biodenta®
we're all about teeth

Bone Level | BL

Surgical Guideline

Dental Implant System

Bone 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 December 24, 2013.
Please find latest updates and information on our homepage **www.biodenta.com**

Some products may not be regulatory cleared / released for sale in all markets.

MM-BSG
ver1352

Contents

Preface

Preface

This surgical guideline will assist in the understanding and the placement of Biodenta Bone Level implants.

Each implantation requires careful planning and surgical expertise. The dentist should be familiar with the use of individual instruments and procedures prior to use.

⚠ As an important basis for the implantation with our system, you should participate the Biodenta surgical training courses.

Please contact Biodenta for course dates or additional questions or concerns.

The Biodenta Support Team warmly welcomes your request and is happy to support you:

Biodenta Swiss AG
Tramstrasse 16
CH-9442 Berneck

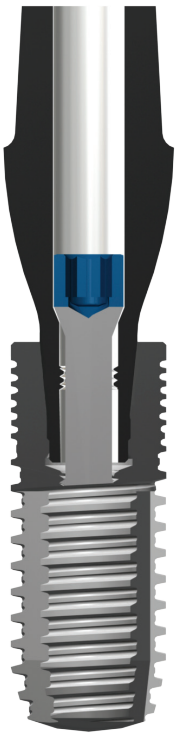
Tel +41 71 747 11 11
Fax +41 71 747 11 12

Europe, Middle East & Africa
emea@biodenta.com

Americas
americas@biodenta.com

Asia & Pacific
apac@biodenta.com

Dental Implant System

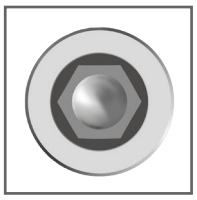


Implant Characteristics

Implant Characteristics

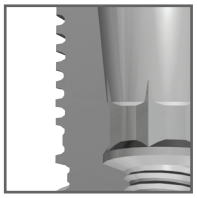
The Biodenta bone level implant is a cylinderically shaped implant with self cutting grooves and specific technical highlights as shown in the following graphic.

1



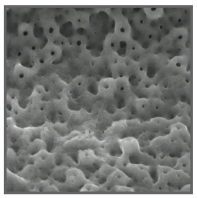
Hex connection system

2



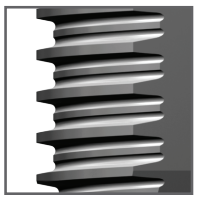
Tight-Fit connection

3

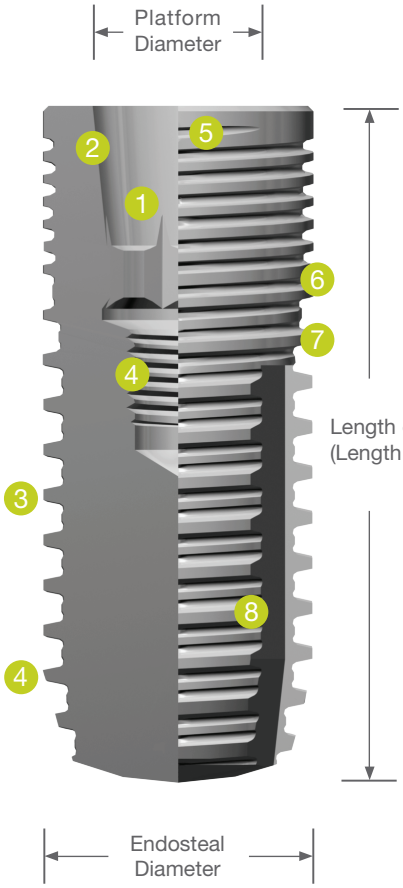


BST surface

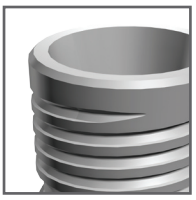
4



Internal thread for stable osseointegration

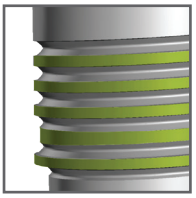


5



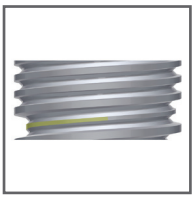
Platform switching

6



Smooth cortical area

7



0.8 mm thread pitch

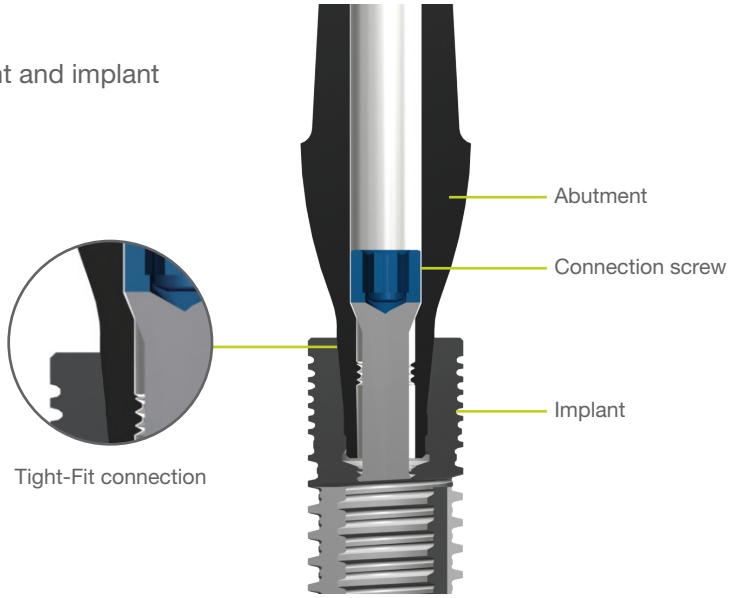
8

Self-cutting grooves

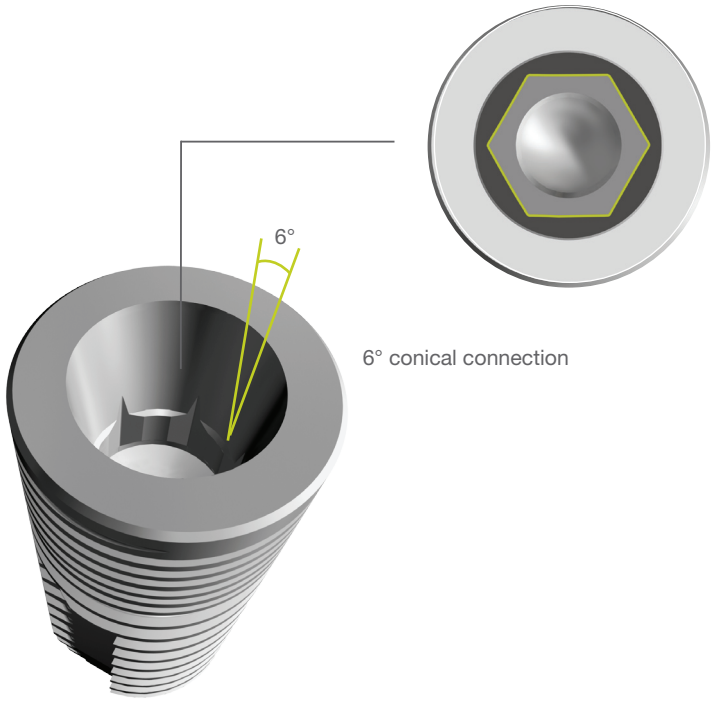
Tight-Fit Connection

Tight-Fit Connection

- 6° conical connection between abutment and implant
- Tight-Fit connection
- Abutment screw locks the connection
- The design intends to minimize micro-movements, micro-leakage and maintain a tight-fit *



Hex connection system



* This assessment is based on bench testing conducted using x-ray analysis of the implant abutment connection without load and under load. These parameters have not shown to provide a meaningful effect clinically.

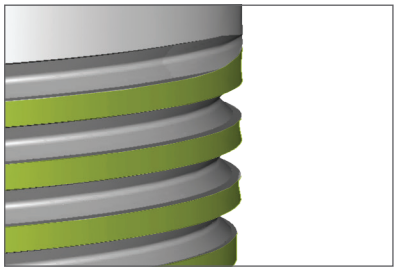
Implant Design

Implant Design

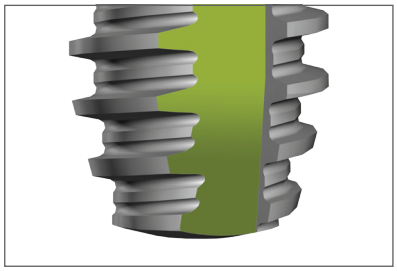
The Biodenta implant has a special structure design. The outer structures include some key main designs. Each design has its unique function. These designs present a well integrated jawbone structure. The implant has a cylindrical outer shape and short conical front.

It has continuous single helix thread, and a dominant and non-dominant turn of the thread. The dominating coil acts as a thread. The non-dominating coil builds a small groove and coils outwards when reaching the top.

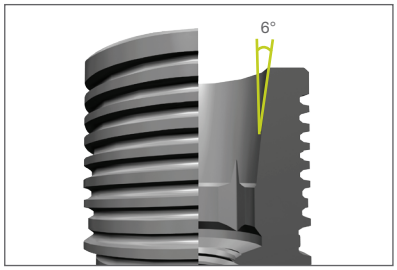
1. The top section has double thin threads that can release stress and helps to support osseointegration.



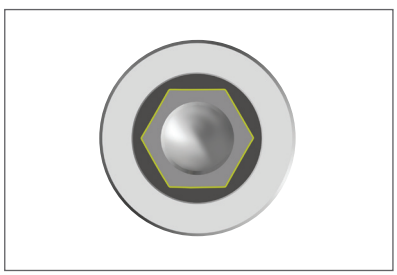
2. Self-cutting grooves are mainly to tap the threads, which reduces implantation torque.



3. Conical connection is a feature for implants near the neck, which has a 6° cone connection for abutment, and healing cap matched to outer shape, providing good load transfer and minimal stress concentration. This 6° conical shape between abutment and implant provides an excellent mechanical joint, which passed 5 million cycles fatigue testing.



4. The middle of the conical contains a hexagonal shaped torque connection.



BST Surface

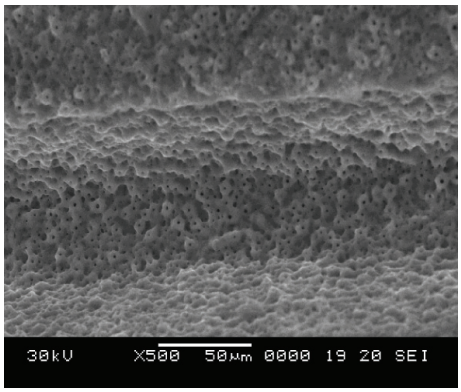
BST Surface

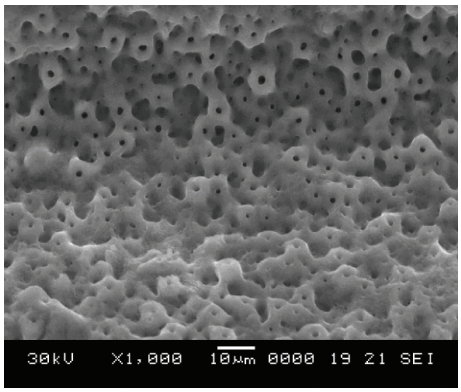
Titanium has been widely used for artificial tooth roots replacement for decades. The integration of dental implants with the alveolar bone relies not only on mechanical force, but also on the biological surface bonding force, thus achieving integration.

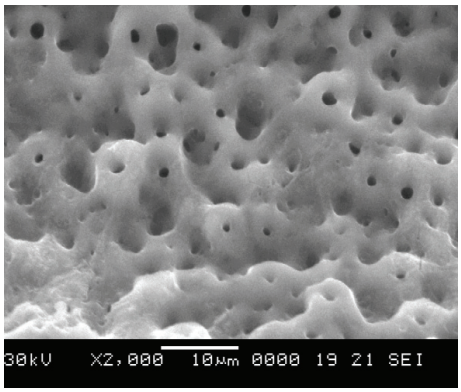
To support osseointegration of biodenta implants an anodization process occurs during the dental implant manufacturing. The BST surface consists of an amorphous titanium oxide layer that has surface roughness enhanced through open porosity. The osteoconduction process allows bone growth onto the surface.

The Biodenta implant was designed with features that make it a good implant choice for many clinical applications. The design allows for high levels of initial stability and a reliable prosthetic platform for most restorative situations.

- Surface activation through the anodization process
- Porous structure via the osteoconduction method
- Enhanced osseointegration





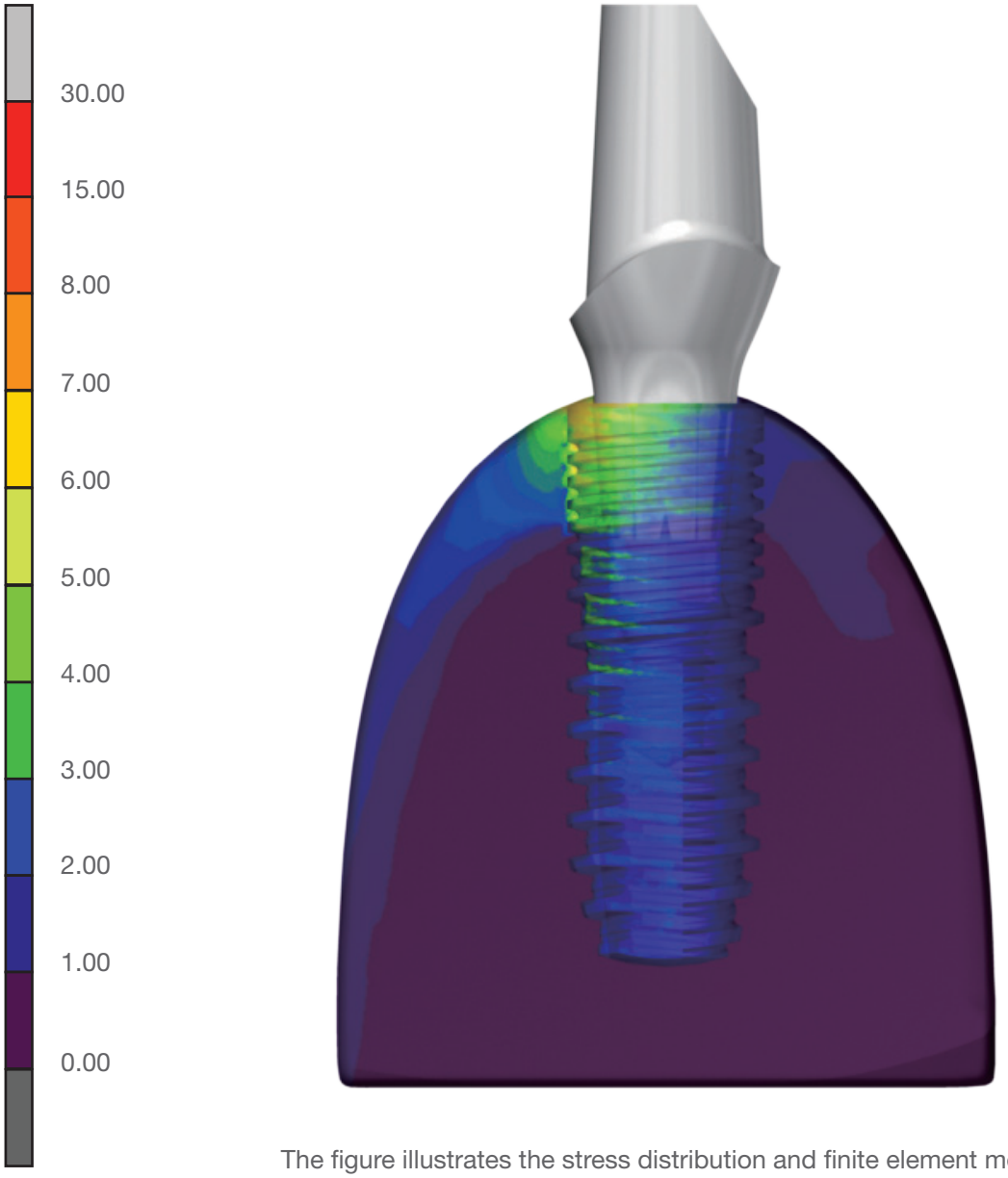


Finite Element Analysis

Finite Element Analysis

This analysis dealt with the stress transference of the thread design of the Biodenta Dental Implant System (bone level model of 3.5 mm endosteal diameter and 8 mm long thread area). All structural materials, cortical and cancellous bones as well as the implant were considered. The Poisson's Ratios were 0.35 for the implant and 0.3 for the bone structures respectively.

The overall results showed the implant design had successfully prevented the transference of high stress to the surrounding bone. Owing to the geometry of the implant and the shape of the threads, the stress was dispersed distributed around the collar and the cancellous region.



The figure illustrates the stress distribution and finite element mesh.

Mechanical Stability

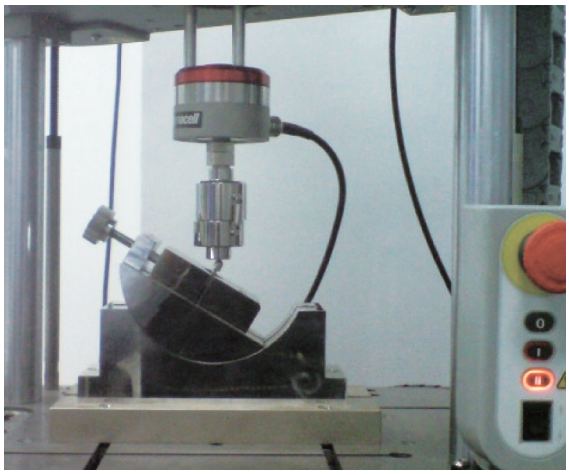
Mechanical Stability

Our well designed implant with a 6° 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.

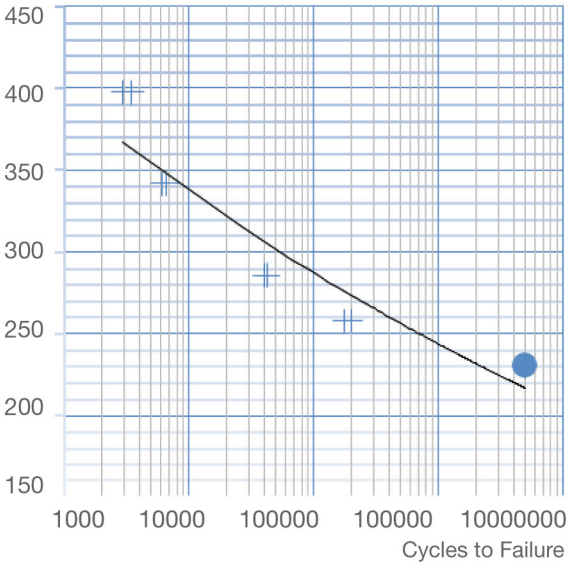
A hemisphere cap, at the top of abutment, adds compressed force, which intersects the off-axis at a point 8 mm higher than bone level.

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.

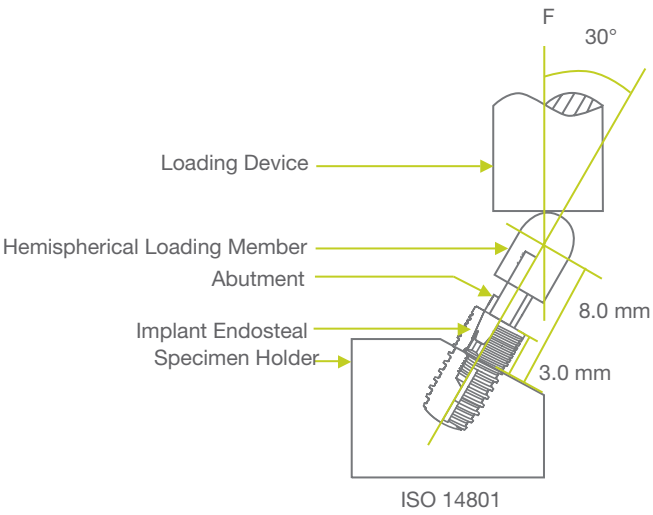
The test confirmed the high mechanical stability of the Biodenta implant system above 200 N for 5 million cycles for the smallest implant with B1 platform.



Implant mount test



X axis : number of cycles, n
Y axis : peak load in Newton
+ : fractured samples
• : surviving samples



Biodenta Quality and Certificates

Biodenta Quality and Certificates

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 logistics 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.

510(k) cleared by the US Food and Drug Association (FDA).

CE 0197
Medical Device Directive 93/42/EEC

510(k) cleared FDA

EN 556-1

EN 980

EN 1041

EN 1642

EN ISO 10451

EN ISO 10993

EN ISO 11137

EN ISO 14630

EN ISO 14971

ISO 14801

ISO 7405

ISO 9001

ISO 13485

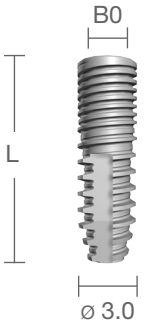
Implant Series | Bone Level

Biodenta Dental Implants I Bone Level
BST Surface

3.0 mm Endosteal Ø 3.0 mm I B0

Length	REF Number
10.0 mm	I-BA30B0L10A
12.0 mm	I-BA30B0L12A
14.0 mm	I-BA30B0L14A

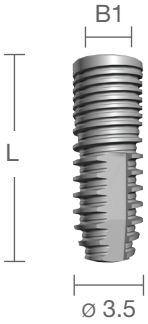
* B0 0.5 mm Closure Screw included



3.5 mm Endosteal Ø 3.5 mm I B1

Length	REF Number
8.0 mm	I-BA35B1L08A
10.0 mm	I-BA35B1L10A
12.0 mm	I-BA35B1L12A
14.0 mm	I-BA35B1L14A

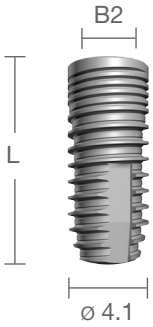
* B1 0.5 mm Closure Screw included



4.1 mm Endosteal Ø 4.1 mm I B2

Length	REF Number
6.5 mm	I-BA41B2L65A
8.0 mm	I-BA41B2L08A
10.0 mm	I-BA41B2L10A
12.0 mm	I-BA41B2L12A
14.0 mm	I-BA41B2L14A

* B2 0.5 mm Closure Screw included

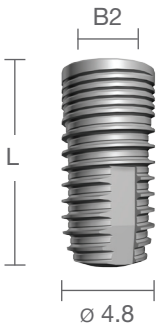


Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

4.8 mm Endosteal Ø 4.8 mm I B2

Length	REF Number
6.5 mm	I-BA48B2L65A
8.0 mm	I-BA48B2L08A
10.0 mm	I-BA48B2L10A
12.0 mm	I-BA48B2L12A
14.0 mm	I-BA48B2L14A

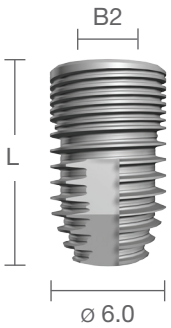
* B2 0.5 mm Closure Screw included



6.0 mm Endosteal Ø 6.0 mm I B2

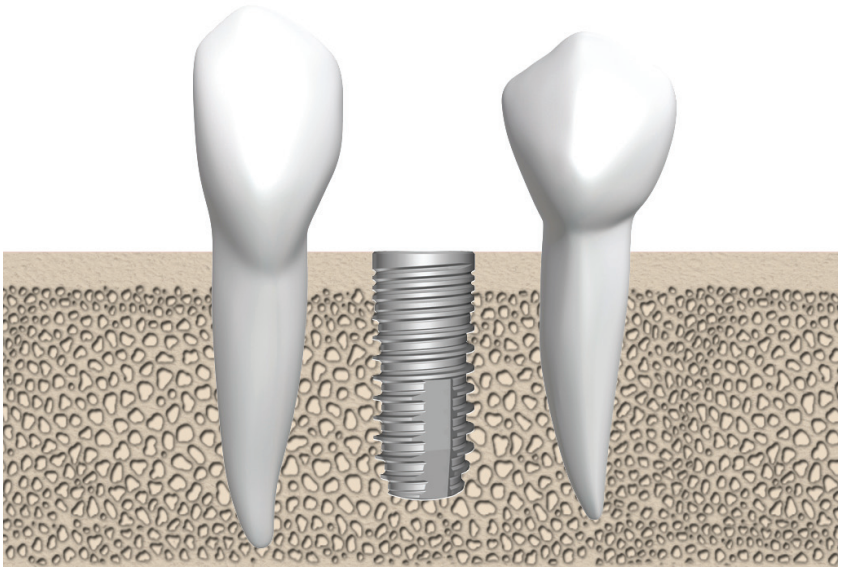
Length	REF Number
6.5 mm	I-BA60B2L65A
8.0 mm	I-BA60B2L08A
10.0 mm	I-BA60B2L10A
12.0 mm	I-BA60B2L12A

* B2 0.5 mm Closure Screw included



Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

Preoperative Planning



Evaluation of Bone Quality, Bone Classes

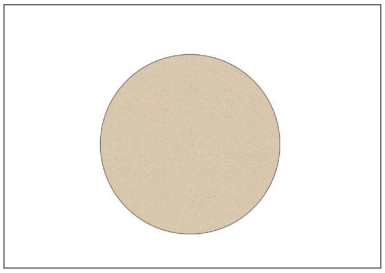
Evaluation of Bone Quality, Bone Classes

The evaluation of bone quality is performed by using both radiographic imaging techniques and clinical examination. Dense cortical bone provides initial stabilization for the implant. Cancellous bone provides less retention and less initial stabilisation.

