CERALOG®
SYSTEM

CERALOG®
Implant system

System information
Implant insertion
Prosthetics

a perfect fit

camlog

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GENERAL
SYSTEM INFORMATION

The CERALOG® Implant System is based on years of clinical and laboratory experience and is a user-friendly, prosthetically oriented implant system.

All CERALOG® Products are manufactured with the latest state-of-the-art technology. These are continuously being further developed by the company's research and development team in collaboration with clinics, universities and dental technicians and therefore stay abreast of the latest technology.

IMPORTANT NOTE:
The descriptions that follow are not adequate to permit immediate use of the CERALOG® Implant System. Instruction by a surgeon experienced in using the implant system is strongly recommended.
CERALOG® Dental implants and abutments should only be used by dentists, doctors, surgeons and dental technicians who have been trained in using the system. Appropriate courses and training sessions are regularly offered by Camlog.

Methodological errors in treatment can result in loss of the implant and significant loss of peri-implant bone.

The images in this document are for reference purposes only and may differ from the actual product.

CERALOG® IMPLANTS

GENERAL

CERALOG® Implants are enossal implants and are available in different lengths. They are placed surgically in the maxillary and/or mandibular bone and serve for the anchoring of functional and esthetic oral rehabilitations in partially or fully edentulous patients. The prosthetic restoration is performed with single crowns, bridges or full dentures that are attached to the CERALOG® Implants with the appropriate CERALOG® Components.
CERALOG® Implants are available as one-piece monobloc implant or as a two-piece screw-retained hexalobe implant with PEKK abutment.

CERALOG® Implants are distinguished by:

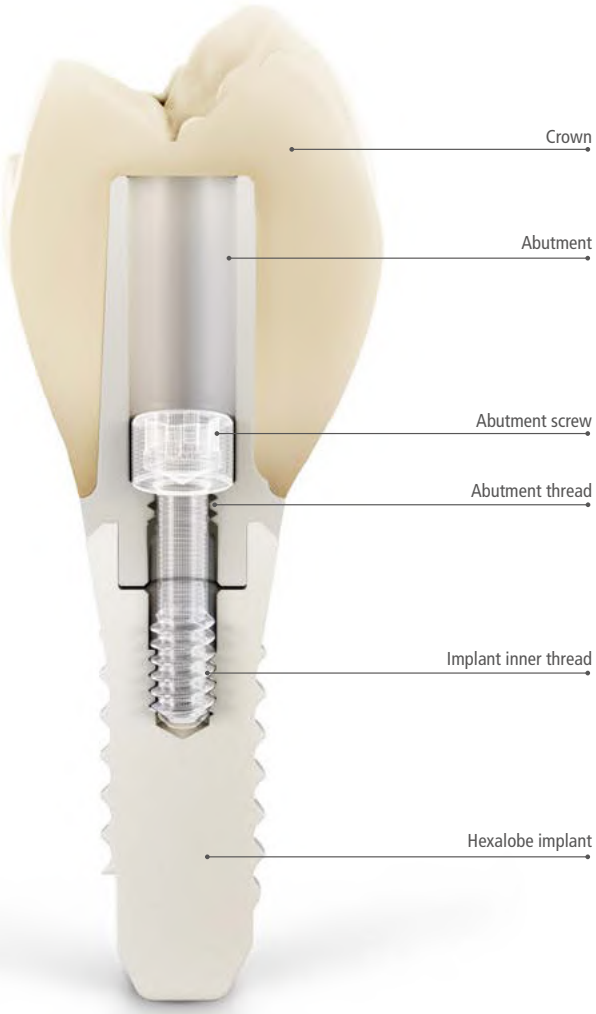
- the properties of zirconia*
- a dual surface texture which combines two defined roughnesses on a single implant:
  A) The enossal area of the implant with a roughness (Ra value of 1.6 µm) for the targeted deposition of bone cells
  B) The neck area of the implant, with an Ra value of 0.5 µm for improved soft tissue deposition
- Production of shape and roughness in a single operation. No abrasive treatment of the zirconia is therefore necessary
- Implant-abutment connection specifically optimized for ceramics

Choices available for therapy planning include the transgingival healing CERALOG® Monobloc implant as well as the both trans- and subgingival healing two-piece CERALOG® Hexalobe implant.

SCOPE OF APPLICATION

CERALOG® Implants, with their ivory color, which closely resembles the color of a natural tooth, are particularly appropriate for esthetically demanding areas.
The following clinical conditions facilitate the process:

- Normal to thick biotype
- Gingival thickness should be at least 3.0 mm
- Minimum width of the attached gingiva should be 1.0 mm
- Minimum distance between the attached gingiva and the mimic musculature should be 2.0 mm



* See [A] in section «Further documentation» on page 63

CERALOG® IMPLANTS

MATERIAL

Components	Made of
CERALOG® Implants	Yttrium-stabilized (Y-TZP) Zirconia
CERALOG® Abutments	PEKK
CERALOG® Abutment screws	Titanium alloy or gold alloy with gold coating (Holisticor)
CERALOG® Cover caps, CERALOG® Healing caps, CERALOG® Scanbodies, CERALOG® Temporary abutments CERALOG® Monobloc impression caps, closed tray	PEEK
CERALOG® Hexalobe impression posts, closed tray CERALOG® Hexalobe impression posts, open tray CERALOG® Cover screws	PEEK and titanium alloy
CERALOG® Hexalobe lab analogs	PEEK or Zirconia
CERALOG® Monobloc lab analogs	Stainless steel

FABRICATION

The CERALOG® Implants are manufactured by Ceramic Injection Molding (CIM). Here, both the outer geometry as well as the surface texture are already created in an injection mold before the sintering and HIP process (HIP = Hot Isostatic Pressing). Due to this procedure, no abrasive processing of the zirconia is necessary to obtain a structured surface.

INNER IMPLANT CONFIGURATION OF THE CERALOG® HEXALOBE IMPLANT

The hexalobe connection has been designed specifically for ceramic implants which offers the following advantages:

- High positioning precision due to minimal rotational freedom
- No complicated transfer key for abutments required
- Material-compatible force transfer when inserting the hexalobe implant

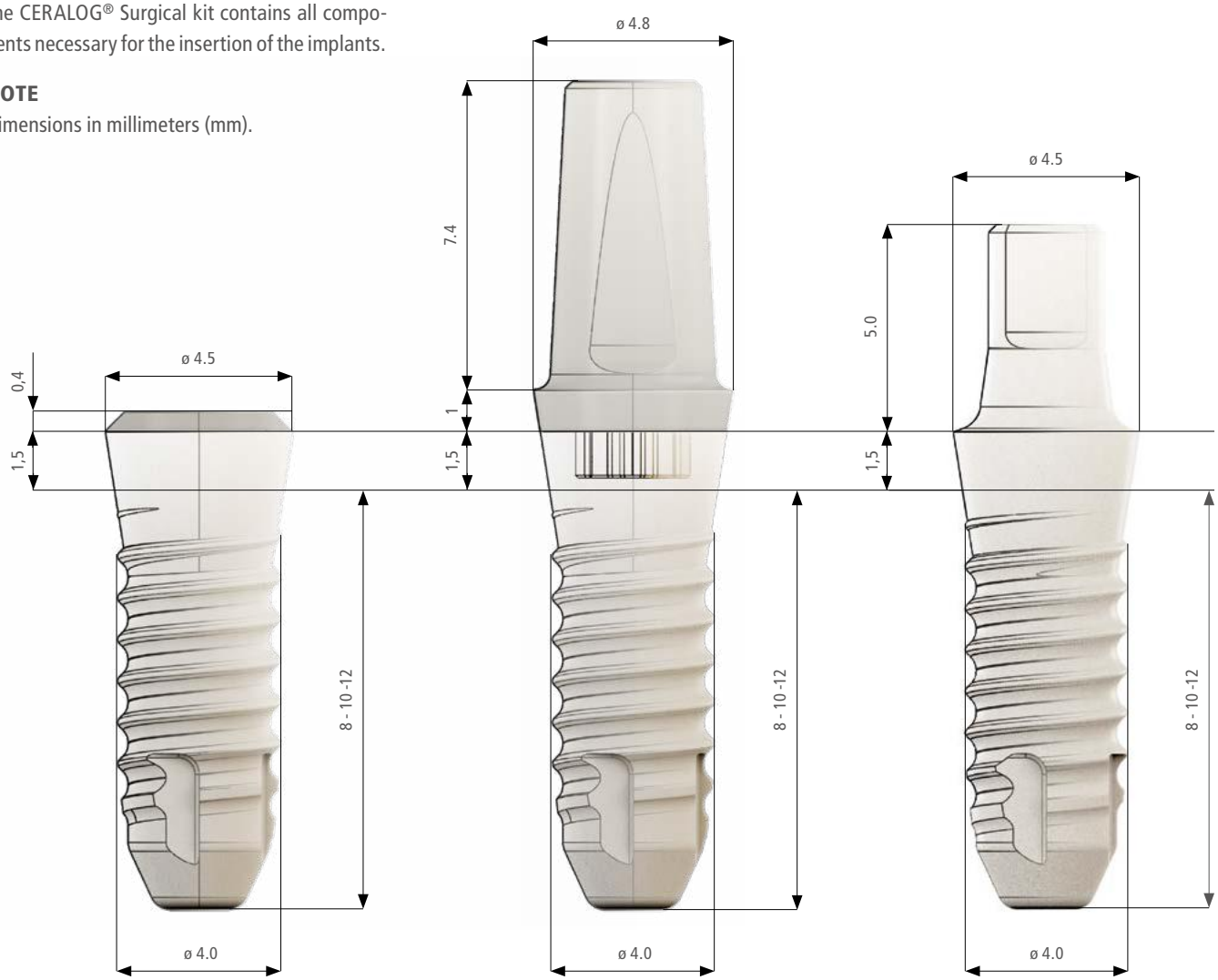
CERALOG® SURGERY

The CERALOG® Hexalobe and CERALOG® Monobloc implants have a 1.5 mm high implant neck which is positioned supracrestally. The implant neck of the Hexalobe implant can also be placed epicrestally by using a bone profile drill and corresponding deepening of the implant bed.

The CERALOG® Surgical kit contains all components necessary for the insertion of the implants.

NOTE

Dimensions in millimeters (mm).

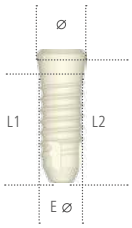


CERALOG® Hexalobe implant

CERALOG® Hexalobe implant
with mounted PEKK abutment

CERALOG® Monobloc implant

CERALOG® HEXALOBE IMPLANT DIMENSIONS

	Article	Type	Art. No.	Ø	L1	L2	E Ø
	**CERALOG® Hexalobe implant** incl. cover cap, sterile **Material** Zirconia/PEEK	M8	H1020.4008	4.5 mm	8 mm	9.25 mm	4.0 mm
		M10	H1020.4010		10 mm	11.25 mm	
		M12	H1020.4012		12 mm	13.25 mm	

L1: Supracrestal insertion depth
L2: Epicrestal insertion depth
E Ø: Enossal diameter

CERALOG® MONOBLOC IMPLANT DIMENSIONS

	Article	Type	Art. No.	Ø	L1	E Ø
	**CERALOG® Monobloc implant** sterile **Material** Zirconia	M8	A1074* H1010.4008*	4.5 mm	8 mm	4.0 mm
		M10	H1010.4010		10 mm	
		M12	A1076* H1010.4012**		12 mm	

L1: Supracrestal insertion depth
E Ø: Enossal diameter

* Manufacturer: AXIS biodental SA, Les Rosées 5, 2336 Les Bois, Switzerland
** New product number available from end of Q3/2021

IMPLANT POSITION PLANNING

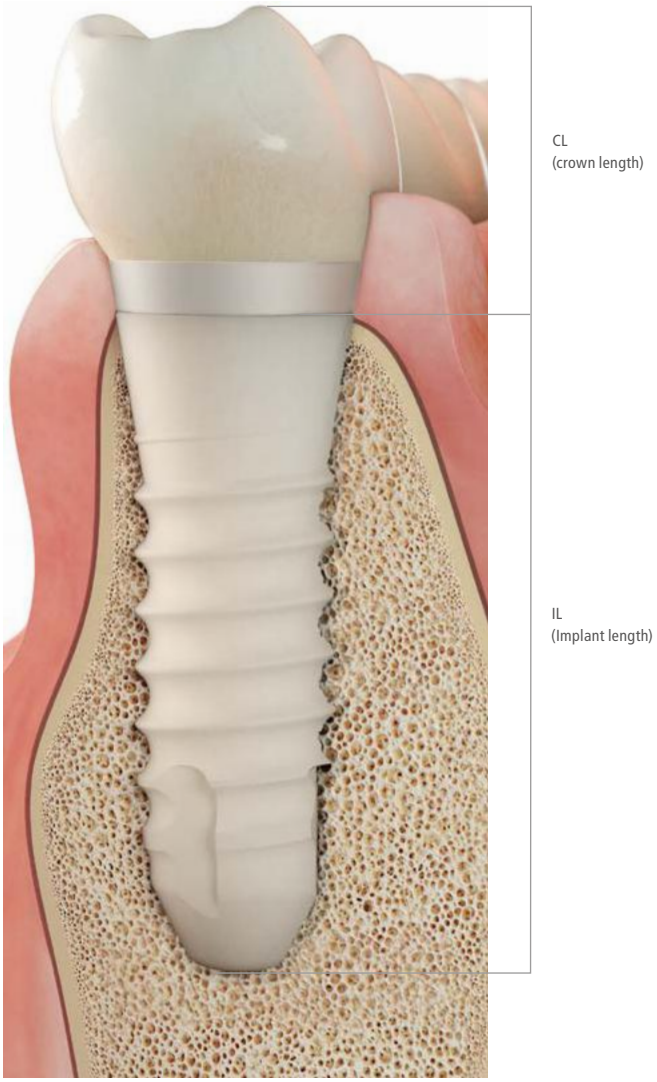
As a matter of principle, the implant should be planned by the team and be based on the prosthetic therapy («Backward Planning»). The following gives some aspects which should be taken into account during planning:

LEVERAGE CONDITIONS ON IMPLANT

The loading of the implant-bone interface is determined by the leverage ratio from the osseointegration-related resistance to the prosthetic load arm (equal to the supracrestal implant length plus crown length from the implant shoulder). If the implant length (IL) is less than the length of the crown (CL), measures must be taken to reduce loading (e.g. using prosthetic splints). If leverage ratios on the implant are unfavorable, a longer implant must be selected.

The ratio of crown length (CL) to implant length (IL) should be 1:1.25 maximum.

Implant distribution should be structured in such a way that spanned segments are kept small. Preparation of the abutment must ensure the common insertion direction of the crown block/bridges. The implant-abutment connection may not be altered.



DISTANCES TO ADJACENT STRUCTURES

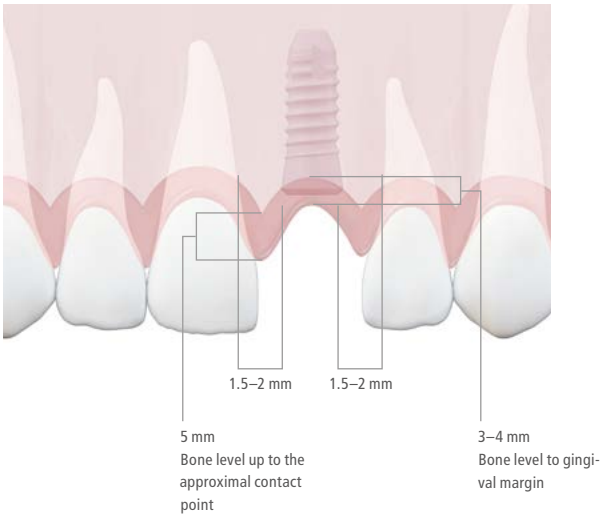
VERTICAL IMPLANT POSITION

The recommendations for the distances to be maintained from adjacent structures must be observed to allow wound healing to proceed optimally and for hard and soft tissue to develop optimally during the healing phase.

