MEDENTiKA®

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Manufacturer
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Fabricante

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MedentiBASE abutment for multi-unit screw-retained bridges and bar elements

Indication
Restoration of the esthetics and functionality of the teeth in partially or fully edentulous patients.

Intended use
For the production of multi-unit, screw-retained bridges and bar elements on implants.

Contraindication
Allergies or hypersensitivity to the chemical components of the materials used.

Compatibility
The MedentiBASE abutment may be used only in combination with a compatible implant system. The respective implant diameters must be observed. The medical device is compatible with the following implant series:

Series of the medical device	Manufacturer of the implant system	Compatible implant system
B-Series	Bredent Medical	SKY®*
C-Series	Camlog	Camlog®*
	Medentika®	Procone
D-Series	Camlog	Conelog®*
E-Series	Nobel Biocare	NobelReplace®* Tapered
F-Series	Nobel Biocare	NobelActive®* NobelReplace®* Conical
H-Series	BIOMET 3i	Certain®*
I-Series	BIOMET 3i	External Hex
K-Series	Nobel Biocare	Brånemark System®*
L-Series	Straumann	Bone Level
N-Series	Straumann	Soft Tissue Level
R-Series	Zimmer Dental	Tapered Screw-Vent®*
	MIS	SEVEN Internal Hex
	BioHorizons	Tapered Internal Tapered Internal Plus Tapered Tissue Level
S-Series	DENTSPLY SIRONA	ASTRA TECH OsseoSpeed®* TX
T-Series	DENTSPLY SIRONA	XiVE®* S
Y-Series	DENTSPLY SIRONA	ANKYLOS®* C/X
	Medentika®	Microcone Quattrocone

*Products indicated with ® are registered trademarks of the corresponding manufacturer

Materials

MedentiBASE abutment	Titanium grade 5
MedentiBASE cover cap	Titanium grade 5
MedentiBASE titanium cap	Titanium grade 5
MedentiBASE titanium base	Titanium grade 5
MedentiBASE adhesive base	Titanium grade 5
MedentiBASE bridge screw	Titanium grade 5
MedentiBASE implant pick-up	Titanium grade 5
MedentiBASE laboratory implant	Titanium grade 5
MedentiBASE gold cap castable	Gold (Au) 60,00%; Platin (Pt) 19,00%; Palladium (Pd) 20,00%; Iridium (Ir) 1,00%
MedentiBASE scanbody	Titanium grade 4, special coated
MedentiBASE placement instrument	Stainless steel

Tightening torques for the abutment screws	
Series	**Ncm**
B	25
C 3,3 C 3,8 / 4,3	20 30
D	20
E	35
F	35
H	20
I	35
K	35
L	35
N	35
R	30

Tightening torques for the abutment screws	
Series	**Ncm**
S	25
T	25
Y	25
Microcone/ Quattrocone RI	25

Tightening torque for the bridge screw	
all series	15

Only use torque values recommended by the manufacturer. Please note that an inadequately maintained torque wrench may tighten to above or below the recommended/adjusted torque setting. This can lead to screw loosening or screw-implant fractures.

Application
The MedentiBASE abutments are directly screwed into the implant and have a universal mounting on the face side for various additional prosthetic parts.
The bridge or bar elements are produced whilst using prosthetic components or digital (scanners) and screwed onto the MedentiBASE abutments.

Bonding of MedentiBASE adhesive base (passive-fit)
Sandblast the outer surfaces of the glue panels (grain 50 µm, 2 bar), Sandblast the inner surfaces of the construction (grain 50 µm, 2 bar).
Clean and dry the glue panels and the construction. Screw the MedentiBASE abutment onto the plaster model with the aid of the M 11-6 / 0-13-37 placement instrument and subsequently coat it with Vaseline to prevent cement from subsequently sticking to it. Screw the adhesive base onto the MedentiBASE abutment and block out the screw head with soft wax.
Coat the screw channel of the construction with Vaseline.
Notice: No Vaseline may be on the bonding surfaces.
Line the screw channel with cotton batting to protect it from the cement. Condition the bonding surfaces in accordance with the manufacturer's instructions. Mix the cement, apply it to the construction and the adhesive base and carefully place the construction on the adhesive base. Once the cement has hardened remove the cotton batting from
the screw channel and carefully remove the wax from the screw head with a probe.

