Prosthetic Guideline
Dental Implant System
Tissue Level
This guideline was developed in close collaboration with experienced implant dentists and dental technicians. Experts from America, Europe and Asia significantly contributed to this handbook. The highest quality, international application, and ease of use are of highest importance to us. Biodenta Swiss AG would like to thank all participating experts for their great support.

This documentation is valid from January 2011. Please find latest updates and information on our homepage www.biodenta.com

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<td>RP / Crown and Bridge</td>
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<td>RP and WP</td>
<td></td>
</tr>
<tr>
<td>Flow Chart based on Implant Shoulder</td>
<td></td>
</tr>
<tr>
<td>NP / Crown and Bridge</td>
<td></td>
</tr>
<tr>
<td>Flow Chart based on Implant Shoulder</td>
<td></td>
</tr>
<tr>
<td>NP / Overdenture</td>
<td></td>
</tr>
<tr>
<td>Flow Chart based on Implant Shoulder</td>
<td></td>
</tr>
<tr>
<td>RP / Crown and Bridge</td>
<td></td>
</tr>
<tr>
<td>Flow Chart based on Implant Shoulder</td>
<td></td>
</tr>
<tr>
<td>RP / Overdenture</td>
<td></td>
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<tr>
<td>Flow Chart based on Implant Shoulder</td>
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Preface

This prosthetic guideline will assist in the understanding and the implementation of prosthetic solutions based on the Biodenta Tissue Level implants.

Each prosthetic restoration requires careful planning and expertise. Dentists and dental technicians should be familiar with the use of all components and procedures prior to use.

Please contact Biodenta if you have any questions or concerns.

The Biodenta Support Team welcomes your request and is here to assist you:

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Implant Characteristics

1.5 mm Neck

Platform Diameter

0.5 mm Shoulder

35°

1.5 mm Neck

Implant Platform Types

The Biodenta tissue level implants have three different platform types. They include:

<table>
<thead>
<tr>
<th>Platform Type</th>
<th>Platform Ø</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP : Narrow Platform</td>
<td>3.7 mm</td>
</tr>
<tr>
<td>RP : Regular Platform</td>
<td>4.8 mm</td>
</tr>
<tr>
<td>WP : Wide Platform</td>
<td>5.5 mm</td>
</tr>
</tbody>
</table>

*Shoulder angle is 45° for 3.5 mm implants with NP platform*
Implant Series | Tissue Level

Biodenta Dental Implants | Tissue Level
1.5 mm Neck | BST Surface

Endosteal Ø 3.5 mm | NP

<table>
<thead>
<tr>
<th>Length</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0 mm</td>
<td>I-TA3537L08A</td>
</tr>
<tr>
<td>10.0 mm</td>
<td>I-TA3537L10A</td>
</tr>
<tr>
<td>12.0 mm</td>
<td>I-TA3537L12A</td>
</tr>
<tr>
<td>14.0 mm</td>
<td>I-TA3537L14A</td>
</tr>
</tbody>
</table>

NP, H 1.0 mm Healing Cap included

Endosteal Ø 4.1 mm | RP

<table>
<thead>
<tr>
<th>Length</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0 mm</td>
<td>I-TA4148L08A</td>
</tr>
<tr>
<td>10.0 mm</td>
<td>I-TA4148L10A</td>
</tr>
<tr>
<td>12.0 mm</td>
<td>I-TA4148L12A</td>
</tr>
<tr>
<td>14.0 mm</td>
<td>I-TA4148L14A</td>
</tr>
</tbody>
</table>

RP, H 1.0 mm Healing Cap included

Endosteal Ø 4.8 mm | RP

<table>
<thead>
<tr>
<th>Length</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0 mm</td>
<td>I-TA4848L08A</td>
</tr>
<tr>
<td>10.0 mm</td>
<td>I-TA4848L10A</td>
</tr>
<tr>
<td>12.0 mm</td>
<td>I-TA4848L12A</td>
</tr>
<tr>
<td>14.0 mm</td>
<td>I-TA4848L14A</td>
</tr>
</tbody>
</table>

RP, H 1.0 mm Healing Cap included

Endosteal Ø 4.8 mm | WP

<table>
<thead>
<tr>
<th>Length</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>8.0 mm</td>
<td>I-TA4855L08A</td>
</tr>
<tr>
<td>10.0 mm</td>
<td>I-TA4855L10A</td>
</tr>
<tr>
<td>12.0 mm</td>
<td>I-TA4855L12A</td>
</tr>
</tbody>
</table>

WP, H 1.0 mm Healing Cap included

Healing Caps & Closure Screws

Healing Caps

The following listed healing caps and closure screws are available.

NP

<table>
<thead>
<tr>
<th>Height</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 mm</td>
<td>SC-A1037M1H</td>
</tr>
<tr>
<td>2.0 mm</td>
<td>SC-A2037M1H</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>SC-A3037M1H</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>SC-A4037M1H</td>
</tr>
</tbody>
</table>

RP

<table>
<thead>
<tr>
<th>Height</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 mm</td>
<td>SC-A1048M2H</td>
</tr>
<tr>
<td>2.0 mm</td>
<td>SC-A2048M2H</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>SC-A3048M2H</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>SC-A4048M2H</td>
</tr>
</tbody>
</table>

WP

<table>
<thead>
<tr>
<th>Height</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.0 mm</td>
<td>SC-A1055M2H</td>
</tr>
<tr>
<td>2.0 mm</td>
<td>SC-A2055M2H</td>
</tr>
<tr>
<td>3.0 mm</td>
<td>SC-A3055M2H</td>
</tr>
<tr>
<td>4.0 mm</td>
<td>SC-A4055M2H</td>
</tr>
</tbody>
</table>

Closure Screws

<table>
<thead>
<tr>
<th>Ø</th>
<th>REF Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP</td>
<td>SC-A0037M1C</td>
</tr>
<tr>
<td>RP</td>
<td>SC-A0048M2C</td>
</tr>
<tr>
<td>WP</td>
<td>SC-A0055M2C</td>
</tr>
</tbody>
</table>

Unit: millimeters
ø = Diameter
H = Height
W = Width
NP = Narrow Platform
RP = Regular Platform
WP = Wide Platform
Tight-Fit Connection

- 7° conical connection between abutment and implant
- Abutment screw locks the connection
- The design intends to minimize micro-movements, micro-leakage and maintain a tight-fit *

Octagonally Shaped Torque Connection

7° Conical Connection to Abutment

Mechanical Stability

Our uniquely designed implant with a 7° conical connection is tested according to ISO 14801. The implant has a standard abutment that is screwed together and then mounted at a fixed 30° off-axis orientation, with a bone level 3 mm higher than the fixture surface.

A hemisphere cap, at the top of abutment, adds compressed force, which intersects the off-axis at a point 8 mm higher than bone level.

The fatigue force testing is started at 80% of static fracture strength and controlled in 15 Hz sine wave. Failure was defined as permanent deformation of material yield, or fracture of any component of test samples. Testing is considered complete at 3 samples, of five million cycles, without failures.

The test confirmed the high mechanical stability of the Biodenta implant system above 200 N for 5 million cycles for the smallest implant with NP platform.

* These parameters have not shown to provide a meaningful effect clinically.
The products of Biodenta Swiss AG are developed and manufactured by following highest international quality standards. As a manufacturer of medical equipment we are following the strict requirements of the European Medical Device Directive 93/42/EEC.

Our products are entitled for the CE sign and Biodenta Swiss AG is frequently controlled by an independent Notified Body.

Research, development, production, sales and logistic are strictly following the quality management systems ISO 9001, ISO 13485 and the GMP guidelines.

Biodenta Swiss AG ensures that the quality of our products and services fulfills the high expectations of our customers.

External and internal specialists are permanently taking care to achieve best solutions of design, reliability and efficiency.

Biodenta Swiss AG only cooperates with well established business partners and high priority is given to sustainability. We support fair business relations and pay high regard to environmental and social conditions.

Blister packaging for prosthetic parts

Bar code labels
Label Explanation

Part Name
LOT number
Article Number
Platform
Height
LOT Number
Part Illustration
EAN Barcode

Gold Abutment (Crown)
RP
12.0
Platform
H mm

92601 First digit is year, 2009.
Next two digits: production week 26.
Last 2 digits: running number from 01 to 99

Storage Element System for clear overview

Pre-operative Planning

Dental Implant System

Pre-operative Planning
Radiographic and drill templates are a perfect aid for positioning implants so that the subsequent prosthetic provision restoration has optimum function (from an aesthetic, functional and financial aspect). The best results are only possible if adequate pre-operative planning is carried out. Close communication between the patient, dentist and dental technician is essential in order to achieve implant-supported prosthesis.

Diagnostic Wax-Up

The diagnostic wax-up is crucial in the treatment planning process. It gives information on what the expected outcome will be following the onset of therapy. Which implants and implants size and implant axes can also be selected at this step. The type of supra-constructure can also be established by means of this wax-up.

Radiographic Templates

The radiographic templates are produced with the help of the Ø 5.0 mm X-ray reference sphere. The desired implant position is marked on the diagnostic model, the X-ray reference sphere is fixed to the place marked and the templates are produced by means of a thermo-plastic.

Radiograph

The film produced with the radiographic templates then imparts information regarding the localised bone supply and the quantity of the available bone. Based on this information the number, positions, diameter and lengths of the implants can be defined. The image of the sphere on the radiographic image supplies the reference value for the magnification factor.
Pre-operative Planning

Implant Positioning

The recipient site of the implant should have sufficient width and height to accommodate the amount of planned implants and sizes selected. The bone quality should be adequate to support the implant and withstand the function of the initial pressure. If the size or the quantity of bone is insufficient, or the biomechanical load is excessive, it can lead to immediate failure. If the position of the implant is improper or deviated, the forces generated may lead to mechanical failure or damage to the implant, including fracture of the implant, abutment, or screw.

Given the greater forces generated in the posterior region, 3.5 mm implants are not recommended in the molar area or premolar area.

The implant surgery and the prosthetic design should be adapted to the patient's individual conditions. Patients with poor occlusion or with heavy occlusal forces such as bruxism may not be ideal candidates.

Distances

Selection of implant position is imperative for dentist and dental technician to achieve a desired prosthetic result in later stage of implant treatment. Consideration should include adequate distances between implants and implant and teeth.

To improve soft tissue aesthetics and quality, overall tooth orientation, and proper implant selection, Biodenta recommend the following step before implant treatment.

1. A diagnostic wax-up on a prepared study model.
2. Define the type of implant restoration.

The following minimum guidelines should be included: implant diameter, implant length, position and quantity of implants. Depending on the planned position of the implant abutment, the following dimensions should be considered:

1. Distance between implant and tooth, or between implants at the level of the bone. Adequate distance must be available between the implants or implant and tooth.
2. Bone width must be adequate in the region of planned implant placement, i.e. buccal and lingual width.

Minimum distances between implants and implant and tooth.

- A. Maintain > 1.5 mm from the implant shoulder to the adjacent tooth.
- B. Maintain > 3.0 mm between two adjacent implant shoulders.
- C. Maintain > 1.0 mm between implant shoulder and interdental contact point.

