



For IMPLANT, For CEREC

ENGLISH INSTRUCTIONS FOR USE

I. Introduction

KATANA Zirconia ONE is a pre-sintered zirconia block, which is designed for CEREC milling systems. KATANA Zirconia ONE consists of 4 graduated shade layers. KATANA Zirconia ONE has 3 sizes: (CROWN, BRIDGE and For IMPLANT). This IFU is for For IMPLANT. For IMPLANT blocks are available in two different sizes for connecting to the titanium base (S and L). For IMPLANT blocks have 10 shade variations: (A1, A2, A3, A3.5, B1, B2, C1, C2, D2, NW). KATANA Zirconia ONE For IMPLANT is indicated for use in manufacturing individually designed restorations (mesostructures), which are glued to a fitted titanium base (TiBase (Sirona Dental Systems GmbH)) after milling/grinding and sintering.

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

II. Intended use and indications

KATANA Zirconia ONE For IMPLANT is intended for use in partially or fully edentulous mandibles and maxillae in support of single cement-retained restorations.

For the 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.

KATANA Zirconia ONE For IMPLANT is used in combination with the TiBase and Sirona Dental CAD/CAM System. KATANA Zirconia ONE For IMPLANT cemented to the TiBase is recommended for two-piece hybrid abutments for single tooth restorations and hybrid abutment crowns, used in conjunction with endosseous dental implants.

Compatible implant systems and TiBase are as follows.

Implant system (Manufacturer)	Platform	Sirona TiBase	
		Name	Size
Replace, Replace Select (Nobel Biocare)	NP	TiBase NB RS 3.5 L	L
	RP	TiBase NB RS 4.3 L	
	WP	TiBase NB RS 5.0 L	
	6.0	TiBase NB RS 6.0 L	
NobelActive NobelReplace Conical Connection (Nobel Biocare)	NP	TiBase NB A 4.5 L	L
	RP	TiBase NB A 5.0 L	
Bone Level (Straumann)	NC (3.3 mm)	TiBase SBL 3.3 L	L
	RC (4.1 mm / 4.8 mm)	TiBase SBL 4.1 L	
Certain (Biomet 3i)	3.4	TiBase B C 3.4 S	S
	4.1	TiBase B C 4.1 L	
	5.0	TiBase B C 5.0 L	
Tapered Screw-Vent (Zimmer)	3.5	TiBase Z TSV 3.5 L	L
	4.5	TiBase Z TSV 4.5 L	
	5.7	TiBase Z TSV 5.7 L	

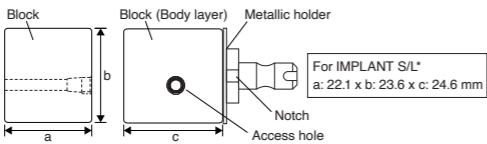
III. Sintering Program

If "CEREC SpeedFire" is used as the sintering furnace. Follow the Operating Instructions of "CEREC SpeedFire" when sintering the block. If a sintering furnace other than "CEREC SpeedFire" is used, review the sintering schedules shown below:

Temperature	Programming Rate	Holding Time
Room Temp. – 500°C (932°F)	336°C/min. (605°F/min.)	–
500°C (932°F) – 1225°C (2237°F)	324°C/min. (583°F/min.)	–
1225°C (2237°F) – 1315°C (2399°F)	60°C/min. (108°F/min.)	–
1315°C (2399°F) – 1475°C (2687°F)	42°C/min. (76°F/min.)	–
1475°C (2687°F) – 1515°C (2759°F)	54°C/min. (97°F/min.)	–
1515°C (2759°F) – 1560°C (2840°F)	90°C/min. (162°F/min.)	–
1560°C (2840°F)	–	20 min.
1560°C (2840°F) – 1450°C (2642°F)	-90°C/min. (-162°F/min.)	–
1450°C (2642°F) – 1350°C (2462°F)	-120°C/min. (-216°F/min.)	–
1350°C (2462°F) – 1250°C (2282°F)	-240°C/min. (-432°F/min.)	–
1250°C (2282°F) – 1150°C (2102°F)	-600°C/min. (-1080°F/min.)	–
1150°C (2102°F) – 980°C (1796°F)	-1,020°C/min. (-1836°F/min.)	–
980°C (1796°F) – 925°C (1697°F)	-330°C/min. (-594°F/min.)	–
925°C (1697°F) – 900°C (1652°F)	-150°C/min. (-270°F/min.)	–

