

INNOVATIVE, UNIQUE, SIMPLE

axiom[®] 2.8



User procedures
axiom[®] 2.8

Anthogyr
PRIME MOVER IN IMPLANTOLOGY



We would like to thank you very much for your trust and confidence as expressed in working with the Axiom® implant system.



For your safety and comfort of use, our products have been designed based on scientific knowledge and clinical use.

The Axiom® range is the result of close collaboration between our committee of experienced implantologists and our R&D team, and is both simple to use and very high performance in biomechanics and aesthetics terms.

This document contains most of the information needed to use the Axiom® device in surgical protocols and prosthetic restorations which are specific to the system with a complete component listing. A few key points for correct use are included as reminders.

Success for you means success for us. Our marketing network and team of experts is completely available to you for any further information you may need.

The Anthogyr team



Indications for use

Axiom® 2.8 implants are intended for use as artificial root structures for replacement of missing teeth. They can be used for fixation of single tooth restorations. Anthogyr dental systems are indicated for one-stage or two-stage surgery. It is up to the practitioner to decide whether immediate or delayed loading is most appropriate, based on clinical factors like good primary stability and appropriate occlusal loading. Axiom® 2.8 implants are aimed for singled replacement of mandibular incisors and lateral maxillary incisors in cases presenting a restricted mesiodistal space. The prosthetic components of the Axiom® 2.8 product line are intended to ensure support for single crowns only.

Warnings and recommendations

The instructions contained in this document describe the different phases of the surgical procedure and prosthetic restoration to be followed for the Axiom® 2.8 implant system. A few general features specific to inserting implantable devices are recalled for information. This is not in any way an exhaustive document about implant and prosthetic practices to which the reader has any right of complaint.

Training:

Axiom® 2.8 components should only be implanted by practitioners who have been trained in implant practice and/or prosthetic techniques, and who are equipped for this type of procedure. Correct knowledge of surgical techniques and prosthetics is required to use this system. Specific training is offered and delivered at the Anthogyr company.

The surgical and prosthetic technique for the Axiom® 2.8 system is performed exclusively in conjunction with the original components and instruments in accordance with the manufacturer's recommendations. Anthogyr can take no responsibility for implantation in case of placement non-compliant with this manual and in case of use of prosthetic parts or instruments foreign to the system. The parts are not interchangeable with other implant systems.

Clinical evaluation of the patient and the choice of treatment solution are the sole responsibility of the practitioner. Patients should also be informed of potential risks associated with implanting this type of device : oedema, bruising, haemorrhage, periodontal complications, transient or permanent nerve damage, local or systemic infections or inflammation, bone fractures, loosening or fracture of the implant, dehiscence, aesthetic problems, aspirating or swallowing the device, iatrogenic trauma etc.

Equipment:

The practitioner using the system is responsible for the follow-up and maintenance procedures required to identify and treat any complications as early as possible (and for ensuring the correct functioning and safety of the device). The references and the batch numbers of all components implanted, temporarily and/or definitively, must be recorded in the medical file of the patient. Follow-up and maintenance are part of the knowledge of a practitioner trained in placing dental implants.

The practitioner is also responsible for defining the different settings for his/her equipment (instrument rotation speed, irrigation flow rate, etc), according to each clinical case, and for confirming that these are in good condition before each procedure.

Reusable instruments must be cleaned, decontaminated and sterilized before each surgery (even when first used) in accordance with current protocols in hospitals and clinics. The organization of the operating room, preparation of operating staff and of the patient (premedication, anaesthesia, etc...) should follow current procedures and are the responsibility of the practitioner.

Anthogyr can under no circumstances be held responsible for any harm arising from defective handling or use.

In order to avoid swallowing or inhaling small components, it is recommended that these are rendered secure by fixing them to the outside of the mouth with a suture thread. Whenever an instrument is changed, confirm that the contra-angle or key are correctly fixed by applying slight traction and ensure that each part is correctly fixed onto the transfer system outside the oral cavity.

Conservation:

In producing our products, we have paid particular care and guarantee that a manufacturing control has been performed on all products made available for sale. In order to guarantee their integrity, it is recommended that they be stored in their original packaging at an ambient temperature of between 15 and 30°C, away from moisture and direct sunlight.

Protect packages from dust and do not store in the same premises as solvents and/or paints containing solvents or chemical substances. The device must be used before the expiration date indicated on the traceability label.

If the package (blister-closure / bag) is damaged or a defect is apparent when the product is opened, it is imperative that the device not be used and that the nature of the defect, part numbers and batch numbers of the components concerned are reported to the distributor or to Anthogyr. The technical specifications contained within these instructions are provided for indicative purposes only and cannot form the subject of any complaint.

The Axiom® 2.8 implant system must not be used on animals.

Single-use devices must not be reused, nor resterilized (risk of contamination and risk of alteration of functional surfaces).

The instructions for use here in may only be reproduced or disseminated with prior approval from the Anthogyr company. Anthogyr reserves the right to vary the technical feature of its products and/or to make changes or improvements to the Axiom® 2.8 system without prior notice.

The Axiom® 2.8 implant system is not compatible with other anthogyr and competitors' systems. If uncertain, the user should contact the Anthogyr company before use.

This brochure invalidates and replaces all previous versions.

TABLE OF CONTENTS

1. Surgical protocols

A/ SURGICAL PHASES OF THE AXIOM® 2.8 IMPLANT	6
B/ RANGE OF IMPLANTS	7
C/ TECHNICAL SPECIFICATIONS	7
D/ DRILLING SEQUENCE	9
E/ POSITIONING THE IMPLANT	10
F/ PARTICULARITY OF THE AXIOM® 2.8 CONNECTION	12
G/ CLOSING THE IMPLANT	12
H/ SURGICAL KIT	15

2. Prosthetic protocols

A/ REMOVING THE HEALING PLUG	16
B/ DESCRIPTION OF THE PREHENSILE WRENCH	17
C/ TEMPORARY ABUTMENTS	18
D/ DESCRIPTION OF THE SAFELOCK FOR IMPACTION OF THE DEFINITIVE PROSTHETIC PARTS	19
E/ METHODS OF IMPACTION FOR THE DEFINITIVE PROSTHETIC PART IN THE IMPLANT	20
F/ ABUTMENTS (STERILE)	21
G/ IMPRESSION-TAKING	22

3. Cleaning and sterilization

A/ GENERAL INFORMATIONS	26
B/ PRODUCTS	27
C/ PROTOCOLS	28

4. Disassemble and assembly

A/ INSTRUMENT KIT	30
B/ RATCHET WRENCH (ART. NB. IN CC)	31
C/ SURGICAL DYNAMOMETRIC RATCHET WRENCH (ART. NB. IN CCDC)	31

D/ PREHENSILE WRENCH

31

5. Part numbers
A/ SURGICAL COMPONENTS

32

B/ SURGICAL INSTRUMENTS

32

C/ PROSTHETIC COMPONENTS

34

D/ PROSTHETIC INSTRUMENTS

36

Symbols used in this manual


Indications to thoroughly respect.



Indications that will make the surgery easier.



Please read this !

Explanations, symbols and diagrams
STERILE R

 Device sterilized
by Gamma radiation


Reference



Expiration date



Non-sterile device


 Do not use autoclave
sterilization

 Do not use the device
if the package is damaged

 Store in relative humidity
between 30 and 70%


Manufacturer

LOT

Batch number



Date of manufacture


 Warning : observe
instructions for use


Autoclave sterilization


 Do not re-use
(single-use device)


Keep away from light



Temperature limit from 15 and 30°C

CE/CE 0459

 Class I, Class IIa or Class IIb medical
device complying with European Directive
93/42/EEC, amended by Directive
2007/47/EC

1. Surgical protocols

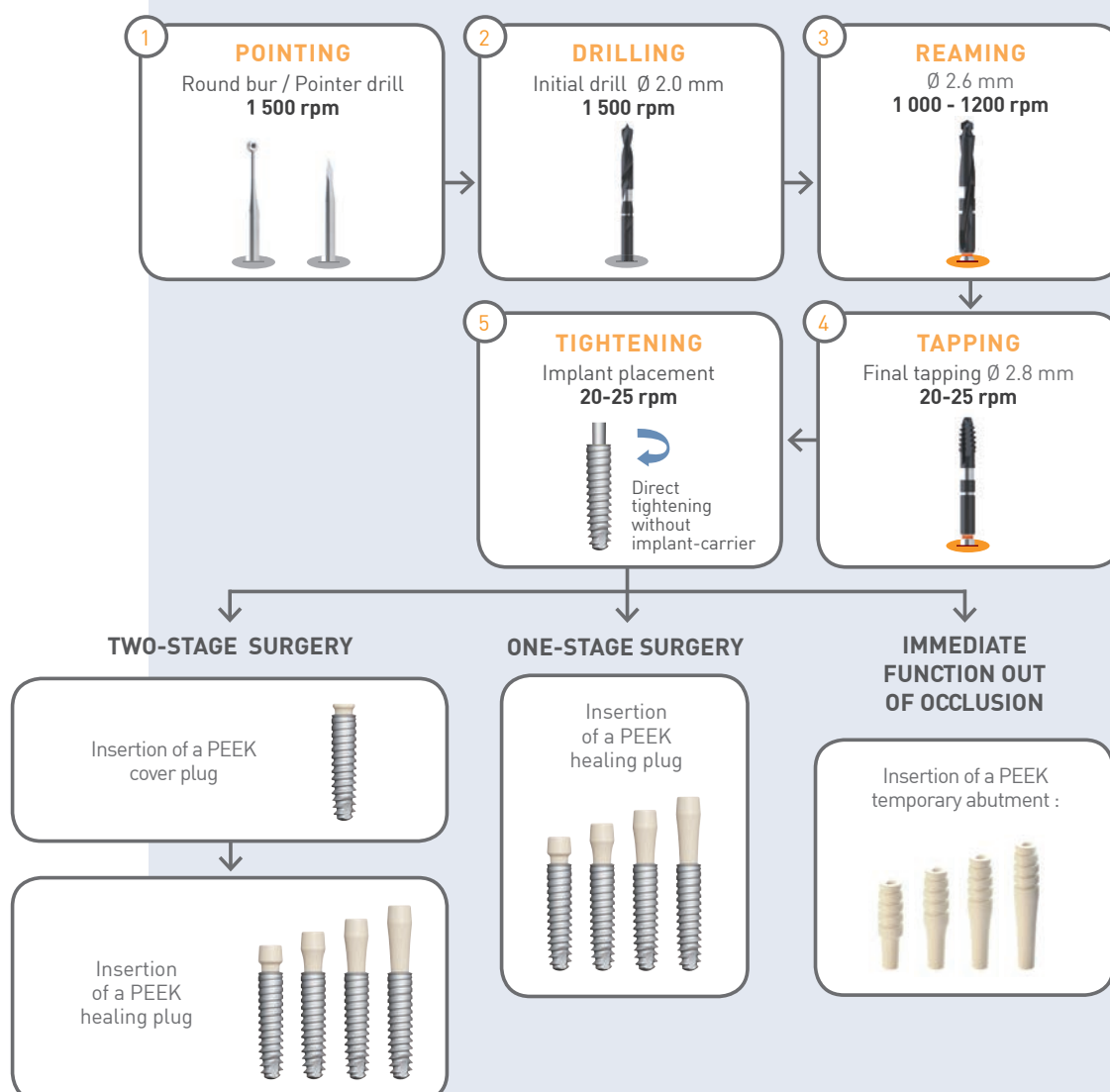
The Axiom® 2.8 implant system has been designed to enhance the functional and aesthetic integration of restorations in case of narrow interdental space. It is exclusively intended to replace mandibular incisors and maxillary lateral incisors (single-tooth restoration), specially in case of agenesis.

