Instruction for use for CAMLOG®, CONELOG®, iSy® and BioHorizons® CAM blanks

1 Product description

English

CAM blanks are prefabricated components for machining customized one-piece abutments and healing caps using CAD/CAM technology. CAM blanks are available for implants of the CAMLOG®, CONELOG® and the iSy® Implant System as well as for BioHorizons® Tapered Internal and Internal implants.
The blanks have a prefabricated implant connection (implant-abutment connection) and screw channel suitable for the respective implant system. Computer-aided manufacturing (CAM) techniques are used to process the cylinder located above the implant connection into the customized abutment or healing cap design. Each blank includes a corresponding abutment screw packaged separately. The blanks consist of titanium alloy respectively cobalt-chromium alloy (CoCr) and are intended for single use.
Abutments made of CoCr blanks can be veneered directly with suitable ceramics.

Two different types of blanks are available:
1. Type IAC: Clamping for customization is performed at the implant-abutment connection. The system-relevant collets for CAM blanks, type IAC, are available as primary chuck for this type.

2. Type ME: Clamping for customization is performed on a cylindrical section opposite the implant-abutment connection. The Preface® Abutment holders for the Preface® Abutments by Medentika® can be used as machine-specific chucks. These collets are available for selected machines from the respective machine manufacturers.

1.1 CAMLOG® CAM blanks, Type IAC and ME

The blanks are available in titanium alloy and CoCr alloy and specific for the implant diameters of all CAMLOG® Implants. The ones which are made from titanium alloy are color-coded by implant diameter according to the respective versions. The implant diameters 5.0 and 6.0 mm are supplied with the same CoCr blank and the same titanium blank, type IAC in the version without color coding (K2411.6013 and K2412.6013).

Platform Switching option for CAMLOG® SCREW-LINE, PROGRESSIVE-LINE and ROOT-LINE 2 implants

The shape of the CAMLOG® blanks enables the fabrication of abutments and healing caps that are apically reduced in diameter in the connection area to the implant for Platform Switching (For minimum shoulder diameter see table in section 5.1.1).

Warning:
All prosthetic components PS for Platform Switching must only be used in conjunction with SCREW-LINE, PROGRESSIVE-LINE and ROOT LINE 2 implants with K article number K10xx.xxxx!

1.2 CONELOG® CAM blanks, Type IAC and ME

The blanks are available in titanium alloy and CoCr alloy and specific for the implant diameters of all CONELOG® Implants. The ones which are made from titanium alloy are color-coded by implant diameter according to the respective versions. The implant diameters 3.8 mm and 4.3 mm are supplied with the same CoCr blank and the same titanium blank, type IAC in the version without color coding (C2411.4313 and C2412.4313).

1.3 iSy® CAM blanks, Type IAC and ME

iSy® CAM blanks of types IAC and ME are available in titanium alloy and CoCr alloy and in one size each for all iSy® Implant diameters.

1.4 BioHorizons® CAM blanks, Type IAC and ME

The blanks are available in titanium alloy (Type ME only) and CoCr alloy and implant diameter specific for all BioHorizons® Tapered Internal and Internal implants. In the titanium alloy version, they are color-coded according to the implant diameter.

2 Intended purpose/intended use

The CAM blanks are intended to create a customized abutment to be connected to an endosseous dental implant to support the placement of customized, dental crown or bridge restorations. Furthermore, CAM Titanium blanks are intended to create a healing cap to shape the peri-implant soft tissue.

3 Indications

3.1 CAMLOG® CAM Titanium Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments and healing caps on CAMLOG® Implants in the maxilla and mandible.

3.2 CAMLOG® CAM CoCr Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments on CAMLOG® Implants in the maxilla and mandible.

3.3 CONELOG® CAM Titanium Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments and healing caps on CONELOG® Implants in the maxilla and mandible.

3.4 CONELOG® CAM CoCr Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments on CONELOG® Implants in the maxilla and mandible.

3.5 iSy® CAM Titanium Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments and healing caps on iSy® Implants in the maxilla and mandible.

3.6 iSy® CAM CoCr Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments on iSy® Implants in the maxilla and mandible.

3.7 BioHorizons® CAM Titanium Blank, Type ME

Semi-finished component for the fabrication of abutments and healing caps on BioHorizons® Tapered Internal and Internal implants in the maxilla and mandible.

