleaning and sterilisation.

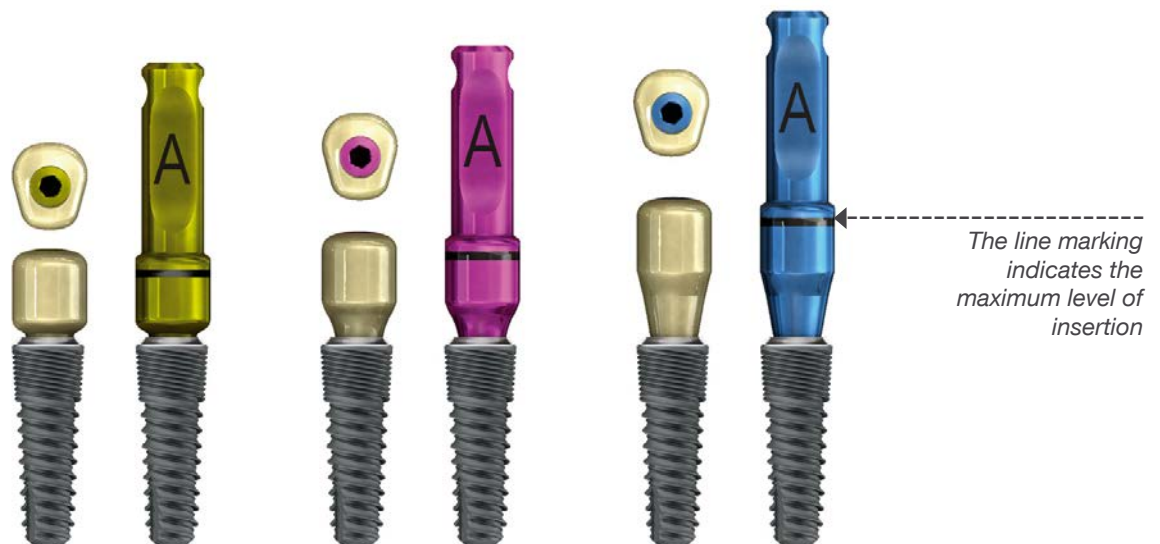
FOR ASTRA TECH®, EASY IMPLANT®, ETK® IMPLANTS



Ref. KIE_3N



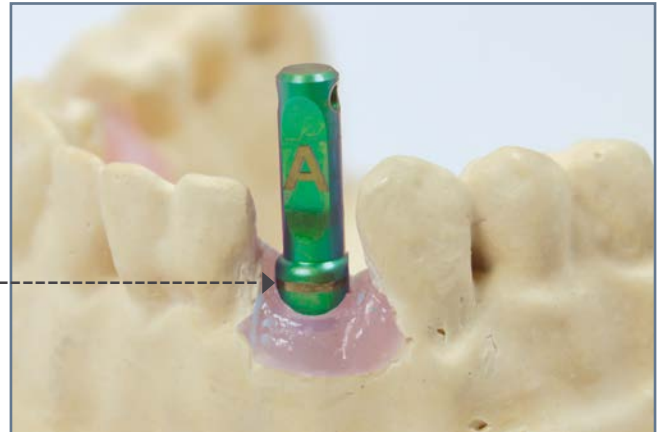
Place the try-in abutment in the implant in the mouth and position as required. The colours and shapes will enable you to select the most suitable Profile Designer.



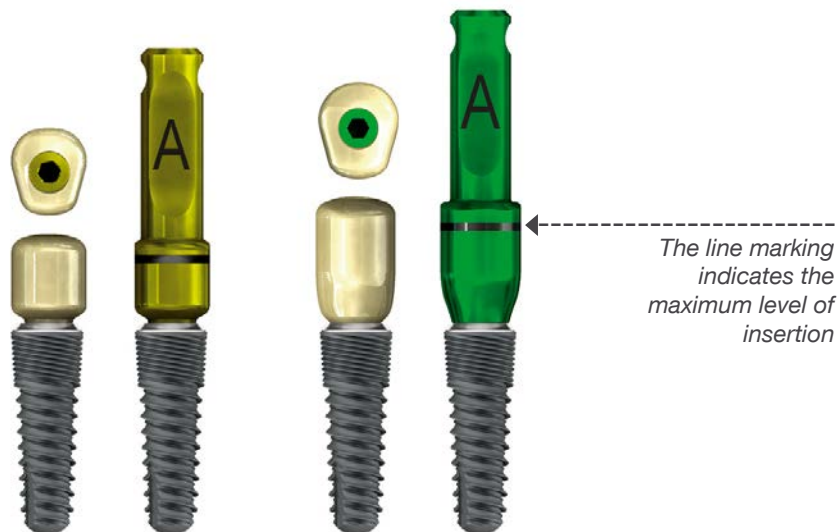
FOR OTHER IMPLANT BRANDS



Ref. KIE_U



Place the try-in abutment in the implant in the mouth and position as required. The colours and shapes will enable you to select the most suitable Profile Designer.