The recommended distances for determining the vertical implant position are shown in the diagram. These must be adapted to the clinical situation.

The implant length must be sized to leave adequate bone (at least 1 mm) around the implant.

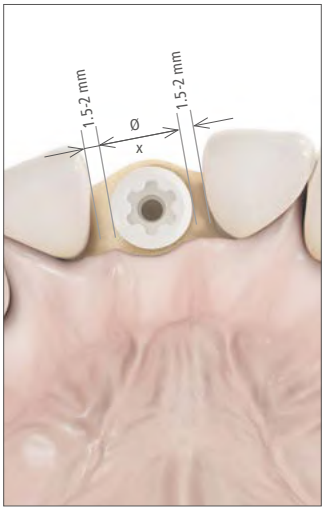
Vertical implant position



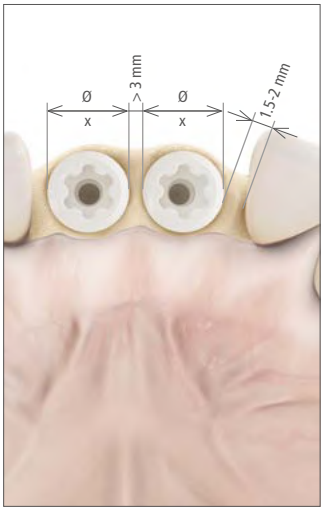
HORIZONTAL IMPLANT POSITION

Maintain a minimum distance of 1.5 mm to an adjacent natural tooth and 3 mm to an adjacent implant.

The implant diameter must be sized to leave adequate bone (at least 1 mm) around the implant.



Mesio-distal implant position at bone level



Distances at bone level

IMPLANT POSITION PLANNING

DESIGN OF PROSTHETIC RESTORATIONS

The hygienic requirements must also be taken into account, if splinting is required by reason of stability.

SPLINTED CROWNS

If leverage ratios on the implant are unfavorable, either a longer implant must be selected or when not possible anatomically, adjacent crowns can be splinted.

Preparation of the abutment must ensure the common insertion direction for the crown block. The implant-abutment connection may not be altered.

Splinted crowns

IMPLANT-SUPPORTED BRIDGES

At positions where implantation is not possible, implant-borne bridges can be inserted. Implant distribution should be structured in such a way that spanned segments are kept small.

Development of a uniform insertion direction for the crown block should be part of the abutment preparation. The implant-abutment connection may not be altered.

Implant-supported bridge

X-RAY/DRILLING TEMPLATE WITH CT-TUBES FOR CT-PLANNING

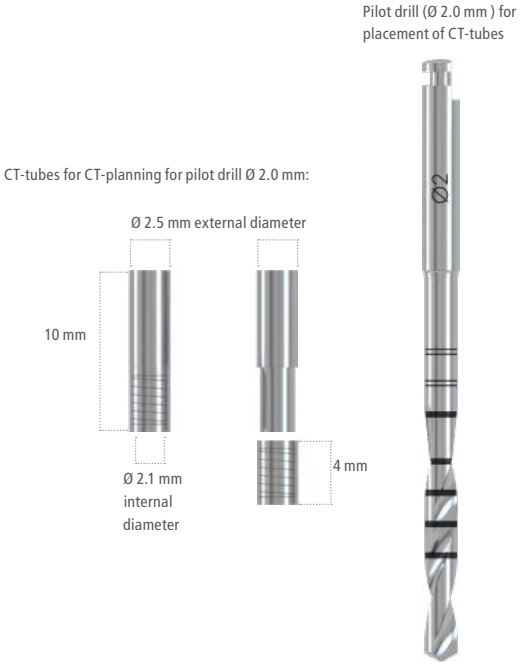
CT-tubes for CT-planning are integrated at the suitable implant positions in the planning templates created from the wax-up/set-up and are used as reference positions in the X-ray image. The two-piece CT-tubes are made of a titanium alloy, as this does not cause scattered radiation in the CT/DVT.

The lower section is polymerized into the template as drill guide. The upper section is pluggable. The entire CT-tube is used for the radiological diagnostics; the upper section must be removed for surgery.

Consistent placing of the CT-tubes directly on the mucosa allow estimating its thickness in the CT/DVT.

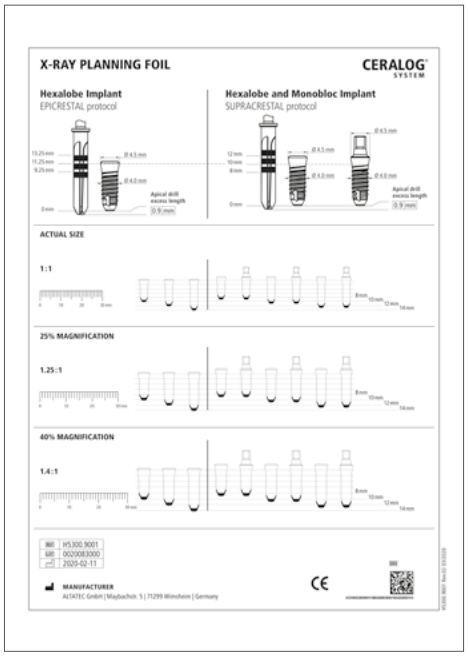
If a planning or x-ray template with CT-tubes for CT-planning was created, it can be converted into a drilling template after adjusting the tube positions based on the implant planning. Pilot drilling is performed with the pilot drill and the CT-tube for CT-planning with an inner diameter of 2.1 mm.

There are ring markings in the working area of the drill whereby the lower edges each show drilling depths for 9, 11, 13, 16, 18 and 20 mm. The 18 and 20 mm markings are not filled in and are used for orientation when using the 4 mm long CT-tube for CT-planning with 2.1 mm internal diameter.



ORTHOPANTOMOGRAM (OPG)

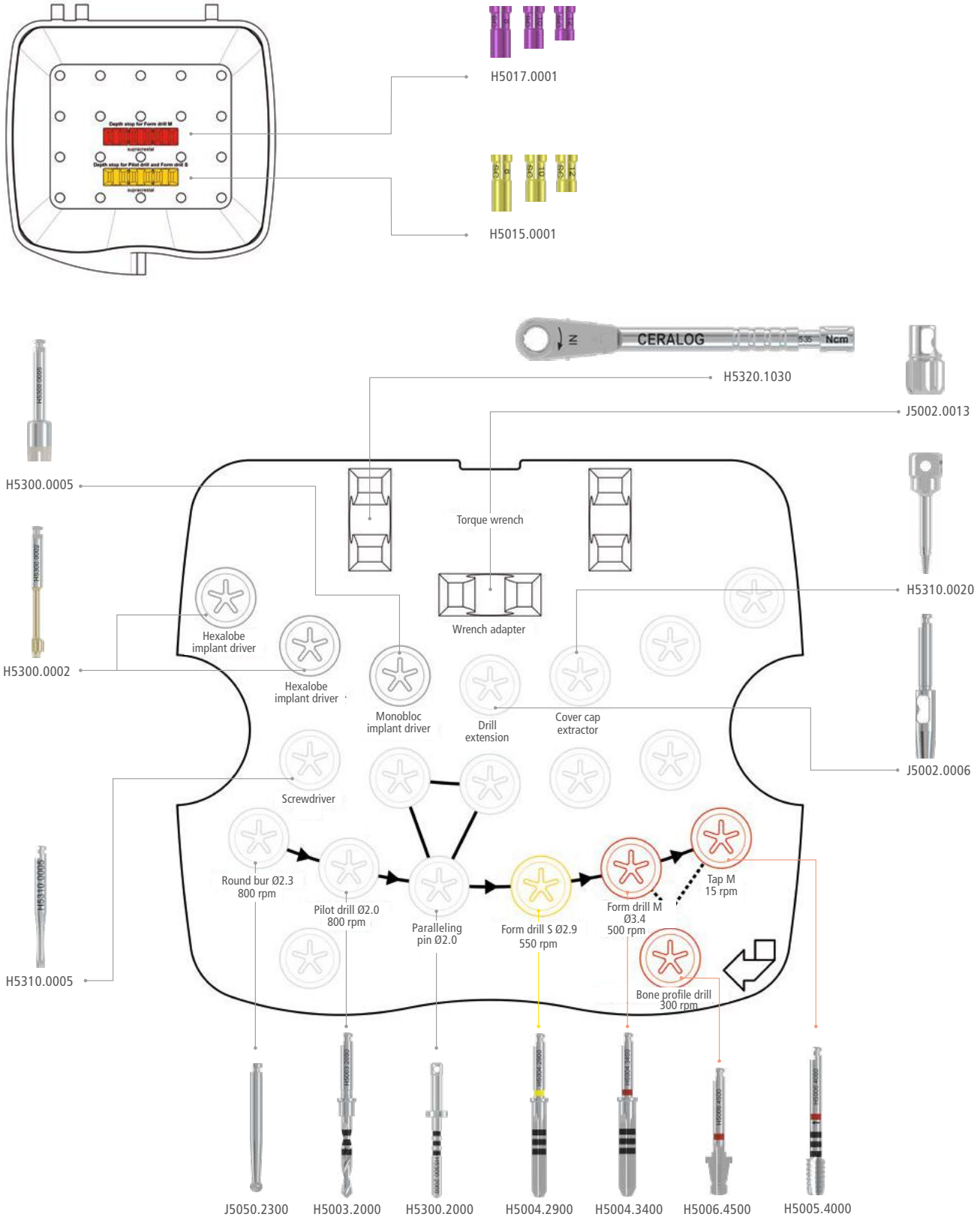
An X-Ray planning foil is available in 1:1, 1.25:1 and 1.4:1 scales for all implant types to check the dimensions on the OPG. The foil magnifications match the delay factors for most orthopantomographs. However, they should be considered only as an aid to implant dimensioning.



INSTRUMENTS

SURGERY SET FOR CERALOG® IMPLANTS

The sterilizable Surgery Set includes all the instruments necessary for standard implant bed preparation.



INSTRUMENTS

FURTHER INFORMATION ON DRILLS

DRILL SPEEDS

Depending on the drill type and diameter, the maximum drill speeds (800-300 rpm) vary according to the table (contra-angle reduction 16:1-20:1).

The maximum speed for taps is 15 rpm (contra-angle reduction 70:1-100:1). The adapter for the torque wrench also permits manual tapping.

COOLING OF DRILLS

Cooling is performed through external irrigation on the angled hand piece with sterile saline solution (pre-chilled to 5 °C).

DRILL LIFE

Drill longevity depends on bone quality and the drilling technique. The pilot drills and form drills are good for a maximum of 10 drilling cycles. If excessive force has to be applied because of a dull drill, then change the drill immediately to prevent overheating of the bone.

Description	⌀	Drilling speed (rpm)
Point drill or Round bur	-	800
Gingiva punch	4.0 mm	800
Pilot drill	2.0 mm	800
Form drill S	2.9 mm	550
Form drill M	3.4 mm	500
Bone profile drill	4.4 mm	300
Tap M	4.0 mm	15

THE CERALOG® HEXALOBE IMPLANT

DRILLING SEQUENCES FOR THE HEXALOBE IMPLANT (SUPRACRESTAL)

The CERALOG® Hexalobe implant can be placed supra- and epicrestally. Overview of the implant bed preparation for the supracrestally placed CERALOG® Hexalobe implant:

a. Punch/mark the desired implant position with the Ø 2.3 mm round bur*
b. Deep drill along the implant axial line with the Ø 2.0 mm pilot dril (incl. depth stop)
c. Checking the drilling depth and drilling axis with the paralleling pin with depth marks
d. Form drilling with the form drill S, Ø 2.9 mm, (incl. depth stop)
e. Form drilling with the form drill M, Ø 3.4 mm, (incl. depth stop)
f. Tap[1]

[1] The use of a tap is recommended for bone quality categories 1** and 2**.

SUPRACRESTAL PLACEMENT OF THE IMPLANT

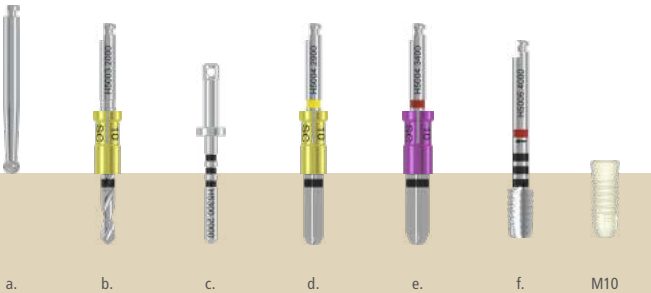
To place the CERALOG® Hexalobe implant supracrestally, either depth stops are used or the pilot and form drillings are performed according to the implant length up to the lower edge of the correspondingly filled depth mark.

The implant lies 1.9 mm supracrestal.

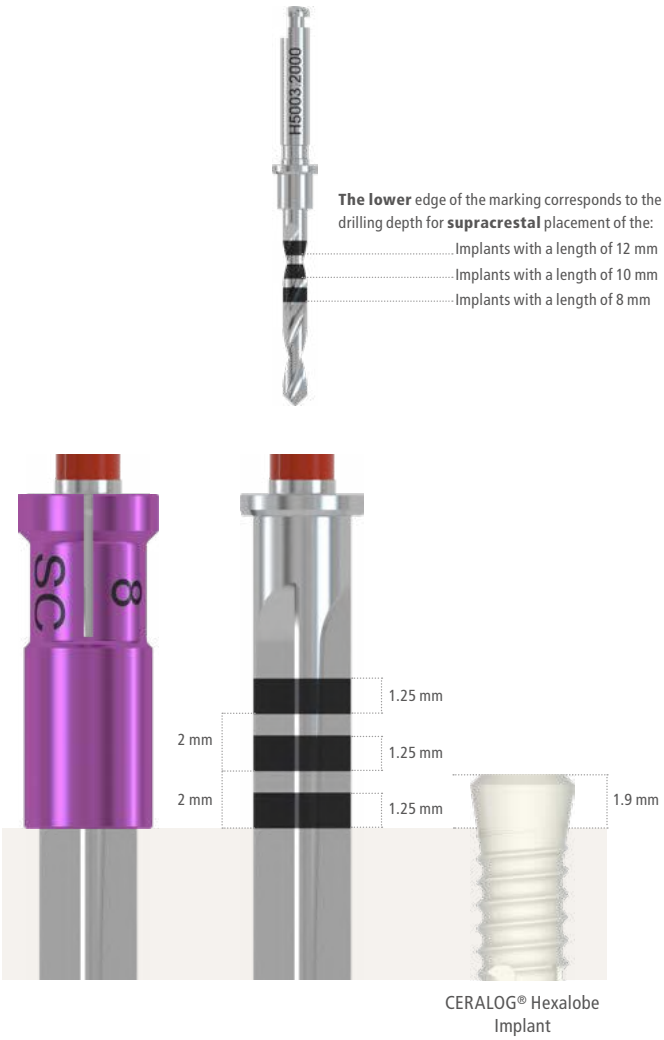
CAUTION:
The maximum apical extension length of the drill is 0.9 mm.