The implant as well as the abutment designs allow to preserve the implant's surrounding tissues. The implant components assembly is capable to withstand occlusal charges, without any risk to damage the restoration nor generating hazardous peak of stress at the prosthetic interface level.

The Axiom® 2.8 implant surgical protocol is particularly user-friendly and efficient.

The all programme is precise in order to provide the surgeons and prosthodontists with an optimal comfort at each step of the treatment.

A. SURGICAL PROTOCOL OF AXIOM® 2.8 IMPLANT



*The immediate function out of occlusion for the single unit restorations is not part of an established consensus and is therefore not recommended by Anthogyr. The choice of this treatment option is at the discretion of the surgeon (depending on his expertise).



A treatment plan shall be established before each implant placement.

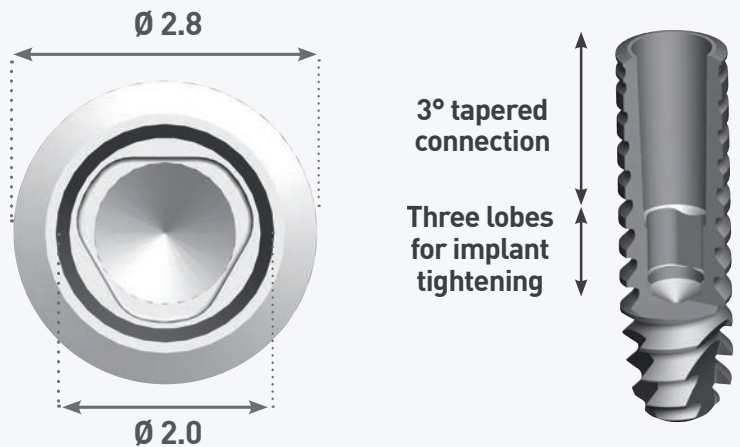
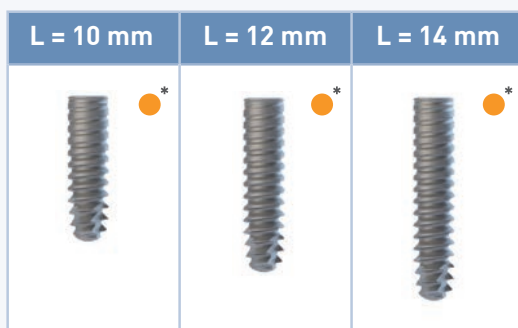
This plan shall ideally include a healing period which can be re-evaluated during the surgery process, if necessary.

WARNING ! INFORMATION ON PEEK COMPONENTS :

- All PEEK components must be placed by exerting manual pressure.
Only definitive titanium abutment have to be placed using the SAFE LOCK[®], once the implant is well osseointegrated..
- The PEEK components should not be placed for more than 6 months.

B. RANGE OF IMPLANTS

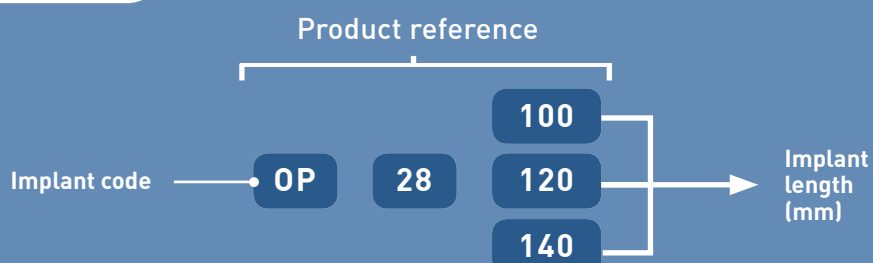
The Axiom[®] 2.8 implant is highly resistant and is specially designed for restoration of incisors with narrow diameter, in case of agenesis for example..



* Identification colour code of the Ø 2.8 implant reproduced on the ancillary and on the packaging.


WARNING !

axiom[®] 2.8 is exclusively designed for the individual replacement of mandibular incisors and lateral maxillary incisors.

C. TECHNICAL SPECIFICATIONS
1. Forms
COMPONENT CODING


2. Drilling depths

The Axiom® 2.8 surgery protocol shall be placed with the implant shoulder located sub-crestally. This positioning facilitates the post-surgery aesthetic management of the restoration. Drilling depth appearing on various instruments guarantees the implant site preparation and the predefined positioning in conformity with the protocol/sequences.



WARNING !

The size(s) of the implant(s) shall be pre-defined in the treatment plan. A radiographic pre-visualisation film and the calibrating films are provided to select the implant diameter and length according to the bone available. The film also takes into consideration the length of the associated drilling.

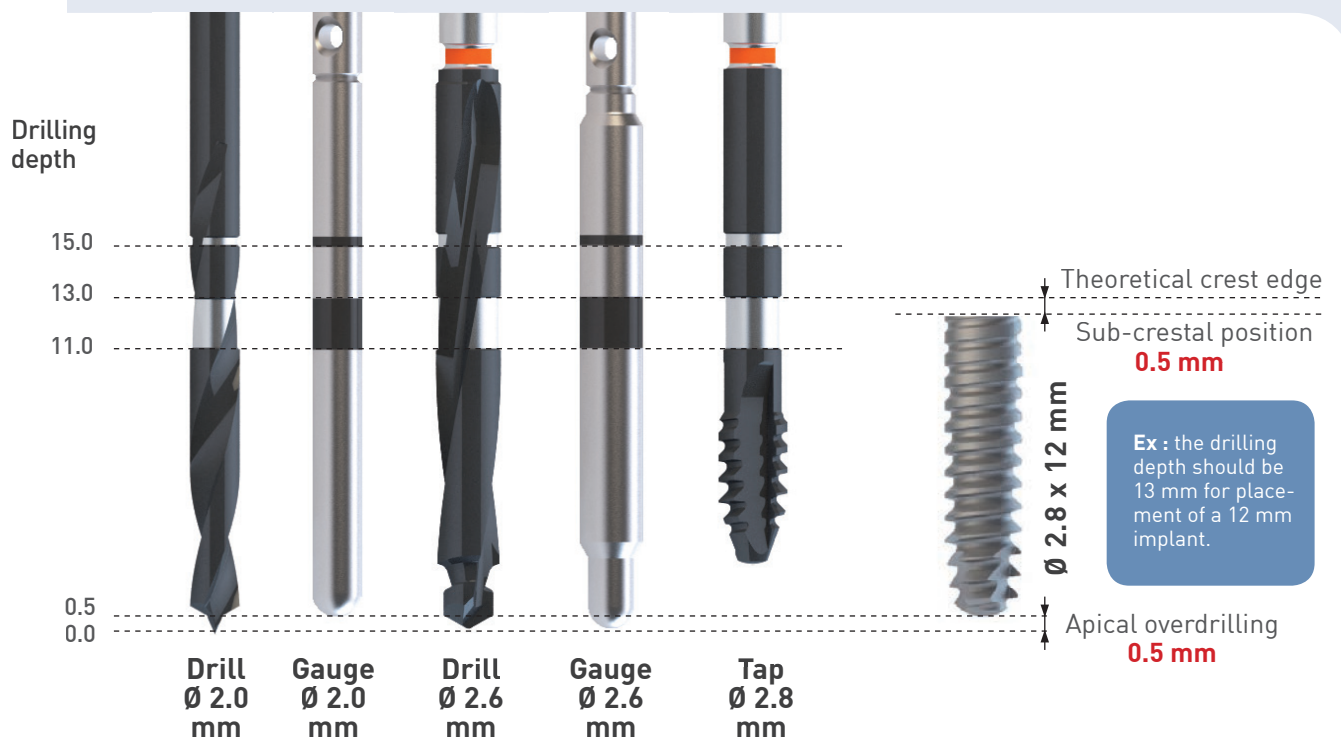
When selecting the implant, take into consideration the length of the drill + 0.5 to 0.6 mm at the tip, added to 0.5 mm sub-crestal positioning. These additional lengths are indicated on the calibrating film.

It allows bone chips to be stored and thus avoids any apical over-compression.

The placement of the implant shoulder in the sub-crestal position may be determined by the aesthetic constraints. In this case, the drilling depth must be adapted accordingly.

Precision of the calibrating film: +/- 2%.

Calibrating film must be replaced as soon as their reading is compromised (wear marks, etc...).



