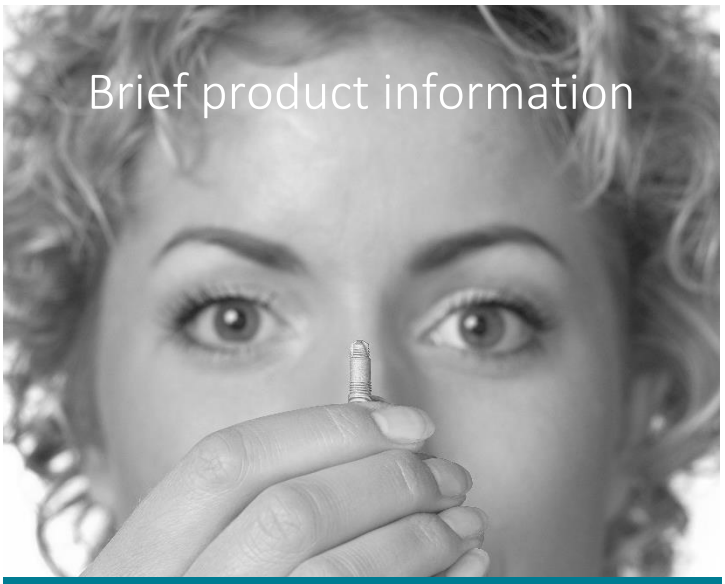

Brief product information

CRANIO MAXILLO FACIAL IMPLANTS

BioComp®

CE 0344

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BioComp® CMF-implant

Article code	Diam. ∅ (mm)	Endosteal Length (mm)	Percutaneous Length (mm)
EO-1110-34VD04	3.4	4	2
EO-1110-40VD03	4.0	3	2.5
EO-1110-40VD04	4.0	4	2
EO-1110-40VD06	4.0	6	0

PRODUCT DESCRIPTION

BioComp CMF implants are intended for use in anchoring maxillo facial prosthetic reconstructions. The self-tapping screw-shaped implants are available in different types, lengths and diameters.

Cover screws are used during the healing phase to prevent bone and soft tissue from growing over and into the implant and the implant's internal thread.

Both animal experimental research and clinical use and studies have shown that BioComp (CMF) implants integrate with the surrounding bone (osseointegration).

Note:
BioComp supplies dental products with two different implant-abutment connections, namely:
- BioComp products with article code BC-xxxx-xxxxxx
- BioComp BioConnect products with article code BCC-xxx-xxxxxx.

CMF products with article code EO-xxxx-xxxx are only interchangeable with BioComp products with article code BC-xxxx-xxxx.
Within each product ranges (with the same platform), the products are interchangeable.

GENERAL

The BioComp® cranio-maxillo-facial (CMF) implant is part of a complete BioComp implant system. BioComp implants may only be used by surgeons who have received suitable training.

Consult the BioComp user manual for a detailed description of the usage of the system.

Optimum performance and safety is assured solely when the BioComp implant is used in combination with original BioComp parts and instruments.

The success of the treatment is largely depending on the use of the appropriate surgical technique, a favourable load, the patient's cooperation, the use of compatible components, and factors specific to the relevant patient such as the quality and quantity of bone.

MATERIAL

The BioComp implant and cover screw are manufactured from the high-quality titanium alloy, TI6AL4V, for medical devices. The alloy is composed of titanium, aluminium and vanadium. The endosteal surface of the implants is blasted, etched and coated with a very thin layer of hydroxyapatite.

INDICATIONS

BioComp cranio-maxillofacial implants are suitable for use in the endosteal anchoring of reconstructions for cranio-maxillofacial defects.

- Ø 3,4 mm CMF implant is indicated for thin-ridged bone for example in the orbita and nasal area
- The length 3 mm CMF implant is indicated if bone-thickness is less than 5 mm
- The Ø 4,0 mm length 4 mm CMF implant is indicated for all-round maxillo- craniofacial placement if bone-thickness is at least 5 mm
- The length 6 mm implant is indicated for the nasal area and skull bone thicker than 7 mm.

Note: When the bone volume allows it, it is preferable to place a ≥4 mm long implant with a diameter of 4 mm. This implant has the largest implant-bone contact area, therefore one can expect this implant to have the highest implant stability.

The cover screw has to be placed in the CMF implant during the healing phase, during a two-stage surgery. The cover screw protects the implant and the internal threads of the implant against the over- and ingrowth of bone and soft tissue.

CONTRA - INDICATIONS

The usual contraindications for cranio-maxillofacial surgery are applicable to BioComp CMF implants.
As the treatment is patient specific, the surgeon has to decide about the number and location of the implants, possibilities and secondary conditions with the final goal as guideline. A regular X-ray or CT scan examination follows the initial assessment of the feasibility of an implant.
The following situations should be regarded as contraindications:

- Insufficient bone quality and/or quantity to guarantee a correct fitting
- Bad skin condition
- Patients with a reduced recuperative and nutritional capacity as a result of disease, use of medicines, therapy (radiation) or habits (alcohol abuse, drug abuse, etc.)
- Psychological factors
- Hypersensitivity to titanium, vanadium, aluminium or hydroxyapatite.

The treatment of children must be carried out with care and previous experience on adults. Special attention must be directed at:

- Physical activity of the child
- Soft and/or thin bone
- Careful installation of the implant

It is recommended to perform a two-stage surgery with enough time for osseointegration.

