MINDFAB

INSTRUCTIONS FOR USE

FAB Zirconia OP Dental zirconium dioxide (3Y-TZP)
FAB Zirconia HT Dental zirconium dioxide (3Y-TZP)
FAB Zirconia ST Dental zirconium dioxide (4Y-TZP)
FAB Zirconia ML Dental zirconium dioxide (4Y-TZP)

This medical device must only be sold for processing by trained specialists, milling laboratories or milling centres that are authorised to process dental prostheses.

INSTRUCTIONS FOR USE

Please read these instructions for use carefully and in full before using the device, and always observe the information contained within. Improper use of the device or failure to observe the information provided may impair the quality of the dental prosthesis and reduce its lifetime.
The device must always be used in compliance with these instructions for use, and must only be used for the specific purpose for which it was developed. MINDFAB GmbH / pritidenta® GmbH accepts no liability for consequential damages or damage to health that arise from the use or incorrect use of this device. By using the MINDFAB GmbH / pritidenta® GmbH device, you are assuming responsibility as its owner and user. You hereby agree to hold MINDFAB GmbH / pritidenta® GmbH harmless for any damage to health or any treatment measures connected to the use of a MINDFAB GmbH / pritidenta® GmbH device. Please store these instructions for use in a secure location for the entire lifetime of the device so that they can be accessed for informational purposes. You should also inform yourself of the current version on a regular basis by checking the website www.cadtools.eu/ifu. Pass the obtained information on to any future owners, downstream processors or users of this device or any articles that are produced based on this device.

Please note the various risks associated with the use of the device:

⚠ **Warning** indicates a hazard situation that can lead to serious damage to health if not avoided.

⚠ **Caution** indicates a hazard situation that could lead to minor or moderate damage to health or damage to property if not avoided.

DEVICE CHARACTERISTICS

FAB Zirconia OP
Disc, diameter: 98,5 mm, available with ledge
Shades: OP 0, OP 1, OP 2, OP 3, OP 4
Heights: 14, 16, 18, 20, 25 mm

FAB Zirconia HT
Disc, diameter: 98,5 mm, available with ledge
Shades: white
Heights: 14, 16, 18, 20, 25 mm

FAB Zirconia ST
Disc, diameter: 98,5 mm, available with ledge
Shades: white, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4
Heights: 14, 16, 18, 20, 25 mm

FAB Zirconia ML
Disc, diameter: 98,5 mm, available with ledge
Shades: white, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4
Heights: 14, 16, 18, 20, 25 mm

Classification in accordance with DIN EN ISO 6872:2019
Dental ceramic, type II, Class 5

INTENDED PURPOSE

FAB Zirconia OP, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** are pre-sintered milling blanks made of zirconium dioxide for use in CNC milling machines for the manufacture of crowns, bridges, inlays, onlays, veneers and zirconium dioxide assemblies for two-piece abutments or hybrid abutments for dental prostheses.

PATIENT TARGET GROUP

Patients with damaged, unaesthetic, dysfunctional tooth areas or missing teeth;
Crowns, bridges, inlays, onlays, veneers and zirconium dioxide assemblies for two-piece abutments or hybrid abutments for dental prostheses made from **FAB Zirconia OP**, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** can be used, in principle, on all patients receiving dental treatment, with no restrictions regarding sex or age.

GENERAL INFORMATIONS

Check the delivery immediately after receipt in order to verify:
- Completeness
- Intactness of the packaging and the device

⚠ **Warning**
The device must not be used if it has any tears, cracks, breakages or colour irregularities. If damage is detected, the blank must no longer be used for the manufacture of a dental prosthesis. The processing of a cracked, broken, damaged or discoloured device can lead to a flawed restoration with a risk of injury to the patient.

If you notice a fault with the device, please contact your dealer or the manufacturer. If particular problems occur that are not dealt with in sufficient detail in these instructions for use, please inform the manufacturer.

STORAGE CONDITIONS

FAB Zirconia OP, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** blanks should be stored in their original packaging. Make sure that:

- The blanks are stored in a dry location.
- The storage temperature is between 5 °C and 50 °C.
- They are not exposed to heavy vibrations.

