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# TiBase

## Operating Instructions

English

This product is covered by one or more of the following US patents:

- US7901209



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# 1 Symbols used



**NOTE!** Observe operating instructions!



This product is a medical device in accordance with Council Directive 93/42/EEC.

**USA: Rx only**

**For the USA only**



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

Article number



Batch number



This product is intended for single use only



unsterile

## 2 Product description

TiBase and Abutment Screw are products which are used for the digital acquisition of an implant position and for the restorative supply of implants.

Instead of a deformation post to transmit the implant position to a model, a Scanbody is required in the digital process, which can be optically acquired in an effective way along with the mouth situation. For this purpose, a titanium base (product name: TiBase) is mounted on an implant or laboratory analog with an Abutment Screw (product name for separate product: Abutment Screw) and depending on the acquisition system a suitable Scanbody is connected to this.

The titanium base is designed on the bottom side in line with the implant's specific requirements and can only be screwed onto specific implants with a certain diameter. The top side is formed for the acquisition of a Scanbody.

A titanium base can also be used for the restorative supply of an implant. For this purpose, a mesostructure is glued onto the titanium base, which can be individually adjusted in line with aesthetic and functional requirements. Depending on the mesostructure design, the product glued to the titanium base can be used as the abutment or directly bolted crown.

An Abutment Screw is also used for the definitive attachment to the implant.

The TiBase product comprises two individual components: Titanium base and Abutment Screw.

The Abutment Screw product comprises two identical Abutment Screws. Abutment Screws are provided separately, as they are either required as a replacement part or as an additional attachment to the laboratory analog.

**Table 1: Overview of the available TiBase, Abutment Screws and tightening torques**

Manufacturer/implant	Implant diameter	Platform	TiBase	REF	Connection	Abutment Screw	REF	Tightening torque
<b>Dentsply Sirona Implants</b>								
AstraTech Osseospeed EV	3	3.0	AT EV 3.0 GH1 S	6586304	S	AT EV 3.0	6586262	25 Ncm
	3,6	3.6	AT EV 3.6 GH1 S	6586312	S	AT EV 3.6	6586270	
	4,2	4.2	AT EV 4.2 GH1 L	6586320	L	AT EV 4.2	6586288	
	4,8	4.8	AT EV 4.8 GH1 L	6586338	L	AT EV 4.8	6586296	
	5,4	5.4	AT EV 5.4 GH1 L	6586346	L	AT EV 5.4	6593714	
AstraTech OsseoSpeed TX	3.5 S / 4.0 S	3.5 / 4.0	AT OS 3.5/4.0 L	6282532	L	AT OS 3.5/4.0	6460344	25 Ncm
	4.5 / 5.0 / 5.0 S	4.5 / 5.0	AT OS 4.5/5.0 L	6282540	L	AT OS 4.5/5.0	6460443	
Ankylos	A, B, C, D	C/X	ANK C/ GH1 S ANK C/ GH2 S ANK /X GH1 S ANK /X GH2 S	6586528 6586536 6586544 6586551	S	Not available		15 Ncm
Frialit / Xive	3,4	3.4	FX 3.4 S	6282433	S	FX 3.4, 3.8, 4.5, 5.5	6460476	25 Ncm
	3,8	3.8	FX 3.8 S	6282441	S			
	4,5	4.5	FX 4.5 L	6282458	L			
	5,5	5.5	FX 5.5 L	6282466	L			
<b>Biomet 3i</b>								
Certain® (Internal connection)	3,4	3.4	B C 3.4 S	6308048	S	B C 3.4, 4.1, 5.0	6460450	20 Ncm
	4,1	4.1	B C 4.1 L	6308097	L			
	5	5.0	B C 5.0 L	6308121	L			
Outer hexagon	3,4	3.4	B O 3.4 L	6282557	L	B O 3.4, 4.1, 5.0	6460468	35 Ncm
	4,1	4.1	B O 4.1 L	6282565				
	5	5.0	B O 5.0 L	6282573				
<b>BioHorizons</b>								
(Internal connection) Tapered internal, Tapered internal tissue level, Tapered plus, Internal dental implant, single stage dental implants	3,0 / 3,8	3.0	BH 3.0 S	6532779	S	BH 3.0	6561240	30 Ncm
	3,0/3,5/3,8/4,0/4,6	3.5	BH 3.5 L	6532894	L	BH 3.5, 4.5, 5.7	6561257	
	4,0/4,6/5,0/5,8	4.5	BH 4.5 L	6532951	L			
	5,0/5,8/6,0	5.7	BH 5.7 L	6536242	L			
<b>Nobel Biocare</b>								
Replace (Three channel internal connection)	3,5	NP	NB RS 3.5 L	6282474	L	NB RS 3.5	6460526	35 Ncm
	4,3	RP	NB RS 4.3 L	6282482				
	5	WP	NB RS 5.0 L	6282490		NB RS 4.3, 5.0, 6.0	6460534	
	6	6.0	NB RS 6.0 L	6282508				
Nobel Active (conical connection)	3,5	NP	NB A 4.5 L	6308188	L	NB A 4.5	6460484	25 Ncm
	4,3 / 5,0	RP	NB A 5.0 L	6308253		NB A 5.0	6460492	35 Ncm
Branemark® (Outer hexagon)	3,3	NP	NB B 3.4 L	6282516	L	NB B 3.4	6460500	35 Ncm
	3,75 / 4,0	RP	NB B 4.1 L	6282524		NB B 4.1	6460518	
<b>Osstem</b>								
Osstem TS	3,5	Mini	O TS 3.5 L	6527035	L	O TS 3.5	6561208	20 Ncm
	4,0/4,5/5,0/6,0/7,0	Standard	O TS 4.0 L	6527043		O TS 4.0	6561232	30 Ncm
<b>Straumann</b>								
Bone Level	3,3	NC (3.3 mm)	S BL 3.3 L	6308154	L	S BL 3.3, 4.1	6460542	35 Ncm
	4,1 / 4,8	RC (4.1 mm / 4.8 mm)	S BL 4.1 L	6308337				
Standard (Tissue Level)	3,3	NN (3.5 mm)	S SO 3.5 L	6284231	L	S SO 3.5	6460559	35 Ncm
	3,3 / 4,1 / 4,8	RN (4.8 mm)	S SO 4.8 L	6284249		S SO 4.8, 6.5	6460567	
	4,8	WN (6.5 mm)	S SO 6.5 L	6284256				
<b>Thommen Medical</b>								
SPI Element, SPI Contact, SPI Element Inicell, SPI Contact Inicell	3,5	3,5	TM 3.5 S	6531854	S	TM 3.5	6561265	15 Ncm
	4	4	TM 4 S	6532829				
	4,5	4,5	TM 4.5 S	6532837		TM 4.0, 4.5, 5.0, 6.0	6561273	25 Ncm
	5	5	TM 5 S	6544360				
6	6	TM 6 S	6544378					
<b>Zimmer</b>								
Tapered Screw-Vent	3,7 / 4,1 4,7 6	3,5 4,5 5,7	Z TSV 3.5 L Z TSV 4.5 L Z TSV 5.7 L	6282581 6282599 6282607	L	Z TSV 3.5, 4.5, 5.7	6460575	30 Ncm
<b>Medentika</b>								
M-Implant	3.5 / 4.0 / 4.5 / 5.0	3.5/5.0	MI 3.5 / 5.0 L	6308295	L	Not available		25 Ncm