* Maintain wider distances if possible.

Distance for Single Implant Placement

The following graphics indicate the distances for all three platforms. The table gives figures which are rounded up. These are suggested guidelines.

Suggested implant sizes based on region. ◊ Do not use Ø 3.5 mm implants in the molar area or premolar area.
From the measurements obtained from the patient’s radiographs, the following chart can be utilized to assist in determining the gap width along with the appropriate implant platform size and restoration.

<table>
<thead>
<tr>
<th>Platform diameter (mm)</th>
<th>Distance between mesial and distal tooth at bone (mm)</th>
<th>Tooth gaps (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP Ø 3.7</td>
<td>7.0</td>
<td>6.0</td>
</tr>
<tr>
<td>RP Ø 4.8</td>
<td>8.0</td>
<td>7.0</td>
</tr>
<tr>
<td>WP Ø 5.5</td>
<td>8.5</td>
<td>7.5</td>
</tr>
</tbody>
</table>

Cases involving multiple Teeth and Implants

In order to comply with the recommended spacing as described above, the following figure shows multiple teeth and implant gaps. This distance requires > 1.5 mm from the implant body diameter to the adjacent tooth. The table below indicates the minimum required distances for different implant combinations.

Distance Examples

In the following examples, distance measurement is from the bone level of the adjacent tooth to the center of the implant.

<table>
<thead>
<tr>
<th>Platform diameter I (mm)</th>
<th>Platform diameter II (mm)</th>
<th>Mesial (mm)</th>
<th>Implant Center (mm)</th>
<th>Distal (mm)</th>
<th>Proximal cervical (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>NP Ø 3.7</td>
<td>NP Ø 3.7</td>
<td>3.5</td>
<td>7.0</td>
<td>3.5</td>
<td>14.0</td>
</tr>
<tr>
<td>NP Ø 3.7</td>
<td>RP Ø 4.8</td>
<td>3.5</td>
<td>7.5</td>
<td>4.0</td>
<td>15.0</td>
</tr>
<tr>
<td>NP Ø 3.7</td>
<td>WP Ø 5.5</td>
<td>3.5</td>
<td>8.0</td>
<td>4.5</td>
<td>16.0</td>
</tr>
<tr>
<td>RP Ø 4.8</td>
<td>RP Ø 4.8</td>
<td>4.0</td>
<td>8.0</td>
<td>4.0</td>
<td>16.0</td>
</tr>
<tr>
<td>RP Ø 4.8</td>
<td>WP Ø 5.5</td>
<td>4.0</td>
<td>8.5</td>
<td>4.5</td>
<td>17.0</td>
</tr>
<tr>
<td>WP Ø 5.5</td>
<td>WP Ø 5.5</td>
<td>4.5</td>
<td>8.5</td>
<td>4.5</td>
<td>17.5</td>
</tr>
</tbody>
</table>
Recommended Mesio-Distal distances for Implants

Depending on the anatomy and space available, select implant diameter, implant length, number of implants, and position. The dimensions described here should be deemed the minimum criteria.

When the minimum distances are observed, it is imperative to design and restore the implant with the ability to maintain hygiene. It is essential to allow the patient to reach the area of the implant neck to keep the area clean.

When evaluating the recipient site of anterior single implant, the distance from the planned implant crown at the level of the bone to the adjacent root structure must be a minimum of 0.5 mm on each side (total 1.0 mm).

Buccal Lingual Position of Implants

The thickness of bone must be adequate to ensure that once the implant is placed, there is at least 1 mm of bone on each side to secure the implant.
The Biodenta Prosthetic Kit is designed for easy use. Dentists can create a custom tool kit to meet their needs. The autoclavable tray contains various sized wells where you can store more optional drills, hex tools and any assortment of abutments. It may be used for cement- and screw- retained restorations.

⚠️ All parts used intraorally must be secured to prevent aspiration!

**Prosthetic Kit diagram**

1. Solid Abutment Drivers
2. LOCATOR® Abutment Drivers
3. Ball Abutment Driver
4. Hex Drivers for Handpiece
5. Hex Drivers for Torque Wrench
6. Handle for Hex Drivers
Handle for Hex Drivers
- REF Number: SI-HLHD000001

Hex Drivers for Torque Wrench
- Length | REF Number
- Extra Short | SI-HDTW14S01
- Short | SI-HDTW16S01
- Long | SI-HDTW23L01
- Extra Long | SI-HDTW35L01

Hex Drivers for Handpiece
- Length | REF Number
- Short | SI-HDHP23S01
- Long | SI-HDHP28L01

Solid Abutment Drivers
- Length | REF Number
- Short | PI-DRSA17S01
- Long | PI-DRSA23L01

Ball Abutment Driver
- REF Number: PI-DRBB19001

Torque Wrench
- Ncm | REF Number
- 20-70 | AI-002

LOCATOR® Parallel Post (4 pcs. per set)
- Height | REF Number
- 8.0 mm | PI-PPLA08001

LOCATOR® Angle Measurement Guide
- REF Number: PI-MGLA15001

LOCATOR® Abutment Drivers
- Length | REF Number
- Short | PI-IDLA15S01
- Long | PI-IDLA21L01

LOCATOR® Core Tool
- Height | REF Number
- 100.0 mm | PI-ADLA10001

Reamer incl. Guide Pins
- REF Number: PI-RM4565001

LOCATOR® Healing Cap / Closure Screw

LOCATOR® Angle Measurement Guide

LOCATOR® Abutment Drivers

LOCATOR® Core Tool

Reamer incl. Guide Pins

LOCATOR® Healing Cap / Closure Screw
Torque Wrench

The torque wrench is used to insert the implant into the implant bed or for tapping. It is also used to connect prosthetic components to the implant for the appropriate connection torque. Please refer to the prosthetic guideline for a detailed explanation related to connection of prosthetic components.

Please refer to the connection procedure chart to see which components can be connected with the wrench. The wrench can be applied in two different directions, ‘IN’ for tightening (clockwise as indicated by the arrow), ‘OUT’ for loosening (counter-clockwise as indicated by the arrow). The wrench has different torque markings. By turning the torque adjustment screw at the end of the wrench, the torque wrench can be set to the desired torque value. To set the torque value correctly, the torque adjustment screw must be turned clockwise to reach the required torque value and set to the exact line marking. In order to change from a higher to a lower value, screw two turns counterclockwise beyond the desired value, then screw clockwise to the exact line marking.

The torque wrench will automatically release if excess torque is applied.

⚠️ Follow the indications in this guide to adjust correct torque values for specified procedures.

⚠️ When using the wrench, please turn it slowly and make sure that it stays in the same axis as the implant. If it is off axis, the torque value will be incorrect.

⚠️ Disassemble the wrench for cleaning as described in the cleaning, disinfection and sterilization section.

⚠️ Follow the instructions that are supplied with the wrench for proper handling, disassembling, sterilization, and maintenance.

Torque Guide

The following table shows which torque should be applied to related procedures.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screwing in implants with NP or B1 platform</td>
<td>max. 50 Ncm</td>
</tr>
<tr>
<td>Screwing in implants with RP, WP or B2 platform</td>
<td>max. 70 Ncm</td>
</tr>
<tr>
<td>Connecting healing -cap / -abutment or closure screw with the implant</td>
<td>Hand Force</td>
</tr>
<tr>
<td>Connecting temporary abutments with the implant</td>
<td>20 Ncm</td>
</tr>
<tr>
<td>Connecting angled- / straight- / solid- / gold- / ball- / LOCATOR®- / bar- abutments with the implant</td>
<td>35 Ncm</td>
</tr>
</tbody>
</table>
Removing the Abutment from the Implant or the Model Analog

1. Unscrew the abutment screw from the abutment and take it out.

2. Take the abutment out of the implant.

Note: the tight-fit connection between abutment and implant. This fit may be very tight due to the precision of the components. If the abutment cannot be easily removed, we suggest inserting the hex driver (without the screw) into the abutment and gently tapping against the wall of the abutment. With this maneuver, the abutment will loosen and can therefore be easily removed.

⚠️ Please check the hex driver after this procedure as it may get deformed in case this procedure is applied several times.

Prosthetic Options
Each implant platform offers several prosthetic options. One can follow the charts in the chapter “Prosthetic Flow Charts” to identify the appropriate system and abutments for the type of restoration you are performing: Impression on implant shoulder, Solid Abutment, Cement-retained, screw-retained or overdenture restoration.

When selecting abutment, the dentist or dental technician needs to know the following:

**Platform:**
The platform of the abutment must correspond to the implant platform.

**Vertical Space:**
In addition to the height of the selected abutment, an additional 1.5 to 2.0 mm space must be available over the prosthetic components to allow for casting and/or veneering material.

**Angulation:**
The position of each implant will determine which abutment can be used, straight or angled, or whether a customized abutment is needed.

### Abutment Selection

1. **Solid Abutment:**
   - RP / WP
   - Abutment for cement-retained crowns and bridges. One Piece structure simplifies impression and prosthetic procedure. It is also an adjustable abutment.

2. **Temporary Abutment:**
   - NP / RP / WP
   - If necessary, the temporary abutment can be modified by the dentist after implant surgery or by the lab technician in the laboratory.

3. **Straight Abutment:**
   - NP / RP / WP
   - Abutment for cement-retained crowns and bridges.

4. **Angled Abutment:**
   - NP / RP / WP
   - Abutment for cement-retained crowns and bridges. Abutments of 15° and 20° A & B type are available. The axis can be corrected to 16 different alignments (in 22.5° graduations).

5. **Gold Abutment:**
   - NP / RP / WP
   - Abutment for screw-retained crowns and bridges. This one-part solution is also ideal for esthetic restorations in the anterior region.

6. **Ball Abutment:**
   - NP / RP
   - Abutment for overdenture restoration. It’s ideal for lower denture construction.

7. **LOCATOR® Abutment:**
   - NP / RP
   - Abutment for overdenture restoration.

8. **Bar Abutment:**
   - RP
   - Abutment for overdenture restoration.
Prosthetic Flow Charts

The following flow charts illustrate all prosthetic options related to the implant platform. A separate flow chart for the solid abutment system is shown.

Flow Chart for Solid Abutment System RP and WP

- **RP** = Regular Platform
- **WP** = Wide Platform
- **NP** = Narrow Platform
- **H** = Height
- ø = Diameter

Unit: millimeters
Flow Chart based on Implant Shoulder RP / Crown and Bridge

- Healing Cap
- Implant
- RP

- Open Tray
- Closed Tray
- Impression Post

- 0° Abutment
- 15° Abutment
- 20° Abutment

- Gold Abutment
- Angled Abutment
- Temporary Abutment

Flow Chart based on Implant Shoulder RP / Overdenture

- Healing Cap
- Implant
- RP

- Open Tray
- Closed Tray
- Impression Post

- Spacer Disc
- Metal Housing
- Housing & Male
- Bar Abutment

- Abutment Analog
- Impression Coping
- LOCATOR® Abutment

- Ball Abutment
- Impression Post

- Plastic Coping & Plastic Shoulder
For the implant prosthesis, the impression can be made directly at the shoulder level or alternatively the solid abutment system can be used (impression at the abutment level).