⚠ **Caution**

Do not store in a humid environment. Humidity may damage the device. Do not store the device near any sources of contamination, as these could contaminate the device.

MATERIAL CHARACTERISTICS

The following specifications apply for **FAB Zirconia OP**, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** blanks once hard-sintering has been performed:

Material properties: FAB Zirconia OP, FAB Zirconia HT

Flexural strength:	≥ 1.150 MPa
CTE:	$(10,5 \pm 0,5) \cdot 10^{-6} \cdot K^{-1}$

Material properties: FAB Zirconia ST, FAB Zirconia ML

Flexural strength:	≥ 1.050 MPa
CTE:	$(10,5 \pm 0,5) \cdot 10^{-6} \cdot K^{-1}$

Chemical composition: FAB Zirconia OP, FAB Zirconia HT

Zirconium dioxide (ZrO_2 / HfO_2):	94,1 - 94,65 %
Yttrium oxide (Y_2O_3):	4,65 - 5,95 %
Aluminium oxide (Al_2O_3):	< 0,4 %
Other oxides:	< 0,7 %

Chemical composition: FAB Zirconia ST, FAB Zirconia ML

Zirconium dioxide (ZrO_2 / HfO_2):	92,1 - 92,65 %
Yttrium oxide (Y_2O_3):	6,65 - 7,95 %
Aluminium oxide (Al_2O_3):	< 0,4 %
Other oxides:	< 0,7 %

The share of individual components that make up the total component quantity may vary within the ranges specified above; the total component quantity does not however exceed 100 % in each individual blank.

PROCESSING

Because **FAB Zirconia OP**, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** are produced from a sensitive, high-performance material, it is recommended that it be handled with care. Avoid handling with wet hands. These devices must only be used by trained technicians. The safety instructions in these instructions for use must be observed. The users bear full responsibility for the use of the devices. The manufacturer has no influence on the processing of the device, and therefore accepts no liability for flawed results.

DESIGN

The following parameters must be taken into account when designing the systems:

		Crowns	Maryland bridges	Bridges
Minimum framework thickness	Anterior	0,6 mm	0,4 mm	0,4 mm
	Posterior	0,6 mm	0,6 mm	0,6 mm
Connectors	Anterior	-	6 mm^2	6 mm^2
	Posterior	-	9 mm^2	9 mm^2
Frame design	Anatomical tooth shapes (supporting veneering ceramic); fully anatomical			

Cantilever bridges: never wider than the width of a pre-molar; connector at least 9 mm^2; crown wall thickness on abutment tooth next to cantilever unit at least 0.6 mm.

MILLING

CNC milling machines, suitable tools and processing parameters are required for processing the blanks. It is highly recommended not to use any cooling agent during the milling process, as this can cause the material to become discoloured and / or to lose transparency. Once processing is complete, the device must be examined for discolouration, tears and cracks. Only use milling systems that are recommended for the processing of zirconium dioxide by their manufacturers. Milling systems must be properly calibrated in order to achieve optimal results. No two systems are the same, which can lead to unwanted results if the minimum material thickness is not complied with. Because the material contracts during the sintering process, it is crucial to take into account the applicable shrinkage factor when milling, in order to guarantee the precise fit of the restoration. Each blank is marked with the specific shrinkage factor to be applied.

⚠ **Warning**

Milling and grinding dust or dust generated by manual adjustments performed during presintering can irritate the eyes, the mucosae and the skin, and can damage the lungs. Processing must therefore only be carried out using a properly functioning dust extraction device, protective goggles and an approved dust mask.

SINTERING

All restorations produced using **FAB Zirconia OP**, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** must go through a sintering cycle prior to final processing. The sintering process must only be performed in high-temperature furnaces that have been approved for this purpose. The sintering procedure specified by MINDFAB / pritidenta® must be used. Please also observe the information provided by the furnace manufacturer. All standard programmable furnaces for dental laboratories can be used. As the output of sintering furnaces varies, it is highly recommended that users calibrate the furnaces on a regular basis in order to guarantee that the recommended cycle is performed correctly. Follow the recommended manufacturer instructions when calibrating the furnaces.