- (14) Seal the screw channel
 - Seal the screw channel with a filling composite using a dental adhesive compatible with zirconium oxide, as used to produce a standard occlusal dental filling. Follow the relevant processing instructions from the manufacturer (setting times for adhesive and filling composite and layer thicknesses with the filling composite).

IV. Image of product



This product has color gradation which varies from the enamel layer to the body layer, utilizing an additional two gradation layers between, for total of 4 layers in the a-axis direction.

* The difference between For IMPLANT S and For IMPLANT L is the diameter of the access hole.

V. Composition

ZrO₂, Y₂O₃ etc.

VI. Physical Properties

Coefficient of Thermal Expansion: 9.8x10⁻⁶/K

VII. Type and Class (ISO 6872: 2015)

Type: II/ Class: 4

VIII. Directions for Use

- (1) Remove the block from the packaging and confirm that the block does not have a crack or other damage.
- (2) Place the block into the milling machine; then begin the milling process following the milling systems technical instructions.
- (3) After milling, remove the restoration from the block and carefully smooth the surface where the restoration was connected to the mandrel with a diamond bur, etc.
- (4) As desired, the pre-sintered restoration can be polished with a fine diamond smoothing instrument, preferably silicone-free polishers.
- (5) The cutting waste or dust, which is attached to the restoration, can be removed with a gentle air stream or a soft brush.
- (6) Put the restoration into the refractory sagger tray and place them in the sintering furnace.
- (7) All of the above processes are recommended to work under dry conditions. In cases where the process is performed under wet conditions and using a sintering furnace other than CEREC SpeedFire, dry the block at 200°C (392°F), 10 minutes in the sintering furnace.
- (8) Before sintering, make sure there are no cutting waste or dust in the access holes. If there is cutting waste or dust inside the access hole, remove it with a gentle air stream or a soft brush.
- (9) Depending on the performance of the sintering furnace used, review the sintering schedule shown above (III. Sintering Program) before sintering the restoration.
- (10) After sintering, adjust the restoration with a diamond bur, as needed.

(11) Confirm that the restoration has no cracks.

(12) Finishing:

- a) Glaze baking: Create a high shine surface by polishing, especially on the contact areas, then apply the glaze on all surfaces in the usual manner. If necessary, before glaze baking, it can be stained or built up with dental porcelain (CERABIEN MiLai, CERABIEN ZR or CZR PRESS LF etc.) following the manufacturer's technical instructions.
- b) Hand polishing: Create a high shine surface on the entire restoration by polishing without using the glaze.

(13) Cement the restoration onto the TiBase.

Prior to cementing, check to make sure that the restoration can be easily placed on the TiBase. No gap should be visible between the restoration and the attachment surface of the TiBase.

Surfaces of the restoration and the TiBase to be cemented must be free of dust and grease.