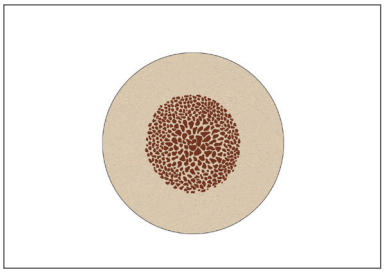
The time needed to develop osseointegration varies with the bone quality. Prior to the insertion of the implant, appropriate modifications should be made to the standard surgical procedure to accommodate the particular type of bone quality. One of the main keys to successful osseointegration is good initial support and stability.

The bone quality is classified into 4 categories: D1, D2, D3 and D4 :

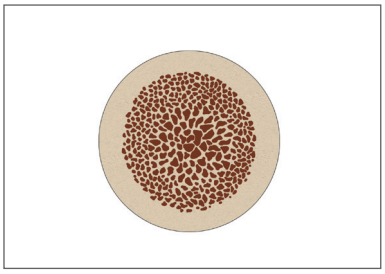
Bone Class D1
Dense cortical bone, little spongy bone. The bone is composed uniformly of dense compact bone.



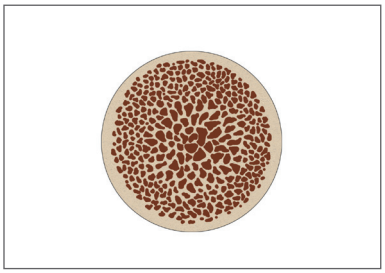
Bone Class D2
Dense cortical bone, large spongy bone. Bone has a thick layer of dense compact cortical layer with the trabecular bone at the core of the bone.



Bone Class D3
Thin cortical bone, fine meshed spongy bone. Bone is surrounded by a thin layer of cortical bone with dense compact trabecular bone at core.



Bone Class D4
No cortical bone, fine spongy bone. The trabecular bone comprises of the low density bone.

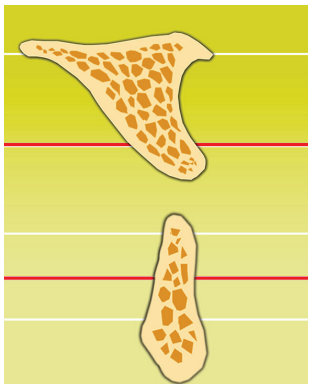


Bone Quantity

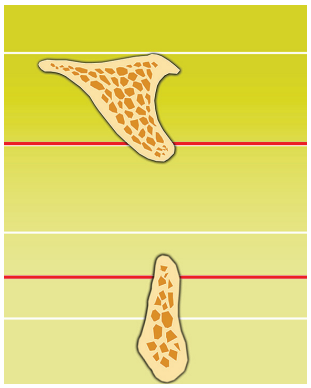
Remarks

The shape and the height of the alveolar ridge can be altered by bone resorption and bone remodeling. If the alveolar ridge reveals no resorption or damages, the selection of a post-resorption implant site is far more important than that of a pre-resorption one.

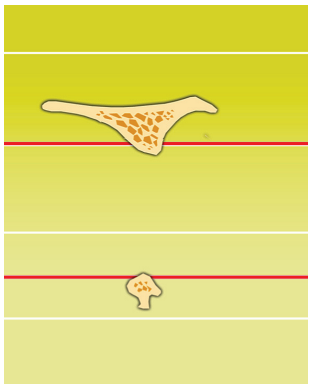
Classification of the Bone Resorption of the Maxilla and the Mandible:



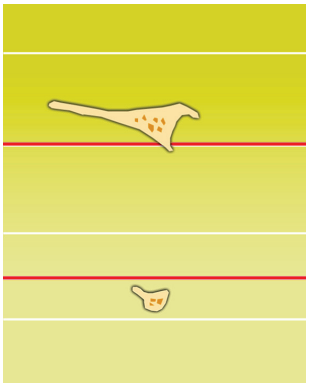
Class I
Most of the alveolar bone remains. Only superficial bone resorption.



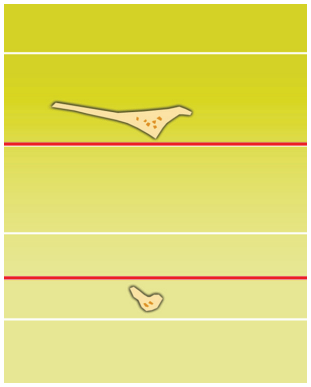
Class II
Resorption of the alveolar bone appears, forming different stature profile of the alveolar ridge.



Class III
The alveolar bone is fully resorbed. Only the base ridge remains.



Class IV
Resorption of the base ridge appears. The alveolar ridge becomes lower, showing varying indentation.



Class V
The maximum resorption of the base ridge develops.

Remarks

Remarks

⚠ When treatment planning for implant restorations, the dentist should examine patient's oral status to ascertain if there is enough interocclusal space for the prosthesis. The opposing occlusion and the remaining alveolar ridge should be separated by at least a minimum of 6 to 8 mm in order to provide the necessary interocclusal space.

In addition to conducting intraoral examination, the "standard" radiographic examination and / or tomography (CT) should be performed.

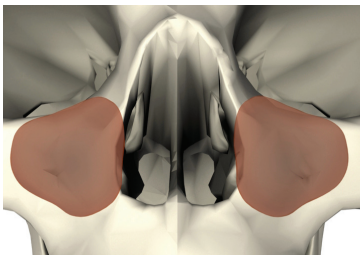
Depending on the implant position, it may be necessary to improve the soft and hard tissue quality with grafting procedures.

In cases where there are limited vertical bone height and thin cortical bone, the cortical bone should be maintained as much as possible during the surgery to maximize initial stability of the implants during initial postoperative phase. It is imperative to avoid premature loading of the implant during this phase.

Maxilla
The location of the maxillary sinus is typically in the region above the maxillary (upper) molars.

The maxillary sinus varies in size and appropriate radiographic scans should be performed during the treatment planning phase.

When indicated, maxillary sinus bony augmentation should be performed to improve the bony support for implants in this region.

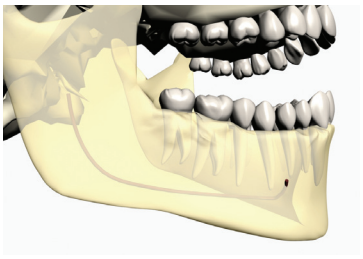


maxillary sinus

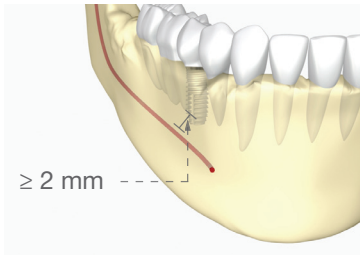
Mandible
Implant placement in the posterior mandible needs appropriate radiographic scan to determine the location of the inferior alveolar nerve. Should implant placement approach the nerve, there is a risk of immediate or long term injuries to the nerves.

Attention must be paid to the location of the mental foramen and the level of nerve in the premolar region.

It is suggested that a minimum distance of 2 mm be maintained between the top of the canal and the apical part of the implant.



Posterior mandible



Minimum distance of 2 mm

Implant Selection and Positioning

Implant Types

Depending on the space availability at the implant placement site, select the proper implant based on below chart. There are different types of bone level implants available with three different endosteal diameters and platforms.

The implants of the Biodenta Dental Implant System are available with the following specifications:

Endosteal Implant Ø	Platform Types	Platform Ø
3.0 mm	B0	2.3 mm
3.5 mm	B1	2.7 mm
4.1 mm	B2	3.1 mm
4.8 mm	B2	3.1 mm
6.0 mm	B2	3.1 mm

Bone Level Implants

BST surface

	B0	B1	B2	B2	B2
					
	3.0 mm	3.5 mm	4.1 mm	4.8 mm	6.0 mm
Length	REF Number	REF Number	REF Number	REF Number	REF Number
6.5 mm			I-BA41B2L65A	I-BA48B2L65A	I-BA60B2L65A
8 mm		I-BA35B1L08A	I-BA41B2L08A	I-BA48B2L08A	I-BA60B2L08A
10 mm	I-BA30B0L10A	I-BA35B1L10A	I-BA41B2L10A	I-BA48B2L10A	I-BA60B2L10A
12 mm	I-BA30B0L12A	I-BA35B1L12A	I-BA41B2L12A	I-BA48B2L12A	I-BA60B2L12A
14 mm	I-BA30B0L14A	I-BA35B1L14A	I-BA41B2L14A	I-BA48B2L14A	

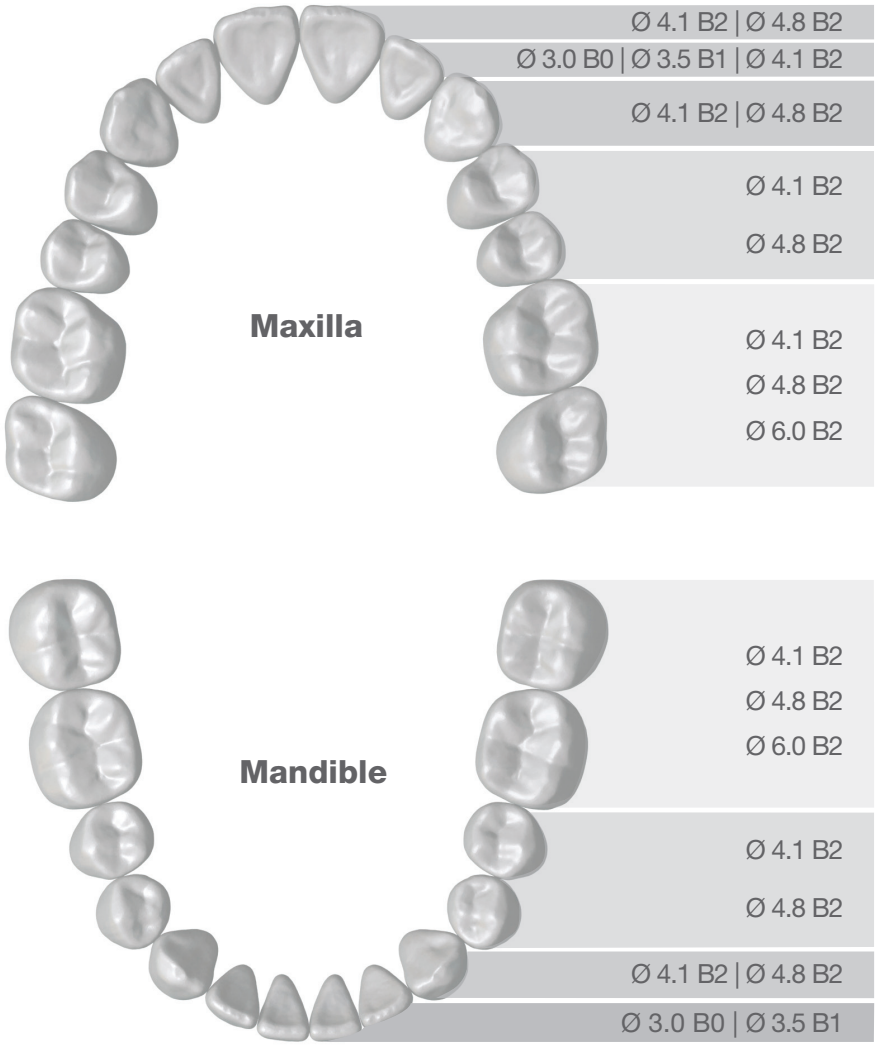
Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

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, 3.0 mm and 3.5 mm implants are not recommended in the molar 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 for implants.



Suggested implant sizes based on region.

⚠ *Do not use Ø 3.0 mm and Ø 3.5 mm implants in the molar area or premolar area.*

⚠ *Immediate loading of single-tooth restoration is not recommended for all 3.0 mm implant diameters.*

Distances

Selection of implant position is imperative for dentists and dental technicians 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 teeth 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.

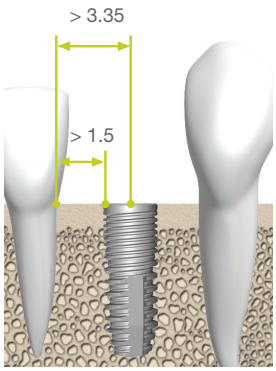
The following minimum guidelines should be included: implant diameter, implant length, position and quantity of implants. Depending on the planned position of the implant abutment, the following dimensions should be considered:

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

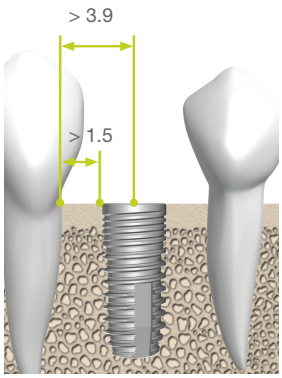
Minimum distances between implants and implant and teeth.
A. Maintain > 1.5 mm from the implant shoulder to the adjacent tooth.*
B. Maintain > 3.0 mm between two adjacent implant shoulders.
C. Maintain > 1.0 mm between implant shoulder and inter dental contact point.

Distance for Single Implant Placement

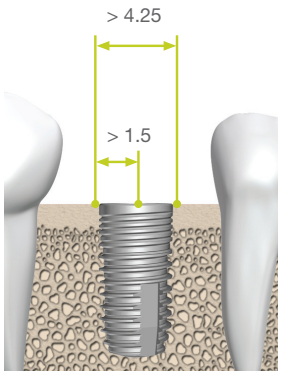
The following graphics indicate the distances for all three platforms. The table gives figures which are rounded up. These are suggested guidelines.



Distance for B1 / Ø 3.5



Distance for B2 / Ø 4.1



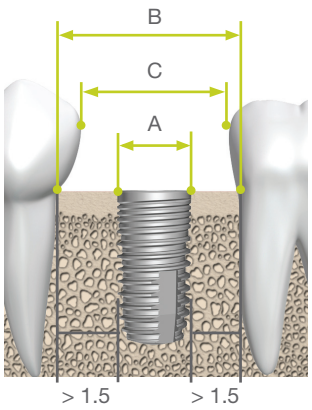
Distance for B2 / Ø 4.8

* Maintain wider distances if possible.

Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

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.

Platform diameter (mm) A	Distance between mesial and distal tooth at bone (mm) B	Tooth gaps (mm) C
B1 Ø 3.5	7.0	6.0
B2 Ø 4.1	8.0	7.0
B2 Ø 4.8	8.5	7.5



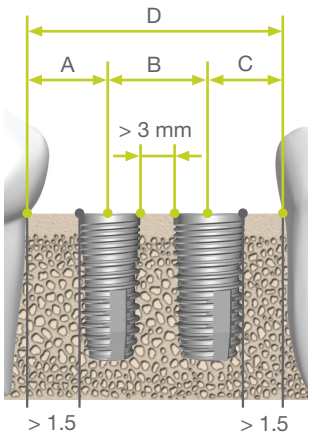
Single implant gap

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.

The following chart is a measurement of bone level from adjacent tooth to the center of implant and between implants when measured from center to center. The minimum distance between two implant shoulders is 3.0 mm. The table gives figures which are rounded up. These are suggested guidelines.

Platform diameter I (mm) I	Platform diameter II (mm) II	Mesial (mm) A	Implant Center (mm) B	Distal (mm) C	Proximal cervical (mm) D
B1 Ø 3.5	B1 Ø 3.5	3.5	7.0	3.5	14.0
B1 Ø 3.5	B2 Ø 4.1	3.5	7.5	4.0	15.0
B1 Ø 3.5	B2 Ø 4.8	3.5	8.0	4.5	16.0
B2 Ø 4.1	B2 Ø 4.1	4.0	8.0	4.0	16.0
B2 Ø 4.1	B2 Ø 4.8	4.0	8.5	4.5	17.0
B2 Ø 4.8	B2 Ø 4.8	4.5	8.5	4.5	17.5



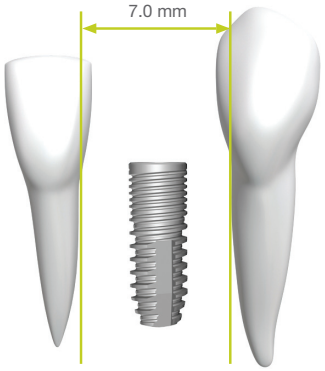
Implant & tooth gaps

Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

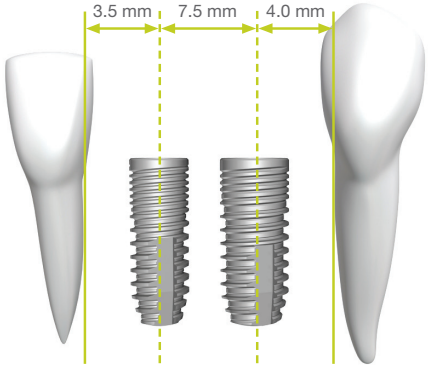
Distance Examples

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

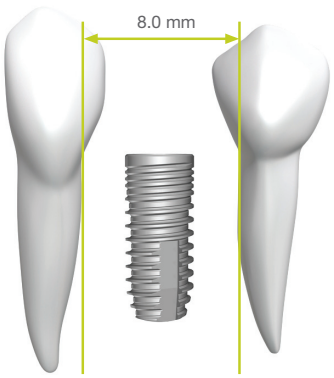
B1



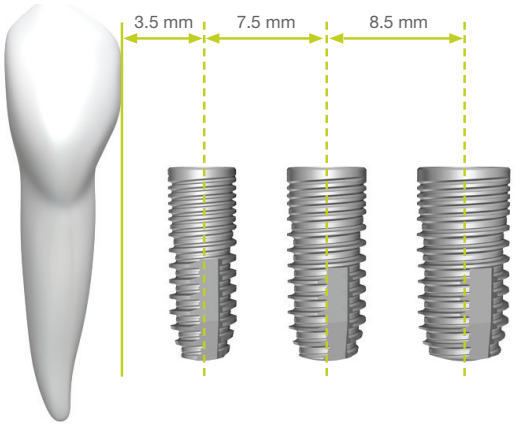
B1 & B2 4.1



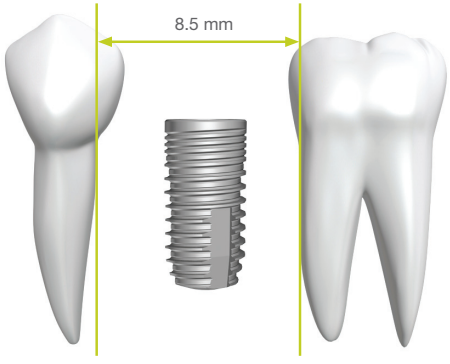
B2 4.1



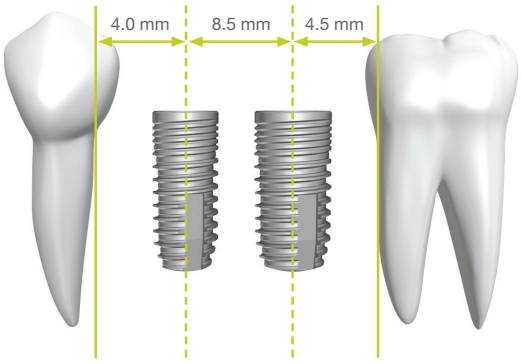
B1 / B2 4.1 / B2 4.8



B2 4.8



B2 4.1 & B2 4.8

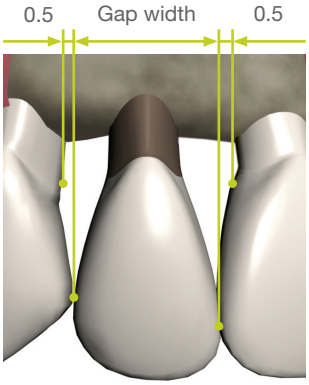


Recommended Mesio-Distal Distances for Implants

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.

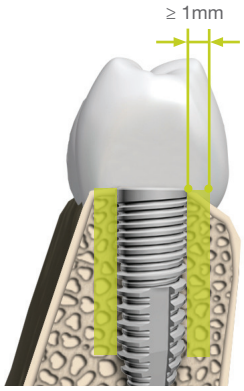
When evaluating the recipient site of anterior single implant, the distance from the planned implant crown at the level of the bone to the adjacent root structure must be a minimum of 0.5 mm on each side (total 1.0 mm).



Bone layer at least 1 mm thickness

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.



At least 1 mm thickness

Radiographic Templates

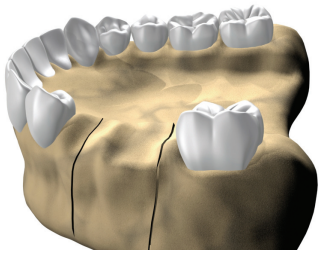
Measurement of available vertical Bone Height

The dentist can use a radiographic template as a positioning guide for implant placement to determine ideal buccolingual, mesiodistal, and axis orientations of the implant. The radiographic template is highly recommended to be used as a guide preoperatively to determine implant size.

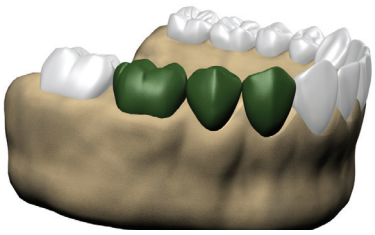
The amount of bone available determines the maximum allowable length and width of the implant to be surgically placed.

An x-ray reference sphere is suggested to be used which will allow the surgeon to measure the magnifying ratio and distortion. With the midline or the remaining teeth as the reference point, the surgeon can measure the distance by which the implant will be installed. The surgeon can also use the radiographic template as a guide for placement of the implant.