Selecting the most suitable kit and try-in abutment for the various implant brands and models is detailed in the “Range and references” document which is downloadable online from the website www.iphysio.dental

The attachment screws used to fix the permanent Profile Designers in the implants are compatible with 1.2 mm hexagonal screwdriver bits. A 1.2 mm external hexagonal key is supplied in the KIE_U kit.



Ensure the correct positioning of the try-in abutment:

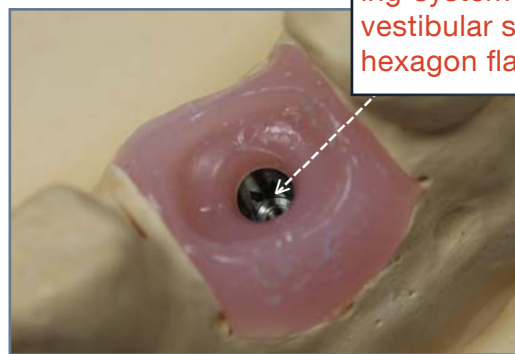
- Orientation of the vestibular surface.
- The coronal part must exceed the soft tissue by a minimum of 1.5 mm (or the visible laser band) to ensure perfect positioning of the side surfaces for the future impression taking.
- Fix a safety thread to the abutment to prevent it from falling into the mouth.

IV. PLACEMENT OF THE IPHYSIO® PROFILE DESIGNER

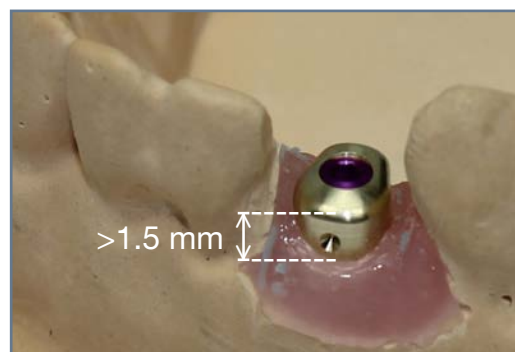
For an ideal orientation of the iphysio® Profile Designer, direct one of the sides of the indexing system (hexagon, octagon, tri-lobe, etc.) of the implant connection on the vestibular side.

At the time of the placement of the implant, align one of the hexagon sides of the direct contact key or mandrel, parallel to the vestibular wall, which guarantees that one of the hexagon faces of the implant is oriented towards the vestibular side.

The iphysio® Profile Designer may then be ideally positioned.



Place the iphysio® Profile Designer in the implant in the mouth according to the desired orientation and screw it in by hand using a 1.2 mm external hexagonal key.



Make sure that the Profile Designer is in the correct position:

- Orientation of the vestibular side.
- The coronary part must be 1.5 mm minimum above the soft tissue (that is to say the laser marking) in order to be perfectly located during the future impression taking.

Tighten the iphysio® Profile Designer at the recommended tightening torque of between 10 and 15N.cm using a dynamometric key.

The coupling torque in N.cm is indicated on the package label.



In order for the iphysio® protocol to be optimal, the Profile Designer, once screwed in, must not be handled until receipt of the final dental restoration. It is only unscrewed once to finally screw in the final prosthesis.

If you would like, you can have an X-ray to check that the Profile Designer has been correctly assembled in the implant. As the Profile Designer is titanium, it is radio-opaque.



If the Profile Designer iphysio® gets stuck during removal.

If the Profile Designer iphysio® gets stuck in the connection during removal, please use the abutment remover to remove the Profile Designer without damaging the implant connection.



V. TAKING OF IMPRESSION



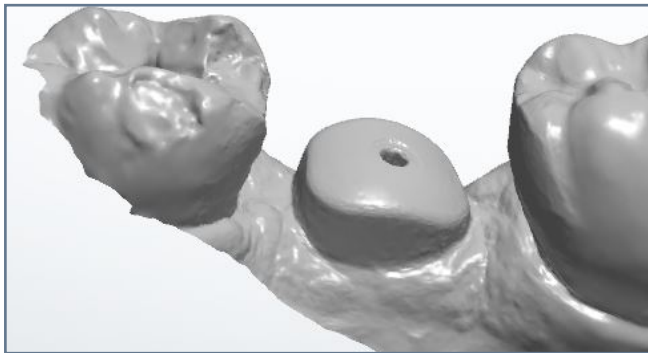
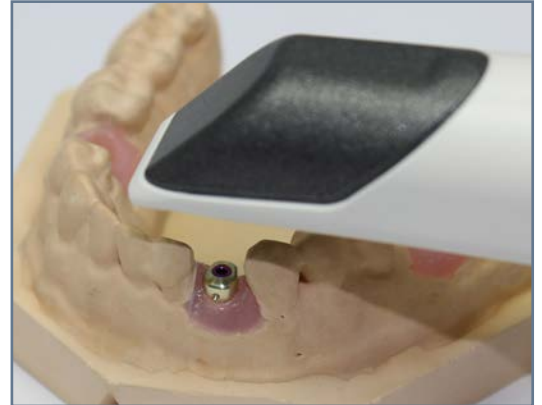
In the case of a restoration with an iphysio[®], make sure the laboratory is equipped with a 3Shape software and the iphysio[®] library for designing and manufacturing the final restoration.

