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Sirona Dental CAD/CAM System inCoris ZI meso

Zirconium oxide ceramic blocks for inLab

Processing instructions: Manufacturing mesostructures

English (US)

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

- US7178731
- US7901209



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Rx only

1 General

The product inCoris ZI meso bears the CE mark in accordance with the provisions of Council Directive 93/42EEC of June 14, 1993 concerning medical devices.

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

Please also observe the instructions provided by the manufacturer of the titanium base or the implant.

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.

2 Scope of supply

inCoris Zi meso blocks are each available in two different colors and in two different sizes for connecting to the titanium base:

REF	Connection size ¹	Color
62 31 802	S	F0.5
62 31 828	S	F2
62 31 810	L	F0.5
62 31 836	L	F2

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

The scanbodies are Sirona products and can be procured from dealers.

Lab implants and titanium bases can be procured from the implant manufacturer.

3 Material

inCoris ZI meso ceramics constitute blocks comprised of zirconium oxide.

The blocks are initially delivered partially sintered; then, enlarged by the CEREC or inLab CAD/CAM system, they are individually processed to specification, and finally, densely sintered.

The advantages of inCoris ZI meso are:

- High strength
- Resistance to corrosion
- Good biological compatibility of the product,
- Coloration of the blocks to match dentin color.

4 Chemical composition

Component	inCoris ZI and inCoris ZI meso
$\text{ZrO}_2 + \text{HfO}_2 + \text{Y}_2\text{O}_3$	$\geq 99.0\%$
Y_2O_3	$> 4.5 - \leq 6.0\%$
HfO_2	$\leq 5\%$
Al_2O_3	$\leq 0.5\%$
Fe_2O_3	$\leq 0.3\%$

5 Technical data

The following specifications apply to material that is densely sintered in an CEREC SpeedFire, inFire HTC or inFire HTC speed sintering furnace.

Colors:

The blocks are tinted in the colors:

- F0.5
- F2

Therefore it is not necessary to carry out subsequent coloring using a submersion solution or liners.

6 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 SSO 3.5 L and SBL 3.3 L titanium bases, the indication is restricted to the 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 implant 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

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

7 Use of inCoris ZI meso blocks and contraindications

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 restorations with angulation correction to the implant axis for Camlog only
- 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.

8 Producing the mesostructure

8.1 Scanning, designing and milling

More details can be found in the following documents:

- CEREC/CEREC Premium/inLab SW, User manual
1. Plug a TiBase onto the lab implant of the master model or a CEREC ScanPost directly onto the implant in the mouth.
Plug a scanbody onto this until it comes to rest on the shoulder of the implant without any gaps. The scanbody is scannable **without** powder or scan spray.
 2. Acquire the situation alternatively with inEos Blue, inEos X5 or CEREC AC.
 3. Use the CEREC/CEREC Premium/inLab SW software to design the individual shape of the mesostructure and mill the shape from an inCoris ZI meso block (see User Manual). The following information must be observed when designing, reworking and sintering zirconium oxide.

8.2 Design information

- Maintain a minimum wall thickness of 0.5 mm circularly around the screw channel.
- Design the outer form of the mesostructure in adherence to the preparation guidelines for the required superstructure.
- If the mesostructure is to be veneered immediately, make sure that this doesn't narrow the screw channel. The connection point to the base and the screw channel should not be coated.
- Make sure that no sharp edges or corners are produced.

8.3 Reworking the milled restoration

After finishing the milling process and prior to sintering the milled mesostructure, separate it from the remaining block and remove the pin with a diamond point tool.

Make sure you do not inhale abrasive dusts. Use a vacuum system and wear a mask.

Block remains and the block holder do not need to be disposed of separately. They can be disposed of as normal household waste.

8.4 Sintering

inCoris ZI mesostructures have to be sintered in dry conditions.

The Sirona inFire HTC, inFire HTC speed or CEREC SpeedFire sintering furnaces offer programs with a pre-drying function.

The sintering process should only be performed in a Sirona sintering furnace.

When sintering in the inFire HTC/HTC speed, use the pre-programmed inCoris ZI program.

When sintering in the CEREC SpeedFire, the CEREC software automatically selects the program. Observe the information in the operating instructions for the furnace.

As an alternative, the sintering process can be carried out in the compatible VITA Zyrcomat or Ivoclar Vivadent Sintramat high temperature furnace. Use a zirconium oxide program for this.

The classic program for sintering with inCoris ZI meso is the same as for inCoris ZI. The sintering result from furnaces other than those specified here cannot be guaranteed by Sirona.

Sintering program for other furnaces

Heating rate °C/min	Holding temperature °C	Holding time min
25	800	0
15	1510	120
30	200	0

In any case, the details in the manuals for the respective furnaces are to be adhered to.

8.5 Additional notes: procedure after sintering

In the case of yellow staining of inCoris ZI mesostructures after the sintering process, the high-temperature furnace should be cleansed by performing an empty run. The details in the manuals for the respective furnaces are to be adhered to in this case.

This is not necessary for CEREC SpeedFire due to the different heating concept.

Sintering beads that adhere are to be removed carefully.

After the sintering process, the inCoris mesostructures must be cooled down to room temperature at atmosphere before further processing.