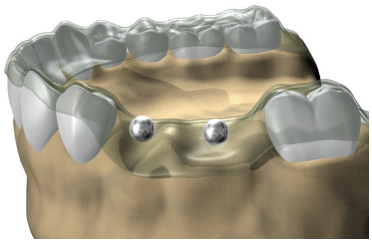
Preparation of vacuum formed Template and use of the Reference Spheres



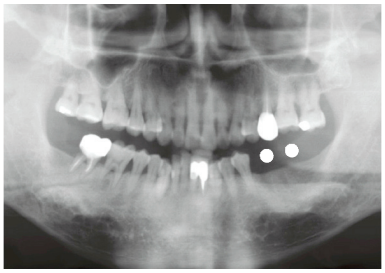
1. The stone models of the patient should be mounted which will allow the dentist to evaluate the location of the remaining dentition, interocclusal distance, and alveolar ridge relationship.



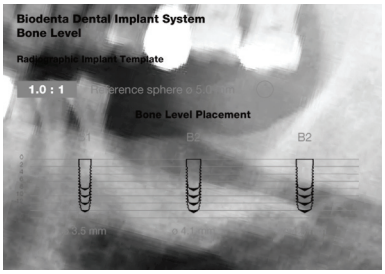
2. Perform a diagnostic wax up according to the planned prosthetic restoration of the patient.



3. Place x-ray reference sphere which has a diameter of 5.0 mm in the vacuum-formed template at the pre-selected implant site. The sphere can be incorporated in the vacuum formed template or adhered to the template.



4. Administer the orthopantomo graph. The x-ray film shows the vertical bone availability and the size of the metal sphere.



5. The dentist analyzes the radiograph by using the template. (see following pages)

6. Remove the sphere leaving holes in the template. It might now be used as template for the implant surgery.

Use of the Radiographic Template

The radiographic template is used for implant measurement and comparison. The template allows the dentist an effective aid to select implant type, width and length. According to the trace distortions of radiograph, select the appropriate proportion on the template. The distortion is typically 1.0:1 to 1.7:1. Scale mark corresponding to the implant sphere, length and width on each template.

The template is for bone level implants, ensure the template is parallel with the coronal area of each implant. All implant types with the available length are shown on the template.

⚠ The gap under each implant should be considered at the planning stage. It can be seen on the template and it is caused by the drill tip which extends approximately 0.6 mm beyond the implant in its final position.

⚠ It is generally NOT recommended to place the implants deeper than the coated area.

Step 1. Calculate distorted value according to the size of reference sphere on the patient's radiograph. The actual size of the x-ray reference sphere is exactly 5.0 mm.

Step 2. Select the corresponding distorted ratio on the radiographic template.

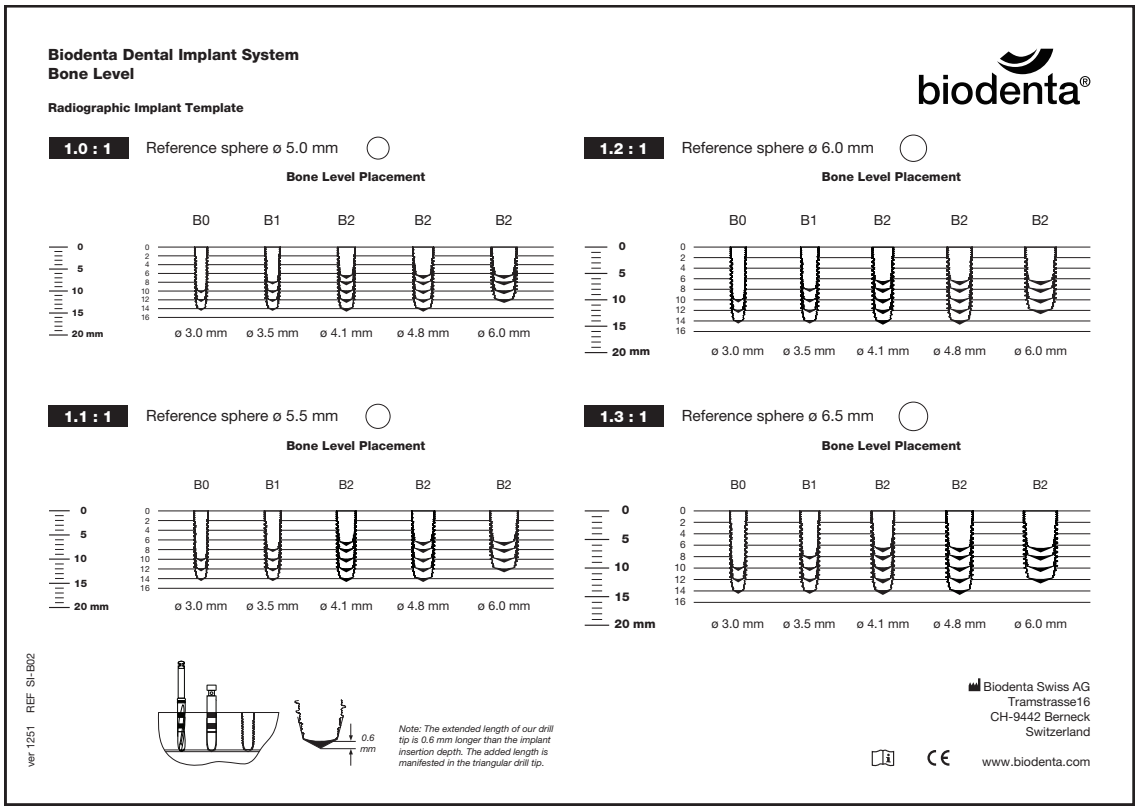
Step 3. Use radiographic template and superimpose it on the patient's radiograph.

Step 4. Determine implant position of insertion according to the available spatial relationship. Confirm implant depth and width.

When performing implant surgery, select the suitable length and width of the implant based on the oral cavity and the conditions of the implant bed. One can also place the assorted implants against the radiograph for comparison and measurements. As mentioned previously, there are radiographic distortions that needs to be taken into consideration.

⚠ A safety distance of 2 mm must be maintained between the implant and the inferior alveolar nerve.

Radiographic Template for Biodenta implants.



1.2 : 1 Reference sphere ø 6.0 mm

Example:
Scale 1.2 : 1 = reference sphere ø 6.0 mm

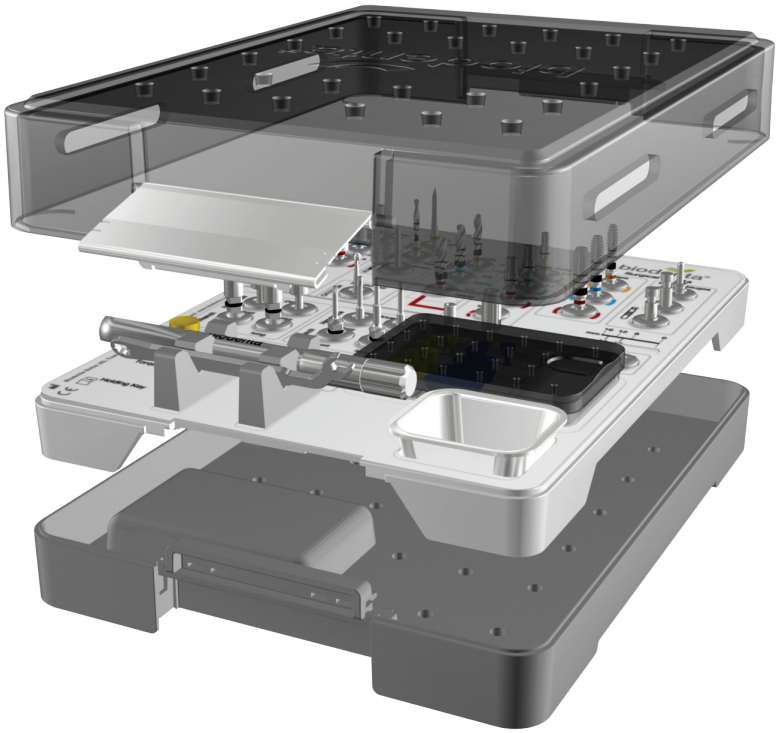
Calculate the bone availability with the following formula:

$$\frac{\text{X-ray reference sphere 5 mm x X-ray bone availability}}{\text{X-ray reference sphere diameter}} = \textbf{Actual Bone Availability}$$

For example:
If the x-ray film shows the bone availability to be 14 mm and the diameter of the reference sphere to be 5.8 mm, the actual bone availability is calculated as 12 mm.

$$\frac{5 \text{ mm x } 14 \text{ mm}}{5.8 \text{ mm}} = \textbf{12 mm}$$

Surgical Instruments



Drill Indications

Depth Markings and Drilling Instructions

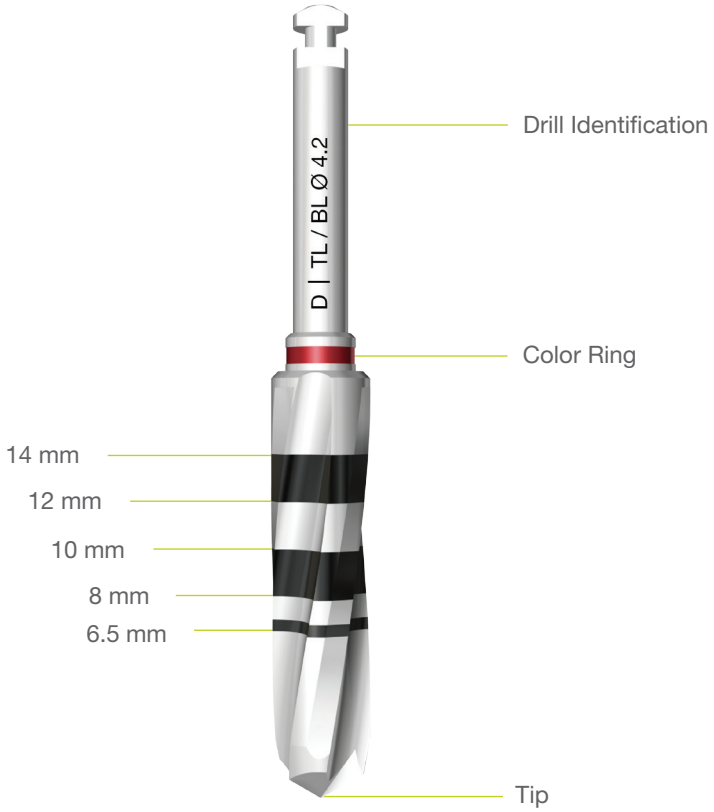
The markings on the drill indicates 6.5, 8, 10, 12, and 14 mm lengths. They are 2 mm increments which corresponds to the lengths of implant body. Specifically, the LOWEST part of the line is the exact distance.

Based on the implant length, determine the length and the position of the drill and the tap to be used.

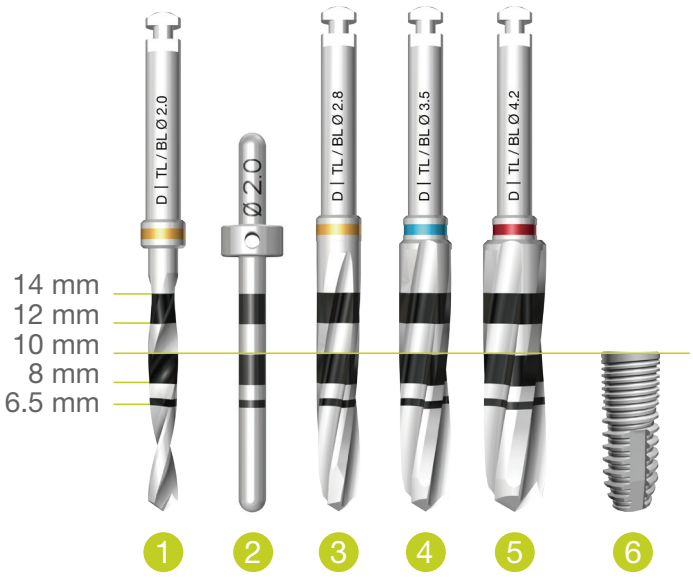
⚠ While drilling, a continuous up and down motion is recommended.

⚠ The surgical instruments are reusable with proper sterilization. Please refer to the cleaning, disinfection and sterilization instructions.

⚠ Cutting instruments **should be replaced after a maximum of 10 uses**. Additional uses are contraindicated due to dulling of the instruments. Frequent replacement will minimize trauma to the bone and surrounding tissue. By using sharp instruments, it will enhance the potential for successful osseointegration.



The following example presents a scenario where a 10 mm implant is utilized. For normal placement, the corresponding 10 mm markings of drills and depth gauges are shown.



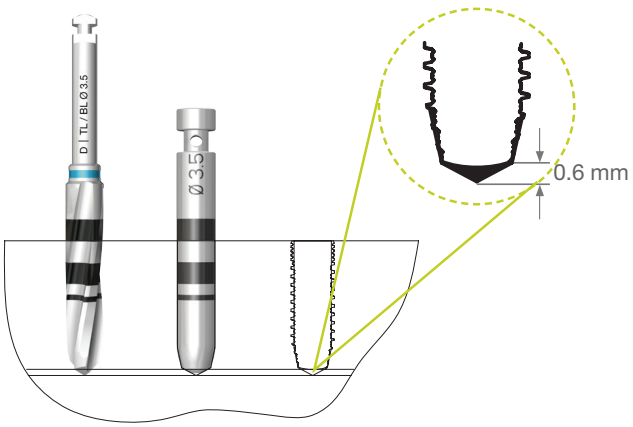
1. Ø 2.0 mm Pilot Drill
2. Ø 2.0 mm Depth Gauge
3. Ø 2.8 mm Drill
4. Ø 3.5 mm Drill
5. Ø 4.2 mm Drill
6. L 10 mm Implant

Color Rings

The color rings refer to the color coding of the diameter of endosteal implants. The instruments should be used in relation to the selected implant type. Please follow the instrument table in the surgical instrument section.

Additional Length of the Drill Tip

Due to the function of the drill, the actual apex of the drill is 0.6 mm greater than the markings on the drill. This distance is very important when the length of the drill impinges on pertinent structures. Calculate the gap between implant insertion depth and apex of final drill.



⚠ The extended length of our drill tip is 0.6 mm longer than the implant insertion depth. The added length is manifested in the triangular drill tip.

Drill Extension

In case the drills are too short for appropriate preparation, they can be extended by the drill extension. Just click the extension on the shaft of the drill. For removal, pull the extension from the shaft. The extension can be connected to all drills, round bur, punches, taps, hex drivers and implant drivers.

Torque Wrench

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 guide for 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 (counterclockwise 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. Ensure that the line on the handle is in straight alignment with the line on the adjustment screw. 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 may be incorrect.

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

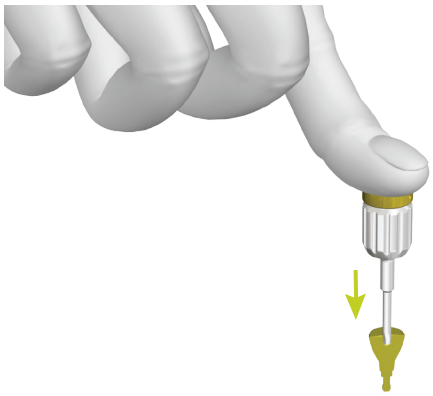
⚠ Follow the instructions that are supplied with the wrench for proper handling, disassembling, sterilization and maintenance.

Torque Guide

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

Procedure	Torque
Inserting implants with B0 platform	max. 35 Ncm
Inserting implants with NP or B1 platform	max. 50 Ncm
Inserting implants with RP, WP or B2 platform	max. 70 Ncm
Connecting healing cap / abutment or closure screw with the implant	Hand Force
Connecting temporary abutments with the implant	20 Ncm
Connecting B0 angled / straight / ball / LOCATOR® abutments with the implant	20 Ncm
Connecting angled / straight / solid / gold / ball / LOCATOR® / swift / multi-use / hybrid sleeve / bar abutments with the implant	35 Ncm
Connecting bridge screw with multi-use abutment	20 Ncm
Connecting prosthetic screw with hybrid sleeve	20 Ncm

⚠ Please ensure the hex driver is fully engaged into the head of the prosthetic screw.



⚠ If it is necessary to reverse a torque tightened abutment screw, we suggest to **replace the abutment screw** once the torque is reversed, in order to maintain the full torque capacity of the abutment screw.

Surgical Kit

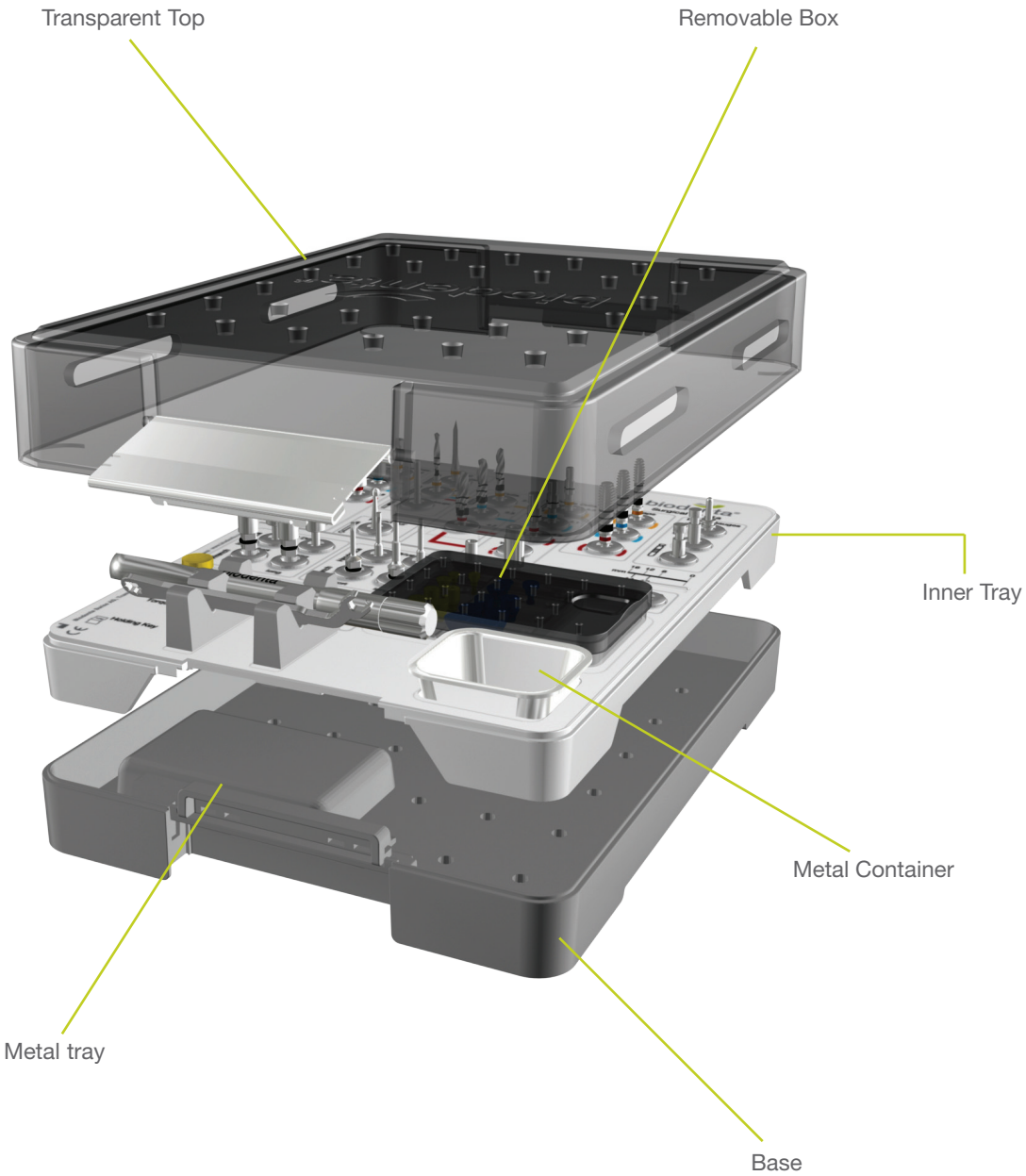
Surgical Kit

The surgical kit contains all required surgical instruments. The following graphic illustrates the elements of the kit and the position of each instrument.

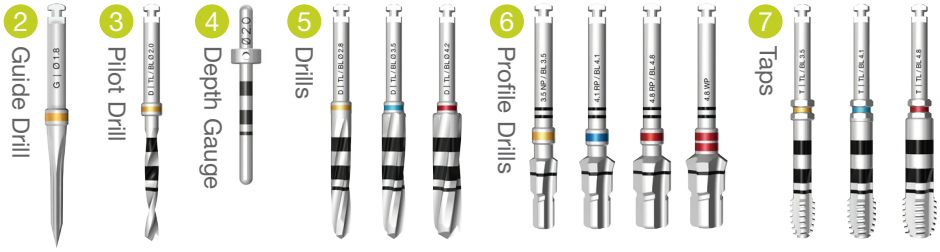
The color markings show the instrument flow to be applied for the related implant.

⚠ Please make sure that each instrument returns to its correct position when preparing the surgical kit. Please carefully follow the instructions as described in the section, cleaning, disinfection and sterilization.

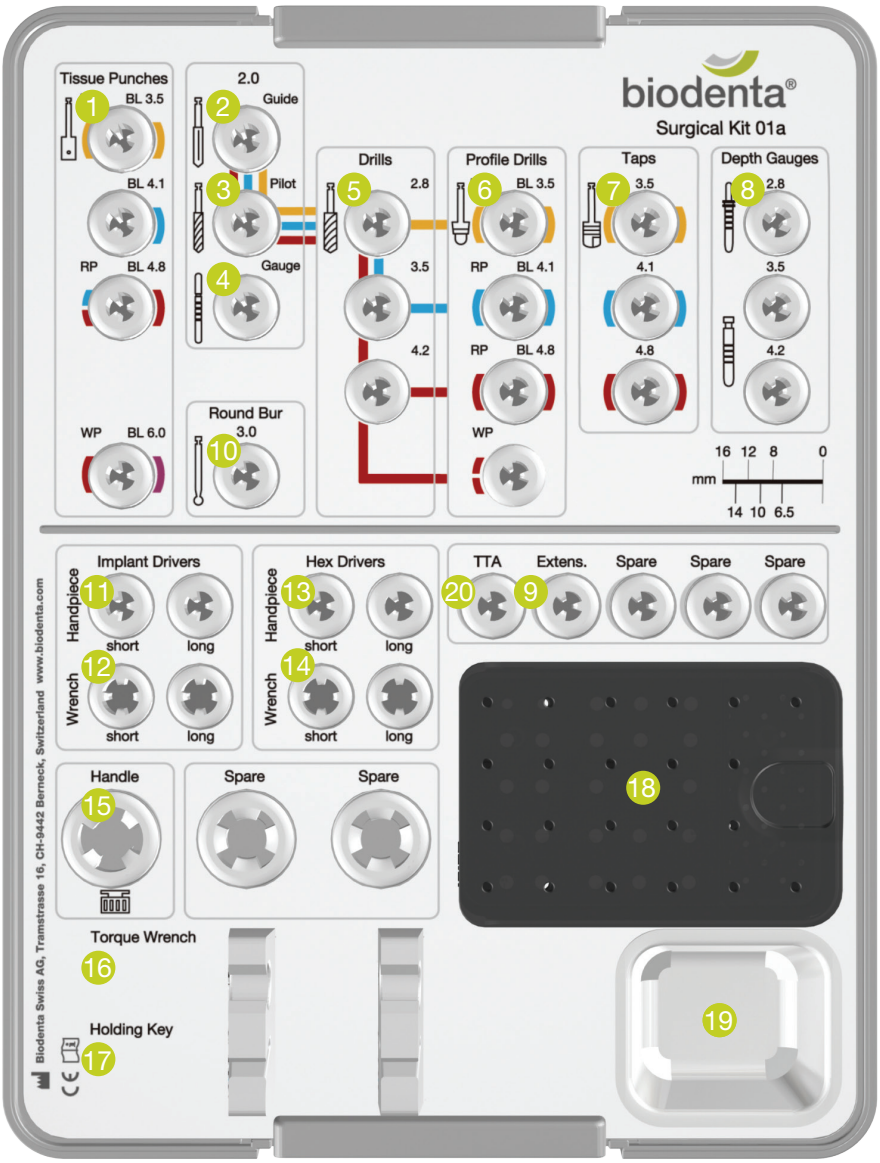
⚠ All parts used intraorally must be secured against aspiration!