3.8 BioHorizons® CAM CoCr Blank, Type IAC and ME

Semi-finished component for the fabrication of abutments on BioHorizons® Tapered Internal and Internal implants in the maxilla and mandible.

4 Contraindications

4.1 CAMLOG® CAM blanks, Type IAC and ME

- Clinical situations which do not permit compliance with construction specifications (see section 10.1)
- Platform Switching on CAMLOG® Implants with article numbers J10xx.xxxx (no longer available and replaced by implants with the article numbers K10xx.xxxx)
- Double crowns on implants with diameter 3.3 mm
- Single-tooth restorations with free-end pontic
- Extension attachments on abutments
- Restorations with a length relationship to the implant length greater than 1:1.25
- Direct laser welding
- Cast-on technique
- Titanium blanks: Ceramic veneers
- Hypersensitivity to any of the metals as listed in section 12 “Technical data”
- Single crown restorations for implant diameter 3.3 mm outside the region of the upper lateral incisors and lower central and lateral incisors

4.2 CONELOG® CAM blanks, Type IAC and ME

- Clinical situations which do not permit compliance with construction specifications (see section 10.1)
- Double crowns on implants with diameter 3.3 mm
- Single-tooth restorations with free-end pontic
- Extension attachments on abutments
- Restorations with a length relationship to the implant length greater than 1:1.25
- Direct laser welding
- Cast-on technique
- Titanium blanks: Ceramic veneers
- Hypersensitivity to any of the metals as listed in section 12 “Technical data”
- Single crown restorations for implant diameter 3.3 mm outside the region of the upper lateral incisors and lower central and lateral incisors

4.3 iSy® CAM blanks, Type IAC and ME

- Clinical situations which do not permit compliance with construction specifications (see section 10.1)
- Single-tooth restorations with free-end pontic
- Extension attachments on abutments
- Restorations with a length relationship to the implant length greater than 1:1.25
- Direct laser welding
- Cast-on technique
- Titanium blanks: Ceramic veneers
- Hypersensitivity to any of the metals as listed in section 12 “Technical data”

4.4 BioHorizons CAM blanks, Type IAC and ME

- Clinical situations which do not permit compliance with construction specifications (see section 10.1)
- Double crowns on implants with diameter 3.0 mm
- Single-tooth restorations with free-end pontic
- Extension attachments on abutments
- Restorations with a length relationship to the implant length greater than 1:1.25
- Direct laser welding
- Cast-on technique
- Titanium blanks: Ceramic veneers
- Hypersensitivity to any of the metals as listed in section 12 “Technical data”
- Single crown restorations for implant diameter 3.0 mm outside the region of the upper lateral incisors and lower central and lateral incisors

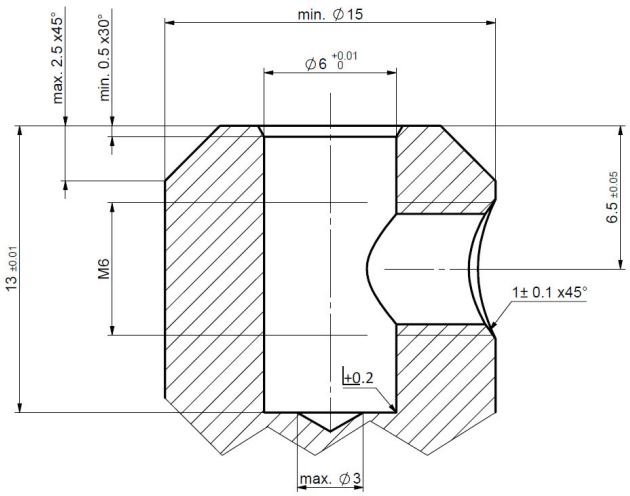
5 Accessories

5.1 Collets for CAM blanks, Type IAC, incl. fixing screws for CAM blanks

To process the type IAC blank, collets and fixing screws are available in corresponding sizes for CAMLOG®, CONELOG® and iSy® CAM blanks. For BioHorizons® CAM blanks, please contact the Camlog respectively BioHorizons® headquarters.
The collets are used to securely fix the blanks in the chuck of the machine. The torque for the fixing screw is 30 Ncm (using a screwdriver, hex, long, manual/wrench and torque wrench).