1. Digital impression directly on the iphysio[®] Profile Designer

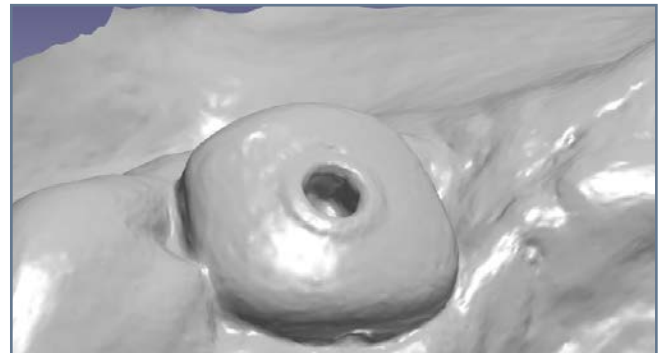
After the healing period, clean the iphysio[®] Profile Designer and the patient's mouth.

Take a digital impression of the patient's mouth with your intra-oral scanner in the following order:

1. The iphysio[®] Profile Designer and the adjacent teeth
2. The antagonist arcade
3. The occlusion



Caution: The resulting optical impression must be similar to this one.



If you get this type of impression, the Profile Designer iphysio[®] screw must be retightened. Here, the Profile Designer iphysio[®] screw is coming out slightly, which may cause an occlusion problem in the final restoration.

Send your digital file in STL format to the laboratory or to the LYRA partner laboratories via your *Communicate* account.

IMPORTANT : it is essential to send the following information in the “*comments*” part of your purchase order:

- a. The **reference of the iphysio[®] Profile Designer** used (shape and height) and the **colour of the screw**
- b. The position of the tooth corresponding to each Profile Designer.
- c. Fixed implant system
- d. The type of desired prosthetic reconstruction:
 - Screw-retained prosthesis: crown screw retained to the titanium Esthétibase
 - Cemented prosthesis: customised abutment and crown to be cemented



The iphysio[®] Profile Designer must not be unscrewed before or after the taking of the impression to save the gum. The subgingival emergence profile will be taken into account at the time of the design. The use of a scanbody type classical digital impression transfer may require a second scan in order to have the emergence profile. **This is not the case with the iphysio[®] Profile Designer.**

2. Silicone impression directly on the iphysio® Profile Designer

After the healing period, clean the iphysio® Profile Designer and the patient's mouth.

Take a traditional impression of the patient's mouth with a closed impression:

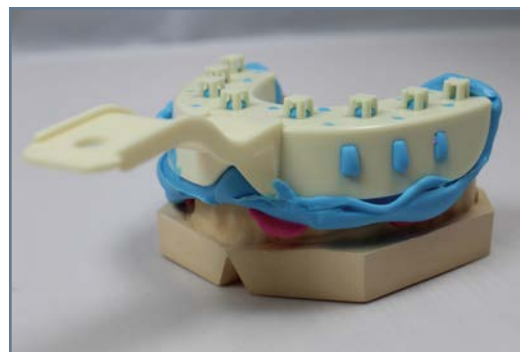
1. The arch with the Profile Designer
2. The antagonist arch

Then take the occlusion.

Send your silicone impressions to your laboratory.

IMPORTANT: it is essential to send the following information in the "comments" part of your purchase order:

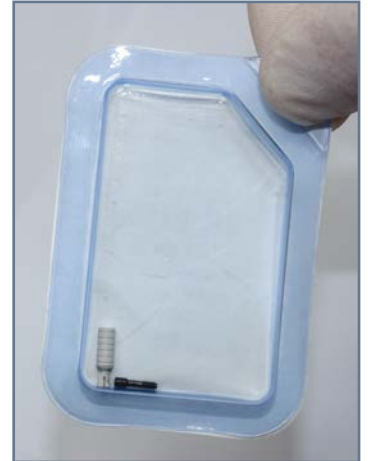
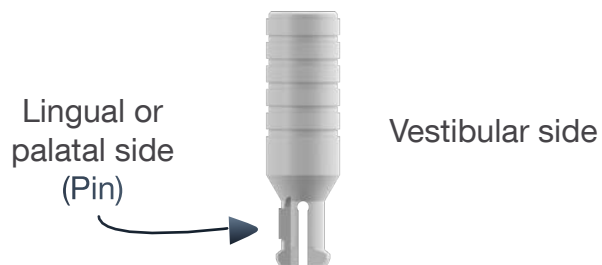
- a. The **reference of the iphysio® Profile Designer** used (shape and height) and the **colour of the screw**
- b. The position of the tooth corresponding to each Profile Designer.
- c. Fixed implant system
- d. The type of the desired prosthetic reconstruction:
 - Screw-retained prosthesis: crown screw retained to the titanium Esthétibase
 - Cemented prosthesis: customised abutment and crown to be cemented