- Sandblast the internal surfaces of the restoration with 50 µm aluminum oxide and up to 2.0 bar (29 psi). (The screw channel of the restoration is also an adhesive surface and must be treated accordingly with the sandblasting technique).
- If the manufacturer recommends that the bonding surface of the TiBase be blasted, the emergence profile and the screw channel should be protected. The bonding surface can be carefully blasted according to the instructions of the manufacturer.
- Clean the adhesive surfaces in an ultrasonic bath or with alcohol or steam followed by drying it with an air stream.
- The screw channel should be sealed with a foam pellet or wax. The bonding surface must not be contaminated in the process.
- Use resin cement for adhesive cementation of the zirconia restoration and the TiBase according to the instructions of the resin cement (PANAVIA SA Cement Universal).
- When using PANAVIA SA Cement Universal (MDP incorporated into the paste itself), it is not necessary to apply a primer onto the TiBase and the zirconia restoration.
- Apply the resin cement to the TiBase, and seat the zirconia restoration as far as it will go. Make sure it latches into the rotation and position stops.
- Remove excess cement immediately.
- Remove residue with a rubber polisher after hardening.
- When the restoration is to be used as a hybrid abutment, after the tightening with abutment screw and sealing the screw channel intraorally, cement a crown with a cement that claims to be usable for zirconia. It is recommended to use resin cement to bond the restoration.

(14) Seal the screw channel

- Seal the screw channel with a filling composite using a dental adhesive compatible with zirconium oxide, as used to produce a standard occlusal dental filling. Follow the relevant processing instructions from the manufacturer (setting times for adhesive and filling composite and layer thicknesses with the filling composite).

- Once the composite has hardened polish the surface following the composite manufacturer's instructions.

Information for the dentist

The TiBase is delivered in a non-sterile condition.

Observe the implant manufacturer's operating instructions.

Sterilization

After being assembled, this device is sterilized and then placed in the patient's oral cavity.

When sterilizing it, follow the instructions given below:

- 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 the abutment device immediately after sterilization, without storing it.
- Use only the validated sterilization procedures specified below to sterilize individual abutments. Observe the sterilization parameters.
- Use a steam sterilizer to sterilize the unwrapped individual abutment and screw with a pre-vacuum cycle (135°C / 275°F for 3 minutes).
- 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 restoration must inform the dentist of the need to sterilize the abutment before inserting it in the patient's mouth.

Application in the mouth

Use the unused abutment screw and the tools provided by the implant manufacturer to screw the TiBase onto the implant, observing the tightening torques specified.

IX. Remarks on Handling

Contraindication:

If the patient is hypersensitive to zirconia or any other components, this product must not be used.

For restorations with angulation correction of more than 20 degrees to the implant axis.

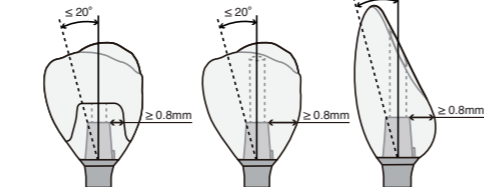
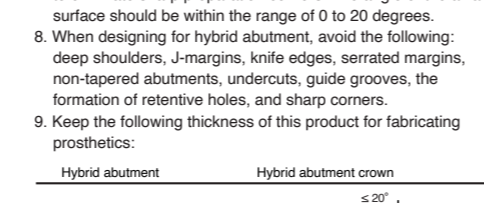
For restorations whose length exceeds a ratio of 1:1.25 in comparison to the length of the implant.

Warning:

• If the patient or the dental professional demonstrates a hypersensitivity reaction, such as rash, dermatitis etc., discontinue use of the product and seek medical attention immediately.

Caution:

1. This product should not be used when malocclusion, clenching or bruxism conditions are present.
2. When milling the block or cutting, grinding and polishing the restoration, use an approved dust mask and vacuum with an air filter to protect your lungs from inhaling dust.
3. When milling the block or cutting, grinding and polishing the restoration, use safety glasses to prevent the dust from getting into your eyes. If the dust gets into your eyes, immediately rinse with copious amounts of water and consult a physician.
4. Do not use for any purposes except for dental restorations. This product is only for dental application.
5. Do not touch the items heated in the furnace with your bare hands.
6. This product is particularly translucent; therefore, one should carefully consider its appropriateness for use when masking the underlying surface, such as a metal abutment, or a very dark or discolored tooth preparation.
7. The margins should be prepared with a deep chamfer and rounded shoulders, with cutting edges and corners rounded to eliminate sharp preparation corners. The angle of the axial surface should be within the range of 0 to 20 degrees.
8. When designing for hybrid abutment, avoid the following: deep shoulders, J-margins, knife edges, serrated margins, non-tapered abutments, undercut, guide grooves, the formation of retentive holes, and sharp corners.
9. Keep the following thickness of this product for fabricating prosthetics:



OR
The minimum wall thickness of the restoration must be 0.8 mm.