* A point drill can also be used as an alternative.
** See [B] in section «Further documentation» on page 63

Hexalobe 10 mm supracrestal



The markings of the drills provide the following information:



CERALOG® Hexalobe Implant

DRILLING SEQUENCES FOR THE HEXALOBE IMPLANT (EPICRESTAL)

Overview of the implant bed preparation for the epicrestally placed CERALOG® Hexalobe implant:

a. Punch/mark the desired implant position with the Ø 2.3 mm round bur*
b. Deep drill along the implant axial line with the Ø 2.0 mm pilot drill
c. Checking the drilling depth and drilling axis with the paralleling pin with depth marks
d. Form drilling with the form drill S, Ø 2.9 mm, (always without depth stop)
e. Form drilling with the form drill M, Ø 3.4 mm, (always without depth stop)
f. Tap[1]
g. Profile drilling:: the bone profile drill must be used in addition for epicrestal placement of the CERALOG® Hexalobe implant as this achieves controlled, circular expansion of the implant bed neck

[1] The use of a tap is recommended for bone quality categories 1** and 2**.

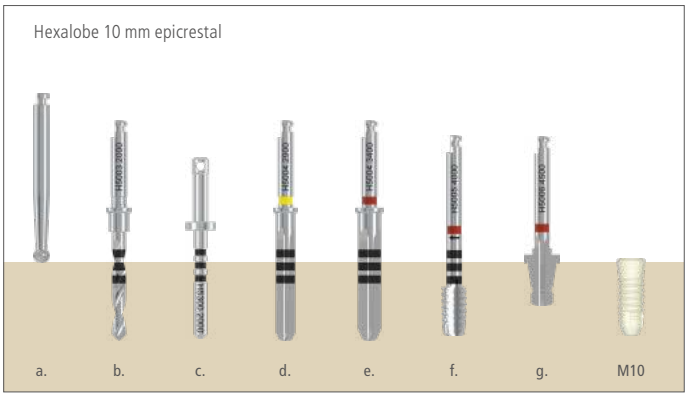
EPICRESTAL PLACEMENT OF THE IMPLANT

To place the CERALOG® Hexalobe implant epicrestally, either depth stops are used or the pilot and form drillings are performed according to the implant length up to the upper edge of the correspondingly filled depth mark.

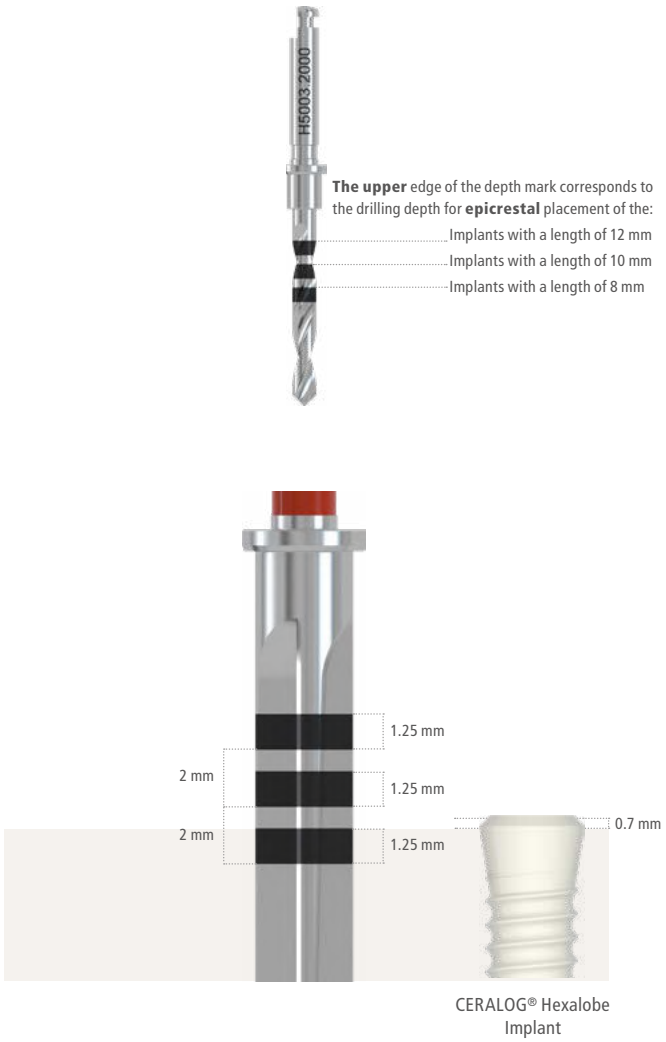
The implant lies 0.7 mm epicrestal.

CAUTION:
The maximum apical extension length of the drill is 0.9 mm.

* A point drill can also be used as an alternative.
** See [B] in section «Further documentation» on page 63



The markings of the drills provide the following information:

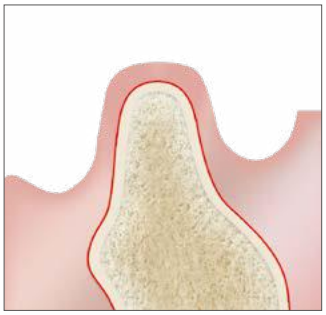


SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

INCISION LINE

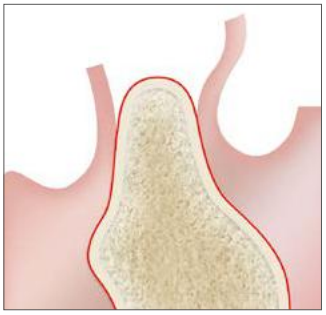
The indication used as an example illustrates the insertion of a L 10 mm CERALOG® Hexalobe implant in the lateral mandible. The implantation technique is two-step transperiosteal. A split flap preparation is selected for the incision line. We recommend this procedure in cases where there is sufficient bone width and no bone augmentation has to be performed. Camlog recommends a split flap preparation only where the thickness of the mucosa is adequate. Otherwise a full mucoperiosteal flap preparation should be performed. After performing a somewhat lingual, paracrestal mucosal incision, a predominantly epiperiosteal flap is created on the vestibular aspect. The muscle is divided and the preparation is continued for approximately another 5 mm. The mucosa is separated 2–3 mm lingually to simplify suturing later.

After marking the desired implant position (if necessary, with a drilling template), the periosteum is removed circularly only in the area around this site (with gingival punch or scalpel). Depending on the selected implant diameter and implant length, the implant bed is then shaped using the instruments designed for the CERALOG® implant.

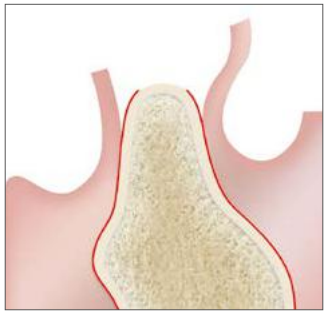


Initial situation

Mucosal incision



Epiperiosteal split-flap preparation



Removal of the periosteum at the implantation site

IMPLANT BED PREPARATION

PUNCH-MARKING THE CORTICAL BONE

The cortical bone can be prepared either with the pointed drill or the round bur. The round bur Ø 2.3 mm as well as the point drill are used for punch-marking the cortical bone, which simplifies the use of the drills to be used later.

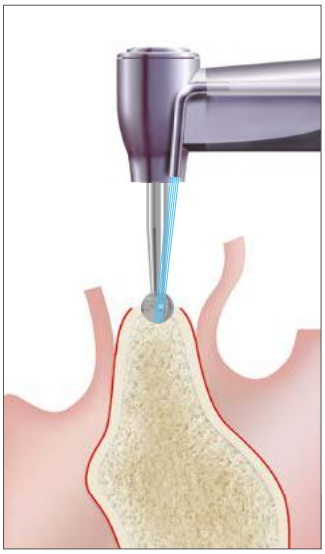
In addition, the round bur can be used for smoothing of the alveolar ridge at the selected implant position. When chamfering the alveolar ridge, the spherical tip of the round bur is lowered up to the equator.

required work step for:

CERALOG® Hexalobe implant

☑ Supracrestal implantation
☑ Epicrestal implantation

Round bur*, Ø 2.3 mm
max. drilling speed: 800 rpm



Punch-marking the cortical bone with the round bur

* A point drill can also be used as an alternative

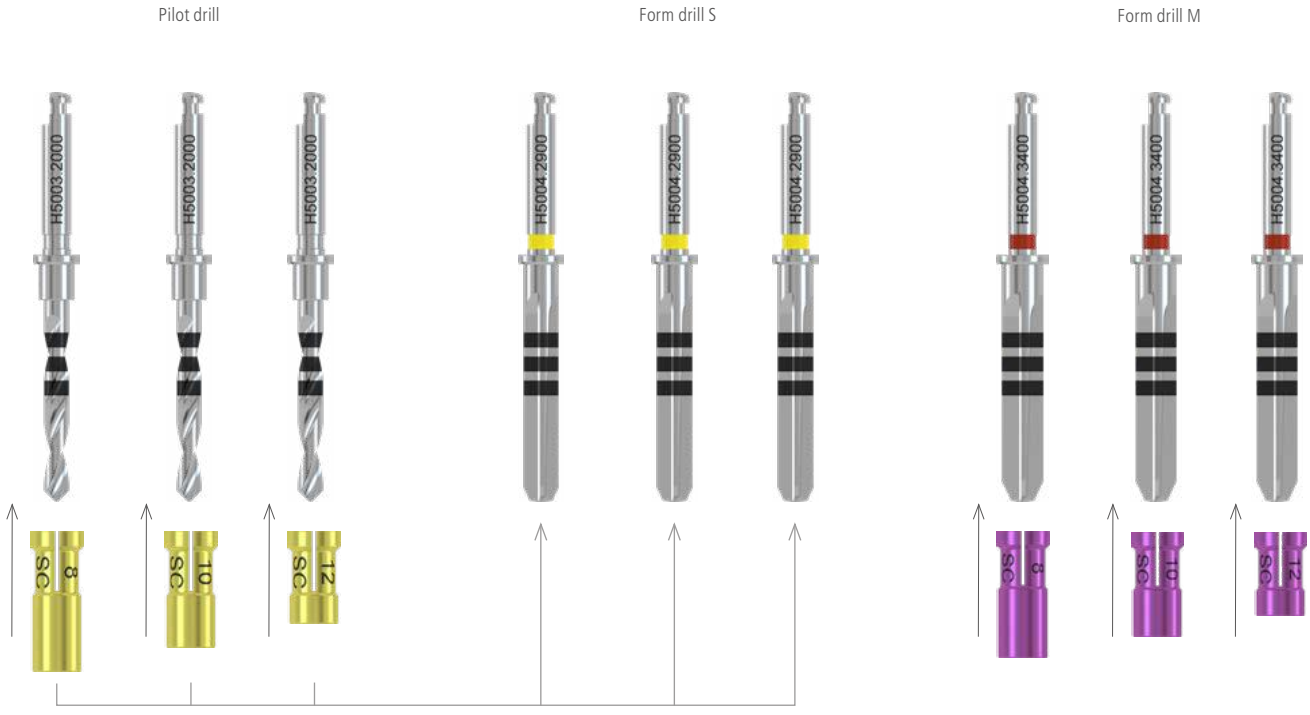
SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

DRILL EXTENSION

A drill extension is available to prevent resting of the angled handpiece on the remaining dentition during preparation of the implant bed adjacent to elongated teeth.

DEPTH STOPS FOR PILOT AND FORM DRILLS

Depth stops are available for pilot drills, form drills S and form drills M to place implants supracrestally.



PILOT DRILLING AND CONTROL OF PARALLELISM

The depth and axis of the implant bed is determined with the pilot drill. The depth marks on the drill correspond to the implant lengths according to the notes in Section «Drilling sequences for the hexalobe implant».

required work step for:

CERALOG® Hexalobe implant

☑ Supracrestal implantation
☑ Epicrestal implantation

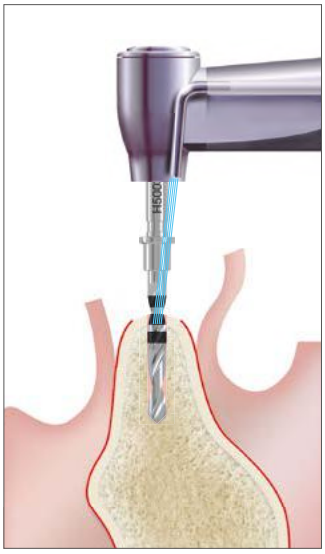
Pilot drill, Ø 2.0 mm
max. drilling speed: 800 rpm

Illustration of the diameter of the implant shoulder

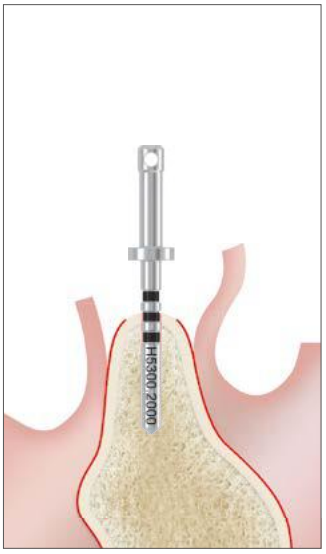
Paralleling pin, Ø 2.0 mm

Once drilling is complete, the depth and axis of the implant bed is checked using the paralleling pins. If several implants are placed, a paralleling pin is inserted into the first drill hole to then align the other implant axes. The surgery set includes three paralleling pins for this purpose.

The pilot drill is aligned parallel to the paralleling pin and visually checked from two planes (sagittal and transversal).



Pilot drilling for the epicrestal insertion of the hexalobe implant



Checking the drilling depth and axis

SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

FORM DRILLING Ø 2.9 mm AND Ø 3.4 mm

To place the CERALOG® Hexalobe implant supracrestally, form drilling is performed with or without depth stop and up to the lower edge of the corresponding depth mark.

required work step for:

CERALOG® Hexalobe implant

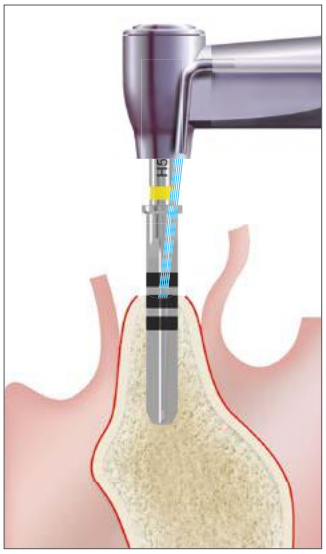
☑ Supracrestal implantation
☑ Epicrestal implantation

Form drill S, Ø 2.9 mm
max. drilling speed: 550 rpm

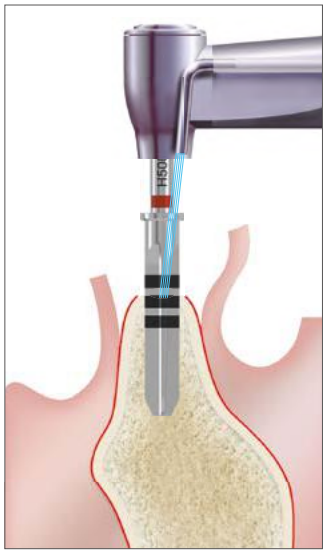
Form drill M, Ø 3.4 mm
max. drilling speed: 500 rpm

Depending on the specified drilling depth (implant length and position), the diameter is expanded progressively with the series of form drills.