8.6 Reworking the sintered mesostructure


The surface condition of ceramic materials is decisive for their bending strength. Reworking sintered mesostructures with milling tools must be avoided at all costs.

Therefore make corrections to the ground mesostructure if possible before sintering.

However, if reworking should be necessary, comply with the following basic rules:

- Reworking in the sintered condition should be performed with a wet grinding turbine (approx. 2.5 – 3 bar) or rubber polishers (low speed) or for primary telescopes with a grinding unit using water cooling and with low grinding pressure. As an alternative it is possible to rework with soft, diamond rubber polishers and a handpiece at low speed and low pressure. The tool must be applied flat and must not “chatter”.
- New diamond burrs with varied grain size should be used if possible.
- Areas that are under tension in clinical use should not be milled.
- We recommend subjecting the framework to thermal treatment after the milling process to reverse any phase transformation which may have occurred on the surface. Microscopic cracks cannot be regenerated.

The following firing adjustment should be selected for this purpose:

Vt. °C	 min.	 min.	 °C/min.	ca. Temp. °C	 min.	VAC min.
500	-	5.00	100	1000	15.00	-

Sand-blast the surfaces on which a superstructure is to be conventionally attached or glued, using the one-way blasting process with maximum 50 µm corundum (Al₂O₃). Pressure < 2.5 bar. Observe the operator manual of the respective restoration material as to the suitability of the fastening material.

NOTICE

Observe usage information

Etching with hydrofluoric acid does not produce a retentive surface.
 Silanization is not required

Please observe the information on use of the fastening materials of the corresponding manufacturers.

The mesostructure must be treated with the usual disinfectant before it is inserted in the patient's mouth.

8.7 Veneer

The areas of the mesostructures to be veneered that are made of inCoris ZI meso must not be sandblasted. Sandblasting could lead to an undesirable phase transformation of the zirconia. For the veneer, this would cause complex diffusions of stress along the interface which might lead to cracks or late cracks in the veneer after the restoration is inserted.

Mesostructures made of inCoris ZI meso can be veneered using all standard veneer ceramics for zirconium oxide ceramic.

In this case the processing instructions of the manufacturer must be observed without fail.

9 Recommended tools and materials

- Modeling wax
 - Scan wax (Sirona) (suitable for scans with the inLab scanner, not for exposures with inEos)
- Wet grinding turbines:
 - KaVo K-AIR plus (KaVo);
 - IMAGO (Steco-System-Technik GmbH & Co.KG);
 - NSK Presto Aqua (Girrbach);
 - Turbo-Jet (Acurata)
- Grinding tools for reworking with the wet grinding turbine/with handpiece
 - Diamond grinding element sets Ceramic-Line, Telescope-Line (Sirius Dental Innovations).
 - Diamond porcelain polisher for handpiece, green-orange (Hager & Meisinger, Art. No. HP 803 104 372 533 170).
 - Diamond polisher for handpiece (green and orange), EVE Diacera.
- Other:
 - Suitable colored contact materials
- Preparation sets:
 - Preparation set acc. to Küpper (Hager & Meisinger, Art. No. 2560);
 - Preparation set acc. to Baltzer and Kaufmann (Hager & Meisinger, Art. No. 2531);

10 Gluing the mesostructure to the titanium base

Prior to gluing, check to make sure that the mesostructure can be easily placed on the titanium base. No gap should be visible between the mesostructure and the attachment surface of the titanium base.

The anti-rotation groove has an especially narrow tolerance. If the mesostructure cannot be easily positioned, first check to see if a small amount of material has to be removed from the groove (see "Reworking the sintered mesostructure" [→ 12]).

CAUTION

Observe the manufacturer's instructions for handling the titanium base.

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

The diameter of the titanium base should not be reduced (e.g. by grinding). Shortening the titanium base is not recommended.

The surfaces of the titanium base intended for gluing to the zirconium oxide ceramics have to be sand-blasted and cleaned.

Surfaces of the zirconium oxide ceramics and the titanium base to be glued must be free of dust and grease.

1. Sand-blast the gluing surfaces of the zirconium oxide ceramics and the titanium base with 50 µm aluminum oxide and up to 2.0 bar.
2. Clean the adhesive surfaces with alcohol or steam. For easier handling during the gluing process, it is recommended that the titanium base be screwed into a lab implant or a polishing tool.
3. Cover the hex head of the abutment screw with wax.

NOTICE

Use "PANAVIA™ F 2.0" (www.kuraray-dental.de) extraoral as the adhesive for connecting the titanium base and the zirconium oxide ceramics.

4. Mix the glue according to the manufacturer's instructions and apply it to the titanium base.
5. Press on the customized zirconium oxide ceramics as far as it will go. Make sure it latches into the rotation and position stops.
6. Remove excess glue immediately.
7. Apply the Airblocker ("Oxygard") to the junction where the ceramic and titanium surfaces meet and to the screw funnel for final hardening.
8. Remove residue with a rubber polisher after hardening.

11 Information for the dentist

inCoris ZI meso blocks are delivered in a non-sterile condition.

Observe the titanium base manufacturer's operating instructions.

11.1 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)

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 titanium base (e.g. TiBase) and the mesostructure must inform the dentist of the need to sterilize the abutment before inserting it in the patient's mouth!

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

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