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1. The identification and general information

1.1. Device trade name(s)

RC-Base, C-Base, Multi-Unit-Abutment (MUA), Hybrid-Abutment, M-Base, LTS-Base

1.2. Manufacturer's name and address

Medteor GmbH
Industriestrasse 2-4
77728 Oppenau

1.3. Manufacturer's SRN (single registration number)

DE-MF-000019576

1.4. Basic UDI-DI & Classification

Ti-Bases & Components (Class IIb)
B-04251777800980, B-04251777801147, B-04251777800973, B-04251777800959, B-04251777801130, B-04251777800942, B-04251777800928, B-04251777801123, B-04251777800911
Screws: (Class IIa)
B-04251777801499, B-04251777801154

1.5. Medical device nomenclature description / text

Abutments: Titanium-Base, Ti-Base, Abutment, Hybridabutment
Screws: DP-Screw, Screw

1.7. Year when the first certificate (CE) was issued covering the device

2013

1.8. Authorised representative :

Megagen Implants, Korea (SRN)

1.9. Products are under surveillance of Notified body (NB)

Medical Device Certification Stuttgart, 0483

2. The intended purpose of the device

2.1. The device's intended purpose

All abutments are intended to fix screw-retained or cemented prosthetic restorations on dental implants with reduced residual dentition or edentulous jaw.

Intended patient 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.

2.2. Indications:

For the restoration of single-tooth gaps to implant-supported restoration of edentulous jaws in patients with completed bone growth. Products and components are intended for single use.

2.3. Contraindications

Allergies or hypersensitivity to the chemical components of the materials used. The Abutments 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. All Abutments and gingiva formers are intended for single use only to avoid the risk of infection.

3. Description of the device:

3.1. Description

The abutments are supplied with screws with a conical head or with a double thread.
Conical screws are inserted into the abutment from the occlusal side, double-threaded screws are inserted from the basal side.

Materials used:
The Multi-Unit-Abutments and their components are 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 anodized or coated 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.
In very rare cases, allergies or sensitivities related to the materials used cannot be excluded. Different metallic alloys in the oral cavity can lead to galvanic reactions. In principle, therefore, metallic supplies should be avoided to prevent the release of ions.

The products can be sterilized both in autoclave and by alcohol.
Abutments are available with straight, 11° degrees, 22° degrees angled screw-/tool channel. They are provided in several heights.

3.2. Previous generation(s)

Compared to the first generation of titanium bases for single-tooth restorations (C/RC base), the manufacturing process has been changed to additive manufacturing.
This increases the elasticity of the abutments without reducing the mechanical strength. In addition, the manufacturing process allows the wall thickness to be increased at points subject to mechanical stress.
In addition, the TiN coating was replaced by an anodization. This passivates any structural defects in the surface with a metal oxide (=ceramic).

All multi-unit abutments are manufactured using the additive process.
By using the double-thread screw, the second occlusal screw hole can be omitted and the mechanical stability is increased many times over.

3.3. Accessories

All accessories are medical devices.

3.4. Combinations

C-/RC-Bases and Multi-Unit-Abutments are intended to be combined with gingiva formers during the healing period.
Prosthetic components for Multi-Unit-Abutments are medical devices Class IIb, too. They are used to securely anchor the prosthetic restoration to the implants.
Pls refer to

4. Risks and warnings, precautions

4.1. Remaining risks and undesirable effects

Special feature: Double Pitch screw

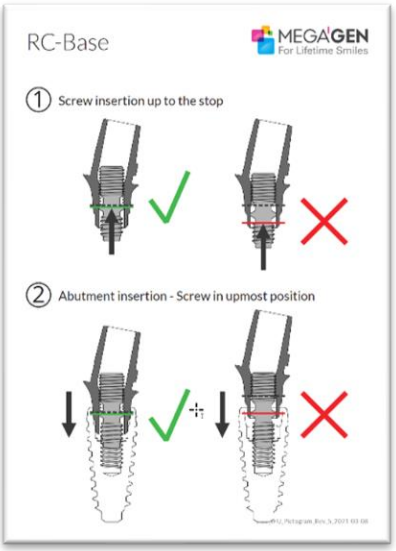
The Multi-Uni-Abutments / MU-Bases are delivered with a new type of Double Pitch (DP) screw, which is already screwed into the abutment. It cannot be removed upwards through the tool channel. It is unscrewed apically for possible replacement.

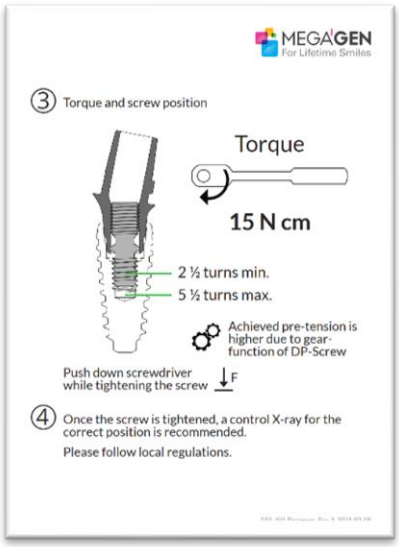
The DP screw provides the same preload force at half the tightening torque as a conventional abutment screw with classic head. This counteracts the risk of twisting of the implant during the surgical phase. When unscrewing the screw, the Abutment is automatically separated from the implant after a few turns.