CAMLOG® Fixing screw for CAMLOG® CAM blank, Type IAC, hex, brown anodized		**CONELOG® Fixing screw for CONELOG® CAM blank, Type IAC, hex, brown anodized**		**iSy® Fixing screw for iSy® CAM blank, Type IAC, hex, yellow-green anodized**	
Implant Ø 3.3/3.8/4.3 mm	Thread M 1.6	Implant Ø 3.3/3.8/4.3 mm	Thread M 1.6	Implant Ø 3.8/4.4/5.0 mm	Thread M 1.6
Implant Ø 5.0/6.0 mm	Thread M 2.0	Implant Ø 5.0 mm	Thread M 2.0		
Tightening torque of all fixing screws for CAM blank: 30 Ncm					

The following geometry is recommended for fixating the collet in the machine-specific chuck:



The chuck or an additional adapter are to be modified or manufactured accordingly.
The collet is secured in its final position using an M6 clamp screw sidewise.

5.1.1 CAMLOG® Collet

The CAMLOG® Collet for CAM blanks, Type IAC, is available specific for the implant diameters of all CAMLOG® Implants. The implant diameters 5.0 and 6.0 mm have the same CAMLOG® Collet for CAM blanks, Type IAC.

Platform Switching option with collet for CAM blank for CAMLOG® SCREW-LINE, PROGRESSIVE-LINE and ROOT-LINE 2 implants

To fabricate customized abutments and healing caps for Platform Switching, the collets and CAM blanks, Type IAC, are screwed together and reduced in diameter at the connection points*.

CAMLOG® implant Ø in mm	Shoulder Ø of CAMLOG® Collets in mm	Minimum shoulder Ø of healing caps for Platform Switching in mm	Minimum shoulder Ø of abutments for Platform Switching in mm
3.3	3.2	Platform Switching not possible as the minimum shoulder Ø is 3.3 mm	Platform Switching not possible as the minimum shoulder Ø is 3.3 mm
3.8	3.7	3.25	3.2
4.3	4.2	3.75	3.7
5.0	4.9	4.35	4.3
6.0	4.9*	5.05	5.0
		The shoulder diameter must meet the minimum diameter required. If the diameter does not meet the minimum requirement, the gingiva may be crushed when inserting an abutment for Platform Switching.	The shoulder diameter must meet the minimum diameter required. If the diameter does not meet the minimum requirement, the internal configuration of the implant is no longer covered.

*An exception is Platform Switching for implant diameter 6.0 mm as the associated collet already has an upper shoulder diameter of only 4.9 mm.

To avoid any trapping of soft tissue between the implant and abutment, care should be taken to design the shoulder of an abutment for the CAMLOG® Implant System smaller than that of the healing cap used. Repeated use of the collet is only recommended when the shoulder support is undamaged.

5.1.2 CONELOG® Collet

The CONELOG® Collet for CAM blanks, Type IAC, is available specific for the implant diameters of all CONELOG® Implants. CONELOG® Implant diameters 3.8 mm and 4.3 mm have the same CONELOG® Collet for CAM blanks, Type IAC.

5.1.3 iSy® Collet

The iSy® Collet for CAM blanks, Type IAC, is available in one size for all iSy® Implant diameters.

5.2 Screwdriver for fixing screws
The screwdriver, hex, long, manual/wrench is used for fixation of the CAM blanks, Type IAC, using the respective CAMLOG®, CONELOG® or iSy® fixing screw.

5.3 Torque wrench
The torque wrench is used to achieve the specified torque of 30 Ncm for the fixing screw for CAM blanks.

5.4 CONELOG® and iSy® Disconnectors
The respective disconnector is used to remove prepared CONELOG® and iSy® CAM blanks, Type IAC, from the collet for CAM blanks after removal of the fixing screw. The CAM blank is pushed out of the collet by turning the disconnector clockwise. If the conical connection does not come loose, the torque wrench (locked setting) can be placed on the disconnector and the fabricated abutment or healing cap can be loosened.

CONELOG® Disconnector		**iSy® Abutment disconnector**	
Implant Ø 3.3/3.8/4.3 mm	Thread M 1.6	Implant Ø 3.8/4.4/5.0 mm	Thread M 1.6
Implant Ø 5.0 mm	Thread M 2.0		

5.5 Lab screws
Lab screws are only used to attach customized abutments to the lab analogs in the working cast. Separate lab screws in various thread sizes are available for each implant system from Camlog. To avoid confusing with abutment screws, the lab screws are color coded.