Surgical Kit I Tissue- and Bone Level



1 Tissue Punches



8 Depth Gauges

9 Drill Extension

10 Round Bur

11 Implant Drivers for Handpiece

12 Implant Drivers for Torque Wrench

13 Hex Drivers for Handpiece

14 Hex Drivers for Torque Wrench

15 Handle for Hex Drivers

20 Tap Adaptor for Torque Wrench

16 Torque Wrench

17 Holding Key

18 Removable Box to sterilize Closure Screws or Healing Caps

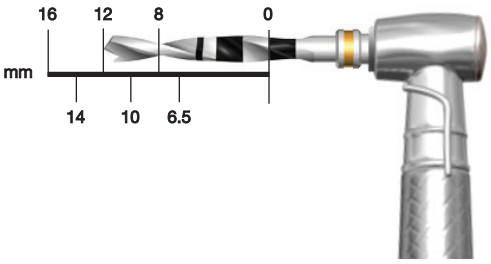
19 Metal Container (Stainless Steel)

Drill Length Scale

The drill length scale in the surgical kit can be used to check the correct drill marking.

The drill marking has to be positioned at the “0” line; the scale then shows how deep the drill will move into bone.

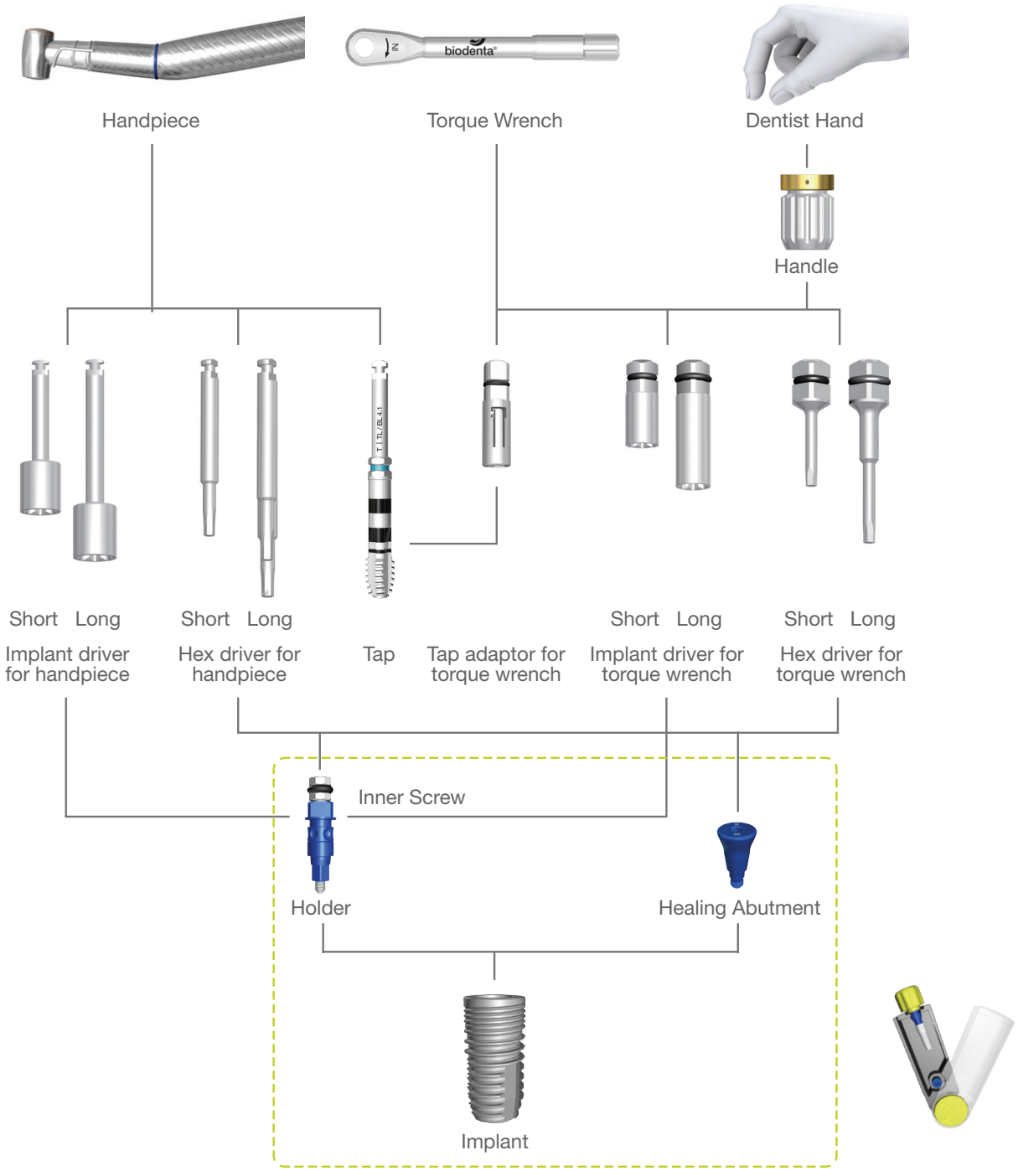
The example shows the 12 mm marking positioned at the “0” line. The drill will drill a bit deeper than 12 mm because of the additional apex (0.6 mm) of the drill.



Connection and Application Charts

Connection Procedure Chart

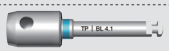
This chart shows how the instruments can be connected to each other. It also shows the elements supplied with the implant housing and how the implant is connected with the instruments via inner screw and holder.



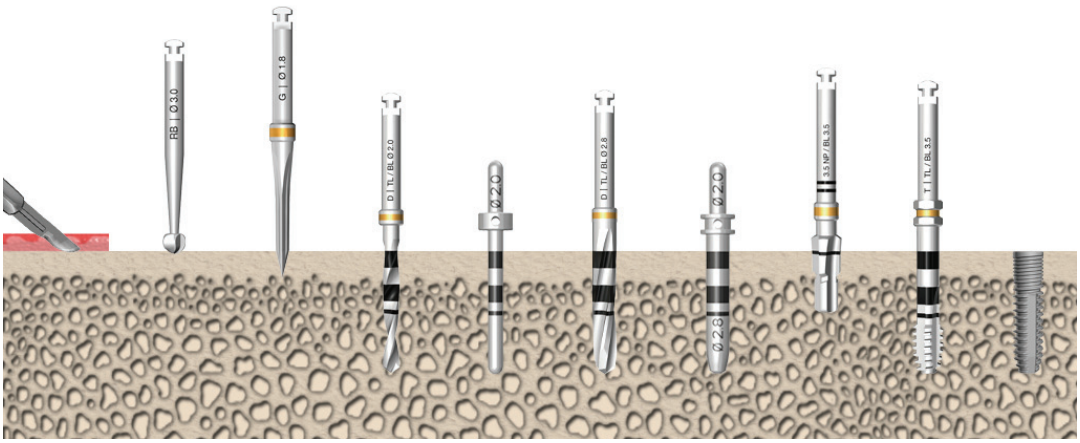
⚠ In order to ensure reliable function, the instruments need to be replaced frequently. If you recognize that the pick-up function of the instruments (hex-driver, direct implant driver, etc.) is ineffective, such instruments need to be replaced immediately!

Application Chart

This table shows the surgical instruments for implant bed preparation. It includes the application, maximum handpiece speed, image, and related implant type.

Instrumentation for implant bed preparation				Implant Type ø (mm)					
Step		max. rpm	Photo	ø 3.0 B0	ø 3.5 NP / B1	ø 4.1 RP / B2	ø 4.8 RP / B2	ø 4.8 WP	ø 6.0 B2
Flapless Operation	*Tissue Punch NP / BL 3.5*	800		●	●				
	Tissue Punch BL 4.1					●			
	Tissue Punch RP / BL 4.8						●		
	Tissue Punch WP / BL 6.0							●	●
Prepare the Alveolar Ridge	*Round Bur ø 3.0 mm*	800		●	●	●	●	●	●
Mark the Implant Site	*Guide Drill ø 1.8 mm*	800		●	●	●	●	●	●
Prepare the Implant Site	*Pilot Drill ø 2.0 mm*	800		●	●	●	●	●	●
Check the Depth and Condition	*Depth Gauge ø 2.0 mm*			●	●	●	●	●	●
Widen the Implant Site for ø 3.0 mm Implant	*Drill 2.5 mm*	600		●					
Widen the Implant Site for ø 3.5 mm Implant	*Drill 2.8 mm*				●	●	●	●	●
Widen the Implant Site for ø 4.1 mm Implant	*Drill 3.5 mm*					●	●	●	●
Widen the Implant Site for ø 4.8 mm Implant	*Drill 4.2 mm*						●	●	●
Widen the Implant Site for ø 6.0 mm Implant	*Drill 5.4 mm*								●
Measure the Depth of the Implant Site	*Depth Gauge ø 2.8 mm*				●	●	●	●	●
	Depth Gauge ø 3.5 mm					●	●	●	●
	Depth Gauge ø 4.2 mm						●	●	●
Prepare the Cortical Region of the Implant Site	*Profile Drill 3.0 B0*	600		●					
	Profile Drill 3.5 NP / BL 3.5				●				
	Profile Drill 4.1 RP / BL 4.1					●			
	Profile Drill 4.8 RP / BL 4.8						●		
	Profile Drill 4.8 WP							●	
	Profile Drill 6.0 B2								●
Tapping	*Tap ø 3.0 mm*	15		●					
	Tap ø 3.5 mm				●				
	Tap ø 4.1mm					●			
	Tap ø 4.8 mm						●	●	
	Tap ø 6.0 mm								●

Surgical Procedures

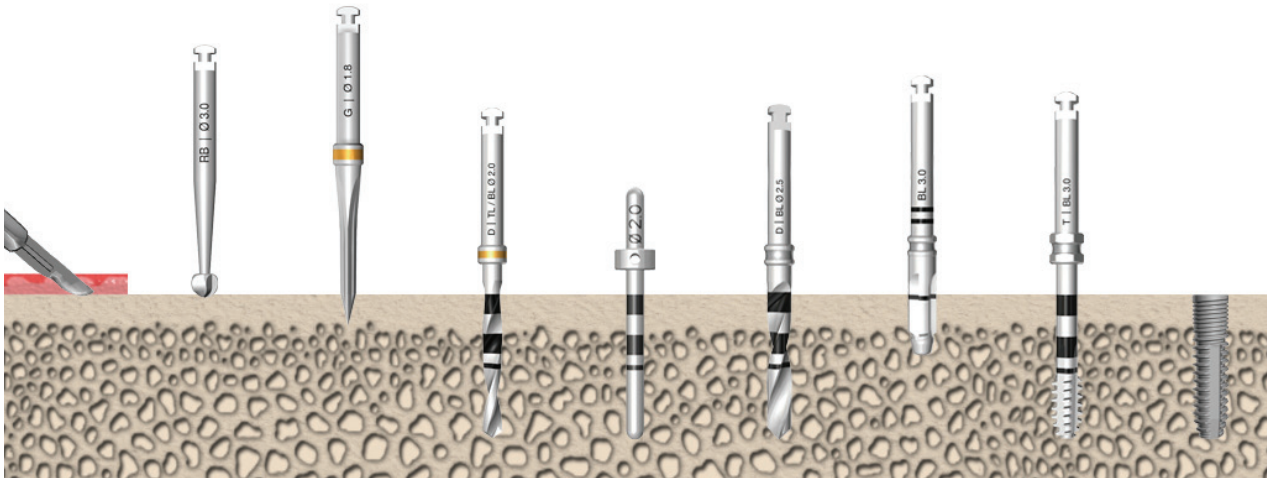


Surgical Procedure Charts

Surgical Procedure Charts

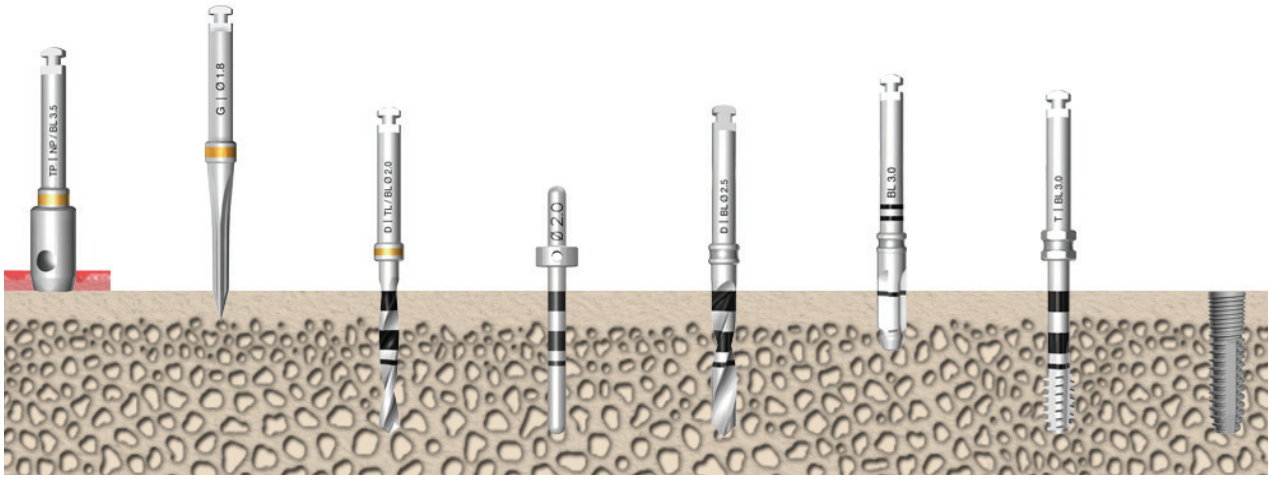
The following surgical charts illustrate the instrument flow for implant bed preparation. Each implant type has two charts, one for flap technique and one for flapless technique. The charts with the 3.0 mm and 3.5 mm implants are shown with the placement of an implant to a length of 14 mm. The charts for all other implant types are shown with the placement of an implant to a length of 12 mm.

3.0 B0 Flap Technique



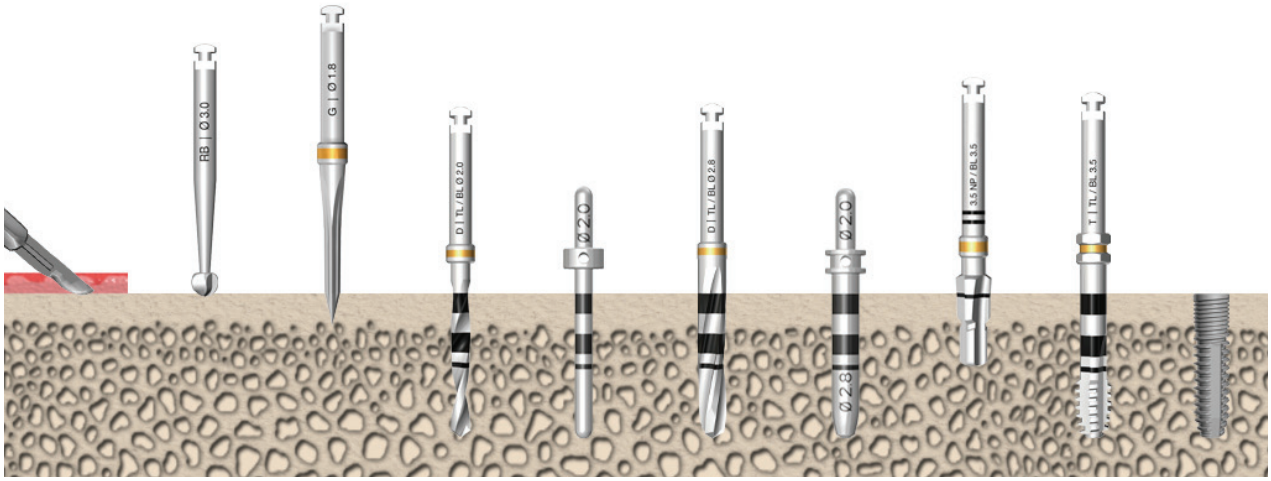
Incision | Ø 3.0 mm Round Bur | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.5 mm Drill | BL Ø 3.0 Profile Drill | Ø 3.0 mm Tap | Ø 3.0 mm / B0 Implant

3.0 B0 Flapless Technique



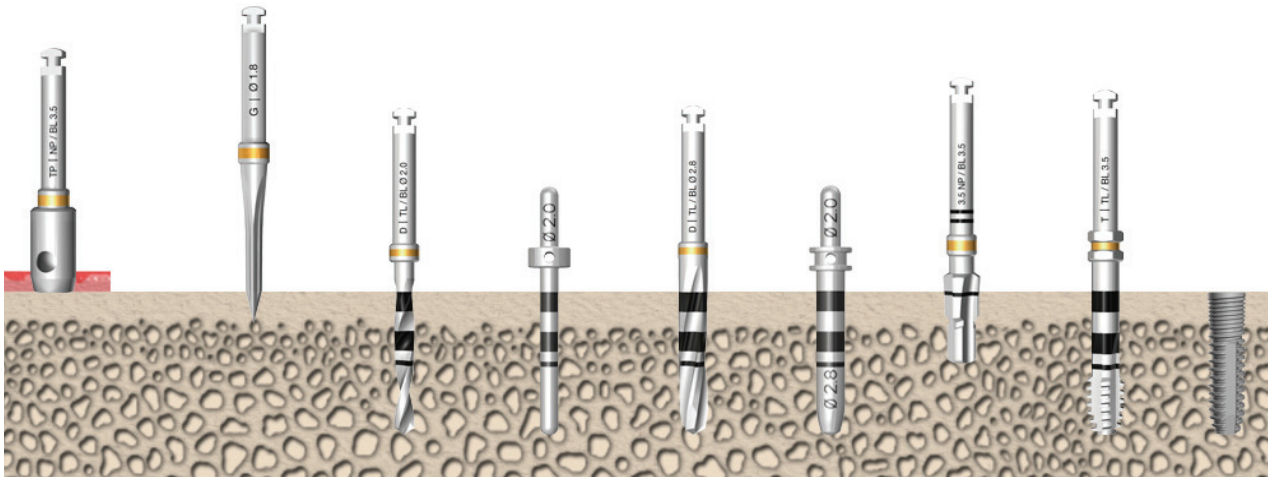
NP / BL 3.5 Tissue Punch | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.5 mm Drill | BL Ø 3.0 Profile Drill | Ø 3.0 mm Tap | Ø 3.0 mm / B0 Implant

3.5 B1 Flap Technique



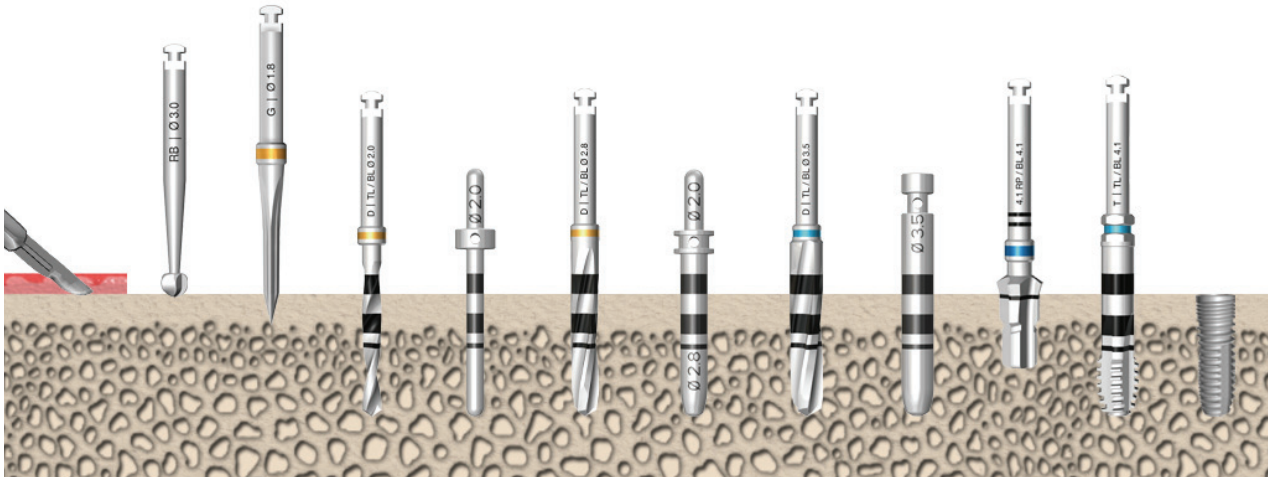
Incision | Ø 3.0 mm Round Bur | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | 3.5 NP / BL 3.5 Profile Drill | TL / BL 3.5 Tap | Ø 3.5 mm / B1 Implant

3.5 B1 Flapless Technique



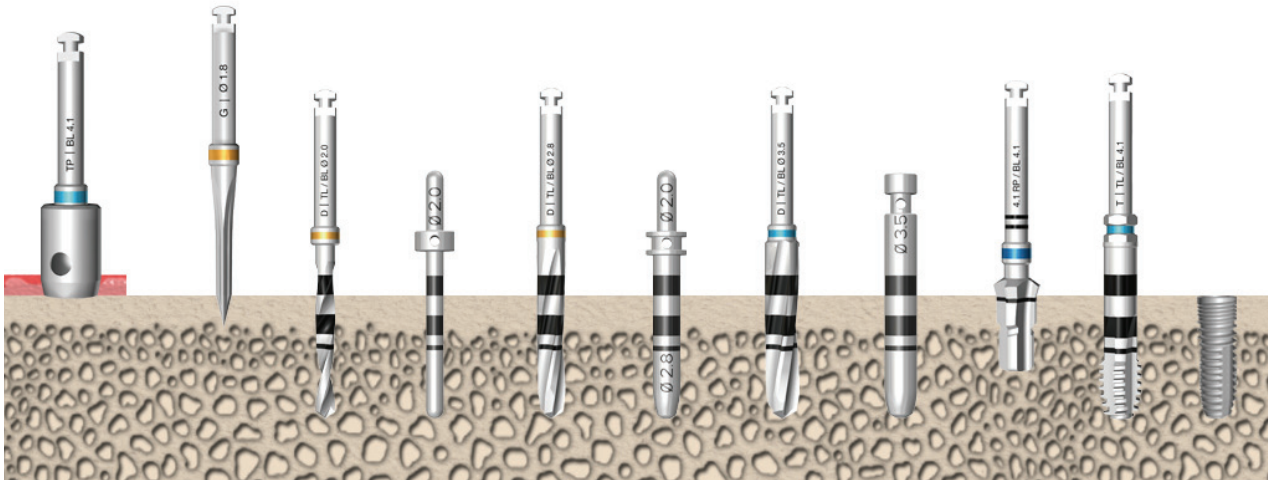
NP / BL 3.5 Tissue Punch | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | 3.5 NP / BL 3.5 Profile Drill | TL / BL 3.5 Tap | Ø 3.5 mm / B1 Implant

