

KDF Zirconia Disc

DENKEN-HIGHDENTAL Co., Ltd.
24-3 Kisshoin Ishiharakyomichi-cho,
Minami-ku, Kyoto, 601-8356, Japan
+81-75-672-2124

Instructions for Use

READ CAREFULLY BEFORE USE

Device Descriptions

Intended use

The purpose of "KDF Zirconia Disc" is to fabricate dental ceramic prosthetics such as inlays, anlays, veneers, artificial teeth, crowns, and bridges.

The prosthetics are designed by a dental technician or dental specialist, and machined into prosthetic shapes by a CAD/CAM machines.

This device is applied to the anterior or molar region.

Operating principle

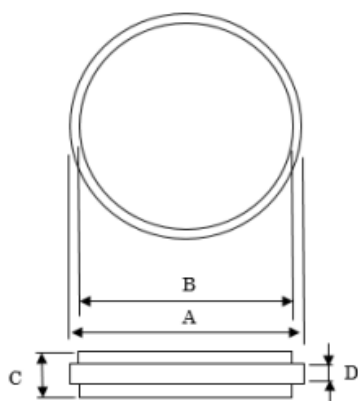
"KDF Zirconia Disc" are manufactured by mixing raw materials, pressing them into disc shapes, and then semi-sintering them in a sintering furnace.

The devices are milled prosthetic shapes using CAD/CAM machines and then fully sintered (secondary sintering), and the zirconia acquires its final physical properties by forming a crystalline structure.

The fabricated prosthesis is chemically bonded to the defect, abutment tooth or conducted core on the remaining tooth using resin cement.

Shapes and Shades

The appearance and dimensions of "KDF Zirconia Disc" are shown below.



Size (mm)			
Diameter (A)	Diameter (B)	Thickness (C)	Thickness (D)
φ 98.5	φ 98.5	10	10
φ 98.5	φ 94	14	10
φ 98.5	φ 94	16	10
φ 98.5	φ 94	18	10
φ 98.5	φ 94	20	10
φ 98.5	φ 94	22	10
φ 98.5	φ 94	25	10
φ 98.5	φ 94	30	10
φ 98.5	φ 94	35	10

"KDF Zirconia Disc" are provided in 18 different shades and are classified into the following three series.

Table-01

Series	Shades
Monochronic	Pure
MT series	MT-BL1, MT-BL2, MT-BL3 MT-A1, MT-A2, MT-A3, MT-A3.5, MT-A4,
MU series	MU-Pure, MU-BL1, MU-BL2, MU-BL3, MU-A1, MU-A2, MU-A3, MU-A3.5, MU-A4

While the monochromatic shade (Pure) has constant shade throughout the disc, MT series is designed to be progressively darker toward the cervical layer in order to reproduce the shade change from the enamel to the cervical.

MT-BL reproduces the white tone of teeth as if teeth whitened. MU series has a gradation not only in color but also in translucency to achieve a more natural tooth-like appearance and excellent esthetics.

Safety notes

Please read the Instructions for Use carefully before removing the product from its package. It contains important information to ensure patient and user safety and correct processing methods.

"KDF Zirconia Disc" are manufactured and tested according to "Dental Medical Device" quality standards. In order to guarantee this quality, please follow the instructions in the instruction manual.

General handling notes

"KDF Zirconia Disc" is white, semi-sintered products. Therefore, handle them with care and store them in their original packaging. Do not subject to shock or vibration.

Use extreme care to avoid staining the surface of this disk. Handle the prosthesis only with clean, dry hands or wearing gloves. Do not stain with liquids (e.g. glue or marker pens) under any circumstances. Coolants will reduce the translucency of the material.

Storage

Avoid high temperature, high humidity, and direct sunlight. Keep this product out of the reach of infants and keep it under proper control where it cannot be handled by anyone other than dental professionals.

Indication

“KDF Zirconia disc” is indicated for the production of dental ceramic restorations, specifically inlays, onlays, veneers, artificial teeth, crowns and bridges, which are manufactured by CAD / CAM processing. The application includes both anterior teeth and posterior teeth areas. All blocks are processed by a dental laboratory or dental technician.

Contraindications

Other materials should be considered if there are contraindications to the use of all-ceramic, such as insufficient occlusal clearance and/or height of the abutment axial surfaces.

- Do not use this product for patients with a history of hypersensitivity such as rash or dermatitis.
- Do not use it for patients with bruxism (occlusal neuropathy). (Because there is a risk of excessive contact with the opposing teeth and wear of the opposing teeth)

Warning

Dentists should consider known cross-reactions or interactions between this medical device and other medical products or materials already present in the oral environment when selecting this product.

