Instructions for use for medical devices:

R2UC-Abutments

Prefabricated Hybrid-Abutments with long-term stability and gingiva formers of identical shape for intraoral individualization for cemented prosthetic restorations on dental implants.

MEDTEOR

CE 0483

Preparation of abutments and gingiva formers before use:

The Hybrid-Abutments, gingiva formers and tools must be cleaned and sterilized by the user according to the RKI guidelines before use in the oral cavity. All components are suitable for repeated reprocessing in the RDG and steam sterilizer. The validated reprocessing and cleaning procedure of the products is described in the document "Information on reprocessing". This can be found as an appendix to these operating instructions or on the company website [1]. For additional information please refer to our WIKI [2].

Article numbers:

In order to simplify the handling of bonding bases and to avoid any mix-ups, the article number includes the implant type and diameter. The article numbers of the R2UC-Abutments and Gingivaformers are assigned as follows.

Gingivaformer:

Structure SKU Gingivaformer
S-MA35-[AA][BB]

R2UC-Abutment:

Structure SKU R2UC-Abutment
D-MA35-[CC][BB]-[DD][EE]-[FF]

Possible Identifiers		
AA	GS	Gingivaformer Small Platform
	GW	Gingivaformer Wide Platform
BB	AC	Anterior Canine
	AN	Anterior Small
	PM	Premolar
	PS	Premolar Straight
	MO	Molar
	MI	Molar Inverse
CC	HS	Hybrid-Abutment Small Platform
	HW	Hybrid-Abutment Wide Platform
DD	ZS	Zirconia Small Platform
	ZW	Zirconia Wide Platform
EE	SB	Short Bright
	LB	Long Bright
	SI	Short Intensive
	LI	Long Intensive
FF		Uncoated
	AD	Anodised
	NT	NT Surface
	TI	Titanium Nitride coated
	MS	Micro Structure
	NW	NW Surface
	SB	Sandblasted
	AS	Anodised Sandblasted

Intended user group:

The following descriptions are not enough for immediate application and further processing of the Hybrid-Abutments. Dental knowledge as well as instruction in the handling of Abutments is required in any case.

Contraindication:

Allergies or hypersensitivity to the chemical components of the materials used. The BASE adhesive bases of the respective series may only be combined with the implant system intended for this purpose. No abutments with an unsuitable connection geometry may be used. Use of the Hybrid-Abutments as telescopic crowns is not indicated. All Hybrid-Abutments and gingiva formers are intended for single use only to avoid the risk of infection.

Materials used:

The adhesive bases were made of Ti6Al4V, Medical Grade 5, according to DIN EN ISO 5832-3. To reduce plaque build-up and improve aesthetics, they can be additionally coated or anodized with titanium nitrite plasma (TiN). The screws with conical head can have a DLC coating, recognizable by the black coloration, to reduce the friction coefficient in the cone.
Depending on the selection, the adhesive bodies consist of zirconium dioxide ceramic, lithium disilicate ceramic, PEEK/PEKKTON® or other dental hybrid materials and correspond to the commercially available materials for the crown and bridge technique. Allergies or sensitivities in connection with the materials used cannot be excluded in very rare cases. Different metallic alloys in the oral cavity can lead to galvanic reactions. In principle, therefore, metallic restorations should be avoided to prevent the release of ions.

Selection of the suitable abutment:

The selection of Hybrid-Abutments is very simple. There are two front teeth, one premolar and one molar each for the upper and lower jaw. All Abutments are adapted to the anatomical conditions by the angled screw channel and offer enough wall thickness for intraoral individualization. An A4L Hybrid-Abutment with straight screw channel can also be used if enough bone is available.
The use can be clarified and simulated in the educational and planning tool "Abutment Finder". It can be started directly on our website [3].
An X-ray planning template can also be downloaded from our website [4]. A4L libraries are also available for DVT planning. Please contact the manufacturer of the planning software or your DVT device.
Further information on exact size specifications and suggested use can be found in our online catalogue for the respective abutment system [5].

Material selection:

We recommend the use of Hybrid-Abutments with zirconium dioxide adhesive bodies due to their high mechanical stability and low plaque accumulation.

Colour selection:

The Hybrid-Abutments are offered in different colours. We recommend the shades "Intensive/Dentin" for use in the premolar and molar region and the shades "Light/Enamel" for use in the anterior region.