When screwing in or unscrewing a restoration over several implants, care must be taken to ensure that the tightening forces are evenly distributed.

The screw with its stopper must be in the uppermost screw-in position before inserting the implant.

If this is not ensured by the user, there is a high risk that the prosthetic restoration will fail. (Probability of occurrence)





Warning: To detect a possible error, either count the number of turns when screwing in the screw (2.5 - 5.5 turns) or take a control X-ray. (Visible gap between the lower end of the screw and the bottom of the screw hole in the implant).

The incorrect fit of the abutment can be eliminated by simply opening the screw counter clockwise to the stop and a palpable click without causing / leaving any damage. The extent of damage is small. (Severity of harm)

The remaining risk of an incorrectly inserted abutment and the associated screw loosening is negligible and can be removed on an outpatient basis by any colleague.

But especially experienced colleagues tend to disregard the instructions for use or provided explanatory videos. This was determined in in-house product monitoring during the first year of using the DP-Screw.

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.

Tightening torque of the screw:

The Multi-Unit-Abutments must be tightened with the appropriate screwdrivers or contra-angle handpiece inserts to a minimum of 15 and a maximum of 20 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 fracture in small diameter implants. The screwdrivers are equipped with a torque limiter and will break outside the abutment if not properly loaded. Bending of the screwdriver indicates overload and is intended for tactile feedback.

Insufficient tightening torque can lead to screw loosening and subsequent screw or Abutment fracture.

Warning: It is essential to retighten the Abutment screws after osseointegration (2-8 weeks) to counteract the risk of screw loosening with possible Abutment loss.

A "movable" implant restoration after the prosthetic restoration usually indicates screw loosening.

Prosthetic fitting:

Several implants restored with Multi-Unit-Abutments can be interlocked with temporary or final restorations via the sleeves/shells and enable a prosthetic restoration in occlusion.

Residual Risks and Side effects	Probability	Severity of harm
Incorrect seating due to incorrect screw position	High (>30%)	Low: to be fixed on an outpatient basis and negligible (retighten the screw)
Overtorqued screw	Low (25%)	Low: to be fixed on an outpatient basis and negligible (Screwdriver fractures)
Tilted abutment	Very low (10%)	Low: Screw cannot be inserted into the threads of the implant
Screw loosening	Very low (10%)	Low: to be fixed on an outpatient basis and negligible Reduced pitch of upper threads

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.

4.2. Warnings and precautions

Explaining Videos for correct insertion of the abutments can be found on our website:
https://medteor.com/ifu

Especially what happens if instructions for use are not followed:
https://medteor.com/user/pages/ifu/01.r2uc-base-rc-base-preform-scanbody-screw/screw_ifu_rev2.mp4?loading=auto

4.3. Other relevant aspects of safety

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.

Cleaning and reprocessing of the 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 under Service> Downloads> Cleaning instructions [1]. For additional information please refer to our WIKI [2]. After use, the screwdrivers and tools used must be cleaned particularly carefully in the area of the working end. It is recommended to use an ultrasonic bath. Persistent soiling, which can occur after insufficient cleaning and subsequent sterilisation, must be removed with a probe tip or similar. The reusable products may only be used after successful reprocessing.
Due to the high mechanical load, the screwdrivers are subject to mechanical wear and must be replaced when there are visible signs of wear.

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 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:

Abutments, sleeves and components 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, since 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.

5. Summary of safety and clinical performance

This Summary of Safety and Clinical Performance (SSCP) is intended to provide public access to an updated summary of the main aspects of the safety and clinical performance of the device. The information presented below is intended for patients or lay persons. A more extensive summary of its safety and clinical performance prepared for healthcare professionals is found in the first part of this document.

The SSCP is not intended to give general advice on the treatment of a medical condition. Please contact your healthcare professional in case you have questions about your medical condition or about the use of the device in your situation. This SSCP is not intended to replace an Implant card or the Instructions For Use to provide information on the safe use of the device.

