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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

Table of contents

1 General

CE 0123

The product inCoris ZI meso bears the CE mark in accordance with the provisions of Council Directive 93/42/EEC 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.

Rx 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 basis:

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 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 adjacent teeth.

4 Chemical composition

$ZrO_2+HfO_2+Y_2O_3$	> 99.0%
Al_2O_3	< 0.5%
Other oxides	< 0.5%

5 Technical data

The following specifications apply to material that is densely sintered in an inFire HTC sintering furnace:

Density:	6.06 g cm^{-3}
Fracture toughness KIC	5.9 MPa $m^{1/2}$
Thermal expansion coefficient (20 - 500 °C):	11,0 10^{-6} K^{-1}
Bending strength:	1200 MPa

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. 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)*

For the USA only

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7 Use of inCoris ZI meso blocks and contra-indications

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 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.

8 Producing the mesostructure

8.1 Scanning, designing and milling

More details can be found in the following documents:

- inLab 3D, User Manual
- inLab 3D for Abutments, User Manual

1. Plug a scanbody onto the lab implant of the master model until it comes to rest on the shoulder of the implant without any gaps. The scanbody is scannable **without** powder or scan spray.
2. Record the situation using inEos, inEos Blue, CEREC 3 Acquisition Unit, CEREC AC or (from a duplicate model) with the scanner (inLab/ inLab MC XL).
3. Use the inLab 3D for Abutments software 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). 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.

8.4 Sintering

inCoris ZI mesostructures have to be sintered in dry conditions.

The sintering process should be carried out exclusively in the high-temperature Sirona inFire HTC furnace. Use the "SIRONA inCoris ZI" program for this.

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.

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.

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 can not 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 (Al_2O_3). 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.

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" [➔ 11]).

⚠ 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. Immediately remove any adhesive residue.
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

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

Observe the titanium bases manufacturer's operating instructions.

11.1 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!

12 References

Materials science

Baltzer, A.; Kaufmann-Jinoian, V.: The toughness of VITA In-Ceram. Quintessenz Zahntech 29, 11, 1318-1342 (2003)

Blatz, M.; Sadan, A.; Kern, M.: Adhesive bonding of high-strength full ceramic restorations.
Quintessenz 55, 1, 33- 41 (2004)

Geis-Gerstorfer, J; Päßler, P.: Investigations of the fatigue behavior of dental ceramics – zirconium dioxide TZP and In-Ceram. Dtsch Zahnärtzl Z 54, 692- 694 (1999)

Kappert, H.F.: On the high strength of dental ceramics. Zm 93, 7, 2003

Kern, M.: Fracture quota lower than the "divorce rate" ZWL 04, 2004, Luthard, R.; Herold, V et al.: Crowns made of high-performance ceramics. Dtsch Zahnärztl Z 53, 4 280-285 (1998)

Luthard, R.; Herold, V et al.: Crowns made of high-performance ceramics. Dtsch Zahnärztl Z 53, 4 280-285 (1998)

Luthard et al.: Comparison of various techniques for the manufacture of crown frameworks from high-performance ceramics. State of the art of the CAD/CAM supported production of full ceramic crowns from oxide ceramics.
Swiss Dent, 19, 6 5 -12 (1998)

Marx, R. et al.: Crack parameters and Weibull modules: subcritical crack growth and long-term strength of full ceramic materials.
Dtsch Zahnärtzl Z 56, 2 90 - 98 (2001)

Report by DGZMK/DGZPW: Are full ceramic crowns and bridges scientifically recognized? Dtsch Zahnärtzl Z 56 10 575 - 576 (2001)

Schweiger, M.: Zirconium oxide. High-strength and break-resistant structural ceramics. Ästh. Zahnmedizin 5, 2004, 248-257

Stephan, M.: Coating behavior of veneering materials on dental ceramics. Dissertation of Geoscientific Faculty, Tübingen (1996)

Tinschert, J; Natt, G.; Spiekermann, H.: Current positioning of dental ceramics.
Dental-Praxis XVIII, 9/10 293 - 309 (2001)

Vollmann, M.: Innovative DeguDent full ceramic system as a benchmark for the processing of zirconium oxide. IJCD 2004, 7, 279-291

Stephan, M.; Corten, A.: Aluminum oxide – corundum, mineralogical analyses of corundum.
Quintessenz Zahntech 31, 2, 128-133 (2005)

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CEREC®/ inLab®

Baltzer, A.; Kaufmann-Jinoian, V.: CAD/CAM in dentistry CEREC inLab. Dental-Labor, XLIX, Volume 5 (2001)

David, A.: CEREC inLab - The CAD/CAM System with a Difference. CJDT Spectrum, September/October, 24 - 28 (2002)

Kurbad, A.; Reichel, K.: CEREC inLab - State of the Art. Quintessenz Zahntech 27, 9, 1056 -1074 (2001)

Kurbad, A.: Manufacturing In-Ceram bridge frameworks with the new CEREC technology.
Quintessenz Zahntech 27, 5, 504 - 514 (2001)

Tsotsos, St.; Giordano, R.: CEREC inLab: Clinical Aspects, Machine and Materials. CJDT Spectrum January/February, 64 - 68 (2003)
Preparation illustrations on p. 5 accd. to Dr. Andres Baltzer, CH-Rheinfelden

Kern, M.: Computer-aided crown and bridge technology with new perspectives. Quint. Zahnt. 30, 9, 966-973 (2004)

Rudolph, H., Quaas, S., Luthard, R.G.: CAD/CAM – New technologies and developments in dentistry. DZZ 58 (2003)10

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

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