⚠ **Warning**

Sintering furnaces must be installed in a well-ventilated, non-flammable area. Do not open the furnace or remove the sintered restoration until the furnace has cooled down to a sufficiently low temperature. This guarantees the safe handling of the device and prevents the risk of burns.

Recommended sintering programs

Single crowns and bridges with up to 4 units

	Temperature 1 °C	Temperature 2 °C	Heating rate °C / min	Holding time min
Heating phase	20	900	9,7	-
Holding phase	900	900	-	30
Heating phase	900	1530	3,5	-
Holding phase	1530	1530	-	120
Cooling phase	1530	800	10,4	-
Cooling phase	800	100	5,8	-

Bridges up to 5 units

	Temperature 1 °C	Temperature 2 °C	Heating rate °C / min	Holding time min
Heating phase	20	900	9,7	-
Holding phase	900	900	-	30
Heating phase	900	1530	2,6	-
Holding phase	1530	1530	-	120
Cooling phase	1530	800	6	-
Cooling phase	800	100	5,8	-

⚠ **Warning**

Always comply with the aforementioned sintering cycles and always use a lid, as otherwise the material may be weakened and may break.

It is strongly recommended not to use any colouring liquids, as this can have a negative effect on the translucency and shade. In case restorations have been shaded with coloring liquids, a sinter firing with zirconium dioxide powder is recommended for cleaning if **FAB Zirconia OP**, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** are sintered in the same furnace.

⚠ **Caution**

In order to avoid unwanted discolourations when sintering pre-dyed zirconium dioxide, it is strongly recommended to use a spacer (made from zirconium dioxide) of at least 1 mm in height between the lid and the sintering tray so that air is able to circulate.

The sintered device must be examined for discolouration, tears and cracks once processing is complete.

CORRECTIONS

Any corrections that need to be made to the hard-sintered restorations must be carried out using watercooled diamond grinders or grinding and polishing tools that are suitable for use on hard-sintered zirconium oxide. This prevents material damage caused by local overheating as well as excessive force on the surface of the restoration. Never use milling tools, as this will damage the surface of the restoration.

Basic rules for handling sintered materials:

- Always process at low pressures.
- Only use diamond grinders that are in a good condition.
- The device should be produced with no sharp edges so as not to injure patients.
- Interdental connectors must not be processed.
- To prepare the restoration for fitting, the inside surfaces should be cleaned and then sandblasted in accordance with the following parameters: Blasting pressure 1 bar, blasting particle size ≤ 50 µm, blasting nozzle distance approx. 10 mm.
- The restoration should be polished prior to clinical use in order to reduce the amount of abrasion on the antagonists.

VENEERING CERAMICS

All veneering ceramics that are recommended for zirconium dioxide ceramics may be used.

FIXING

FAB Zirconia OP, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** restorations can be cemented in place either conventionally, using zinc phosphate or glass ionomer cements, or alternatively using adhesives and self-adhesive luting composites. It must be ensured that there is sufficient surface retention and a minimum stump height of 3 mm.

⚠ **Warning**

The final restoration must not be used if it has any tears, cracks, breakages or colour irregularities. Damaged devices must not be used on the patient. Using a damaged device risks injury to the patient's oral cavity and risks the device or individual parts of the device being inhaled by the patient.

SIDE EFFECTS AND RISKS

Treatments involving a dental restoration pose the general risk of iatrogenic damage to the dental hard tissue, the pulp and/or the oral soft tissue. The use of luting systems and treatment involving a dental restoration pose the general risk of post-operative hypersensitivity.
Possible complications and risks during dental treatment are breakage, chipping, detachment, roughness of the occlusal surface, gaps, overcontouring, marginal discrepancy (marginal gap), secondary caries, inflammation or other endodontic or periodontal problems.