PACKAGING
The implant is press-fitted in a plastic cap. This cap is press-fitted in a plastic vial. The cover screw is packed in the chamber in the cap. This chamber is closed with a lid. The sterile products are packaged in a peel-off blister pack.

STERILISATION
BioComp supplies implants that have been sterilized with gamma radiation. An intact blister pack protects the implant from external influences and guarantees the sterility until the expiry date.

Note: Do not use implants from damaged blister packs, since the sterility is no longer guaranteed.

STORAGE AND TREATMENT OF THE PACKAGING
BioComp implants must be stored in the sealed blister packaging in a dry place, without direct sunlight, at room temperature. The blister pack may only be opened shortly before or during the operation. Implants may not be used after the expiry date.

REGISTRATION
For the purposes of traceability, the data on the implant's label must be recorded in the patient's file (or the peel-off label from the label of the blister packaging can be transferred to the file).
In addition, we advise to hand over the relevant data to the patient in an implant passport. Implant passports are available for free at BioComp.

PROCEDURE
Application of the BioComp products is only permitted for professionals after proper training and thoroughly reading the manual and related publications.

Note: The use of an incorrect procedure can have irreversible consequences for the patient.

In brief, the following steps can be distinguished in the treatment:
- Patient research and selection
- Implant (site) selection
- Operation planning (signed informed consent statement)
- Preparation of the patient and the implant bed
- Placing the implant manually or mechanically
- Installation of cover screw, percutaneous abutment
- Percutaneous healing period
- Aftercare

The surgical procedure requires a high degree of precision and care. Endeavours must be made to minimize the injury to the host tissue, i.e. the bone and the soft tissues.

Caution must be exercised to minimize damage to the host tissue, i.e. bone and soft tissue. Particular attention should be paid to the result of thermal and surgical trauma and to the elimination of contaminants and sources of infection.

The following chart gives an overview of the usage of the different drills for preparation of the implant-bed:

	Preparation drills			Implant specific drills		
						
Implant	Rosen	Lindemann	Pilot	L 3 mm	L 4 mm	L 14 mm
L 3	✓	-	(✓)	✓	-	-
L 4	✓	-	(✓)	(✓)	✓	-
≥ L 6	✓	(✓)	✓	-	-	✓

NOTE
- The implant bed is in fact prepared to a depth up to 0.9 mm deeper than the length of the implant.

During drilling the quality and quantity of the cortical bone and the spongiosa should be reviewed, visually and with a blunt tool (dissector).

The permitted speed of drilling depends on the quality of the bone. Drills may be used at a maximum of 2000 RPM, for a maximum of 5 seconds, under pressure and with plenty of cooling. The maximum torque that may be applied to drills is 52 Ncm.

Following the completion of the implant bed the implant is fitted into the implant bed, by screwing it in at a low speed – at a maximum of 15 RPM and 45 Ncm.

Cover the implant with a cover screw (two-stage-surgery) or a percutaneous abutment (one-stage-surgery) before closing the wound. Use the BioComp hexagonal screwdriver for placing the percutaneous abutments.

After placement, the implant must be left in place, unloaded, for at least three months. More details are given in the BioComp CMF implant manual.

VERIFICATION
The CMF implant with an incorporated stop (length 3 and 4 mm) is in place when the implant flange is in contact with the bone.

The implant without an incorporated stop (length ≥6 mm) is in place when the top is flush with the bone.

In case a console-abutment will be placed on the implant it is important that one vertex of the internal hexagon of the implant is directed into the direction of the "arm" of the console-abutment.

The cover screw should be placed with a torque of 15 Ncm
The percutaneous abutment should be placed with a torque of 20-25 Ncm

SIDE-EFFECTS
The literature includes references to the following temporary side-effects: Pain, skin irritation and inflammation.

References are made to the following long-term complications as a result of surgery with implants: chronic pain as a consequence of permanent paraesthesia and anaesthesia; loss of marginal bone height; local or systemic infection; exfoliation of the implant; hyperplasia; loss of skin graft; numbness around the abutment; bone-infection; osseonecrosis; periimplantitis; perforation of the dura-mater; subdural hematoma; meningitis and osteoradionecrosis.

WARNINGS
It is important to devote sufficient attention to the motivation, hygiene and collaboration of the patient. Unrealistic expectations must be avoided at all times.

Factors such as bone quality, quantity and local infections play a crucial role in the fitting of implants.

In the event that drills, instruments or implants perforate the bone there is a risk of the perforation of a blood vessel. A correct evaluation of the clinical and radiological situation and a carefully-considered plan for the treatment are essential to the safe completion of the treatment.

Both the mechanical performance of the implant, abutment and prosthetic components and the long-term osseointregration can be detrimentally influenced by the absence of a passive fit of the restoration, an incorrect design of the prosthetic structure, trauma of tissues, and various other forms of biomechanical overloading.

Traumatic burdens arising from a non-passive connection between bridge and implants, substantial transverse forces and bending moments, can have a detrimental effect on osseointegration, and can result in implant failure.

An implant is intended for single use. Reuse of implants is not allowed. Because the surface can never be completely cleaned. Tissue can remain behind and can seriously disrupt integration, with risk of inflammation. Host versus Graft complications can arise, with rejection of the implant as a result.

Due to the limited size of the products, there is a risk of aspiration and / or ingestion of the products.

DISPOSAL MATERIALS
In the unfortunate event that an implant does not integrate or is lost overtime, we ask you to return the product to BioComp according to our guarantee scheme.

Dispose of waste according to the disposal rules established in your practice, in accordance with the current guidelines.

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