The diameter expansion with the form drill S (with yellow ring) increases the diameter by 0.9 mm. The form drill M (with red ring) additionally increases the diameter by 0.5 mm.



Form drilling Ø 2.9 mm without depth stop for the epicrestal insertion of the hexalobe implant



Form drilling Ø 3.4 mm without depth stop for the epicrestal insertion of the hexalobe implant

TAP Ø 4.0 mm

Use of a tap M (red ring) is recommended for bone quality 1* and 2*.
The thread must be tapped over the entire implant bed.

required work step for:

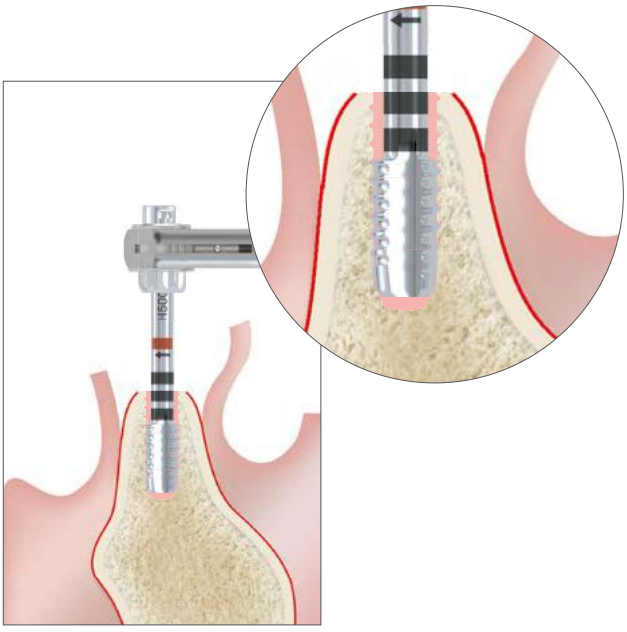
CERALOG® Hexalobe implant

☑ Supracrestal implantation
☑ Epicrestal implantation

Tap M
max. drilling speed: 15 rpm

The wrench adapter and the locked torque wrench are used to manually tap the thread. Pay attention to the axial alignment of the implant bed when inserting and removing the tap.
For automated tapping: the maximum speed of 15 rpm must not be exceeded.

Camlog recommends manual tapping.



Tapping of implant bed

* See [B] in section «Further documentation» on page 63

SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

BONE PROFILE DRILL

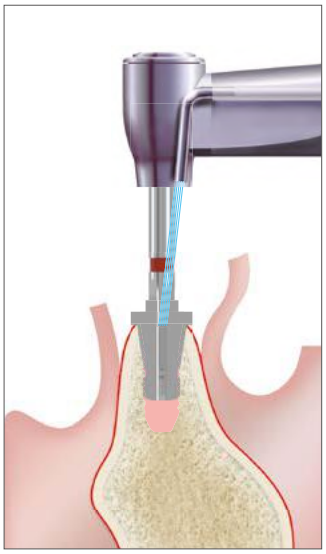
The bone profile drill must be used in addition for epicrestal placement of the CERALOG® Hexalobe implant as this achieves controlled, circular expansion of the implant bed neck.

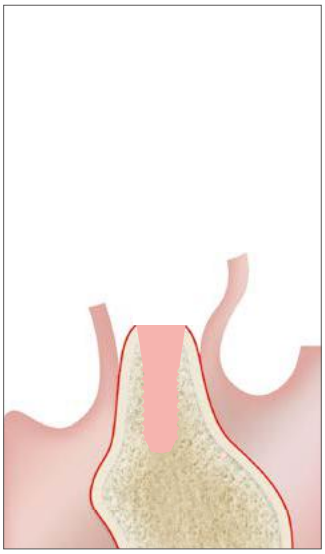
Bone profile drill
max. drilling speed: 300 rpm

required work step for:

CERALOG® Hexalobe implant

☐ Supracrestal implantation
☑ Epicrestal implantation





Drilling the implant neck

GENERAL INFORMATION ON PACKAGING

CERALOG® Hexalobe Implants are packaged single-sterile. The primary packaging (blister) contains the implant and the cover cap.

Non-sterile

Secondary packaging with label

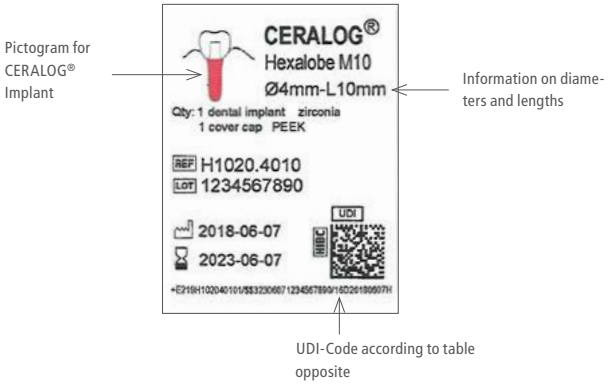
Blister with the Tyvek® foil

Sterile

Interior packaging with cover cap

Secondary packaging (carton box) with label:
the label on the secondary packaging contains relevant system information.

Example product label on the back of the secondary packaging:



UDI CODE

A B C DE F G H I J K

+E219H102040101/$$320230607XXXXXXXXXX /16D20180607H

Sections of the primary code (UDI-DI)	Code	Explanation
A	+	Protected HIBC-ID (1 digit)
B	E219	Manufacturer's code (Altatec)
C	H10204010	Article number (max. 13 digits)
D	1	Quantity index (number of packaging units, 1 digit)
Sections of the secondary code (UDI-DI)	**Code**	**Explanation**
E	/	Separator primary/secondary
F	$$3	Identifier for expiry date
G	20230607	Expiry date (8 digits) 07.06.2023
H	XXXXXXXXXX	Manufacturer's batch (10 digits)
I	/16D	Identifier for date of manufacture
J	20180607	Date of manufacture (8 digits) 07.06.2018
K	H	Variable test marks

Further information on the secondary packaging:
The bottom side of the CERALOG® Implant packaging refers to the instruction for use in electronic form: https://ifu.camlog.com. In addition, it includes a QR code which links directly to the corresponding Internet page.

The left side view of the CERALOG® Implant packaging contains the CE label, the corresponding ISO warnings (see instructions for use) as well as the address of the manufacturer.

SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

IMPLANTATION

OPENING THE PACKAGING

The secondary packaging is opened by separating the label.

NOTE:
If the label is partially or fully separated, the packaging is deemed damaged and the implant may no longer be used.

The blister with the Tyvek® foil forms the sterile barrier. As long as both the blister as well as the Tyvek® foil are undamaged, sterility of the content is assured.
Furthermore, two self-adhesive patient labels are affixed to the label of theTyvek® foil. Two further labels are included with the blister.

IMPORTANT NOTE:
One of these patient labels must be affixed to the patient's personal implant passport and handed over to the patient. The other labels can, for example, be used for the patient records, the letter of referral or the order for the technician.

The patient is to be informed about the measures and precautions to be taken during the healing phase, an appointment for follow-up care of the wound must be ensured and the updated implant passport with the affixed patient label is to be handed over.

OPENING THE BLISTER

The blister is fitted with a tab which allows easy separation of the Tyvek® foil from the blister. Remove the blister seal and place the sterile inner packaging on a sterile base.

PICKING UP THE IMPLANT

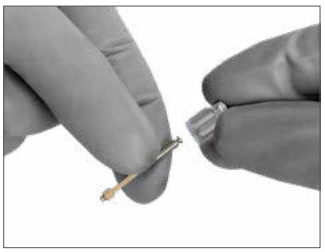
CERALOG® Hexalobe implants are picked up from the packaging with the Hexalobe implant driver. To insert the implants, either the adapter for wrench (section A) is attached to the implant driver or the angled hand piece (section B) is used.

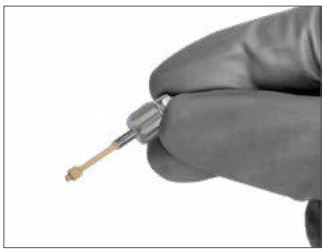
Hexalobe implant driver

NOTE:
The Hexalobe implant driver is equipped with a pre-defined breaking point to prevent excessive torque and excessive loading. If the load is too high, the Hexalobe implant driver breaks at the pre-defined breaking point.

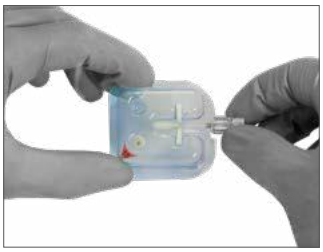
A. MANUAL INSERTION WITH TORQUE WRENCH

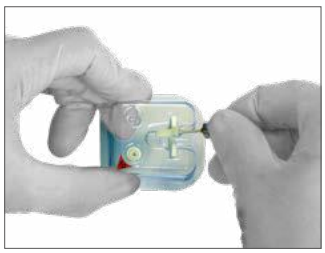
The wrench adapter is connected to the implant driver.





The inner packaging is held with two fingers. The wrench adapter with the implant driver is inserted into the implant **with force**. The implant is then lifted upwards - inclining the apical area downwards.





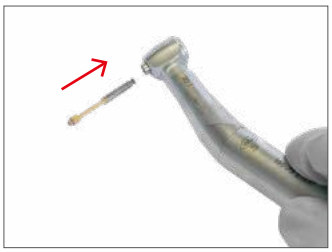
NOTE:
It should be noted that the insertion tool is firmly seated in the implant.

Camlog recommends confirming the correct placement of the implant holder by exerting pressure on the implant in the sterile cavity of the interior packaging. This manipulation ensures that the insertion tool is connected securely to the implant.

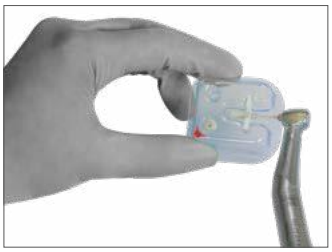
SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

B. SCREW INSERTION OF THE IMPLANT WITH THE ANGLED HAND PIECE

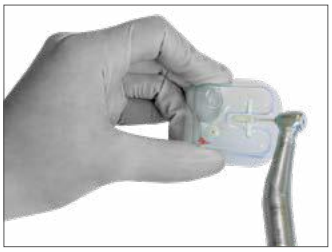
The hexalobe implant can also be picked up directly with the insertion tool with ISO shaft and the angled hand piece as follows:



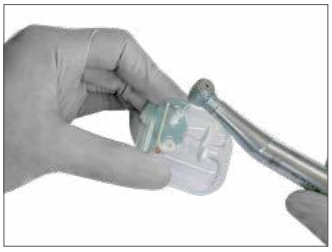
The inner packaging is held with two fingers and the machine implant driver with angled hand piece is inserted into the implant **with slight force.**



To pick up the implant from the packaging, it is then lifted upwards via the implant insertion tool with angled hand piece - inclining the apical area downwards.



Camlog recommends confirming the correct placement of the implant driver by exerting pressure on the implant in the sterile cavity. This manipulation ensures that the implant driver is connected securely to the implant.



IMPLANT INSERTION

Using the implant driver, the implant is inserted into the implant bed and carefully screwed in clockwise either manually or with the angled hand piece. Pay attention to the axial alignment of the implant bed.

The following parameters must be observed when screwing in the implant:

- Manual or power-assisted insertion: a maximum torque of 35 Ncm must not be exceeded.
- power-assisted insertion: a maximum speed of 15 rpm must not be exceeded.

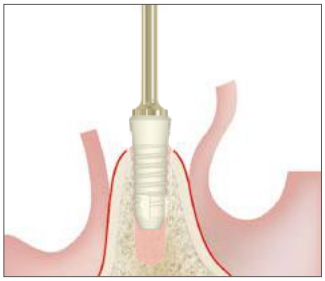
NOTE:
If required, the drill extension can be used.

Implant insertion with adapter for the torque wrench

Insertion of the implant with the angled hand piece

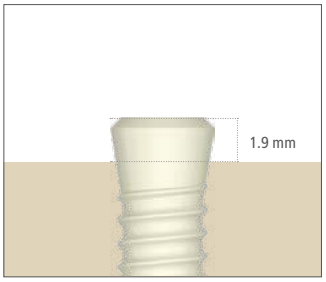
In the case of manual insertion, once the implant has been inserted into the implant bed, the implant can be screwed into its final position with the torque wrench.

If the thread was cut in advance, the positions of the threaded ends in the bone and on the implant must match.
It is recommended to first rotate the implant driver with the implant carefully to the left manually, until the thread socket can be felt. Then the implant is screwed in clockwise manually with the insertion tool.

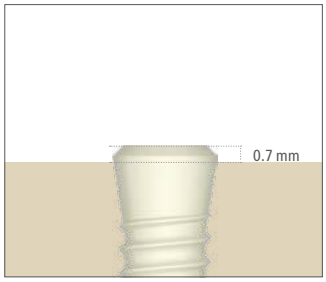


Screw insertion of implant with implant driver (max. 35 Ncm)

If the implant bed was planned for a supracrestal position, the implant must be screwed in to the end of the thread, until the upper edge of the implant shoulder lies 1.9 mm above bone level. If the implant bed was planned for an epicrestal position, the implant must be screwed in to the end of the thread, until the upper edge of the implant shoulder lies 0.7 mm above bone level.



The protocol-conform epicrestal insertion depth is achieved when the implant has been inserted into the implant bed slightly below the implant shoulder surface.
The implant lies 1.9 mm supracrestal.



The protocol-conform epicrestal insertion depth is achieved when the implant has been inserted into the implant bed up to 0.7 mm below the implant shoulder surface.
The implant lies 0.7 mm epicrestal.

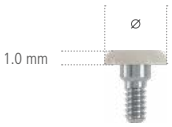
NOTE:
To avoid damage to the implant, the predefined breaking point of the implant implant driver will break at excess loading.
For this situation, a second implant driver is available in the surgery set to remove the implant again. Prior to reinserting an implant, the implant bed must be further prepared, e.g. with the tap and/or the bone profile drill, to reduce the insertion torque.

SURGICAL PROCEDURE FOR HEXALOBE IMPLANTS

HEALING PHASE AND PATIENT INFORMATION

The patient is to be informed about the measures and precautions to be taken during the healing phase, an appointment for follow-up care of the wound must be ensured and the updated implant passport with the affixed patient label is to be handed over.

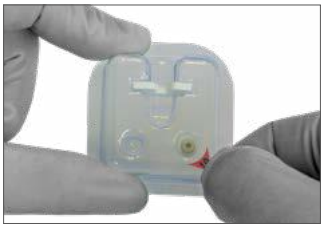
As a rule, the osseointegration of CERALOG® Implants takes between 3 and 6 months. The healing time depends both on the general health status of the patient as well as the quality of the bone surrounding the implant. The usual methods can be applied to check osseointegration.