Detach all the screws with the screwdriver provided and take the finished product from the model (the screw channel must be free of residual cement!). Once the frame has been detached remove the excess cement with a silicone polisher and subsequently finish the work accordingly.
Notice: Please observe the user instructions of the cement manufacturer.
Recommendation for cement: Multilink® Implant, IvoclarVivadent.

Safety notice
Metal dust is harmful to health. When machining and sandblasting use a suction with a fine dust filter that is usual in practice and wear protective goggles as well as a face mask.

Side effects
Allergies or sensibilities in connection with the alloy cannot be ruled out in very rare instances.

Interactions
Various alloy types in the same mouth cavity can lead to galvanic reactions in the event of occlusal or proximal contact.

Cleaning and sterilization
Please refer to the relevant section of the Preparation instructions
https://www.medentika.com/en/ifu

Warning
The product has to be inspected prior usage. The packing must be sealed without any visible damage. The following descriptions are not sufficient for the immediate use of the product. Dental skills and prior instruction of how to use the product are at any rate required.
The information conveyed orally, in writing or in practical seminars is based on tests and experience and can therefore only be considered to be standard values. Our products are subject to constant further development. In this connection we reserve the right to make product changes in relation to the design and composition.
In general, when inserting the abutment, it must be ensured that the patient cannot aspirate or swallow the abutment screw.

MRI information
These products are fabricated from a metal that can be affected by MRI energy. Further information on MRI Safety Information can be found at
https://www.medentika.com/en/ifu

Signs and symbols

LOT	Lot number
REF	Article number
	Manufacturer
	Date of manufacture
	See Instructions for Use
Rx ONLY	US Federal law restricts this device to sale by or on the order of a doctor.
NON STERILE	Non-sterile
	Do not re-use
CE 0483	CE marking with the identification number of the Notified Body
	Attention
MD	Medical Device
	Keep dry

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Multi-unit Abutment

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Multi-unit abutment

Multi-unit abutment and multi-unit prosthetic components for multi-unit, screw-retained bridges and bar elements

1. Indication
Restoration of the esthetics and functionality of the teeth in the partially or fully edentulous patient.

2. Intended use
For the production of multi-unit, screw-retained bridges and bar elements on implants, and in connection with the Multi-unit screw patrix on the Multi-unit abutment, for the production of the overdenture or partial prostheses.

3. Contraindications
Allergies or hypersensitivity to the chemical components of the materials used.

4a. Compatibility
The multi-unit abutment may only be used in combination with a compatible implant system. The respective implant diameters must be observed.
The medical device is compatible with the following implant series:

Series of the medical device	Manufacturer of the implant system	Compatible implant system
C-Series	Camlog	Camlog®*
	Medentika®	Procone
DT-Series	Dentium	SuperLine, Implantium, Implantium II
E-Series	Nobel Biocare	NobelReplace®* Tapered
EV-Series	DENTSPLY SIRONA	ASTRA TECH OsseoSpeed®* EV
F-Series	Nobel Biocare	NobelActive®* NobelReplace®* Conical
H-Series	BIOMET 3i	Certain®*
L-Series	Straumann	Bone Level
MG-Series	Megagen	AnyRidge®
N-Series	Straumann	Soft Tissue Level
NE-Series	NEOSS®	ProActive®
OT-Series	Osstem Implants	TS System
	HiOssen Implant®*	ET-System
	T-Plus Implant Tech	A+ Implant ST Implant
R-Series	Zimmer Dental	Tapered Screw-Vent®*
	MIS	SEVEN Internal Hex
	BioHorizons	Tapered Internal Tapered Internal Plus Tapered Tissue Level
S-Series	DENTSPLY SIRONA	ASTRA TECH OsseoSpeed®* TX
Y-Series	DENTSPLY SIRONA	ANKYLOS®* C/X
	Medentika®	Microcone Quattrocone