4.1 B2 Flap Technique



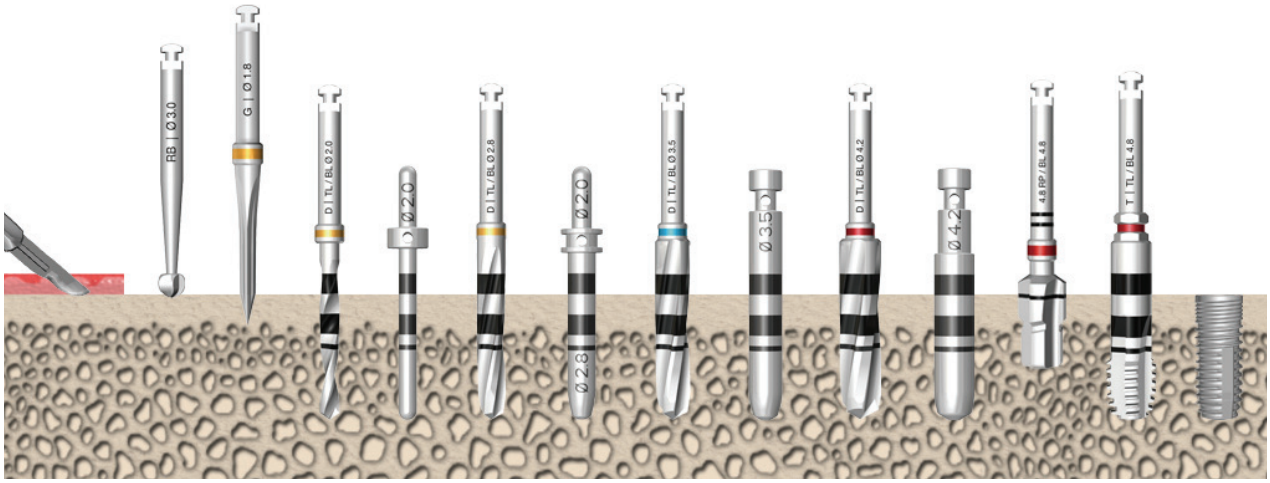
Incision | Ø 3.0 mm Round Bur | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | Ø 3.5 mm Drill | Ø 3.5 mm Depth Gauge | 4.1 RP / BL 4.1 Profile Drill | TL / BL 4.1 Tap | Ø 4.1 mm / B2 Implant

4.1 B2 Flapless Technique



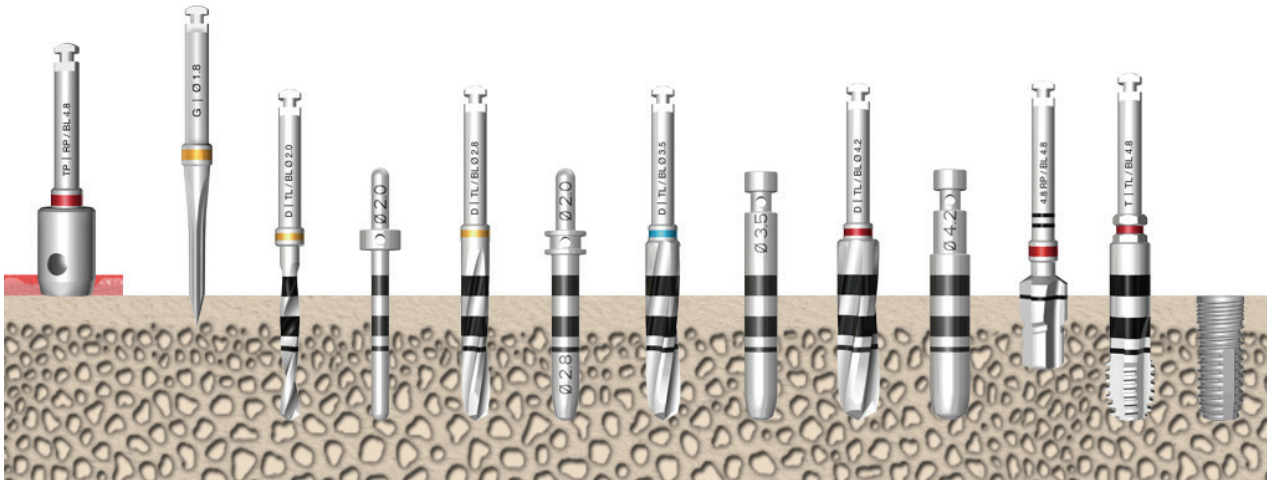
BL 4.1 Tissue Punch | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | Ø 3.5 mm Drill | Ø 3.5 mm Depth Gauge | 4.1 RP / BL 4.1 Profile Drill | TL / BL 4.1 Tap | Ø 4.1 mm / B2 Implant

4.8 B2 Flap Technique



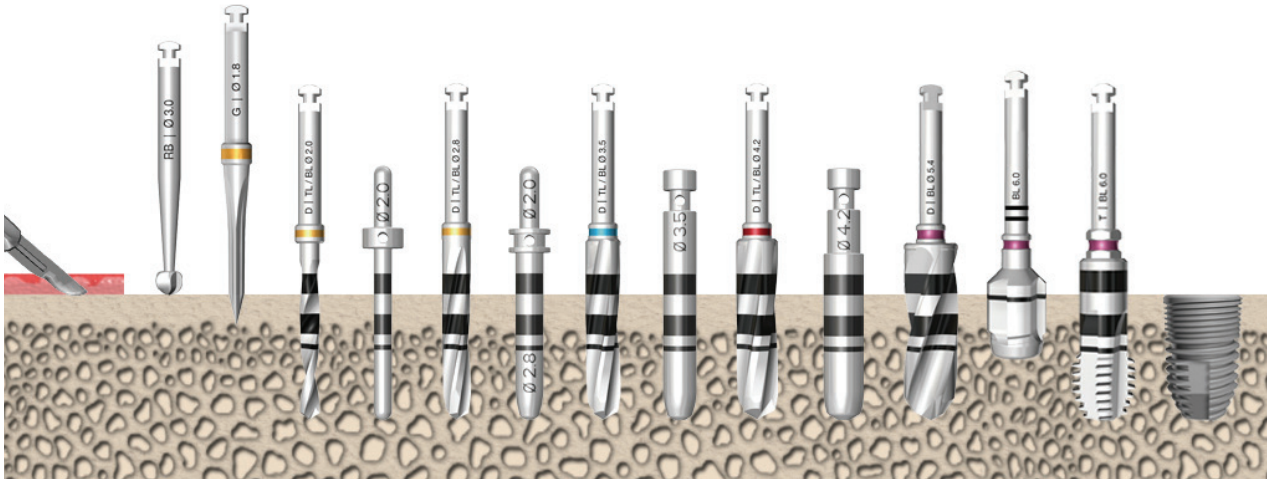
Incision | Ø 3.0 mm Round Bur | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | Ø 3.5 mm Drill | Ø 3.5 mm Depth Gauge | Ø 4.2 mm Drill | Ø 4.2 mm Depth Gauge | 4.8 RP / BL 4.8 Profile Drill | TL / BL 4.8 Tap | Ø 4.8 mm / B2 Implant

4.8 B2 Flapless Technique



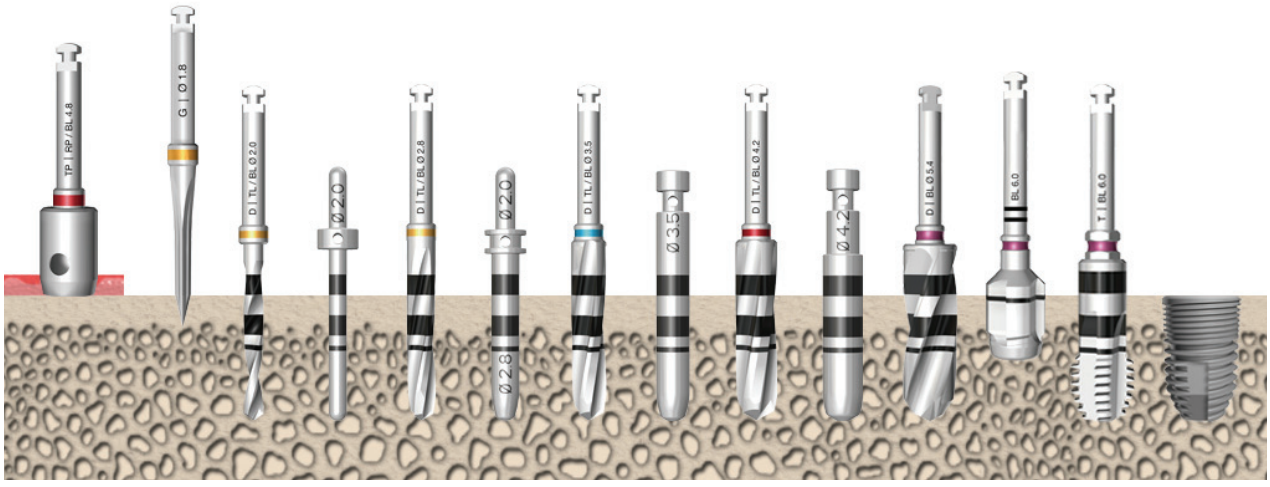
RP / BL 4.8 Tissue Punch | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | Ø 3.5 mm Drill | Ø 3.5 mm Depth Gauge | Ø 4.2 mm Drill | Ø 4.2 mm Depth Gauge | 4.8 RP / BL 4.8 Profile Drill | TL / BL 4.8 Tap | Ø 4.8 mm / B2 Implant

6.0 B2 Flap Technique



Incision | Ø 3.0 mm Round Bur | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | Ø 3.5 mm Drill | Ø 3.5 mm Depth Gauge | Ø 4.2 mm Drill | Ø 4.2 mm Depth Gauge | Ø 5.4 mm Drill | BL 6.0 Profile Drill | BL 6.0 Tap | Ø 6.0 mm / B2 Implant

6.0 B2 Flapless Technique



RP / BL 4.8 Tissue Punch | Guide Drill | Ø 2.0 mm Pilot Drill | Ø 2.0 mm Depth Gauge | Ø 2.8 mm Drill | Ø 2.8 mm Depth Gauge | Ø 3.5 mm Drill | Ø 3.5 mm Depth Gauge | Ø 4.2 mm Drill | Ø 4.2 mm Depth Gauge | Ø 5.4 mm Drill | BL 6.0 Profile Drill | BL 6.0 Tap | Ø 6.0 mm / B2 Implant

Surgical Procedure

Surgical Procedure

The following is the step by step instructions for surgery. Please note that step 1 is different depending on if it is either flap or flapless technique. Step 2 can be omitted when utilizing the flapless technique. The procedures are same from step 3 on.

⚠ For flapless surgery, it is generally recommended to prepare a drill template to improve orientation since there is no direct visualization of the bone.

Follow the specific protocol to perform the implant site preparation and implant installation. This includes stringent bone preparation and complete cooling measures. The dentist must obtain precise information on the depth and the direction of the implant. Choose the appropriate endosteal length and platform width of the implant.

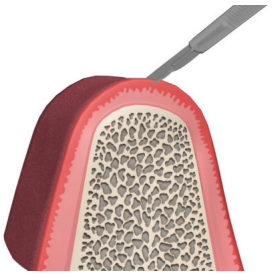
Step 1 (flap technique)

After appropriate local anesthesia, the mucoperiosteal flap procedure is selected for implant placement in the area of the jawbone.

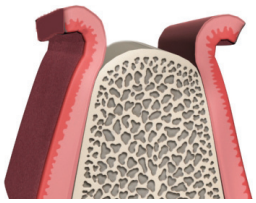
Make an incision at the planned surgical site with a sharp blade. The flap design should be a full thickness flap.

Raise the flap over the height of the alveolar crest.

⚠ For additional information on flap design and techniques, please consult related literature.



Incision

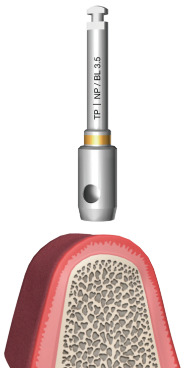


Flap operation

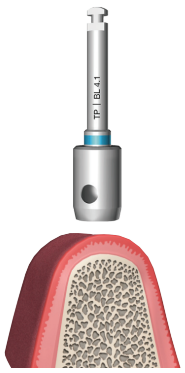
Step 1 (flapless technique)

Attach the tissue punch to the implant handpiece. While operating, the handpiece forms a round hole at the predetermined implant site on the alveolar ridge. Be sure to remove the separated soft tissue prior to preparing the implant site. Upon completing the implant placement, place the closure screw for the implant. This will protect the internal structure of the implant. No suture is required after the surgery.

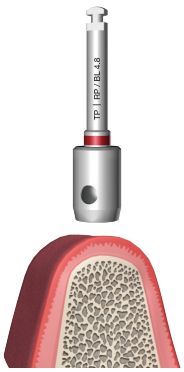
Maximum speed: 800 rpm.



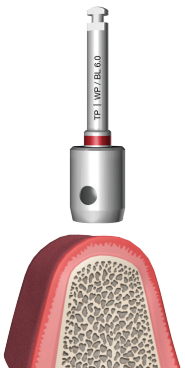
Tissue Punch NP / BL 3.5



Tissue Punch BL 4.1



Tissue Punch RP / BL 4.8



Tissue Punch WP / BL 6.0

Incision Technique

Guided by tomographic radiographs and X-ray films, the surgeon can remove the soft tissues above the implant site with a scalpel, instruments or dental laser prior to the osseous component of the surgery.

⚠ When utilizing this technique, care should be taken to remove minimum amount of keratinized gingiva. This will maximize the amount of protective gingiva around the implant. By doing so, it may increase the risk of peri-implantitis. This procedure is therefore not recommended for patients with serious periodontal disease or with minimal amount of keritinized tissue. This surgical technique also runs the risk of reducing the accuracy of implant installation in the alveolar bone, or increasing the difficulty of bone graft in the case of insufficient bone tissue.

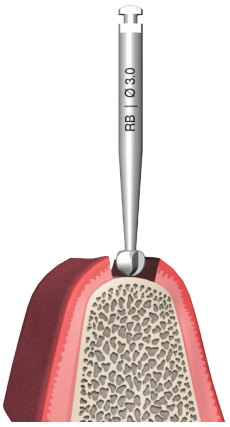
Step 2

Prepare the alveolar ridge with the Ø 3.0 mm round bur.

After separating the soft tissues, the round bur can be used to modify the alveolar ridge to remove irregular sharp edges or protrusions in the bony ridge.

During this procedure, continuous irrigation must be applied.

Maximum speed: 800 rpm.



Ø 3.0 mm Round Bur

Step 3

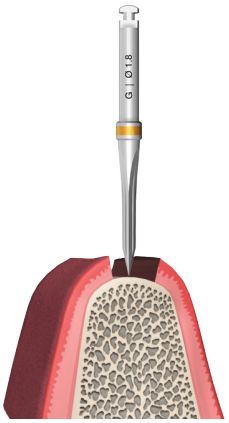
Mark the implant site with the guide drill.

Use the guide drill to mark the location of the implants for each site.

Apply the guide drill to the alveolar ridge to perform the initial preparation. If the ridge (alveolar bone) is thin, the cortical regions on either side must not be perforated.

Use the guide drill to mark each position. Penetrate the cortical bone from the height of the ridge. This will also allow you to evaluate the bone quality along with the thickness of the cortical bone.
Irrigation must be continuously applied during this step.

Maximum speed: 800 rpm.



Ø 1.8 mm Guide Drill

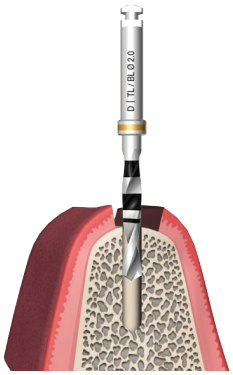
Step 4

The purpose of the 2.0 mm diameter drill is mainly for fixing the depth and the axis of the implant hole.

⚠ Generally, drilling should be performed with continuous up down motion until the desired depth is obtained.

Both short and long versions of the 2.0mm drill are available in the DIS system.

Maximum: 800 rpm.



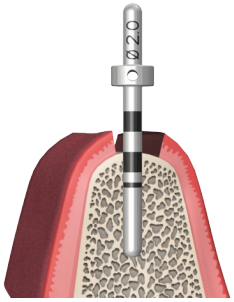
Ø 2.0 mm Pilot Drill

Step 5

Check the depth and condition with the Ø 2.0 mm depth gauge.

The 2.0 mm depth gauge should now be placed in the prepared implant site. The depth should be evaluated closely to assure the appropriateness of the initial placement. A radiograph is suggested to verify this placement. Should there be multiple implants, the depth gauge should be placed in all sites to ensure appropriate position and direction.

Proper evaluation of the bite and the vertical and horizontal overlap of the prosthesis should be confirmed.



Ø 2.0 mm Depth Gauge

Step 6

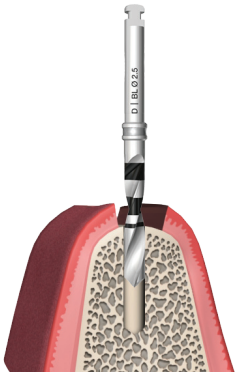
Widen the implant site with the Ø 2.5 mm drill. This step is only required for 3.0 mm implants and can be skipped for all wider diameter implants.

Following the use of 2.0 mm depth gauge, use the 2.5 mm drill to widen the implant site. An up and down motion is recommended.

Maximum speed: 600 rpm.

⚠ For 3.0 mm diameter implants, please continue the implant bed preparation from step 14.

⚠ For implant diameters of 3.5 mm or wider, the use of 2.5 mm drill is not required. The first required drill is the 2.8mm drill (Step 7).



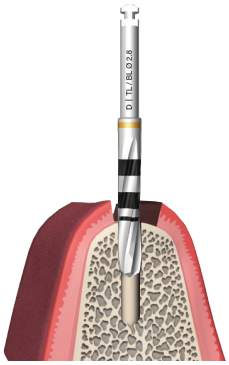
Ø 2.5 mm Drill

Step 7

Widen the implant site with the Ø 2.8 mm drill.

Following the use of 2.0 mm depth gauge, use the 2.8 mm drill to widen the implant site. An up and down motion is recommended.

Maximum speed: 600 rpm.



Ø 2.8 mm Drill

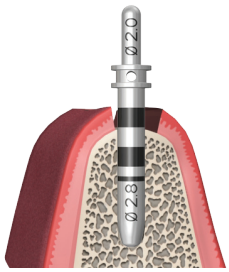
Step 8

Measure the depth of the implant site with the Ø 2.8 mm depth gauge.

Following the use of 2.8 mm drill, use the 2.8 mm depth gauge to measure depth and width of implant site.

If several implants are placed, the gauge can also be used to determine the angulation between implants.

⚠ For the 3.5 mm B1 implant, the implant bed preparation ends here. Please proceed to step 14.



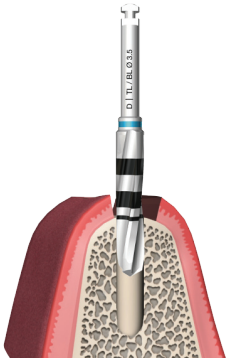
Ø 2.8 mm Depth Gauge

Step 9

Widen the implant site with the Ø 3.5 mm drill.

Following the use of 2.8 mm depth gauge, use the 3.5 mm drill to widen the implant site.

Maximum speed: 600 rpm.



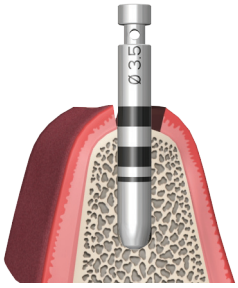
Ø 3.5 mm Drill

Step 10

Measure the depth of the implant site with the Ø 3.5 mm depth gauge.

Following the use of 3.5 mm drill, use the 3.5 mm depth gauge to measure depth and width of implant site. If several implants are placed, the gauge can also be used to determine the angulation between implants.

⚠ For the 4.1 mm B2 Implant, the implant bed preparations continues from step 14.



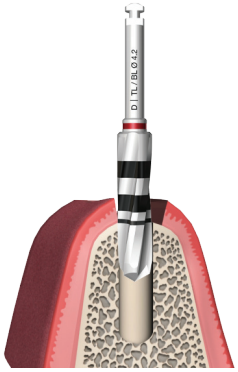
Ø 3.5 mm Depth Gauge

Step 11

Widen the implant site with the Ø 4.2 mm drill.

Following the use of 3.5 mm depth gauge, use 4.2 mm drill to widen the implant site.

Maximum speed: 600 rpm.



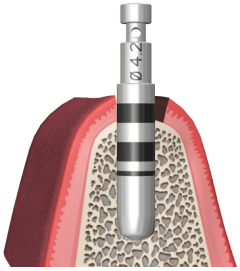
Ø 4.2 mm Drill

Step 12

Measure the depth of the implant site with the Ø 4.2 mm depth gauge.

Following the use of 4.2 mm drill, use the 4.2 mm depth gauge to measure depth of implant site. If several implants are placed, the gauge can also be used to determine the angulation between implants.

⚠ For the 4.8 mm B2 Implant, the implant bed preparations continues from step 14.



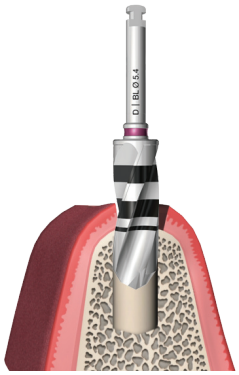
Ø 4.2 mm Depth Gauge

Step 13

Widen the implant site with the Ø 5.4 mm drill.

Following the use of 4.2 mm depth gauge, use the 5.4 mm drill to widen the implant site.

Maximum speed: 600 rpm.

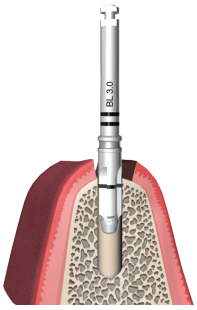


Ø 5.4 mm Drill

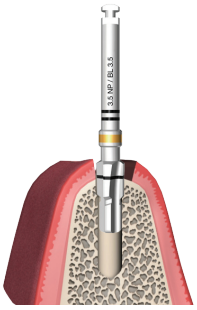
Step 14

Profile Drills (optional)

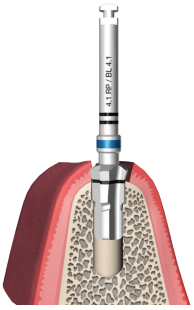
The profile drills widen the implant bed in the cortical region and should be used to reduce the insertion torque if required. Typically, the profile drills should be applied if the bone is dense. Each implant diameter has its individual profile drill.



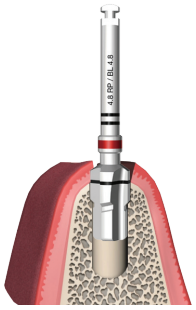
Profile Drill for Ø 3.0 mm implant with B0 platform



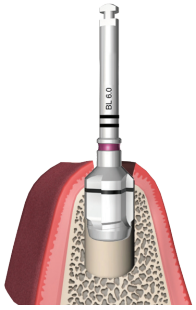
Profile Drill for Ø 3.5 mm implant with B1 platform



Profile Drill for Ø 4.1 mm implant with B2 platform



Profile Drill for Ø 4.8 mm implant with B2 platform



Profile Drill for Ø 6.0 mm implant with B2 platform

Maximum speed: 600 rpm.

Try to insert the implant without using the profile drill at first. If the insertion torque of the implant is too high, then use the profile drill. The following table recommends for which implant dimensions and bone classes the profile drills might be applied. If even after applying the profile drill the insertion torque is still too high, then use the tap drill as the next step (see next chapter).

The following table recommends where the profile drill should be applied.