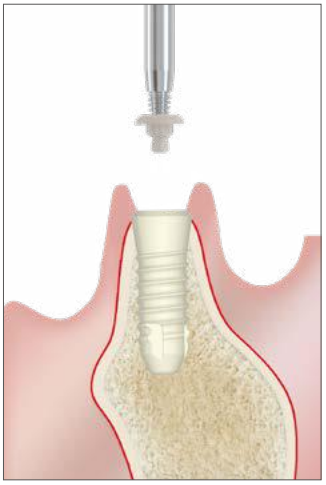
	Article	Art. No.	∅
	**Cover cap** sterile **Material** PEEK	H2020.4505	4.5 mm
	**Cover screw** sterile **Material** PEEK/Titanium alloy	H2019.4508	4.5 mm

SUBMERGED HEALING

WITH COVER CAP

The cover cap is located in the blister of the implant underneath a separate transparent foil. To insert the cover cap, the CERALOG® Extractor for cover caps is screwed into the occlusal opening of the cover cap. Three cams are located directly below the flat part of the cover cap and must be placed in the hexagonal indentations of the implant. The cover cap is carefully inserted into the implant until the flat part of the cap makes contact with the implant shoulder. Here, one should make sure that no soft tissue trapped is between the implant and cover cap.
The extractor is unscrewed anti-clockwise from the cap and the soft tissue sutured tightly with atraumatic suture material.



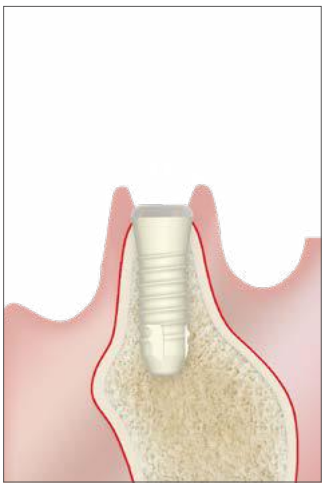


Applying the cover cap with the extractor

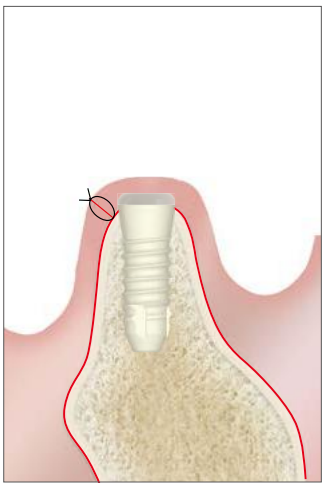
WITH COVER SCREW

The screwdriver is inserted into the separately available cover screw.
Then the cover screw is carefully screwed manually into the implant (maximum torque: 15 Ncm). Here, one should make sure that no soft tissue is trapped between the implant and the cover screw.
Pull the screwdriver from the cover screw, and suture the soft tissue tightly with atraumatic suture material.

IMPORTANT NOTE:
The cover cap and cover screw must not remain in the oral cavity for longer than 180 days.



CERALOG® Hexaloabe Implant with mounted cover cap



Wound closure

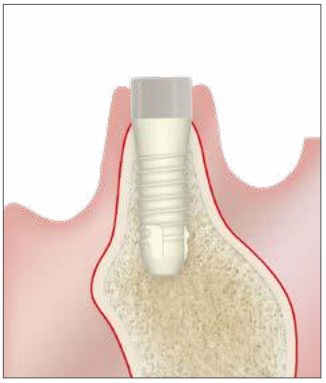
B. TRANSGINGIVAL HEALING

The subsequent use of the CERALOG® gingiva formers supports the development of peri-implant soft tissue. Gingiva formers for gingiva heights of 3.0 mm and 4.4 mm are available. The gingiva height is selected such that the healing cap lies supragingival by 1-1.5 mm.

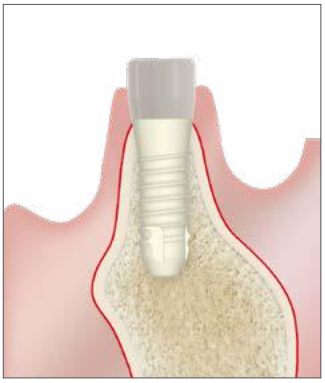
The healing cap is inserted into the implant and fixed to the implant either with the supplied titanium abutment screw or with a gold abutment screw, which must be ordered separately.

The screws are carefully screwed manually into the implant (maximum torque: 15 Ncm).

The impression is taken after stabilization of the peri-implant soft tissue.



Healing cap, cylindrical,
Height 3.0 mm



Healing cap, cylindrical,
Height 4.4 mm

IMPORTANT NOTE:
The healing cap must not remain in the oral cavity for longer than 180 days.

	Article	Art. No.	∅	GH
	**Healing cap** incl. titanium abutment screw, sterile **Material** PEEK/Titanium alloy	H2020.4525	4.5 mm	3.0 mm
		H2020.4540	5.0 mm	4.4 mm

PROSTHETIC PROCEDURE FOR HEXALOBE IMPLANTS

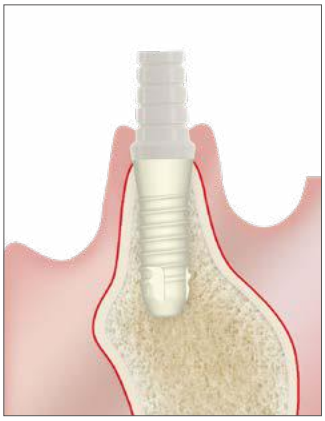
TEMPORARY RESTORATION

A temporary restoration can be performed on Hexalobe Implants with temporary abutments made of PEEK (poly ether ether ketone), provided sufficient primary stability has been achieved.
An immediate restoration should be planned as a non-functional restoration.

After exposure of the implant, the cover cap is removed with the cover cap extractor or the cover screw or gingiva former are unscrewed with the screwdriver.

The temporary abutment is inserted into the implant and fixed to the implant either with the supplied titanium abutment screw or with a gold abutment screw, which must be ordered separately. The screws are carefully screwed manually into the implant.

IMPORTANT NOTE:
The temporary abutment must not remain in the oral cavity for longer than 180 days.
New unused abutment screws must be used for final fixation of the abutments.



CERALOG® Temporary abutment

	Article	Art. No.	Ø	GH
	**Temporary abutment** incl. titanium abutment screw **Material** PEEK/Titanium alloy	H2221.4500	4.8 mm	1.0 mm

If the temporary restoration is placed after osseointegration is complete, the screws can be tightened with a maximum torque of 25 Ncm for titanium alloy and 15 Ncm for gold alloy. All screws must be retightened with the corresponding torque after at least 5 minutes.

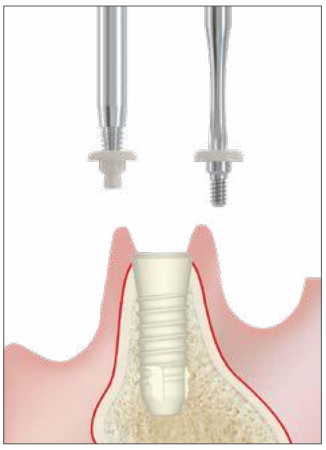
IMPRESSION TAKING

Impression taking for the definitive restoration can be performed after successful osseointegration of the implant and healing of the peri-implant soft tissue as follows:

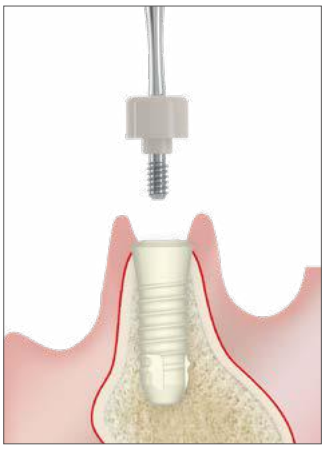
EXPOSURE OF THE IMPLANT SHOULDER

After exposure of the implant, the cover cap is removed with the extractor for the cover cap or the cover screw is unscrewed with the screwdriver.

If a healing cap was selected for the healing phase, this can be removed with the aid of the screwdriver.



Removing the cover cap respectively the cover screw



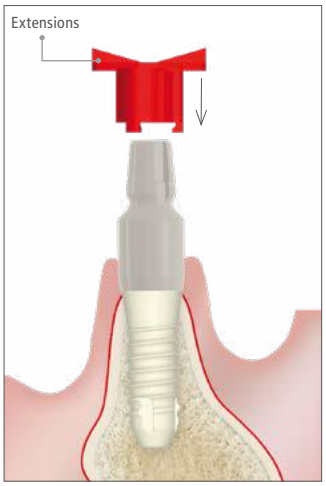
Removing the healing cap

INSERTION OF THE IMPRESSION POSTS

CLOSED TRAY:

The impression post, closed tray, is supplied non-sterile.
The fixing screw of the impression post must be carefully hand-tightened with the screwdriver. For tight and/or thick gingiva in particular, the correct seating of the impression post must be checked prior to taking the impression.
The impression cap is now installed, using the guide grooves on the impression post, until a detectable pressure point is reached and the impression cap is definitely fastened. Three guide grooves on the impression post (placed at 120° staggered intervals) facilitate contact-free placement relative to adjacent impression caps or adjacent teeth. The extensions of the impression caps must not be removed.

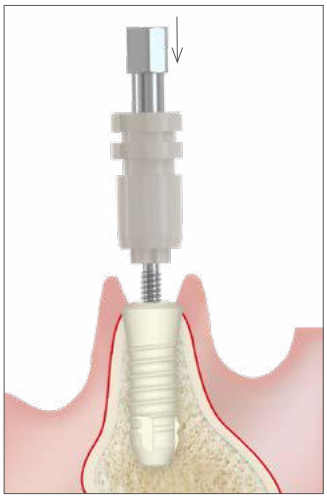
Impression posts, closed tray



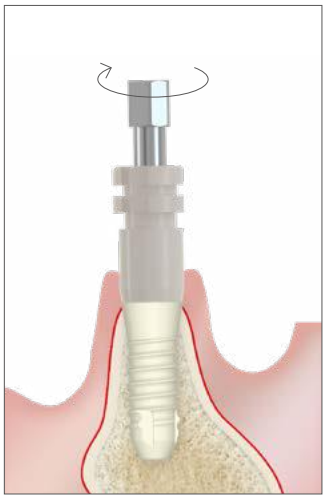
Fixation of the impression cap

OPEN TRAY:

The impression post, open tray, is supplied sterile.
After exposure of the implant shoulder, the impression post open tray is inserted into the implant. To this purpose the impression post is first placed on the implant and carefully rotated until it engages in the implant. Then the fixing screw is carefully hand-tightened.



Insertion of the CERALOG® Impression post, open tray



Tightly screw the CERALOG® Impression post, open tray

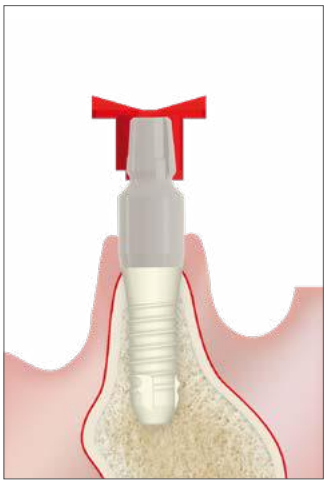
PROSTHETIC PROCEDURE FOR HEXALOBE IMPLANTS

IMPRESSION TAKING

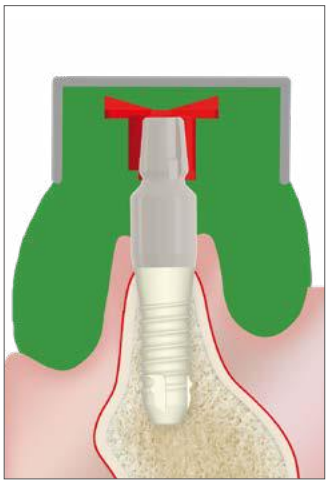
Light Body impression material is applied around the impression post for impression taking. In addition, Heavy Body impression material is placed in the impression tray.

- **with the impression post, closed tray:**
  Right before taking the impression, check again to ensure that the impression caps are seated correctly.
  The impression caps should remain in the impression after the impression tray is lifted. If this is not the case, repeat the impression-taking.

- **with the impression post, open tray:**
  Before taking the impression, check the tray for a precision fit. The fixing screws protruding from the perforations must not touch the tray. To remove the impression, loosen the fixing screw, pull it back completely and then lift off the impression tray.

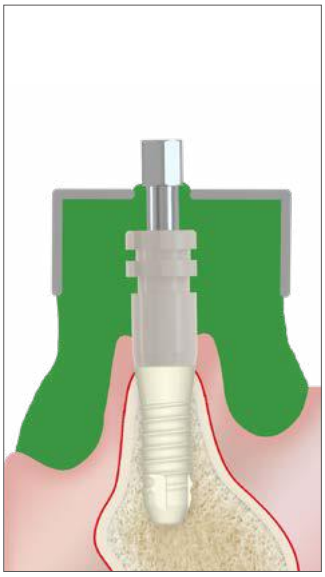


Check of correct seating of the impression cap



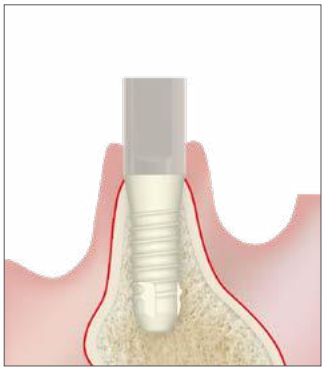
Impression tray with the impression post, closed tray

Check of correct seating of the impression post



Impression tray with the impression post, open tray

- **Digital recording of the implant/lab analog position:**
  The CERALOG® Scanbody is used for optical 3-dimensional localization of the CERALOG® Hexalobe Implants in the mouth and of CERALOG® Lab analogs in the working model.
  The CERALOG® Scanbody is supplied sterile with a titanium abutment screw. The CERALOG® Scanbody is screwed hand-tight into the implant or laboratory analog with the screwdriver.



Mounted CERALOG® Scanbody

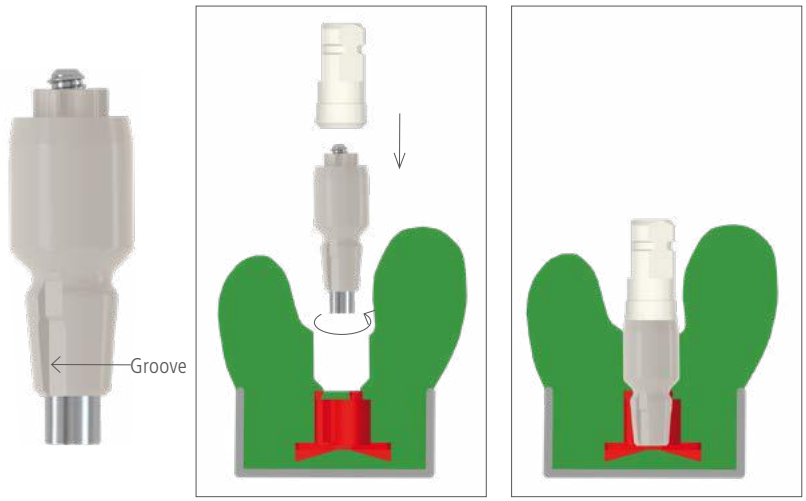
CAST FABRICATION

CLOSED TRAY

After the impression is taken, the impression cap remains in the impression. In the dental laboratory, the impression posts, closed tray, are attached to the corresponding lab analogs (note proper seating).

A screwdriver is used to hand-tighten the fixing screw. The components are repositioned into the impression caps. Make sure that the grooves correctly engage in the impression cap.

Do not use bonding material!

