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sirona
The Dental Company

Sirona Dental CAD/CAM System TiBase

Operating Instructions

English (US)

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

- US7901209

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1 Symbols used

NOTICE! Observe Operating Instructions!

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

Rx 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

non-sterile

2 Product description

Each delivery includes a TiBase, the titanium base from Sirona, an abutment screw and a scanbody in non-sterile form. All parts are intended for single use only.

Individually manufactured mesostructures or provisional restorations can be glued onto the TiBase. The glued parts are screwed onto the matching implant with the abutment screw in the patient's mouth.

The scanbody is used only to scan the position of the implant for creating the design in the inLab SW 4.x software.

The Sirona TiBase comes in various versions, each of which is compatible with a specific diameter of a specific implant system.

Product				compatible with implant system			compatible with grinding blocks[1]
TiBase	Abutment screw	Scan body[1]	REF	Implant manufacturer	Implant system	Implant diameter	
NBRS 3.5	M1.8	L	6282474	Nobel Biocare	Replace® NP	3.5 mm	inCoris ZI meso L
NBRS 4.3	M2	L	6282482		Replace® RP	4.3 mm	inCoris ZI meso L
NBRS 5.0	M2	L	6282490		Replace® WP	5.0 mm	inCoris ZI meso L
NBRS 6.0	M2	L	6282508		Replace® 6.0	6.0 mm	inCoris ZI meso L
NBB 3.4	M1.6	L	6282516	Nobel Biocare	Brånemark®	3.3 mm	inCoris ZI meso L
NBB 4.1	M2	L	6282524		Brånemark®	3.75 / 4.0mm	inCoris ZI meso L
NB A 4.5	M1.6	L	6308188	Nobel Biocare	Nobel Active NP	3.5mm	inCoris ZI meso L
NB A 5.0	M2	L	6308253		Nobel Active RP	4.3 / 5.0mm	inCoris ZI meso L
SSO 3.5	M1.8	L	6284231	Straumann®	Tissue level NN	3.5 mm	inCoris ZI meso L
SSO 4.8	M2	L	6284249		Tissue level RN	4.8 mm	inCoris ZI meso L
SSO 6.5	M2	L	6284256		Tissue level WN	6.5 mm	inCoris ZI meso L
S BL 3.3	M1.6	L	6308154	Straumann®	Bone Level NC	3.3mm	inCoris ZI meso L
S BL 4.1	M1.6	L	6308337		Bone Level RC	4.1 / 4.8mm	inCoris ZI meso L
ATOS 3.5/4.0	M1.6	L	6282532	Astra Tech	OsseoSpeed™	3.5 S / 4.0 S mm	inCoris ZI meso L
ATOS 4.5/5.0	M2	L	6282540		OsseoSpeed™	4.5 / 5.0 mm	inCoris ZI meso L
FX 3.4	M1.6	S	6282433	Friadent	Frialit® / Xive®	3.4 mm	inCoris ZI meso S
FX 3.8	M1.6	S	6282441		Frialit® / Xive®	3.8 mm	inCoris ZI meso S
FX 4.5	M1.6	L	6282458		Frialit® / Xive®	4.5 mm	inCoris ZI meso L
FX 5.5	M1.6	L	6282466		Frialit® / Xive®	5.5 mm	inCoris ZI meso L
BO 3.4	M2	L	6282557	Biomet 3i	Ex. hex	3.4 mm	inCoris ZI meso L
BO 4.1	M2	L	6282565		Ex. hex	4.1 mm	inCoris ZI meso L
BO 5.0	M2	L	6282573		Ex. hex	5.0 mm	inCoris ZI meso L
B C 3.4	M1.6	S	6308048	Biomet 3i	Certain®	3.4mm	inCoris ZI meso S
B C 4.1	M1.6	L	6308097		Certain®	4.1mm	inCoris ZI meso L
B C 5.0	M1.6	L	6308121		Certain®	5.0mm	inCoris ZI meso L
ZTSV 3.5	M1.8	L	6282581	Zimmer	Tapered Screw-Vent®	3.5 mm	inCoris ZI meso L
ZTSV 4.5	M1.8	L	6282599		Tapered Screw-Vent®	4.5 mm	inCoris ZI meso L
ZTSV 5.7	M1.8	L	6282607		Tapered Screw-Vent®	5.7 mm	inCoris ZI meso L

1. The letter S and L identifies the connection geometry with respect to the titanium bases

3 Materials

TiBase, abutment screw	Ti6Al4V, medical grade 5, ASTM 136
Scanbody	ABS (Cycolac GPM 5500 / WH4A015F)