Bone Class	Ø 3.0 mm			Ø 3.5 mm				Ø 4.1 mm					Ø 4.8 mm					Ø 6.0 mm			
	L10	L12	L14	L8	L10	L12	L14	L6.5	L8	L10	L12	L14	L6.5	L8	L10	L12	L14	L6.5	L8	L10	L12
D1	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
D2	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
D3	●	●	●	●	●	●	●		●	●	●	●		●	●	●	●	●	●	●	●
D4																					

⚠ Please note that the table just gives a basic orientation.

⚠ It is generally not recommended to use the profile drills for very short implants of length 6.5 mm for diameters up to 4.8 mm in soft bone (D3 and D4).

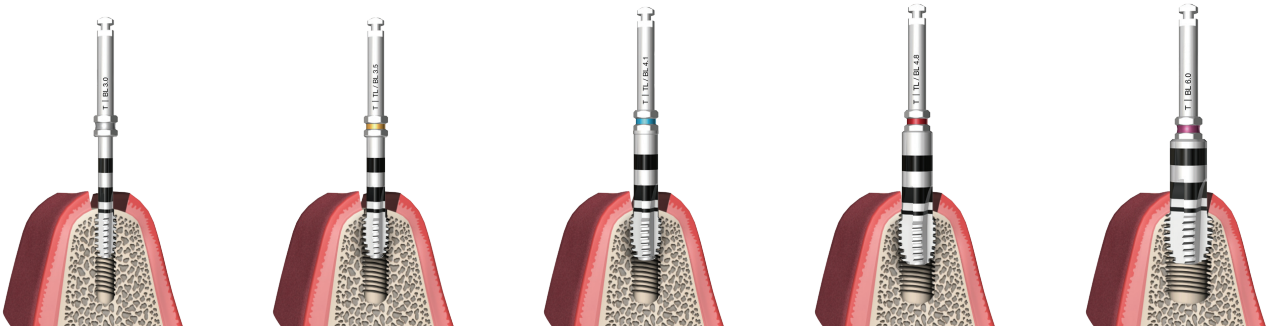
⚠ It is generally not recommended to use the profile drills in very soft bone (D4).

Step 15

Tapping the dense bone with the tap (optional).

Biodenta implants are designed with self tapping features. However, depending on bone density and implant type, it might be necessary to apply taps in order to achieve a smooth implant insertion. The tapping process is achieved manually with the torque wrench or utilizing the handpiece. Taps should only be used after using profile drills as explained in previous chapter.

A low speed must be used for tapping and installing the implant to prevent overheating and damaging the bone. The maximum speed is 15 rpm.



Ø 3.0 mm Tap | Ø 3.5 mm Tap | Ø 4.1 mm Tap | Ø 4.8 mm Tap | Ø 6.0 mm Tap

Maximum speed: 15 rpm.

The following table recommends for which implant dimensions and bone classes the taps might be applied.

Bone Class	Ø 3.0 mm	Ø 3.5 mm	Ø 4.1 mm	Ø 4.8 mm	Ø 6.0 mm
D 1	Cortical	Complete	Complete	Complete	Complete
D 2	Cortical	Cortical	Cortical	Complete	Complete
D 3					Cortical
D 4					

Class 1: hardest bone / Class 4: soft bone

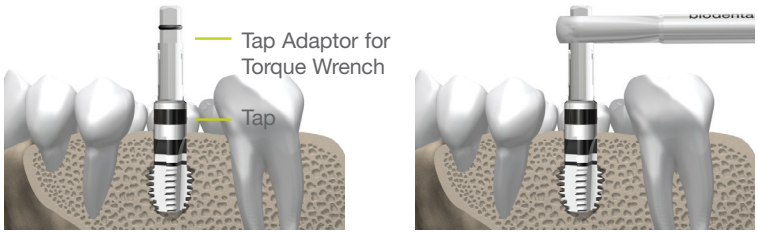
Cortical = thread tapping in the Cortical area of the implant site.

Complete = thread tapping over full depth of the implant site.

⚠ Please note that the table just gives a basic orientation.

⚠ It is generally not recommended to use the taps in very soft bone.

Instead of the handpiece, the tap can also be used in connection with the torque wrench by using tap adaptor for torque wrench as shown on the image below. The tap adaptor for torque wrench clicks to the tap and is attached to the torque wrench.

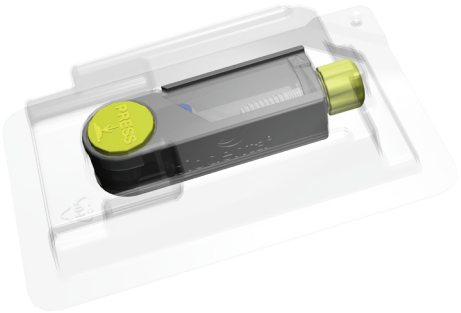


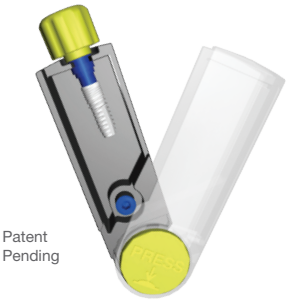
After completing all steps for implant bed preparation, the implant can be unpacked and installed as described in the following chapter.

Product Packaging

Product Packaging

The following section explains the implant packaging, labeling - details, opening and handling.





Patent
Pending

The implant with all its packaging components and parts are completely sterilized by gamma irradiation.

Housing

Handle

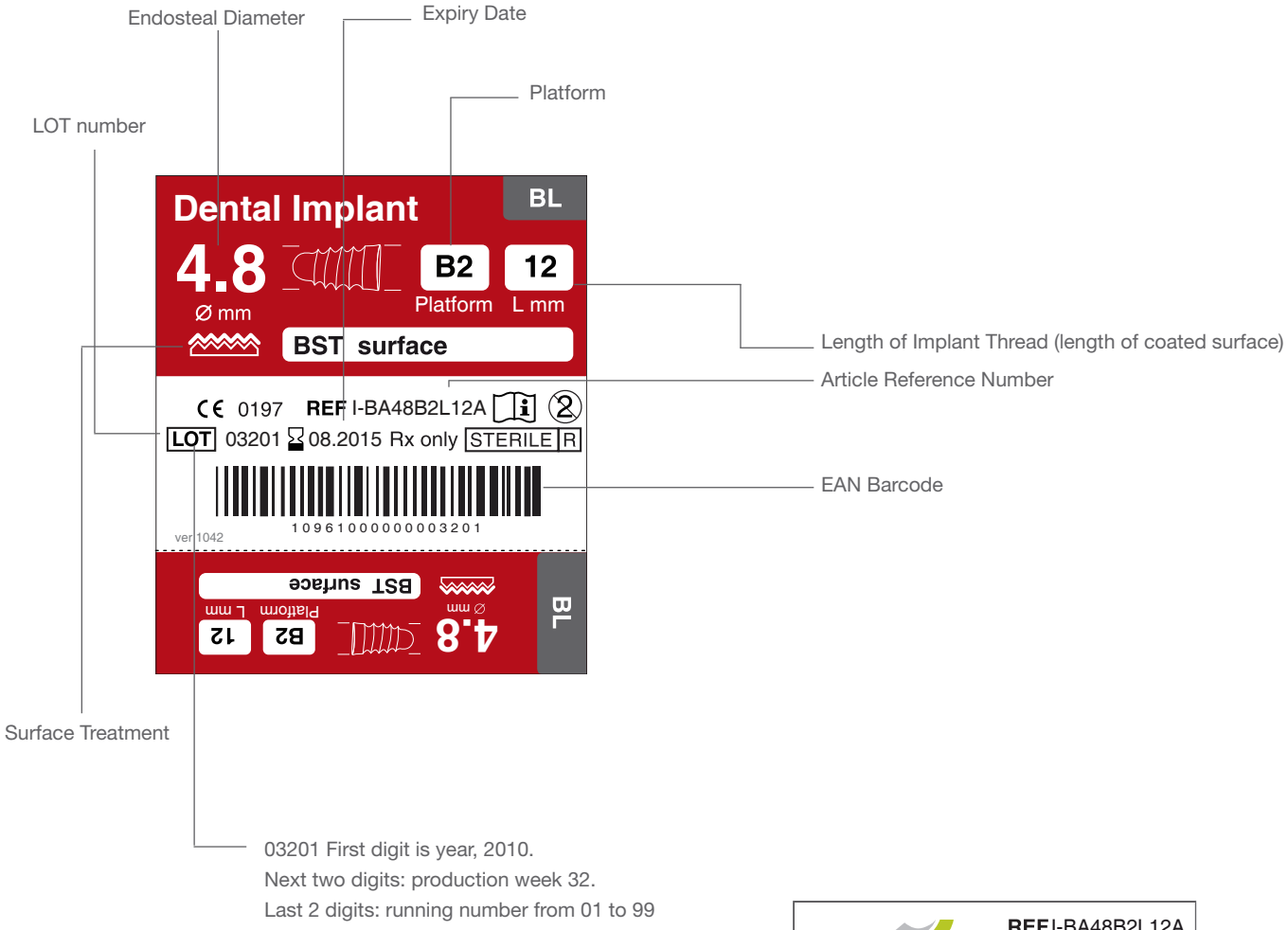
Implant

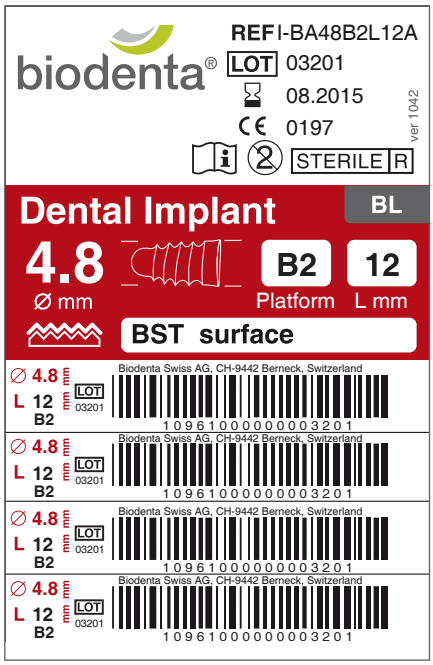
Holder

Inner Screw

Closure Screw

Implant Labeling





Opening

Step 1. Open the box
Open the outer box as shown and take out the inner package.

Open the box

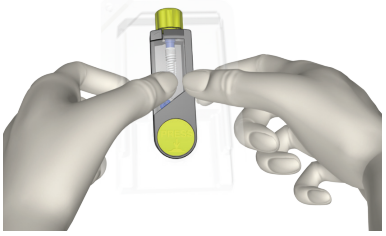
Step 2. Stick label on case history / patient's implant passport
Remove the implant label from the inner package label and place it on the patient's record and implant passport to record information such as implant date, implant site, etc.

Stick label on case history

Step 3. Take implant out of inner package
Open the sealed inner package by pulling away the label.

Rip the seal

Step 4. Remove the implant
Please press from backside in order to remove implant out of the inner package.



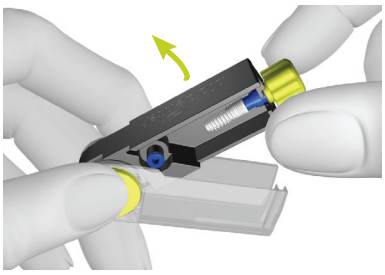
Take implant housing out of blister

Implant Installation

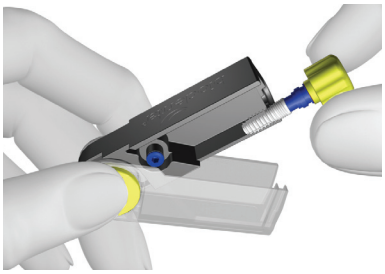
Implant Installation

There are three different options to install the implant: (A) installation by handle and torque wrench, or (B) installation by handpiece or (C) installation by Direct Implant Driver.

A. Installation by Handle and Torque Wrench
Press the green button to open the housing.

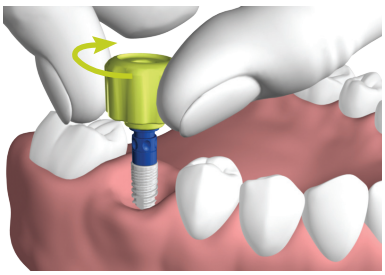


Take the implant with the green handle out of the housing and ensure the implant does not touch the housing.

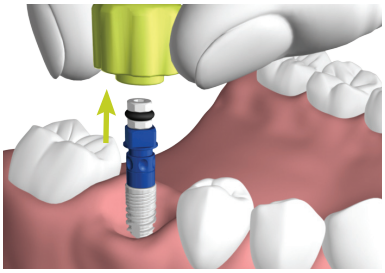


Commence the Implantation Procedure
Carefully and slowly rotate the implant into the prepared site.

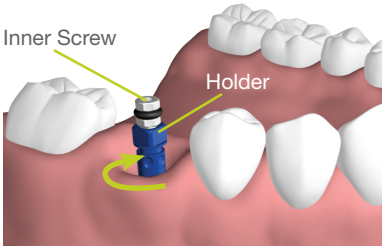
⚠ The implant should be aligned with the long axis of the prepared implant site.



When the implant is completed insertion, remove the handle in upward direction.



⚠ Check if the inner screw is loose – if it is loose, tighten by hand. If instruments are changed many times, the holder and inner screw may become loose. In that case, please re-tighten carefully by hand.



Use the torque wrench to place the implant into the prepared implant site. After the initial installation by hand, the torque wrench is used to apply the final tightening twist. By utilizing the torque wrench, the dentist can also get an impression of the stability of the implant from the tactile sensation.

Adjust the torque wrench to the required torque as explained before in the section “Torque Wrench”.

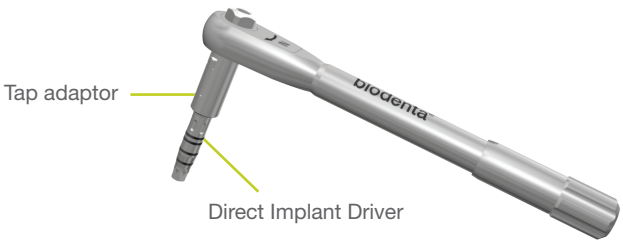
⚠ Biodenta implants with **B0 platform** should be inserted in at a **max.** of **35 Ncm**. High insertion torque is only suggested for high bone density, preferable lower insertion torque shall be applied. Adjust the torque value to max. 35 Ncm to ensure that excess forces are not applied. If the 35 Ncm force is not sufficient to insert the implant into its final position, then unscrew the implant and widen the implant bed or prepare a thread by the tap.

⚠ Biodenta implants with **B1 platform** should be screwed in at a **max.** of **50 Ncm**. High insertion torque is only suggested for high bone density, preferable lower insertion torque shall be applied. Adjust the torque wrench to the 50 Ncm marking to ensure that excess forces are not applied. The torque wrench will automatically release if excess torque is applied. If the 50 Ncm force is not sufficient to insert the implant into its final position, then unscrew the implant and widen the implant bed or prepare a thread by the tap.

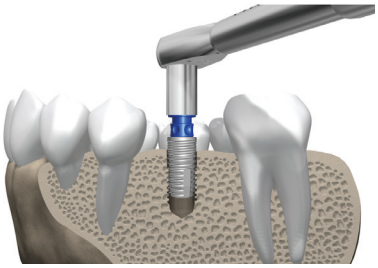
⚠ Biodenta implants with **B2 platform** should be screwed in at a **max.** of **70 Ncm**. High insertion torque is only suggested for high bone density, preferable lower insertion torque shall be applied. Adjust the torque wrench to the 70 Ncm marking to ensure that excess forces are not applied. The torque wrench will automatically release if excess torque is applied. If the 70 Ncm force is not sufficient to insert the implant into its final position, then unscrew the implant and widen the implant bed or prepare a thread by the tap.

Adjust the torque wrench to the required torque as explained before in the section “Torque Wrench”.

⚠ If excessive torque is applied, the implant holder will fail as a part of the safety protection mechanism. In this case, the implant needs to be unscrewed and should not be reused as it might be damaged. Please use the Biodenta “Direct Implant Driver” for unscrewing an implant. It replaces the holder and can be used directly with either the handpiece or torque wrench through the tap adaptor. It is stronger than the holder. Short and long drivers are available for each implant platform.



Connect the implant driver for torque wrench with the torque wrench itself and then to the implant holder. Make sure that the torque wrench is set to ‘IN’ position.



⚠ Care must be taken to slowly screw the implant into position. The surgeon must prevent the final tightening twist from stripping or bone fracture.

Make sure that the implant is fully inserted and the correct depth is reached.

The holder displays small round markings*. These marks indicate the hex positions within the implant connection. The mark is directed towards each flat side of the hex connection. By utilizing these round markings, the surgeon can place the implant exactly to the preferred final abutment position.

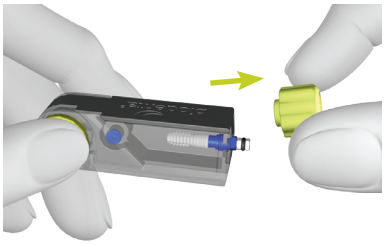
The holder also shows depth indication markings* in order to indicate 2, 4, and 5 mm gingiva heights. These markings correspond to the gingiva heights of the Biodenta healing abutments and help to select the appropriate healing abutment.

Remove the torque wrench together with the implant driver from the holder and then follow the instruction “Remove the Implant Holder”.

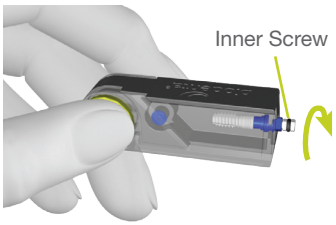
* ⚠ Those markings are not yet applied on the previous (pink colored) holder version.

B. Installation by Handpiece

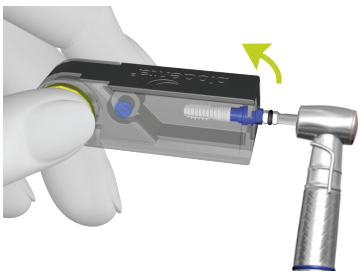
Prior to opening the housing, remove the handle by pulling it upwards.



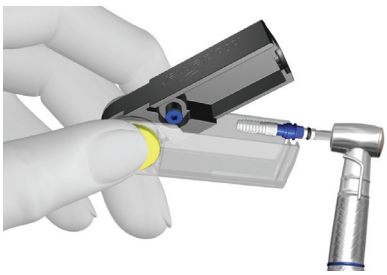
⚠ Check if the inner screw is loose – if it is loose, tighten by hand. If instruments are changed many times, the holder and inner screw may become loose. In that case, please re-tighten by hand.



Connect the Implant Driver to the handpiece and then connect it with the holder. Press the green button to open the housing.



Remove the implant from the housing. Avoid contacting the housing during this process.



Install the Implant

Adjust the surgical unit to the recommended torque value.

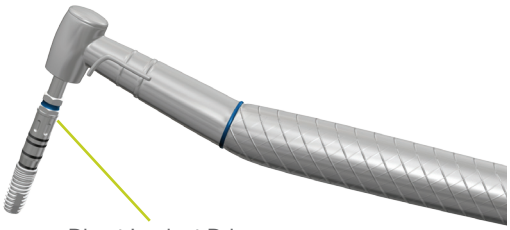
⚠ Biodenta implants with **B0 platform** should be inserted in at a **max.** of **35 Ncm**. High insertion torque is only suggested for high bone density, preferable lower insertion torque shall be applied. Adjust the torque value to max. 35 Ncm to ensure that excess forces are not applied. If the 35 Ncm force is not sufficient to insert the implant into its final position, then unscrew the implant and widen the implant bed or prepare a thread by the tap.

⚠ Biodenta implants with **B1 platform** should be screwed in at a **max.** of **50 Ncm**. High insertion torque is only suggested for high bone density, preferable lower insertion torque shall be applied. Adjust the torque value to max. 50 Ncm to ensure that excess forces are not applied. If the 50 Ncm force is not sufficient to insert the implant into its final position, unscrew the implant and widen the implant bed or prepare a thread by the tap.

⚠ Biodenta implants with **B2 platform** should be screwed in at a **max.** of **70 Ncm**. High insertion torque is only suggested for high bone density, preferable lower insertion torque shall be applied. Adjust the torque value to max. 70 Ncm to ensure that excess forces are not applied. If the 70 Ncm force is not sufficient to insert the implant into its final position, unscrew the implant and widen the implant bed or prepare a thread by the tap.

Adjust the torque wrench to the required torque as explained before in the section “Torque Wrench”.

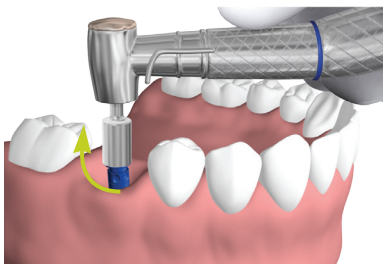
⚠ If excessive torque is applied, the implant holder will fail as a part of the safety protection mechanism. In this case, the implant needs to be unscrewed and should not be reused as it might be damaged. Please use the Biodenta “Direct Implant Driver” for unscrewing an implant. It replaces the holder and can be used directly with either the handpiece or torque wrench through the tap adaptor. It is stronger than the holder. Short and long drivers are available for each implant platform.



Direct Implant Driver

While turning clockwise, carefully and slowly screw the implant into the prepared position with a maximum rotation speed of 15 rpm. When the implant approach the floor of the bone cavity, a gradual increase in resistance will be noticed.

⚠ The implant should be aligned with the long axis of the implant hole.



Ensure that the implant is fully inserted and the correct position is reached.

Maximum speed: 15 rpm.

The holder displays small round markings*. These marks indicate the hex positions within the implant connection. The mark is directed towards each flat side of the hex connection. By utilizing these round markings, the surgeon can place the implant exactly to the preferred final abutment position.

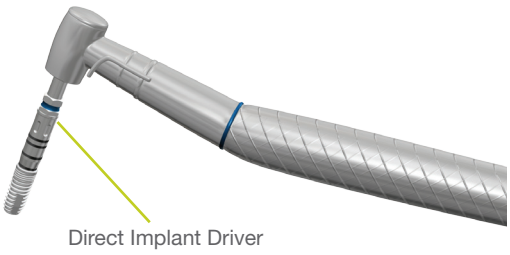
The holder also shows depth indication markings* in order to indicate 2, 4, and 5 mm gingiva heights. These markings correspond to the gingiva heights of the Biodenta healing abutments and help to select the appropriate healing abutment.

Remove the torque wrench together with the implant driver from the holder and then follow the instruction “Remove the Implant Holder”.

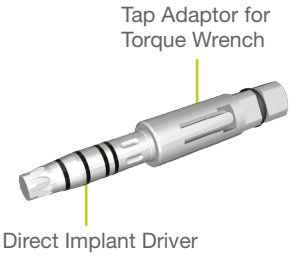
* ⚠ Those markings are not yet applied on the previous (pink colored) holder version.

C. Installation by Direct Implant Driver

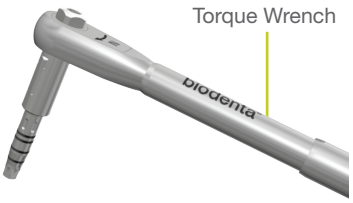
In specific cases such as small interproximal spaces, the implant holder can be replaced by the 'Biodenta Direct Implant Drivers'. After the first step of inserting the implant, remove the holder carefully and replace it with the direct implant driver for handpiece. These implant drivers are available short or long in B0, B1 and B2 connections.



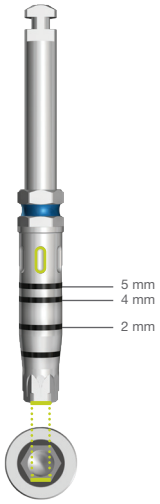
Instead of the handpiece, the direct implant driver can also be used in connection with the torque wrench by using tap adaptor for torque wrench as shown on the image.