→ DRILLING DEPTH = LENGTH OF IMPLANT + 1 mm

D. DRILLING SEQUENCES

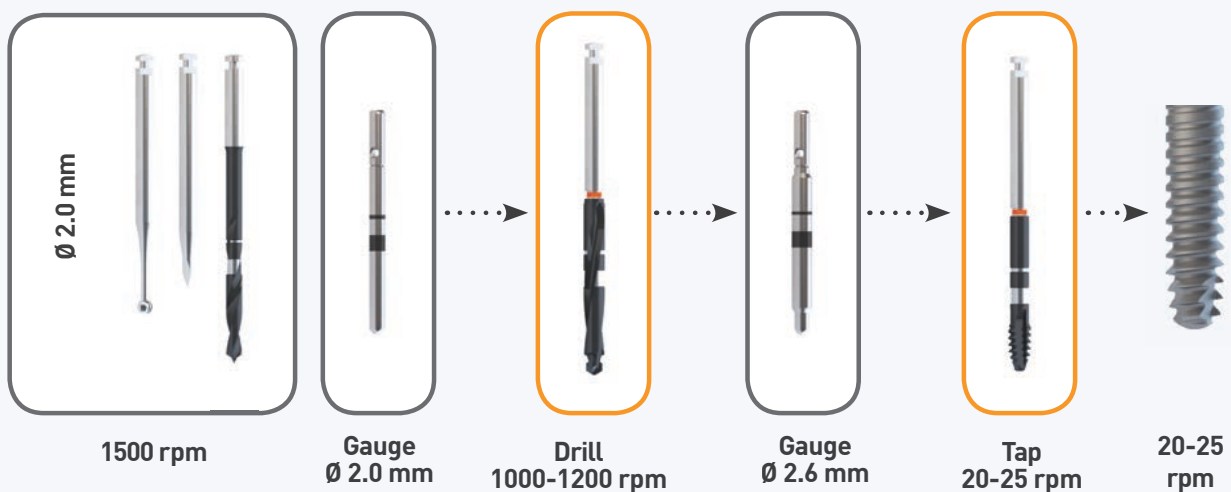


Before first used and after each surgery, the surgical kit must be carefully decontaminated, dried and sterilized following the manufacturer's recommendations. For high performance and optimal clinical results, we recommend that all cutting instruments (drills, taps, reamers...) be limited to 20 uses. They shall be used under external irrigation.

Prior to surgery

The instruments must be used in the chronological order shown below.

RECOMMENDED DRILLING SEQUENCES AND SPEEDS



For placement of implant in the lower jaw, we advise to always use the tap, whatever bone density may be, and continue tapping beyond the cortical, as long as you feel strength.

Warning: the time period between tapping and implant placement should be as short as possible (around 5 min).

E. POSITIONING THE IMPLANT



Before opening the package, always confirm the dimensions of the desired implant.



All implants come with 4 self-sticking, removable, repositionable traceability labels which must be included in the patient record.

1. Opening the package

The implant is supplied in a capped tube contained within a blister pack with a sealing cover. The whole pack is sterilized by gamma radiation.

DO NOT resterilize an implant if the package has been opened although the implant has not been used.

- Place the outer box on the back table to remove the blister pack. A red indicator dot on the sealing cover will confirm that the blister pack has been sterilized



- Remove the sealing lid from the blister by pulling it off, being careful not to touch the sterile content. Carefully place the opened blister pack on a sterile drape.



2. Transporting the implant into the mouth



WARNING!

The implant handling will be performed in order to avoid any direct contact with the outside surface of the implant. Make sure the implant cannot fall into the patient's mouth during transport.

→ Open the packaging using one hand only



→ Pick-up the implant using the contra angle (or the manual wrench).



REPOSITIONING THE IMPLANT in the packaging during surgery



→ OPT. 1 : POSITIONING WITH THE CONTRA-ANGLE

Set the contra-angle speed to **25 rpm**.
Tighten the implant with the contra-angle
to the desired depth.



WARNING !

Regularly check the tightening torque in order not to exceed **65 N.cm**. Do not hesitate to unscrew and re-screw during the implant insertion to reduce screwing forces.



→ OPT. 2 : MANUAL POSITIONING

Manually pre-screw the implant into the implant cavity using the screw key. Assemble the surgical ratchet wrench and insert to the desired depth.



WARNING!

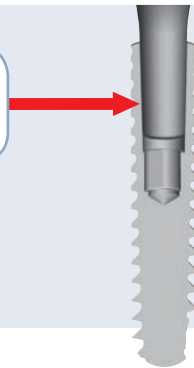
No torque control. Be careful not to apply high force to the connection. Do not hesitate to unscrew and re-screw during the implant insertion to reduce screwing forces. However, it is possible to evaluate the torque using the surgical dynamometric ratchet wrench **Ref. IN CCDC**

It is unnecessary to control the positioning of the implant's three lobes after tightening down.

F. PARTICULARITY OF THE AXIOM® 2.8 CONNECTION

Axiom® 2.8 implant has a special connection :
only definitive prosthetic parts are locked into the implant with impaction.

→ A friction conical cone connection.



The cover plug, the healing plug as well as the temporary abutments have to be placed by exerting a manual pressure using Art. Nb. OPCF100.

Definitive prosthetic components are inserted with the SAFE LOCK®.

G. CLOSING THE IMPLANT

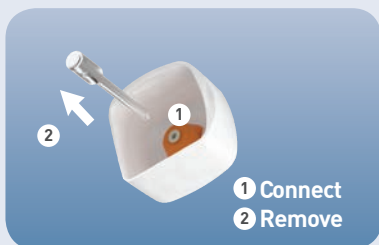


WARNING!

Peek temporary parts have to be placed by exerting manual pressure. Do not use the SAFE LOCK®.
These components are single-use and are supplied STERILE.

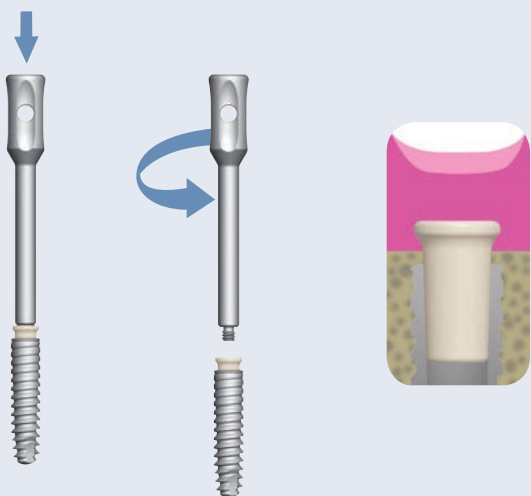
→ Two-stage surgery : cover plug insertion

Use the threaded gripper wrench to pick-up and insert the cover plug into the implant (Art. Nb. **OPCF100**).



- 1 Thread the threaded gripper wrench into the cover plug.
- 2 Pull out the cover plug from the cap.

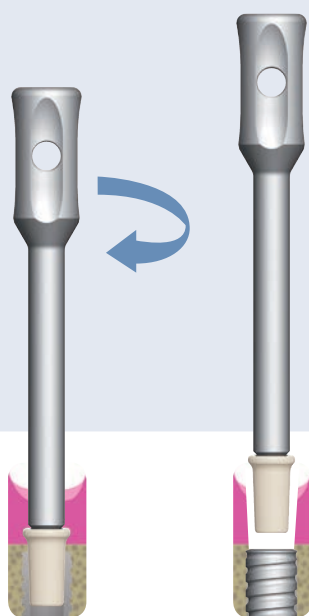
Use the threaded gripper wrench to pick-up and insert the cover plug into the implant (Art. Nb. **OPCF100**).



- Insert the cover plug into the implant and apply moderate hand pressure onto the wrench to secure the cover plug in the implant.
- Remove the wrench by rotating it counterclockwise.
- Suture the area to enhance healing



Remove the cover plug as described below:



- Thread the threaded gripper wrench into the cover plug and pull.

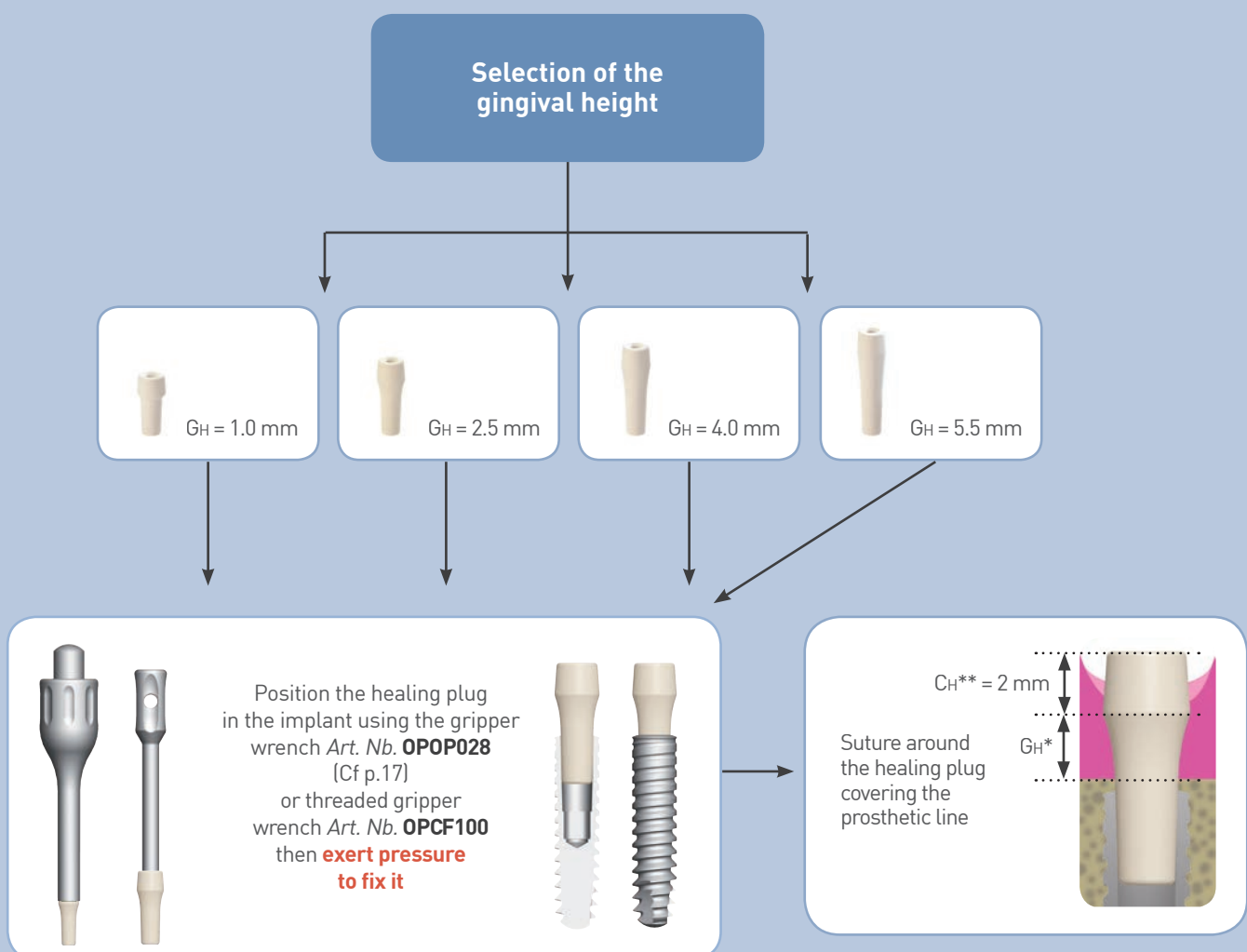
See below for healing plug insertion during the second stage of a two-stage surgery or in a one-stage technique.