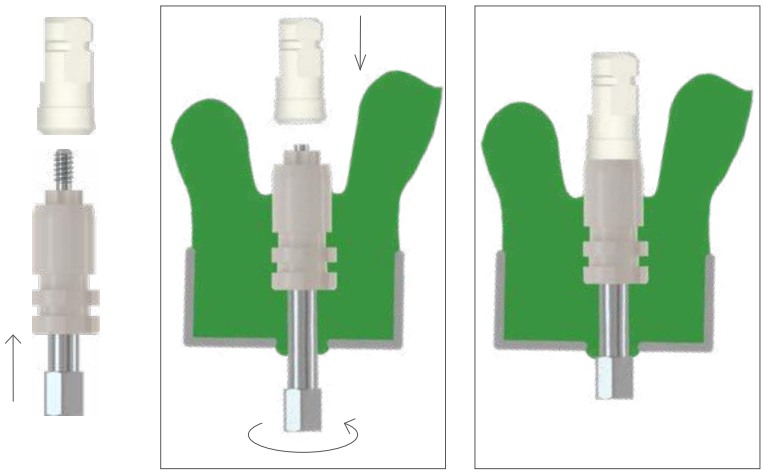


OPEN TRAY

After the impression is taken, the impression posts, open tray, are located in the impression.

In the dental laboratory, the impression posts, open tray, are attached to the corresponding lab analogs (note proper seating).

For the open tray impression posts, the fixing screw is hand-tightened with a screwdriver.



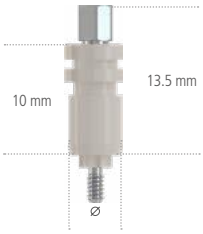
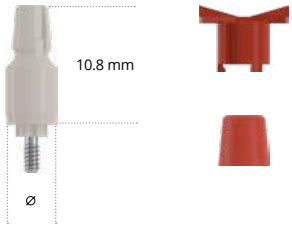
DIGITAL CAST FABRICATION

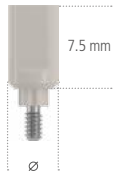
The following worksteps are necessary for this purpose:

- Digital imaging either in the laboratory or directly with an intra-oral scanner in the patient's mouth.
- Printing of the model with a 3D printer
- Imaging the laboratory analog with the handle for hexalobe laboratory analogs by screwing the handle into the laboratory analog.
- Clicking the laboratory analog into the printed model.

The CAD libraries can be found on the Camlog website: https://www.camlog.de/de/service/media-center/cad-bibliotheken/.

PROSTHETIC PROCEDURE FOR HEXALOBE IMPLANTS

	Article	Art. No.	∅
	**Hexalobe Impression post open tray, long** incl. fixing screw, sterile **Material** PEEK/Titanium alloy	H2121.4550	4.8 mm
	**Hexalobe Impression post open tray, short** incl. fixing screw, sterile **Material** PEEK/Titanium alloy	H2122.4550	4.8 mm
	**Hexalobe Impression post closed tray** incl. fixing screw, Impression cap and bite registration cap **Material** PEEK/Titanium alloy	H2120.4550	4.8 mm
	**Impression caps** for impression post and impression cap, closed tray, (5 units) **Material** POM	J2111.4300	-
	**Bite registration caps** (5 units) **Material** POM	J2112.4300	-

	Article	Art. No.	∅
	**Hexalobe lab analog** for printed and cast models **Material** Zirconia	H3020.4500	4.5 mm
	**Handle for Hexalobe lab analog** **Material** Stainless steel/PEEK	H3025.0010	3.4 mm
	**CERALOG® Scanbody** incl. titanium abutment screw sterile **Material** PEEK/Titanium alloy	H2610.4580	4.5 mm

PROSTHETIC PROCEDURE FOR HEXALOBE IMPLANTS

PROSTHETIC RESTORATION

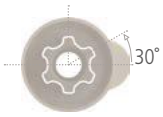
The CERALOG® System offers three different abutments made of PEKK (poly ether ketone ketone):

- PEKK abutment, straight
- PEKK abutment, 15° angled, type A.
- PEKK abutment, 15° angled, type B.

The difference between the abutments type A and B lies in the 30° offset indexing:

Type A
Cam alignment in the direction of the angle

Type B
Cam alignment 30° offset

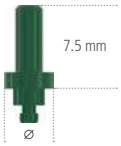


	Article	Art. No.	Ø	GH
	**PEKK abutment, straight** incl. titanium abutment screw **Material** PEKK/Titanium alloy	H2231.4580	4.8 mm	1.0 mm
	**PEKK abutment, 15° angled, Type A** incl. titanium abutment screw **Material** PEKK/Titanium alloy	H2233.4580	4.8 mm	1.0 mm
	**PEKK abutment, 15° angled, Type B** incl. titanium abutment screw **Material** PEKK/Titanium alloy	H2234.4580	4.8 mm	1.0 mm

PLANNING OF THE PROSTHETIC RESTORATION

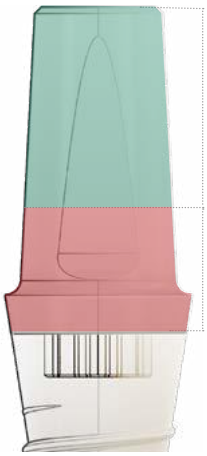
For planning the prosthetic restoration, users of the CERALOG® System can choose between straight and 15° angled abutments (type A and type B). The selection abutments can be inserted directly into the lab analog and are reusable.

IMPORTANT NOTE:
The selection abutments must not be used on the patient.

	Article	Art. No.	⌀
	**Selection abutment, straight** **Material** PPSU	H3511.4580	4.5 mm
	**Selection abutment, 15° angled, Type A** **Material** PPSU	H3513.4580	4.5 mm
	**Selection abutment, 15° angled Type B** **Material** PPSU	H3514.4580	4.5 mm

MODIFICATION OF THE PEKK ABUTMENT

The abutment can be shortened occlusally depending on the anatomical situation. A minimum height of 3 mm (area marked in red) must be adhered to. The abutment is made of a high performance polymer (PEKK) and is easy to adapt using a tungsten carbide bur.



PROSTHETIC PROCEDURE FOR HEXALOBE IMPLANTS

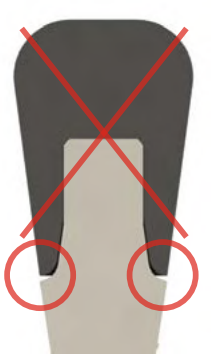
FABRICATION AND BONDING OF THE CROWN

After fabricating the cast, the abutment is placed in a corresponding lab analog and fixed hand-tight with a lab screw using the lab screwdriver. The abutment must be seated in the lab analog correctly.
Laboratory analog and abutment are used for the fabrication of crowns in conventional procedures.
The abutment can be used for a screw-retained crown or a crown cemented in the patient's mouth.

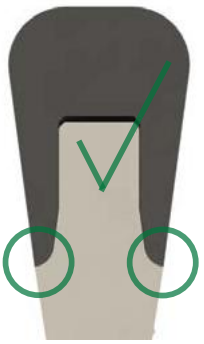
IMPORTANT NOTE:
Prior to being used on the patient, the components are cleaned with alcohol (ammonium, chloride or other aldehyde-containing cleaning agents may not be used)!

The components are bonded using a suitable cement. The cement is mixed according to manufacturer's instructions and applied to the abutment.
The crown must lie on the abutment shoulder to ensure optimal mechanical stability. The cement gap should be as small as possible.

NOTE:
For bonding the crown to the abutment part, we recommend a resin-containing adhesive monomer MDP (such as "PANAVIA™ v5" from Kuraray Europe GmbH or "RelyX TM Unicem 2 Automix" from 3M ESPE for example). Observe the manufacturer's processing instructions.



The crown does not fit correctly on the abutment as the crown does not rest fully on the abutment.



Correct fit of the crown on the abutment.

INSERTION OF THE ABUTMENT

THE FOLLOWING WORKSTEPS ARE RECOMMENDED:

IN CASE OF A CEMENTED SOLUTION:

- Thoroughly clean and dry the inner configuration of the implant prior to final integration of the abutment.
- Insert the abutment in the implant.
- The abutment is fixated with a new unused titanium or gold abutment screw.
- Disinfect crown and fixate on the abutment.

IN CASE OF A SCREW-RETAINED SOLUTION:

- Thoroughly clean and dry the inner configuration of the implant prior to final integration of the abutment.
- Clean the abutment/crown bonding connection and insert into the implant.
- The abutment is fixated with an unused titanium or gold abutment screw.
- The screw head can be protected with gutta-percha or a similar material before cementing the crown or closing the screw channel.

NOTE:
The abutment screw is tightened with the screwdriver at the following maximum tightening torques:

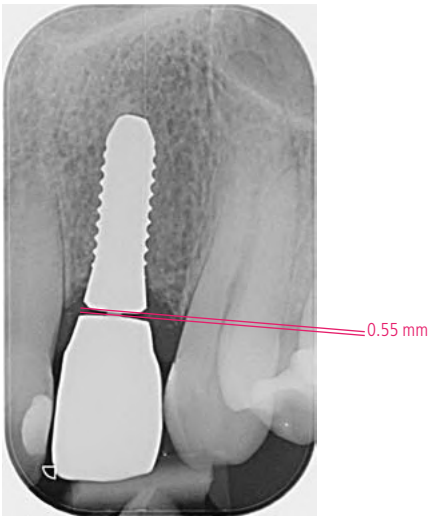
- 25 Ncm for the titanium abutment screw.
- 15 Ncm for the gold abutment screw.
- All screws must be retightened with the corresponding torque after at least 5 minutes!

	Article	Art. No.	Thread
	**Titanium abutment screw** for definitive screw retention into the implant **Material** Titanium alloy	H4001.1600	M1.6
	**Gold abutment screw** for definitive screw retention into the implant **Material** Holisticor	H4011.1600	M1.6

PROSTHETIC PROCEDURE FOR HEXALOBE IMPLANTS

XRAY IMAGE WITH THE PEKK ABUTMENT

The PEKK abutment is not radiopaque and therefore the distance between the implant and tooth crown can be easily determined in the X-ray image: the abutment is correctly positioned in the implant when the gap between the implant shoulder surface and the lower edge of the crown measures 0.55 mm in the x-ray image.



(With kind permission of Dr. F. Hermann, Zug, Switzerland)

THE CERALOG® MONOBLOC IMPLANT

DRILLING SEQUENCES FOR THE MONOBLOC IMPLANT (SUPRACRESTAL)

The CERALOG® Monobloc implant is placed supracrestally.
Overview of the implant bed preparation with the CERALOG® Monobloc implant:

a. Punch/mark the desired implant position with the Ø 2.3 mm round bur*
b. Deep drill along the implant axial line with the Ø 2.0 mm pilot drill (incl. depth stop)
c. Checking the drilling depth and drilling axis with the paralleling pin with depth marks
d. Form drilling with the form drill S, Ø 2.9 mm, (incl. depth stop)
e. Form drilling with the form drill M, Ø 3.4 mm, (incl. depth stop)
f. Tap[1]

[1] The use of a tap is recommended for bone quality categories 1** and 2**.

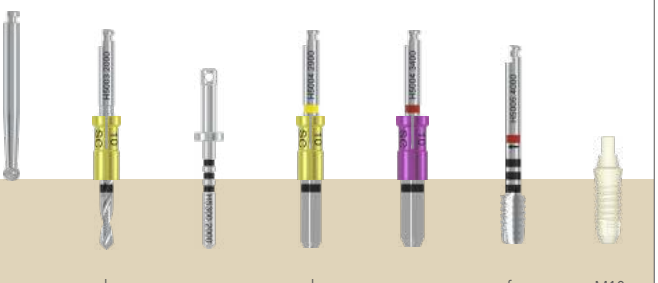
SUPRACRESTAL PLACEMENT OF THE IMPLANT

To place the CERALOG® Monobloc implant 1.5 mm supracrestally, either depth stops are used or the pilot and form drillings are performed according to the implant length up to the lower edge of the correspondingly filled depth mark.

CAUTION:
The maximum apical extension length of the drill is 0.9 mm.

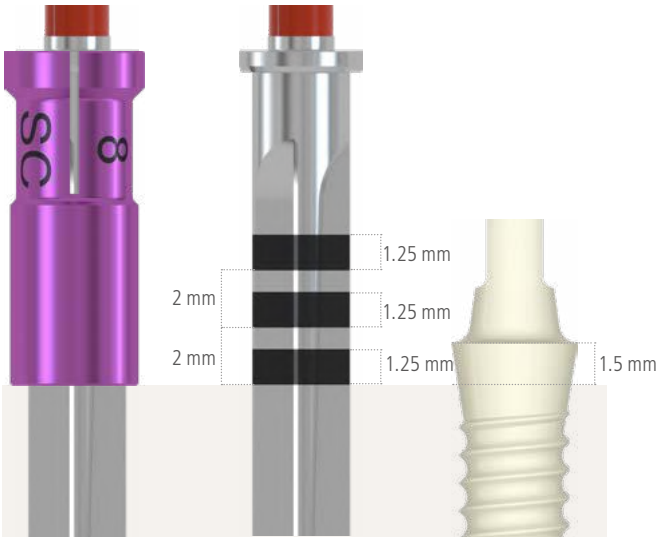
* See [B] in section «Further documentation» on page 63
** A point drill can also be used as an alternative

Monobloc 10 mm supracrestal



The markings of the drills provide the following information:

The lower edge of the marking corresponds to the drilling depth for **supracrestal** placement of the:
- Implants with a length of 12 mm
- Implants with a length of 10 mm
- Implants with a length of 8 mm



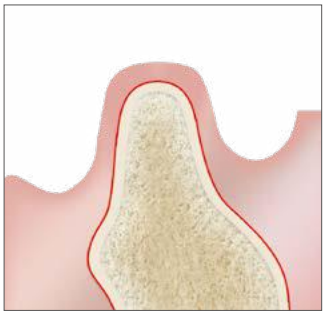
CERALOG® Monobloc Implant

SURGICAL PROCEDURE FOR MONOBLOC IMPLANTS

INCISION LINE

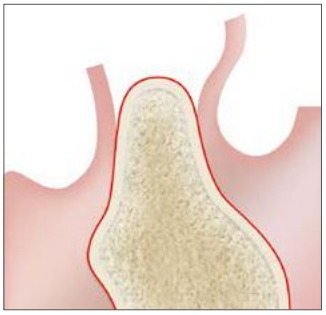
The indication used as an example illustrates the insertion of a L 10 mm CERALOG® Monobloc implant in the lateral mandible. The implantation technique is two-step transperiosteal. A split flap preparation is selected for the incision line. We recommend this procedure in cases where there is sufficient bone width and no bone augmentation has to be performed. Camlog recommend a split flap preparation only where the thickness of the mucosa is adequate. Otherwise a full mucoperiosteal flap preparation should be performed. After performing a somewhat lingual, paracrestal mucosal incision, a predominantly epiperiosteal flap is created on the vestibular aspect. The muscle is divided and the preparation is continued for approximately another 5 mm. The mucosa is separated 2–3 mm lingually to simplify suturing later.

After marking the desired implant position (if necessary, with a drilling template), the periosteum is removed circularly only in the area around this site (with gingival punch or scalpel). Depending on the selected implant diameter and implant length, the implant bed is then shaped using the instruments designed for the CERALOG® implant.

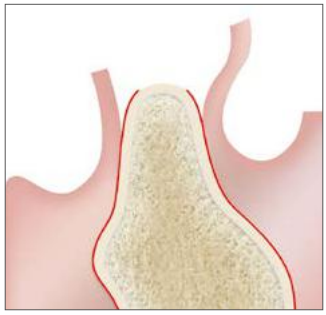


Initial situation

Mucosal incision



Epiperiosteal split-flap preparation



Removal of the periosteum at the implantation site

IMPLANT BED PREPARATION

PUNCH-MARKING THE CORTICAL BONE

The cortical bone can be prepared either with the pointed drill or the round bur. The round bur Ø 2.3 mm as well as the point drill are used for punch-marking the cortical bone, which simplifies the use of the drills to be used later.