The parameters of this product for fabricating prosthetics are as following:

Item	Parameter
Abutment post height*1	4.0 mm - 16.7mm
Angulation	0°- 20°
Wall thickness	0.8 mm - 9.5 mm
Diameter	3.3 mm - 6.0 mm ²
Gingival height	1.0 mm ²

*1 The abutment post height is considered by FDA to be the "stump" portion above the gingival collar where the restorations are attached.

*2 Parameters of diameter and gingival height are depended on a selected TiBase.

10. Choose a shade color that is brighter than the intended color for a thick restoration, as it may look duller depending on the thickness of the restoration.
11. When sintering this product in CEREC SpeedFire for the first time, confirm with the supplier of CEREC SpeedFire that it is compatible with this product.
12. Check the coefficient of thermal expansion of the porcelain glaze in the manufacturer's technical instructions to confirm compatibility.
13. Do not take the restoration out of the sintering furnace during high temperature, as the quenching causes the breaking.
14. If CEREC SpeedFire is used as a sintering furnace, remove the restoration from CEREC SpeedFire according to the guidance of the sintering program.
15. When using a sintering furnace for the first time and changing a sintering condition, colors after sintering may vary. Sinter a small piece of Zirconia beforehand and confirm the color.
16. Small diameter implants and angled abutments are not recommended for the posterior region.
17. Do not use any cement, materials, or any components of the CAD/CAM System that are not specifically identified as compatible to this device.

Caution in conjunction with usage:

1. The notch side of metallic holder is the body layer; the opposite side is the enamel layer. Depending on the setting of the scanner or milling machine, the enamel layer and the body layer may be machined in the opposite direction. Confirm that the block is compatible before processing.
2. Dry milling is recommended. If wet milling/grinding is performed by using cooling water contaminated by silica-based glass ceramics (lithium disilicate glass, etc.), the translucency of the zirconia may be reduced after baking. Before wet milling/grinding, clean the milling/grinding chamber, cooling water tank and filter insert. The cooling water must be changed in order to assure optimum results.
3. Do not use the block if there is a crack noticed after removing it from the package.
4. If you find a crack in the restoration, do not use.
5. Dispose of this product as medical waste to prevent infection.

MRI Safety Information:

This device made of ceramic is considered to be MR safe. However, if the restoration consists of multiple parts, it must be classified according to the part with the lowest safety level. For more information, please refer to the <http://kuraraydental.com/product-category/chairside-products/chair-side-cad-cam/>.

Storage:

1. Store in a cool and dry place. Keep away from direct sunlight.
2. The product should be stored at 10–30°C (50–86°F).
3. Do not remove the block from its packaging during storage.
4. The block is fragile and requires care when handling.
5. The product must be stored in an appropriate place where only dental personnel have access.
6. The product must be used by the expiration date indicated on the package.

[WARRANTY]

Kuraray Noritake Dental Inc. will replace any product that is proven to be defective. Kuraray Noritake Dental Inc. does not accept liability for any loss or damage, direct, consequential or special, arising out of the application or use of or the inability to use these products. Before using, the user shall determine the suitability of the products for the intended use and the user assumes all risk and liability whatsoever in connection therewith.

