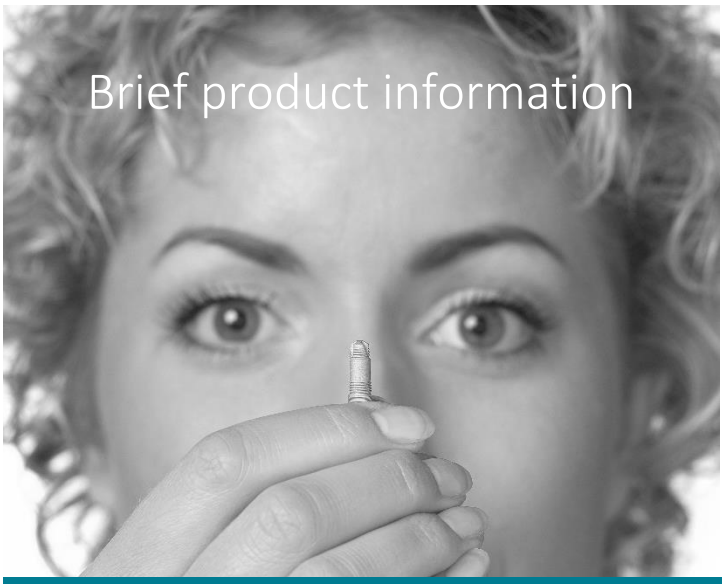

CRANIO MAXILLO FACIAL ABUTMENTS

BioComp®

BioComp® CMF abutment

Article	Length (mm)	Angle (°)
Percutaneous abutment	2/3/4/5	0
Console abutment	3,4	30/60/90

PRODUCT DESCRIPTION

BioComp CMF percutaneous abutments are cylindrical abutments intended for defining the percutaneous passage and, after the healing period, as a base for fitting a magnacap or bush for a bar construction.
After the skin is healed and calm, the percutaneous abutments can also be substituted by a console-abutment. The console abutment provides a shift and possible angulation-change of the connection for the magnacap or bush for bar.

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 all product ranges (with the same platform), the products are interchangeable.

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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 abutments manufactured from the high-quality titanium alloy, TI6AL4V, for medical devices. The alloy is composed of titanium, aluminium and vanadium.

INDICATIONS

Percutaneous abutments define the percutaneous transition during the healing process, of osseointegrating CMF implants. They can be placed directly after placement of the implant (one-stage-surgery) or after osseointegration of the, unloaded, implant (two-stage surgery).

After the implant is osseointegrated and the skin is healed and calm the percutaneous- or console-abutment is used as a base for the connection for the bar- or magnet construction. The console abutment provides a shift and possible angulation-change of the connection, possibly providing a better removal and placement handling for the patient.

CONTRA - INDICATIONS

Hypersensitivity to titanium, vanadium or aluminium.

Assuming that the placement of an implant is indicated correctly, no additional contraindications are known.

PACKAGING

The abutment is press-fitted in a plastic cap. This cap is press-fitted in a plastic vial.

Note: Percutaneous- and console-abutments are delivered *not* sterile.

STERILISATION

The percutaneous- and console-abutment must be cleaned and sterilized before it is placed on the implant.

Cleaning
- Clean by ultrasonic cleaning, in water, for 5 minutes.
- Clean by ultrasonic cleaning, in cleaning fluid (for example Secudrill) and rinse.
- Clean by ultrasonic cleaning, in alcohol, for 5 minutes.
- Dry.

Sterilization
- Packed with a class B autoclave
- Prion program 134 °C

STORAGE AND TREATMENT OF THE PACKAGING

BioComp CMF abutments are to be stored in the intact package in a dry place at room temperature.