**Prosthetic Systems**

**Solid Abutment System**

The solid abutment system is characterized by its ease of application. Solid abutments can be used both for cemented crowns and cemented bridges on RP and WP. It can also be utilized adjacent to regular dentition. This system is color-coded. It is important to make sure that for a provision with solid abutment the implants must be placed so the removal of excess cement can be assured. The height of the abutments is determined inside the patient’s mouth and the appropriate abutment can be selected. Precise prefabricated impression caps are available for the impressions. The system also offers the option of modifying the abutments inside the patient’s mouth.

Production of the crowns is comparable to the conventional crown production processes. Burn out copings are available to the technician for producing the coping or substructure.

With the solid abutment system the RP parts come in yellow, grey and blue. For WP, the colors are green and brown. The different colors identify the various abutment heights per platform. The abutments, impression copings, and laboratory analogs are all color coordinated.
Impression at Implant Shoulder Level

Base on the octagonally shaped internal implant connection, the impression can be made directly on the implant shoulder without an abutment. With precise transfer parts, the dental technician can transfer the implant position accurately on to the model. In addition, the color-coded platform identification on the transfer parts simplifies handling of the different platforms.

This system is characterized by its variety of prosthetic provision options. Screwed or cemented crowns and bridges, as well as various options for over-denture prosthetics can be easily solved with this system.

A planning kit is available for the technician to select the secondary parts. This enables the correct prosthetics for each case to be designed simply and efficiently. The technician is also provided with burn out copings for producing the frame.

Solid Abutment System

The system is very simple in its application. Solid abutments can be used for cemented crowns and bridges on both RP and WP in all locations. It is important to make sure that the removal of all excess cement can be assured.

The system also offers the option of modifying secondary parts in the patient’s mouth. The crown production is comparable to the conventional processes of crown production.

Parts for Dentist

<table>
<thead>
<tr>
<th>Parts for Dentist</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solid Abutments</td>
<td>RP / WP</td>
</tr>
<tr>
<td>Protective Caps</td>
<td>RP / WP</td>
</tr>
<tr>
<td>Impression Caps</td>
<td>RP / WP</td>
</tr>
<tr>
<td>Impression Caps for adjustable Solid Abutments</td>
<td>RP / WP</td>
</tr>
<tr>
<td>Hex Drivers for Torque Wrench</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Hex Drivers for Hand-Piece</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Solid Abutments Drivers</td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Torque Wrench</td>
<td>Stainless Steel</td>
</tr>
</tbody>
</table>
### Parts for Lab Technician

<table>
<thead>
<tr>
<th>Description</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abutment Analogs</td>
<td>Aluminum</td>
</tr>
<tr>
<td>Planning Abutments</td>
<td>Plastic</td>
</tr>
<tr>
<td>Shoulder Analogs for modified Solid Abutment</td>
<td>Plastic</td>
</tr>
<tr>
<td>Plastic Copings</td>
<td>Burn-out Plastic</td>
</tr>
<tr>
<td>Reamer</td>
<td>Stainless Steel</td>
</tr>
</tbody>
</table>

### Procedure of Placing the Solid Abutment

RP type of solid abutments are inserted with the solid abutment driver. The solid abutment features a groove and the driver has a mark on the shaft. The abutment is then inserted into the driver, with the groove. It is hand-tightened in the patient’s mouth. Then the torque wrench is positioned on the solid abutment driver and the abutment is tightened to 35 Ncm.

**Connection Torque: 35 Ncm**

△ Make sure to use the solid abutment driver correctly as explained above. Wrong application may lead to slight deformations of the solid abutment. Such deformation may cause imprecise placement of the crown or bridge.
WP type of solid abutments are inserted with the hex driver.

The hex driver fits into the occlusal opening of the abutment analogue. It can be engaged with the opening and rotated in the mouth. Then the torque wrench is positioned onto the hex driver and the abutment tightened to 35 Ncm.

**Connection Torque: 35 Ncm**

**Variant A: Non-modified Solid Abutment**

1. Expose the platform surface of the implant: Remove the healing cap and ensure that the top of the implant is clear of any soft or hard tissue.

2. Hand-tighten the RP solid abutment onto the implant by using solid abutment driver. Tighten the WP solid abutment by using hex driver.

3. The abutments are screwed onto the implant by hand and tightened with the torque wrench to 35 Ncm.

**Connection Torque: 35 Ncm**

4. Select the proper color of impression cap. Position the impression cap on the abutment and firmly push until it clicks.
Only temporary cement should be used to secure the protective caps.

Using a medium to heavy body impression material (polyvinylsiloxane or polyether rubber), inject around the impression cap and fill the impression tray. Seat the impression tray into the patient’s mouth. Once set, remove the impression tray from the patient’s mouth. The impression cap should be removed with the impression. Check to be sure there is no mobility of the cap within the impression material.

Care should be taken to align the flat side of the positioning cylinder with the flat side of the abutment.

The color of the impression cap in the impression identifies which analog must be used. The corresponding analog is then positioned in the impression. Care should be taken to properly align the flat side of the analog with the flat side of the impression cap. The analog is then pushed into the impression until it snaps securely into place.

The working model can be finished with the stone pouring procedure. Once the stone is set up, remove the impression tray.

Process of the copings:
A plastic coping for crown or bridge is available to the lab technician. The plastic coping can be adjusted according to the height of the abutment.

The plastic copings are equipped with a click-on mechanism, which makes them easier to fix onto the analog. The click-on mechanism must be removed after casting.

Proceed with wax up model for the prosthesis on the plastic copings.
12. After casting crown/bridge, remove the click-on mechanism using a reamer.

△ Working under a stereo microscope is highly recommended.

Specific information for reamer and reamer head: Please refer to the chapter “Straight Abutment System”.

13. After the cast coping is trimmed and polished, it can be placed back onto lab analog. Proceed with porcelain stacking/placement.

14. Delivering the final restoration: Solid abutment does not need to have any pathway indicators; the original abutment is inside of the patient’s mouth. The lab abutment analog is only for the technician’s use in the lab. After the case is sent back to the dental clinic, the prosthetics are ready for seating on the original abutment.

**Variant B: Modified Solid Abutment**

1. Expose the head of the implant: remove the healing cap to ensure that the top of the implant is clear of any soft or hard tissue. A solid abutment is inserted into the implant and torqued to 35 Ncm. The dentist then modifies the abutment in the patient’s mouth using an appropriate grinding wheel and irrigation. To help ensure proper stability and retention of the restoration, the solid abutment must maintain a minimum height of 3.0 mm.

2. Place the impression cap for adjustable solid abutments. If a WP solid abutment is used, the remaining occlusal opening of the abutment must be sealed with wax and guttapercha. The impression cap for modified abutment is pushed over the abutment and onto the implant shoulder until the cap clicks into place. When the cap is seated correctly, it can be rotated smoothly on the implant.

3. Use a medium to heavy body impression material (polyvinylsiloxane or polyether rubber).

Impression material is injected through the occlusal and lateral openings during the impression process.

4. Once set, remove the impression tray from the patient’s mouth, with the impression coping.
5. Fabricating the model:
The RP shoulder analog and the WP shoulder analog are repositioned in the modified impression cap; the shoulder analogs have to click into place precisely.

6. Extra hard stone plaster is recommended in fabricating a working model. The impression cap should fill with stone to the level of the implant shoulder.

7. Construct the suprastructure:
The subsequent procedure is identical to the procedure for conventional crown and bridge work.

⚠️ The prefabricated plastic copings cannot be used to construct the suprastructure on modified abutments.

⚠️ Where there are markedly divergent abutments, we recommend pouring the die with modeling resin in order to reduce the risk of breakage.

Impression & Transfer based on Implant Shoulder

For impression based on implant shoulder, there are two options:

Open tray
With this impression technique, the impression tray must be perforated. The impression post is screwed firmly onto the implant by hand. After impression material has set, the guide pin is loosened by hand or with the hex driver. The impression post, together with the impression, can be removed from the patient’s mouth. The working model can now be produced with the appropriate color analog model.

Closed tray
With this impression technique, a closed tray is necessary. The impression post is screwed firmly onto the implant. After impression material has set, the impression tray is taken out of the patient’s mouth and the impression post will remain in the mouth. The guide can then be loosened in the mouth with the hex driver and the impression post can be removed from the patient’s mouth. The impression post is screwed together with the appropriate colored analog and reset into the impression. The working model can be produced.
### Impression Technique - Open Tray

1. Use the impression post with guide pin.

   - The Biodenta impression post with guide pin is “self-seating”. This means that the screw will not engage the implant if the impression post is not correctly seated. However, a radiograph is recommended if there is any uncertainty or risk of soft tissue entrapment.

2. Expose the platform surface of the implant:
   - Remove the healing cap or temporary abutment and ensure that the top of the implant is clear of any soft or hard tissue.

3. Place impression post with guide pin onto the implant and tighten the screw. This can be accomplished either by hand or use of the hex driver.

   - Before screwing down guide pin, make sure the connection between implant and impression post is precisely connected.

4. Try-in the custom impression tray and prepare holes so that the screws can protrude through the tray when the impression is taken.
5. Using a medium to heavy body impression material (polyvinyl siloxane or polyether rubber), inject around the impression post and fill the impression tray. Ensure that the screw is clearly visible.

△ Block the holes on top of the screws with wax or other suitable material.

6. Seat the impression tray into the patient’s mouth. After the impression material has set, use tweezers to clean out extra impression material or wax on top of the screw.

Remove the tray with the impression post. Verify the impression post is securely positioned in the impression material. Remove the tray with the impression post. Verify the impression post is securely positioned in the impression material.

7. Screw the impression post with guide pin and implant analog together with hex screwdriver. Make sure that the seating is correct and tighten by hand.

△ When tightening the screw, hold the retentive section of the analog in order to prevent the impression post with guide pin from rotating.

The dentist can either restore the implant with a temporary crown by using the temporary abutment or replace the healing cap on the implant after taking the impression.

Impression Technique - Closed Tray

1. Use the impression post with guide pin as supplied.

△ The Biodenta impression post with guide pin is "self-seating". This means that the screw will not engage the implant if the impression post is not correctly seated. However a radiograph is recommended if there is any uncertainty or risk of soft tissue entrapment.

2. Expose the platform surface of the implant: Remove the healing cap or temporary abutment and ensure that the top of the implant is clear of any soft or hard tissue.

3. Place impression post with guide pin onto the implant and tighten the screw. This can be accomplished either by hand or use of the hex driver.

△ Before screwing down guide pin, make sure connection between implant and impression post is precisely connected.

4. Using a medium to heavy body impression material (polyvinyl siloxane or polyether rubber), inject around the impression post and fill the impression tray.
5. Seat the impression tray into the patient mouth. After the impression material has set, remove the impression tray from the patient’s mouth.

6. Unscrew and remove the guide pin and impression post from the patient.

7. Screw impression post with guide pin to the corresponding implant analog with the hex driver. Make sure that the seating is correct and hand tighten.