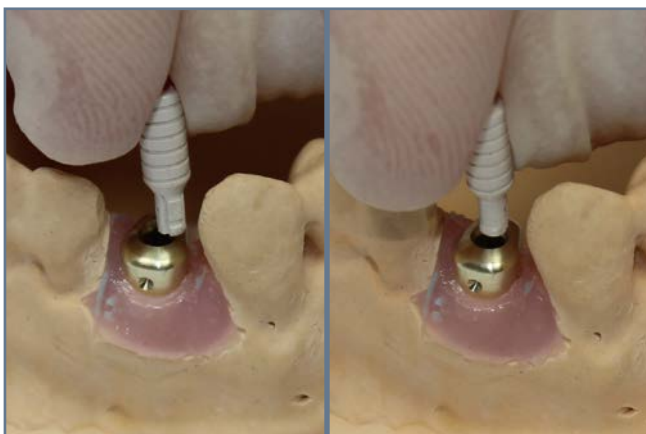
The iphysio® Profile Designer must not be unscrewed before or after taking of the impression to save the profile of the gingiva. The subgingival emergence profile will be taken into account at the time of the design.

VI. PLACEMENT OF THE TEMPORARY TOOTH

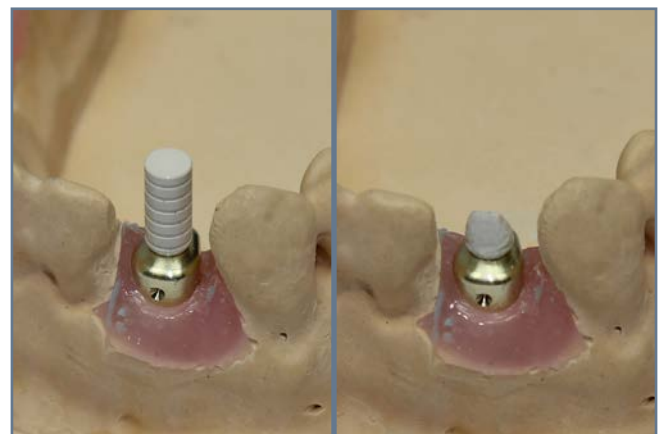
To use the temporary abutment, attach the iphysio® Profile Designer with the black attachment screw provided with the temporary abutment (see photo of packaging below). Do not fix the Profile Designer with the coloured screw as this would make it impossible to clip the temporary abutment into place.



1. Before placement of the Profile Designer in the mouth, replace the coloured screw with the short black screw above the sterile field.



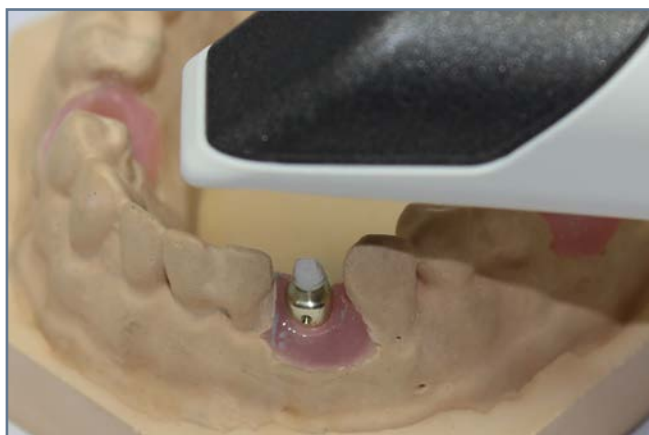
2. Turn the temporary abutment in such a manner that the pin is in the direction of the smallest side of the iphysio® (in vestibular). A single insertion point of the temporary abutment in the Profile Designer is possible.



3. Clip the temporary abutment in the Profile Designer.
4. Do all the touch-ups required to obtain the correct occlusal height and shape of the stump.

Use your regular technique to fit the temporary tooth:

- Using a temporary retail polycarbonate crown;
- With the assistance of a temporary retail thermoformed shell;
- Using a denture mold made in the pre-operational phase before extraction;
- In CAD/CAM technique, using your intra-oral scanner and your machining tool.



6. Digitise the arcade work sector.



7. Design your temporary tooth on your 3D modelling tool.



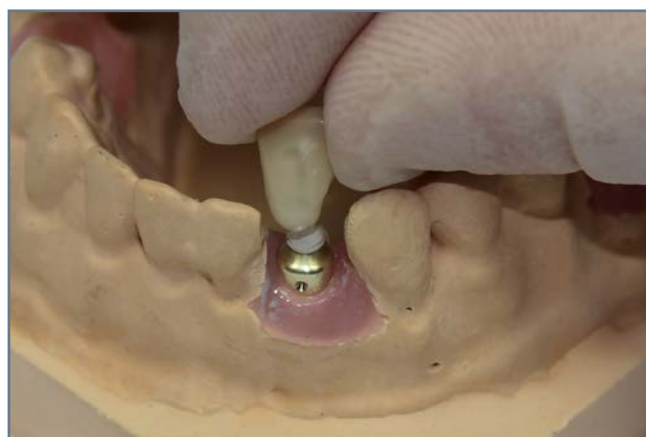
8. Use the crown on your machining tool and carry out the finishing on the temporary tooth.



