**Instruction for use**

MedentiBASE Abutments

**Caution:** Federal (USA) law restricts this device to sale by or on the order of a licensed dentist or physician.

**Indications for Use**

Medentika abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Abutments are compatible with the following implant systems:

<table>
<thead>
<tr>
<th>Implant System</th>
<th>Series</th>
<th>Implant Diameters (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nobel Biocare®/NobelReplace® Tapered</td>
<td>E-Series</td>
<td>3.5, 4.3, 5.0, 6.0</td>
</tr>
<tr>
<td>Nobel Biocare®/NobelActive® - NobelReplace® Conical</td>
<td>F-Series</td>
<td>3.0, 3.5, 4.3, 5.0</td>
</tr>
<tr>
<td>BIOMET 3i®/Certain®</td>
<td>H-Series</td>
<td>3.25, 4.0, 5.0</td>
</tr>
<tr>
<td>BIOMET 3i®/External Hex</td>
<td>I-Series</td>
<td>3.25, 3.75, 4.0, 5.0</td>
</tr>
<tr>
<td>Nobel Biocare®/Brånemark®</td>
<td>K-Series</td>
<td>3.3, 3.75, 4.0, 5.0</td>
</tr>
<tr>
<td>Straumann®/Bone Level®</td>
<td>L-Series</td>
<td>3.3, 4.1, 4.8</td>
</tr>
<tr>
<td>Straumann®/Soft Tissue Level®</td>
<td>N-Series</td>
<td>3.3, 4.1, 4.8</td>
</tr>
<tr>
<td>Zimmer Dental®/Tapered Screw-Vent®</td>
<td>R-Series</td>
<td>3.3, 3.7, 4.1, 4.7, 6.0</td>
</tr>
<tr>
<td>MIS®/SEVEN® Internal Hex MIS®/SEVEN®</td>
<td>S-Series</td>
<td>3.0, 3.5/4.0, 4.5/5.0</td>
</tr>
<tr>
<td>BioHorizons®/BioHorizons® Tapered Internal - Tapered Internal Plus - Tapered Tissue Level</td>
<td>T-Series</td>
<td>3.4, 3.8, 4.5, 5.5</td>
</tr>
<tr>
<td>DENTSPLY Implants®/ASTRA TECH OsseoSpeed® TX</td>
<td>Y-Series</td>
<td>3.5, 4.5, 5.5, 7.0</td>
</tr>
</tbody>
</table>

**Contraindications**

The abutments of each series can only be combined with the corresponding compatible implant system, e.g. the E-Series only in combination with the implant system Nobel Biocare®/NobelReplace® Tapered. No inappropriate in connection geometry abutments should be used. Any post-processing at the connection geometry to the implant may result in fitting inaccuracies prohibiting further use.

**How Provided**

All abutments are provided with the abutment screw for attachment to the dental implant.

**Composition**

MedentiBASE Abutments, MedentiBASE Covercap, MedentiBASE Titanium Cap, MedentiBASE Titanium Adhesive Cap, MedentiBASE Bridgescrew: Ti-6Al-4V, medical grade 5.

MedentiBASE Gold Cap Castable: Gold (Au) 60.00%; Platinum (Pt) 19.00%; Palladium (Pd) 20.00%, Iridium (Ir) 1.00%

MedentiBASE Scanbody: Stainless steel, special coated

MedentiBASE Implant Pick Up, MedentiBASE Lab Analog, MedentiBASE Screw Driver/Ratched: Stainless steel

**Warnings**

All abutments are intended for single use. Side effects: Allergies or sensibilities in connection with the alloy are rare but cannot be ruled out. Interactions: Various alloy types in the same mouth cavity can lead to galvanic reactions in the event of occlusal or proximal contact.

**MR Safety statement**

The MedentiBASE Abutment has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of the MedentiBASE Abutment in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.

**Torque**

Only the implant manufacturer’s recommended torque is to be used.

<table>
<thead>
<tr>
<th>Ncm</th>
<th>Abutment</th>
</tr>
</thead>
<tbody>
<tr>
<td>15</td>
<td>F-Series 3.0; S-Series 3.0</td>
</tr>
<tr>
<td>20</td>
<td>C-Series D-Series H-Series</td>
</tr>
<tr>
<td>25</td>
<td>B-Series; S-Series 3.5/4.0 4.5/5.0; T-Series; Y-Series</td>
</tr>
<tr>
<td>30</td>
<td>R-Series</td>
</tr>
<tr>
<td>35</td>
<td>I-Series; K-Series; L-Series; N-Series; E-Series; F-Series NP/RP</td>
</tr>
</tbody>
</table>

**Application**

Caution: The following descriptions are not sufficient for the immediate use of the MedentiBASE Abutment. Dental skills and prior instruction of how to use the MedentiBASE Abutments are required.

The MedentiBASE Abutments are directly screwed into the implant and have a universal mounting for various additional prosthetic parts.

The bridge or bar elements are produced using prosthetic components and screwed onto the MedentiBASE Abutments.
Bonding of MedentiBASE Titanium 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 insertion tool and subsequently coat it with Vaseline to prevent cement from subsequently sticking to it. Screw the glue panels 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 glue panels and carefully place the construction on the glue panels [Suggestion: Wipe the excess cement away with a fine paint brush]. 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, Ivoclar-Vivadent

Cleaning and Sterilization
The abutments of the B-, C-, D-, E-, F-, H-, I-, K-, L-, N-, R-, S-, T and Y-Series are delivered in a non-sterile state in the appropriate packaging. The product has to be cleaned and sterilized according to following details:
Cleaning:
Automatic cleaning procedure based on Vario TD program:
Cold water rinse 1 min.
Cleaning at 55°C/131°F (± 2°C/35,6°F) for 5 min. with cleaning agent neodisher® MediClean (0.5% v/v)
Neutralization with cold water for 2 min.
Cold water rinse 1 min.
Sterilization:
Seal in a suitable FDA cleared autoclavable pouch.
Steam sterilization with 3x fractionated pre-vacuum: exposure at 132°C (270°F) for 4 minutes, drying time: 20 minutes

Precautions
The product has to be inspected prior to 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.