The tap adaptor for torque wrench clicks to the direct implant driver and is attached to the torque wrench.



The direct implant drivers display small round markings. These marks indicate the hex positions within the implant connection. The mark is directed towards each flat side of the hex connection. By utilizing these round markings, the surgeon can place the implant exactly to the preferred final abutment position.



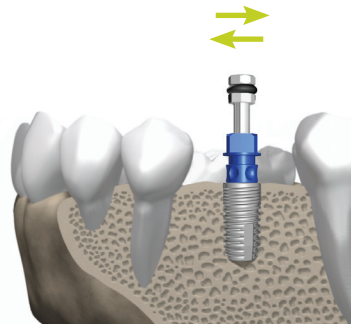
Remove the Implant Holder

Remove the Implant Holder

The holder together with its inner screw must be removed after the implant is installed. The holder can be removed by the handle (1), manually (2) or with the hex driver (3). Occasionally, it might be necessary to remove the holder with the holding key (4).

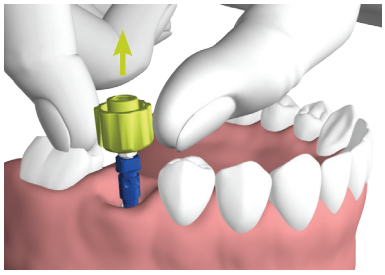
⚠ Care must be taken not to disturb the implant in its position while removing the implant holder. If the screw can not be taken out easily, then utilize the holding key to secure the implant when removing the implant holder as explained at item 4.

⚠ When the maximum torque values are exceeded during implant installation, the holder may be difficult to remove (see chapter “implant installation” for details on torque values). In order to remove the holder, we recommend loosening the inner screw and gently shaking against the inner wall of the holder. This should allow the loosening of the holder for removal. Care should be taken not to disturb the implant in its position.

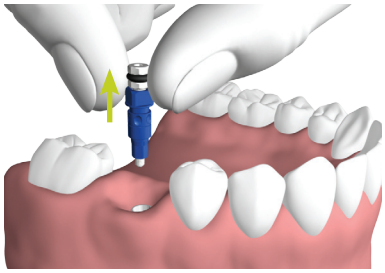


1. Removal by Handle
Use the top side of the handle to remove the inner screw. Rotate in the reverse direction. The inner screw is connected with the holder. After a few turns, it will be disconnected from the implant and can be removed together with the holder.

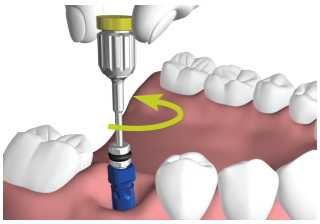
⚠ Do not screw the inner screw too far as it should not be disconnected from the holder.

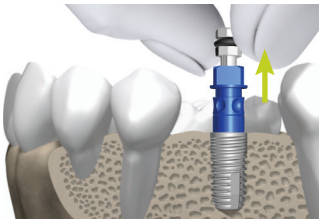


2. Manual Removal
Use the hand to remove the inner screw and remove the holder from the implant.



3. Removal by Hex Driver
Place a hex driver firmly to the hexagonal hole atop the inner screw. Press lightly and turn the hex driver counter clockwise to loosen the inner screw and the holder.





4. Removal by Holding Key
Normally, the implant holder can be easily removed. However, on occasion, it may be necessary to utilize the holding key to secure the implant when removing the implant holder. When the implant holder is connected tightly with the implant, use the holding key to secure the quadrangle of the holder allowing you to remove the inner screw. After a few turns, the inner screw will be disconnected from the implant and then it can be removed automatically with the holder.

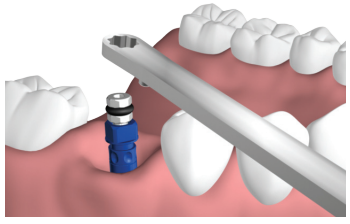
⚠ Do not screw the inner screw too far as it should not be disconnected from the holder.

⚠ Care must be taken not to disturb the implant in the implant position.

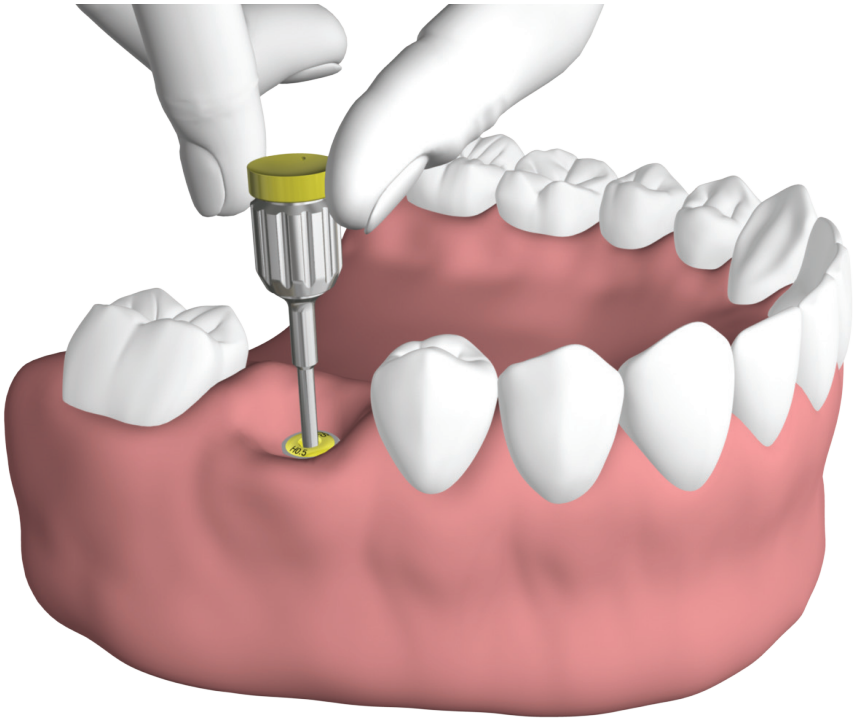
The different angulation of the holding key allows for easy access for difference oral situations.

Forked End
When there is adequate space around the holder, use the forked end of the holding key to attach directly to the quadrangle of the holder.

Closed End
When there is limited interdental space, use the closed end of the holding key to place on the quadrangle of the holder.



Soft Tissue Treatment



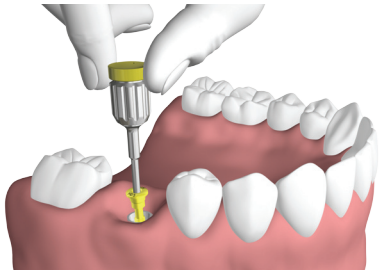
Healing Abutments and Closure Screws

Healing Abutments and Closure Screws

After implantation, the closure screw or the healing abutment is placed on the implant to protect its internal structure during the healing period. Prior to placing the healing abutment or closure screw, thoroughly irrigate with sterile saline and apply suction to remove the debris at the surgical site. Check underneath the flap for residual bone fragments or blood clots. Use bone forceps to remove unnecessary or sharp bones on the edge of the cortical bone. Care should be taken not to disturb the implant during this procedure.

⚠ Healing abutments or closure screws are connected with the implant by using the hex driver. Connect by applying hand force only!

Healing abutments or closure screws supplied together with the implant housing are sterilized by gamma irradiation.



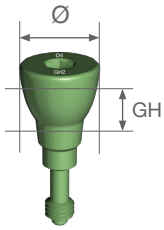
Overview

The following listed healing abutments and closure screws are available.

Healing Abutments

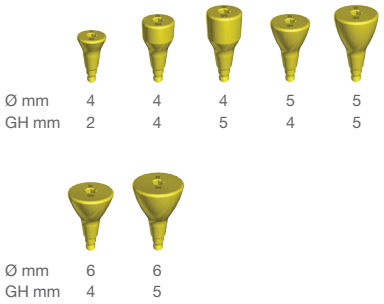
B0

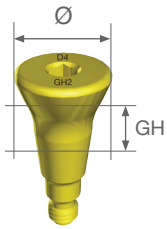
Ø	GH	REF Number
4.0 mm	2.0 mm	HA-B2040B0H
4.0 mm	4.0 mm	HA-B4040B0H
4.0 mm	6.0 mm	HA-B6040B0H



B1

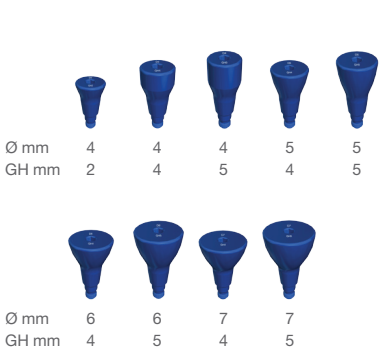
Ø	GH	REF Number
4.0 mm	2.0 mm	HA-B2040B1H
4.0 mm	4.0 mm	HA-B4040B1H
4.0 mm	5.0 mm	HA-B5040B1H
5.0 mm	4.0 mm	HA-B4050B1H
5.0 mm	5.0 mm	HA-B5050B1H
6.0 mm	4.0 mm	HA-B4060B1H
6.0 mm	5.0 mm	HA-B5060B1H

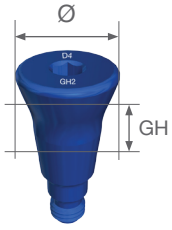




B2

Ø	GH	REF Number
4.0 mm	2.0 mm	HA-B2040B2H
4.0 mm	4.0 mm	HA-B4040B2H
4.0 mm	5.0 mm	HA-B5040B2H
5.0 mm	4.0 mm	HA-B4050B2H
5.0 mm	5.0 mm	HA-B5050B2H
6.0 mm	4.0 mm	HA-B4060B2H
6.0 mm	5.0 mm	HA-B5060B2H
7.0 mm	4.0 mm	HA-B4070B2H
7.0 mm	5.0 mm	HA-B5070B2H

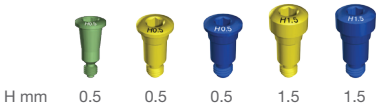


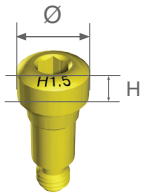


Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

Closure Screws

Ø	H	REF Number
B0	0.5 mm	CS-B0030B0C
B1	0.5 mm	CS-B0035B1C
B2	0.5 mm	CS-B0018B2C
B1	1.5 mm	CS-B0135B1C
B2	1.5 mm	CS-B0118B2C





Unit: millimeters
Ø = Diameter
L = Length
GH = Gingiva Height

Healing Abutment Guide

Healing Abutment Guide

The following table demonstrates the best possible combinations between healing abutments and final abutments. We carefully harmonised the shape of the healing abutments to the shape of the final abutments. Healing abutments and final abutments fit exactly when the same diameter is chosen (show black dot). In this case there will be no compression on the gingiva. After measuring the gingiva height (use Biodenta abutment depth gauge), a choice should be made according to the table below.

Healing abutments should be selected according to the clinical outcome and the patient's gingiva height. For all abutments including LOCATOR® or ball abutments you should choose a healing abutment gingiva height which is higher than patient's gingiva height.

Platforms B1 & B2	Healing Abutment								
	D4 GH2	D4 GH4	D4 GH5	D5 GH4	D5 GH5	D6 GH4	D6 GH5	D7 GH4	D7 GH5
Straight Abutment									
D4 GH2	●	●	●	○	○				
D5 GH4	○	○	○	●	●	○	○		
D5 GH5	○	○	○	●	●	○	○		
D6 GH4				○	○	●	●	○	○
D6 GH5				○	○	●	●	○	○
Angled Abutment									
D4 GH2	●	●	●	○	○				
D5 GH4	○	○	○	●	●	○	○		
D5 GH5	○	○	○	●	●	○	○		
LOCATOR® Abutment									
GH2	●								
GH4		●							
GH6			●						
Ball Abutment									
GH2	●								
GH4		●							
GH6			●						

Gold Abutment	
	Healing abutment will be selected according to the clinical situation

Bar Abutment	
	Healing abutment will be selected according to the clinical situation

Temporary Abutment	
	Ideal for forming the emerged profile

Please note: This table is only meant as an orientation illustrating the ideal combinations of healing and final abutments.

- ● Healing abutments and final abutments have the same diameter
- ○ Healing abutments and final abutments differ 1 mm

Tissue Closure

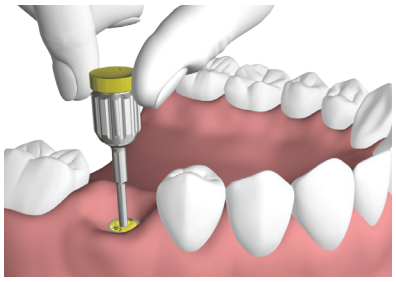
Tissue Closure

There are two different options to close the tissue. In the One Stage Technique, the tissue surrounds the healing abutment. In the Two Stage Technique, the tissue is closed above the implant with its closure screw.

One Stage Technique
Attach the Healing Abutment
Healing abutments are taller than the closure screws. It is generally utilized when uncovering the implant.

A healing abutment usually allows the gingival tissue to form around the shape of the healing abutment. When indicated, such as highly aesthetic cases, it can be utilized to help contour the tissue during the healing phase yielding the appropriate emergence profile of the future restoration.

There is no need for additional surgery and the gingival tissue will be matured once the implant is ready to be loaded.



Two Stage Technique
Stage 1:

Use the closure screw when a two stage technique is utilized. It is placed under the gingival tissue allowing the bone to heal and integrate. If necessary, utilize a scalpel to dissect the mucoperiosteal membrane.

Close Mucoperiosteum
Replace the flap in its original position. Apply sutures at the proper positions. Suture is applied away from the edge of the incision. Tension should be minimized.

Stage 2:

Upon healing (see recommended healing time), you need to carefully localize the implant. Open the mucoperiosteal by an incision up to the closure screw and remove the closure screw / healing abutment. Thoroughly clean the inside of the implant with a sterile irrigation solution. Choose the appropriate height of healing abutment. This is based on the thickness of tissue and desired profile of the final restoration. The new healing abutment is inserted into the implant to allow the soft tissue to heal around the site.

Healing Phase

Healing Time

Allow the standard 12 week healing period for osseointegration to occur, immediately loading is not recommended. The clinician should closely monitor patients for any of the following conditions: peri-implantitis, peri-implant bone loss, changes to implant's response to percussion or radiographic changes in bone to implant contact along the implant's length. If the implant indicates mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinician has chosen a short implant, the clinicians should consider a two-stage surgical approach, allow longer periods of osseointegration, splinting a short implant to an additional implant, and placement of the widest possible implant.

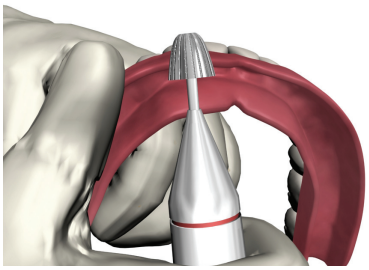
⚠ The dentist needs to decide the adequate healing time before loading the implant based on each individual cases.

⚠ In cases where the implant area is not completely in contact with the bone or if bone augmentation is necessary the healing phase should be increased.

Prosthesis Treatment

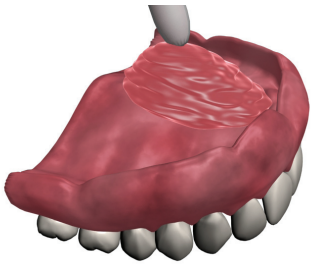
Prosthesis Treatment

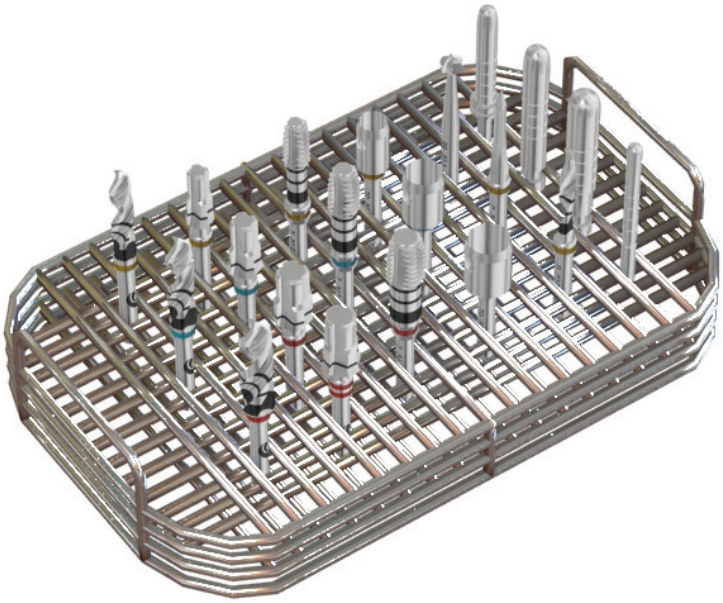
Avoid premature loading on the implant during the healing phase of the mucosa. If there is a removable prosthesis, when possible, the patient should not wear the prosthesis. Once the mucosa begins to heal, the patient can resume wearing the prosthesis. However, the prosthesis should be relieved in the surgical site and relined with a soft liner until osseointegration.



Relieve implant site. Care should be taken not to load the implants during the healing phase.

Apply soft liner over the implant site until osseointegration.





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 phase, 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 plastic (except PEEK) should not be sterilized by chemical, dry heat, or autoclave. Please refer to the table “Material Declaration” for the appropriate sterilization/disinfection method for each product.

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.

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

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

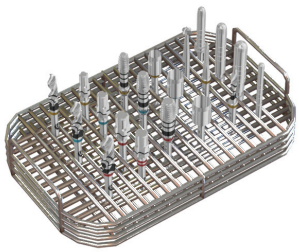
Soak the instruments in an instrument detergent (mild alkaline, aldehydefree) for minimum 5 minutes and a maximum 15 minutes. Prolonged soaking in the detergent may lead to surface damage.

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.

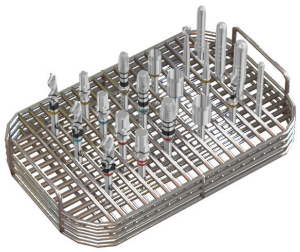


- 4 min pre-washing with cold water, then emptying
- 5 min washing at 55°C (131°F) with instrument detergent, then emptying
- 3 min neutralizing with warm water > 40°C (104°F), then emptying
- 2 min intermediate rinsing with warm water > 40°C (104°F), then emptying

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

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 permanufacturer'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.

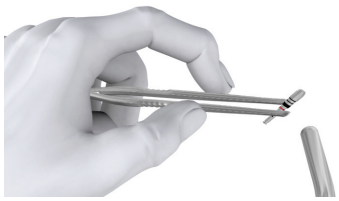
4. Drying

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

A. Automated Drying

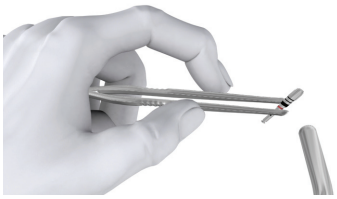
Parts need to be dried by going through the drying cycle of the automated thermal disinfection washer.

If needed, additional manual drying can be performed by using sterile compressed air.



B. Manual Drying

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.

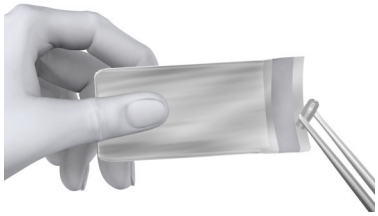
The instruments should be placed in the center of each holder so that it has minimum surface contact.

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 abutments 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.

For USA: Use ANSI/AAMI ST79 conform pouches.



7. Sterilization

Sterilization should be performed by applying a pre-vacuum steam sterilization process under consideration of the respective country requirements (for USA refer to ANSI/AAMI ST79; for EU, CH and NO refer to EN 13060, EN ISO 17665-1, EN ISO 14937).

Please use the following parameters for the pre-vacuum steam sterilization process:

- Temperature: minimum 132°C (270°F)
- Holding time: minimum 4 min
- Drying time: minimum 20 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).

Annex

Product Information

Biodenta Dental Implant System
Tissue Level, Bone Level, Bone Level Tapered 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 maxilla 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 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, -abutments and closure screws 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 analog.

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 disorders, bone metabolism disturbances, chemotherapy 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 guideline 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 placement or restoration can result in implant failure and substantial loss of surrounding bone.

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

(2) Inserting 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, B0, B1, P1) in the molar or premolar region due to risk of implant fracture. Highly angled abutments on small diameter implants are not recommended for use in the molar region.

(4) It is recommended to place smaller diameter implants (NP, B0, B1 and P1) in the maxillary lateral incisors and mandibular anterior zone.

(5) Physiological and anatomic conditions may negatively affect the performance of dental implants. When an implant or abutment is loaded excessively beyond its functional capability, bone loss, breakage of a dental implant or restoration malfunction may occur.

(6) Misuse of small unsecured components inside the mouth of the patient has the potential of being aspirated.

(7) If the irrigation is not flowing during the drilling process, discontinue immediately. Disregarding this can lead to necrosis of bone and failure of the implant to integrate.

(8) Re-using single use devices may damage the device or lead to contaminations.

(9) Allow the standard 12 week healing period for osseointegration to occur, immediately loading is not recommended. The clinician should closely monitor patients for any of the following conditions: peri-implantitis, peri-implant bone loss, changes to implant's response to percussion or radiographic changes in bone to implant contact along the implant's length. If the implant indicates mobility or greater than 50% bone loss, the implant should be evaluated for possible removal. If the clinician has chosen a short implant, the clinicians should consider a two-stage surgical approach, allow longer periods of osseointegration, splinting a short implant to an additional implant, and placement of the widest possible implant.

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. abutments, instruments) are labeled 'NON STERILE'.

⚠ Before every use, all instrumentation products intended for intraoral application must be sterilized (Use ANSI/AAMI ST79 conform pre-vacuum steam sterilizers and pouches. Sterilization parameters: pre-vacuum steam sterilization at 132°C (270°F) with minimum
4 minutes exposure time. Allow a drying time of at least 20 min).

⚠ 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 not been evaluated for safety and compatibility in the MR environment and 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 guideline 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 abutments. Therefore, it should be carefully evaluated before surgery. The final prosthesis should be designed prior to the placement of the dental implant.

(2) Continuous use of 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 contra angle handpiece for surgical tools in the surgical guideline. 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.

The indication for all overdenture abutment restorations is the following recommendations. The maxilla will require a minimum of 4 implant placements and two implant placements in the mandible.

Potential unfavorable consequences

Potential unfavorable consequences associated with the use of dental implants may include: failure to integrate initially, dehiscence of bone, perforation of bone or oral soft tissue, infection symptoms (like inflammation, suppuration abscess, 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 home page: 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.