Time of insertion:

There are basically several clinical procedures:

A) The Hybrid-Abutments can be placed on an osseointegrated implant during the uncover, provided that the implant has been placed according to the manufacturer's instructions regarding rotation around the longitudinal axis. A gingiva former is not required.
B) The Hybrid-Abutments are placed at the same time as the implant. A gingiva former is not required.
C) The gingiva former is inserted at the same time as the implant. The gingiva formers are replaced with a Hybrid-Abutment of the same shape after osseointegration of the implant.

In both the first two cases, the Abutments should not and need not be removed from the implant after the soft tissue has healed.

Both procedures offer the possibility of growing soft tissue to the surface of the titanium base.
Warning: if the selected rotationally symmetrical gingiva former from the implant manufacturer is too small, it is generally not possible to exchange a Hybrid-Abutment for the healing cap from the implant manufacturer without a gradual shaping of the soft tissue or a surgical relief incision.

Recommended incision:
An optimal incision should allow for the tightest possible postoperative wound closure mesially and distally of the Abutment on the one hand, and the largest possible amount of attached gingiva and preservation or reconstruction of the papilla on the other.
We recommend a modified "Papilla-split-finger" technique after mixing. Periosteal slitting and mobilization of the buccal flap can be advantageous. Various incisions are shown on our website [6].

Positioning of the implant:
A) Orofacial: according to current studies, the implant shoulder should be positioned at least 1.5-1.8 mm from the buccal bone edge [7]. The Hybrid-Abutments are optimized for a central implant position on the alveolar ridge with reduced bone availability.
In the anterior region in particular, the implant position should be corrected palatally if the implant diameter is smaller. A gap (chamber) created between the implant and the buccal alveolar wall during immediate implant placement should be filled with bone replacement material [Degidi]. The anterior Hybrid-Abutments and gingiva formers are prepared for this procedure and are well adapted to the anatomical conditions. They offer very good soft tissue support.
However, a position that is too far orally chosen should be avoided [Bragger'15].
Due to the angulation of the Hybrid-Abutments in relation to the implant axis, the implant does not have to be positioned as perpendicular as possible to the masticatory plane (risk of apical perforation of the buccal lamella), but rather in the centre and thus with maximum stability in the existing bone.

B) Mesiodistal: the minimum distance from the implant to the adjacent tooth should be 1.5 mm and between two implants at least 3 mm. If necessary, a smaller implant diameter should be selected.
Tip: check the position of the pilot drilling with regard to the distance to the adjacent tooth by trying in the Hybrid-Abutment.

C) Apicocoronal (insertion depth): according to the manufacturer's instructions, the implant should only be inserted so deeply into the bone that the buccal shoulder is minimally below the bone edge (0.5 - 1 mm). The implant design in the shoulder region (rectangular or bevelled) must be considered. The design of the Hybrid-Abutments optimizes the transition from the implant shoulder to the Abutment in order to achieve the most long-term stable soft tissue situation possible. The latest clinical studies advise against an excessively deep position of the implant in the bone, as the stability of the implant is mainly gained in the area of the implant shoulder [Cochran].

D) Rotational position: as with all angled abutments, the implant must be aligned in the surgical procedure so that the angulation of the Abutment points in the desired direction and is ideally positioned with respect to the interlocking to the adjacent tooth and opposing jaw. In premolars or molars, for example, the "backpacker" (= groove-shoulder attachment) must be aligned exactly orally. Most implant manufacturers have therefore made a marking on the implant insertion instrument that provides information about the position of the anti-rotation protection. For example, the Straumann BL® system has three punctiform markings that must be aligned buccally. For Camlog® implants, a "nose" of the anti-rotation guard must point buccally. In case of a closed healing of the implant, we recommend the intraoperative try-in of the final Abutment, or at least a gingiva former, during implantation to ensure exact alignment. Both components can be reprocessed and sterilized again.

E) Contouring of the surrounding bone: the development of bacteria-proof implant-Abutment connections (usually conical connections) and the biocompatible coated surface of the Hybrid-Abutments reduces the biological width. A small distance between the basal surface of the Abutment does not necessarily lead to bone loss. However, to ensure a secure fit of the Abutment in the implant, care must be taken to ensure that the basal surface of the Abutment does not touch the bone crest. In this case, contouring of the bone, for example with a rose drill in mesio-distal and orofacial direction, is necessary.

