US-EN

INSTRUCTIONS FOR USE

(For use in the United States only)

priti®multidisc ZrO2

Multi Translucent PLUS | Dental zirconium dioxide (4Y and 5Y-TZP)

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This medical device may only be sold for processing by trained specialists, milling laboratories or milling centers that are authorized to process dental prostheses. ℞ only

INTRODUCTION

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 may only be used for the specific purpose for which it was developed. 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 pritidenta® GmbH device, you are assuming responsibility as its owner and user. You hereby agree to hold pritidenta® GmbH harmless for any damage to health or any treatment measures connected to the use of a 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.pritidenta.com/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 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

priti®multidisc ZrO2 Multi Translucent PLUS:

Disc, diameter: 98.5 mm, available with and without ledge
Shades: White, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4, OM1, OM2, OM3
Heights: 14, 16, 18, 20, 25, 30 mm

Classification in accordance with DIN EN ISO 6872:2019

Dental ceramic, type II, Class 5

INTENDED PURPOSE

priti®multidisc ZrO2 Multi Translucent PLUS 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 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 **priti®multidisc ZrO2 Multi Translucent PLUS** can be used, in principle, for all patients receiving dental treatment, with no restrictions regarding sex or age.

GENERAL INFORMATION

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

⚠ **WARNING: The device may not be used if it has any tears, cracks, breakage or color irregularities. If damage is detected, the blank may no longer be used for the production of a dental prosthesis. The processing of a cracked, broken, damaged or discolored 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 covered in sufficient detail in these instructions for use, please inform the manufacturer.

STORAGE CONDITIONS

priti®multidisc ZrO2 Multi Translucent PLUS 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 to **priti®multidisc ZrO2 Multi Translucent PLUS** blanks once hard sintering has been performed:

Material properties:

Flexural strength: typical mean value ≥ 1100 MPa
CTE: $(10.5 \pm 0,5) \cdot 10^{-6} \cdot K^{-1}$

Chemical composition: priti®multidisc ZrO2 Multi Translucent PLUS

Zirconium dioxide (ZrO_2/HfO_2): 89.89 - 94.65%
Yttrium oxide (Y_2O_3): 4.65 - 10.11%
Aluminum oxide (Al_2O_3): < 0.2%
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 exceed 100% in each individual block, however.

PROCESSING
Because **priti®multidisc ZrO_2 High Translucent** are produced from a sensitive, high-performance material, it is recommended that they be handled with care. Avoid handling with wet hands. These devices may 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	0,4 mm	0,4 mm	0,6 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
Framework 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 that no cooling agent be used during the milling process, as this can cause the material to become discolored and/or to lose transparency. Once processing is complete, the device must be examined for discoloration, tears and cracks. Only use milling systems that are recommended by their manufacturers for the processing of zirconium dioxide. 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 pre-sintering can irritate the eyes, the mucosa and the skin, and can damage the lungs. Therefore, processing may only be carried out using a properly functioning dust extraction device, protective goggles and an approved dust mask.**

SINTERING
All restorations produced using **priti®multidisc ZrO_2 Multi Translucent PLUS** must go through a sintering cycle prior to final processing. The sintering process may only be performed in high-temperature furnaces that have been approved for this purpose. The sintering procedure specified by 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 program:
Temperature increase from room temperature to 1450°C at a rate of 10°C/min, hold time of 2 hours at sintering temperature, cooling to room temperature at a rate of 10°C/min. Depending on the furnace being used, cooling occurs naturally from a temperature of approx. 600°C.

Fast sintering (optional):
Fast sintering can be performed under the following conditions: Crowns and bridges with up to three units. Temperature increase from room temperature to 1500°C at a rate of 10°C/min, hold time: 30 minutes, cooling to room temperature at a rate of 40°C/min.

⚠ **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 that no coloring liquids be used, as this can have a negative effect on the translucency and shade. If restorations have been dyed using coloring liquids, it is recommended that the furnace be cleaned by performing a sintering cycle with zirconium dioxide powder before sintering the **priti®multidisc ZrO_2 Multi Translucent PLUS** in the same furnace.

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

The sintered device must be examined for discoloration, 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 water-cooled 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 these 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 good condition.
- The device should be produced with no sharp edges in order not to injure patients.
- Interdental connectors may 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
priti®multidisc ZrO_2 Multi Translucent PLUS 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 is important to ensure that there is sufficient surface retention and a minimum stump height of 3 mm.

⚠ **WARNING: The final restoration may not be used if it has any tears, cracks, breakage or color irregularities. Damaged devices may not be used on the patient. If a damaged device is used, there is a risk of injury to the patient's oral cavity, or a risk of the device or individual parts of the device being inhaled by the patient.**

SIDE EFFECTS AND RISKS
Treatments involving a dental restoration pose a 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 a 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 may not be used:
- For the fabrication of implants
- For the fabrication of abutments
- 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

otherwise you will risk severe patients' injuries.

INFORMATION ON THE PROCESSING OF A ZIRCONIUM OXIDE ASSEMBLY FOR THE FABRICATION OF A 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:
Pay attention to the instruction of the adhesive manufacturer regarding handling of the titanium bonding base.
1. Blast the adhesive surfaces of the zirconium oxide ceramic and the titanium base with ≤ 50 µm aluminum oxide and 1.0 bar. Distance of the spray nozzle approx. 10 mm.
2. Clean the adhesive surfaces with alcohol or vapor. 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.
5. Mix the adhesive in accordance with the manufacturer's specifications and apply it to the titanium base.
6. Slide the customized zirconium oxide ceramic up to the limit stop.
7. Remove any coarse excess adhesive material immediately.
8. To achieve final curing of the adhesive, apply the air blocker ("Oxyguard") to the ceramic/titanium junction and into the screw channel.
9. After curing, remove excess material with a rubber polisher.

Sterilization indications:
The individual abutments and abutment screws should be cleaned and sterilized before use. In addition, the locally applicable legal regulations and the hygiene regulations applicable to a dental practice must be observed. To sterilize the hybrid abutments, use only the validated sterilization procedures listed below.
Pay attention to the sterilization parameters. Before inserting the zirconium oxide assembly into the patient's mouth, the assembly must be sterilized.
Steam sterilization can be performed using the fractionated vacuum process or the gravitation process.
Sterilization 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 **priti®multidisc ZrO_2 Multi Translucent PLUS** must be reported by the user or patient to pritidenta® GmbH and to the responsible authorities of the member state in which the user/patient resides.

TECHNICAL CUSTOMER SERVICE

For technical customer service, please contact the manufacturer.

Manufacturer:
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Explanation of symbols