New as of: 12.2010

sirona
The Dental Company

# TiBase

Operating Instructions

**English**

# Table of contents

# 1 Symbols used

**NOTICE!** Observe Operating Instructions!

CE
0123

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 3D 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 |
|---|---|---|---|---|---|---|---|
| TiBase | Abutment screw | Scan body | 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 |
| MI 3.5/5.0 | M1.6 | L | 6308295 | Medentika® Implant | M-Implant | 3.5/5.0mm | inCoris ZI meso L |

# 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 indicated for taking optical impressions to record the topographical characteristics of teeth, dental impressions, or stone models by computer aided design and fabrication in patients that require dental restorative prosthetic devices. The system also features the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments.

The system that features the processing of mesostructures comprises.

- Titanium bases TiBase
- inCoris ZI meso blocks
- Sirona Dental CAD/CAM Design and fabricating devices

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.

inCoris ZI meso blocks are used in manufacturing individually designed mesostructures, which are glued to a fitting titanium base after milling and sintering.

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 with a length to implant length ratio of more than 1:1.25.

Sirona Dental CAD/CAM Design and fabricating devices feature the processing of mesostructures, a dental restorative prosthetic device used in conjunction with endosseous dental implant abutments, i.e. it is an accessory to it. Devices which feature the processing of mesostructures comprises CEREC 3, CEREC AC, inEos, inEos Blue, CEREC MC XL and inLab MC XL.

### For the USA only

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# 5 Processing hints

## 5.1 Scanning

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, inEos, CEREC 3 or CEREC AC.
4. Use the inLab 3D for Abutments software V3.65 or inLab 3D V3.80 software (or higher) to design the individual shape of the mesostructure and mill the shape from an inCoris ZI meso block (see inLab 3D/ inLab 3D for Abutments 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.

## 5.2 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.

## 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 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 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 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.

Sterilization methods must be validated in compliance with EN ISO 17664.

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 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 |
| MI | 25 |

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


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