CAMLOG® Lab screw, hex, brown anodized		**CONELOG® Lab screw, hex, brown anodized**		**iSy® Lab screw, yellow-green anodized**	
Implant Ø 3.3/3.8/4.3 mm	Thread M 1.6	Implant Ø 3.3/3.8/4.3 mm	Thread M 1.6	Implant Ø 3.8/4.4/5.0 mm	Thread M 1.6
Implant Ø 5.0/6.0 mm	Thread M 2.0	Implant Ø 5.0 mm	Thread M 2.0		
Screwdriver, hex				**iSy® Lab screwdriver**	
Tightening torque for all lab screws: tightened by hand					

CAMLOG® or CONELOG® Lab screws are identical to CAMLOG® or CONELOG® Fixing screws for CAM blanks, Type IAC.

Important note: Lab screws must not be used on the patient!

5.6 Abutment screws
Separate abutment screws in various thread sizes are available for each implant system and diameter. Each CAM blank includes a corresponding abutment screw packaged separately.

CAMLOG® Abutment screw, hex		**CONELOG® Abutment screw, hex**		**iSy® Abutment screw**		**BioHorizons® Abutment screw for Multi-Unit Abutment**	
Implant Ø 3.3/3.8/4.3 mm	Thread M 1.6	Implant Ø 3.3/3.8/4.3 mm	Implant Ø 3.8/4.4/5.0 mm	Implant Ø 3.8/4.4/5.0 mm	Thread M 1.6	Implant Ø 3.0/3.5/4.5/ 5.7 mm	Thread M 1.8
Implant Ø 5.0/6.0 mm	Thread M 2.0	Implant Ø 5.0 mm	Thread M 2.0				
Screwdriver, hex				**iSy® Screwdriver**		**Screwdriver, hex**	

- **Definitive tightening torque of all abutment screws for healing caps: tightened by hand**
- **Definitive tightening torque of all abutment screws for abutments:**
  20 Ncm for CAMLOG®, CONELOG®, iSy® Implants
  30 Ncm für BioHorizons® Implants

Important notes:
- **Abutment screws are only used for the definitive fixation of customized abutments and healing caps in the implant.**
- **Abutment screws must be passed to the end user in the original unopened packaging.**

6 Clinical benefit

Prosthetic components allow the replacement of missing teeth and / or the restoration of masticatory function and the corresponding improvement in quality of life.

7 Undesirable side-effects

The use of abutments and healing caps made from CAM blanks are part of an invasive treatment which may be associated with typical side effects such as:

Temporary side effects
- pain, swelling, muco-gingival inflammation
- speech difficulties

Prolonged or permanent side effects
- fractures of the restoration
- aesthetic problems

Caution:
Using different alloys in the patient's mouth can lead to galvanic effects!

8 Intended user & patient population

8.1 Intended user

CAM blanks are intended to be used by professional users (dental lab technician or cutting machine operator) only.

8.2 Intended patient population

Abutments and healing caps made from CAM blanks are to be used in skeletally mature patients subject to dental implant treatment. Please make sure that the contraindications and precautions are considered.

9 Preparation

9.1 Preparation

CAM blanks are delivered non-sterile. The abutments and healing caps made from CAM blanks must be cleaned and disinfected before and after each use on a patient. We recommend an additional sterilization for abutments. Fabricated healing caps must be sterilized before use in the patient (see also section 11 Sterility & reprocessing).

9.2. Handling of packaging

The packaging must be checked before opening for damage.
Should the original packaging be damaged, items may not be returned to the manufacturer.

9.3 Storage conditions

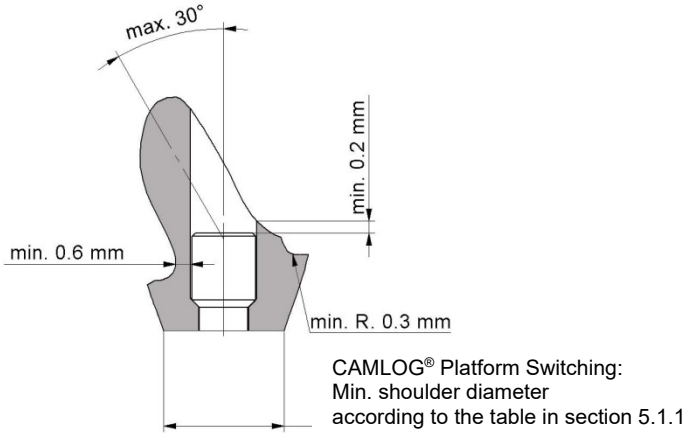
CAM blanks are not subject to any special considerations for storage or handling (during transport and storage). It is recommended to keep the packaged products dry, out of direct sunlight and at room temperature to maintain an optimal visual appearance of the packaging.