**Overview of compatible Scanbodies and mesostructure blocks**

Depending on the connection, the following components are compatible:

**Connection size S**

Designation	REF
Scanbodies for Omnicam S*	6431311
Scanbodies for Bluecam S**	6431295
inCoris ZI meso S F0.5	6231802
inCoris ZI meso S F2	6231828
CEREC Zirconia meso S BL2	6548692
CEREC Zirconia meso S A1	6623016
CEREC Zirconia meso S A2	6582428
CEREC Zirconia meso S A3	6582436
CEREC Zirconia meso S A3.5	6582444

**Connection size L**

Designation	REF
Scanbodies for Omnicam L*	6431329
Scanbodies for Bluecam L**	6431303
inCoris ZI meso L F0.5	6231810
inCoris ZI meso L F2	6231836
CEREC Zirconia meso L BL2	6548700
CEREC Zirconia meso L A1	6623024
CEREC Zirconia meso L A2	6582451
CEREC Zirconia meso L A3	6582469
CEREC Zirconia meso L A3.5	6582477

\* suitable for CEREC AC Omnicam

\*\* suitable for CEREC AC Bluecam and inEos X5

### 3 Materials

TiBase, abutment screw
------------------------

Ti6Al4V, medical grade 5, ASTM 136
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## 4 Intended use, indications and contraindications

### 4.1 Intended use

Titanium base for manufacturing a two-part abutment, comprising TiBase and inCoris ZI or CEREC Zirconia mesostructure.

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### 4.2 Indications

TiBase titanium bases are attached to an implant as prosthetic titanium base for adhesion to mesostructures to restore function and aesthetics in the oral cavity.