The offered products show a acceptable and positive benefit-risk ratio based on clinical evaluation results and clinical data evaluating undesirable side-effects.
This SSCP will be available in Eudamed and on MEDTEOR website: ifu.medteor.com

5.1 Device identification and general information

- Trader: MEGAGEN Implants
- Trade name: RC-Base, C-Base, Multi-Unit-Abutment (MUA), Hybrid-Abutment, M-Base, LTS-Base
- Manufacturer: MEDTEOR GmbH, Industriestrasse 2-4 77728 Oppenau
  Ti-Bases & Components (Class IIb)
  B-04251777800980, B-04251777801147, B-04251777800973, B-04251777800959, B-04251777801130, B-04251777800942, B-04251777800928, B-04251777801123, B-04251777800911
  Screws: (Class IIa)
  B-04251777801499, B-04251777801154
- Year of first CE mark: 2013

5.2 Intended use of the device

- Intended purpose: to fix prosthetic restorations on dental implants
- Indications and intended patients group: patients with completed bone growth
- Contraindications: patients with allergies against Ti-alloys

5.3 Device Description

- materials substances in conflict with patient tissues: Ti Grade 5, PVD coated or anodized
- Ti-Baes for single tooth restorations and Multi Unit Abutments can be combined with gingiva formers and prosthetic components (sleeves)

5.4 Risks and warnings

Contact your healthcare professional if you believe that you are experiencing side-effects related to the device or its use or if you are concerned about risks. This document is not intended to replace a consultation with your healthcare professional if needed.
Potential risk of screw loosening is reduced by lower pitch.
Over torquing of screws is prevented by a fracture zone in screwdriver
Tilted abutments cannot be screwed in
incorrect seating of an abutment due to a not correctly inserted abutment screw is explained by videos, animations and IFU´s
There are no undesirable effects known. No field safety corrections were performed. The products lifetime is not limited.

5.5 Summary of clinical evaluation and Post market clinical follow up

The offered products represent an improvement of the titanium bases previously available on the market. They are better adapted to the anatomy due to the implemented angulation. And they show a lower adhesion of bacteria.
Due to the additive manufacturing process, the abutments have a higher elasticity with greater mechanical stability.
The surface coatings (PVD as well as anodization) reduce the adhesion of bacteria and reduce the risk of peri-implantitis.
Long-term mechanical and biological stability has been adequately demonstrated after 9 years of incorporation of the angled solution products.
Recent case reports with long term observation also confirm an equivalent clinical performance of the additively manufactured products. (Int. journal of Future Dentistry: 2022 Vol.2: No2 Alshafi Y, Restoring Implants with angled channel using RC-Base 1year follow up
Since date of first CE mark Feedback from application, clinical studies, data collection, subject matter experts and universities, market requirements and new regulatory standards was evaluated. Likewise, all complaints from customers and clinical data from device registries were evaluated and have been incorporated into the products. There have been no recalls to date and the long-term safety and performance has been confirmed.

Various studies and research projects are currently being conducted with the abutments in order to fundamentally further improve biological acceptance and the risk of peri-implantitis:
Internal studies and studies conducted at KIT have shown that a microstructured surface with a suitable groove structure can influence the direction of soft tissue cell growth.

In this way, an attachment of the soft tissue to the abutment should be achieved. The penetration of bacteria into the implant sulcus is thus prevented.

In another project, the elasticity of the abutments is to be increased so that they can act as stress breakers. However, the mechanical stability should not be reduced. New super elastic titanium alloys, which can currently only be produced additively, are currently being tested.

6. Possible diagnostic or therapeutic alternatives

As an alternative to the abutments offered by MEDTEOR, competitor products, e.g., from MEDENTIKA, Antogyr, NT-Trading or similar companies, can be used.
In this case, care must be taken to ensure an optimal fitting of the components to the implant system.
Please contact your healthcare professional in case you have questions about therapeutic alternatives.

7. Suggested profile and training for users

Before the professional user uses the abutments with double-threaded screws in particular, he should be familiarized with the special features of an abutment screw inserted from basal by the sales representatives or at least by online training.
The information must be available to both the surgeon and the prosthodontist.
The handling of the product must also be internalized in the dental laboratory and among the assistants (hygiene).

8. Reference to any harmonised standards and CS applied

1. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC Artikel 32

2. Council Directive 93/42/EEC of 14 June 1993 concerning medical devices
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01993L0042-20071011

3. Council Directive of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (90/385/EEC)
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:01990L0385-20071011

4. The European Survey on Language Competences: measuring foreign language student proficiency. Patrícia Costa and Patrícia Albergaria-Almeida / Procedia - Social and Behavioral Sciences 191 (2015) 2369 – 2373
https://www.sciencedirect.com/science/article/pii/S187704281502515X

5. Summaries of Clinical Trials Results for Laypersons
https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-10/2017_01_26_summaries_of_ct_results_for_laypersons.pdf

6. Common European Framework of Reference for Languages: Learning, teaching, assessment (CEFR)
https://www.coe.int/en/web/common-european-framework-reference-languages/home

7. WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects
https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/

8. EK-MED MDCG 2019-9

9. Revision history

SSCP Rev. #	Date issued	Change description	Revision validated by MDC-CE
0	2022-12-17	First release	Yes ( ) Validation language: EN No ( ) (only applicable for class IIa or some IIb implantable devices (MDR, Article 52 (4) 2nd paragraph) for which the SSCP is not yet validated by the NB)