10 Application

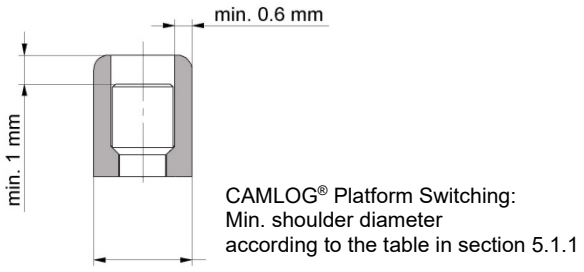
10.1 CAD design

The following requirements must be met when designing the abutment or healing cap:
- Angle of the prosthetic axis to screw axis up to max. 30°.
- Wall thickness in the load-bearing region is min. 0.6 mm.
- Radius of curves is min. 0.3 mm.
- Min. height above the screw head in the abutment is 0.2 mm.

- Min. height above the screw head in the healing cap is 1.0 mm
  (for secure attachment of the sealing material).
- CAMLOG® Platform Switching: min. shoulder diameter according to the table in section 5.1.1.



Abutment



Healing cap

10.2 Review of the dataset

Before customization of the blank, the dataset from the computer-aided design of the abutment or healing cap (CAD file) must be checked for compliance with the requirements according to section 10.1. If compliance with the requirements is not met, the geometry of the abutment or healing cap must be adapted accordingly.

10.3 Preparation

10.3.1 CAM blanks, Type IAC

10.3.1.1 CAMLOG®, CONELOG® and iSy® CAM blanks, Type IAC

Collet and fixing screw must be checked for damage and contamination before use, and if necessary, replaced or cleaned. The blank is secured in the collet for CAM blanks, Type IAC, specific to the implant type and size in the chuck of the machine. The screwdriver, hex, long, manual/wrench and torque wrench are used to tighten the associated fixing screw to 30 Ncm.

The fixing screw for the respective implant system can be identified by its shape or color:	
Implant system	**Features of the fixing screw**
CAMLOG®	Brown anodized, cylindrical shaft
CONELOG®	Brown anodized, waisted shaft
iSy®	Yellow-green anodized, cylindrical shaft

10.3.1.2 BioHorizons® CAM blanks, Type IAC

For the requirements to process the CAM blanks, please contact the Camlog respectively BioHorizons® headquarters.

10.3.2 CAM blanks, Type ME

The collet must be checked for damage and contamination before use, and if necessary, replaced or cleaned.
The blank is fixated in the proper position in the machine-specific collet for the Preface® Abutments by Medentika®. It should be ensured that the blank is precisely in its final position.

10.4 Machining

After properly adjusting the axis alignment incl. correct positioning of the antirotational mechanism of the blank in the machine, the blank is customized based on the specified dataset using machining techniques. To prevent deformation of the contact surface to the implant, the following must be observed when using a blank Type IAC:

- Limitation of cutting forces by selecting suitable processing parameters.
- Use of appropriate tools that are not worn out.

Warning:
Machining of titanium and titanium alloys can lead to the spontaneous combustion of the chips. Ensure adequate cooling lubrication while processing.

To prevent notching effects and the associated risk of fracture of the abutment or healing cap, sharp transitions on the individual geometry must be avoided. If necessary, the abutment or healing cap must be discarded or shapes that may cause notching must be eliminated by polishing under microscopic examination.

The contact surfaces between the abutment and healing cap and the implant must not be abrasive blasted or processed mechanically!

10.5 Cleaning

After successful machining and removal of burs, if necessary, the fabricated abutment or healing cap must be completely cleaned of processing residues and other contamination using a suitable validated method.

10.6 Handoff

The user (dentist or dental technician) of the abutment or healing cap must be informed of the diameter and exact type designation of the associated implant.
The specific abutment screw included with the CAM blank must be clearly assigned and passed to the recipient of the abutment or healing cap in its original unopened packaging.