[NOTE]

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FRANÇAIS MODE D'EMPLOI

I. Introduction

KATANA Zirconia ONE est un bloc préfritté de zircone, conçu pour les systèmes de fraiseage CEREC. KATANA Zirconia ONE est composé d'un dégradé de 4 couches de nuances. KATANA Zirconia ONE possède 3 tailles: (CROWN, BRIDGE et For IMPLANT). Ce document est pour les blocs For IMPLANT. Les blocs For IMPLANT sont disponibles en deux tailles différentes pour être assemblé à la base en titane (S et L). Les blocs For IMPLANT possèdent 10 variations de teinte: (A1, A2, A3, A3.5, B1, B2, C1, C2, D2, NW).

KATANA Zirconia ONE For IMPLANT est indiqué pour la fabrication de restaurations conçues individuellement (mésosstructures), qui sont collées sur une base en titane adaptée (TiBase (Sirona Dental Systems GmbH)) après fraiseage/meulage et sintérisation.

Veillez également respecter les instructions fournies par le fabricant de TiBase ou de l'implant.

II. Utilisations prévues et indications

KATANA Zirconia ONE For IMPLANT est destiné aux mandibules et aux maxillaires partiellement ou totalement édentés pour la réalisation de restaurations unitaires scellées.

Pour les bases en titane SBL 3,3 L, l'indication est limitée au remplacement des incisives latérales unitaires du maxillaire et des incisives latérales et centrales de la mandibule.

KATANA Zirconia ONE For IMPLANT est utilisé en combinaison avec le TiBase et le système CAD/CAM de Sirona Dental. KATANA Zirconia ONE For IMPLANT collé a TiBase est recommandé pour les piliers hybrides en deux parties pour les restaurations de dents unitaires et les couronnes à piliers hybrides, utilisés en conjonction avec des implants dentaires endo-osseux.

Les systèmes d'implant compatibles avec TiBase sont les suivants.

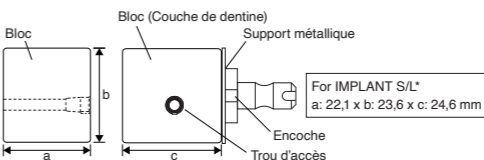
Système d'implant (fabricant)	Plate-forme	Sirona TiBase	
		Nom	Taille
Replace, Replace Select (Nobel Biocare)	NP	TiBase NB RS 3.5 L	L
	RP	TiBase NB RS 4.3 L	
	WP	TiBase NB RS 5.0 L	
	6.0	TiBase NB RS 6.0 L	
NobelActive NobelReplace Conical Connection (Nobel Biocare)	NP	TiBase NB A 4.5 L	L
	RP	TiBase NB A 5.0 L	
Bone Level (Straumann)	NC (3,3 mm)	TiBase SBL 3.3 L	L
	RC (4,1 mm / 4,8 mm)	TiBase SBL 4.1 L	
Certain (Biomet 3i)	3.4	TiBase B C 3.4 S	S
	4.1	TiBase B C 4.1 L	
	5.0	TiBase B C 5.0 L	
Tapered Screw-Vent (Zimmer)	3.5	TiBase Z TSV 3.5 L	L
	4.5	TiBase Z TSV 4.5 L	
	5.7	TiBase Z TSV 5.7 L	

III. Programme de sintérisation

Lorsque «CEREC SpeedFire» est utilisé comme four de sintérisation, suivez les instructions de fonctionnement de «CEREC SpeedFire» lors de la sintérisation du bloc. Si un four de sintérisation autre que le «CEREC SpeedFire» est utilisé, choisir le programme de sintérisation indiqué ci-dessous:

Température	Taux de programmation	Temps de maintien
Temp. pièce – 500°C (932°F)	336°C/min. (605°F/min.)	–
500°C (932°F) – 1225°C (2237°F)	324°C/min. (583°F/min.)	–
1225°C (2237°F) – 1315°C (2399°F)	60°C/min. (108°F/min.)	–
1315°C (2399°F) – 1475°C (2687°F)	42°C/min. (76°F/min.)	–
1475°C (2687°F) – 1515°C (2759°F)	54°C/min. (97°F/min.)	–
1515°C (2759°F) – 1560°C (2840°F)	90°C/min. (162°F/min.)	–
1560°C (2840°F)	–	20 min.
1560°C (2840°F) – 1450°C (2642°F)	-90°C/min. (-162°F/min.)	–
1450°C (2642°F) – 1350°C (2462°F)	-120°C/min. (-216°F/min.)	–
1350°C (2462°F) – 1250°C (2282°F)	-240°C/min. (-432°F/min.)	–
1250°C (2282°F) – 1150°C (2102°F)	-600°C/min. (-1080°F/min.)	–
1150°C (2102°F) – 980°C (1796°F)	-1,020°C/min. (-1836°F/min.)	–
980°C (1796°F) – 925°C (1697°F)	-330°C/min. (-594°F/min.)	–
925°C (1697°F) – 900°C (1652°F)	-150°C/min. (-270°F/min.)	–

IV. Image du produit



Ce produit est doté d'une gradation des couleurs qui varie de la couche d'émail à la couche collet (dentine) en utilisant deux couches de gradation supplémentaires, intermédiaires pour un total de 4 couches dans le sens de l'axe a.

* La différence entre For IMPLANT S et For IMPLANT L est le diamètre du trou d'accès.

V. Composition

ZrO₂, Y₂O₃ etc.

VI. Propriétés physiques

Coefficient de dilatation thermique: 9,8x10⁻⁶/K

VII. Type et Classe (ISO 6872: 2015)

Type: II/ Classe: 4

VIII. Instructions

- (1) Retirez le bloc de l'emballage et assurez-vous que le bloc ne présente pas de fissure ou tout autre dommage.
- (2) Placez le bloc dans la machine d'usinage ; puis débutez le processus de fraiseage en suivant les instructions techniques du système de fraiseage.
- (3) Après le fraiseage, retirez les restaurations du bloc et lissez soigneusement la surface où la restauration était reliée au mandrin avec une fraise diamantée, etc.
- (4) Si vous le souhaitez, vous pouvez polir la restauration pré-frittée à l'aide d'un instrument de lissage à diamant fin, de préférence des polissoirs sans silicone.
- (5) Les déchets ou la poussière de coupe attachés à la restauration, peuvent être enlevés avec un léger soufflé d'air ou une brosse douce.
- (6) Placez les restaurations dans le plateau de sintérisation réfractaire puis dans le four de frittage.
- (7) Tous les processus ci-dessus sont recommandés afin de travailler à sec. Dans le cas où le processus est exécuté dans des conditions humides et qu'un four de sintérisation autre que le CEREC SpeedFire, faites sécher le bloc à 200°C (392°F) pendant 10 minutes dans le four de sintérisation.
- (8) Avant la sintérisation, assurez-vous qu'il n'y a pas de déchets de coupe ou de poussière dans les trous d'accès. Si l'y a des déchets de coupe ou de la poussière dans le trou d'accès, éliminez-les avec un léger soufflé d'air ou une brosse douce.
- (9) En fonction du rendement du four de sintérisation utilisé, revoir le programme de sintérisation indiqué ci-dessus (III. Programme de sintérisation) avant la sintérisation des restaurations.
- (10) Après la sintérisation, ajustez si nécessaire les restaurations avec une fraise diamantée.
- (11) Assurez-vous que la restauration ne présente pas de fissures.
- (12) Finitions :

- a) Glaçage : Créez une surface de haute brillance par polissage, en particulier sur les zones de contact puis appliquez le glaçage sur toutes les surfaces de la manière habituelle. Si nécessaire, avant la cuisson de l'émail, elle peut être colorée ou reconstituée avec de la porcelaine dentaire (CERABIEN MiLai, CERABIEN ZR ou CZR PRESS LF, etc.) en suivant les instructions techniques du fabricant.
- b) Polissage manuel : Créez une surface de haute brillance sur l'ensemble de la restauration par polissage sans utiliser le glaç