Type/Class of dental ceramic

- Pure : Type II/Class 5 (ISO 6872:2015)
- MT : Type II/Class 5 (ISO 6872:2015)
- MU : Type II/Class 4 (ISO 6872:2015)

Physical properties

- Pure , MT
Coefficient of thermal expansion (25-500°C) : $10.7 \times 10^{-6}K^{-1}$
Flexural Strength : 1000 ± 150 MPa
- MU
Coefficient of thermal expansion (25-500°C) : $10.7 \times 10^{-6}K^{-1}$
Flexural Strength : 700 ± 150 MPa

Precautions

Dust generated during processing of the material may cause irritation of the eyes, skin, or respiratory tract. Keep product dust away from eyes and avoid contact with mucous membranes. Wash hands after use. Avoid eating, drinking, and inhalation of dust when using the product. Use local suction and appropriate mouth/face (eyes) protection during grinding. For more information, please refer to SDS.

Adverse Effects

“KDF Zirconia Discs” If processed and used properly, there is little chance that this medical product will cause adverse effects. In the unlikely event of an allergic reaction or localized paresthesia (irritating taste or irritation of the oral mucosa) when using zirconia, consult your dentist or physician immediately. Please note that we are not aware of all associated risks and adverse effects.

Cautions for use

- Do not process this product on equipment other than CAD/CAM machine intended for installation in dental laboratories.
- Be sure to check the shrinkage factor indicated on each disc.
- Please note that if the extension pontic or bridge pontic is more than one(2-tooth connected points,etc),it may cause breakage.
- Do not use “multi-graduation” for bridges that contain more than two connected pontics.
- Margin formation should be a deep (heavy) chamfer or round shoulder. Round the corners and edges of the incisal edge to eliminate sharp edges. In addition, the axial plane angle should be 5° to 15° .
- Do not prepare hollows or crevices in molars or bridge connections in the form of very sharp wedges.
- Use dry milling.
- When stacking porcelain on a frame, stack and shape the pieces individually.
- Do not use regular cement to bond the prosthesis.
- Do not spray alumina particles, glass beads, or other materials on workpieces that have not undergone final sintering.

Operation Instructions

Cutting process

- “KDF Zirconia disc” is to be placed in direction of the arrowhead. The arrow point (↑) is on the occlusal side.
- Fix the discs according to the instruction manual of the CAD/CAM system. Enter the information for each disc, such as the shrinkage factor. Start the system to cut and machine the discs.
- Refer to the instructions for use of the cutting machine and adhere to the parameters of the CAD / CAM software. Carefully separate the finished prosthesis from the discs using the appropriate tools. Then, in thin edge areas, set the thickness thicker in the machining process beforehand (to avoid cracking), and adjust the thickness later.

Visual inspection

Before final sintering the disc, it is necessary to inspect the appearance for the following defects. -surface gloss (indicating milling machine wear) -discoloration -material delamination (due to cutting process) -cracks -defective restorations should not be processed further.

Final Sintering

- Firing should be performed using a dental firing furnace and referring to the program below.
- Depending on the size of the case, it is recommended that you slowly heat restorations to the required temperatures and cool them down slowly.

Sintering schedule(Normal)

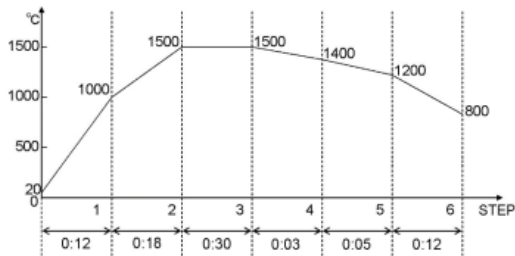
	Normal
Heating Rate	3°C/min-8°C/min
Firing Temp.	1500°C
Hold Time	120minutes.

Cooling Rate	Naturally cooling in furnace or 3°C/min-8°C/min
--------------	--

Sintering schedule(High Speed)

High Speed (Sintering furnace: Zircom Speed)	
Heating Rate	20°C-1000°C : For 12min. About 82°C/min 1000°C-1500°C : For 18min. About 28°C/min.
Firing Temp.	1500°C
Hold Time	30minutes.
Cooling Rate	1500°C-1400°C : For 3 min. About 33°C/min. 1400°C-1200°C : For 5min. About 40°C/min. 1200°C-800°C : For 12min. About 33°C/min.

The program at the "Zircom Speed" is shown below.



Glossary

Rx Only	Prescription Use Only.
LOT	LOT No.
Enamel↑	Direction of a disc
DOM	Date of manufacture
SF	Shrinkage factor
	Consult instructions for use.

Further processing of the finally sintered restorations

If possible, do not grind the fired product by hand. However, As a general rule, these should not be polished as this can cause prosthetic damage.

Grinding

To protect the opposing teeth (occlusal wear) and for material engineering reasons, polished occlusal contact points and surfaces should be high gloss polished and/or glaze fired after trial fitting. Do not apply excessive force when grinding (do not apply excessive loads when grinding the prosthesis after sintering).

Cementation

The inner surface of the restoration should be sandblasted to obtain mechanical retention. You blasted inner surface must be cleaned with alcohol before applying the cement to the interior. Self-adhesive and adhesive cements should be used.

use-by date

12 years from date of manufacture