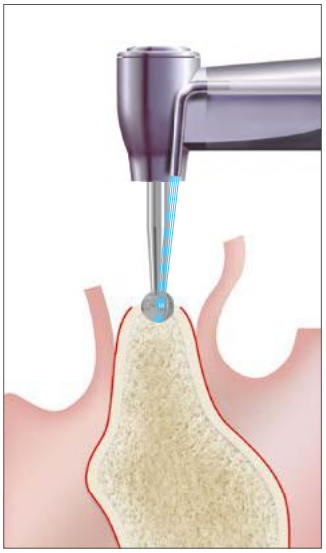
In addition, the round bur can be used for smoothing of the alveolar ridge at the selected implant position. When chamfering the alveolar ridge, the spherical tip of the round bur is lowered up to the equator.

Round bur* Ø 2.3 mm
max. drilling speed: 800 rpm

required work step for:

CERALOG® Monobloc implant

☑ Supracrestal implantation
☐ Epicrestal implantation



Punch-marking the cortical bone

* A point drill can also be used as an alternative

SURGICAL PROCEDURE FOR MONOBLOC IMPLANTS

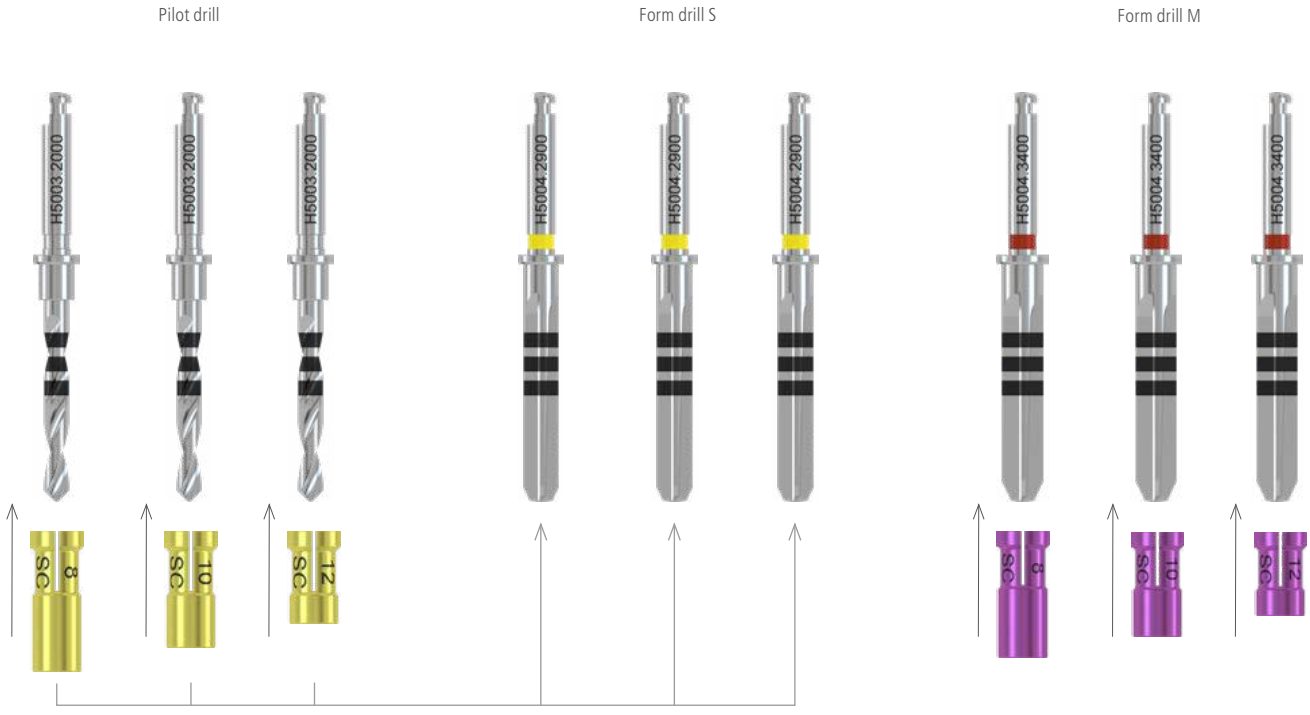
DRILL EXTENSION

A drill extension is available to prevent resting of the angled handpiece on the remaining dentition during preparation of the implant bed adjacent to elongated teeth.

GENERAL

DEPTH STOPS FOR PILOT AND FORM DRILLS

Depth stops are available for pilot drills, form drills S and form drills M to place implants supracrestally.



PILOT DRILLING AND CONTROL OF PARALLELISM

The depth and axis of the implant bed is determined with the pilot drill. The depth marks on the drill correspond to the implant lengths according to the notes in Section «Drilling sequences for the monobloc implant».

required work step for:

CERALOG® Monobloc implant

☑ Supracrestal implantation
☐ Epicrestal implantation

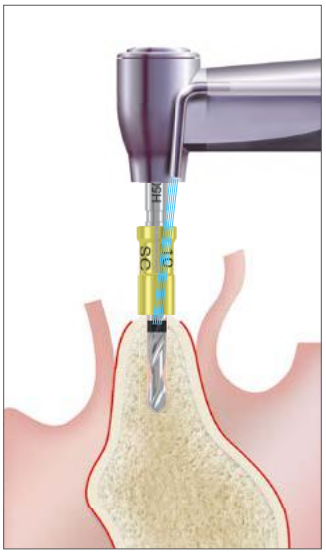
Pilot drill, Ø 2.0 mm
max. drilling speed: 800 rpm

Illustration of the diameter of the implant shoulder

Paralleling pin
Ø 2.0 mm

Once drilling is complete, the depth and axis of the implant bed is checked using the paralleling pins. If several implants are placed, a paralleling pin is inserted into the first drill hole to then align the other implant axes. The surgery set includes three paralleling pins for this purpose.

The pilot drill is aligned parallel to the paralleling pin and visually checked from two planes (sagittal and transversal).



Pilot drilling

Checking the drilling depth and axis

SURGICAL PROCEDURE FOR MONOBLOC IMPLANTS

FORM DRILLING Ø 2.9 mm AND Ø 3.4 mm

To place the CERALOG® Monobloc implant supracrestally, form drilling is performed with or without depth stop and up to the lower edge of the corresponding depth mark.

required work step for:

CERALOG® Monobloc implant

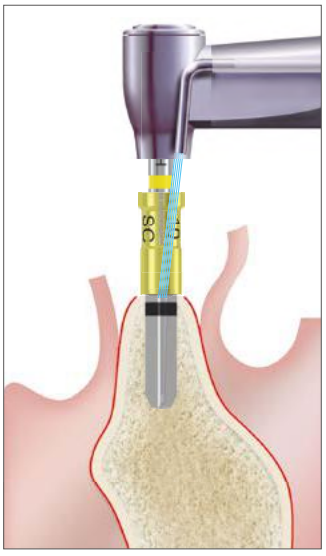
☑ Supracrestal implantation
☐ Epicrestal implantation

Form drill S, Ø 2.9 mm
max. drilling speed: 550 rpm

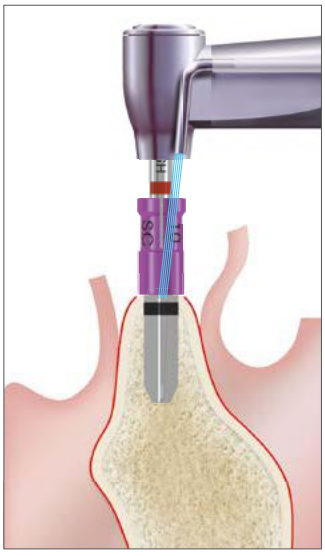
Form drill M, Ø 3.4 mm
max. drilling speed: 500 rpm

Depending on the specified drilling depth (implant length), the diameter is expanded progressively with the series of form drills.

The diameter expansion with the form drill S (with yellow ring) increases the diameter by 0.9 mm. The form drill M (with red ring) additionally increases the diameter by 0.5 mm.



Form drilling Ø 2.9 mm with depth stop for the insertion of the monobloc implant



Form drilling Ø 3.4 mm with depth stop for the insertion of the monobloc implant

TAP Ø 4.0 mm

Use of a tap M (red ring) is recommended for bone quality categories 1* and 2*.
The thread must be tapped over the entire implant bed.

required work step for:

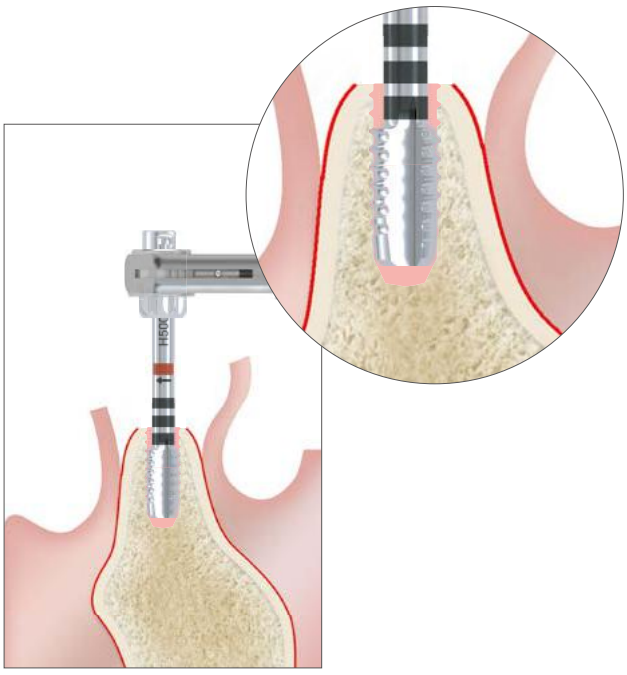
CERALOG® Monobloc implant

☑ Supracrestal implantation
☐ Epicrestal implantation

Tap M
max. drilling speed: 15 rpm

The wrench adapter and the locked torque wrench are used to manually tap the thread. Pay attention to the axial alignment of the implant bed when inserting and removing the tap.
For automated tapping: a maximum speed of 15 rpm must not be exceeded.

Camlog recommends manual tapping.



Tapping in the upper region of the implant bed

* See [B] in section «Further documentation» on page 63

SURGICAL PROCEDURE FOR MONOBLOC IMPLANTS

GENERAL INFORMATION ON PACKAGING

CERALOG® Monobloc implants are packaged single-sterile. The primary packaging (blister) contains the implant.

Secondary packaging with label

Non-sterile

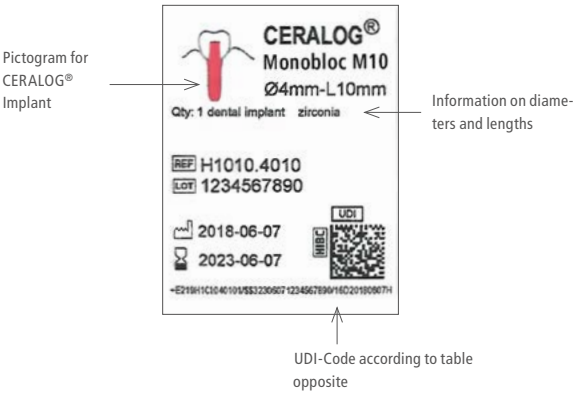
Blister with the Tyvek® foil

Sterile

Interior packaging with cover cap

Secondary packaging (cardboard) with label:
The label on the secondary packaging contains relevant system information.

Example product label on the back of the secondary packaging:



UDI CODE

A B C DE F G H I J K

+E219H101040101/$$320230607XXXXXXXXXX /16D20180607H

Sections of the primary code (UDI-DI)	Code	Explanation
A	+	Protected HIBC-ID (1 digit)
B	E219	Manufacturer's code (Altatec)
C	H10104010	Article number (max. 13 digits)
D	1	Quantity index (number of packaging units, 1 digit)
Sections of the secondary code (UDI-DI)	**Code**	**Explanation**
E	/	Separator primary/secondary
F	$$3	Identifier for expiry date
G	20230607	Expiry date (8 digits) 07.06.2023
H	XXXXXXXXXX	Manufacturer's batch (10 digits)
I	/16D	Identifier for date of manufacture
J	20180607	Date of manufacture (8 digits) 07.06.2018
K	H	Variable test marks

Further information on the secondary packaging:
The bottom side of the CERALOG® Implant packaging refers to the instruction for use in electronic form: https://ifu.camlog.com. In addition, it includes a QR code which links directly to the corresponding Internet page.

The left side view of the CERALOG® Implant packaging contains the CE label, the corresponding ISO warnings (see instructions for use) as well as the address of the manufacturer.

IMPLANTATION

OPENING THE PACKAGING

The secondary packaging is opened by separating the label.

NOTE:
If the label is partially or fully separated, the packaging is deemed damaged and the implant may no longer be used.

The blister with the Tyvek® foil forms the sterile barrier. As long as both the blister as well as the Tyvek® foil are undamaged, sterility of the content is assured.
Furthermore, two self-adhesive patient labels are affixed to the label of theTyvek® foil. Two further labels are included with the blister.

IMPORTANT NOTE:
One of these patient labels must be affixed to the patient's personal implant passport and handed over to the patient. The other labels can, for example, be used for the patient records, the letter of referral or the order for the technician.

The patient is to be informed about the measures and precautions to be taken during the healing phase, an appointment for follow-up care of the wound must be ensured and the updated implant passport with the affixed patient label is to be handed over.

OPENING THE BLISTER

The blister is fitted with a tab which allows easy separation of the Tyvek® foil from the blister. Remove the blister seal and place the sterile inner packaging on a sterile base.

SURGICAL PROCEDURE FOR MONOBLOC IMPLANTS

PICKING UP THE IMPLANT

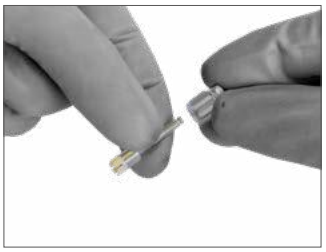
CERALOG® Monobloc implants are picked up from the packaging with the Monobloc implant driver. To insert the implants, either the adapter for wrench (section A) is attached to the implant driver or the angled hand piece (section B) is used:

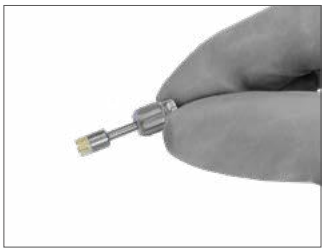
Monobloc implant driver


Iso wrench adapter

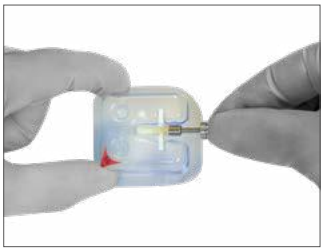
A. PICKING UP THE IMPLANT WITH THE TORQUE WRENCH

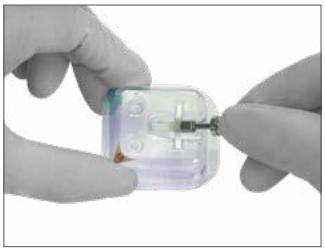
The wrench adapter is connected to the implant driver for CERALOG® Monobloc Implants.





