New as of: 2022-10

Dentsply Sirona

TiBase

Operating Instructions (not valid for USA)

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 compliant with EU Medical Device Regulation 2017/745 including all amendments.



This product is a medical device.



Article number



Batch number



This product is intended for single use only



unsterile

For the USA only

Rx only

CAUTION: According to US Federal Law, this product may be sold only to or by instruction of physicians, dentists, or licensed professionals.

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 esthetic 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 comprises two individual components: Titanium base and Abutment Screw.

The Abutment Screw 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.

An important performance feature of the TiBase product is its suitability for constant supply of dental implants as abutments with inCoris ZI meso or directly as screw-retained crowns with CEREC Zirconia meso.

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
Dentsply Sirona								
AstraTech Implant EV	3,0	XS	AT EV 3.0 GH1 S	6586304	S	AT EV 3.0	6586262	25 Ncm
	3,6	S	AT EV 3.6 GH1 S	6586312	S	AT EV 3.6	6586270	
	4,2	M	AT EV 4.2 GH1 L	6586320	L	AT EV 4.2	6586288	
	4,8	L	AT EV 4.8 GH1 L	6586338	L	AT EV 4.8	6586296	
	5,4	XL	AT EV 5.4 GH1 L	6586346	L	AT EV 5.4	6593714	
PrimeTaper EV	3,0	XS	AT EV 3.0 GH1 S	6586304	S	AT EV 3.0	6586262	25 Ncm
	3,6	S	AT EV 3.6 GH1 S	6586312	S	AT EV 3.6	6586270	
	4,2	M	AT EV 4.2 GH1 L	6586320	L	AT EV 4.2	6586288	
	4,8 / 5,4	L	AT EV 4.8 GH1 L	6586338	L	AT EV 4.8	6586296	
OmniTaper EV	3,0	XS	AT EV 3.0 GH1 S	6586304	S	AT EV 3.0	6586262	25 Ncm
	3,4	S	AT EV 3.6 GH1 S	6586312	S	AT EV 3.6	6586270	
	3,8	M	AT EV 4.2 GH1 L	6586320	L	AT EV 4.2	6586288	
	4,5	L	AT EV 4.8 GH1 L	6586338	L	AT EV 4.8	6586296	
	5,5	XL	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	
	3,0 S	3.0	AT TX 3.0 S	6598085	S	AT TX 3.0	6598051	15 Ncm
	3.5 S / 4.0 S	3.5 / 4.0	AT TX 3.5/4.0 L	6598093	L	AT TX 3.5/4.0	6598069	20 Ncm
	4.5 / 5.0 / 5.0 S	4.5 / 5.0	AT TX 4.5/5.0 L	6598101	L	AT TX 4.5/5.0	6598077	25 Ncm
Ankylos	A, B, C, D	C/X	ANK C/ GH1 S	6586528	S	Not available		15 Ncm
			ANK C/ GH2 S	6586536				
			ANK /X GH1 S	6586544				
			ANK /X GH2 S	6586551				
Xive	3,0	3.0	Xive 3.0 S	6597319	S	Xive 3.0	6597434	24 Ncm
	3,4	3.4	Xive 3.4 S	6597327	S	Xive 3.4, 3.8, 4.5, 5.5	6597442	
	3,8	3.8	Xive 3.8 S	6597335	S			
	4,5	4.5	Xive 4.5 L	6597343	L			
	5,5	5.5	Xive 5.5 L	6597350	L			
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			
Biomet 3i								
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				
BioHorizons								
(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			
Nobel Biocare								
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		NB RS 4.3, 5.0, 6.0	6460534	
	5	WP	NB RS 5.0 L	6282490				
	6	6.0	NB RS 6.0 L	6282508				
Nobel Active (concical 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	
Osstem								
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
Straumann								
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 / 4,1 / 4,8	RN (4.8 mm)	S SO 4.8 L	6284249	L	S SO 4.8, 6.5	6460567	35 Ncm
	4,8	WN (6.5 mm)	S SO 6.5 L	6284256				
Thommen Medical								
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		TM 4.0, 4.5, 5.0, 6.0	6561273	25 Ncm
	4,5	4,5	TM 4.5 S	6532837				
	5	5	TM 5 S	6544360				
	6	6	TM 6 S	6544378				
Zimmer								
Tapered Screw-Vent	3,7 / 4,1	3,5	Z TSV 3.5 L	6282581	L	Z TSV 3.5, 4.5, 5.7	6460575	30 Ncm
	4,7	4,5	Z TSV 4.5 L	6282599				
	6	5,7	Z TSV 5.7 L	6282607				

2.1 Permissible combinations

TiBase may only be combined or used for manufacture and application with products permitted for that purpose.

TiBase may only be combined with the implants or lab analogs and screws that are listed in Table 1 [→ 5].