   △ When tightening the screw, hold the retentive section of the analog in order to prevent the impression post with the guide pin from rotating.

   Reposition the impression post back into the tray.

The dentist can either restore the implant with a temporary crown by using the temporary abutment or replace the healing cap on the implant after taking the impression.

Temporary Restoration

Temporary Abutment

Should a temporary abutment be utilized, it can be fabricated by the dentist after implant surgery or by the dental technician in the laboratory. Temporary abutments are suitable for the provisional supply of crowns or bridges for a maximum of 6 months.

There are two options:

A. for dentists
B. for dental technicians

<table>
<thead>
<tr>
<th></th>
<th>NP</th>
<th>RP</th>
<th>WP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bridge</td>
<td>![Bridge NP]</td>
<td>![Bridge RP]</td>
<td>![Bridge WP]</td>
</tr>
</tbody>
</table>

Please note that there are three types of temporary abutments available for NP, RP, and WP platforms: One with rotation security for individual crowns and one without rotation security for bridges.

Unit: millimeters
\[d = \text{Diameter}\]
\[H = \text{Height}\]
NP = Narrow Platform
RP = Regular Platform
WP = Wide Platform
Temporary Restoration / Option A: by dentist

1. The temporary abutment is adjusted out of occlusion and the screw channel is sealed with wax.

2. The abutments can be covered with an opaque before veneering the composite. This will reduce it from showing through the composite. The temporary crown is constructed with conventional coating techniques, with preformed templates or premade acrylic temporary crowns.

3. After the occlusion is adjusted, the screw channel is reopened and the temporary prosthesis is taken out of the mouth. The temporary prosthesis is then adjusted, if necessary, and polished.

4. The temporary prosthesis is tightened to 20 Ncm onto the implant and the screw channel is sealed.

Connection Torque: 20 Ncm

Temporary Restoration / Option B: by dental technician

1. The temporary abutment is shortened according to the occlusion.

2. A preformed acrylic temporary crown can be relined at chairside. The temporary crown can be made by means of custom wax up or by a silicone index. To avoid the temporary abutment showing through the acrylic, it should be coated with an opaque liner prior to veneering.

3. The finished temporary prosthesis is inserted into the patient’s mouth and tightened to 20 Ncm.

Connection Torque: 20 Ncm
Crown & Bridge Solutions based on Implant Shoulder
Crown & Bridge Solutions based on Implant Shoulder

Based on the location and angulation of the implant, we offer different implant abutments for the treatment of implant supported crowns and bridges. The following table is a list of available abutments.

1. Cement-retained restoration

<table>
<thead>
<tr>
<th>Abutment Type</th>
<th>Height</th>
<th>NP</th>
<th>RP</th>
<th>WP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Straight Abutment</td>
<td>5.5 mm</td>
<td><img src="image1.png" alt="Image" /></td>
<td><img src="image2.png" alt="Image" /></td>
<td><img src="image3.png" alt="Image" /></td>
</tr>
<tr>
<td>Angled Abutment 15°</td>
<td>5.7 mm</td>
<td><img src="image4.png" alt="Image" /></td>
<td><img src="image5.png" alt="Image" /></td>
<td><img src="image6.png" alt="Image" /></td>
</tr>
<tr>
<td>Angled Abutment 20°</td>
<td>5.7 mm</td>
<td><img src="image7.png" alt="Image" /></td>
<td><img src="image8.png" alt="Image" /></td>
<td><img src="image9.png" alt="Image" /></td>
</tr>
<tr>
<td>Gold Abutment (Bridge)</td>
<td>12.0 mm</td>
<td><img src="image10.png" alt="Image" /></td>
<td><img src="image11.png" alt="Image" /></td>
<td><img src="image12.png" alt="Image" /></td>
</tr>
<tr>
<td>Gold Abutment (Crown)</td>
<td>12.0 mm</td>
<td><img src="image13.png" alt="Image" /></td>
<td><img src="image14.png" alt="Image" /></td>
<td><img src="image15.png" alt="Image" /></td>
</tr>
<tr>
<td>Burnout Coping / Plastic Shoulder</td>
<td></td>
<td><img src="image16.png" alt="Image" /></td>
<td><img src="image17.png" alt="Image" /></td>
<td><img src="image18.png" alt="Image" /></td>
</tr>
</tbody>
</table>

2. Screw-retained restoration

<table>
<thead>
<tr>
<th>Abutment Type</th>
<th>Height</th>
<th>NP</th>
<th>RP</th>
<th>WP</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gold Abutment (Bridge)</td>
<td>12.0 mm</td>
<td><img src="image19.png" alt="Image" /></td>
<td><img src="image20.png" alt="Image" /></td>
<td><img src="image21.png" alt="Image" /></td>
</tr>
<tr>
<td>Gold Abutment (Crown)</td>
<td>12.0 mm</td>
<td><img src="image22.png" alt="Image" /></td>
<td><img src="image23.png" alt="Image" /></td>
<td><img src="image24.png" alt="Image" /></td>
</tr>
</tbody>
</table>
Plan Set

For planning of the prosthetic components on the model, Biodenta offers a planning abutment kit. It can be placed onto the analog of the model. With it in the position, one can decide which abutment offers the best solution.

**Planning Abutment Kit**

Place the planning abutment into the analog. Check the height, axial alignment and screw axis. This makes it easy to determine which abutment, straight, angled type A or type B offers the best solution.

Not for intraoral application!

---

**Lab procedure**

**Planning Abutments for NP:**

- NP (H 4.5 mm)
- NP (H 5.7 mm)
- NP (H 5.7 mm)
- NP (H 5.7 mm)
- NP (H 5.7 mm)

**Planning Abutments for RP:**

- RP (H 5.5 mm)
- RP (H 5.7 mm)
- RP (H 5.7 mm)
- RP (H 5.7 mm)
- RP (H 5.7 mm)

**Planning Abutments for Solid Abutment System:**

- RP (H 4.0 mm)
- RP (H 5.5 mm)
- RP (H 7.0 mm)
- WP (H 4.0 mm)
- WP (H 5.5 mm)

**Planning Abutments for WP:**

- WP (H 5.5 mm)
- WP (H 5.7 mm)
- WP (H 5.7 mm)

Unit: millimeters

ø = Diameter
H = Height
NP = Narrow Platform
RP = Regular Platform
WP = Wide Platform
Straight Abutment System

Straight Abutment System

Straight abutments enable the production of cementable crowns and bridge restorations for NP / RP / WP. Burn-out plastic copings made of a residue-free burn out plastic are available for producing the substructure. The copings can be obtained in single-crown variants with and without rotation security for bridge restorations.

Laboratory Technique:

1. Fabrication of the substructure: Insert the abutment into the implant analog inside the working case by using the hex driver.

2. Process of the burn-out plastic copings: When occlusal space is limited, the abutment can be shortened.

Δ The minimum height of the abutment is recommended to be no less than 4 mm.

3. The burn-out plastic copings are equipped with a click-on mechanism, which makes them easier to fix onto the analog. The click-on mechanism must be removed after casting.

4. The burn-out plastic coping can be adjusted according to the height of the abutment.

5. Burn-out plastic has the property of expanding on combustion. It is important that the whole cap is covered with wax. The edge must be covered with wax at a minimum of 0.3 mm. The wax, during the casting process, will melt first allowing room for the plastic to expand.

6. After casting, the clip edge is removed with a rubber wheel and the shoulder is smoothed with the reamer.

△ Working under a stereo microscope is highly recommended.

The guide pins for the reamer for straight abutments can be obtained to correspond to the shoulder platform. The pins are marked accordingly, and can be used for crown and bridge copings:

- NP / Straight crown & bridge
- RP / Straight crown & bridge
- WP / Straight crown & bridge

The reamer heads are obtainable in two types and are likewise marked:

- Reamer head NP
- Reamer head RP / WP
7. After the casting is trimmed and polished, it can now be veneered with porcelain in the conventional way. Proceed to next step, carrying out the porcelain.

8. Delivering the final restoration:
The restoration is delivered to the dentist with the original abutment and original screw on the master cast.

To ensure correct transfer of the position of the abutment from the master cast to the patient, an individual index can be fabricated on the cast. Use Duralay or pattern resin.

9. Remove the healing cap or temporary restoration.
Thoroughly clean and dry the interior of the implants. Remove the original abutment from the implant analog by using the hex driver. Place the abutment in the patient’s mouth and tightening the abutment screw with 35 Ncm. The suprastructure can now be cemented by the conventional technique.

Before cementing the superstructure, the occlusal abutment opening must be re-sealed with wax or gutta-percha.

Connection Torque: 35 Ncm

Angled Abutment System

Angled Abutment System

15° and 20° A & B type

The angled abutments can be obtained for NP / RP / WP platforms. The abutments enable the production of cementable crowns and bridges with synchronized balance for diverging implant axes. The abutments can be obtained with angles of 15° and 20°, and in A & B variants. To determine the ideal abutment to use, please consult the plan set. The abutments can be filed and modified.

Type A: angle over the surface
Type B: angle over the nut

This enables 16 different alignments-8 for A-type and 8 for B-type in 22.5° graduations.

1. Fabricating a cementable single crown on an angled abutment:
Positioning the plastic shoulder with the click-on mechanism on the analog shoulder. Pressure should be placed until the snap-on mechanism clicks audibly indicating that it is in the correct position.

The plastic shoulder can be adjusted as necessary.

2. The abutment must be properly positioned in the implant before the screw is hand-tightened. The occlusal opening must be sealed (e.g. composite, gutta-percha, silicone).

3. Modelling can be carried out in wax Duralay or pattern resin. The suprastructure can now be cemented by the conventional technique.
4. Wax up the crown or bridge and cast the burn-out plastic coping. The click-on mechanism of the plastic shoulder must be carefully removed with a polishing rubber under the microscope.

5. After the burn-out plastic coping is trimmed, it can be placed back onto the laboratory analog. Proceed to the next step, stacking the porcelain.

6. Delivering the final restoration: The restoration is delivered to the dentist with the original abutment and screw on the master cast. Remove the original abutment from the analog by using the hex driver.

△ Use a hard material such as Duralay to make a transfer indication and to fit the suprastructure then place the abutment in the patient’s mouth.

7. The abutment screw is tightened with 35 Ncm.

△ Before cementing the suprastructure, the occlusal abutment opening must be resealed with wax or gutta-percha.

**Connection Torque: 35 Ncm**

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### Gold Abutment System

**Gold Abutment System**

Gold Abutment is intended for the fabrication of single screw retained crown or bridge restorations. Alternatively, individually manufactured customized abutments for cemented crowns and bridges can be made. The abutment is meant to be processed and consists of cast-alloy Ceramicor® and a residue free burn out plastic.

Please note that there are three types of gold abutments available for NP, RP and WP platforms: One with rotation security for individual crowns and one without rotation security for bridges.