CONTRAINDICATIONS

⚠ **Warning** The restoration must not be used:

- for the manufacture of implants
- on patients with parafunctional habits
- on patients with a known intolerance to individual components
- with inadequate preparation
- if there is insufficient space in the patient's mouth
- on patients with inadequate oral hygiene
- for a provisional fitting

INFORMATION ON THE PROCESSING OF A ZIRCONIUM OXIDE ASSEMBLY FOR THE FABRICATION OF THE TWO-PIECE-ABUTMENT

Construction indications

- Maintain a circular wall thickness of at least 0.5 mm.
- Maintain a maximum height of 6.4 mm.
- Shape the outer form of the zirconium oxide assembly so that it satisfies the preparation guidelines for the desired suprastructure.
- If the zirconium oxide assembly must be directly veneered, make sure that the screw canal is not narrowed as a result. The connecting point for the bonding base and the screw canal may not be wetted.
- Make sure that, in general, no sharp corners or edges have been created.

Bonding indications

Follow the adhesive manufacturer's instructions when handling the titanium adhesive base.

1. Blast the adhesive surfaces of the zirconium oxide ceramic and the titanium base with ≤ 50 µm aluminium oxide and 1.0 bar. Distance of the spray nozzle approx. 10 mm.
2. Clean the adhesive surfaces with alcohol or vapour. For easier handling during bonding, it is recommended that the titanium base be screwed into a lab analogue or a polishing aid.
3. Cover the hexagon socket head of the abutment screw with wax.
4. In order to bond the titanium base and the zirconium oxide ceramic, use „PANAVIA™ F 2.0" (www.kuraraynoritake.eu) extraorally as an adhesive.
   Mix the adhesive in accordance with the manufacturer's specifications and apply it to the titanium base.
5. Slide the customised zirconium oxide ceramic up to the limit stop.
6. Remove any coarse excess adhesive material immediately.
7. To achieve final curing of the adhesive, apply the air blocker ("Oxyguard") to the ceramic / titanium junction and into the screw channel.
8. After curing, remove excess material with a rubber polisher.

Sterilisation indications

- The individual abutments and abutment screws should be cleaned and sterilised before use. In addition, the locally applicable legal regulations and the hygiene regulations applicable to a dental practice must be observed. To sterilise the hybrid abutments, use only the validated sterilisation procedures listed below.
- Pay attention to the sterilisation parameters. Before inserting the zirconium oxide assembly into the patient's mouth, the assembly must be sterilised.

- Steam sterilisation can be performed using the fractionated vacuum process or the gravitation process.
- Sterilisation time: 5 minutes at 132 °C, or 15 minutes at 121 °C, or 3 minutes at 135 °C.

DISPOSAL

Leftover materials must be disposed of in accordance with official and local regulations.

REPORTING OBLIGATION

Serious incidents (i.e. the death or temporary or permanent serious deterioration of a patient's, user's or other person's state of health or a serious public health threat) that occur or that could have occurred in connection with **FAB Zirconia OP**, **FAB Zirconia HT**, **FAB Zirconia ST** and **FAB Zirconia ML** must be reported by the user or patient to MINDFAB GmbH / pritidenta® GmbH and to the responsible authority of the member state in which the user / patient resides.

TECHNICAL CUSTOMER SERVICE

For technical customer service, please contact the manufacturer.

Manufacturer
pritidenta® GmbH CE 0483
Meisenweg 37
70771 Leinfelden-Echterdingen, Germany
T: +49 (0) 711 320 656-0
e-Mail: info@pritidenta.com

Global business partner
MINDFAB GmbH
Max-Josef-Metzger-Str. 6
86157 Augsburg, Germany
T: +49 (0) 821 455252-0
e-Mail: augsburg@mindfab.com

EXPLANTION OF SYMBOLS


Manufacturer


Use-by date


Keep dry

Catalogue number


Temperature limit


Incisal / occlusal


Caution

Batch code

Medical device

Only available by prescription in the United States


Consult instructions for use


Electronic instructions for use are found on the website www.cadtools.eu/ifu

CE mark

ID number for the notified body

REF 364 Rev 002 Druckdatum: 13.06.2023