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4b. Materials:

	Materials
Multi-unit abutment	Titanium Grade 5
Multi-unit cover cap	Titanium Grade 5
Multi-unit titanium cap	Titanium Grade 5
Multi-unit titanium base	Titanium Grade 5
Multi-unit implant pick-up	Titanium Grade 5
Multi-unit laboratory implant	Titanium Grade 5
Multi-unit bridge screw	Titanium Grade 5
Multi-unit screw patrix	Titanium Grade 5 Coating: ADLC (Novaloc) TiN (MedentiLOC)

	Materials
Multi-unit scanbody	Special coating with titanium grade 4
Multi-unit gold cap, castable	Gold (Au) 60.00%; platinum (Pt) 19.00%; palladium (Pd) 20.0%; iridium (Ir) 1.00%
Multi-unit placement instrument	Stainless steel
Multi-unit CoCr cap	CoCr alloy: Cobalt (Co) 67 % Chromium (Cr) 28 % Molybdenum (Mo) 5 % Carbon (C), silicon (Si), manganese (Mn), iron (Fe) and nitrogen (N) < 1 % CTE: 14.1 10-6K-1 (25-500°C)

5. Product description
The multi-unit abutment is used to produce multi-unit, screw-retained bridges and bar elements on implants.
The multi-unit abutment is available in three different variants:
- Straight
- Angled 17°
- Angled 30°

The multi-unit abutment also has various gingival heights (these vary depending on implant connection).
The multi-unit abutments are supplied sterile and can therefore be used in the implant without further preparation. Observe the cleaning instructions in the laboratory after use.

Please observe the following torque values:

Torque values

Series	Multi-unit abutment (Ncm)
C 3,3 C 3,8 / 4.3 / 5,0 / 6,0	20 30 / 20 for angled design
DT	25
E	35
EV	25
F 3,0 F NP/RP/WP	15 35
L	35
MG	30
N	35
NE	32
OT Mini OT Regular	30 / 20 for angled design 30
R	30
S 3,5 / 4,0 S 4,5 / 5,0	20 25
Y	25
Microcone NI	15
Microcone/ Quattrocone RI	25
Quattrocone30 AI	25
Multi-unit bridge screw Multi-unit screw patrix Prosthetic parts (Ncm)	
All series	15

Only use torque values recommended by the manufacturer. Please note that an inadequately maintained torque wrench may tighten to above or below the recommended/adjusted torque setting. This can lead to screw loosening or screw-implant fractures.

6a. Application
The multi-unit abutments are screwed directly into the implant with the corresponding placement instrument M 11-11 (multi-unit abutment, straight) or with the placement instrument designed for the implant series. The front of the multi-unit abutment features a universal holder for a range of further prosthetic components. Using the prosthetic components for the manual workflow or digital (scanner), the bridges or bar elements are created with the aid of a scanbody and are screwed to the multi-unit abutment using the bridge screw.
The multi-unit titanium base Flex can be individually shortened at the designated grooves and can be seen in the digital workflow (library).

6b. Work-up
Any form of reworking of the insertion geometry in relation to the implant will lead to inaccurate fitting, preventing any further use. Furthermore, the bonding surfaces of the titanium base must not be ground down or changed, since these are vital for ensuring adequate stability. Exception: trimming of the chimney at the specifically designated sites/notches. Diamond tools in perfect condition should be used, with water cooling and low pressure, for processing structures, e.g. zirconium. The minimum wall thickness is 0.5 mm, and ridges and edges must be avoided. Caution: Note the manufacturer's instructions on the material used!