<table>
<thead>
<tr>
<th>NP</th>
<th>RP</th>
<th>WP</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="crown.png" alt="Crown" /></td>
<td><img src="bridge.png" alt="Bridge" /></td>
<td><img src="bridge.png" alt="Bridge" /></td>
</tr>
</tbody>
</table>

**Screw-Retained Crowns or Bridges**

1. **Fabricating the coping:**
   Screw the gold abutment into the implant analog. When occlusal space is limited, the plastic shell can be shortened. The screw head should always be out of occlusion in order to prevent torquing of the screw head.

   ![Step 1](step1.png)

2. **Proceed to prosthetic wax up:**
   For optimal esthetic result, a diagnostic wax up should be performed. A silicone or PVS impression should be made over the wax up. There should be adequate room for sufficient thickness of wax between the abutment and impression. This is especially important in the region of the margin.

   ![Step 2](step2.png)

△ 0.7 mm wax up coating is recommended. The cement margin must not be no more than 2.0 mm below the gingiva.
3. Trimming the cast coping:
   Care must be taken during the trimming process. If the casting is trimmed where the abutment is exposed, the surface cannot be covered with ceramic. It is a non-oxidizing alloy and porcelain will not adhere to it.

   △ Never use sand-blasting for removing the investment. It will destroy the abutment. Casting pearls cannot be removed from the shoulder part of the gold abutment with the reamer.

4. Delivering the final restoration:
   The restoration is delivered to the dentist with the prosthesis on the master cast. Remove the prosthesis from the implant analog by using the hexdriver. Thread the prosthesis with the abutment screw in the patient’s mouth by using the hex driver.

   △ It is recommended that the abutment screw is tightened to a torque of 35 Ncm. The occlusal abutment opening will be sealed with composite.

   **Connection Torque: 35 Ncm**

**Customized Abutments for cemented Crowns or Bridges**

1. Fabricating the customized abutment of cement-retained crown or bridge:
   Screw the gold abutment onto the implant analog. When occlusal space is limited, the plastic shell can be shortened. The recommended minimum height of the abutment is 4.0 mm.

2. The wax up of customized abutment:
   The wax layer must be a minimum of 0.7 mm. Do not cover the margin of the abutment with wax. Make sure a clean and sharp-edged finish of the screw channel.

3. After casting, the finished customized abutment is trimmed and polished and ready for the fabricated single crown or bridge.

4. After blocking out the screw channel, the metal coping is waxed directly over the customized abutment.
   After the trimming of the cast coping, the metal coping will fit precisely on the customized abutment.

5. Delivering the final restoration:
   The restoration is delivered to the dentist with the prosthesis on the master cast. Cement the prosthesis with permanent cement. Upon placement of the substructure, the substructure abutment screw is tightened to a torque of 35 Ncm. Cement the prosthesis with a permanent cement.

   △ Before cementing prosthetic, screw channel need to be seal with wax or cotton pellet.

   **Connection Torque: 35 Ncm**
Important Information and Tips

Burn-out Plastic Copings and Gold Abutments (Ceramicor®)

The success of utilizing a pre-fabricated parts / burn-out plastic parts can be enhanced when the following are observed:

Burn-out Plastic Copings

- The outer surface of the burn-out plastic copings must be completely covered with wax. It is imperative that a wax coating of at least 0.3 mm is maintained in all regions especially the edges. Please do not cover the edge of the cap.
- The inner surface of the burn-out plastic coping must be completely covered with wax. It is imperative that a wax coating of at least 0.3 mm is maintained in all regions especially the edges.
- The casting channel must allow wax and plastic to flow out and must not obstruct the in flow of the alloy.
- Use as minimal amounts of wax softening agent. The plastic is smooth so that the embedding compound can easily be filled into all the fine contours with the help of a thin, blunt instrument or a fine brush during embedding the cap’s interior configuration.
- In the event that a wax softening agent is used, care must be taken not to use a harsh softening agent as this can affect the upper surface of the burn-out plastic copings. If used, the burn-out plastic coping must then be carefully blown dry with compressed air. Softening agent residues can lead to a reaction with the embedding compound and consequently lead to errors in casting.
- Please pay attention to the embedding compound manufacturer’s instruction manual when performing the embedding. Keep exactly to the recommended mix ratios and the pre-heating times.
- The use of embedding compound for the fast heating process (speed-embedding) is not recommended.

Gold Abutment / Ceramicor®

- The wax thickness on the Ceramicor® alloy must be at least 0.7 mm. The delicate edge of the secondary part must not be covered by wax.
- In order to avoid the cast alloy overflowing on to the sensitive circular edge and the interior of the secondary part, the secondary part must be thoroughly cleaned before embedding with a cotton bud soaked in alcohol or a brush.
- When selecting the cast alloy it is imperative to make sure that it is compatible with the high-melting alloy of Ceramicor®. Ceramicor® forms no adherence oxide for ceramic blending materials. The melting area of the cast alloy must not exceed the liquid temperature of 1350 °C / 2462 °F.

Suitable dental cast alloys:

- High-quality genuine alloys
  - Genuine metal alloys with a minimum content of gold and platinum metals of 25 %.
  - Alloys based on palladium with a minimum palladium content of 50 %.
- Base metal casting alloys may not be cast on to Ceramicor® as gold combined with nickel or cobalt will lead to destruction of the Ceramicor® components!

Alloys which comply with the ISO norms 9693, 1562 and 8891 are suitable for casting processes with prefabricated Ceramicor® components.

The alloy manufacturer’s recommendations relating to the respective alloy used must be observed.

Components made from a non-suitable alloy may create reduced corrosion resistance or low melting intervals due to “diffusion processes” in the border area of the alloy / gold cap phases where there is less stability.

Embedding may not be done by sand blasting as this destroys the secondary parts.

In cases where the casting alloy is drilled through during processing and the Ceramicor® upper surface can be seen, the abutment cannot be veneered with ceramic. The casting must be repeated, as Ceramicor® is a non-oxidising alloy as described above.

With errors in casting, such as incomplete effluxion, metal excess, casting beads or casting streaks in the internal configuration, the work must be repeated. The long-term success of the implants also depends on the accuracy of fit of the prosthetic work.
Ball Abutment System

The retentive ball abutment system allows the simple and secure mounting of full prosthetics. It is available for NP and RP platforms. Mounting by means of ball abutments enables easy insertion and removal of the prosthesis. Impression can be done without any kind of aids.

An elliptical matrix with an individually activated gold lamella insert is provided in the prosthetic as a counter support. The gold lamella insert can be changed if necessary.

⚠️ To ensure the retentive ball abutment functions perfectly over a long period of time, the implants must be placed as parallel as possible to one another and vertical to the occlusal plane to create a tangential axis of rotation.

<table>
<thead>
<tr>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ball Abutment NP / RP</td>
</tr>
<tr>
<td>Ball Abutment Analog</td>
</tr>
<tr>
<td>Metal Housing Dalbo®-PLUS Matrix</td>
</tr>
<tr>
<td>Spacer Disc</td>
</tr>
<tr>
<td>Duplicating Aid</td>
</tr>
<tr>
<td>Ball Abutment Screwdriver</td>
</tr>
</tbody>
</table>
Impression technique for ball overdenture

1. Remove the healing cap from the implant and measure the tissue depth. This will allow you to select the appropriate abutment height.

2. Insert the ball abutment into the implant by using the ball abutment driver. The ball abutment has a square neck to accommodate the driver.

   Connection Torque: 35 Ncm

3. The impression is taken with an elastomeric impression material (polyvinylsiloxane or polyether rubber) directly over the ball abutment without any aids.

4. Insert the ball abutment analog into the impression. The laboratory fabricates the working model.

Ball Overdenture Construction

1. Fabricating working model:
   Ensure that the ball abutment analog is correctly seated into the impression opening and pour up the stone model.

2. Fabricate an appropriate denture wax-up for patient try-in.

   The manufacture and integration of a metal reinforced housing is recommended for stabilization of the prosthesis especially in mandibular prosthesis.

3. For the completion of the prosthesis, place the spacer disc over the ball abutment analog (to preserve a space for the finished denture) and then connect the metal housing.

4. The metal housings must be aligned to the correct axis position (parallel insertion direction).
5. The prosthesis can now be finished in the usual style and manner.

Initially, use the lowest retaining force of the matrix. Refer to the chapter “Adjusting the Retentive Force”. Proceed in small increments as necessary, until the desired retention force is obtained. Problems can occur with removing the prosthesis from the mouth, when the retention is too great.

Insertion of the Metal Housing into an existing Prosthesis

1. The position of the metal housing is cut out through the prosthesis and space is then created in the denture base.

2. Cofferdam is laid over the metal housing which prevents the plastic from flowing in. The metal housings must be aligned to the correct axis position (parallel insertion direction). The prepared prosthetics are fixed into the mouth and the plastic is inserted through the perforations.

3. The rough areas are adjusted and polished.

Explanation of the Metal Housing (Dalbo®-PLUS Matrix)

The metal housing is used for the fixation of removable full dentures on Biodenta implants in conjunction with the ball abutment. It consists of a housing in which a gold lamella retention insert is screwed (Elitor® Protor® 3, yellow precious metal alloy).

Titanium female part with threaded precious metal lamella insert allows the retention force to be finely, permanently and instantly adjusted with a special screwdriver (can be purchased from dental material supplier). Tuning the female part with a reduced inner diameter for integration into an existing denture can be used with worn spherical anchors of other manufacturers. This enables the retention of existing dentures to be improved.

To replace the Lamella retention insert, the thread on the metal housing is unscrewed counter clockwise using the special screwdriver. The threaded ring is then screwed back in place and hand tightened.
Adjusting the Retentive Force

The integrated Lamella retention insert can be identified by its yellow color. It is activated by rotating the special screwdriver clockwise and deactivated by rotating it counter clockwise. The initial retention force is approximately 200 g, which is also the minimum that can be set. The maximum retention force is approximately 1400 g. The lamella retention insert must not project out of the housing.

△ The retentive force should only be adjusted when trying in the finished denture.

The connection between tightening angle and retention force:

<table>
<thead>
<tr>
<th>Activation / Rotation angle</th>
<th>0°</th>
<th>90°</th>
<th>180°</th>
<th>270°</th>
<th>360°</th>
</tr>
</thead>
<tbody>
<tr>
<td>Retentive force</td>
<td>1400g</td>
<td>700g</td>
<td>500g</td>
<td>300g</td>
<td>200g</td>
</tr>
</tbody>
</table>

LOCATOR® Abutment System

The LOCATOR® abutment system is designed for use with overdentures or partial dentures. The self locating design allows patients to seat their denture easily. The system is characterized by its low construction height and its dual retention. In addition, a 40° divergence between two implants can be easily accommodated. Incorporating the male retentive element into the denture can be made in two ways. The system is available for NP and RP platforms.

A. By lab technician on the model.
B. Chair-side by the dentist: directly connecting into the patient’s denture in the mouth.
A. By lab technician on the model

1. Expose the platform surface of the implant, remove the healing cap and ensure that the top of the implant is clear of any soft or hard tissue.

   ![Step 1](image1)

2. Select the height of the LOCATOR® abutment by determining the height of the gingiva. The top margin of the abutment should be 1.0 mm above the mucosa. Inserting the prosthesis is easier for the patient if the LOCATOR® abutments are at the same level as the gingiva.