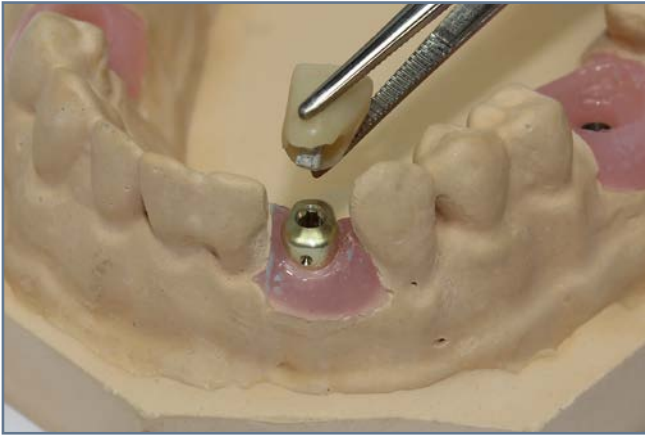
9. Apply the separating vaseline on the supra-gingival zone of the iphysio® Profile Designer whilst avoiding placing it on the temporary pillar.



10. Fill the crown bottom with self-cure resin or photo-curable resin



11. Seal the crown on the temporary abutment whilst taking care to recover the Profile Designer properly.



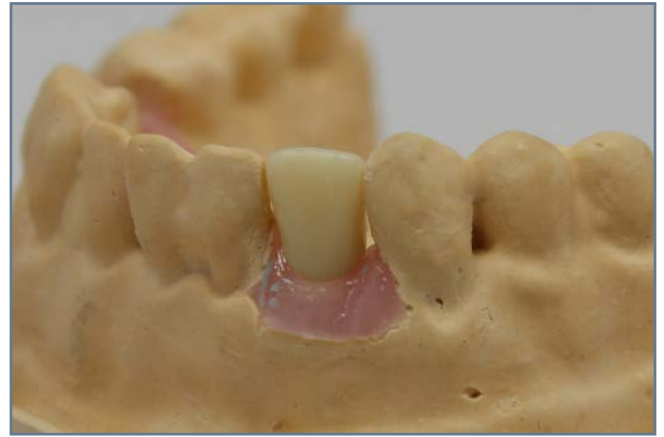
12. Unclip the crown after full polymerization of the resin.



13. Touch up the crown or the resin if necessary.



13. Polish the crown.



14. Clip the crown and check that it is secure. If it is not sufficiently secure, it is possible to seal the temporary tooth with temporary cement after having protected the head of the iphysio® Profile Designer screw head. If necessary, you can apply vaseline to the Profile Designer to facilitate the insertion and removal of the temporary tooth.

VII. THE KEY DESIGN POINTS OF THE FINALPROSTHESIS IN THE LABORATORY

The LYRA organisation has developed the library of digital image files for the 3Shape® prosthetic design software.

Before using any of the iphysio® products, please ensure that you are equipped with the 3Shape® software tool and the library of iphysio® digital image files supplied by LYRA for the design and realization of the final restoration.

This manual is not a user manual for the 3Shape® CAD software tool. Its purpose is to explain the main points for optimizing the iphysio® protocol.

Your dentist could either send you a digital image taken from a digital impression by intra-oral scanner, or a silicon impression.

For silicon impressions, a cast model of the patient's mouth must be made first:

- **The arch integrating the Profile Designer**
- **The opposing arch**

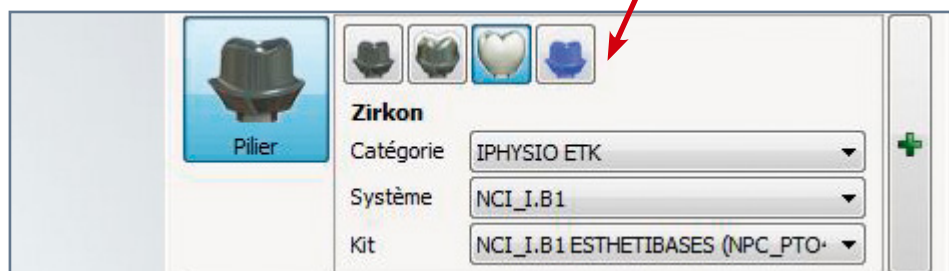


Scan the cast model using the 3Shape® scanner.