10.7 Post-processing on the cast

The following must be observed when manually processing the abutment or healing cap on the cast:

Warnings:

- **During machining or thermal processing of CoCr material (e.g. milling, grinding) dust and fumes can be produced which could entail a health risk if inhaled. Therefore, suitable measures must be applied to reduce dust and vapor exposure, such as the use of extraction and ventilation systems or, for short-term use, suitable personal protective equipment for respiratory air filtration.**
- **The contact surfaces between the abutment and healing cap and the implant must not be abrasive blasted or processed mechanically!**
- **The surface quality and wall thickness may not be changed or reduced in the load-bearing regions!**

10.8 Veneering of CoCr alloy abutments

For direct ceramic veneering, the processing instructions of the veneering material manufacturer must be observed. If no information on the surface conditioning of the abutments for the selected veneering material is available from the respective manufacturer, the abutments must be blasted with pure aluminum oxide with a grain diameter of 110 µm and a blasting pressure of 2 to 4 bar. Finally, the abutments must be cleaned with a steam jet and degreased with ethyl alcohol.

Caution:
When directly veneering CoCr abutments with ceramic, the firing temperature must not exceed 1040°C!

10.9 Preparation

The products must be cleaned and disinfected before use on the patient. We recommend sterilization of the fabricated abutments. Fabricated healing caps must be sterilized before use in the patient. See also the “Preparation Instructions for the CAMLOG®/CONELOG® Implant System”, Art. No. J8000.0032 respectively “Preparation Instructions for the iSy® Implant System”, Art. No. 8000.0171. These documents are available at https://ifu.camlog.com or from your local Camlog distributor.

10.10 Insertion

Definitive insertion of the abutment or healing cap in the implant is performed as follows:

- Remove implant cover screw or temporary restoration.
- Clean the inside of the implant.
- Insert the abutment or healing cap in the implant.
- Use new unused abutment screws that belong to the specific implant system. Use the screwdriver that belongs to the specific implant system.
- Tighten the abutment screws for fixation of the abutments with a definitive torque of 20 Ncm for CAMLOG®, CONELOG® and iSy® implants and 30 Ncm for BioHorizons® implants. Only hand-tighten abutment screws for fixation of healing caps. Note the proper seating in the implant (radiographic check recommended).
- Retighten with the same torque after at least 5 minutes.
- For hygiene reasons, the screw channels of abutments must be sealed with suitable removable materials. To protect the screw head, this is to be covered beforehand with cotton.

Important note: for healing caps, the screw channel must be sealed with a removable material to secure the only hand-tightened abutment screw. To protect the screw head, cover beforehand with cotton.

11 Sterility & reprocessing

11.1 Information on sterility and reusability

The CAM blanks are delivered non-sterile and must be used one time only and solely on one patient. The abutments and healing caps made from CAM blanks must be cleaned and disinfected before and after each use on a patient, e. g. for shipping to the dental laboratory. We recommend an additional sterilization for abutments. Fabricated healing caps must be sterilized before use in the patient.

Warning: The use of non-sterile healing caps may lead to infection.

11.2 Reprocessing of the prosthetic components

CAM blanks are supplied non-sterile. The abutments and healing caps made from CAM blanks must be cleaned and disinfected before and after each use on a patient, e. g. for shipping to the dental laboratory. Additional sterilization is recommended for abutments. Fabricated healing caps must be sterilized before use in the patient.

Warnings:

- **The use of non-sterile healing caps may lead to infection.**
- **Camlog products intended for single use must not be reused on the patient because safe preparation and/or functional safety cannot be ensured.**

Attention:
All non-sterile packaged products must not be sterilized in the original packaging!

Important note: Detailed information on the preparation of instruments and prosthetic components of the CAMLOG® and CONELOG® Implant System is described in the "Preparation Instructions for the CAMLOG®/CONELOG® Implant System", Art. No. J8000.0032, respectively of the iSy® Implant System in the "Preparation Instructions for the iSy® Implant System", Art. No. J8000.0171 and must be observed!

These preparation instructions are available at https://ifu.camlog.com, www.camlog.com, or may be requested from a local Camlog representative.