Insertion torque:
The insertion torque of the implant during insertion should be measured and documented using a torque ratchet or resonance-frequency analysis (e.g. ISQ value with Osstell-Mentor® [8]). This is not only necessary for forensic reasons, but also serves to decide whether a final abutment, a gingiva former or a cover screw can be screwed onto the inserted implant.
If the implant insertion torque exceeds 30 Ncm or the ISQ value exceeds 65, the final Hybrid-Abutment can be placed on the implant immediately. The tightening torque of the screw is then lower than the insertion torque of the implant.
If the insertion torque is 20-30 Ncm or an ISQ of 60-65, a Healing Abutment should be used. This can be exchanged for the Hybrid-Abutment of the same shape at a later date without extending the treatment period.
If the primary stability is low, we recommend a conventional procedure in which the implant heals in a closed position and is exposed later.
Further information and illustrated instructions can be found on the Abutments4life website [9].
Ideally, an implant system with high primary stability should be used.

Placement of the abutment:
The Abutment must not be tilted during insertion and must engage securely in the anti-rotation device before the Abutment screw can be tightened to the prescribed torque. The implant interface must be free of any bone chips or tissue residues or other impurities. X-ray inspection can be used to ensure that the Abutment is correctly inserted in the implant interface.

Wound closure:
Primary wound closure, especially mesial and distal to the abutment, should be as tight as possible to prevent bacteria from advancing from the oral cavity to the bone. Contamination of the basal surface of the Abutment can thus be effectively counteracted. It is recommended to cover a remaining defect temporarily without pressure using suitable materials (e.g. Reso-Pac®, Haager & Werken [10]).
Monofilament, non-absorbable sutures are more suitable than braided or absorbable products.

Tightening torque of the screw:
The Hybrid-Abutments must be tightened manually with the appropriate screwdrivers or contra-angle handpiece inserts in a ratchet to a minimum of 17 and a maximum of 23 N cm according to the instructions on the packaging. Note that the torque of a poorly maintained mechanical ratchet can easily exceed 40 N cm, which can lead to wall rupture for small diameter implants.
Too low a tightening torque can lead to screw loosening and subsequent screw or abutment fracture.

Warning: It is essential to retighten the screws of the Hybrid-Abutments after osseointegration (8-12 weeks) to counteract the risk of screw loosening with possible abutment loss.
A "movable" implant restoration after the prosthetic restoration usually indicates screw loosening.

Healing phase:
The soft tissue should heal for at least three (!) months, regardless of the system used [Tarnow]. The osseointegration of the implant is therefore usually faster than the soft tissue integration.
During the healing phase, single-tooth implants must not be exposed to occlusal loads from the opposing jaw. Temporaries on Hybrid-Abutments must be shortened until the infra-occlusion is reached. They must also not be subjected to proximal forces from adjacent teeth, as their mobility may hinder osseointegration. Transversal loads caused by excessive tongue or cheek pressure must also be absorbed by means of (deep-drawn) splints.
Temporaries must not have any contact with the gingiva, especially around the Abutments, and must be shortened in order not to impair wound healing. Note that the soft tissue on the Hybrid Abutment may grow coronally [11].
Several implants restored with Hybrid-Abutments can be splinted with temporary restorations and allow a prosthetic restoration in occlusion. Please also observe the current guidelines of the consensus paper of the European Consensus Conference (EuCC) [12].
If A4L gingiva formers have to be used due to lower primary stability of the implant, they should be shortened extraorally to an epigingival level as far as possible to keep any mechanical stress away from the implant. Use low speeds to avoid heating of the PEEK and clogging of the tool. The screw head of the Abutments4life healing abutments is deliberately placed deep in order to be able to be used even with low gingival heights.

Preparation:
The preparation of Hybrid-Abutments is used to adjust the preparation margin to an exact epigingival level. This prevents subgingival cement residues. In the case of zirconium, only diamond tools approved for zirconium may be used to avoid damaging the lattice structure of the ceramic. Abutments4life offers a preparation set designed for the processing of Hybrid-Abutments. The internal geometry of the Hybrid-Abutments is designed by angling the screw channel in such a way that the minimum material wall thicknesses of the adhesive bodies are retained.
Warning: always use adequate water cooling.
As a rule, no retraction threads are required to represent the preparation margin, but they can be used in the aesthetically visible area.

Mechanical notes:
No metallic parts of the adhesive bases may be removed, for example, to allow greater angulation or to create more space for the veneer, as these are essential to ensure sufficient stability and fit.
Any kind of reworking of the connection geometry to the implant leads to fitting inaccuracies, which preclude further use.

Impression:
All common methods for taking impressions are suitable.
Warning: make sure that no torn off residues of the (low viscosity) impression material remain in the sulcus.