→ One-stage surgery: healing plug insertion

STERILE PEEK HEALING PLUG (SINGLE USE)

Constant emergence profile concept: the height of the plug will determine the choice of the final abutment.

Healing plug, according to the height of gum of the patient, is available in 4 gingival heights : 1.0 mm, 2.5 mm, 4.0 mm and 5.5 mm (you can choose it depending on the patient's gingival thickness).



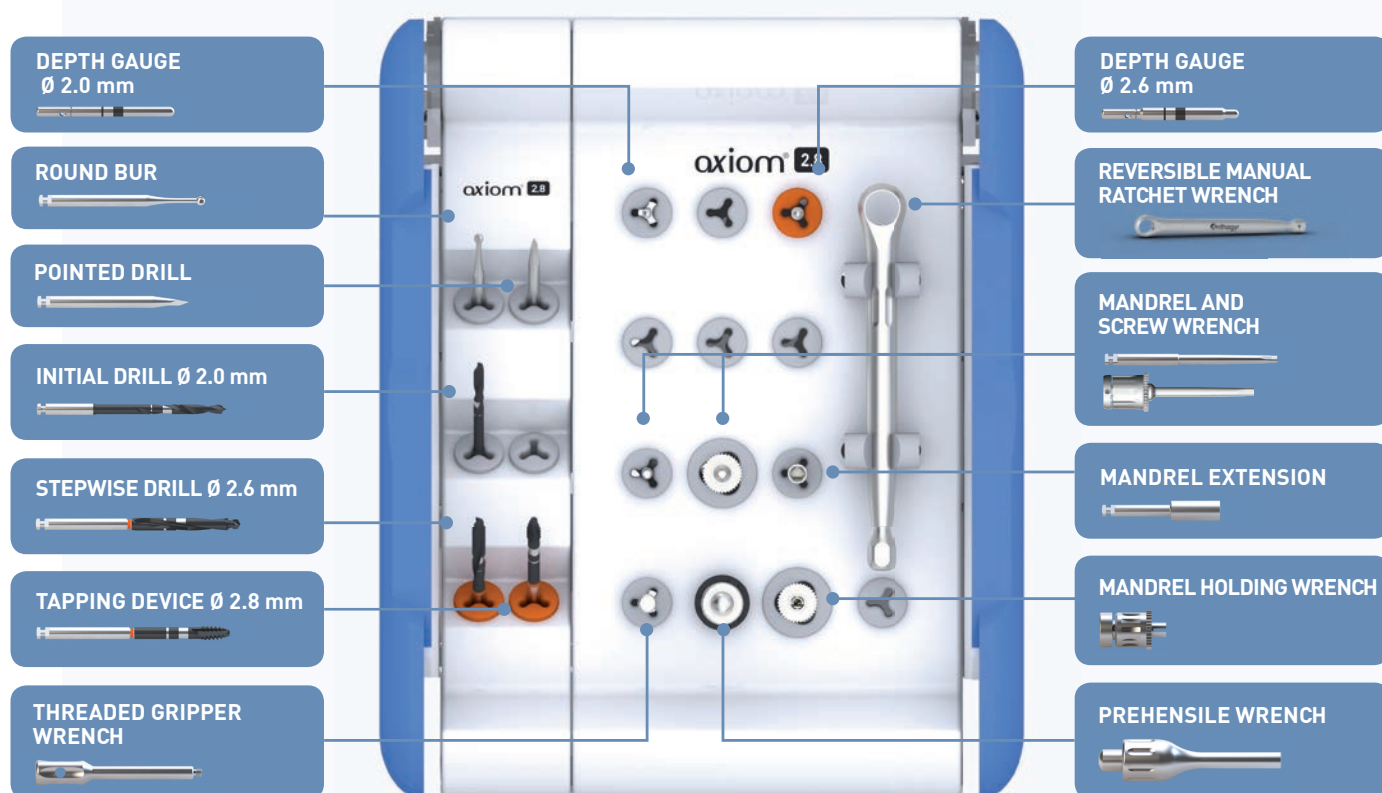
*GH : gingival height.
**CH : coronary height.

H. SURGICAL KIT



WARNING !

Before the first and after each surgery, all the instruments and instrument supports must be pre-disinfected, cleaned, decontaminated, dried and sterilised using a specific protocol.

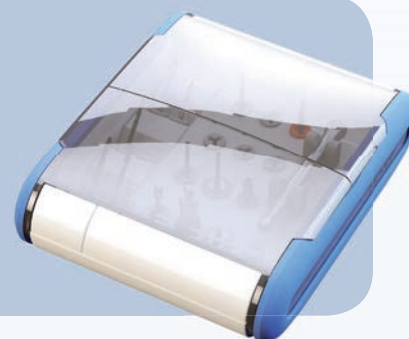


TECHNICAL SPECIFICATIONS

The kit is designed using medical grade materials enabling it to tolerate heat disinfection and autoclave sterilisation.

The protective covers allow the positioning of the kit to be varied in order to optimize instrument accessibility.

Free grommets are available to customize the surgical kit.



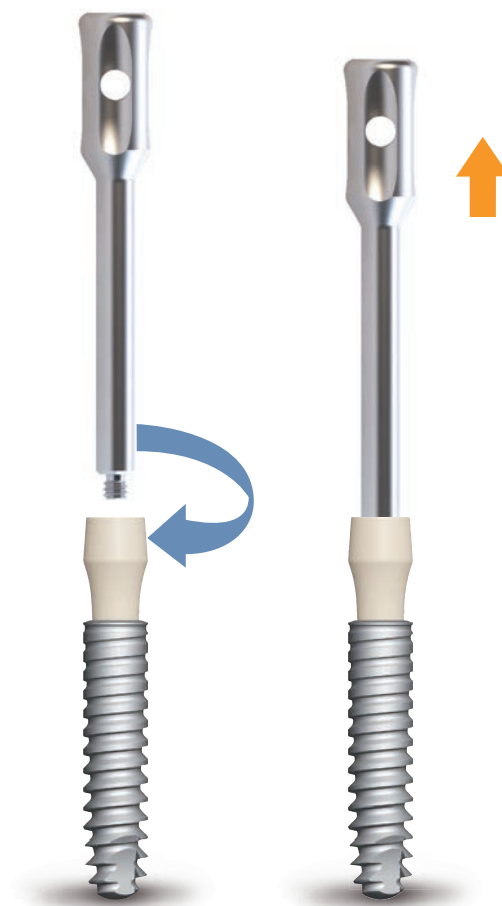
2. Prosthetic protocols

The prosthetic range for Axiom® 2.8 dental implant system enables to respond to all types of situations for cases of mandibular incisors as well as maxillary lateral incisors, thanks to :

- the straight abutments.
- the abutments pre-angled at 7°, 15° and 23°.

Reduced handling helps not only to preserve peri-implant tissue but also to shorten the treatment time.

A. REMOVING THE HEALING PLUG



After healing period, the healing plug must be removed from the implant using the threaded gripper wrench.



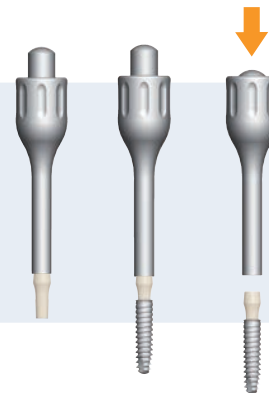
B. DESCRIPTION OF THE PREHENSILE WRENCH

The prehensile wrench facilitates the placement of the healing plug, the temporary abutment or Axiom[®] 2.8 abutment in cases presenting restricted mesiodistal space.