12 Technical data

CAM blanks are available in various versions:

Material of CAM blank	Type of CAM blank	Implant system	Implant Ø [mm]
Titanium alloy	IAC	CAMLOG®	3.3/ 3.8/ 4.3/ 5.0/ 6.0
		CONELOG®	3.3/ 3.8/ 4.3/ 5.0
		iSy®	3.0/ 4.4/ 5.0
	ME	CAMLOG®	3.3/ 3.8/ 4.3/ 5.0/ 6.0
		CONELOG®	3.3/ 3.8/ 4.3/ 5.0
		iSy®	3.0/ 4.4/ 5.0
		BioHorizons®	3.0/ 3.5/ 4.5/ 5.7
CoCr alloy	IAC	CAMLOG®	3.3/ 3.8/ 4.3/ 5.0/ 6.0
		CONELOG®	3.3/ 3.8/ 4.3/ 5.0
		iSy®	3.0/ 4.4/ 5.0
		BioHorizons®	3.0/ 3.5/ 4.5/ 5.7
	ME	CAMLOG®	3.3/ 3.8/ 4.3/ 5.0/ 6.0
		CONELOG®	3.3/ 3.8/ 4.3/ 5.0
		iSy®	3.0/ 4.4/ 5.0
		BioHorizons®	3.0/ 3.5/ 4.5/ 5.7

Materials:	
CAM Titanium blanks:	Titanium alloy Ti-6Al-4V ELI according to ASTM F136 & DIN EN ISO 5832-3 Chemical composition (wt %): Al 5.5 – 6.5 V 3.5 – 4.5 Fe ≤ 0.25 Others (O, C, N, H) < 0.4 Ti balance
CAM CoCr blanks:	CoCr according to ASTM F1537-10 and ISO 5832-12 (CTE value (25 to 500°C): 14.2 – 14.4 x 10^{-6}/K) Chemical composition (wt %): Cr 26.0 – 30.0 Mo 5.0 – 7.0 Fe ≤ 0.75 Ni ≤ 0.1* Others (Mn, Si, N, C) < 2.5 Co balance * ASTM F1537-10 and ISO 5832-12: ≤ 1.0 %
Collets for CAM blanks, Type IAC:	Unhardened, corrosion-resistant steel (X8CrNiS18-9)
Fixing screws for CAM blanks:	Titanium alloy Ti-6Al-4V ELI according to ASTM F136 & DIN EN ISO 5832-3

13 Disposal

Products to be disposed of must be treated and decontaminated as dental surgery waste in compliance with the relevant regulations.

14 General safety instructions and warnings

14.1 General safety instructions and warnings

- Improper procedures when using products of the implant systems from CAMLOG Biotechnologies GmbH can lead to failures such as implant loss, bone loss or unsatisfactory esthetic results. The products must only be used by dentists, surgeons and dental technicians trained on the implant systems. Every patient must be thoroughly examined and evaluated with regard to his/her radiographic, psychological and physical status. This includes the condition of their teeth and deficits in the related hard and soft tissues that might jeopardize the final outcome. Close collaboration between dentists, surgeons and dental technicians is essential for successful treatment. The implant systems from Camlog and the corresponding procedures are developed and clinically tested by experts in the field. Detailed information about the choice of suitable implants, prosthetic components, treatment planning and use of the products from Camlog is contained in the user information available at https://ifu.camlog.com or www.camlog.com from CAMLOG Biotechnologies GmbH. In addition, Camlog regularly offers courses or technical consultations regarding the use of its products. Your local Camlog distributor will be glad to advise you.
- Since safe application of Camlog products requires specialized knowledge and skills in oral implant dentistry, these products are sold only to dentists/surgeons and dental laboratories or on their prescription.
- Technical advice/training on the proper use of products from Camlog is provided orally, in writing, by electronic media and/or by demonstration. The delivered information represents the scientific and technological State of the Art at the point in time the products are placed on the market. This does not exempt the user from the responsibility of personally testing the products for suitability for the intended purposes, indications and procedures. Handling and use of the products take place outside the control of Camlog and are the direct responsibility of the user. All liability for damages resulting from such use is disclaimed by ALTATEC GmbH/CAMLOG Biotechnologies GmbH.
- The implant systems from Camlog are each part of a comprehensive treatment concept and must be used only with the pertinent original parts and tools complying with the recommendations and instructions for use provided by the manufacturer. The components of the respective implant systems are matched precisely to one another. The use of third-party components may affect the function and safety of the system. ALTATEC GmbH/CAMLOG Biotechnologies GmbH do neither warrant nor provide replacement services when non-system components are used.
- Drills and instruments are dedicated for specific implant systems and implant diameters. Use with different implant systems and/or implant diameters can lead to tissue injury or esthetically unsatisfactory results. Only the system-relevant drills, instruments and prosthetic components or those approved by ALTATEC GmbH/CAMLOG Biotechnologies GmbH may be used with the respective implant systems.
- Because of the small sizes involved, it may happen that a product is swallowed and/or aspirated. Aspiration can lead to dyspnoea and in the worst case to asphyxiation. For this reason, the products should be secured appropriately to prevent them from being swallowed or aspirated during intraoral use.
- Where indications are listed for a particular product, it should be noted that any indications that are not listed are in fact contraindicated.
- Within the framework of our sales and delivery conditions, we guarantee the high quality of our products.
- Not all Camlog products are available in all countries.
- Damaged and/or corroded products must not be reused.
- Unidentifiable products or products the function of which is doubtful, e.g., by poor readability of the markings and/or inscriptions, must not be used but are to be replaced.