   ![Step 2](image2)

3. Connect the locator abutment driver with abutment and use the torque wrench to screw in the abutment.

   **Connection Torque: 35 Ncm**

   ![Step 3](image3)

4. The block out spacer is placed on the abutments. The spacer prevents plastic from penetrating the region below the impression coping. To take the impression, place the impression copings on the abutments and put the impression material directly over the impression copings.

   ![Step 4](image4)

5. After the impression process is completed, insert the female abutment analog into the impression coping which is located within the impression material. Fabricate the working model and denture in the usual way.

   ![Step 5](image5)

6. Place the processing caps onto the female analogs. The processing male serves to fix the cap on the analog, giving optimal stability.

   ![Step 6](image6)

   △ The caps with the black processing males must be securely seated on the analogs. Then the denture is relined using the conventional technique.

7. Remove the black male by using the core tool. Place the removal tip end into the black processing male and turn the handle two rotations counter clockwise.

   ![Step 7](image7)

   Please refer to the chapter “Function of the LOCATOR® Core Tool”.

---

**Connection Torque: 35 Ncm**
8. For checking angulation of LOCATOR® abutments, attach the parallel posts to the abutments and determine the degree of divergence. Hold the angle measurement guide behind the placed parallel posts and read off the angle for each abutment.

Δ If the divergence is less than 10°, use the clear, pink or blue replacement males. If the angle is greater than 10° use the green, orange or red replacement males. Please refer to the chapter “choice of LOCATOR® Replacement Males”.

9. Use the LOCATOR® core tool to firmly push the replacement male into the empty processing cap located within the denture. Please refer to the chapter “Function of the LOCATOR® Core Tool”.

The male replacement must sit flush with the rim of the processing cap.

Δ For this step, the dentist can process chairside or via an appointed lab technician to place the male replacement male before sending the case back to the dental clinic.

10. Check for pressure spots and adjust the occlusion after the replacement male insertion.

B. Chair-side by the dentist: directly connecting into the patient’s denture in the mouth.

1. Expose the platform surface of the implant: Remove the healing cap and ensure that the top of the implant is clear of any soft or hard tissue.

2. Select the height of the LOCATOR® abutment by determining the height of the gingiva. The top margin of the abutment should be 1.0 mm above the mucosa. Inserting the prosthesis is easier for the patient if the LOCATOR® abutments are at the same level as the gingiva.

3. Hand-tighten the abutment onto the implant using the LOCATOR® driver.

Δ A radiograph is recommended to determine if the abutment is completely seated on the implant. Then torque the abutment by using the torque wrench.

Connection Torque: 35 Ncm

4. The block out spacer is placed on the abutments. The spacer prevents the plastic from penetrating the region below the impression coping. Then place the processing caps with black male on the abutments.

5. Try in the denture over the processing cap to verify that it is fully seated on the ridge without contact to the cap.
6. Bond the processing cap to the denture by using a light cured composite resin or permanent selfcuring acrylic. Place the denture into position in the mouth and have the patient gently close into a very light centric occlusion. Stay in this position until the acrylic / resin sets.

7. After the acrylic / resin is cured, remove the denture and discard the block out spacers.

   △ It is critical that there is NO space between the tissue and the processing cap. It is necessary to block any remaining undercuts to prevent acrylic / resin from locking the denture onto the abutment. This can be done by stacking additional block out material.

8. Remove the black male by using the core tool. Place the removal tip end into the black processing male and turn the handle two rotations counter clockwise. Please refer to the chapter “Function of the LOCATOR® Cap Tool”.

9. Select the proper replacement male. Please refer to the chapter “Choice of LOCATOR® Replacement Males”. Use the LOCATOR® Core Tool to firmly push the replacement male into the empty located within the denture. The male replacement must sit flush with the rim of the processing cap.

10. Check for pressure spots and adjust occlusion after the replacement male insertion.

   △ The attachment retention on the abutment may be reduced by placing the pink replacement male or the blue male rather than the clear male. The dentist should place different replacement males depending on patient’s desires.

---

**Choice of LOCATOR® Replacement Males**

Patients should be able to insert and remove their LOCATOR® retained dentures easily and reliably. In order to achieve this, the divergence of the path of insertion of the individual abutment must be determined to assist in selecting the appropriate replacement males. If the divergence is less than 10°, clear, pink or blue males are recommended. If the divergence between implants are between 10° and 20°, green, orange, or red replacement males are recommended.

Choose the final replacement males determined by angle measurement of each implant. See the following chart for appropriate replacement males:
Function of the LOCATOR® Core Tool

The tip is used for removing replacement males from the processing cap. Unscrew the tip by turning it two full turns. A gap is visible between the tip and the middle section.

The sharp edges of the tip hold the replacement male while it is being removed. To remove the replacement male from the instrument, the tip must be screwed clockwise completely onto the middle section.

The middle section of the core tool is used for inserting replacement males into the processing cap located inside of the denture. When a click is heard, the replacement male is fixed firmly in the housing.

The end (gold-colored) of the core tool is used by the dental technician for screwing and unscrewing the abutments.

Bar Abutment System

The bar abutment system stabilizes the implants by means of stress distribution. It is available for RP implant platform. This type of restoration also offers security for the prosthesis against pulling and lifting forces. The force distribution can be optimally designed and consequently the implants will bear less strain.

Depending on which bar principle and profile is used, a resilient mounting with mucous membrane support or a bar abutment provision will be formed.

A 15° cone allows implant divergence flexibility up to 30°. The bar abutment can be easily shortened.

The bar abutments can be obtained in two types:
- Bar abutment in Ceramicor® for soldered or laser-welded gold bar.
- Bar abutment in titanium for titanium laser welding.

<table>
<thead>
<tr>
<th>Bar Abutment System</th>
<th>Ø</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bar Abutment with Screw</td>
<td>RP</td>
<td>Ti-Alloy</td>
</tr>
<tr>
<td>Bar Abutment with Screw Ceramicor®</td>
<td>RP</td>
<td>Ceramicor®</td>
</tr>
<tr>
<td>Hex Drivers</td>
<td></td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Bar Abutment Holder</td>
<td></td>
<td>Stainless Steel</td>
</tr>
<tr>
<td>Implant Analog</td>
<td>RP</td>
<td>Ti-Alloy</td>
</tr>
</tbody>
</table>

Bar Abutment System

Overdenture Solutions

94 95

Overdenture Solutions

94 95

Overdenture Solutions
Impression Technique for Bar Overdenture

1. Expose the platform surface of the implant:
   Remove the healing cap or temporary abutment and ensure that the top of the implant is clear of any soft or hard tissue.

2. Place the impression post with guide pin onto the implant and tighten the screw. If hand tightening is insufficient, use the hex driver.
   △ The Biodenta impression post with guide pin is "self-seating". This means that the screw will not engage the implant if the impression post is not correctly seated. However a radiograph is recommended if there is any uncertainty or risk of soft tissue entrapment.

3. Try-in the custom impression tray. Prepare holes so that screws can protrude through the custom during the impression.

4. Using a medium to heavy body impression material (polyvinylsiloxane or polyether rubber), inject around the impression post with guide pin and fill the impression tray. Ensure that the screw is clearly visible.
   △ Block out the holes on top of the screws with wax or other suitable material.

5. Seat the impression tray into the patient’s mouth. After the impression material has set, use tweezers to clean out extra impression material or wax on top of the screw. Unscrew and remove the screw from the impression post with guide pin, and then remove the impression from the patient’s mouth.

6. Screw the impression post with guide pin and implant laboratory analog with a hex screwdriver. Make sure the seating is correct then tighten by hand.
   △ When tightening the screw, hold the retentive section of the analog in order to prevent the impression transfer coping from rotating.
Bar Framework

1. The laboratory fabricates the working model with the implant analogs.

2. Fabrication of the suprastructure:
   Screw the bar abutment into the implant analog with the abutment screw by using a hex driver. The 15° cone allows implant divergence flexibility up to 30°.

3. Joining the segments between bar abutments. There needs to be adequate space between the bar and gingiva for proper hygiene (a min. 2.0 mm is recommended). Use a residue free burn out plastic to fix the bar segments to the abutments. Laser welding can take place directly on the plaster model.

4. Remove the bar framework from the working model after loosening the screws. Place the framework on the abutment holder and hand-tighten the screws. The abutment holder ensures that the abutments are connected accurately in the soldering investment during soldering.

5. The bar segments can be soldered or laser welded, depending on the dentist. Proceed to the soldering investment. 

   △ Preheat the soldering investment to 500°C-600°C (932-1112°F) in a preheating furnace.

6. After the invested bar has been preheated, it is ready for soldering. Once soldering has been completed and before taking out bar framework, the investment should be cooled to room temperature. Devest and clean the bar in an ultrasonic bath.

   Remove the oxides and soldering flux residues in an acid bath. Stress-free repositioning of the bar on the implant analogs should be possible without securing it with the screws.

   Shorten the bar abutment if necessary and polish it.

7. The finished bar framework is screwed back into the stone model. After polishing and cleaning, it can be sent back to the dentist for try in.

   △ Use a new screw for the final insertion of the abutment.
Bar Overdenture Fabrication

1. Do an aesthetic try in according to modern full denture principles. Upon satisfactory aesthetics and verified bite, the denture can be sent back to the lab for the final denture processing.

2. Vary the retention strength of the bar system. Once the bar system is confirmed, it is ready for the completion of the denture processing.

3. Connection of final restoration. Screw the bar framework back into patient’s mouth by using the hex driver.

   △ Tightening torque of 35 Ncm is recommended. A new screw needs to be replaced when final restoration is sent back to dentist office.

   **Connection Torque: 35 Ncm**

4. Deliver the final denture to the patient. Depending on patient’s desires and preferences, the dentist can adjust the retention of the bar matrix. Check the occlusal relationships, confirm the resiliency and hinge axis movement.

   **Cleaning, Disinfection and Sterilization**
Cleaning, Disinfection and Sterilization

Important information

- Successful implantation requires optimized hygienic conditions. Please follow those instructions carefully.
- Improper care of instruments may lead to damage.
- New instruments must be cleaned and sterilized prior to initial use. If the instrument is reused, it must be re-sterilized prior to each use.
- The Biodenta reprocessing procedure of the instruments was successfully validated with the use of the following equipment and material:
  - Automated thermal disinfection washer: Miele G 7735 CD, cleaning program: Vario TD
  - Rack for dental instruments: Miele E 491za
  - Instrument detergent: Mediclean 0.5%, mixture of cold water and Mediclean (Mediclean, Dr. Weigert, Hamburg, Germany)
- Cleaning and disinfection detergents are commercially available. Use as directed by the manufacturer.
- The dentist is responsible for the applied reprocessing process, equipment and material to achieve the required results. Routine controls of the standardized reprocessing procedure should be carried out. If a different procedure, equipment or material is applied, the effectiveness and possible adverse effects should be evaluated.
- Drills may lose cutting performance when they are not handled carefully. Never allow drills to touch each other during the cleaning process. It is highly suggested that a proper rack (such as the Miele E 491 rack) be utilized during the cleaning process.
- Care should be taken to immediately remove remnants from surgery (blood, tissue, bone, etc.) to reduce the risks of these debris drying on the instruments.
- Parts made of stainless steel should not be exposed to cleaning or disinfection solutions containing a high percentage of chlorine and / or oxalic acid.
- Parts made of plastics should not be sterilized by chemical or dry heat.
Products for Sterilization or Disinfection

Please refer to the "Material Declaration". It indicates which products should be sterilized or disinfected. Please follow this declaration carefully. The table also indicates which parts are intended for intraoral application and which ones are for extraoral use only.