The prehensile wrench is also recommended for positioning the try-in abutments

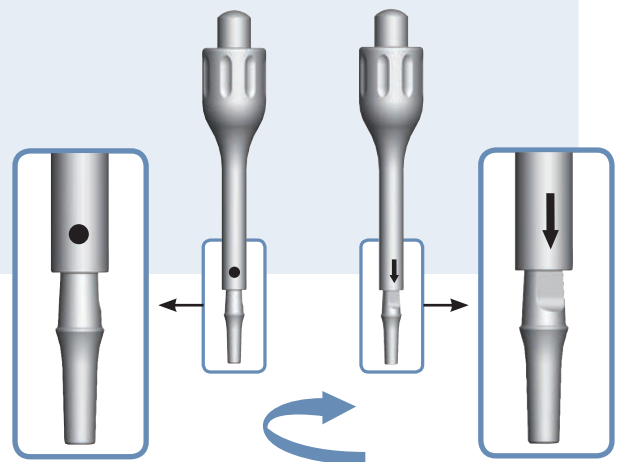
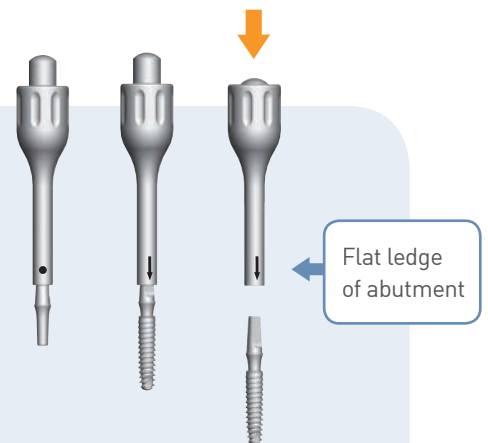
FOR THE INSERTION OF THE HEALING PLUG OR TEMPORARY ABUTMENT :

- Insert the plug into the wrench.
- Place the plug into the implant.
- Press the button on the wrench to release the plug.
- Apply pressure to the plug to secure it in the implant.



FOR THE INSERTION OF THE DEFINITIVE ABUTMENT :

- **Insert the abutment in the key aligning the arrow marked on the key with the flat ledge of the abutment.**
- Place the abutment in the implant using the arrow to position the ledge in the vestibule or, where necessary, to place the flat part of the straight abutments in the lingual surface.
- Press the button on the key to release the abutment.
- Activate the impaction according to the protocol (see p. 19).



TO POSITION THE TRY-IN ABUTMENTS:

- Insert the try-in abutments into the key, lining up the arrow of the key with the flat ledge of the prosthesis.
- Hold the try-in abutments in the implant with the key to position the ledge in the vestibule or, where necessary, to place the flat ledge of the try-in abutments in the lingual surface.
- Select the definitive abutment.

The prehensile wrench is suitable for autoclave sterilisation.

C. TEMPORARY ABUTMENTS


1. Indication

- Single-tooth restoration.

INSTRUCTIONS FOR USE

- The temporary abutment is supplied decontaminated and sterile, ready to use.
- The coronal geometry of the temporary abutment ensures optimal adhesion of resin. Circular grooves may enhance fixation.
- The temporary abutment can be inserted into the implant in any orientation.



Must be fixed by hand pressure

2. User protocol
a/ Selection of the temporary abutment

Select the temporary abutment among the **4 available gingival heights (1.0, 2.5, 4.0 and 5.5mm)** depending on the initial healing plug and respecting the principle of constant emergence profile between the several prosthetic components.

b/ Performing the temporary restoration
OPTION 1 : Direct intraoral placement
INSERTION OF THE TEMPORARY ABUTMENT :

- Insert the temporary abutment into the implant using the prehensile wrench (see page 17) or the threaded gripper wrench, and hand press the abutment to lock it inside the implant.

FABRICATION OF THE PROVISIONAL RESTORATION :

- Cement or fix the temporary crown onto the temporary abutment.

1

Ref. **OPOP028**



Ref. **OPCF100**



or



2

OPTION 2 : Fixation of the crown in the dental laboratory

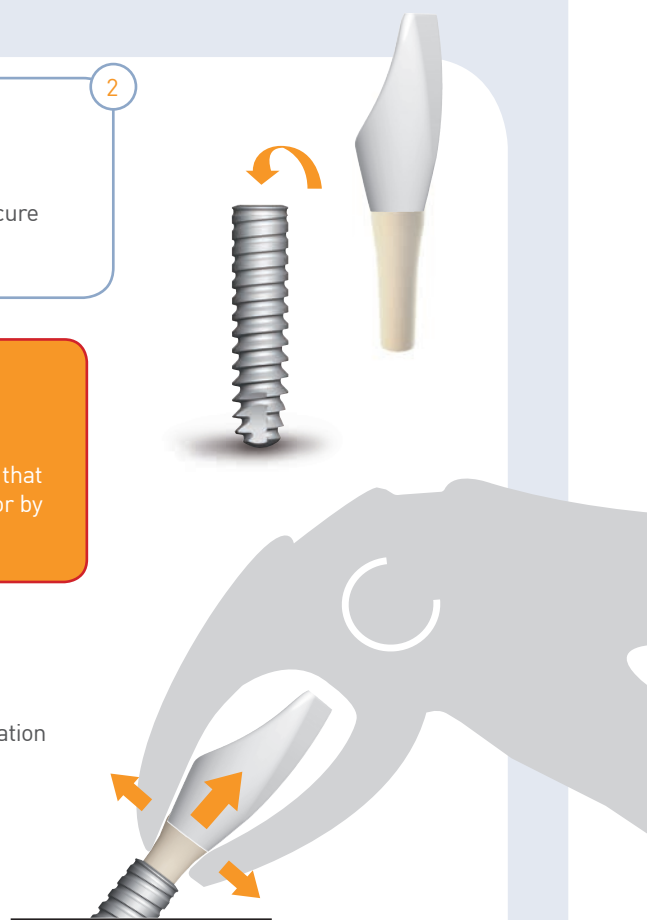
- The crown is permanently fixed onto the abutment in the dental laboratory. Then, the assembly is placed in the patient's mouth and hand pressed to secure it inside the implant


In all clinical situations :

- The temporary crown **MUST BE** placed out of occlusion.
- To avoid disinsertion of the temporary abutment, you must ensure that you have protected the temporary prosthesis by a **DENTAL SPLINT** or by the positioning of a **RESTRAINT ON THE ADJACENT TEETH**.

c/ Removing the temporary restoration

After removing the dental splint or restraints, take off the temporary restoration using dental forceps by making slight movements back and forth.



D. DESCRIPTION OF THE SAFELOCK FOR IMPACTION OF THE DEFINITIVE PROSTHETIC PARTS

The SAFE LOCK® automatic locking device must be connected to the micro-motor of your dental unit. It produces regular micro-strokes which intensity can be adjusted with the motor speed.

However, we recommend adjusting the motor speed at 10 000 rpm maximum so as to easily count the number of micro-strokes.



Insertion of the **axiom® 2.8** prosthesis parts with this instrument enables the impaction to be perfectly controlled.



There is no need to disassemble the SAFE LOCK® before sterilizing it in autoclave. He can be placed in a thermo disinfectant washer. (See chapter VII, the SAFE LOCK® notice **NOT 6920**).


WARNING !

In accordance with these provisions, this medical device must only be used by someone with experience of dental medicine for the application described, and in compliance with the provisions in effect in relation to the prevention of accidents at work, protection of employment and the instructions for use. This medical device must be prepared and maintained only by people trained in the prevention of infection.

This device may only be used with the Axiom® 2.8 range.

E. METHODS OF IMPACTION FOR THE DEFINITIVE PROSTHETIC PART:



During placement of the final prosthetic abutment, respect of the following is essential:

1. Make sure about the proper osseointegration of the implant.
2. Thoroughly clean and dry the connection before impaction, it must be free of any fluid or other substance capable of jeopardize implant-abutment junction.
3. Check that the gingiva or the bone does not interfere with the insertion of the abutment into the implant.
4. Check contact points with adjacent teeth.
5. Achieve impaction by aligning the Safe-Lock® as close as possible to the implant axis.

Impaction using
automatic locking system
SAFE LOCK® (Ref. **6920**)

Select the impaction tip which
is adapted to the abutment

If necessary, make
a local anaesthesia

Position the flat ledge of the abutment
in the vestibule (or in the lingual surface
in the case of straight abutments) using
the prehensile wrench.



Tighten the impaction tip on the SAFE LOCK®,
Adjust the motor speed to **10 000 rpm maximum**.
Position the tip on the abutment before pressing the pedal.
Press the pedal and **wait for 5 strokes**.



If the prosthesis is sealed outside of the
mouth, use an impaction tip that can be
adapted to the incisors, and proceed as
previously explained.



After impaction, the placement of the abutment in the implant is definitive.

F. ABUTMENTS (STERILE)



1. Indications

→ Single-unit cemented restoration.



After impaction, the abutment is definitively placed into the implant. Do not remove it or otherwise the conical connection may be damaged. However, in case of later complications, it is possible to extract the abutment using dental forceps, while taking care not to deform the implant.

INSTRUCTIONS FOR USE

→ The abutment is supplied decontaminated and sterilised for direct placement into the patient's mouth.

2. Selection of the abutment

Select the abutment from the **4 gingival heights (1.0, 2.5, 4.0 and 5.5 mm)** and the **4 angulations (0, 7, 15, 23°)** available. The choice of abutment is determined ideally according to the existing healing plug while ensuring that the emergence profile is maintained.

Choose the abutment so that no adjustment is necessary.

Use the try-in abutments to determine this choice and to determine the gingival height and the angulation best suited for the clinical case.

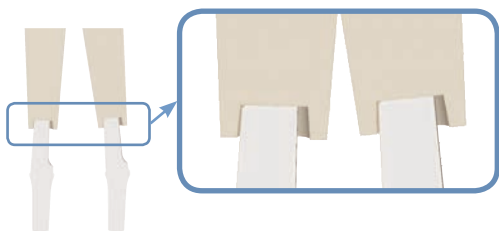
3. Impaction of the abutment



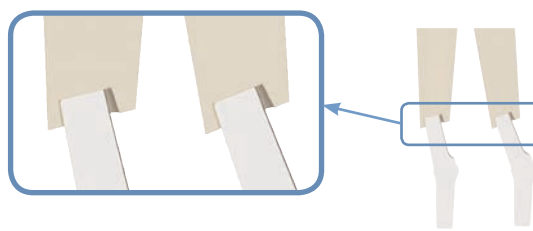
Before impacting the abutment, make sure the connection is free of any fluid or other substance that may affect the grip of the abutment into the implant.

The impaction of the abutment is made using the SAFE LOCK®, equipped with an impaction tip. Two impaction tips are available:

Tip for 0 and 7° abutments
(Ref. **OPIP100**)



Tip for 15 and 23° abutments
(Ref. **OPIP200**)



The impaction tips can be re-used. Before use, pre-desinfect, clean, decontaminate, dry and sterilize the tips.