14.2 Reporting in case of a serious incident

Any serious incident that has occurred in relation to the Camlog device must be reported to the manufacturer and the competent authority of your country.

A serious incident means any malfunction or deterioration in the characteristics or performance of the implant or restoration that indirectly led, might have led or might lead to the temporary or permanent serious deterioration of the patient's state of health or the patient's death.

14.3 Trademarks and copyright

15 MRI safety information

Caution:
BioHorizons® CAM blanks and CAMLOG®, CONELOG® and iSy® CAM CoCr blanks have not been evaluated for safety (heating or migration) and compatibility in the MR environment.

16 Further documentation

The latest version of these instructions for use is available at https://ifu.camlog.com or from your local Camlog distributor. Further information is available in the current CAMLOG®, CONELOG®, iSy® and BioHorizons® Documents. These documents are available at https://ifu.camlog.com respectively https://www.biohorizons.com/Education/IFU or from your local Camlog / BioHorizons® distributor.

Basic UDI-DI numbers

Product	Basic-UDI-DI number
CAMLOG® CAM Titanium Blank, type IAC	++E21900014010000000000RN
CAMLOG® CAM Titanium Blank, type ME	++E21900014010000000000RN
CAMLOG® CAM CoCr Blank, type IAC	++E21900014010000000000RN
CAMLOG® CAM CoCr Blank, type ME	++E21900014010000000000RN
CONELOG® CAM Titanium Blank, type IAC	++E21900018010000000000WS
CONELOG® CAM Titanium Blank, type ME	++E21900018010000000000WS
CONELOG® CAM CoCr Blank, type IAC	++E21900018010000000000WS
CONELOG® CAM CoCr Blank, type ME	++E21900018010000000000WS
iSy® CAM Titanium Blank, type ME	++E21900019010000000000Y3
iSy® CAM CoCr Blank, type IAC	++E21900019010000000000Y3
iSy® CAM CoCr Blank, type ME	++E21900019010000000000Y3
iSy® CAM Titanium Blank, type IAC	++E21900019010000000000Y3
BioHorizons® CAM Titanium Blank, type ME	++E21900025010000000000UA
BioHorizons ® CAM CoCr Blank, type IAC	++E21900025010000000000UA
BioHorizons ® CAM CoCr Blank, type ME	++E21900025010000000000UA

17 Color-Coding for implant systems according to implant Ø

17.1 CAMLOG® Implant system

Implant Ø	3.3 mm	3.8 mm	4.3 mm	5.0 mm	6.0 mm
Color	gray	yellow	red	blue	green

17.2 CONELOG® Implant system

Implant Ø	3.3 mm	3.8 mm	4.3 mm	5.0 mm
Color	gray	yellow	red	blue

17.3 BioHorizons® Implant system

Implant Ø	3.0 mm	3.5 mm	4.5 mm	5.7 mm
Color	gray	yellow	green	blue

18 Explanation of symbols

The following symbols per ISO 15223-1 may be present on the device labelling or in information accompanying the device. Please refer to the device labelling or accompanying information for the applicable symbols.

CE 0123	CE-label
	Consult instructions for use
	Caution, observe the warning notices
MD	Medical Device
REF	Article number
LOT	Lot number
STERILE R	Sterilized using irradiation
	Single sterile barrier system with protective packaging outside
	Non-sterile
	Date of manufacture
	Use-by date
	Do not resterilize
	Do not reuse
	Do not use if package is damaged
	Keep away from sunlight
	Temperature limit
	Manufacturer
MR	MR-Conditional
Rx only	Caution: US Federal law restricts this device to sale by or on the order of a dentist or physician.

19 Contact

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