6c. Bonding the multi-unit titanium cap/Flex; multi-unit titanium base/ASC
Sandblast the exterior surface of the multi-unit titanium cap; multi-unit titanium base/Flex (particle size 50 µm, 2 bar).
Note: Protect the internal surface of the multi-unit titanium cap/base during sandblasting by screwing on the multi-unit laboratory implant or using wax or a suitable material.
Prepare the internal surface of the construction as recommended by the material manufacturer. Clean & dry the multi-unit titanium cap/Flex; multi-unit titanium base/ASC and the construction. Coat the multi-unit abutment with Vaseline to prevent cement adhering to it at a later stage. Screw the multi-unit titanium cap/Flex; multi-unit titanium base/ASC to the multi-unit abutment and block the screw head with soft wax. Coat the screw channel of the construction with Vaseline.
Note: Ensure that there is no Vaseline on the adhesive surfaces.
Fill the screw channel with cotton wool to protect if from cement.
Condition the adhesive surface according to the manufacturer's instructions. Mix cement and apply to the construction and adhesive caps. Then carefully place the construction on the adhesive caps.
After mixing the cement, remove the cotton wool from the screw channel and carefully release the wax from the screw head using a probe. Loosen all screws with the specific screwdriver and remove the construction from the model (ensure that there are no cement residues in the screw channel).

Use of multi-unit screw patrix
The multi-unit screw patrix is used to secure the overdenture or partial prostheses to multi-unit abutments. The multi-unit screw patrix is screwed directly onto the multi-unit abutment and has a defined slot for the Novaloc matrix system on its front surface.
Please refer to the following webpage for further information on the matrix system: http://www.valoc.ch/959.php

Any form of reworking of the insertion geometry in relation to the multi-unit abutment and the front attachment points in relation to the matrix system is prohibited.
The multi-unit screw patrix is screwed to the multi-unit abutment, straight, or the multi-unit abutment, angled with the series-specific placement instrument. A torque of 15 Ncm must be applied.

Using the multi-unit titanium cap Flex:

The multi-unit titanium cap Flex has variable chimney heights. The titanium cap Flex is supplied with a chimney height of 14.5 mm. This can be individually shortened at the predefined grooves at intervals of 2 mm to 4.5 mm. These chimney heights are defined in the CAD library.

7. Side effects
Allergies or sensitivities connected with the alloy cannot be ruled out in very rare isolated cases.

8. Interactions
Different alloy types in the same mouth can, in the event of occlusal or approximal contact, lead to galvanic reactions.

9. Cleaning, disinfection and sterilization
Pleaser refer to the relevant section of the Preparation instructions
https://www.medentika.com/ifu

10. Warning
The integrity of the product must be inspected before use. If the packaging is damaged the product may not be used. The descriptions are insufficient to allow immediate use of the abutments. Dental/technical skills and instruction in the handling of the abutments are also essential.
Since the information conveyed orally, in writing or in practical seminars is based on tests and experience, it can only be considered as standard values. Our products are subject to constant further development. In this respect, we reserve the right to make product changes in relation to the design and composition.
In general, when inserting the abutment, it must be ensured that the patient cannot aspirate or swallow the abutment screw. For angled Multi-unit abutments, where the abutment screw is already pre-assembled in the screw channel, the abutment screw may become loose from the screw channel.

11. MRI Safety Information
These products are fabricated from a metal that can be affected by MRI energy. Further information on MRI Safety Information is available at https://www.medentika.com/ifu.

12. Signs and symbols

LOT	Lot number
REF	Article number
	Manufacturer
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	See Instructions for Use
Rx ONLY	US Federal law restricts this device to sale by or on the order of a doctor.
NON STERILE	Non-sterile
STERILE R	Sterilized using irradiation
	Use-by date
	Do not re-use
CE 0483	CE marking with the identification number of the Notified Body
	Attention
MD	Medical Device
	Keep dry
	Do not use if packaging is damaged

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