For 15 and 23° angulated abutments, position the laser marking of the tip on the flat surface of the abutment.



G. IMPRESSION TAKING

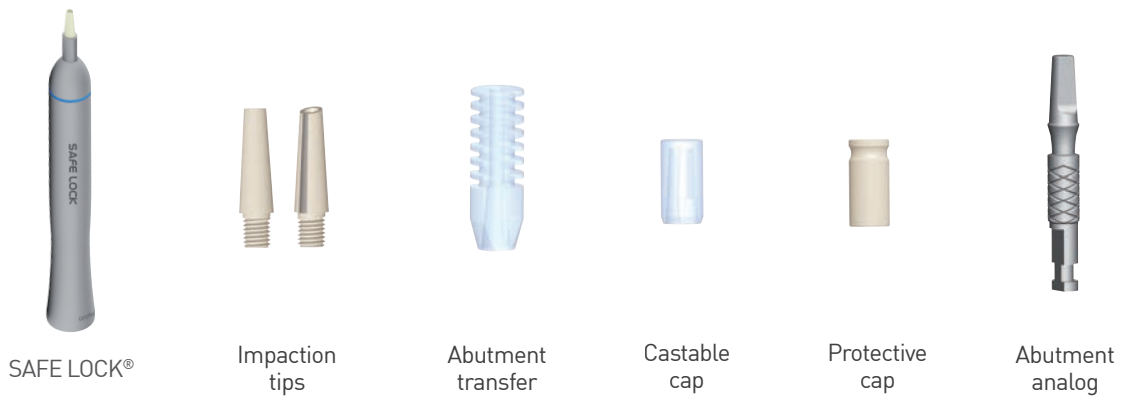
According to the prosthetic restoration, 2 impression-taking procedures are possible : direct or indirect procedure.



Direct impression-taking procedure : abutment transfer technique

→ The impression taking is made at the abutment level, in order to reduce periodontal manipulations

Material required



IMPACTION OF THE ABUTMENT :

- Make a local anaesthesia, if necessary.
- Remove the healing plug.
- **Position the abutment using of the threaded gripper wrench (see p. 16) aligning the ledge of the abutment in the vestibule or in the lingual surface as necessary** and insert the abutment with 5 impactions with the impactor suitably calibrated.

1



WARNING !

Position the flat ledge of the abutment in the vestibule (or the lingual surface, is necessary, for straight abutments), using the prehensile wrench.

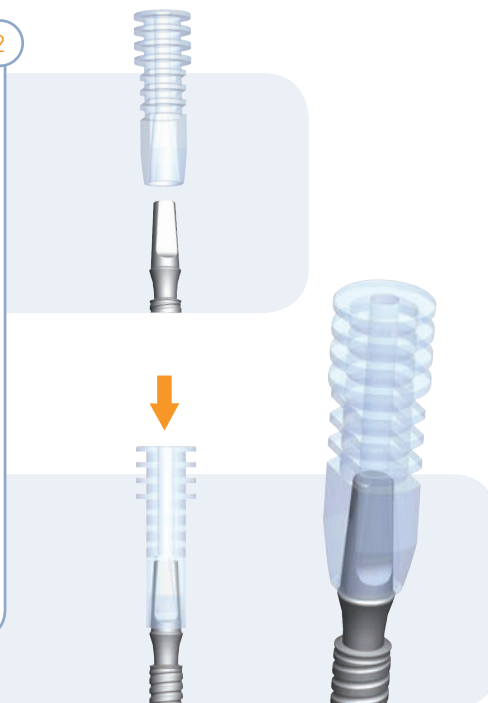
Do not remove the abutment after impaction.

Single-use recommendation/WARNING : analogs should be used only once to guarantee the integrity of the component design and specifically the connection.

2

IMPRESSION-TAKING AT THE ABUTMENT LEVEL :

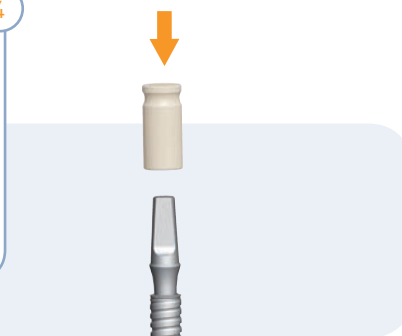
- Position the impression transfer on the impacted abutment paying attention to place it on the flat surface of the abutment.
- Once the index is in place, press the transfer on the intact abutment.
- Take a classical impression using an impression-tray.



4

PROTECTING THE ABUTMENT :

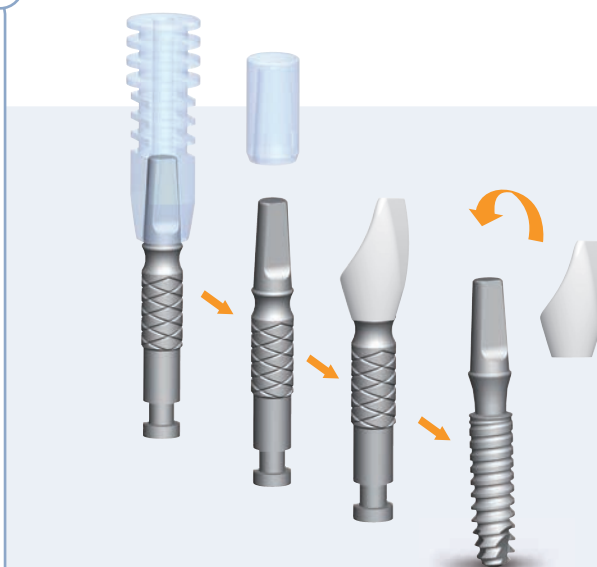
- Clean the abutment thoroughly.
- Seal the protecting cap using temporary cement.



5

MASTER-MODEL AND PROSTHESIS :

- Insert the abutment analog (there is only 1 for all angulations) in the transfer into the impression intrados, after visualising the relative position of the analog in the impression.
- Check that the analog is correctly fixed in the impression (if necessary, repeat the procedure) and perform the master-model.
- Use the anti-rotational castable coping to perform the metallic cap. Put spacer on the analog to stabilize the castable cap on the master-model.
- Prepare the final prosthesis according to current restoration protocols.
- Cement the crown onto the abutment in the mouth.



**NEW
DESIGN!**



2. Indirect impression-taking procedure : Pop-in transfer technique

- Impression is taken directly on the implant by a Pop-in type impression transfer.
The prosthesis and the possible reworking of the abutment are performed at the laboratory.

Material required



Impaction
tips



Implant
analog



Pop-in
transfer

IMPRESSION-TAKING :

- Remove the healing plug.
- Insert the Pop-In transfer into the implant, press slightly.
- Take an impression using an impression tray (Pop-In technique). Gently remove the Pop-in transfer from the implant using dental forceps. Place it in the implant analog and re-position it in the impression material.
- Reposition the healing plug in the implant exerting pressure.

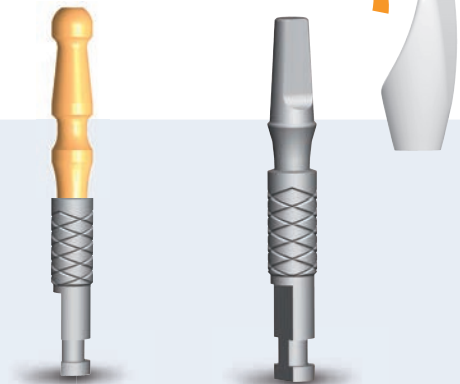
1



IMPRESSION TRANSFER AND PREPARATION OF MASTER-MODEL:

- Perform the master-model with the implant analog.
- **Insert the selected abutment thoroughly into the analog, aligning the flat ledge of the abutment in the vestibule (or in the lingual surface, if necessary, for straight abutments).**
- If necessary, drill the abutment to adjust the volume of the definitive prosthesis.

2



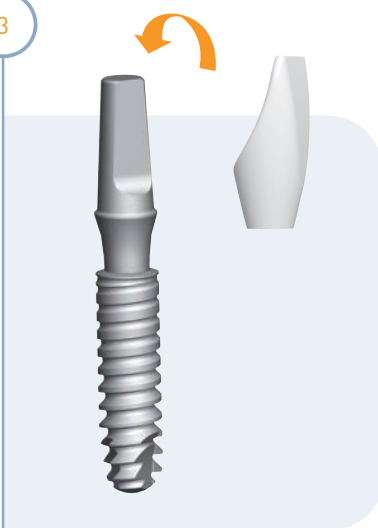
Placement of the titanium definitive abutment :

2 options are possible : intra-oral or extra-oral cementation.

3

INTRA-ORAL CEMENTATION:

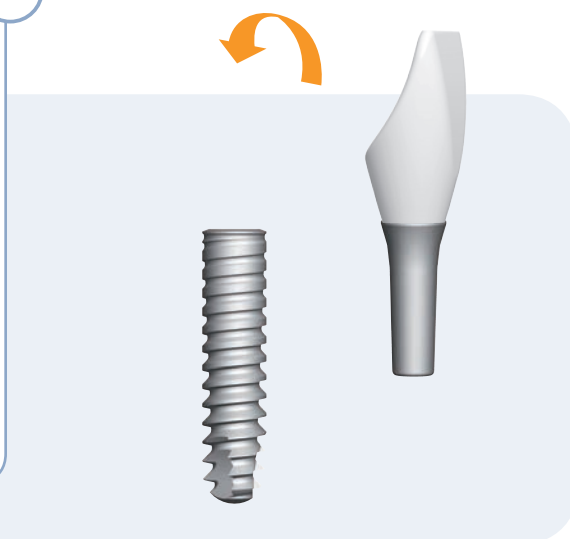
- Make a local anaesthesia, if necessary. The patient may prefer to be given a local anaesthetic.
- Remove the healing plug using the threaded prehensile wrench.
- **Position the flat ledge of the abutment well in the vestibule (or in the lingual surface in the case of straight abutments)** using the prehensile wrench and the abutment repositioning key provided by the laboratory. Using the SAFE LOCK®, insert the abutment impacting 5 times with the correct calibration.
- Cement the crown definitively onto the abutment intra-orally.