### 4.3 Contraindications

- Insufficient oral hygiene
- Insufficient space available
- Bruxism
- For restorations with angulation correction of more than 20° to the implant axis
- For individual tooth restorations with free end saddle
- For restorations whose length exceeds a ratio of 1:1.25 in comparison to the length of the implant



## 5 Processing hints

### 5.1 Scanning

1. Mount the TiBase on the matching laboratory analog in the master model or onto the implant in the mouth of the patient and screw it tight using the supplied abutment screw. In doing so, it is insignificant in which direction the small cam on the top side of the titanium base points.
2. Plug a suitable Scanbody (see Table 2 in the Section "Product description [→ 4]") onto the TiBase so that it is seated free of gaps, and therefore flush while watching out for the intended guide groove in the Scanbody, guide it over the small cam on the TiBase. The scanbody is scannable without powder or scan spray.
3. Acquire the situation alternatively with inEos X5, inEos Blue, CEREC 3 or CEREC AC.

#### CAUTION

##### **Intraoral application**

The TiBase should only be used in the mouth once the correct positioning of the Scanbody has been checked without any concerns. This is difficult to perform on deeply positioned implants. In such cases, ScanPost is recommended.

4. Use the CEREC SW/inLab SW software to design the individual shape of the mesostructure and mill the shape from one of the materials allowed for this purpose (e.g. inCoris ZI meso or CEREC Zirconia meso). Be sure to observe the information on design, post-processing and gluing with the TiBase provided in the Operating Instructions/Processing Instructions for the corresponding material.

## 5.2 Processing the TiBase

The diameter of the TiBase must not be reduced e.g. by grinding. Shortening the TiBase is not permitted.

The contact surfaces of the TiBase to the implant should not be sand-blasted or otherwise processed.

Only the surfaces of the TiBase intended for gluing with a mesostructure must be sandblasted (50µm aluminum oxide, max. 2.0 bar) and then cleaned (with alcohol or steam).

Use "PANAVIA™ F 2.0" ([www.kuraray-dental.de](http://www.kuraray-dental.de)) as an adhesive extraorally to connect the TiBase and the sintered inCoris ZI mesostructure or CEREC Zirconia mesostructure. Other glues are required for attaching different materials. Observe the operating instructions for the material used.

1. For easier handling during the gluing process, it is recommended that the TiBase be screwed into a lab implant or a polishing tool.
2. Cover the hex head of the abutment screw with wax.
3. Sand-blast the gluing surfaces of the TiBase with 50 µm aluminum oxide and up to 2.0 bar and clean the surfaces with alcohol or steam.
4. Ensure that the mesostructure can be fully slid onto the TiBase.
5. Apply metal primer and glue to the TiBase while observing the manufacturer specifications.
6. Push the sintered mesostructure in as far as it will go. Make sure it latches into the rotation and position stops.
7. Remove excess glue immediately. Make sure that there is no glue residue left in the screw channel.
8. Follow the recommendations of the glue manufacturer with regard to the final hardening of the glue.
9. Remove residue with a rubber polisher after hardening.

## 5.3 Information for the dentist

The titanium bases TiBases are delivered in non-sterile condition.

Observe the implant manufacturer's operating instructions.

### 5.3.1 Sterilization

The individual abutments and abutment screws must be cleaned and sterilized prior to insertion. Furthermore, the locally applicable legal regulations and the hygiene standards applicable for a dental practice must be observed.

Use only the validated sterilization procedures specified below to sterilize individual abutments. Observe the sterilization parameters.

Steam sterilization can be performed with the fractionated vacuum or the gravitation method.

The following sterilization parameters have been validated:

- Sterilization time: 5 minutes at 132°C (270°F)
- Sterilization time: 15 minutes at 121°C (250°F)
- Sterilization time: 3 minutes at 135°C (275°F)

The abutments are to be used immediately after sterilization and must not be stored.

Steam sterilization may be performed only using devices that comply with EN 13060 or EN 285 standards.

Sterilization methods must be validated in compliance with EN ISO 17664 and ANSI/AAMI ST79:2010, A1:2010, A2:2011, A3:2012, A4:2013.

The responsibility for the sterility of the individual abutment lies with the user. It must be ensured that only suitable devices, materials and product-specifically validated methods are used to perform sterilization. It must be ensured that the methods used have been validated. The equipment and devices must be properly maintained and serviced at regular intervals.

The fabricator (dental technician) of the TiBase and the mesostructure must inform the dentist of the need to sterilize the abutment before inserting it in the patient's mouth!

### 5.3.2 Application in the mouth

#### **WARNING**

##### **Risk of aspiration of small parts**

- Position the patient in such a way that the risk of aspiration of small parts is kept to a minimum.
- Secure all intraorally used components against aspiration and being swallowed.

#### **WARNING**

Use the unused Abutment Screw and the tools provided by the implant manufacturer to screw the TiBase onto the implant, observing the tightening torques specified in table 1 (see "Product description [→ 4]").



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We reserve the right to make any alterations which may be required due to technical improvements.

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