4 Indications for use

The Sirona Dental CAD/CAM System is intended for use in partially or fully edentulous mandibles and maxillae in support of single or multiple-unit cement retained restorations. For the titanium bases SSO 3.5 L and SBL 3.3 L the indication is restricted for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. The system consists of three major parts: TiBase, inCoris mesostructure, and CAD/CAM software. Specifically, the inCoris mesostructure and TiBase components make up a two-piece abutment which is used in conjunction with endosseous dental implants to restore the function and aesthetics in the oral cavity. The inCoris mesostructure may also be used in conjunction with the Camlog Titanium base CAD/CAM (types K2244.xxxx) (K083496) in the Camlog Implant System. The CAD/CAM software is intended to design and fabricate the inCoris mesostructure. The inCoris mesostructure and TiBase two-piece abutment is compatible with the following implants systems:

- Nobel Biocare Replace (K020646)
- Nobel Biocare Branemark (K022562)
- Friadent Xive (K013867)
- Biomet 3i Osseotite (K980549)
- Astra Tech Osseospeed (K091239)
- Zimmer Tapered Screw-Vent (K061410)
- Straumann SynOcta (K061176)
- Straumann Bone Level (K053088, K062129, K060958)
- Biomet 3i Certain (K014235, K061629)
- Nobel Biocare Active (K071370)

⚠ CAUTION

Small diameter implants and large angled abutments in the anterior region of the mouth due to possible failure of the implant system.

⚠ CAUTION

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5 Use of TiBase devices and contra-indications

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

Contra-indications are:

- 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.

6 Processing hints

6.1 Scanning and designing

1. Mount the TiBase on the matching laboratory analog in the master model and screw it tight using the supplied abutment screw.
2. Plug the supplied scanbody onto the TiBase so that it is seated free of gaps, and therefore flush while watching out for the intended guide groove. The scanbody is scannable without powder or scan spray.
3. Acquire the situation alternatively with inEos Blue or CEREC AC.
4. Use the inLab SW 4.0 (or higher) to design the individual shape of the mesostructure and mill the shape from an inCoris ZI meso block (see inLab SW 4.x User Manual). Be sure to observe the information on design, postprocessing and sintering of zirconia provided in the Operating Instructions for inCoris ZI meso blocks.

Observe the safety limits during the design.

The known safety limits of the inCoris ZI meso and the TiBase materials are:

- Minimum wall thickness: 0.5 mm
- Maximum angle: 20°

⚠ CAUTION

Exceeding specified safety limits of your device results in the construction of a misbranded device which may lead to premature abutment fracture. In this case the patient must be informed that he is going to receive a device that is beyond the labeled specifications.

6.2 Processing the TiBase

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

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). The TiBase should be fastened in a laboratory analog to protect the internal connection.

Use "PANAVIA ™ F 2.0" (www.kuraray-dental.de) as an adhesive extraorally to connect the TiBase and the sintered inCoris ZI mesostructure.

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. Mix the glue according to the manufacturer's instructions and apply it to the TiBase.
4. Push the sintered inCoris ZI mesostructure in as far as it will go. Make sure it latches into the rotation and position stops.
5. Remove excess glue immediately.
6. Apply the Airblocker ("Oxyguard") to the junction where the ceramic and titanium surfaces meet and to the screw funnel for final hardening.
7. Remove residue with a rubber polisher after hardening.

⚠ CAUTION

The fixture to the abutment connection is essential to the mechanical stability of the dental implant system. Any modification to this connection qualifies as a change to a Class II medical device and qualifies the creator as a medical device manufacturing facility. Any change to this connection will characterize your facility as a medical device manufacturer subject to FDA registration, fees, regulation and restrictions.

6.3 Information for the dentist

The TiBases are delivered in non-sterile condition.

Observe the implant manufacturer's operating instructions.

6.3.1 Sterilization

The individual abutments must be 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 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 sterilization time is 5 minutes at 134°C (273.2°F) and 15 minutes at 121°C (249.8°F). Steam sterilization may be performed only using devices that comply with EN 13060 or EN 285 standards.

It must be ensured that only suitable devices are used to perform sterilization.

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!

6.3.2 Tightening torques

Use the tools provided by the implant manufacturer to screw the restoration onto the implant, observing the tightening torques specified in the following table:

TiBase	Tightening torque in Ncm
NBRS	35
NBB	35
SSO	35
ATOS	25
FX	25
BO	35
ZTSV	30
B C	20
S BL	35
NB A NP	25
NB A RP	35

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

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