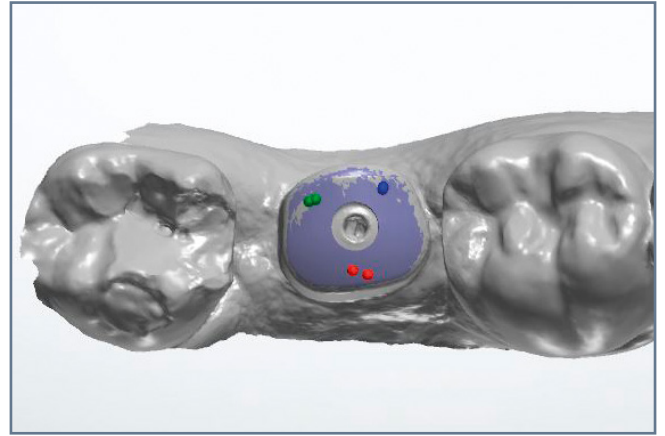
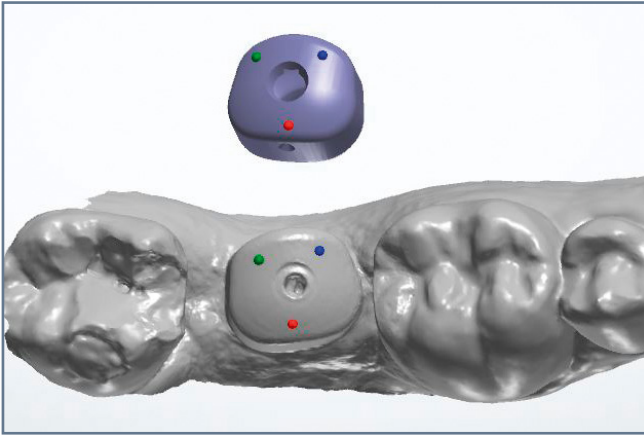


Commentaires	
Iphysio en B1	
Restaurations	
Types	Type Couronne transvissée
Matériau	Zr-Ti Base
Fabricant	Euroteknika
Système	Naturactis
Connexion	NP
Types	Type 👤 Couronne
Teinte	👤 Vita A2
Matériau	👤 Zircono KATANA STML (Super Translucide Dégradée)

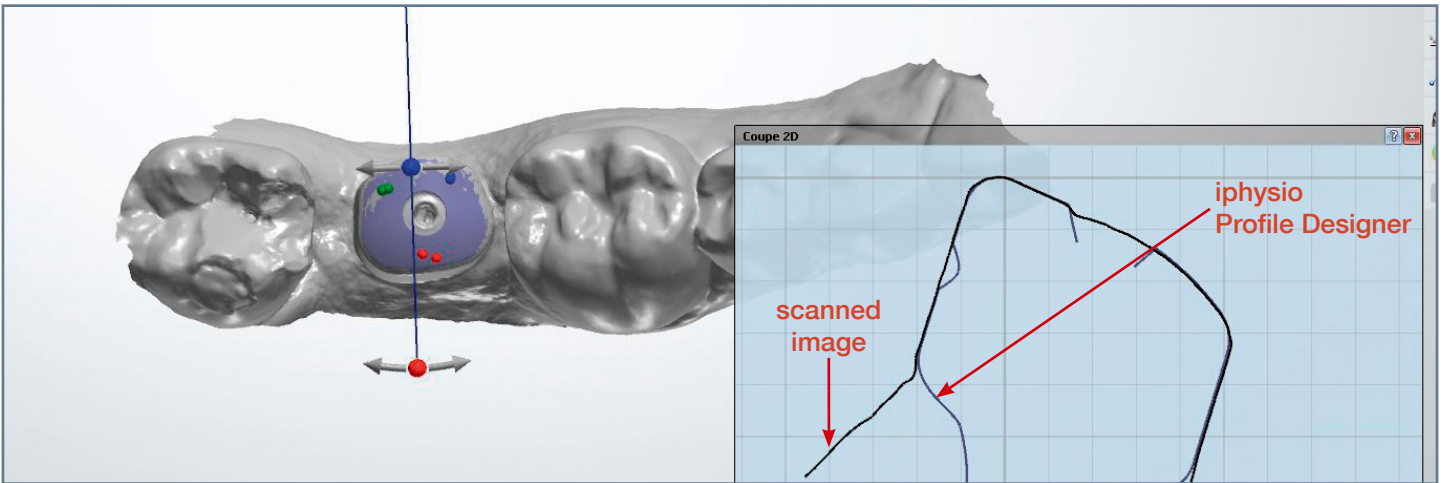
1. On opening your order package with the 3Shape®software, you will find all the information relating to the intraorally screw-retained Profile Designer specified by your dentist in the “Iphysio B1” (Shape B, Height 1) comments box