Parts indicated for sterilization should be cleaned using the following steps consecutively:

1. Pre-cleaning
2. Cleaning
3. Disinfection
4. Drying
5. Visual inspection for cleanliness
6. Packing
7. Sterilization
8. Storage

Parts indicated for disinfection are for single use and should follow the following steps prior to use:

1. Cleaning
2. Disinfection
3. Drying

Each individual step is explained in detail below.

Automated or Manual Procedure

It is optional to utilize manual or automated procedures for cleaning, disinfection and drying. In the automated thermal disinfection washer, the three procedures are performed automatically.

1. Pre-cleaning

Soak the instruments in an instrument detergent (mild alkaline, aldehydefree) for minimum 5 minutes and a maximum 15 minutes. Prolonged soaking in the detergent may lead to surface damage.

Scrub the inside and outside of the instruments with a suitable soft bristled nylon brush until all visible debris is removed.

2. Cleaning

A. Automated Cleaning

Put the parts on a rack for dental instruments and put the rack into the automated thermal disinfection washer and start the cycle. The following is a minimum amount of time per cycle.

- 4 min pre-washing with cold water, then emptying
- 5 min washing at 55°C (131°F) with instrument detergent, then emptying
- 3 min neutralizing with warm water > 40°C (104°F), then emptying
- 2 min intermediate rinsing with warm water > 40°C (104°F), then emptying

Special instructions of the manufacturer of the automated thermal disinfection washer have to be followed.

Instruments for Disassembly

The table in the chapter "Material Declaration" shows instruments which are required to be disassembled during the cleaning and disinfection process. Upon completion, these instruments are required to be reassembled prior to sterilization. Please refer to the related description of those instruments about components, correct assembly and maintenance.
Automated or Manual Procedure

B. Manual Cleaning

Put the parts on a rack for dental instruments and place the rack into the ultrasonic bath for 15 min at 40°C (104°F).

Care should be taken so that cutting instruments such as blades and burs do not contact other instruments and metal surfaces.

Flush the parts, and if applicable the internal chambers, with water to remove the disinfection detergent.

3. Disinfection

A. Automated Disinfection

Perform automated thermal disinfection in the automated thermal disinfection washer under consideration of national requirements in regards to the A0-Value (A0 value: 3000, e.g. 5 min. at 90°C (194°F); refer to EN 15883).

B. Manual Disinfection

Submerge the parts in a suitable disinfection detergent for rotary instruments (alkaline, aldehyde-free, VAH approved) as per manufacture’s recommendations. Appropriate time, temperature and concentration of the disinfecting detergent must be followed.

Flush the parts, and if applicable the internal chambers, with water to remove the disinfection detergent.

4. Drying

⚠️ Make sure that the parts are completely dry before packing them!

A. Automated Drying

Parts need to be dried by going through the drying cycle of the automated thermal disinfection washer.

If needed, additional manual drying can be performed by using sterile compressed air.
5. Visual Inspection for Cleanliness

Visually inspect the parts to ensure that they are clean and undamaged. If residues or contamination remains, repeat the procedures until no visible contamination is left.

Parts showing the following defects are to be discarded immediately: deformations (e.g. bent, fractured), corroded surfaces, blunt / chipped blades. Cutting instruments are not allowed to be used more than 10 times.

6. Packing

For sterilization, the surgical instruments should be placed into the Surgical Kit. Please place each instrument back to its correct position.

The instruments should be placed in the center of each holder so that it has minimum surface contact.

Place the completed Surgical Kit into a sterilization bag. Do not use a form fitting sterilization pouch. Adequate space is necessary to allow circulation of air.

Healing caps and closure screws can be placed into the removable box of the Surgical Kit for sterilization.

Abutments and further parts designated for sterilization should be packed into sterilization bags.

7. Sterilization

Sterilization should be performed by applying a fractionated pre-vacuum process (refer to EN 13060 / EN ISO 17665-1) under consideration of the respective country requirements.

Please follow the following parameters for the pre-vacuum process:

- 3 pre-vacuum phases with at least 60 mbar
- heat up to a sterilization temperature of 134°C (273°F)
- holding time: minimum 18 min
- drying time: minimum 10 min

8. Storage

Store the sterilized products in a dry, clean and dust free environment at temperatures between 5 to 40°C (41 to 104°F).
Product Information

Biodenta Dental Implant System
Tissue Level, Bone Level and One Piece Implants.
The following content is relevant to the dental implants, surgical instruments and prosthetic components of the Biodenta dental implant system.

⚠️ For detailed information about the products, implantation and prosthetic procedures, the following Biodenta manuals should be consulted:

Product Catalog for an overview of products and components, Surgical Guidelines for surgical protocol of implant placement, Prosthetic Guidelines for abutment placement, prosthetic protocol and dental lab procedures. You will also find detailed and updated information on our home page: www.biodenta.com

Product Description
Biodenta dental implants with BST surface are manufactured from biocompatible pure grade 4 titanium. Other associated surgical instruments and components are manufactured from medical grade titanium alloy, noble metal alloy, stainless steel and polymers. Please refer to respective product labels for individual product information.

Indications for Use
Biodenta dental implants are intended for surgical placement in mandibles or maxillae to support single or multiple tooth restorations, terminal or intermediate abutment support for fixed or removable bridgework and to retain overdentures.

Intended Use
The products are to be implanted in a surgical procedure by a trained and experienced Dental practitioners in a professional setting. The implantation is conducted with specified tools. The Implants are intended to be used in a manner in which they integrate with the bone (osseointegration).

Supplementary Indications
Biodenta healing caps are used to cover the platform surface of the implants to prevent bone and soft tissue growth into the internal implant connection during osseointegration.

The abutments are intended for use as additions to endosseous dental implants to support prosthetic devices in a partially or edentulous patient. These are intended for use to support single and multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw-retained, cement-retained or attachment-retained to the implant.

The transfer parts are used to transfer the implant position to the model analogue.

Handling & Storage
Products should be stored at room temperature in a dry location.

Contraindications
⚠️ Placement of dental implants may be contraindicated based on patient’s medical condition. Contraindications contain but are not limited to: uncontrolled diabetes, vascular diseases, clotting chemotherapies or radiation therapy, metabolic or systemic disorders associated with wound and or bone healing, use of pharmaceuticals that inhibit or alter natural bone remodeling, any disorders which inhibit a patient’s ability to maintain adequate daily oral hygiene, chronic periodontal inflammation, insufficient soft tissue coverage, poor general state of health, psychoses, drug / alcohol abuse or uncontrollable endocrine disorders.
Oral contraindications include but are not limited to: uncontrolled parafunctional habits (e.g. bruxism, clenching), insufficient height and/or width of bone, insufficient interarch space, intraoral infection, xerostomia, inadequate patient oral hygiene. Please refer to surgical guide for detailed contraindications.

**Important Warning**
This routine treatment is not recommended for children and teenagers until epiphyseal closure has occurred (growth has stopped). Treatment planning and placement of dental implants requires special considerations. Improper technique in either implant and placement of dental implants requires special precautions.

1. The following should be evaluated before implantation surgery: sufficient bone quality and quantity, proper oral hygiene and other contraindications as mentioned previously.

2. Driving the implant into the osteotomy deeper than the depth established by the drills will have the consequence of stripping the driver interface inside the implant, the driver, or the walls of the osteotomy and may reduce initial implant fixation.

3. It is not recommended to place small diameter implants (implants with platforms NP, B1, P1) in the molar or premolar region due to risk of implant fracture.

4. Undue bone loss or breakage of a dental implant or restoration parts may come about when an implant or abutment is loaded excessively beyond its functional capability. Physiological and anatomic conditions may negatively affect the performance of dental implants.

5. Misuse of small unsecured components inside the mouth of the patient has the potential of being aspirated.

**Sterile Packaging**
All sterile products are labeled ‘STERILE’. All implants are supplied “sterile”. They are sterilized by gamma irradiation.

- All products sold sterile are for single use only and should be used before the expiry date printed on the product label. Do not use sterile products if the packaging has been previously opened or broken. To use re-sterilized implants is forbidden.

**Unsterile Packaging**
Components and instruments which are not delivered sterile (e.g. titanium abutments only abutments, instruments) are labeled ‘NON STERILE’.

- Before every use, all instrumentation products intended for intraoral application must be sterilized (steam sterilization at 134°C (273°F) with minimum 18 minutes holding time) or disinfected (disinfection solution) according to the instructions in the guidelines.

**Precautions**
These products or devices should only be used by trained and experienced professionals. The surgical and restorative techniques required to properly utilize these devices are highly specialized and complicated procedures. Improper technique can lead to implant failure, loss of supporting bone, restoration fracture, screw loosening and aspiration.

“RX only” indicated on the product means that Federal law restricts this device to sale by or on the order of a dentist.

The Biodenta Dental Implant System has been tested for safety and compatibility in the MR environment. The Biodenta Dental Implant System has not been tested for heating or migration in the MR environment.

**Procedural Precautions of Surgery**
All efforts must be made to minimize damage to the host tissue, paying special attention to thermal and surgical trauma and to the elimination of contaminants and sources of infection. Please refer to the surgical guide for details of the procedural precautions.

1. In the planning stage before surgery, it is important to determine the vertical dimension from the alveolar crest to the opposing dentition for the confirmation of the available space which will conform to the selected abutment and the final crown restoration. Each patient will have different dimensions and suitable abutment. Therefore, it should be carefully evaluated before surgery. The final prosthesis should be designed prior to the placement of the dental implant.

2. Using continuous irrigation with a cool, irrigating sterile saline to avoid thermal damage to the surrounding tissue during the entire procedure.

3. Avoid excessive pressure during preparation of the bone site. Please check the recommended speed and torque of the handpiece for surgical tools in the surgical guide. Minimizing trauma to the bone and surrounding tissue by using sharp instruments enhances the potential for successful osseointegration.

4. All non-sterile devices should be cleaned and/or sterilized prior to use, to eliminate contaminants and other sources of infection.

5. Cutting instruments (such as drills) are not recommended to be used more often than 10 times.

**Procedural Precautions of Restoration**
The healing period of each implant depends on bone quality at the implantation site, the tissue response to the implant and the surgeon’s evaluation of the patient’s bone density at the time of the surgical procedure. To avoid excessive force applied to the dental implant during the healing period, proper occlusion should be evaluated on the implant restoration.