The following scanners and software products may be used in the manufacturing process:

- Scanner
  - inEos Blue
  - inEos X5
  - CEREC 3
  - Bluecam
  - Omnicam
  - Primescan
- Software
  - CEREC SW
  - inLab SW
  - Connect SW

The following products may be combined for scanning and for gluing to mesostructures:

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 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 A1	6623024
CEREC Zirconia meso L A2	6582451
CEREC Zirconia meso L A3	6582469
CEREC Zirconia meso L A3.5	6582477

* Suitable for scanning with Primescan and Omnicam

** Suitable for scanning with Bluecam and inEos X5

For gluing of mesostructures made of inCoris ZI meso or CEREC Zirconia meso, Panavia™ F2.0 (www.kuraray-dental.eu) must be used.

3 Materials

TiBase, abutment screw	Ti6Al4V, medical grade 5, ASTM 136

4 Intended use, indications and contraindications

4.1 Intended use

Titanium base for the manufacture of a two-piece abutment consisting of TiBase and inCoris ZI meso or a screw-retained crown consisting of TiBase and CEREC Zirconia meso.

4.2 Indications

Abutments or screw-retained crowns are intended for attachment to dental implants in the upper or lower jaw.

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

4.4 Risks

Breakage or loosening of the screw or titanium base

Observe the tightening torques to be used for abutment screws, which are listed in chapter "Product description [→ 4]", Table 1 [→ 5].

Note that abutment screws are intended for single use only!

Only use materials whose combination with TiBase is permitted (see chapter "Permissible combinations [→ 6]") and observe the instructions for processing the TiBase (see chapter "Processing the TiBase [→ 12]").

All components must be free from contamination (e.g. adhesive residues).

Failure of the connection between meso structure and TiBase

Observe the processing instructions in the chapter "Processing the TiBase [→ 12]" for conditioning the TiBase surface and for processing the luting composite.

Also observe the operating instructions for the combination products (e.g. inCoris ZI meso or CEREC Zirconia meso).

Infections or irritations

Use only clean components and sterilize the final abutment immediately before use in the patient's mouth in compliance with the sterilization conditions (see chapter "Sterilization [→ 13]").

Injury to the patient in case of aspiration or incorporation

Position the patient in such a way that the risk of aspiration of small parts is kept to a minimum (see chapter "Application in the mouth [→ 14]").

Premature loss of the abutment and retreatment

Observe the intended purpose of the TiBase product (see chapter "Intended use, indications and contraindications [→ 9]") and the processing instructions for TiBase and all combination products! Incorrect processing can lead to premature loss of an abutment.

Damage to the environment

Observe the information on correct disposal in the chapter "Disposal [→ 14]".

4.5 Side effects

- Allergic reactions
- Aspiration or incorporation of components
- Injury due to failure/breakage of components

4.6 Users

- Dentists
- Dental technicians
- Dental assistants

4.7 Patient population

All patients for whom a dental implant that is to be supplied with an abutment or screw-retained crown is indicated.

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 Section "Overview of compatible scanbodies and mesostructure blocks" [→ 6]) onto the TiBase so that it is seated free of gaps and therefore flush while ensuring that you guide the provided guide groove in the scanbody over the small cam on the TiBase. The scanbody is scannable without powder or scan spray.
3. Scan the situation with a scanner of the CEREC or inLab CAD/CAM system.

⚠ 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 inLab SW or CEREC 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 (50 µm aluminum oxide, max. 2.0 bar) and then cleaned (with alcohol or steam).

Use "PANAVIA™ F 2.0" (www.kuraray-dental.eu) as cement for bonding the TiBase and the sintered mesostructure made of inCoris ZI meso or CEREC Zirconia meso extraorally. 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 supplied with the TiBase and the tool provided by the implant manufacturer for screwing to the implant, observing the tightening torques specified in table 1 (see "Overview of available TiBase, abutment screws and tightening torques [→ 5]").

⚠ WARNING

Risk of injury to the patient

TiBase has not been evaluated for safety and tolerability in a magnetic resonance imaging (MRI) study. Heating, migration, or formation of image artifacts in an MR environment were not investigated. The safety of the TiBase in the MR environment is unknown. Scanning a patient with a TiBase may cause injury to the patient.

5.3.3 Reporting of serious incidents

IMPORTANT

Immediately notify the manufacturer and the national competent authority of any serious incident that has occurred with the product.

5.3.4 Brief report about the safety and clinical performance

A brief report about the safety and clinical performance of the TiBase product is provided in the Eudamed database of the EU.

5.3.5 Disposal

TiBase can be disposed of with normal waste in compliance with local regulations. Parts that have already come into contact with patients must be handled in compliance with statutory hygiene requirements.

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

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