3 bis

EXTRA-ORAL CEMENTATION:

- At the laboratory, the crown is definitively cemented onto the abutment.
- Make a local anaesthesia, if necessary. The patient may prefer to be given a local anaesthetic.
- Remove the healing plug using the threaded prehensile wrench.
- Position the abutment topped by the prosthesis using the crown repositioning key provided by the laboratory, and impact it using the impaction tip.



3. Cleaning and sterilisation



WARNING!

All re-usable products (instruments and kits) must be pre-disinfected, cleaned, disinfected, dried and sterilized before the first use and after each surgery.

All products for single use supplied non-sterile must be cleaned, disinfected, dried and sterilized before placement into the patient's mouth. They may be disinfected or sterilized using a heat disinfectant and an autoclave with the product placed outside of its original packaging, in a suitable bag for the procedure. In the event of any specific component restrictions, always disinfect and cold sterilise with CHLORHEXIDINE (see labelling).

No products supplied sterile (sterilized by gamma irradiation) must be re-sterilized. Observe the sterile parts within the bags or blisters/closures when unpacking, placing the contents on a sterile drape. Observe the product expiration date.

A. GENERAL INFORMATION

1. PRELIMINARIES

All cleaning-disinfection, drying and sterilisation protocols must be followed by correctly trained protected staff in accordance with current regulations. In order to avoid any risk of infection or injury, it is essential to wear appropriate clothing (protective mask, gloves and glasses).



When following the protocol, it is mandatory to follow current regulations, referring to the «*Good Hospital Pharmacy Practice*» recommendations, the «*Good Disinfection Practice*» guide, the «*Good Sterilisation Practice*» guide and the guide for «*Correct execution of treatments applying to re-usable medical devices*» in reference FD S98-135 - April 2005.

All cleaning-disinfection, drying and sterilisation protocols must be appropriate for the risks of infection. The user or medical staff must ensure that the protocol used achieves the sterility objective. The protocol must enable all chemical and organic residues to be removed from the treated device (in particular ensure that used products are correctly rinsed).

2. COMPATIBILITY WITH MATERIALS

In order not to deteriorate or damage components, it is mandatory to use cleaning and decontamination products that are compatible with the different materials treated.

Detergent and disinfectant solutions must be of neutral pH or weakly alkaline.



WARNING! For aluminium alloys, the use of sodium hydroxide solutions is strictly prohibited. For stainless steels, the use of sodium hypochlorite (bleach) is strictly prohibited: high risk of corrosion. Components finished in Bee-COLOR® should never be cleaned with hydrogen peroxide [H₂O₂] or hydrogen peroxide as there is a risk of chemical stripping.



The material composition of each component and full list of the part numbers can be found at the end of this document.

B. PRODUCTS

1. DETERGENT-DISINFECTANT PRODUCTS

In order to guarantee sufficient decontamination before sterilization, the detergents and disinfectants must be chosen according to the risks of infection depending on their field of activity: standard microbial activity (bacteria, fungicide, virucide) and their cleaning capacity.

The detergents and disinfectants used must be consistent with the cleaning method used.

The user must refer to the manufacturer's instructions for each cleaning and disinfecting product:

- Observe the concentrations, temperatures and exposure times.
- Observe solution replacement and lifespan of the products.
- Observe instructions for disposal of used products.
- Never mix products.



WARNING! Do not use substances liable to bind proteins (alcohol, aldehydes,...).



For more information, the user may refer to guide FD S98-135, the «*Guide for prevention of healthcare related infections in dental surgery and stomatology*» July 2006 and the positive list of dental disinfectants 2009 published by SFHH and ADF.

2. WATER QUALITY

The water used for pre-disinfection, cleaning, decontamination, rinsing and sterilisation must meet current regulations. The user may refer to document FD S 98-135 §9-4.

The water quality must be compatible with the sterility objective and equipment used.

It is important that conductivity, Ph, water hardness, ion and impurity concentration and microbiological pollution be monitored.

3. PRECAUTIONS FOR USE

The user must pay particular attention to cleaning dirt residues and deposits from all parts of the instruments. During the different stages of the procedure, it is important to ensure that cutting instruments are not knocked as this carries a risk of reducing their cutting performance.

These instruments must be replaced after being used a maximum of 20 times.

A visual control must be performed before each sterilisation. All worn, corroded or damaged components must be treated separately and removed.

Medical waste must be disposed of in accordance with current regulations on medical waste management.



WARNING! Any used component intended to be returned to the After-Sales Service must be sent sterile after pre-disinfection, cleaning, decontamination and drying in accordance with current legislation, with proof of sterility.

C. PROTOCOLS

1. PRE-DISINFECTION

Any re-usable components must be pre-disinfected immediately after each surgery (see Instructions for dismantling and assembly):

- Pre-disinfect separately, detaching systematically whenever possible from all assembled devices.
- Completely immerse in the pre-disinfection solution.
- Rinse with osmosed, demineralised water to avoid any deposits.
- Carefully dry with soft, sterile wipes (combined with medical grade compressed air).

2. CLEANING – DISINFECTION

Dismantled components must be cleaned separately (kits and ratchet wrenches) (See «*Dismantling and Assembly Instructions*»).

Cleaning by brushing

- Brush meticulously with a soft brush (For example nylon).
- Completely immerse in a detergent disinfectant solution following the manufacturer's recommendations.
- Rinse with osmosed, demineralised water to avoid any deposits.
- Carefully dry immediately with soft, sterile wipes (combined with medical grade compressed air).
- Check the result and repeat the cleaning procedure if necessary.

Ultrasound cleaning (only for re-usable products)

- Place the components in a low frequency ultrasound tank (25 to 50 kHz).
- Fill with detergent disinfectant solution compatible with the procedure.
- Clean the components by ultrasound following the manufacturer's recommendations.
- Rinse with osmosed, demineralised water to avoid any deposits.
- Carefully dry immediately with soft, sterile cloths (combined with medical grade compressed air).
- Check the result and repeat the cleaning procedure if necessary.



WARNING! Do not place cutting instruments in contact during ultrasound cleaning. Rubbing of the parts against each other or against the tank may cause defects and premature wear.

3. HEAT-DISINFECTION (RE-USABLE PRODUCTS ONLY)

Heat disinfection must only be performed for assembled re-usable components or a complete kit, placed flat with cover open.

- Perform a 10 minute heat-disinfection cycle at 95°C (203°F).
- Perform a drying cycle. Do not exceed 140°C (284°F).
- Check the result and repeat the heat disinfection if necessary.

4. STERILIZATION

No components may be sterilised without prior cleaning-disinfection and drying (+ pre-disinfection for reusable components).

Autoclave sterilization (reusable product and single-use components)



- Put each component separately in a sealed sterilisation bag in accordance with standard NF EN ISO 11607 and consistent with the sterilisation method (complete kit placed in a flat bag, with covers closed).
- Perform a steam autoclave cycle at 135°C (275°F) at 2.13 bars (30.88 psi) for a minimum of 20 minutes.
- Enter the sterilisation dates and expiration date on the bags, consistent with the sterility time limits set depending on the type of packaging and storage conditions (maximum 1 month).



WARNING! Do not use any other sterilization method for instruments and ancillaries. anthogyr recommends class B autoclaves.

- Follow the manufacturer's recommendations and instructions for use and maintenance of the autoclave.
- Observe the spaces between bags in the autoclave.
- Observe the storage conditions for the sterile components in accordance with the bag manufacturer's recommendations.



French circular DGS/5C/DH0/E2 n°2001-138 – March 14th, 2001.

Cold sterilization

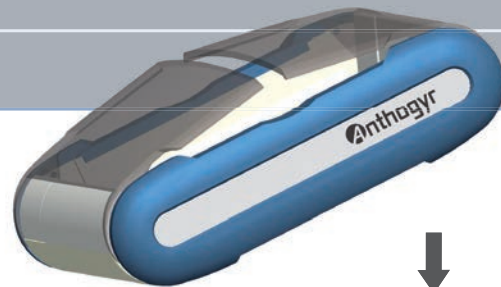


If autoclave sterilisation is not permitted, disinfect and cold sterilise by immersing in a solution of CHLORHEXIDIN.

4. Disassemble and assembly

A. INSTRUMENT KIT

→ Open the covers.



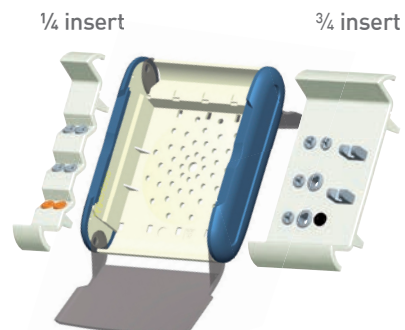
1

→ Unclip the insert pegs located on the back of the kit.

→ Remove the 1/4 and 3/4 inserts from the main kit body.



2



→ Carefully remove the side arms from the main body.

→ Detach the transparent cover pivot pegs.

→ Remove the covers



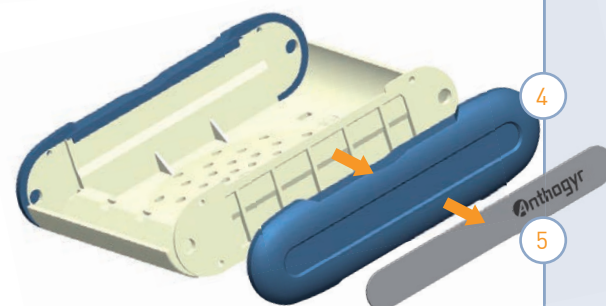
3

→ Remove the side covers from the main body.

→ Detach the side covers from the side of the kit.

→ Remove the side cover ends around the stainless steel plates.

→ Detach the silicone cover plates.



4

5

Repeat each stage in reverse order to assemble.