Sealing of the screw channel:
All screw channels must be closed in order to prevent food residues from being tapped in the screw channel and thus increase and adversely affect the bacterial flora.
For temporary closure during the healing phase, a light-curing one-component filling material for temporary inlay/onlay restorations (e.g. Voco Clip®) over a foam pellet has proven effective.
For permanent closure, we recommend the highly compressed insertion of PTFE tape (Teflon) into the screw channel. Occlusal sealing can be achieved with light-curing glass ionomer cements or composites.

Cementation:
For cementing the prosthetic restoration, temporary cements based on zinc oxide eugenol are recommended (e.g. ZAKK® Implant, R-dental or TempBond®, Kerr).
Cementation can also be done with zinc phosphate cement.
Resin-reinforced cements are only recommended in exceptional cases, since cement surpluses are difficult to detect.

Cleaning and reconditioning of tools:
The validated reprocessing and cleaning procedure of the products is described in the document "Information on reprocessing". This can be found as an attachment to these instructions for use or on the company website [1]. For additional information please refer to our WIKI [2]. The screwdrivers and tools used must be cleaned particularly carefully after use in the inner area of the working end. The use of an ultrasonic bath is recommended. Stubborn soiling, which can occur after insufficient cleaning and subsequent sterilization, should be removed with a probe tip or similar. If this is not done with the necessary care, the tool may not completely surround the screw head of the Abutment and destroy it permanently. The reusable products may only be used after successful reprocessing.Due to the high mechanical load, the screwdrivers must be replaced when there are visible signs of wear.

Special features for prophylaxis:
Excessive use of dental floss can permanently destroy the sensitive soft tissue complex around abutments on dental implants.
The use of small plastic-coated interdental brushes is preferable.
Patients should be instructed accordingly.

Invoicing:
Since the Hybrid-Abutments and gingiva formers from MEDTEOR can be used at the same time as the dental implants, they are certified as surgically implantable components according to class IIb, analogous to the implants. This results in a reduced tax rate for Hybrid-Abutments and gingiva formers in Germany.
The reduced tax rate does not apply to semi-finished components such as adhesive bases, which cannot be inserted intraorally without additional work steps.
Please note that in Germany discounts granted on implants or abutments must be given to patients [Bribery & Corruptibility in the legal system; 13].

Batch traceability:
Implants and abutments are subject to batch traceability. This means that the practice must always be able to trace which patient has been restored with which implant or Abutment batch. This traceability is required by law due to possible recall actions.
Attention: Not all dental associations have yet implemented this EU directive in their areas.
It is therefore strongly recommended to document the batch information provided in the patient file or implant passport.
The information can be found on the delivery note, the invoice and on the packaging. All A4L labels for intraorally usable medical devices are additionally provided with 2D barcodes for article number and batch information. They can be read with a standard barcode reader, which simulates a keyboard input, independent of the software provider. The label is removable and can be glued into the index card.
Warning: ensure that there is no mix-up during sterile preparation of the Abutments.
Warning: for reasons of batch traceability of medical devices, opened packages cannot be returned! The products are not intended for reuse, but only for single use.

Shelf-life and storage:
Hybrid-Abutments and gingiva formers should be stored in a dry place at room temperature and preferably without direct exposure to light. Gingiva formers should be stored protected from strong UV radiation, as UV light can affect the colour of the material. If stored correctly, the products have an unlimited shelf life and can be used safely.
The manufacturing date can be derived from the first digits of the lot/batch number.

Warranty:

We give a 5-year warranty on the mechanical stability of the adhesive bases above the implant shoulder - if processed professionally and in accordance with our processing instructions.
Regardless of this, the information conveyed verbally, in writing or in lectures is based on tests and empirical values and can therefore only be considered as standard values.
Our products are subject to constant further development. In this context, we reserve the right to make product changes regarding design and composition or dimension.

Notes:
All serious incidents occurring in connection with the device must be reported to the manufacturer and the competent authority of the Member State (e.g. BfArM) where the user and/or patient is located.

Legend:

	Article number
	Batch number
	For single use only
	Follow instructions for use
	Non-sterile

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Links:
[1] https://ifu.medteor.com
[2] http://abutments4life.de/mediawiki/index.php?title=Sterile_Aufbereitung_in_der_Zahnarztpraxis
[3] https://abutments4life.de/en/abutmentfinder/
[4] https://abutments4life.de/en/downloads/
[5] http://shop.medteor.com/
[6] https://abutments4life.de/en/soft-tissue-management/
[7] http://onlinelibrary.wiley.com/doi/10.1002/9781119140474.ch11/summary
[8] http://www.osstell.com/
[9] https://abutments4life.de/en/one-abutment-the-1st-time/
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