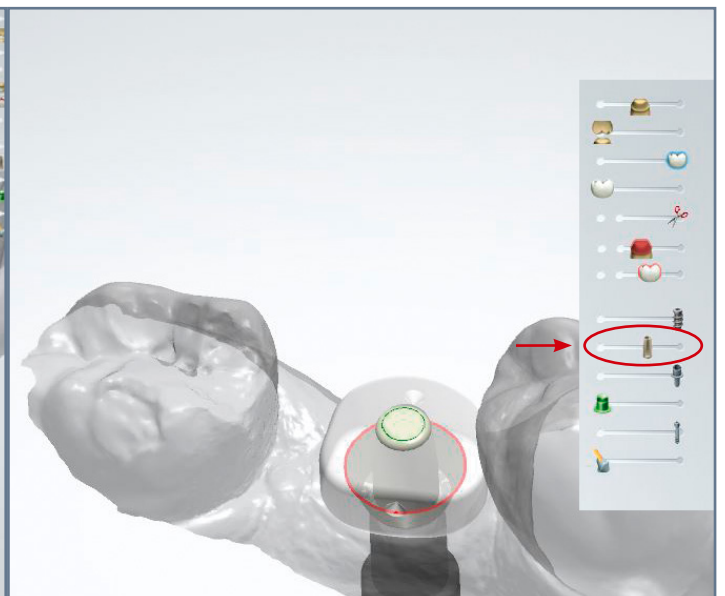
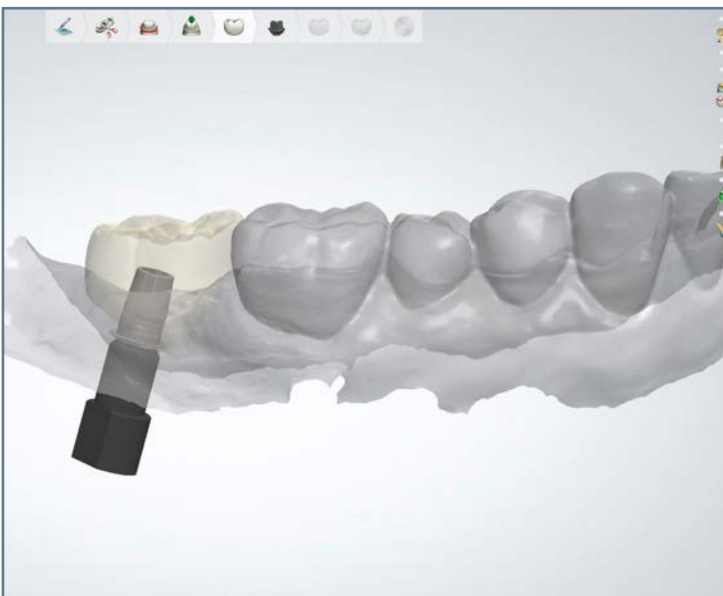
2. Following the instructions given by your dentist, select the following menu options:
- From the “category” menu select “Iphysio” followed by the brand name of the intraorally fitted implant.
 - From the “system” menu select the Iphysio® Profile Designer reference which you will find on the product label attached to the packaging.
 - From the “kit” menu select the type of restoration: either a customised combined abutment-and-crown or a screw-retained tooth on Esthetibase interface.



3. To replace the iphysio® image file from the library of scanned images, select 3 points on the iphysio® image file, then do the same on the scanned iphysio® Profile Designer image in the same areas.

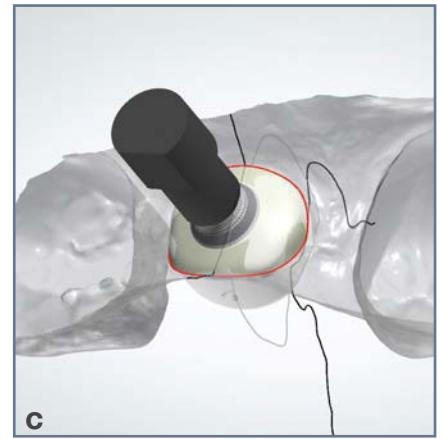
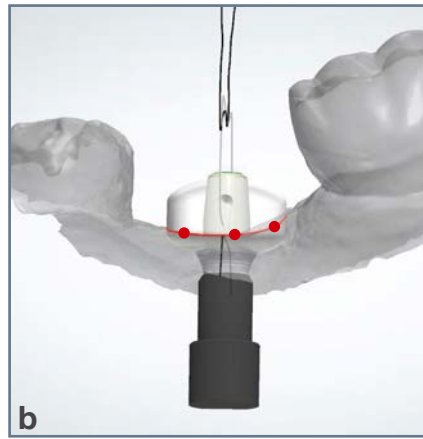
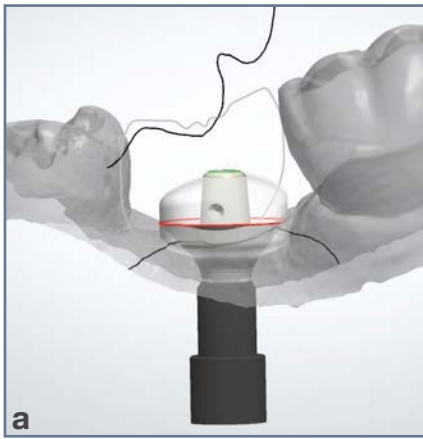