B. REVERSIBLE RATCHET WRENCH REF. IN CC

Disassembling / Re-assembling

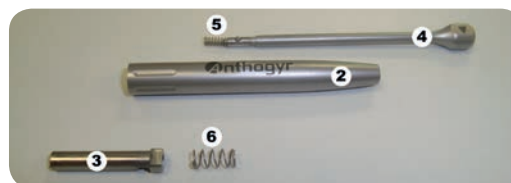
- Unscrew the head **1** and remove it from the main body **2**.
- Remove the set « ratchet **3** + rod **4** » from the body, by pushing slightly against each other the back wheel of the rod **4** and the ratchet **3** while simultaneously rotating the ratchet **3** ¼ turn anti-clockwise in order to unlock the bayonet.
- Repeat the disassembling operation above in reverse order. Insert the set « rod **4** + spring **5** » through the back part of the body **2**. Fit the spring **6** around the rod **4** through the front part of the body **2**. Assemble the ratchet **3** by pushing it onto the rod **4** and rotating it ¼ turn clockwise to lock the bayonet. Screw the head **1** onto the body **2**.



1



2

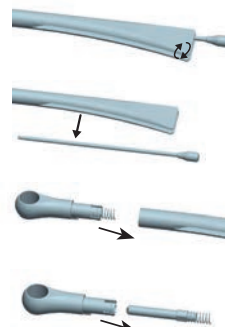


3

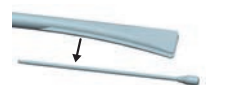
C. SURGICAL DYNAMOMETRIC RATCHET WRENCH ART. NB. IN CCD

Disassembling / Re-assembling

- Unscrew the flexible rod by turning it anti-clockwise using the button.
- Remove the parts « rod + button » from the sleeve.
- Remove the head from the main body by pulling gently.
- Remove the parts « ratchet + spring » from the head.



1



2



3

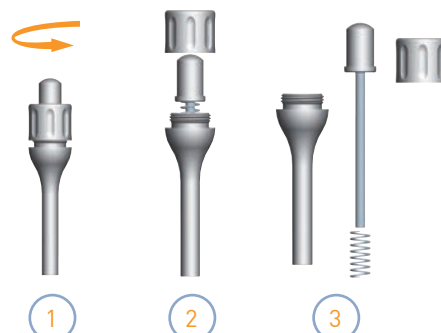


4

D. PREHENSILE WRENCH

Disassembling / Re-assembling

- Unscrew the top part of the wrench (1 and 2).
- Take out the shank and the spring (3).



1

2

3

To assemble: reverse the order of each step beginning by inserting the spring around the shank.

5. Component references

A. SURGICAL COMPONENTS

IMPLANTS		REFERENCES
	Axiom® 2.8	STERILE
	Ø 2.8 mm Cover plug included	
	Grade V Titanium	OP28100 OP28120 OP28140
	Axiom® 2.8 Ø 2.8 x 10 mm	
	Axiom® 2.8 Ø 2.8 x 12 mm	
	Axiom® 2.8 Ø 2.8 x 14 mm	

B. SURGICAL INSTRUMENTS

DRILLS & TAPS		REFERENCES
	Round bur Medical grade stainless steel Round bur	NON STERILE IN FB20
	Pointer drill Medical grade stainless steel Pointer drill	NON STERILE OPP015150
	Initial helicoidal drill Medical grade stainless steel Helicoidal drill Axiom® 2.8 Ø 2.0 x 25 mm	NON STERILE OPFI20250
	Helicoidal drill Medical grade stainless steel Helicoidal drill Axiom® 2.8 Ø 2.6 x 25 mm	NON STERILE  OPFE26250
	Tap Medical grade stainless steel Implant tap Axiom® 2.8 Ø 2.8 x 25 mm	NON STERILE  OPTA28250

**NEW
DESIGN!**

MANDRELS & WRENCHES		REFERENCES
	Implant tightening mandrel Medical grade stainless steel Implant mandrel Axiom [®] 2.8	NON STERILE OPMV028
	Implant tightening wrench Medical grade stainless steel Manual wrench Axiom [®] 2.8	NON STERILE OPCV028
	Mandrel extension Medical grade stainless steel Mandrel extension	NON STERILE IN EXM
	Mandrel holding wrench Medical grade stainless steel Mandrel holding wrench	NON STERILE IN CPM
	Reversible manual ratchet wrench Medical grade stainless steel Ratchet wrench	NON STERILE IN CC
	Surgical dynamometric wrench Medical grade stainless steel Reversible wrench	NON STERILE IN CCDC

SURGICAL ACCESSORIES		REFERENCES
	Depth gauge Ø 2.0 mm Grade V Titanium Depth gauge Axiom [®] 2.8 Ø 2.0 mm	NON STERILE OPJD028
	Depth gauge Ø 2.6 mm Grade V Titanium Depth gauge Axiom [®] 2.8 Ø 2.6 mm	NON STERILE OPJD026

PROSTHESIS ACCESSORIES		REFERENCES
	Prehensile wrench Medical grade stainless steel Prehensile wrench Axiom [®] 2.8	NON STERILE OPOP028
	Threaded gripper wrench (For PEEK components) Medical grade stainless steel Threaded prehensile wrench Axiom [®] 2.8	NON STERILE OPCF100

SURGICAL KITS		REFERENCES
	Complete surgical kits Drills and taps Mandrels and wrenches Surgical accessories SAFE LOCK®	IN KIT OP28
	Empty surgical kit	IN MOD OP28V
	Calibrating film Axiom® 2.8	NOT OPFC28

C. PROSTHETIC COMPONENTS

All prosthetic components are single-use.

TEMPORARY PARTS		REFERENCES
	Cover plug 180 days implantable grade PEEK Cover plug in PEEK Pack of 4 cover plug in PEEK	STERILE OPIM028 OPIM028-4
	Healing plug 180 days implantable grade PEEK Healing plug in PEEK H1.0 Healing plug in PEEK H2.5 Healing plug in PEEK H4.0 Healing plug in PEEK H5.5	STERILE OPHS210 OPHS220 OPHS240 OPHS250

TEMPORARY ABUTMENTS		REFERENCES
	Temporary abutments 180 days implantable grade PEEK Temporary abutment in PEEK H1.0 Temporary abutment in PEEK H2.5 Temporary abutment in PEEK H4.0 Temporary abutment in PEEK H5.5	STERILE OPTP210 OPTP220 OPTP240 OPTP250

ANALOGS		REFERENCES
	Abutment analog Grade V Titanium Abutment analog	NON STERILE OPAT028
	Implant analog Grade V Titanium Implant analog	NON STERILE OPIA028

TRANSFERS		REFERENCES
	Abutment transfer Medical grade plastic (PC LSG) Abutment transfer	NON STERILE OPTT028
	Pop-in Transfer Grade V titanium nitride Pop-in Transfer	NON STERILE OPPI028
DEFINITIVE ABUTMENTS		REFERENCES
	Straight impacted abutment Grade V Titanium Straight impacted abutment H1.0 0° Straight impacted abutment H2.5 0° Straight impacted abutment H4.0 0° Straight impacted abutment H5.5 0°	STERILE OPAT210 OPAT220 OPAT240 OPAT250
	7° angulated impacted abutment Grade V Titanium 7° angulated impacted abutment H1.0 7° 7° angulated impacted abutment H2.5 7° 7° angulated impacted abutment H4.0 7° 7° angulated impacted abutment H5.5 7°	STERILE OPAT211 OPAT221 OPAT241 OPAT251
	15° angulated impacted abutment Grade V Titanium 15° angulated impacted abutment H1.0 15° 15° angulated impacted abutment H2.5 15° 15° angulated impacted abutment H4.0 15° 15° angulated impacted abutment H5.5 15°	STERILE OPAT212 OPAT222 OPAT242 OPAT252
	23° angulated impacted abutment Grade V Titanium 23° angulated impacted abutment H1.0 23° 23° angulated impacted abutment H2.5 23° 23° angulated impacted abutment H4.0 23° 23° angulated impacted abutment H5.5 23°	STERILE OPAT213 OPAT223 OPAT243 OPAT253
SECONDARY PARTS		REFERENCES
	Protective cap 180 days implantable grade PEEK Protective cap	NON STERILE OPPC028
	Chape calcinable PMMA Chape calcinable	NON STERILE OPCA028

**NEW
DESIGN!**

TRY-IN ABUTMENTS FOR AXIOM® 2.8			REFERENCES	
	Straight try-in abutments		NON STERILE	
	Grade V Titanium			
	Straight try-in abutment	H1.0 0°		OPAF210
	Straight try-in abutment	H2.5 0°		OPAF220
	Straight try-in abutment	H4.0 0°		OPAF240
	Straight try-in abutment	H5.5 0°	OPAF250	
	Try-in abutments angulated at 7°		NON STERILE	
	Grade V Titanium			
	Try-in abutment angulated at 7°	H1.0 7°		OPAF211
	Try-in abutment angulated at 7°	H2.5 7°		OPAF221
	Try-in abutment angulated at 7°	H4.0 7°		OPAF241
	Try-in abutment angulated at 7°	H5.5 7°	OPAF251	
	Try-in abutments angulated at 15°		NON STERILE	
	Grade V Titanium			
	Try-in abutment angulated at 15°	H1.0 15°		OPAF212
	Try-in abutment angulated at 15°	H2.5 15°		OPAF222
	Try-in abutment angulated at 15°	H4.0 15°		OPAF242
	Try-in abutment angulated at 15°	H5.5 15°	OPAF252	
	Try-in abutments angulated at 23°		NON STERILE	
	Grade V Titanium			
	Try-in abutment angulated at 23°	H1.0 23°		OPAF213
	Try-in abutment angulated at 23°	H2.5 23°		OPAF223
	Try-in abutment angulated at 23°	H4.0 23°		OPAF243
	Try-in abutment angulated at 23°	H5.5 23°	OPAF253	

C. PROSTHETIC INSTRUMENTS

DÉSIGNATIONS		REFERENCES
	Impaction tips	NON STERILE
	PEEK	
	0° and 7° abutment tip 15° and 23° abutment tip	
	Impaction tip for definitive prosthesis	NON STERILE
	PEEK	
	Definitive prosthetic impaction tip	
	SAFE LOCK® 3 impaction tips included	NON STERILE

Notes



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