**Potential unfavorable consequences**
Potential unfavorable consequences associated with the use of dental implants may include: radiolucency, etc.), numbness, paresthesia, persistent pain, excessive bone loss, implant breakage or fracture, systemic infection, nerve injury, loss of integration eventually.

**Guarantee**
Biodenta declares the terms and conditions of guarantee on our homepage: www.biodenta.com.

**Disclaimer of liability**
The Biodenta dental implant is part of an overall concept and may only be used in conjunction with the associated original components and instruments according to the instructions and recommendations of Biodenta Swiss AG. Use of products made by third parties in conjunction with the Biodenta dental implant system will void any warranty or other obligation, express or implied, of Biodenta Swiss AG.
Torque Guide

The following table shows which torque should be applied to related procedures.

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Torque</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screwing in implants with NP or B1 platform</td>
<td>max. 50 Ncm</td>
</tr>
<tr>
<td>Screwing in implants with RP, WP or B2 platform</td>
<td>max. 70 Ncm</td>
</tr>
<tr>
<td>Connecting healing -cap / -abutment or closure screw with the implant</td>
<td>Hand Force</td>
</tr>
<tr>
<td>Connecting temporary abutments with the implant</td>
<td>20 Ncm</td>
</tr>
<tr>
<td>Connecting angled-/ straight- / solid- / gold- / ball- / LOCATOR®- / bar- abutments with the implant</td>
<td>35 Ncm</td>
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</tbody>
</table>

Material Declaration

**Implant**

<table>
<thead>
<tr>
<th>Item</th>
<th>Material</th>
<th>Sterilization Disinfection</th>
<th>Disassembly</th>
<th>Reusability</th>
<th>Intraoral Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dental Implants</td>
<td>Pure Titanium</td>
<td>Delivered Sterile</td>
<td>NO</td>
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**Surgical Instruments**

<table>
<thead>
<tr>
<th>Item</th>
<th>Material</th>
<th>Sterilization Disinfection</th>
<th>Disassembly</th>
<th>Reusability</th>
<th>Intraoral Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue Punches</td>
<td>Stainless Steel</td>
<td>Sterilization</td>
<td>NO</td>
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<tr>
<td>Round Burr</td>
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<td>Sterilization</td>
<td>NO</td>
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<tr>
<td>Guide Drill</td>
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<td>Pilot Drill</td>
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<td>Drills</td>
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<td>Depth Gauges</td>
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<td>Taps</td>
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<td>Bone Graft Container</td>
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<td>Extra Tool Container</td>
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<td>Torque Wrench 20-70 Ncm</td>
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<td>X-ray Reference Sphere</td>
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**Closure Screws & Healing Caps**

<table>
<thead>
<tr>
<th>Item</th>
<th>Material</th>
<th>Sterilization Disinfection</th>
<th>Disassembly</th>
<th>Reusability</th>
<th>Intraoral Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closure Screws</td>
<td>Titanium Alloy</td>
<td>Sterilization</td>
<td>NO</td>
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<tr>
<td>Healing Caps</td>
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### Abutments

<table>
<thead>
<tr>
<th>Item</th>
<th>Material</th>
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<th>Disassembly</th>
<th>Reusability</th>
<th>Intraoral Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bar Abutments</td>
<td>Titanium Alloy</td>
<td>Sterilization</td>
<td>NO</td>
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<tr>
<td>Bar Abutment Holder</td>
<td>Stainless Steel</td>
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<td>Straight Abutments</td>
<td>Titanium Alloy</td>
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<td>Angled Abutments</td>
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<tr>
<td>Solid Abutments</td>
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<td>Protective Caps for Solid Abutments</td>
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<td>Temporary Abutments</td>
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<td>Burnout Plastic Copings for Solid Abutments</td>
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<td>Burnout Plastic Shoulders for Angled Abutments</td>
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### Gold Abutments

<table>
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<th>Item</th>
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<th>Intraoral Application</th>
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<tbody>
<tr>
<td>Gold Abutments</td>
<td>Ceramcor®</td>
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<td>Sheath</td>
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### Transfer Parts

<table>
<thead>
<tr>
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<th>Reusability</th>
<th>Intraoral Application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Impression Posts for Solid Abutments</td>
<td>Plastics</td>
<td>Disinfection</td>
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<tr>
<td>Screw Type Impression Posts</td>
<td>Aluminum or Titanium Alloy</td>
<td>Disinfection</td>
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<td>Guide Pins</td>
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<td>Implant Analogs for Solid Abutments</td>
<td>Aluminum</td>
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<td>NO</td>
<td>NO</td>
<td></td>
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<tr>
<td>Implant Analogs for Screw Type Impression Posts</td>
<td>Titanium Alloy</td>
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### LOCATOR®- and Ball Abutments

<table>
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<tr>
<th>Item</th>
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<th>Disassembly</th>
<th>Reusability</th>
<th>Intraoral Application</th>
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<tbody>
<tr>
<td>LOCATOR® Abutments</td>
<td>Titanium Alloy</td>
<td>Sterilization</td>
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<tr>
<td>LOCATOR® Processing Cap</td>
<td>Stainless Steel</td>
<td>Sterilization</td>
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<tr>
<td>LOCATOR® Replacement Males</td>
<td>Plastics</td>
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<td>LOCATOR® Block Out Spacer</td>
<td>Plastics</td>
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<tr>
<td>LOCATOR® Female Analog</td>
<td>Aluminum</td>
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<tr>
<td>LOCATOR® Impression Coping</td>
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<td>Ball Abutments</td>
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<td>Ball Abutment Analog</td>
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<td>Metal Housing for Ball Abutments</td>
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### Prosthetic Instruments

<table>
<thead>
<tr>
<th>Item</th>
<th>Material</th>
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<th>Disassembly</th>
<th>Reusability</th>
<th>Intraoral Application</th>
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<tbody>
<tr>
<td>Solid Abutment Driver</td>
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<td>Reamer for 45° Shoulder</td>
<td>Special Steel</td>
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<td>Prosthetic Kit Box</td>
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<td>Stainless Steel</td>
<td>Sterilization</td>
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<td>Ball Abutment Driver</td>
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<td>LOCATOR® Core Tool</td>
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<td>LOCATOR® Parallel Post</td>
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Material Information

Pure Titanium

The properties of pure grade 4 titanium for Biodenta implants

A. Chemical Composition (wt%):

<table>
<thead>
<tr>
<th></th>
<th>C</th>
<th>O</th>
<th>N</th>
<th>H</th>
<th>Fe</th>
<th>Ti</th>
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<tbody>
<tr>
<td>Max.</td>
<td>0.10</td>
<td>0.40</td>
<td>0.05</td>
<td>0.0125</td>
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B. Mechanical Properties:

<table>
<thead>
<tr>
<th></th>
<th>Elongation (A)</th>
<th>Tensile Strength (Rm)</th>
<th>Yield Strength (Rp)</th>
<th>Reduction of Area (Z)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unit</td>
<td>%</td>
<td>Mpa</td>
<td>Mpa</td>
<td>%</td>
</tr>
<tr>
<td>Min.</td>
<td>15</td>
<td>550</td>
<td>483</td>
<td>25</td>
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C. Technical Information:

Grade 4 titanium conforms to ASTM F67-06 Grade 4 & ISO 5832-2:1999
Titanium Alloy

The properties of wrought titanium 6-Al 4-V alloy for Biodenta Abutments, Abutment Screws, Closure Screws, Healing Caps and Depth Gauges.

A. Chemical Composition (%):

<table>
<thead>
<tr>
<th></th>
<th>Al</th>
<th>V</th>
<th>C</th>
<th>O</th>
<th>N</th>
<th>H</th>
<th>Ir</th>
<th>Ti</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max.</td>
<td>5.5 to 6.75</td>
<td>3.5 to 4.5</td>
<td>0.08</td>
<td>0.20</td>
<td>0.05</td>
<td>0.015</td>
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B. Mechanical Properties:

<table>
<thead>
<tr>
<th>Unit</th>
<th>Tensile Strength (Rm)</th>
<th>Proof stress of nonproportional elongation (Rp)</th>
<th>Percentage elongation after fracture (A)</th>
<th>Mandrel diameter for bend test</th>
</tr>
</thead>
</table>
| Sheet and Strip | 860                   | 780                                          | 8                                        | 10 t
| Bar             | 860                   | 780                                          | 10                                      | Not applicable |

1) t = thickness of the sheet or strip
2) Maximum diameter or thickness = 75 mm

C. Technical Information:

Wrought titanium 6-Al 4-V alloy conforms to ISO 5832-2:1996

Material Data Sheet for Ceramicor®

1. Composition

<table>
<thead>
<tr>
<th>Pt group - metals</th>
<th>Au</th>
<th>Pt</th>
<th>Ir</th>
<th>Au</th>
<th>Pd</th>
<th>Pt</th>
<th>Ir</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>100.00 %</td>
<td>60.00 %</td>
<td>20.00 %</td>
<td>19.00 %</td>
<td>1.00 %</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

2. Physical Properties

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Melting range</td>
<td>1400-1490 °C</td>
</tr>
<tr>
<td>Density</td>
<td>17.5 g/cm³</td>
</tr>
<tr>
<td>Density</td>
<td>12.2X10⁻⁶/K</td>
</tr>
<tr>
<td>Linear Coeff. of thermal expansion (25-500°C)</td>
<td>11.9 x10⁻⁶ K⁻¹</td>
</tr>
<tr>
<td>Linear Coeff. of thermal expansion (25-600°C)</td>
<td>12.2 x10⁻⁶ K⁻¹</td>
</tr>
<tr>
<td>Colour</td>
<td>white</td>
</tr>
</tbody>
</table>

3. Mechanical Properties

<table>
<thead>
<tr>
<th>Condition</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hardness: HV5</td>
<td>&gt; 215 Mpa</td>
</tr>
<tr>
<td>Tensile Strength (Rm)</td>
<td>&gt; 750 Mpa</td>
</tr>
<tr>
<td>0.2% Proof stress (Rp 0.2%)</td>
<td>&gt; 650 Mpa</td>
</tr>
<tr>
<td>Elongation</td>
<td>&gt; 2 %</td>
</tr>
</tbody>
</table>
Symbols

- **LOT**: Lot number
- **REF**: Article reference number
- **X**: Do not reuse
- **Use before expiry date**: Use before expiry date
- **Sterilized by gamma irradiation**: Sterilized by gamma irradiation
- **Manufacturer**: Manufacturer
- **Refer to Instructions for use**: Refer to Instructions for use
- **Not for intraoral application**: Not for intraoral application
- **Non sterile. This product is not sterilized**: Non sterile. This product is not sterilized
- **Attention! Important warning**: Attention! Important warning

Notes

- **CE 0197**
Biodenta Swiss AG products should only be used according to the manufacturer instructions and recommendations. The user of Biodenta products should determine their suitability for particular patients and indications. Biodenta disclaims any liability, expressed or implied, and shall have no responsibility for any direct, indirect, punitive or other damages arising out of, or in connection with, any inaccuracy in professional judgment or practice in the use or placement of the Biodenta products. The user is also obligated to regularly check the latest developments of the Biodenta Dental Implant System and their applications.

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