Instrument Application Table

Surgical and Prosthetic Instruments		REF Number	TL	BL	TP	OPI
Tissue Punches	NP / BL 3.5	SI-A370E23P	●	●	●	
	BL 4.1	SI-B410E23P		●	●	
	RP / BL 4.8	SI-A480E23P	●	●	●	
	WP / BL 6.0	SI-A550E23P	●	●	●	
	OPI 3.25	SI-C300E23P				●
	OPI 4.0	SI-C370E23P				●
	OPI 5.0	SI-C480E23P				●
	OPI 5.6	SI-C550E23P				●
Round Bur	Ø 3.0	SI-A300E26R	●	●	●	●
Guide Drill	Ø 1.8	SI-A180E32U	●	●	●	●
Pilot Drills	TL / BL Ø 2.0	SI-A200E31D	●	●	●	
	OPI Ø 2.0	SI-C200E40D				●
Drills	BL Ø 2.5	SI-B250E31D		●		
	TL / BL Ø 2.8	SI-A280E31D	●	●		
	TL / BL Ø 3.5	SI-A350E31D	●	●		
	TL / BL Ø 4.2	SI-A420E31D	●	●		
	BL Ø 5.4	SI-B540E31D		●		
	Ø 2.0 Short	SI-A200E2SD	●	●	●	
	TP Ø 3.0 L 10	SI-P300E10D			●	
	TP Ø 3.0 L 12	SI-P300E12D			●	
	TP Ø 3.0 L 14	SI-P300E14D			●	
	TP Ø 3.5 L 6.5	SI-P350E65D			●	
	TP Ø 3.5 L 8	SI-P350E08D			●	
	TP Ø 3.5 L 10	SI-P350E10D			●	
	TP Ø 3.5 L 12	SI-P350E12D			●	
	TP Ø 3.5 L 14	SI-P350E14D			●	
	TP Ø 4.1 L 6.5	SI-P410E65D			●	
	TP Ø 4.1 L 8	SI-P410E08D			●	
	TP Ø 4.1 L 10	SI-P410E10D			●	
	TP Ø 4.1 L 12	SI-P410E12D			●	
	TP Ø 4.1 L 14	SI-P410E14D			●	
	TP Ø 4.8 L 6.5	SI-P480E65D			●	
	TP Ø 4.8 L 8	SI-P480E08D			●	
	TP Ø 4.8 L 10	SI-P480E10D			●	
	TP Ø 4.8 L 12	SI-P480E12D			●	
	TP Ø 4.8 L 14	SI-P480E14D			●	
	TP Ø 6.0 L 6.5	SI-P600E65D			●	
	TP Ø 6.0 L 8	SI-P600E08D			●	
	TP Ø 6.0 L 10	SI-P600E10D			●	
	TP Ø 6.0 L 12	SI-P600E12D			●	

Surgical and Prosthetic Instruments		REF Number	TL	BL	TP	OPI
	OPI Ø 2.7	SI-C270E40D				●
	OPI Ø 3.4	SI-C340E40D				●
	OPI Ø 4.4	SI-C440E40D				●
	OPI Ø 5.0	SI-C500E40D				●
Dense Bone Drills	TP Ø 3.0	SI-P300E00C			●	
	TP Ø 3.5	SI-P350E00C			●	
	TP Ø 4.1	SI-P410E00C			●	
	TP Ø 4.8	SI-P480E00C			●	
	TP Ø 6.0	SI-P600E00C			●	
Dense Bone Drills +	TP Ø 4.8	SI-P480E01C			●	
	TP Ø 6.0	SI-P600E01C			●	
Direction Indicator	Ø 2.0	SI-P200E20G	●	●	●	
Depth Gauges	Ø 2.0	SI-A200E24G	●	●	●	
	Ø 2.8	SI-A280E24G	●	●		
	Ø 3.5	SI-A350E24G	●	●		
	Ø 4.2	SI-A420E24G	●	●		
	Ø 2.0 / L 14	SI-C200E14G				●
	Ø 2.0 / L 22	SI-C200E22G				●
Profile Drills	BL 3.0	SI-B300E29S		●		
	3.5 NP / BL 3.5	SI-A350E29S	●	●		
	4.1 RP / BL 4.1	SI-A410E29S	●	●		
	4.8 RP / BL 4.8	SI-A480E29S	●	●		
	BL 6.0	SI-B600E29S		●		
	4.8 WP	SI-A550E29S	●			
	OPI 3.25	SI-C362E27C				●
	OPI 4.0	SI-C460E27C				●
	OPI 5.0	SI-C560E27C				●
	OPI 5.6	SI-C620E27C				●
Taps	BL 3.0	SI-B300E30T		●		
	TL / BL 3.5	SI-A350E30T	●	●		
	TL / BL 4.1	SI-A410E30T	●	●		
	TL / BL 4.8	SI-A480E30T	●	●		
	BL 6.0	SI-B600E30T		●		
Shaping Drills	OPI Ø 3.0	SI-C300E33S				●
	OPI Ø 3.8	SI-C380E33S				●
	OPI Ø 4.8	SI-C480E33S				●
	OPI Ø 5.4	SI-C540E33S				●
Drill Extension		SI-A350E25E	●	●	●	●
Tap Adaptor		SI-WATW00001	●	●	●	

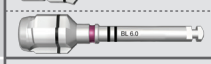
Surgical and Prosthetic Instruments		REF Number	TL	BL	TP	OPI
Kirschner Bur		SI-C101E33K				●
Implant Drivers for Handpiece	Short	SI-IDHP21S01	●	●		
	Long	SI-IDHP26L01	●	●		
		SI-IDHP24N01				●
Implant Drivers for Torque Wrench	Short	SI-IDTW13S01	●	●		
	Long	SI-IDTW18L01	●	●		
Implant Drivers for Wrench / P1	Short	SI-IDW116S01				●
	Long	SI-IDW121L01				●
Implant Drivers for Wrench / P2	Short	SI-IDW211S01				●
	Long	SI-IDW216S01				●
	Extra Long	SI-IDW221L01				●
Implant Driver Extension for Wrench		SI-IDW016E01				●
Direct Implant Drivers	Short	SI-B300IIDS		●	●	
	Long	SI-B300IIDL		●	●	
	Short	SI-B350IIDS		●	●	
	Long	SI-B350IIDL		●	●	
	Short	SI-B180IIDS		●	●	
	Long	SI-B180IIDL		●	●	
Hex Drivers for Handpiece	Short	SI-HDHP23S01	●	●	●	
	Long	SI-HDHP28L01	●	●	●	
Hex Drivers for Torque Wrench	Short	SI-HDTW16S01	●	●	●	
	Long	SI-HDTW23L01	●	●	●	
	Extra Short	SI-HDTW14S01	●	●	●	
	Extra Long	SI-HDTW35L01	●	●	●	
Handle for Hex Drivers		SI-HLHD00001	●	●	●	
Holding Key		SI-A550999H	●	●		
Healing Abutment Box		SI-PHABOX			●	
Metal Tray		SI-PMTRAY	●	●	●	●
Metal Container		SI-PBGCONT	●	●	●	●
Plastic Mat		SI-PLASM	●	●	●	●
Depth Indicator Gauge		PI-P01		●	●	
Titanium Forceps		PI-P02	●	●	●	●
Torque Wrench	20 - 70 Ncm	AI-002	●	●	●	
Wrench		AI-003				●
X-ray Reference Sphere	Ø 5.0 mm	SI-001	●	●	●	●
X-ray Templates		SI-002	●			
		SI-B02		●		
		SI-P02			●	
		SI-C02				●

Surgical and Prosthetic Instruments		REF Number	TL	BL	TP	OPI
Guide Cylinders	3.5 B1	SI-B350S50C		●	●	
	4.1 B2	SI-B410S50C		●	●	
	4.8 B2	SI-B480S50C		●	●	
Reamer (incl. Guide Pins)		PI-RM4565001	●	●	●	
LOCATOR® Core Tool		PI-ADLA10001	●	●	●	
LOCATOR® Parallel Post		PI-PPLA08001	●	●	●	
LOCATOR® Angle Measurem. Guide		PI-MGLA15001	●	●	●	
Plan Set (with all Planning Abutm.)		PI-A001PBOX	●			
		PI-B001PBOX		●	●	
Swift Plan Set (with all Planning Abutm.)		PL-BS001PBOX		●	●	
Storage Box for Planning Abutm.		PI-A000PBOX	●			
		PL-BS000PBOX		●	●	
Abutment Depth Gauge		PI-B01		●	●	
LOCATOR® Abutment Drivers	Short	PI-IDLA15S01	●	●	●	
	Long	PI-IDLA21L01	●	●	●	
Solid and Swift Abutment Drivers	Short	PI-DRSA17S01	●	●	●	
	Long	PI-DRSA23L01	●	●	●	
Swift Abutment Drivers B1	Short	PI-DRSW17S01		●	●	
	Long	PI-DRSW23L01		●	●	
Multi-Use Straight Abutment Driver	Short	PI-DRMU17S01		●	●	
	Long	PI-DRMU23L01		●	●	
Ball Abutment Driver		PI-DRBB19001	●	●	●	
Abutment Removal Tools	B0	PI-B00		●	●	
	B1	PI-B10		●	●	
	B2	PI-B20		●	●	
Surgical Kit (without instr.)		SI-ABOX9991	●	●		
		SI-CBOX9991				●
Surgical Kit (instr. & wrench)		SI-ASKS0001	●	●		
		SI-CSKS0001				●
Surgical Box TP 01		SI-PBOX9991			●	
Surgical Kit TP 01 - Complete Kit		SI-PSKS0001			●	
Surgical Kit TP 01 - Basic Kit		SI-PSKS0002			●	
Storage Element		SI-ABOX0001	●	●	●	●
Prosthetic Kit (without instr.)		PI-PK0000001	●	●	●	
Prosthetic Kit (without wrench)		PI-PKSK00001	●	●	●	
Prosthetic Kit (instr. & wrench)		PI-PKSK00002	●	●	●	

TL: Tissue Level Implant Line
BL: Bone Level Implant Line
TP: Bone Level Tapered Implant Line
OPI: One Piece Implant Line

Surgical Instrument Application Chart

This table shows the surgical instruments for implant bed preparation. It includes the application, maximum handpiece speed, image, and related implant type.

Instrumentation for implant bed preparation				Implant Type ø (mm)					
Step		max. rpm	Photo	ø 3.0 B0	ø 3.5 NP / B1	ø 4.1 RP / B2	ø 4.8 RP / B2	ø 4.8 WP	ø 6.0 B2
Flapless Operation	*Tissue Punch NP / BL 3.5*	800		●	●				
	Tissue Punch BL 4.1					●			
	Tissue Punch RP / BL 4.8						●		
	Tissue Punch WP / BL 6.0							●	●
Prepare the Alveolar Ridge	*Round Bur ø 3.0 mm*	800		●	●	●	●	●	●
Mark the Implant Site	*Guide Drill ø 1.8 mm*	800		●	●	●	●	●	●
Prepare the Implant Site	*Pilot Drill ø 2.0 mm*	800		●	●	●	●	●	●
Check the Depth and Condition	*Depth Gauge ø 2.0 mm*			●	●	●	●	●	●
Widen the Implant Site for ø 3.0 mm Implant	*Drill 2.5 mm*	600		●					
Widen the Implant Site for ø 3.5 mm Implant	*Drill 2.8 mm*				●	●	●	●	●
Widen the Implant Site for ø 4.1 mm Implant	*Drill 3.5 mm*					●	●	●	●
Widen the Implant Site for ø 4.8 mm Implant	*Drill 4.2 mm*						●	●	●
Widen the Implant Site for ø 6.0 mm Implant	*Drill 5.4 mm*								●
Measure the Depth of the Implant Site	*Depth Gauge ø 2.8 mm*				●	●	●	●	●
	Depth Gauge ø 3.5 mm					●	●	●	●
	Depth Gauge ø 4.2 mm						●	●	●
Prepare the Cortical Region of the Implant Site	*Profile Drill 3.0 B0*	600		●					
	Profile Drill 3.5 NP / BL 3.5				●				
	Profile Drill 4.1 RP / BL 4.1					●			
	Profile Drill 4.8 RP / BL 4.8						●		
	Profile Drill 4.8 WP							●	
	Profile Drill 6.0 B2								●
Tapping	*Tap ø 3.0 mm*	15		●					
	Tap ø 3.5 mm				●				
	Tap ø 4.1mm					●			
	Tap ø 4.8 mm						●	●	
	Tap ø 6.0 mm								●

Drill Usage Chart for Bone Level Implants

Dr. or clinic name: _____ Account number: _____

Address: _____ Phone number: _____

_____

Biodenta Drills	Product Number	Drill Usage (Replace twist-type drills after 10 uses)															Date Replaced
Round Bur: 3.0 (optional) 	SI-A300E26R	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Guide Drill: 1.8 	SI-A180E32U	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Pilot Drill: 2.0 	SI-A200E31D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Twist Drill: 2.5 	SI-B250E31D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Twist Drill: 2.8 	SI-A280E31D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Twist Drill: 3.5 	SI-A350E31D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Twist Drill: 4.2 	SI-A420E31D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Twist Drill: 5.4 	SI-B540E31D	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Profile drill: 3.0 	SI-B300E29S	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Profile Drill: 3.5 	SI-A350E29S	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Profile Drill: 4.1 	SI-A410E29S	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Profile Drill: 4.8 	SI-A480E29S	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	

Dr. or clinic name: _____ Account number: _____

Address: _____ Phone number: _____

_____

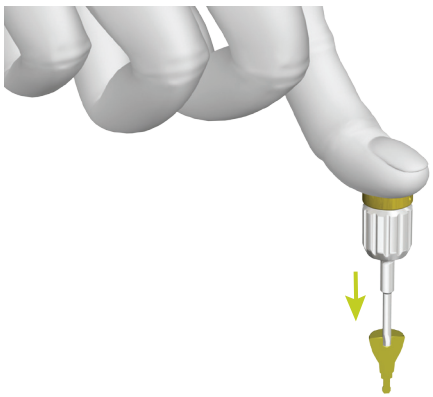
Biodenta Drills	Product Number	Drill Usage (Replace twist-type drills after 10 uses)															Date Replaced
Profile Drill: 6.0 	SI-B600E29S	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Tap: 3.0 	SI-B300E30T	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Tap: 3.5 	SI-A350E30T	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Tap: 4.1 	SI-A410E30T	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Tap: 4.8 	SI-A480E30T	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
Tap: 6.0 	SI-B600E30T	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	

Torque Guide

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

Procedure	Torque
Inserting implants with B0 platform	max. 35 Ncm
Inserting implants with NP or B1 platform	max. 50 Ncm
Inserting implants with RP, WP or B2 platform	max. 70 Ncm
Connecting healing cap / abutment or closure screw with the implant	Hand Force
Connecting temporary abutments with the implant	20 Ncm
Connecting B0 angled / straight / ball / LOCATOR® abutments with the implant	20 Ncm
Connecting angled / straight / solid / gold / ball / LOCATOR® / swift / multi-use / hybrid sleeve / bar abutments with the implant	35 Ncm
Connecting bridge screw with multi-use abutment	20 Ncm
Connecting prosthetic screw with hybrid sleeve	20 Ncm

⚠ Please ensure the hex driver is fully engaged into the head of the prosthetic screw.



⚠ If it is necessary to reverse a torque tightened abutment screw, we suggest to **replace the abutment screw** once the torque is reversed, in order to maintain the full torque capacity of the abutment screw.

Material Declaration

Implant

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Dental Implants	Pure Titanium	Delivered Sterile	NO	NO	YES

Surgical Instruments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Tissue Punches	Stainless Steel	Sterilization	NO	YES	YES
Round Bur	Stainless Steel	Sterilization	NO	YES	YES
Guide Drill	Stainless Steel	Sterilization	NO	YES	YES
Pilot Drill	Stainless Steel	Sterilization	NO	YES	YES
Drills	Stainless Steel	Sterilization	NO	YES	YES
Drill Extension	Stainless Steel	Sterilization	NO	YES	YES
Depth Gauges	Titanium Alloy	Sterilization	NO	YES	YES
Profile Drills	Stainless Steel	Sterilization	NO	YES	YES
Taps	Stainless Steel	Sterilization	NO	YES	YES
Holding Key	Stainless Steel	Sterilization	NO	YES	YES
Surgical Kit 01 Box	Plastics	Sterilization	YES	YES	NO
Metal Container	Stainless Steel	Sterilization	NO	YES	NO
Removable Box	Plastics	Sterilization	NO	YES	NO
Metal Tray	Stainless Steel	Sterilization	NO	YES	NO
Torque Wrench 20-70 Ncm	Stainless Steel	Sterilization	YES	YES	YES
Hex Drivers for Wrench	Stainless Steel	Sterilization	NO	YES	YES
Handle for Hex Drivers	Stainless Steel	Sterilization	NO	YES	YES
Hex Drivers for Handpiece	Stainless Steel	Sterilization	NO	YES	YES
Implant Drivers for Handpiece	Stainless Steel	Sterilization	NO	YES	YES
Implant Drivers for Wrench	Stainless Steel	Sterilization	NO	YES	YES
Tap Adaptor for Wrench	Stainless Steel	Sterilization	NO	YES	YES
X-ray Reference Sphere	Stainless Steel	Sterilization	NO	YES	YES

Closure Screws & Healing Abutments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Closure Screws	Titanium Alloy	Sterilization	NO	NO	YES
Healing Abutments	Titanium Alloy	Sterilization	NO	NO	YES

Abutments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Bar Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Bar Abutments	Gold Alloy	Sterilization	NO	NO	YES
Bar Abutment Holder	Stainless Steel	Sterilization	NO	NO	NO
Straight Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Angled Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Abutment Screws	Titanium Alloy	Sterilization	NO	NO	YES
Temporary Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Temporary PEEK Abutments	Plastics	Sterilization	NO	NO	YES
Swift Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Multi-Use Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Hybrid Sleeve	Titanium Alloy	Sterilization	NO	NO	YES
Multi-Use Temporary Cylinder	Titanium Alloy	Sterilization	NO	NO	YES
Protective Caps for Swift Abutments	Plastics	Disinfection	NO	NO	YES
Protective Caps for Multi-Use	Titanium Alloy	Sterilization	NO	NO	YES
Protection Cap for Sleeve	Titanium Alloy	Sterilization	NO	NO	YES
Burnout Plastic Copings for Swift Abutments	Plastics	NO	NO	NO	NO
Multi-Use Full Burnout Cylinder	Plastics	NO	NO	NO	NO
Multi-Use Bridge Screw	Titanium Alloy	Sterilization	NO	NO	YES
Prosthetic Screw for Hybrid Sleeve	Titanium Alloy	Sterilization	NO	NO	YES

Gold Abutments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Gold Abutments	Ceramicor®	Sterilization	NO	NO	YES
Sheath	Plastics	NO	NO	NO	NO
Multi-Use Semi Burnout Cylinder	Ceramicor	Sterilization	NO	NO	YES

Transfer Parts

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Screw Type Impression Posts	Titanium Alloy	Disinfection	NO	NO	YES
Impression Cap for Swift Abutments	Plastics	Disinfection	NO	NO	YES
Multi-Use Impression Post	Titanium Alloy	Disinfection	NO	NO	YES
One Piece Hybrid Interface / Impression Post	Titanium Alloy	Disinfection	NO	NO	YES
Guide Pins	Stainless Steel	Disinfection	NO	NO	YES
Implant Analogs	Titanium Alloy	NO	NO	NO	NO
Implant Analogs for Swift Abutments	Titanium Alloy	NO	NO	NO	NO
Multi-Use Analog	Titanium Alloy	NO	NO	NO	NO
Analog for Sleeve	Titanium Alloy	NO	NO	NO	NO

LOCATOR® - and Ball Abutments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
LOCATOR® Abutments	Titanium Alloy	Sterilization	NO	NO	YES
LOCATOR® Processing Cap	Stainless Steel	Sterilization	NO	NO	YES
LOCATOR® Replacement Males	Plastics	Disinfection	NO	NO	YES
LOCATOR® Block Out Spacer	Plastics	NO	NO	NO	NO
LOCATOR® Female Analog	Aluminum	NO	NO	NO	NO
LOCATOR® Female Analog	Aluminum	NO	NO	NO	NO
LOCATOR® Impression Coping	Aluminum	Disinfection	NO	NO	YES
Ball Abutments	Titanium Alloy	Sterilization	NO	NO	YES
Ball Abutment Analog	Titanium Alloy	NO	NO	NO	NO
Metal Housing for Ball Abutments	Elitor® - Metal Alloy	Disinfection	NO	NO	YES

Prosthetic Instruments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Prosthetic Kit Box	Plastics	Sterilization	NO	YES	NO
LOCATOR® Abutment Driver	Stainless Steel	Sterilization	NO	YES	YES
Ball Abutment Driver	Stainless Steel	Sterilization	NO	YES	YES
LOCATOR® Core Tool	Stainless Steel	Sterilization	YES	YES	NO
LOCATOR® Parallel Post	Plastics	Sterilization	NO	YES	NO
LOCATOR® Angle Measurement Guide	Stainless Steel	Sterilization	NO	YES	NO
Abutment Depth Gauge BL1	Titanium Alloy	Sterilization	NO	YES	YES
Solid and Swift Abutment Drivers	Stainless Steel	Sterilization	NO	YES	YES
Multi-Use Straight Abutment Drivers	Stainless Steel	Sterilization	NO	YES	YES
Reamer (incl. Guide Pin)	Special Steel	NO	YES	YES	NO

Planning Abutments

Item	Material	Sterilization Disinfection	Disassembly	Reusability	Intraoral Application
Planning Abutment / Straight	Plastics	YES	NO	YES	YES
Planning Abutment / Angled	Plastics	YES	NO	YES	YES
Planning Abutment / Swift	Plastics	YES	NO	YES	YES
Storage Box for Planning Abutments	Plastics	NO	NO	YES	NO

Material Information

Pure Titanium

The properties of pure grade 4 titanium for Biodenta implants

A. Chemical Composition (wt%):

	C	O	N	H	Fe	Ti
Max.	0.10	0.40	0.05	0.0125	0.50	Balance

B. Mechanical Properties:

	Elongation (A)	Tensile Strength (Rm)	Yield Strength (Rp)	Reduction of Area (Z)
Unit	%	Mpa	Mpa	%
Min.	15	550	483	25

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 abutments and depth gauges.

a) Chemical Composition (%):

	Al	V	C	O	N	H	Ir	Ti
Max.	5.5 to 6.5	3.5 to 4.5	0.08	0.13	0.05	0.012	0.25	Balance

b) Mechanical Properties:

	Tensile Strength (Rm)	Proof stress of nonproportional elongation (Rp)	Percentage elongation after fracture (A)	Mandrel diameter for bend test
Unit	Mpa	Mpa	Min.	
Sheet and Strip	860	795	10	10 t[1)]
Bar[2)]	860	795	10	Not applicable

1) t = thickness of the sheet or strip
2) Maximum diameter or thickness = 44.45 mm

c) Technical Information:
Wrought titanium 6-Al 4-V alloy conforms to ISO 5832-3:1996 and ASTM F136-11

Symbols

Lot number

Article reference number

Do not reuse

Use before expiry date

Sterilized by gamma irradiation

Manufacturer

Refer to instructions for use

Not for intraoral application

Rx only U.S. Federal Law restricts this device to sale by or on the order of a licensed dentist or physician

Non sterile. This product is not sterilized

Attention! Important warning

Implant surface. Indicates which implant surface is applied

CE 0197

Unit : millimeters
Ø : Diameter
L : Length
GH : Gingiva Height

Notes

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 disclaim 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 study the latest developments of the Biodenta Dental Implant System and their applications.

biodenta®
we're all about teeth

+swiss design

www.biodenta.com

Biodenta Regional Hubs

AMERICAS
(North & South America)

Biodenta North America
11 Firstfield Rd
Gaithersburg, MD
20878, USA

Tel +1 240 482 8484
Fax +1 301 215 6933

usa@biodenta.com

EMEA
(Europe, Middle East & Africa)

Biodenta Swiss AG
Tramstrasse 16
9442 Berneck
Switzerland

Tel +41 71 747 11 11
Fax +41 71 747 11 12

emea@biodenta.com

APAC
(Asia & Pacific)

Biodenta Corporation Taiwan
2F, No.51, Sec. 4, Zhongyang Rd.,
Tucheng Dist., New Taipei City
236, Taiwan

Tel +886 2 2267 3937
Fax +886 2 2267 3973

apac@biodenta.com