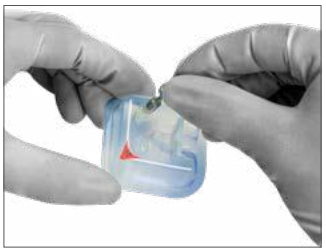
The inner packaging is held with two fingers. The implant driver with wrench adapter is inserted into the implant with force.
An audible "click" indicates that a secure seat of the implant driver in the implant has been achieved.





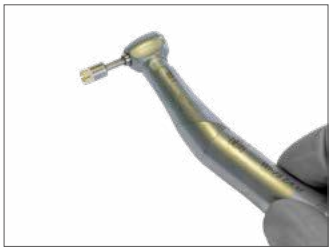
To pick up the implant from the packaging, it is then lifted upwards via the wrench adapter - inclining the apical area downwards.

Camlog recommends confirming the correct placement of the implant driver by exerting pressure on the implant in the sterile cavity. This manipulation ensures that the implant driver is connected securely to the implant.

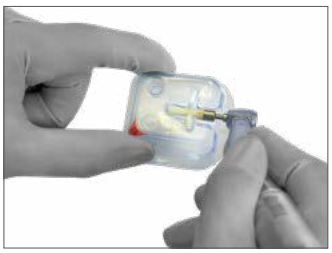


B. PICKING UP THE IMPLANT WITH THE ANGLED HAND PIECE

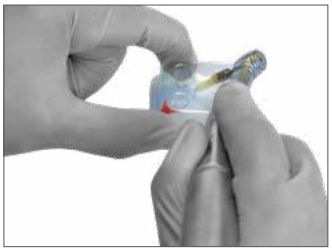
The Monobloc implant can also be picked up directly with the machine implant driver with ISO shaft and the angled hand piece as follows:



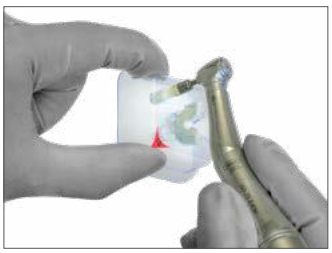
The inner packaging is held with two fingers and the insertion tool with angled hand piece is inserted into the implant with force. An audible "click" indicates that a secure seat of the implant driver in the implant has been achieved.



To pick up the implant from the packaging, the implant is then lifted upwards via the angled hand piece - inclining the apical area downwards.



Camlog recommends confirming the correct placement of the implant driver by exerting pressure on the implant in the sterile cavity. This manipulation ensures that the implant driver is connected securely to the implant.



SURGICAL PROCEDURE FOR MONOBLOC IMPLANTS

IMPLANT INSERTION

Using the implant driver, the implant is inserted into the implant bed and carefully screwed in clockwise either manually or with the angled hand piece. Pay attention to the axial alignment of the implant bed.

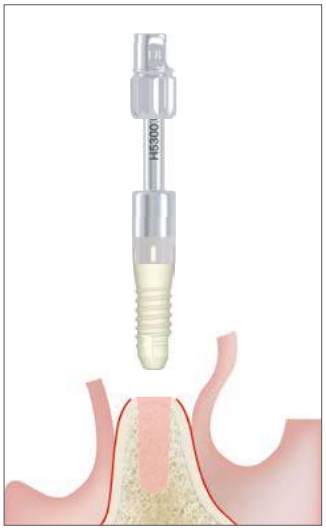
The following parameters must be observed when screwing in the implant:

- Manual or automated insertion: a maximum torque of 35 Ncm must not be exceeded
- Automated insertion: a maximum speed of 15 rpm must not be exceeded

In the case of manual insertion, once the implant has been inserted into the implant bed, the implant can be screwed into its final position with the torque wrench.

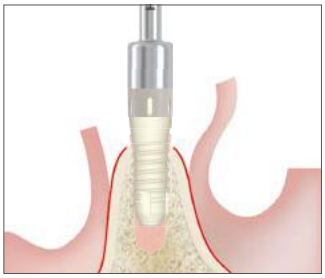
NOTE:
If required, the drill extension can be used.

If the thread was cut in advance, the positions of the threaded ends in the bone and on the implant must match.
It is recommended to first rotate the implant driver with the implant carefully to the left manually, until the thread socket can be felt. Then the implant is screwed in clockwise manually with the implant driver.



Insertion of implant with a manual implant driver

Insertion of implant with a machine implant driver



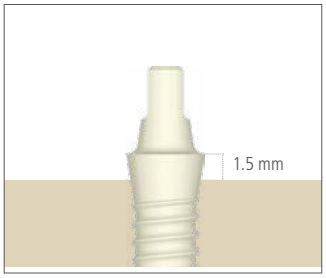
Screw insertion of implant with implant driver (max. 35 Ncm)

HEALING OF THE IMPLANT

The patient is to be informed about the measures and precautions to be taken during the healing phase, an appointment for follow-up care of the wound must be ensured and the updated implant passport with the affixed patient label is to be handed over.

Healing is performed transgingivally with the CERALOG® Monobloc System.

As a rule, the osseointegration of CERALOG® Implants takes between 3 and 6 months. The healing time depends both on the general health status of the patient as well as the quality of the bone surrounding the implant. The usual methods can be applied to check osseointegration.



The implant neck lies 1.5 mm supracretally.

The protocol-conform supracrestal insertion depth is achieved when the implant has been inserted into the implant bed up to the end of the thread.

PROSTHETIC PROCEDURE FOR MONOBLOC IMPLANTS

IMPRESSION TAKING

Impression taking for the definitive restoration can be performed after successful osseointegration of the implant and healing of the peri-implant soft tissue as follows:

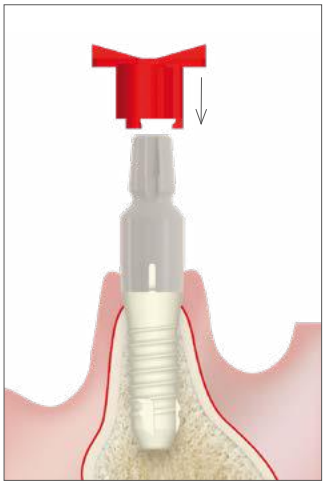
INSERTION OF THE IMPRESSION CAP, CLOSED TRAY

The impression post, closed tray, is supplied non-sterile. After exposure of the implant shoulder, the impression cap, closed tray, can be fixated to the abutment part of the implant via a plug mechanism. For tight and/or thick gingiva in particular, the correct seating of the impression cap must be checked prior to taking the impression.
The impression cap is now installed, using the guide grooves on the impression post, until a detectable pressure point is reached and the impression cap is definitely fastened. Three guide grooves on the impression cap (placed at 120° staggered intervals) facilitate contact-free placement relative to adjacent impression caps or adjacent teeth. The extensions of the impression caps must not be removed.

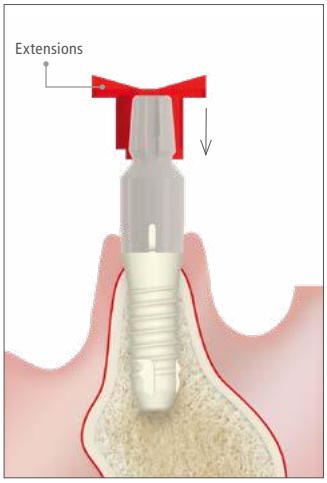
IMPRESSION TAKING

Light Body impression material is applied around the impression cap for impression taking. In addition, Heavy Body impression material is placed in the impression tray. Right before taking the impression, check again to ensure that the impression caps are seated correctly. The impression caps should remain in the impression after the impression tray is lifted. If this is not the case, repeat the impression-taking.

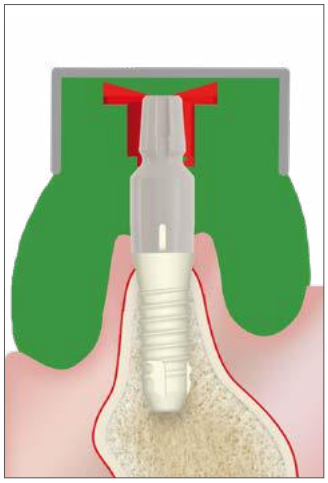
CERALOG® Impression cap, closed tray



Fixation of the impression cap



Check of correct seating of the impression cap

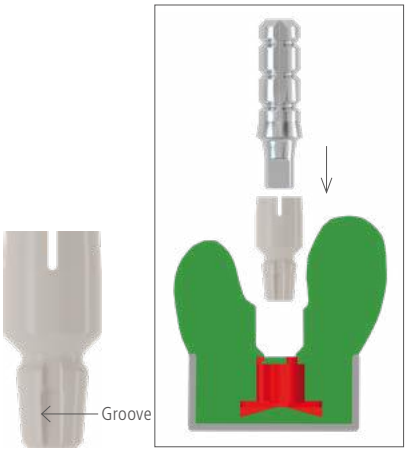


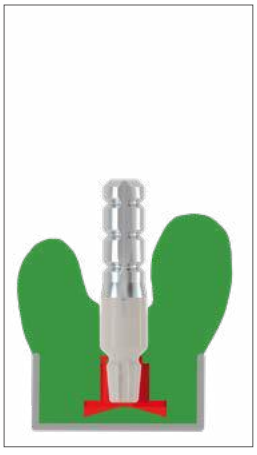
Impression tray with the CERALOG® Impression cap, closed tray

CAST FABRICATION

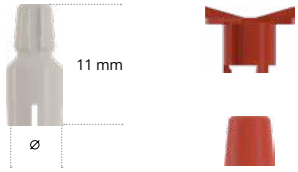
After the impression is taken, the impression cap remains in the impression. In the dental laboratory, the impression caps, closed tray, are attached to the corresponding lab analog (note proper seating).
The components are repositioned into the impression caps. Make sure that the grooves correctly engage in the impression cap.

Do not use bonding material!





PROSTHETIC PROCEDURE FOR MONOBLOC IMPLANTS

	Article	Art. No.	∅
	**Monobloc lab analog** for casted models **Material** Stainless steel	D1037* H3010.4500**	4.5 mm
	**Monobloc Impression cap, closed tray** incl. impression cap and bite registration cap **Material** PEEK	H2110.4550	5.0 mm
	**Impression caps** for impression post and impression cap, closed tray, (5 units) **Material** POM	J2111.4300	-

* Manufacturer: AXIS biodental SA, Les Rosées 5, 2336 Les Boïs, Switzerland
** New product number available from end of Q3/2021

PROSTHETIC RESTORATION

MODIFICATION OF THE ABUTMENT PART

The abutment part can be shortened occlusally depending on the anatomical situation. A minimum height of 2.5 mm (area marked in red) must be retained.

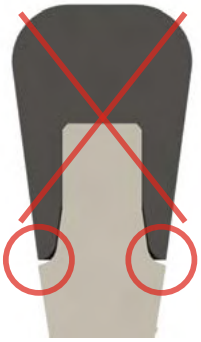
NOTE:
Processing of the abutment part may only be performed using an appropriate liquid-cooled diamond milling cutter and at slight pressure to avoid heating and the formation of micro-cracks.
To avoid micro-cracks, the neck of the abutment part must not be modified.

DIGITAL RECORDING

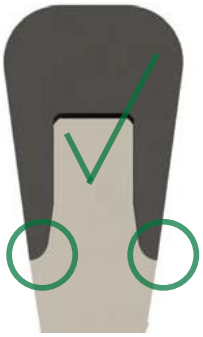
The abutment part can be scanned as tooth stump.

FABRICATION AND BONDING OF THE CROWNS

The crown is fabricated along conventional methods. The abutment part is used for a crown cemented in the patient's mouth.
The components are bonded using a suitable cement. The cement is mixed according to manufacturer's instructions and applied to the abutment.
The crown must lie on the shoulder of the abutment to ensure optimal mechanical stability. The cement gap should be as small as possible.



The crown does not fit correctly on the abutment as the crown does not rest fully on the abutment.



Correct fit of the crown on the abutment.

NOTE:
For bonding of the abutment and crown, we recommend using a resin-containing adhesive monomer MDP (for example, "PANAVIA™ v5" from Kuraray Europe GmbH or "RelyX TM Unicem 2 Automix" from 3M ESPE). Observe the manufacturer's processing instructions.

APPENDIX 1 – MATERIALS STRUCTURE OF THE CERALOG® SYSTEM

Zirconia - Y-TZP

Properties (ISO 13356)		
Chemical structure (in %):	$ZrO_2 + HfO_2 + Y_2O_3$	≥ 99.0
	Y_2O_3	4.5 < … ≤ 6.0
	HfO_2	≤ 5
	Al_2O_3	≤ 0.5
	other oxides	≤ 0.5
Mechanical properties:	Transversal strength	≥ 800 MPa
	Microstructure Median grain size	≤ 0.4 µm
Physical properties:	Density	≥ 6 g/cm³
	Radioactivity	≤ 200 Bq/kg

PEKK

Properties		
Mechanical properties:	Tensile strength (MPa)	138 MPa
	Transversal strength (MPa)	193 MPa
	Compressive strength (MPa)	207 MPa
	Elongation at break	> 30%
Physical properties:	Melting temperature	360 °C
	Density	1.3 g/cm³
	Water absorption after 24h	< 0.2 %
	Modulus of elasticity	4.5 GPa

PEEK

Properties		
Mechanical properties:	Tensile strength (MPa)	100 MPa
	Transversal strength (MPa)	165 MPa
	Compressive strength (MPa)	135 MPa
	Elongation at break	40 %
Physical properties:	Melting temperature	340 °C
	Density	1.3 g/cm³
	Water absorption after 24h	0.5 %
	Modulus of elasticity	4.1 GPa

Titanium alloy Ti6Al4V ELI

Properties (ASTM F136)		
Chemical structure (in %):	Al	5.5–6.5
	V	3.5–4.5
	Fe	≤ 0.25
	C	≤ 0.08
	N	≤ 0.05
	O	≤ 0.13
	H	≤ 0.012
	Ti	Rest
Mechanical properties:	Tensile strength	≥ 860 MPa
	Elongation at break	≥ 10 %

Holisticor

Properties		
Chemical structure (in %):	Precious metal content (Au, Pt, Pd, Rh)	74.5%
	Au	61%
	Ag	16.5%
	Pt	13.5%
	Cu	9.0%
Mechanical properties:	Hardness HV5	> 250
	Tensile strength (Rm)	> 800 MPa
	0.2% Elongation limit (Rp 0.2%)	> 700 MPa
	Elongation at break	> 6%
Physical properties:	Melting range	950–1050°C
	Density	15.7 g/cm³
	Modulus of elasticity	96 GPa
	Color	Bright yellow

FURTHER DOCUMENTATION

Further information on the CERALOG® products is available in the following documentations:

- CERALOG® Product Catalog
- CERALOG® Instructions for use
- CERALOG® Preparation instructions

[A] CERALOG Implant System – Numbers and Facts at a Glance (White Paper), Art.-No. X.J6718.02/2017

[B] Bone quality according to Lekholm U, Zarb GA. «Patient selection and preparation», In: Branemark PI, Zarb GA, Albrektsson T, editors. «Tissue-integrated prostheses- Osseointegration in Clinical Dentistry», Chicago: Quintessence Publishing Co 1985; p. 199–209.

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Headquarters
CAMLOG Biotechnologies GmbH | Margarethenstr. 38 | 4053 Basel | Switzerland
Phone +41 61 565 41 00 | Fax +41 61 565 41 01 | info@camlog.com | www.camlog.com

Manufacturer CERALOG® Products: ALTATEC GmbH | Maybachstr. 5 | 71299 Wimsheim | Germany

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