REGISTRATION

For the purposes of traceability, the data on the 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

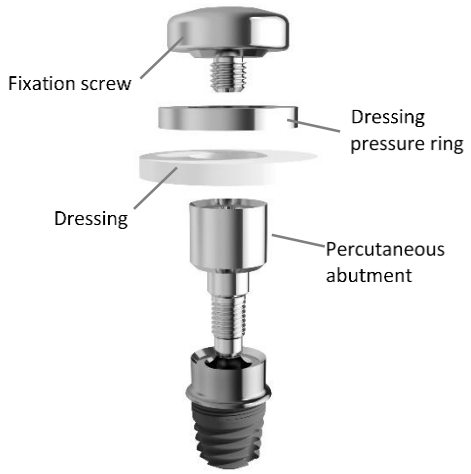
A percutaneous abutment can be fitted immediately or during the second-phase operation:

- The hole for the percutaneous transition must be punched with a ø 4.0 mm biopsy punch or made with a surgical knife exactly over the implant position.
- Place the abutment of the desirable height in the implant using the hexagon screwdriver.
- The percutaneous abutment should be tightened, manually or with the machine, with a torque of 20-25 Ncm (one-stage: hand tight)

PROCEDURE – HEALING PERIOD

To ensure skin-bone contact and to prevent a hematoma formation, there needs to be a dressing in place and a certain pressure applied on the skin. Many types of dressing are available and can be used depending on the situation and the wishes of the professional and the patient.

- Use the biopsy punch or cut a Ø4,0 mm hole in the dressing
- Use the biopsy punch of Ø8,0 mm, or bigger, to obtain dressing rings or cut a patient specific shape.
- Place the dressing ring around the percutaneous abutment directly on the (surgically) closed, not infected, wound
- Place the dressing pressure ring
- Tighten the fixation screw hand-tight
- Place a covering, for example a mastoid, pressure bandage



The day after surgery the outer pressure bandage may be removed. The patient must be made aware of the fact that the wound should not get in contact with water until 7 days after surgery (until the covers crew and dressing have been removed and the wound has healed).

Depending on the dressing the wound should be cleaned and new dressing should be applied after 5 to 6 days. One to two weeks after surgery the fixation screw and the dressing pressure ring and dressing may be removed. If present, the sutures can be removed. Assess the wound and treat and clean accordingly. When the skin is not yet fully healed, make a new appointment after one week and repeat previously described steps.

Ensure that the patient receives and understands the aftercare instructions to maintain a durable solution.

NOTE:

- Keep in mind that the tissue surrounding the implant will alter during healing, thus a different height percutaneous abutment may be needed before making the final prosthesis.
- Be careful not to overpressure the skin. This can delay the wound healing or even cause necrosis.

PROCEDURE – PERCUTANEOUS CONNECTOR

After the skin is healed and calm, the percutaneous abutment can be used as a base for fitting a magnet cap or bush for a bar construction on. The percutaneous abutments can also be substituted by a different height abutment, a console abutment, or an application specific abutment.

- Remove the fixation screw from the percutaneous abutment, using the BioComp hexagon screwdriver
- If applicable, remove the percutaneous abutment and place a different height percutaneous abutment or console-abutment. The abutment should be tightened, manually or with the machine, with a torque of 20-25 Ncm.
- Tighten the bush or cap, manually or with the machine, with a torque of 10-20 Ncm

Note:

- It is advised to leave the initially placed percutaneous abutment in situ unless it is really necessary to change the height or angle of the connection.
- During placement, the percutaneous abutment must be exactly aligned with the longitudinal axis of the implant.
- All secondary parts, tertiary parts and impression copings can be placed with the BioComp hexagon screwdriver.

VERIFICATION

The chosen abutment should, after placement, protrude above the tissue.

No gap may be present between the abutment and the implant.

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

WARNINGS

It is absolutely necessary that the top of the implant is free of residues before the abutment is placed.

Good hygiene is key for maintaining a durable percutaneous transition and prosthesis anchorage solution.
The patient should be instructed to take care of correct hygiene.
If an infection occurs, the cleaning routine should be checked.
Treat local infections in a timely fashion

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 abutment is intended for single use. Reuse of abutments 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 a product does not function, 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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