4. Check the superposition using the section view tool.



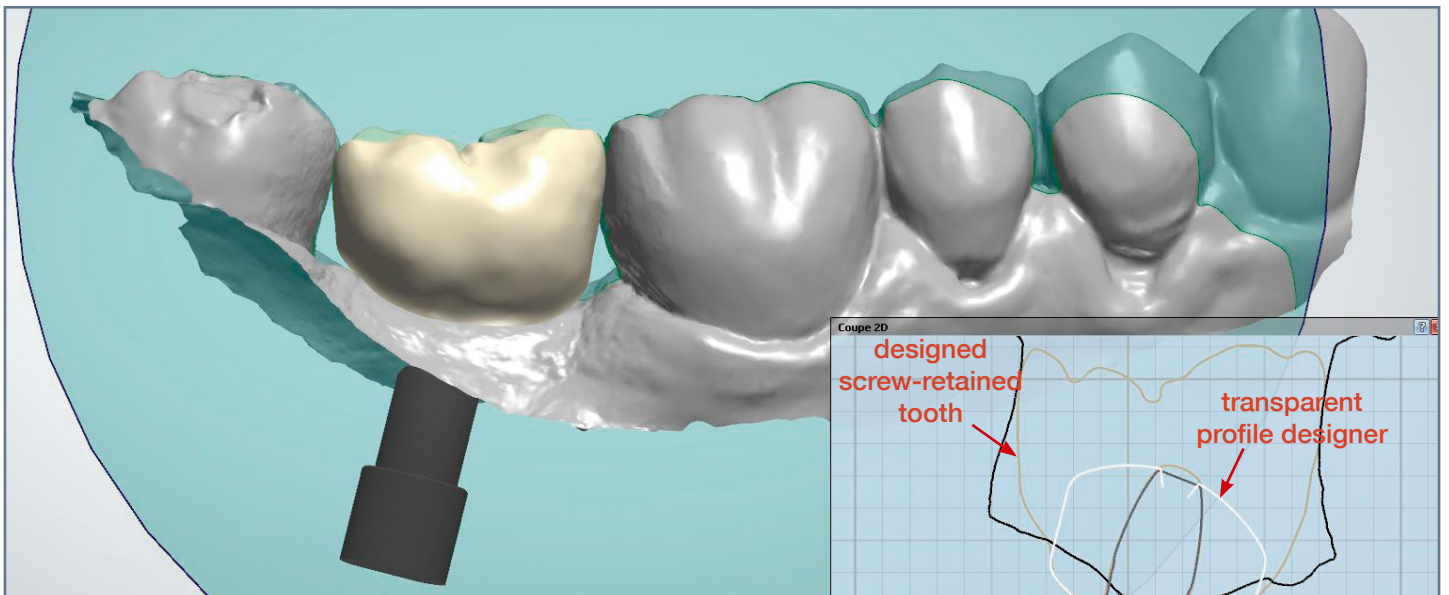
5. Insertion of the tooth to be designed.

6. To draw the emergence profile, superimpose the transparent iphysio® Profile Designer image using the 3Shape® tool. These tools are displayed in the right hand corner of your design display screen.



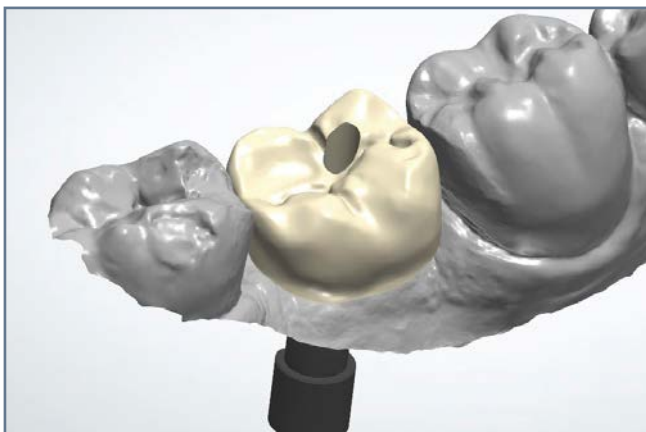
7. From the superimposed transparent Profile Designer image (picture a):

- Firstly, trace the gingival arch of the emergence profile (picture b) ;
- Secondly, draw the transmucosal profile as closely as possible to the superimposed transparent Profile Designer (picture c).



8. Design your restoration (see here a screw-retained tooth) by superimposing the transparent Profile Designer image.

By respecting the gingival emergence profile of the superimposed Profile Designer, your dental surgeon will obtain a precise adjustment of the intraoral prosthetic restoration without pressure points on the gum.



9. Final result of the designed prosthetic restoration following the iphysio® protocol.

NOTES

A series of horizontal dotted lines for writing notes.

More information on
www.iphysio.dental

Manufactured by euroteknika - 726 rue du Général de Gaulle, 74700 Sallanches (France)

The iphysio® Profile Designer manufactured by euroteknika and distributed by LYRA France is a Class II b medical device (European Union Directive 93/42/CEE) which conforms to current standards and bears the CE0459 marking. Non-funded by Social Security, it must be used by oral health professionals. Carefully read the instruction leaflet and the user manual. LYRA FRANCE, S.A.S. with a capital of 10,000 LYRA - 25 rue Bleue, 75009 Paris - RCS Paris 799 960 067 – All documents compiled by LYRA refer to our general sales conditions in force.
Non-contractual photos - All reproduction, even partial, shall be forbidden.

Distributed by

LYRATM

+33 1 56 03 11 80

info@lyra.dental

www.iphysio.dental